Protocol

Date

PAROXETINE 29060/329

September 25 1996

Agreed By:

<u>Title:</u> A Multi-Center, Double-Blind, Placebo Controlled Study of Paroxetine and Imipramine in Adolescents with Unipolar Major Depression

Item attached for approval: Protocol Amendment #2

Coordinating Author:	(signed)	
		Date
Biostatistician	(signed)	
		Date

_(signed)_____

Approved By:

Clinical Project Director:

Date	

Comments and questions can be directed to

SmithKline Beecham Pharmaceuticals Clinical Research & Development

1250 South Collegeville Road P.O. Box 5089 Collegeville, PA 19426-0989

STUDY DRUG: BRL 29060/PAROXETINE (PAXIL)

A MULTI-CENTER, DOUBLE-BLIND, PLACEBO CONTROLLED STUDY OF PAROXETINE AND IMIPRAMINE IN ADOLESCENTS WITH UNIPOLAR MAJOR DEPRESSION

PROTOCOL NUMBER 29060/329

PROTOCOL August 20, 1993 Date of approval: August

26, 1993

Amendment #1: March 24, 1994 Date Amendment Approved: April 17,

1994

Amendment #2: October 2, 1996 Date Amendment Approved: October

29, 1996

CONFIDENTIAL

STUDY DRUG: BRL 29060/PAROXETINE (PAXIL)

A MULTI-CENTER, DOUBLE-BLIND, PLACEBO CONTROLLED STUDY OF PAROXETINE AND IMIPRAMINE IN ADOLESCENTS WITH UNIPOLAR MAJOR DEPRESSION

PROTOCOL NUMBER 29060/329

Principal Investigators:			
_	Nam	e	
_	Study Site	Address	
SB Responsible Physician:			
I, the undersigned, have reviewed Amendment #1 and I will conduct to the Ethical and Regulatory Con	t the clinical study as desc		adhere
Investigator's Signature		Month	Year

STUDY DRUG BRL 29060/PAROXETINE (PAXIL)

PROTOCOL NUMBER 29060/329 Approved: 26 August 1993

A MULTICENTER DOUBLE BLIND PLACEBO CONTROLLED STUDY OF PAROXETINE AND IMIPRAMINE IN ADOLESCENTS WITH UNIPOLAR MAJOR DEPRESSION

Amendment #1 Approved: April 17, 1994

Section 5.2.1 Screening Phase

Revised:

1) Diagnostic assessments will be done using the K-SADS-L in

place of the K-SADS-P.

2) In subjects for whom a diagnosis of major depression may be equivocal, the case will be discussed with a principal investigator at a separate site (see Appendix H) who will have access to the interview tapes. If the external reviewer and

investigator disagree on inclusion, the external reviewer's opinion

shall take precedence.

Rationale: The K-SADS-L is an enhancement of the K-SADS-P in that it

includes disorders omitted from the K-SADS-L (e.g. ADHD, antisocial personality disorder, social phobia). Additionally, the K-SADS-L provides for lifetime inquiry. The external review

was added to assure uniformity of diagnosis.

Section 5.2.3 Treatment Phase Assessments

Added: In addition to the 12 lead EKG performed at weeks 4 and 8, a

rhythm strip EKG will be carried out at all other visits.

Revised: The criterion for heart rate level requiring a dose adjustment has

been changed. Patients whose heart rate exceeds 110 bpm on two consecutive visits or 130 bpm at any time will have their dosage decreased by one level if they are at dose level 5 or 6; if the patient is currently treated at dose level 4 or below, the

patient will be removed from the study.

Added: Blood levels of imipramine and designamine will be analyzed in

real time following the week 4 and 8 visits. Patients whose combined serum levels of imipramine and desipramine exceed

500 mcg/ml will be withdrawn from the trial.

Rationale: The rhythm strips and the serum analysis have been added to

provide additional safety monitoring for patients receiving tricyclic anti-depressants. The revised heart rate criterion agrees

with FDA guidelines for studies in adolescents.

Section 7.5.2 Reporting Serious Adverse Events

Revised: The SB medical monitor has been changed from

STUDY DRUG; BRL 29060/PAROXETINE (PAXIL)

PROTOCOL NUMBER 29060/329 Approved: 26 August 1993 Amendment #1 Approved 17 April 1994

A MULTICENTER DOUBLE BLIND PLACEBO CONTROLLED STUDY OF PAROXETINE AND IMIPRAMINE IN ADOLESCENTS WITH UNIPOLAR MAJOR DEPRESSION

Amendment #2 Approved: October 28, 1996

Study

Phase

Medication: Study medication supplies are limited necessitating change in

target enrollment in both the acute and continuation phase.

<u>Acute Phase</u>: For the acute phase, the target enrollment will be reduced from

300 patients to approximately 275 patients. It is anticipated that this reduction in sample size will have no adverse effect on the estimated 80% power of this study to detect a four point

difference between placebo and active groups. The initial sample size of 300 patients was based on an effect size of 0.4 in the HAMD. However, the actual variability in the HAMD measured for the initial 100 patients enrolled (standard deviation of 8) is smaller than estimated in the protocol at study start (standard deviation of 10). Thus, if the lower variability is maintained, 275

patients would provide greater than 80% power to detect the

estimated difference of 4 points on the HAMD.

Continuation The limited supply of blinded continuation medication may

preclude up

to 10 qualified patients from entering the extension phase. This amendment provides two options for responding patients who qualify for further treatment, but for whom blinded medication is unavailable.

Option #1) Provide same medication as used in acute phase of the trial. In this case, the patient will be withdrawn from the trial and continued treatment will be provided by a third party not associated with the trial. The third party will be provided the identity of the study medication.

Option #2) Initiate open label paroxetine. In this case, the patient is withdrawn from the trial but can elect to remain under

the care of the present study physician. If this option is deemed appropriate, the patient will be down titrated and after a one week wash out period, may begin open label paroxetine for up to six months.

There was no formal hypothesis established for the continuation phase. The primary objective is to provide long term safety data. Thus the small reduction in the number of patients entering this phase should not significantly impact the objective.

Regardless of which option is selected, the study medication identity will not be revealed to any personnel associated with the trial, unless required to treat an adverse event.

Information collected after the acute phase of the trial from patients selecting either of the two options will not be included in the formal study analysis. However, in so far as data are available, these will be summarized separately using descriptive statistics.

Section 7.5.2: The address and phone number of the SB Medical Monitors has been changed to reflect new location.

SYNOPSIS

Par		ole-Blind, Placebo Controlled Study of amine in Adolescents with Unipolar Major
DRUG UNDER S		Imipramine (up to 300 mg) Paroxetine (up to 40 mg) Placebo
INTENDED INDI	CATION	Treatment of adolescents with unipolar major depression
OBJECTIVES OF	STUDY	1. To compare the safety and efficacy of imipramine and Paroxetine to placebo in the treatment of adolescents with unipolar major depression.
		2. To assess the rate of relapse among imipramine, Paroxetine and placebo responders who are maintained on treatment).
INVESTIGATOR	S	Multicenter, USA
STUDY DESIGN	1	Multicenter, double blind, placebo controlled, parallel group study
DURATION OF T	TREATMENT	8 Week acute phase with a 6 month extension.
NUMBER OF PA	TIENTS	300 patients with 100 randomized to each treatment group.

PRINCIPAL END POINTS	Primary Efficacy Variables
	☐ Change in total HAMD score from beginning of treatment phase to the endpoint of the acute phase.
	☐ The proportion of responders at the end of the eight week acute treatment phase. Responders are defined as 50% or greater reduction in the HAM-D or a HAM-D score equal to or less than 8.
	Secondary Efficacy Variables
	Change from baseline to endpoint (acute phase) in the depression items of the K-SADS-L, global impressions, autonomic function checklist, self perception profile and sickness impact scale.
	☐ The number of patients who relapse during the maintenance phase.
	Safety Variables
	□ Safety evaluation will be based on adverse experience monitoring, laboratory evaluation, cardiovascular parameters, vital signs and physical examinations.
DURATION OF STUDY	It is anticipated the study will start in November '93. Recruitment will be for three years, the 8-month study should complete 2Q97.

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1.0 INTRODUCTION

Similarities between adolescent and adult depression in symptomotology, family history, and prospective course provide compelling rationale for investigating the efficacy of antidepressant drug therapy in young patients with depression. But unlike adults, the evidence from trials in adolescents does not support drug efficacy, although the existing studies have collectively evaluated fewer than 200 patients, a number hardly adequate for reliable clinical or statistical inferences.

This apparent difference in response between adults and younger patients has been the subject of much debate, and recent reviews (Conners, 1992; Strober, 1992; Jenson et al., 1992) have focused on three major areas of concern. These include: (1) deficiencies in study design, methodology and conduct; (2) the adequacy of diagnostic criteria and various nosological problems; and (3) developmental issues in that children and adolescents who suffer from adult-like depression may respond in a pharmacologically different manner due to quantitative and/or qualitative developmental differences in neurotransmitter/receptor systems.

The study outlined in this protocol proposes to re-examine antidepressant therapies in adolescents with unipolar major depression using a study plan designed to avoid the perceived flaws of previous studies. This will be a multi-center placebo controlled trial with a target enrollment that will provide sufficient power to detect clinical differences among treatment groups, if these differences exist. The study has rigorous inclusionary and exclusionary criteria so that the study population is more homogenous than reported in previous trials. Diagnostic interviews will be reviewed among the various sites to confirm criteria symptoms of depression and to promote uniformity in diagnosis. Responders will be prospectively defined.

One of the treatment arms will be paroxetine (Paxil), an orally administered antidepressant with a chemical structure unrelated to other selective serotonin reuptake inhibitors (SSRI), or heterocyclic or other antidepressant medications. It has recently been approved by the Food and Drug Administration for the treatment of depression based, in part, on clinical trial data in over 3000 adult patients with major depressive illness. Paroxetine has not been systematically studied in adolescent depression.

A second arm will be imipramine. This tricyclic has been the subject of two small open labeled clinical trials in adolescents, one of which has demonstrated a modest therapeutic response in patients with nondelusional depression.

Please refer to the Paxil (paroxetine) and Tofranil (imipramine) prescribing information for detailed information.

Adolescents from ages 12 years 0 months through 18 years 11 months inclusive who are currently in an episode of major depressive disorder (DSM-III-R) with a minimum duration of eight weeks and have a Hamilton severity score of 12 or greater will be included in this 8 week double-blind placebo controlled study. At the completion of the 8 week acute study, clinical responders will be blindly continued on the same medication in a 6 month extension study. Non-responders at the end of the 8 week acute period will be withdrawn and treated openly.

2.0 OBJECTIVES

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2.1	Primary
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		To compare the efficacy and safety of imipramine and paroxetine to placebo in the treatment of adolescents with unipolar major depression .
2.2	Seconda	ıry
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To identify predictors of treatment outcomes across clinical
subtypes. The following indicators of differential response will
be examined, but no directional hypotheses are formulated:
endogenous subtype, age at onset, number of prior episodes,
duration and severity of current episode, comorbidity with
separation anxiety disorder, attention deficit disorder, and
conduct disorder.

- ☐ To provide information on the safety profile of paroxetine and imipramine when these agents are given for an extended period of time.
- ☐ To estimate the rate of relapse among imipramine, paroxetine and placebo responders who are maintained on treatment.

3.0 STUDY PLAN

3.1 Study Design

This will be a multicenter double-blind placebo controlled trial. Adolescents from ages 12 years 0 months through 18 years 11 months inclusive who are currently in an episode of major depressive disorder (DSM-III-R) with a minimum duration of eight weeks and have a Hamilton severity score of 12 or greater will be included in this 8 week double-blind placebo controlled three cell study of the efficacy of paroxetine and the efficacy of imipramine versus placebo.

The treatment period will be of 8 weeks duration. During this time, patients will make weekly visits to the clinic and the effects of treatment on depression will be evaluated using standardized instruments and as well as global assessments. In addition, various safety assessments will be carried out at each visit. Section 5 below describes the study procedures in detail and Appendix D presents the study flow in schematic fashion.

At the completion of the 8 week acute study, clinical responders will be blindly continued on the same medication in a 6 month extension study. Non-responders at the end of the 8 week acute period will be withdrawn and treated openly. Throughout the study, at each site the number of subjects assigned will be approximately equal and each cell will be approximately group balanced for several potentially important covariates.

4.0 STUDY POPULATION

4.1 Number of patients

Three hundred patients will be entered in up to 6 centers and randomized to receive either imipramine (100 patients) paroxetine (100 patients) or placebo (100 patients). Each center will recruit approximately 12 -15 patients per year.

4.2 Inclusion criteria

- 1. Adolescents between the ages of 12 years 0 month and 18 years 11 months inclusive.
- 2. Currently in an episode of major depression (DSM-III-R) for at least 8 weeks. A diagnosis of major depression will be made on summary data aggregating parent and child report. In addition, both adolescent and parent(s) must agree that the adolescent has a disorder meriting treatment.
- 3. A severity score less than 60 on the Child Global Assessment Scale (C-GAS).
- 4. A score of 12 or greater on the 17-item Hamilton Depression Scale (HAM-D).
- 5. Medically healthy as determined by physical examination, medical history and laboratory screening.
- 6. IQ □ 80 by Peabody Picture Vocabulary Test.

4.3 Exclusion Criteria

- 1. Patients with current or lifetime DSM-III-R diagnosis of bipolar disorder, schizo-affective disorder, anorexia nervosa, bulimia, alcohol or drug abuse/dependence, obsessive/compulsive disorder, autism/pervasive mental disorder, or organic psychiatric disorder.
- 2. Patients with a current diagnosis (within 12 months) of post traumatic stress disorder (DSM-III-R).

- 3. Patients who have had an adequate trial of anti-depressants within 6-months prior to beginning this study. An adequate trial is defined as a treatment of at least four weeks or more with imipramine, desipramine, or amitriptyline at a dosage of 150 mg per day or greater, with nortriptyline at a dosage of 50 mg per day or greater, or with fluoxetine at a dosage of 20 mg per day or greater.
- 4. Patients who have suicidal ideation with a definite plan, or who have made a suicide attempt within the current episode, or who have ever made a suicide attempt by medication overdose.
- 5. Patients with medical illness which contraindicate the use of heterocyclic antidepressants (e.g. cardiovascular disease).
- 6. Patients using (1) psychotropic medications including anticonvulsants, anxiolytics, neuroleptics, lithium carbonate, or (2) illicit drugs as documented by a drug screen within two weeks of starting the study.
- 7. Patients with organic brain disease, epilepsy or mental retardation.
- 8. Patients who are pregnant or lactating.
- 9. Sexually active girls who are not using a reliable methods of contraception (oral contraception, surgical sterilization. I.U.D., diaphragm in conjunction with spermicidal foam and condom on partners).
- 10. Use of an investigational drug within 30 days of entry into the study or within five half lives of the investigation drug (the longer period will apply).

5.0 CONDUCT OF STUDY

The study will be conducted according to Good Clinical Practice, the Declaration of Helsinki (Appendix A) and US 21 CRF Part Protection of Human Subjects, and Part 56 - Institutional Review Board.

5.1 Ethical Considerations

5.1.1 Ethics Review Committee (ERC)/Institutional Review Board (IRB)

This protocol will be submitted to an appropriate Committee or Board and their written unconditional approval obtained and submitted to the sponsor before commencement of the study.

SB will supply relevant data for the investigator to submit to the hospital/university/independent ERC/IRB for the protocol's review and approval. Verification of the ERC/IRB's unconditional approval of the protocol and either the written informed consent statement or sample oral witnessed consent form with written information to be given to the subjects will be transmitted to the SB Study Monitor prior to shipment of drug supplies and CRFs to the site. This approval must refer to the study by exact protocol title and number, identify the documents reviewed and state the date of review.

The ERC/IRB must be informed by the investigator of all subsequent protocol amendments and of serious or unexpected adverse experiences occurring during the study which are likely to affect the safety of the subjects or the conduct of the study. Approval for such changes must be transmitted in writing to the SB Study Monitor via the investigator.

5.1.2 Informed Consent

The principals of informed consent in the current edition of the Declaration of Helsinki (Appendix A) should be implemented in each clinical study before protocol-specified procedures are carried out. Informed consent will be obtained in accordance with 21 CFR 50.25.

Information should be given in both oral and written form whenever possible and deemed appropriate by the ERC/IRB. Subjects, their relatives, guardians or, if necessary, legal representatives must be given ample opportunity to inquire about details of the study.

The consent form generated by the investigator with the assistance of SB, must be approved (along with the protocol) by the ERC/IRB and be acceptable to SB. Consent forms must be in a language fully comprehensible to the prospective subject or the subject's legally authorized representative.

The written consent document will embody the elements of informed consent as described in the Declaration of Helsinki and will also comply with local regulations. This form may be read to the subject or the subject's legally authorized representative, but, in any event, the investigator shall give either the subject or the representative adequate opportunity to read it before it is signed.

Consent must be documented either by the subject's dated signature or by the signature of an independent witness who records the subject's assent. In either event the signature confirms the consent is based on information that has been understood. Each subject's signed informed consent form must be kept on file by the investigator for possible inspection by Regulatory Authorities and/or SB professional and Regulatory Compliance persons.

5.2 Study Method

A patient log will be kept of all patients considered for the study including those not entering the trial. The reasons for excluding patients from the study will be recorded.

The study will consist of three phases: 1) a screening phase of 7-10 days to assess the suitability of a patient for inclusion into the trial; 2) an acute treatment phase of 8 weeks duration in which eligible patients will be randomly assigned to receive either imipramine, paroxetine or placebo, and 3) an extension phase of 6 months duration during which clinical responders will be blindly continued

on their randomized medication. Non responders at the end of the 8-week acute period will be withdrawn and treated openly.

Appendix D provides a summary in tabular form of the study procedures and timings.

5.2.1 Screening Phase

Subjects will initially be screened by telephone. All sites will use the Screening for Youth Depression. This screen will review depressive syndrome criteria and major inclusion and exclusion criteria. Subjects who appear likely to meet the study criteria will be evaluated promptly thereafter.

Revised

24 March 1994

Diagnostic assessment will be done using the K-SADS-L with both

the adolescent and parent(s). The K-SADS-L semi-structured clinical interview (revised to include present and past psychiatric disorders) will be administered in the fashion described in the instructions for that instrument and will be used to assess the presence or absence of each of the criteria symptoms for depression including a scale for atypical depression. The parent(s) and the adolescent are separately interviewed to assess each symptom. The clinician forms a summary rating based on best overall information combining all sources. For those symptoms where there is significant discrepancy between information provided by the adolescent and information provided by the parent(s), the clinician, adolescent and parent(s) all sit together and discuss the information provided by each source and reach a best conclusion.

Overall global functioning will be assessed at the initial interview using the Child Global Assessment Scale (C-GAS).

All K-SADS interview data will be directly confirmed by a senior clinician (psychiatrist or psychologist) who will interview both the adolescent and parent(s) and will confirm each of the positive criteria for depression by direct interview. The psychiatrist or psychologist will also review each of the items for the Hamilton Depression Rating Scale.

Diagnostic interviews will be audiotaped. If a prospective subject refuses to be audiotaped, this will not be a reason to deny entry. Cases will be reviewed by the Principal

investigator or Co-Principal Investigator at the local site who will confirm each patient meets the study entrance criteria.

Added 24 March 1994 If a subject meets 6 or fewer DSM III-R criteria for major depression disorder or the investigator reviewing the diagnosis is uncertain, the investigator must contact one of the principal investigator at a separate site (see Appendix H) to discuss the case. The external reviewer must review the audiotape and return a decision within 2 days. If investigator and external reviewer disagree on inclusion, the external reviewer's opinion shall take precedence.

Following the initial assessment of an adolescent who meets the inclusion criteria and signs the informed consent, the subsequent seven to ten days will be used to obtain medical or psychiatric records of prior treatment where indicated, and to document that the depressive symptomotology is stable after the initial psychiatric contact.

During this time a physical examination will also be conducted to assure the patient is in good medical health. The exam will include clinical laboratory studies (Appendix E) and a cardiovascular evaluation to include 12 lead EKG, heart rate and blood pressure measurements.

At the end of this interval, the adolescent will return to the clinic and will be re-evaluated. Only subjects continuing to meet inclusion criteria (DSM-III-R major depression and the Hamilton Rating Scale total score of 12 or greater) will be included.

Additional instruments to be administered at the end of the assessment period include the Autonomous Functioning Checklist, the Self Perception Profile for Adolescents and the Sickness Impact Scale.

During the assessment interval, a family history will be obtained on all first degree family members using the mother as informant (or other parent or parent surrogate if required). The mother will be interviewed about her lifetime history using the SADS-L and family history of all other first degree relatives using the Family History-Research Diagnostic Criteria (FH-RDC).

A brief description of the various scales and instruments is provided in Appendix F.

5.2.2 Randomization

Randomized Assignment of Subjects to Treatment

A computer generated randomization list will be used in which treatments are balanced within blocks of 6 consecutive patients. Patients will be allocated from 001 to 360. The master randomization list will be held by SmithKline Beecham. The treatment codes may be broken during the study for an individual patient in case of emergency. However, every effort should be made to contact SmithKline Beecham Medical Monitor prior to breaking the treatment code.

5.2.3 Treatment Phase

Assessments during study visits

During the eight week acute phase of the study, each patient will make weekly visits to the clinic. At each visit the following assessments will be carried out:

	HAM-D
	Depression section from the K-SADS-L (every other
	week)
	Clinical Global Improvement Scale
	Adverse Events
	Cardiovascular Functioning
Į	Clinical Laboratory Studies (Week 8)

Cardiovascular functioning will be assessed at baseline by obtaining a 12 lead EKG, heart rate, and blood pressure measurements. At each clinic visit, each subject will have a repeat blood pressure sitting and standing and heart rate assessment.

Revised

A 12 Lead EKG will be performed at visits 4 and 8. Rythym strip

24 March 1994 EKG will be carried out at all other visits. Cardiovascular limits to titration (i.e. acceptable limits requiring no change in study medication) will be as follows, using criteria developed by

resting heart rate < 130*.
resting systolic BP < 140; resting diastolic BP < 85
PR interval < 0.21
QRS interval < 0.12 and less than 150% of baseline
QTC < 0.48

* If the resting heart rate exceeds 110 bpm on two consecutive visits, a dose adjustment is required.

Cardiovascular parameters outside those described above will result in decreasing medication dosage by one tablet level. If a patient is at level 4 or below (see Section 6.0 - Study Drug Administration), he or she will be removed from the study.

Serum Levels

Revised

24 March 1994

Blood samples for analysis of paroxetine as well as imipramine and

desipramine will be obtained on all subjects no matter to which treatment they are assigned. Blood will be collected at baseline and after 4 and 8 weeks of treatment and the samples shipped to the Clinical Trials Center of SmithKline Clinical Laboratories (SBCL) in VanNuys California. Written instructions for the collection, preparation and shipping of the samples will be provided to each investigator.

The paroxetine samples will be stored by SBCL until the completion of the study when the plasma will be analyzed for paroxetine concentration. The imipramine/desipramine sample will be analyzed when received by the SBCL. The concentration of imipramine and desipramine data will be retained by SBCL until the completion of the trial. However, if in a given patient, the combined levels of imipramine and desipramine exceed 500 mcg/ml of serum, the investigator will be immediately notified and that patient will be withdrawn from the study. Any further treatment will be as deemed appropriate.

Medical Management -- Psychotherapy

Experience in protocols in depressed adolescents suggest that patients and families expect psychotherapy and are reluctant to consider a course of medication treatment alone, especially Modified

24 March 1994

where the medication may be solely placebo. On the other hand, a provision of treatment with a psychotherapy which, in retrospect, turned out to be extraordinarily efficacious might well preclude the demonstration of a real, significant, and clinically meaningful medication effect. There are currently several research groups beginning the process of examining different specific psychotherapies (e.g. cognitive behavioral and interpersonal) for adolescent depression. As of yet, however, there are no completed controlled studies which would suggest a "reference" psychotherapy treatment. The present study will include supportive psychotherapy, similar to the management as described by Fawcett in Appendix G.

Please note, however, that the procedures in this appendix are meant to serve as a guideline. Where differences exists between the appendix and the protocol (e.g. dosing criteria), the protocol takes precedence.

Weekly visits will consist of a 45 minute visit with the therapist. In unusual circumstances, emergency contact of greater duration is permitted. Duration of all contact including phone calls will be systematically documented.

<u>Definition of "responders" and "non-responders" at the end of eight-week acute treatment</u>

To be classified as a "responder" and continue to the continuation phase, a subject must have a HAM-D score \leq 8 or a decrease in baseline HAM-D total score \Box 50%:

Termination at end of acute study for non-responders

At the end of the acute phase subjects who are "non-responders", as defined above, will be terminated from the study. Medication/placebo will be tapered off over a 7-17 day period at which time their care will be transferred to clinical personnel who are not part of this study. The patient and family, all clinical personnel, and all research personnel will remain blind to medication assignment of all subjects even after termination of the acute phase.

In some subjects, for safety reasons, it may be necessary for the clinical personnel to be informed which medication the subject was on. The decision to unblind the clinical personnel will be made jointly with clinical personnel at the site and clinical personnel at SmithKline Beecham.

5.2.4 Extension study

Subjects who are "responders" at the end of the double-blind acute study will be blindly continued on the current (final) dose of imipramine/paroxetine/placebo for an additional six months. For the purposes of this study, it is estimated that 65% of subjects in both active treatment will be "responders" and 40% of subjects on placebo will be a "responder".

The aims of the continuation phase are: 1) to provide an estimate of the benefits of extended treatment with anti-depressant medications and 2) to provide a safety profile of antidepressants given for an extended period of time.

Procedures for 6-month follow-up:

- 1. Maintain last medication/placebo dose blindly.
- 2. Monthly psychiatric and safety assessments:

 - b) Hamilton depression rating scale
 - c) Adverse Events

a)

- d) Clinical Global Assessment Scales
- e) EKG rhythm strip, blood pressure, and heart rate assessment

Affective section of K-SADS-L interview

- f) Clinical Laboratory Studies (Week 20)
- g) Serum Drug Levels (Week 20)
- 3. Assessment at termination of the 6-month extension:
 - a) Full K-SADS-L
 - b) Hamilton Depression rating scale
 - c) Adverse Events
 - d) Clinical Global Assessment Scales
 - e) 12 lead EKG strip, blood pressure, and heart rate assessment
 - f) Clinical Laboratory Studies
 - g) Serum Drug Levels

Revised 24 March 1994

6.0 DRUG SUPPLIES AND PACKAGING

6.1 Formulations

Medication will be administered in the form of green capsules. Paroxetine will be provided as 10 mg over encapsulated tablets, imipramine will be 50 mg over encapsulated tablets while placebo will be provided in a tablet dosage form identical in appearance to paroxetine, over encapsulated.

6.2 Study Drug Administration

Dose of study medication

There will be six dosing levels. All patients will be titrated to level 4 regardless of response. Levels 5 and 6 are optional for those who do not respond after reaching level 4. The timings and dosage at each level are as follows:

	DAY	IMIPRAMINE	PAROXETINE
Level 1	1 - 7	50 mg	20 mg
Level 2	8 - 14	100 mg	20 mg
Level 3	15 - 21	150 mg	20 mg
Level 4	22 - 28	200 mg	20 mg
Level 5	*	250 mg	30 mg
Level 6	*	300 mg	40 mg

6.3 Blinding

The study will use 10 and 20 mg paroxetine tablets and the corresponding placebos. Also to be used will be the 50 mg imipramine tablets and corresponding placebo tablets. The "paroxetine placebos" will be identical in size, color and shape to the 10 and 20 mg paroxetine un-monogrammed tablets. Likewise, the imipramine placebo tablet will be the same size, shape and color as the active imipramine.

6.4 Concomitant Medication

All concomitant medication taken during the study must be recorded in the case report form with indication, daily dose, and dates of administration.

Subjects will not be allowed to take other psychotropic medications. Subjects will be permitted to take medications without CNS effects for medical illnesses or conditions as necessary. Medications which are not psychotropic, but which may have CNS effects (e.g. prednisone, antihistamines) should be avoided or used for the minimum length of time consistent with good medical care.

6.5 Packaging

The capsules will be packaged using blister cards. One card will hold sufficient supplies for a one week treatment period (10 days). Patients will be instructed to take medication twice daily, one dose in the morning and one at night. The number of capsules for each dose will depend on the dosing level achieved; the minimum number of capsules to be taken daily is two, the maximum is six.

6.6 Labeling and Preparation

For all phases, the tear off portion of the label must be affixed to the CRF when medication is dispensed to the patient. All unused cards must be returned to the sponsor at the end of the study.

6.7 Storage

Study medications must be kept in a locked area and dispensed according to the protocol. Records of dispensed supplies must be kept current on forms which the sponsor will also supply. All unused supplies must be returned to the sponsor at the end of the study.

6.8 Drug Accountability

The investigator will sign that he or she has received the clinical supplies for this study and that the study supplies will be handled and stored safety and properly.

6.9 Assessment of Compliance

A record of the amount of drug dispensed, taken, and returned will be recorded in the CRF for each patient, to assess compliance. The patient will be instructed to return the previous intervals drug container, including any unused medication at each visit.

If a patient takes less than 80% or more than 120% of study drug at each of two consecutive visits, the patient will be considered non-compliant and withdrawn from the study. A patient who misses two consecutive visits will also be withdrawn from the study.

6.10 Overdosage

The following information on overdosage is provided in the prescribing information for Paxil and Tofranil.

For paroxetine, treatment should be consistent with those general measures employed in the management of overdosage with any antidepressant. There are no specific antidotes for paroxetine. Establish and maintain an airway, ensure adequate oxygenation and ventilation. Gastric evacuation either by the induction of emesis or lavage or both should be performed. In most cases, following evacuation, 20 to 30 grams of activated charcoal may be administered every 4-6 hours during the first 24-36 hours after ingestion. An ECG should be taken and monitoring of cardiac function instituted if there is any evidence of abnormality. Supportive care with frequent monitoring of vital signs and careful observation is indicated. Due to the large volume of distribution of paroxetine, forced diuresis, dialysis, hemoperfusion, and exchange transfusion are unlikely to be of benefit.

A specific caution involves patients taking paroxetine or recently having taken paroxetine who might ingest by accident or intent excessive quantities of a tricyclic antidepressant or a MAO inhibitor. In such a case, accumulation of the parent tricyclic and its active metabolite may increase the possibility of clinically significant sequalae and extend the time needed for close observation.

In managing overdosage, consider the possibility of multiple drug involvement. The physician should consider contacting a poison control center for additional information on the treatment of overdosage.

For imipramine:

Children have been reported to be more sensitive than adults to an acute overdosage of imipramine hydrochloride. An acute overdose of any amount in infants or young children, especially, must be considered serious and potentially fatal.

Signs and Symptoms:

These may vary in severity depending upon factors such as the amount of drug absorbed, the age of the patient, and the interval between drug ingestion and the start of treatment. Blood and urine levels of imipramine may not reflect the severity of poisoning; they have chiefly a qualitative rather than quantitative value, and are unreliable indicators in the clinical management of the patient. CNS abnormalities may include drowsiness, stupor, coma, ataxia, restlessness, agitation, hyperactive reflexes, muscle rigidity, athetoid and choreiform movements, and convulsions.

Cardiac abnormalities may include arrhythmia, tachycardia, ECG evidence of impaired condition, and signs of congestive failure.

Respiratory depression, cyanosis, and diaphoresis may also be present.

Treatment:

The recommended treatment for overdosage with tricyclic antidepressants may change periodically. Therefore, it is recommended that the physician contact a poison control center for current information on treatment. Because CNS involvement, respiratory depression and cardiac arrhythmia can occur suddenly, hospitalization and close observation may be necessary, even when the amount ingested is thought to be small or the initial degree of intoxication appears slight or moderate. All patients with ECG abnormalities should have continuous cardiac monitoring and be closely observed until well after cardiac status has returned to normal; relapses may occur after apparent recovery.

In the alert patient, empty the stomach promptly by lavage. In the obtunded patient, secure the airway with a cuffed endotracheal tube before beginning lavage (do not induce emesis). Instillation of activated charcoal slurry may help reduce absorption of imipramine.

Minimize external stimulation to reduce the tendency to convulsions. If anticonvulsants are necessary, diazepam, and phenytoin may be useful.

Maintain adequate respiratory exchange. Do not use respiratory stimulants.

Shock should be treated with supportive measures, such as appropriate position, intravenous fluids, and if necessary, a vasopressor agent. The use of corticosteroids in shock is controversial and may be contraindicated in cases of overdosage with tricyclic antidepressants. Digitalis may increase conduction abnormalities and further irritate an already sensitized myocardium. If congestive heart failure necessitates rapid digitalization, particular care must be exercised.

Hyperpyrexia should be controlled by whatever external means are available, including ice packs and cooling sponge baths, if necessary.

Hemodialysis, peritoneal dialysis, exchange transfusions and forced diuresis have been generally reported as ineffective because of the rapid fixation of imipramine in tissues. Blood and urine levels of imipramine may not correlate with the degree of intoxication, and are unreliable indicators in the clinical management of the patient.

The slow intravenous administration of physostigmine salicylate has been used as a last resort to reverse CNS anticholinergic manifestations of overdosage with tricyclic antidepressants; however, it should not be used routinely, since it may induce seizures and cholinergic crises.

7.0 ADVERSE EXPERIENCES

The recording of adverse experiences is an important aspect of study documentation. Detailed guidelines are set out below.

7.1 Eliciting and Documenting Adverse Experiences

It is the responsibility of the investigator to document all adverse experiences which occur during the investigation. An adverse experience includes any noxious, pathologic or unintended change in anatomical, physiologic or metabolic functions as indicated by physical signs, symptoms and/or laboratory changes occurring in any phase of the clinical trial whether associated with drug or placebo and whether or not considered drug related.

This includes an exacerbation of pre-existing conditions or events, intercurrent illnesses, drug interaction or the significant worsening of the disease under investigation that is not recorded elsewhere in the case report form under specific efficacy assessments. Anticipated day-to-day fluctuations of the disease under study that do not represent a clinically significant exacerbation or worsening need not be considered an adverse event.

All adverse experiences occurring after the start of the study must be reported. Subject entry into the study is defined as the time at which informed consent is obtained. (This must be before any protocolspecific diagnostic procedures or interventions.) All subsequent adverse experiences, whether no drug (ie. during reference 'run-in' or 'wash-out' period) or when active drug or placebo is being administered, must be reported REGARDLESS OF WHETHER OR NOT THEY ARE CONSIDERED DRUG RELATED.

At each visit/assessment, adverse experiences will be evaluated by the investigator. Adverse experiences not previously documented in the study will be recorded in the adverse experience section of the subject's case record form. The nature of each experience, data and time (where appropriate) of onset, duration, severity and relationship to treatment should be established. Details of changes to the dosage schedule or any corrective treatment should be recorded on the appropriate pages of the case record form.

Adverse experiences already documented in the CRF ie. at a previous assessment and designated as 'continuing' should be

reviewed. If these have resolved, the documentation in the CRF should be completed. NB. If an adverse experience changes in frequency or severity during a study period, a new record of the experience will be started.

Ask the subject a non-leading question such as: "Do you feel different in any way since starting the new treatment/the last assessment."

7.2 Assessment of Severity

Maximum intensity should be assigned to one of the following categories:

Mild: For example, an adverse experience which is easily

tolerated by the patient, causing minimal discomfort and

not interfering with everyday activities.

Moderate: For example, an adverse experience which is sufficiently

discomforting to interfere with normal everyday

activities.

<u>Severe</u>: For example, an adverse experience which is

incapacitating and prevents normal everyday activities.

7.3 Assessment of Causality

Every effort should be made by the investigator to explain each adverse experience and assess its relationship, if any, to study drug treatment. Causality should be assessed using the following categories: unrelated, probably unrelated, possibly related, related.

The degree of certainty with which an adverse experience is attributed to drug treatment (or alternative causes, e.g. natural history of the underlying diseases, concomitant therapy, etc.) will be determined by how well the experience can be understood in terms of the following:

- Known pharmacology of the drug
- Reaction of similar nature being previously observed with this drug or class of drug
- The experience having often been reported in literature for similar drugs as drugs related, e.g. skin rashes, blood dyscrasia

 The experience being related by time to drug ingestion terminating with drug withdrawal (dechallenge) or reproduced on rechallenge.

7.4 Following-up of Adverse Experiences

Investigators should follow-up subjects with adverse experiences until the event has subsided (disappeared) or until the condition has stabilized. Reports relative to the subject's subsequent course must be submitted to the clinical study monitor.

7.5 Serious Adverse Experiences

7.5.1 Definition of Serious Adverse Experiences:

A serious adverse experience is any event which is fatal, life threatening, disabling or incapacitating or results in hospitalization, prolongs a hospital stay or is associated with congenital abnormality, cancer or overdose (either accidental or intentional). In addition any experience which the investigator regards as serious or which would suggest any significant hazard, contraindication, side effect or precaution that may be associated with the use of the drug should be reported as a serious event.

Life threatening - definition:

An adverse experience is life threatening if the subject was at immediate risk of death from the event as it occurred; i.e. it does not include a reaction that if it had occurred in a more serious form might have caused death. For example, drug induced hepatitis that resolved without evidence of hepatic failure would not be considered life threatening even though drug induced hepatitis can be fatal.

Disability/incapacitating definition:

An adverse experience is incapacitating or disabling if the experience results in a substantial and/or permanent disruption of the subject's ability to carry out normal life functions.

7.5.2 Reporting Serious Adverse Experiences

Any serious adverse experiences which occur during the clinical study or within 30 days (or five half lives whichever is the longer) of receiving the last dose of study medication, whether or not related to the study drug, must be reported by the investigator to the study monitor (by telephone within 24 hours).

All serious adverse experiences must be reported by telephone within 24 hours to the study monitor:

Revised 24 March 1994

The Medical Monitor for this protocol is:



The Back-up Monitor for this protocol is:



The telephone report should be followed by a full written summary detailing relevant aspects of the adverse experiences in question. Where applicable, information from relevant hospital case records and autopsy reports should be obtained.

Instances of death, cancer or congenital abnormality if brought to the attention of the investigator AT ANY TIME after cessation of study medication and linked by the investigator to a previous clinical trial, should be reported to the study monitor.

7.6 Overdosage

Any instance of overdosage (suspected or confirmed) must be communicated to SmithKline Beecham within 24 hours and be fully documented as a serious adverse experience. Details of any signs or symptoms and their management should be recorded including details of any antidote(s) administered.

7.7 Pregnancy

Subjects who become pregnant during the study should discontinue the study immediately, unless the protocol states otherwise.

Patients should be instructed to notify the investigator if it is determined after completion of the study that they become pregnant either during the treatment phase of the study or within 30 days or five half-lives after the treatment period, whichever is longer.

Whenever possible a pregnancy should be followed to term, any premature termination reported, and the status of the mother and child should be reported to SmithKline Beecham after delivery.

7.8 Breaking the Study Blind

Only in the event of a serious adverse experience which the investigator feels cannot be adequately treated without knowing the identity of the study medication, may the medication code be broken for a particular subject. Every effort must be made to contact an SB Medical Monitor prior to breaking the code. If this is not possible and the situation is an emergency the investigator may break the code and contact the Medical Monitor as soon as possible thereafter.

8.0 SUBJECT COMPLETION AND WITHDRAWAL

8.1 Definitions

For the purpose of this protocol, a patient will be considered to be a "completed subject if they complete the 8 week acute phase". A withdrawal will be any subject who enters the study i.e. gives informed consent, and does not complete the 8 week study period (whether or not subject received study medication).

Because the extension phase is addressing maintenance therapy, it is anticipated that some patients will relapse. Accordingly, the definition of a "completed subject will be modified to be any patient who completes the full six months of therapy or any patient who withdrawals from therapy because of a relapse".

8.2 Procedures for Handling Withdrawals

It is anticipated that in a few subjects the study will be terminated early because of medication side effects. potential reasons for early termination include cardiovascular side effects beyond those permitted (see above), allergic reaction to medications, etc. Decisions for early study termination for medical or other reasons should be the responsibility of the principal investigator at each site. In all cases, subjects terminated early for any reason including medical reasons will be included in data analysis. Decision to terminate or not will be made blind to actual medication/placebo status--the blind will be broken only after termination is decided.

Should a patient decide to terminate the study early, a discontinuation taper is strongly recommended. If this accepted by the family, the medication will be tapered off in a linear fashion over a 7 to 17 day period.

8.3 Reason for withdrawal

A patient may withdraw from the study prior to completion for one of six possible reasons:

- 1. Adverse experiences including intercurrent illness
- 2. Insufficient therapeutic effect
- 3. Deviation from protocol including non-compliance

- 4. Lost to follow-up
- 5. Termination by SB
- 6. Other (specify).

The investigator should determine the primary reason for withdrawal and cite the one reason.

9.0 DATA EVALUATION

9.1 Criteria for Efficacy

9.1.1 Primary efficacy variables

- a) The change in total HAMD score from beginning of the treatment phase to the endpoint of the acute phase.
- b) The proportion of responders at the end of the eight week acute treatment phase.

9.1.2 Secondary efficacy variables

a)	Changes from baseline to endpoint in the following
	parameters:

	Depression items in K-SAD-L
	Global Impressions
	Autonomic Function Checklist
	Self Perception Profile
П	Sickness Impact Scale

- b) Predictors of response (endogenous subtypes, age, prior episodes, duration and severity of present episode, comorbidity with separate anxiety, attention deficit, and conduct disorder).
- c) The number of patients who relapse during the maintenance phase.

9.2 Statistical Methods

9.2.1 Comparisons of interest

The comparison of primary interest is active treatment versus placebo. Hypotheses concerning these comparison will be tested at the alpha level of 0.05

9.2.2 Sample size determination

This study is designed to have adequate power to detect a clinically meaningful difference in both active-placebo comparisons at a two tailed alpha level of 0.05 and power 0.80. The sample size estimates are further based on an effect size of 0.40. The rationale for this effect size is as follows:

- A difference of 4 in the HAMD Total change from baseline scores at endpoint. This is a smaller difference than that seen in previous studies with antidepressants in adults, yet it is large enough to be clinically meaningful, and
- A standard deviation of 10. This is 20% larger than observed in studies with anti-depressants in adults and should reflect the greater variability in response expected in adolescent depression.

These parameter estimates result in 100 patients per treatment group.

9.3 Efficacy Analysis

9.3.1 Intent to Treat Analysis

All patients who receive double-blind medication will be considered as part of the ITT population. This patient population will be considered the primary population.

9.3.2 Patients Valid For The Efficacy_Analysis

All patients randomized to study treatment and for whom at least one valid post-treatment efficacy evaluation is available will be valid for inclusion in an 'intent-to-treat' analysis. Patients who meet the following criteria will be eligible for the efficacy analysis:

- a) No major protocol violation exists with regard to inclusion or exclusion criteria.
- b) No other major protocol violation during the first 8 weeks of active treatment has occurred.

Only primary efficacy variables will be analyzed using this population. Patients to be excluded from the efficacy analysis will be identified before the randomization code is broken.

9.3.3 Statistical Methodology

Psychometric scales using at least an ordinal measurement scale will be analyzed using parametric analysis of variance, effects in the model will include treatment, investigator and treatment by investigator interaction. If the treatment by investigator interaction is not significant (p > 0.1) the interaction term will be dropped from the model. This analysis will be performed using the General Linear Models procedure of the SAS system. The ordinal scales which have very few levels (such as the CGI Severity of Illness) will also be analyzed using nonparametric methodology to ensure that the results are consistent across modes of analysis.

Dichotomous variables such as response (based on HAMD criteria) will be analyzed using Logistic Regression methodology. Effects in the model will include treatment, investigator, and treatment by investigator interaction; if the interaction is not significant then it will be dropped from the model. These analyses will be performed using the LOGISTIC procedure of the SAS system.

Summary statistics will be presented for demography, disease history, and baseline measures of efficacy.

An analysis of covariance will be performed to evaluate the effect of possibly important prognostic variables on the HAMD total score at endpoint. These include endogenous subtype, age at onset, gender, number of prior episodes, duration and severity of current episode, comorbidity with separate anxiety disorder, attention deficit disorder and conduct disorder.

9.3.4 Test of Significance

Tests of hypothesis regarding model assumptions such as the significance of treatment by investigator interactions will be made at the 10% level.

All other statistical tests will be two-tailed and performed at the 5% significance level.

9.3.5 Patient Characteristics At Baseline

Demographic and diagnostic variables at baseline will be checked for homogeneity between the treatment groups. If major differences exist for variables predictive of treatment response, their impact on the trial results will be investigated.

9.4 Safety Analysis

9.4.1 Patients Valid for Clinical Safety & Tolerability

All patients who receive coded medication will be assessed for clinical safety and tolerability.

9.4.2 Adverse Experiences

Adverse experiences will be coded for each subject with reference to body system and preferred terms. The treatment groups will be compared regarding the incidence of the reported adverse experiences with reference to both preferred term and body system. The comparison between treatments with regard to incidence of adverse experiences will be performed primarily by using descriptive statistics.

9.4.3 Other Clinical Safety Variables

Information regarding demographic data, vital signs, physical examination, adverse experiences and abnormal laboratory values will be presented as listings and tables. All deviations from the study protocol and study withdrawals will be documented.

10.0 ADMINISTRATIVE MATTERS

To comply with Good Clinical Practice, important administrative obligations relating to investigator responsibilities, monitoring, archiving data, confidentiality and publications must be fulfilled as given in Appendix B.

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Appendices

APPENDIX A

DECLARATION OF HELSINKI

WORLD MEDICAL ASSOCIATION DECLARATION OF HELSINKI

Recommendations guiding physicians in biomedical research involving human subjects

Adopted by the 18th World Medical Assembly,
Helsinki, Finland, June 1964,
Amended by the 29th World Medical Assembly,
Tokyo, Japan, October 1975,
35th World Medical Assembly,
Venice, Italy, October 1983
and the
41st World Medical Assembly
Hong Kong, September 1989

INTRODUCTION

It is the mission of the physician to safeguard the health of the people. His or her knowledge and conscience are dedicated to the fulfillment of this mission.

The Declaration of Geneva of the World Medical Association binds the physician with the words, "The health of my patient will be my first consideration", and the International Code of Medical Ethics declares that, "A physician shall act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient."

The purpose of biomedical research involving human subjects must be to improve diagnostic, therapeutic and prophylactic procedures and the understanding of the aetiology and pathogenesis of disease.

In current medical practice most diagnostic, therapeutic or prophylactic procedures involve hazards. This applies especially to biomedical research.

Medical progress is based on research which ultimately must rest in part on experimentation involving human subjects.

In the field of biomedical research a fundamental distinction must be recognized between medical research in which the aim is essentially diagnostic or therapeutic for a patient, and medical research, the essential object of which is purely scientific and without implying direct diagnostic or therapeutic value to the person subjected to the research.

Special caution must be exercised in the conduct of research which may affect the environment, and the welfare of animals used for research must be respected.

Because it is essential that the results of laboratory experiments be applied to human beings for further scientific knowledge and to help suffering humanity, the World Medical Association has prepared the following recommendations as a guide to every physician in biomedical research involving human subjects. They should be kept under review in the future. It must be stressed that the standards as drafted are only a guide to physicians all over the world. Physicians are not relieved from criminal, civil and ethical responsibilities under the laws of their own countries

I. BASIC PRINCIPLES

- 1. Biomedical research involving human subjects must conform to generally accepted scientific principles and should be based on adequately performed laboratory and animal experimentation and on a thorough knowledge of the scientific literature.
- 2. The design and performance of each experimental procedure involving human subjects should be clearly formulated in an experimental protocol which should be transmitted for consideration, comment and guidance to a specially appointed committee independent of the investigator and the sponsor provided that this independent committee is in conformity with the laws and regulations of the country in which the research experiment is performed.
- 3. Biomedical research involving human subjects should be conducted only by scientifically qualified persons and under the supervision of a clinically competent medical person. The responsibility for the human subject must always rest with a medically qualified person and never rest on the subject of the research, even though the subject has given his or her consent.
- 4. Biomedical research involving human subjects cannot legitimately be carried out unless the importance of the objective is in proportion to the inherent risk to the subject.
- 5. Every biomedical research project involving human subjects should be preceded with careful assessment of predictable risks in comparison with foreseeable benefits to the subject or to others. Concern for the

- interests of the subject must always prevail over the interests of science and society.
- 6. The right of the research subject to safeguard his or her integrity must always be respected. Every precaution should be taken to respect the privacy of the subject and to minimize the impact of the study on the subject's physical and mental integrity and on the personality of the subject.
- 7. Physicians should abstain from engaging in research projects involving human subjects unless they are satisfied that the hazards involved are believed to be predictable. Physicians should cease any investigation if the hazards are found to outweigh the potential benefits.
- 8. In publication of the results of his or her research, the physician is obliged to preserve the accuracy of the results. Reports of experimentation not in accordance with the principles laid down in this Declaration should not be accepted for publication.
- 9. In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she should be informed that he or she is at liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participation at any time. The physician should then obtain the subject's freely-given informed consent, preferably in writing.
- 10. When obtaining informed consent for the research project, the physician should be particularly cautious if the subject is in a dependent relationship to him or her or may consent under duress. In that case the informed consent should be obtained by a physician who is not engaged in the investigation and who is completely independent of this official relationship.
- 11. In case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation. Where physical or mental incapacity makes it impossible to obtain informed consent, or when the subject is a minor, permission from the responsible relative replaces that of the subject in accordance with national legislation. Whenever the minor child is in fact able to give a consent, the minor's consent must be obtained in addition to the consent of the minor's legal guardian.

12. The research protocol should always contain a statement of the ethical considerations involved and should indicate that the principles enunciated in the present Declaration are complied with.

II. MEDICAL RESEARCH COMBINED WITH PROFESSIONAL CARE (Clinical Research)

- 1. In the treatment of the sick person, the physician must be free to use a new diagnostic and therapeutic measure, if in his or her judgment it offers hope of saving life, re-establishing health or alleviating suffering.
- 2. The potential benefits, hazards and discomfort of a new method should be weighed against the advantages of the best current diagnostic and therapeutic methods.
- 3. In any medical study, every patient including those of a control group, if any, should be assured of the best proven diagnostic and therapeutic method.
- 4. The refusal of the patient to participate in a study must never interfere with the physician-patient relationship.
- 5. If the physician considers it essential not to obtain informed consent, the specific reasons for this proposal should be stated in the experimental protocol for transmission to the independent committee (I,2).
- 6. The physician can combine medical research with professional care, the objective being the acquisition of new medical knowledge, only to the extent that medical research is justified by its potential diagnostic or therapeutic value for the patient.

III. NON-THERAPEUTIC BIOMEDICAL RESEARCH INVOLVING HUMAN SUBJECTS

(Non-clinical biomedical research)

- 1. In the purely scientific application of medical research carried out on a human being, it is the duty of the physician to remain the protector of the life and health of that person on whom biomedical research is being carried out.
- 2. The subjects should be volunteers -- either healthy persons or patients for whom the experimental design is not related to the patient's illness.

- 3. The investigator or the investigating team should discontinue the research if in his/her or their judgment it may, if continued, be harmful to the individual.
- 4. In research on man, the interest of science and society should never take precedence over considerations related to the well-being of the subject.

APPENDIX B

ADMINISTRATIVE MATTERS

I. RESPONSIBILITIES OF THE INVESTIGATOR

- To ensure that he/she has sufficient time to conduct and complete the study and has adequate staff and appropriate facilities which are available for the duration of the study and to ensure that other studies do not divert essential subjects or facilities away from the study at hand.
 To submit an up-to-date curriculum vitae and other credentials (e.g. medical license number in the United States) to the sponsor and -where required to relevant authorities.
 To acquire the normal ranges for laboratory tests performed locally and, if required by local regulations, obtain the Laboratory License or
- To prepare and maintain adequate case histories designed to record observations and other data pertinent to the study.

II. PROTOCOL AMENDMENTS

Certification.

No changes to the study protocol will be allowed unless discussed in detail with the SmithKline Beecham (SB) Medical Monitor and filed as an amendment/modification to this protocol.

Any amendment/modification to the protocol will be adhered to by the participating centre (or all participating centres) and will apply to tall subjects following approval as appropriate by the Ethical Review Committee or Institutional Review Board.

III. SPONSOR'S TERMINATION OF STUDY

SB reserves the right to discontinue the clinical study at any time for medical or administrative reasons. When feasible, a 30-day written notification will be tendered.

IV. CASE REPORT FORM INSTRUCTIONS

Prior to screening the first potential participant, the investigator will provide a list showing the signature and handwritten initials of all individuals authorized to make or change entries and case report forms (CRFs). If the authorized individuals should change during the study, the investigator is to inform SB.

CRFs (and subject diary cards, if applicable), will be supplied by SB for recording all data. It is the responsibility of the investigator or co-investigator to ensure that CRFs (and subject diary cards) are legible and completely filled in with a black ink ballpoint pen. Include the subject's identification (2-3 alphabetic letters representing initials or first letter of subject's name) on the front page of the CRF, the allocation number (if not pre-printed) and the visit date.

Errors must be corrected by drawing a single line through the incorrect entry and writing in the new value/data positioned as close to the original as possible. The correction must then be initialed, dated and justified by the authorized individual making the change. Do not obliterate, write over, or erase the original entry when making a correction.

When a subject completes a visit, it is anticipated that relevant sections of the CRF will be completed by the investigator (or designated staff) within 24 hours of the last data becoming available, but in no case later than 5 days. Similarly, when a subject completes a study, it is anticipated that all relevant CRF pages will be completed with in 24 hours of the last data becoming available, but in no case later than 5 days. This also applies to forms for potential study participants who were not randomized to a treatment group.

As soon as the subject has completed/withdrawn from the study and the CRF is completed the principal investigator or designated physician(s) under his/her supervision will sign the adverse experience page(s) as well as study conclusion page of the CRF to confirm that they have reviewed the data and that the data are completed and accurate. If sections of a CRF are to be brought into SB prior to study conclusion, a section conclusion signature is required.

An original (top copy) CRF must be submitted for all subjects who have undergone protocol specific procedures, whether or not the subject completed the study.

While completed CRFs will be reviewed by an SB professional monitor at the study side, error detected by subsequent in-house CRF review may necessitate

clarification or correction of errors and documentation and approval by the investigator.

Any questions or comments related to the CRF should be directed to the assigned study monitor.

V. MONITORING BY SMITHKLINE BEECHAM (i.e. the Sponsor)

Monitoring visits by a professional representative of the sponsor will be scheduled to take place before entry of the first subject, during the study at appropriate intervals and after the last subject is completed.

These visits are for the purpose of verifying adherence to the protocol and the completeness and exactness of data entered on the CRF and Drug Inventory Forms. The monitor will verify CRF entries by comparing them with the hospital/clinic/office records which will be made available for this purpose. The monitor will retrieve completed CRF sections at each visit. Adequate time and space for these visits should be made available by the investigator.

Investigator must ensure provision of reasonable space and adequate qualified personnel for monitoring visits.

VI. ARCHIVING OF DATA

The investigator must retain subject records and CRFs as well as drug disposition records in an easily retrievable form until disposal has been agreed in writing with SB. The investigator must have a 'key' linking the subject's study identification number (i.e., treatment number) to the subject's clinical file. If the investigator moves or retires, he/she should nominate someone in writing to be responsible for record keeping. Archived data may be held on microfiche or electronic record, provided that a back-up exists and a hard copy can be obtained from it if required.

SB agrees to retain a copy of the protocol, documentation, approvals and all other documents related to the study, including certificates that satisfactory audit and inspection procedures have been carried out.

VII. AUDITS

For the purpose of compliance with Good Clinical Practice and Regulatory Agency Guidelines it may be necessary for SB or a Drug Regulatory Agency to conduct a site audit. This may occur at any time from start to after conclusion of the study.

When an investigator signs the protocol, he agrees to allow Drug Regulatory Agency and SB auditors to inspect his/her study records. Furthermore, if an investigator refuses an inspection, his/her data will not be accepted in support of a New Drug Registration and/or Application.

SB has a substantial investment in clinical studies. Having the highest quality data and studies are essential aspects of drug development. SB has a Regulatory Compliance staff who audit investigational sites. Regulatory Compliance assesses the quality of data with regard to accuracy, adequacy and consistency. In addition, Regulatory Compliance assures that SB sponsored studies are in accordance with the relevant Good Clinical Practices regulation/guidelines are being followed.

To accomplish these functions, Regulatory Compliance selects investigational sites to audit. These audits usually take 1 to 2 days. The SB audits entail review of source documents supporting the adequacy and accuracy of CRFs, review of documentation required to be maintained, and checks on drug accountability. The SB audit therefore helps prepare an investigator for a possible regulatory agency inspection as well as assuring SB of the validity of the database across investigational sites.

The Inspector will be especially interested in the following items:

Log of visits from the sponsor's representatives
ERC/IRB approval
Test article accountability
Approved study protocol and amendments
Informed consent of the subjects (written or witnessed oral consent)
Medical records supportive of CRF data
Reports to the ERC/IRB and the sponsor
Record retention.

SB will gladly help investigators prepare for an inspection

VIII. CONFIDENTIALITY AND PUBLICATION

You agree that all information communicated to you by SB is the exclusive property of SB and you will ensure that the same shall be kept strictly confidential by you or any other person connected with the work and shall not be disclosed by you or such person to any third party.

We agree that you shall have the right to publish or permit the publication of any information or material relating to or arising out of the work after prior submission to us provided that if we shall so request you will delay publication for a maximum of six months to enable us to protect our rights

in such information or material. Any proposed publication or presentation (e.g. manuscript, abstract or poster) for submission to a journal or scientific meeting, should be sent to the study monitor prior to submission. SB will undertake to comment on such documents within four weeks.

All rights and interest worldwide in any inventions, know-how or other intellectual or industrial property rights which arise during the course of and/or as a result of the clinical study which is the subject of this protocol or which otherwise arise from the information or materials supplied under this Agreement, shall be assigned to, vest in and remain the property of SmithKline Beecham plc.

In drafting this section, additional stipulations can be included in accordance with local custom and practice but the above aspects.

APPENDIX C

SAMPLE INFORMED CONSENT

Study Title: A Multicenter, Double-blind Placebo Controlled Study of

Paroxetine and Imipramine in Adolescents with Unipolar

Major Depression.

Protocol Number: 29060/329

1. Nature and Purpose of the Project

Procedures

I understand that if I participate in this research study, I will be interviewed by the research team to determine my history of emotional or psychiatric disturbance, and I will be asked questions about the psychiatric status of other members of my family. I also understand that I may be asked permission for research staff to contact these members of my family for further history of their emotional disturbance, and that I may deny this request.

I will also undergo various standard medical tests, including a complete physical exam, blood and urine tests, and <u>a test of heart function</u> to make sure that I am free of any physical or medical problems that would advise against use of the medications to be used in this study. I understand that at intake my urine will be screened for any drugs in my system.

It has been explained to me that I will be eligible to enter the study after the research staff has determined that I meet the criteria for depression and am in generally good medical health. At this point, I will be assigned randomly to receive paroxetine, imipramine, or a placebo sugar substitute. I will not find out what kind of mediation I am taking until completion of the study, which could run for as long as five years. In order to learn the benefits of anti-depressant medication, it is essential that neither I nor my doctors know to which treatment I have been assigned.

During the study, I will be interviewed by members of the research team every week for eight consecutive weeks. If my condition improves I may elect to continue treatment for additional 6 months. During this time I will be interviewed by the research team on a monthly basis. At the interviews, I will be asked questions about my behavior and mood and whether I have been taking the prescribed number of pills on a regular basis. I understand that no costs will be incurred for my participating in this phase of the research. Payment for lengthy sessions (two or more hours) with the adolescent and family for initial evaluation will be \$ per subject. Participants will be reimbursed for the weekly and subsequently monthly evaluation sessions including blood drawing at \$ per visit. No visit in connection with my participation in this phase of the study will be billed to me or my insurance carrier.

2. <u>Discomforts and Risks</u>

It is possible that paroxetine or imipramine will relieve depression in some adolescents as in adults. If so, assignment to placebo treatment might result in a lesser degree of treatment.

I understand that I may experience some discomfort as a result of the medication I receive. Treatment with paroxetine could produce side effects, the most common side effects are:

General fatigue and muscular pain, sweating, nausea, itching, rashes, decreased appetite, sleepiness, dizziness, insomnia, nervousness, coughs, running nose, muscular tremors, changes in weight, and changes in heart rate.

Treatment with imipramine could produce side effects. The most common are:

Dry mouth, blurred vision, rashes, nausea, and stomach upset, changes in heart rate, fainting, restlessness and agitation.

I understand that I am not more likely to experience side effects as a result of my participation in this study than if I were being treated with paroxetine or

imipramine in the usual manner. If I experience side effects, the doctors will attempt to adjust the dose.

If I cannot continue to take the medication because of side effects, I will not continue in the study and will receive the best alternative treatment. I understand that if I am a female I will be counseled by the research staff as to the risks involved in becoming pregnant while participating in the study. I am also aware that I may experience discomfort when having blood drawn; this may be a source of mild pain, and some mild swelling may occur at the site of the blood draw. Although it is uncommon, this may also cause me to feel faint, to bleed slightly, or to develop an infection at the site of the blood draw.

The interviews that I will receive during the course of the study involve no specific risks or discomforts beyond those of a standard clinical interview situation such as feeling upset at a review of my psychiatric status, boredom, or fatigue.

3. Benefits

I understand that the possible benefits to society include furthering our knowledge of the treatment of depression in teenagers. I also understand that of the treatment, medication, and testing will be free of charge.

4. Appropriate Alternative Procedures Beneficial to the Subject

The findings of this study will contribute to the understanding of a possible role for antidepressant medication in adolescent patients with depression. The researchers also expect to learn more about the longer term effects of both paroxetine and imipramine in the teenage population. I understand that I may choose not to participate in this study. If I do not participate, I will receive the best available treatment as prescribed by my doctor.

5. Confidentiality

All records relating to this project will be handled and safeguarded according to standard University policy for medical records. Any information obtained in connection with this study that can be identified with the subject will remain confidential, and will be disclosed only with my permission. Information of a sensitive personal nature will <u>not</u> be part of the medical record, but will be stored in the investigators' research file and identified only by a code number. The code key connecting name to numbers will be kept in a separate secure location. If the data are used for publication in the medical literature or for teaching purposes, no names will be used, and other identifiers, such as audiotapes, will be used only with special written permission. I understand that I may hear the audiotape before

giving this permission. Should the research staff discover use of other drugs by me such information will be kept confidential to the extent allowed by law. No information about me will be released without my consent except as required by law.

6. Risk of Injury

The investigators do not expect any (further) unusual risks as a direct result of participation in this project. However, should any unforeseen physical injury occur, appropriate medical care will be provided, but no financial compensation will be given.

7. Contact

I understand that if I have any questions, comn	nents, or concerns about this study
or the informed consent process I may call Dr.	at,
or write to him at	. If I have any questions about my
rights as a subject, I may call	·
If I become ill or injured as a result of participal treatment will be provided, and the reasonable by SmithKline Beecham. If I have any question compensation/medial care or if I thing I have e injury I will contact	cost of such treatment will be paid ons concerning the availability of

8. Refusal/Withdrawal

I will be given a copy of this form to keep.

I understand that participation in this study is voluntary and that refusal to participate at any time will involve no penalty of loss of benefits to which I am otherwise entitled. I know that I can refuse to answer any question that I may not wish to answer and that I may refuse to participate or withdraw from the study at any time without negative consequences or effect on medical care being provided. Since abrupt discontinuation of medication can result in unwanted side-effects, if I wish to withdraw, I agree to permit the slow tapering of my medication over two week period.

**	***						
I ACKNOWLEDGE THAT I HAVE READ AND FULLY UNDERSTAND THAT ABOVE EXPLANATION OF THE PROJECT, THAT ALL MY QUESTIONS HAVE BEEN SATISFACTORILY ANSWERED. I AGREE TO PARTICIPATION THIS RESEARCH PROJECT.							
Signature of Participant	Date						
**	***						
I CERTIFY THAT I HAVE EXPLAINED FULLY TO THE ABOVE PATIENT THE NATURE AND PURPOSE, PROCEDURES, POSSIBLE RISKS AND							

POTENTIAL BENEFITS OF THIS RESEARCH PROJECT.

Signature of Investigator

Date

APPENDIX D

SUMMARY OF STUDY PROCEDURES

Assessment Continuation Phase		eline	Acute Phase								Continuation Phase					
Time (Weeks)		0	1	2	3	4	5	6	7	8	12	16	20	24	28	32
Informed Consent	Х															
Medical History and Physical Exam	Х															
Clinical Laboratory Studies	Х									Х			Х			Х
Serum Pregnancy	X						X*							Х*		
ECG-12 Lead	Х					Х				Х			Х			Х
ECG Rhythm Strip			X	Х	Х		X	X	Χ		X	Х		Х	Х	
Hamilton Depression Scale	X	Х	X	Х	Х	Х	X	Х	Х	Х	X	Х	Х	Х	Х	Х
Full K-SADS-L	X															Х
Affect Section of K-SADS-L		Х		Х		X		X		Х	X	Х	Х	X	Х	X
C-GAS		Х														
CGI		X	X	Х	Х	X	X	X	X	X	X	X	X	X	X	X
SADS-L		Х														
FH-RDC		Х														
Autonomous Functioning Checklist										X						
Self Perception Profile										X						
Sickness Impact Scale										X						
Randomization		Х														
Adverse Events		Х	X	Х	Х	X	Х	X	X	X	X	Х	Х	Х	X	X
Supportive Psychotherapy		Х	X	Х	Х	Х	X	Х	X	Х	Х	Х	Х	Х	Х	Х
Plasma Sampling for Drug Analysis		Х				Х				Х			Х			Х
Study Medication Record			X	Х	Х	X	X	X	Χ	Х	Х	Х	Х	Х	Х	X
Concomitant Medication	X	Х	X	Х	Х	X	X	Х	Х	Х	X	Х	Х	Х	Х	Х

^{*} On suspicion of pregnancy

<u>APPENDIX E</u>

CLINICAL LABORATORY PARAMETERS

Blood						
Hematology:	RBC WBC (total and differential) Platelets					
Biochemistry:	Liver function: Bilirubin, alkaline phosphatase SGOT, SGPT					
	Renal function: Urea, creatinine, uric acid					
	Other biochemistry Glucose, serum proteins					
<u>Urine</u>						
Blood, protein, glucose. If blood or protein noted in urine, microscopy will be performed. In addition a drug abuse screen will be performed at baseline.						
Prenancy Test - at baseline and on suspicion						
Plasma and Serum Drug Concentration						

APPENDIX F

INSTRUMENTS

Family History Screen (FHE), Subject Version: The Family History Screen is a brief computer-scorable instrument which collects a pedigree and screens for DSM-III-R diagnoses in family members. The instrument has been shown to have good levels of sensitivity and specificity for adults reporting on themselves. (Lish et at)

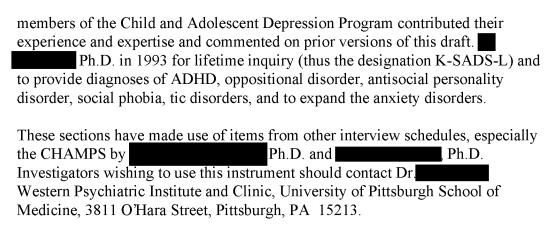
Self Perception Profile for Adolescents: This scale (Harter, 1987) is an upward extension of the Self Perception Profile for Children which in turn is based on the Perceived Competence Scale (Harter, 1985). It is a measure of "self" as a dimension of competence in the proposed research. it consists of 45 item self report questionnaire, assessing perceived competence in 9 domains: Scholastic, social, athletic, physical appearance, job, romantic, conduct/morality, close friendship, and global self-worth. Psychometric information regarding this scale is available for a parochial school population. Subscale reliability is generally very high. Validity of the perceive competence scale has been supported by a number of recent studies (Cauce 1987; Nottelman 1987). Scores do not correlate with age.

Autonomous Functioning Checklist: The AFC is a parent-completed checklist designed to measure behavioral autonomous functioning in adolescents between the ages of twelve and eighteen. It contains seventy-eight items and is subdivided into four conceptually distinct subscales: Self-and Family Care, Management, Recreational Activity, and Social and Vocational Activity. Each item in the first three subscales is a short description of a behavior. The parent rates the adolescent in relation to each item on a five-point scale ranging from 0 (does not do) to 4 (does every time three is an opportunity). The items on the fourth subscale, Social and Vocational Activity, are rated by the parent on a dichotomous, yes/no scale. For each scale, high scores indicate that the adolescent routinely performs many of the activities listed.

Revised The K-SADS-L was initially developed by M.D. and

24March 1994 M.D. The authors took as point of departure the audit SADS

(developed by M.D. and Ph.D. with the assistance of other participants in the NIMH clinical Research Branch Collaborative Project on the Psychobiology of Depression), from which many items and scales remain. Guidelines for the unstructured interview were modified from Interview with the child (Isle of Wight Study). A fourth version was written by M.D. and M.D. and present and past



The Sickness Impact Profile (SIP) is a behaviorally based measure of health-related dysfunction that was developed to provide a measure of health status useful in the assessment of individuals or populations with both chronic and acute illnesses. It may be either interviewer or self administered and is scored as a total SIP score or as two dimensions, physical and psychological. It has undergone extensive field testing and has demonstrated good reliability (internal consistency, Cronbach's alpha, ranges from 0.94 to 0.97; overall reproducibility score ranges from 0.88 to 0.92) and validity (SIP to self assessment of sickness ranges from 0.54 to 0.69 and dysfunction ranges from 0.52 to 0.69; SIP to NHIS ranges from 0.55 to 0.61). It is easily understood by patients and the version used in this study has been modified for an adolescent population and has been piloted in an adolescent outpatient affective disorders clinic where it has demonstrated good utility. (Bergner et al., 1976; ibid. 1985).

APPENDIX G

CLINICAL MANAGEMENT FOR ADOLESCENT DEPRESSION

Adolescent Depression Collaborative Research Group

A Modification of

Clinical

Management - Imipramine/Placebo Administration Manual. Psychopharmacology Bulletin 23:309-324, 1987.

INTRODUCTION

The intent of The Clinical Management for Adolescent Depression (CMAD) Manual is to define a psychosocial interaction between clinicians and adolescent patients which will maximize the chance of observing a pharmacotherapeutic effect in a study of antidepressant medication, assure the careful and safe monitoring of patients, and maintain consistency of approach among clinicians. It attempts to encompass elements of care used by clinicians who have experience with psychiatrically-ill adolescents, and it intentionally includes the "nonspecific" effects associated with other psychosocial therapies, such as warmth, empathy, genuine interest in the patient's welfare, and optimism about the outcome of treatment. These aims are shared by the approach defined in the Clinical Management - Imipramine/- Placebo Condition (CMIPC), developed for the NIMH Treatment of Depression Collaborative Research Program (Fawcett, et. al., 1987), of which CMAD is a modification. We are indebted to Drs.

who developed the CMIPC and consented to this modification of their manual.

The CMIPC had a secondary aim of minimizing overlap with two psychotherapy conditions which were being compared in that study, Interpersonal Psychotherapy and Cognitive Therapy. This study does not contrast psychosocial therapies, so this is not a principal aim. Consistency across pharmacotherapeutic conditions is the first priority in this study. Nevertheless, the current study intends that observed clinical change will reflect effects of the medication under study rather than of active psychotherapies. Thus, while there is slightly greater overlap with interpersonal and cognitive therapies than with CMIPC, this clinical management condition intentionally maintains clear distinctions from those therapies. An additional rationale for maintaining these distinctions is the possibility of using this clinical management manual in future studies of active psychotherapies with adolescents.

A further intent of this approach is to maximize compliance with the treatment under study. Attrition from treatment trials and clinical studies can be high with adolescents.

The investigators share the impression that maintaining rapport with the adolescent patients and their families requires the addition, to the CMIPC, of defined contract with parents, a more specific educational component about the illness and its treatment, and a modest increase in the time spent in contract with the patients. For these reasons, the length of sessions was increased and four psychoeducational conjoint sessions, with the adolescent and at least one parent, were added. Additional adjustments to treatment with adolescents include an emphasis on flexibility and active concern about the adolescent's social, school and family life.

Because of the central importance of maintaining consistent adherence of therapists to the psychosocial approach - particularly in a multicenter study - a means of rating tapes of therapy sessions is needed. Considerable work went into the development of the Collaborative Study Psychotherapy Rating Scale (CSPRS-6) and an accompanying Raters Manual. Review of these instruments indicates that they can be used without modification to rate tapes of sessions with adolescents.

Modifications of the CMIPC manual are intentionally minimal. They consist essentially of setting aside discussions of the adult psychotherapy study, rephrasing references to medications to fit the current study medications and their administration, lengthening of sessions, and modifying references to family contact.

Adaptation of the clinical management approach to the context of adolescence is provided by added descriptions of the initial session, a subsequent session, and illustrations of approaches to three potential problem situations - a depressed adolescent's refusal to attend school because of conflicts with peers, a dispute between an adolescent and parents, and an increase in an adolescent patient's suicidal ideation.

I. Purpose of Study

The major aim of the study for which this manual has been generated is to evaluate the effectiveness of two antidepressant medications, paroxetine and imipramine, for treating nonbipolar nonpsychotic outpatient depressive illness in adolescents. The medications will be compared to treatment with a placebo, and all three conditions will be accompanied by a program of education and support, defined in this manual. The clinical management approach (CMAD) which this program follows and augments has been observed to be effective with many depressed adults (Elkin, et. al., 1989). Thus, it is intentionally not therapeutically neutral but rather a presumably effective supportive therapy which will be constant across the three treatment groups.

II. Aims of the CMAD

A. General Aims

In order to provide valid data with which to compare the effectiveness of the treatment and with which to address other major questions posed by this study, each of the study treatment conditions must be provided in an optimal fashion allowing for maximal therapeutic effectiveness. The purpose of this manual is to describe the Clinical Management Condition and to outline the procedures involved in the optimal delivery of this condition. The CMAD has been designed to resemble as closely as possible the manner in which medications would be most effectively adolescent administered in the clinical management of depressed adolescent outpatients.

B. Specific Aims

One of the main goals of the CMAD is to foster and maintain the kind of therapeutic relationship between patient and pharmacotherapist that will promote compliance with the treatment regimen in general and, in particular, compliance with medication. A second major goal of the CMAD is to promote the patient's continuation in the study throughout the entire 8-week study period. This will be most difficult to achieve both early and late in treatment: early if the patient is not receiving obvious benefit; later if the patient has a partial or complete therapeutic response and does not appreciate the need to continue therapy. Maintaining a very low attrition rate is crucial in producing reliable data.

III. Protocol for the CMAD

A. General Organization and Focus of the Psychopharmacotherapy Sessions

The pharmacotherapist must be responsive to the adolescent's complaints and needs while also maintaining control in the interview. This can best be accomplished through a rational and organized structuring of sessions. The pharmacotherapist's ability to focus and appropriately sequence the inquiry and discussion is of great importance for an effective psychopharmacotherapy session. In considering the issue of initial focusing, it is important to remember that the patient is finally entering a treatment situation after several weeks of preliminary screening and data gathering. The patient's clinical needs and treatment expectations are of the highest priority and deserve the utmost respect and attention as the pharmacotherapist proceeds with organizing the interview. The initial sessions should ideally be developed as therapist-patient collaborative efforts to characterize general and specific features of the depressive episode. A therapeutic agenda can thus be established on which to base treatment expectations consistent with the psychopharmacotherapy approach.

The appropriate organization and structuring of the CMAD sessions together with the inclusion of the appropriate content should sufficiently distinguish the sessions from psychotherapy and help prevent the pharmacotherapist from straying into "psychotherapeutic territory." We do not wish to encourage an interview structure or process so rigidly structured as to preclude opportunities from empathy, support, and those naturally spontaneous and more casual exchanges that permit treatment to be carried out in a warm and truly human way. However, open-ended inquiry into or discussion of interpersonal relationships is to be especially avoided.

The appropriate sequencing of clinical inquiry and therapeutic discussion is also an important factor influencing the effectiveness of the session. Generally, sessions should begin with a general review of the previous week's events and activities, with therapist eliciting information about domains not specifically covered, including school, home, friends, family, and specific inquiry about previously-identified important situations, activities, or relationships. Specific target symptoms should be asked about if not brought up spontaneously. Potential or past side effects should then be reviewed. Among the more frequent examples of inappropriate sequencing are the discussion of medication effects prior to the elicitation of target symptoms and the premature discussion of side effects prior to a thorough discussion of therapeutic benefits of the medication.

B. Initial Session

The initial patient visit will consist of a 1-hour session, divided approximately into 30 minutes with the adolescent and parent(s) and 30 minutes with the patient alone. During this session the pharmacotherapist will attempt to establish a positive relationship with the adolescent and parents in the content of a thorough discussion of the course of the present as well as previous episodes of depressive illness. The elucidation of the past history, family history, and relevant medical history will focus on elaborating information about clinical symptoms of major depression.

Considerable attention will be devoted to the establishment of the target symptoms* as a basis for ongoing clinical assessment and management within CMAD. The content of subsequent sessions will depend on the accurate and comprehensive establishment of target symptoms in the initial sessions. In addition to providing material for future sessions, discussion of target symptoms will help structure sessions so that active psychotherapeutic interventions can be avoided, thus keeping the pharmacotherapy sessions as free from "psychotherapeutic contamination" as possible. The initial comprehensive determination of target and accessory symptoms will also be necessary for later detection of study medication side effects. **The Symptom, Sign, Side-Effect Checklist will provide a basic inventory and format for obtaining the baseline and subsequent medication side-effect assessments. Also, in the process of assessing the patient's symptoms and experience of depressive illness, the pharmacotherapist should routinely and completely assess suicidal ideation and impulses. This will be particularly crucial in patients with a previous history of depressive illness involving suicidal ideation or behavior.

- * Target the symptoms include sleep disturbance, appetite disturbance, diurnal mood variations, anhedonia, feelings of hopelessness, suicidal ideation, etc. Symptoms such as anxiety, irritability, and hypochondriacal preoccupation's should also be explored.
- ** The Term "study medication" will be used throughout the CMAD as a generic term for the active drugs or placebo.

A basic and easily understandable explanatory model of how and why antidepressant medication is effective should be provided. Theoretical and practical aspects of the treatment rationale should be presented in the patient's own language, and discussion of the patient's concerns and questions should be actively facilitated.

The rationale for the use of medication in the treatment of depression should be explained and any resistance to the idea of medication therapy should be addressed. The patient should be allowed and even encouraged to express his or her concerns, fears, and attitudes regarding medication in general and psychotropic drugs in particular. Common concerns of adolescents and parents should be addressed, such as the risk of becoming dependent on the medication, how long one needs to take medication, and potential side effects. The interpersonal ambience should provide the patient an opportunity to air prejudices, distortions, and fantasies regarding either the positive or negative effects of the medication. These distortions should be corrected by responding to the patient's questions with further clarification and support.

It is critically important to obtain a comprehensive history of previous experiences with and responses to pharmacotherapy (including specific medication dosages and the duration of treatment) prior to explanation and discussion of the current treatment. Educating the patient about the individual variability of responses often encountered with different antidepressants, coupled with assurances that medication response will be closely monitored, will help the patient and parents overcome possible negative attitudes based on previous experiences and/or ignorance or misinformation about antidepressant pharmacotherapy.

The adolescent and the parents should be instructed about the importance of taking the prescribed dosage of study medication and apprised of the fact that adjustment of the dosage may be necessary to achieve the desired effect. The patient should also be instructed that it may be 2 to 6 weeks before a therapeutic response is achieved and should be informed about which symptoms (e.g., sleep disturbance, appetite disturbance) are likely to respond to treatment initially. The concept of gradual response or progressive improvement should be discussed so that patients do not unrealistically expect an early "all or none" response.

The possibility of the occurrence of side effects during treatment should be discussed. Pharmacotherapists should mention the side effects which most frequently occurred during treatment (dry mouth, dizziness or lightheadedness, especially on changing positions, blurred vision, nonspecific sedative effects, and delayed micturition). The patient should be instructed that these side effects are not dangerous if reported to the pharmacotherapist and managed correctly. If mild side effects do occur, the patient will be instructed to continue the medication at the prescribed dose, if possible, until the physician can be reached. If more severe side effects occur and the patient is not able to reach the

pharmacotherapist immediately, the medication should be temporarily discontinued until the therapist is contacted.

The patient should be instructed that future visits will be 20 to 45 minutes in length, generally with patient alone. Up to 15 minutes of a session may be spent with the adolescent and parents(s) if the clinician, patient, or parents feel this is necessary. The session will be devoted to reviewing the patient's general progress, the current status of depressive signs and symptoms, and possible side effects, as well as to discussing his or her questions and concerns. It should be made clear that this time limit is relatively inflexible and will not be modified unless there is some pressing need. The patient should be instructed that these sessions will be conducted on a weekly basis but that in case of severe side effects or worsening symptoms of the illness, it will be possible to reach the pharmacotherapist or an associate by telephone.

Especially during the initial session, the pharmacotherapist should attempt to develop an accepting, understanding, and supportive relationship with the patient and to convey hope and optimism regarding the outcome of treatment. The pharmacotherapist should also clearly communicate any expectation that the patient will improve and should explicitly link this expectation of improvement or mitigation of target symptoms with the idea of positive therapeutic outcome as a result of antidepressant pharmacotherapy. By assisting the patient in developing a positive set of hopeful expectations linking the relief of core symptoms with medication effects, the pharmacotherapist creates opportunities for ongoing therapeutic discussions focused on those aspects of the medical treatment of depressive illness that are personally important to the patient.

Here we would like to present a brief sketch of an ideal first session. In such an idealized version of the initial psychopharmacotherapy session, we see the pharmacotherapist warmly greeting and welcoming the adolescent and his/her parent(s), and providing an explicit introduction that unambiguously establishes his/her role as the doctor who will be in charge of the patient's clinical care for the duration of the study. This introduction should distinguish the pharmacotherapist's role as primary managing clinician from the research roles of various study personnel the patient has previously seen. It is during the initial exchange that the pharmacotherapist clearly establishes the overall importance of the patient's clinical care and well-being in the study context. The psychiatrist should also demonstrate knowledge about the study in general.

After acknowledging review of the patient's diagnostic summary, the psychiatrist should begin an independent evaluation with the primary objective of establishing a set of core or target symptoms, manifestations of the underlying disease process which will serve as indicators of potential response to the treatment that will be prescribed. The therapist should inquire about all domains of the adolescent's life, e.g., school, home, friends, family, favorite activities, and how the symptoms have affected these. Accessory signs and symptoms can be simultaneously elicited. Screening for the presence of possible medication side effects at baseline can also be done as an associate component of this phase of the session; however, the use of the Symptom, Sign, Side-Effect Checklist as a primary device or method to maintain structure is definitely not recommended. At appropriate junctures, clinical attention and questions should be directed towards life problems with the objective of information gathering, learning about the patient as a person, and conveying empathic concern. The pharmacotherapist should not, however, engage in psychodynamic incursions and digressions.

We recommend that time be allowed for the psychiatrist to establish and convey a sense of warmth, concern, and authoritative responsibility and knowledgeability about the pharmacotherapy, to appropriately educate the patient about how and why the medication can help, and to allow for questions from the patient and further discussion.

C. Second and Subsequent Sessions

At the second and subsequent sessions, the pharmacotherapist will meet with the patient for approximately 20 to 30 minutes, extending to 45 minutes if necessary because of clinical concerns. Parents may be included for up to 15 minutes of this time, as described above. A systematic inquiry into the presence, intensity, and features of the already established target symptoms that characterize the patient's depression should provide the basis for the assessment of response to treatment, following the general sequence described in A. This systematic inquiry should also provide a framework for ongoing assessment during subsequent sessions. Similarly, a systematic evaluation for side effects will be made during the second and all subsequent sessions.

The Symptoms, Sign, Side-Effect Checklist will serve as a standard format for evaluating the above. Regarding technique when administering the Symptom, Sign, Side-Effect Checklist, we suggest that the pharmacotherapist inquire about the presence of items by presenting them in groups of related items, e.g., "Have you ever had weakness, faintness, dizziness, lightheadedness, headaches, visual disturbances?" This allows the screening for symptoms and signs to be done efficiently, leaving more time for other therapeutic tasks. Sitting and standing blood pressures should be routinely taken during the first, second, fourth and sixth sessions to assess for postural hypertension. If at any other time the patient presents with signs or symptoms suggestive of postural hypotension (i.e.,

dizziness or lightheadedness upon arising from a sitting or recumbent position), then the sitting and standing blood pressure should be taken, recorded, and appropriate clinical management initiated.

During the second session the patient will be asked about reactions to the medication, possible side effects, and possible early therapeutic effects. Patients who are unusually sensitive to the medication or who have idiosyncratic reactions (palpitations, etc.) will be identified at this time.

Since it is highly possible that no therapeutic response will have occurred by the second session, special effort will usually be necessary to reinforce the patient's continued hope and optimism regarding improvement. The patient should be encourage to continue the medication and should also be instructed that higher doses usually produce symptomatic improvement. Although it is unlikely that the patient will have any appreciable side effects to the medication at this point, there may be minor side effects, especially in patients who are apprehensive about taking medication. Further education efforts regarding the "hows" and "whys" of antidepressant medication may be helpful and perhaps necessary to avoid dropouts and/or noncompliance during the early stages of the pharmacotherapeutic treatment.

Here, we would like to emphasize the importance of flexibility in determining the duration of pharmacotherapy sessions. Time should be allowed to indicate general interest in the adolescent's life and to maintain a positive relationship. For some patients whose clinical course has demonstrated significant improvement, a 20-minute visit may be quite adequate and appropriate. On the other hand, we do not recommend visits under 15 minutes or over 45 minutes, except in extraordinary circumstances when the clinical management definitely requires an extended period of time.

D. Prescription of Study Medication

Study medication will be prescribed each week and will consist of identical containers of identical capsules for all three conditions. A sufficient number of capsules should be provided to cover the possibility of a missed appointment by the patient or pharmacotherapist, i.e., an additional 2 to 3 days of study medication may be prescribed. However, medication may only be prescribed for a maximum period of 10 days. If there is risk of an overdose, the pharmacotherapist may choose to have the patient return for an additional appointment that week in order to limit the total amount of medication the patient has in his/her possession at any one time. Patients are instructed to return all unused medication to the therapist at each session. The physician must maintain an accurate record of all unused study medication. The number of capsules prescribed and the number of unused capsules should be recorded at each session.

The CMAD dosage schedule is designed to optimize the possibility of a full response to the study medication by approximating usual clinical practice. To accomplish this, an attempt should be made to systematically expose each patient to a full dose of medication by the third week of the study a nd to maintain this dosage of study medication for a period of at least 4 weeks. If, at any dosage, the patient manifests severe side effects which appear to be dose related (e.g., anticholinergic effects, drowsiness), this may signify that a lower dose is the maximum tolerated dose at that time. If the patient dose not appear to be responding optimally to the study medication at a given dosage level, the dosage may be increased up to the ceiling dose. This potential range of dosage combined with flexibility in the dosage schedule should assure an adequate trial of medication for each patient (see Appendix).

The very first dosages taken by the patient should constitute a test for hypersensitivity. If overwhelmingly severe side effects (e.g., extreme dysphoria or anxiety, massive sedation, headache) emerge in response to the initial dosage of the medication, the dose may be dropped. However, if the patient is not able to achieve a dosage of (x) without significant or severe side effects, he/she should then be considered hypersensitive to the medication and withdrawn according to the study guidelines.

If moderately severe side effects emerge as the dose is being increased, the patient should attempt to contact the pharmacotherapist. Several alternatives are then available. For example, the dosage may be redistributed over the course of the day in an attempt to increase patient tolerance, or the dosage may be temporarily reduced in order to allow the patient to accommodate. If dosage has been decreased because of side effects, the pharmacotherapist should later attempt to increase the dosage more gradually until a therapeutic level has been achieved unless there is a resurgence of severe side effects, the appearance of new and serious side effects, or clinical deterioration. Over the ensuing weeks, the pharmacotherapist may increase the medication up to the maximum dosage based on the patient's response to treatment.

Not all patients may be able to tolerate maximal levels of study medication. If only lower doses are tolerated, therapist should note the reason for this and use direct patient quotations when possible. Under no circumstances should patients be prescribed less than (x) per day of study medication. In the rare case where a patient cannot tolerate at least (x) of study medication, the patient should be withdrawn from the study and an appropriate referral should be made. If a patient misses a dose of medication, it should be recorded and the patient advised not to make up the missed dose, but to continue with the prescribed dosage schedule.

We would like to emphasize the importance of dosage flexibility. The schedule guidelines recommended here are not meant to be absolute, although there is, indeed, an upper limit of (x) of study medication which is not to be exceeded.

Some patients, because of unusual sensitivity to the medication, may need to be advanced more slowly than suggested. In these cases, the pharmacotherapist may adopt a scheduling strategy of alternating doses every other day to achieve a more gradual dosage increase.

Dosage changes and titration's are also recommended to manage side effects, although the therapist should, if possible, attempt to deliver the maximal therapeutic dose. In addition, dosage flexibility is also recommended during the latter weeks of treatment as patients may experience relapse when a decrease in dosage occurs. In such circumstances we recommend that the patient continue on sufficient medication to maintain the therapeutic response.

E. Pharmacotherapy Management Issues

Drug interaction with other medication. Patients should be instructed to avoid all other medications, including over-the-counter compounds, if possible, during the study treatment. The use of proprietary (nonprescription) medication that the patient may take under ordinary circumstance such as aspirin or acetaminophen for headache or laxatives for constipation is acceptable, but the use of prescription medication is not allowed. If the patient is using other medication (e.g., laxatives), he/she should be advised to allow at least a 2-hour interval between the time of ingesting study medication and the time of ingesting the laxative to avoid possible interference with absorption of the study medication. If the ingestion of a prescription medication is unavoidable (e.g., antibiotic for an acute febrile bacterial illness), the medication, dose, and reason for prescribing should be recorded. Patients should also be told that if they require dental work while on study medication, their dentist should be advised that they might be on a tricyclic medication that could interact adversely with the epinephrine-like medication often used in local anesthetic preparations.

Adolescents should be advised to refrain from the use of alcohol, marijuana, or other drugs. Substance use should be discussed frankly as something which may prolong their depression and make treatment ineffective. One should not, however, attempt to deter substance used by exaggerating the risks of concomitant use with study medication. Adolescents have often been given inaccurate information about effects of substance abuse and this approach is likely to impair the credibility of the therapist.

<u>Laboratory work.</u> At any time during the course of treatment, the CMAD psychiatrist may request laboratory tests (e.g., liver function tests) or an evaluation of the patient by a pediatrician.

<u>Side-effects management.</u> The thorough discussion and successful management of disconcerting or troublesome side effects early on in the course of treatment is often of critical significance with regard to pharmacotherapy compliance in

general. Detecting anxiety associated with an increase in dosage or disturbing side effects resulting from such an increase is necessary for the successful management of further dosage adjustments. Mild side effects may often be adequately managed by explaining to patients that the severity of side effects usually decreases over time. This is most effectively accomplished through discussion carried out in the context of a concerned, reassuring, and supportive attitude on the part of the pharmacotherapist. Moderately severe side effects are usually best managed by a temporary lowering of the dose. Advice may be given regarding physiological management of side effects (e.g., laxative diet for the mitigation of constipation). Managing more severe side effects may require a permanent lowering of the dosage. Other than the ordinary use of proprietary medication, adjunctive medication for the management of side effects (e.g., urecholine for the management of urinary retention) is not permitted.

F. General Management Issues

Avoiding dropouts. The avoidance of dropouts from the clinical management condition will depend to a great extent on the nature of the relationship established between the pharmacotherapist, the adolescent patient, and the parents. In order to avoid dropouts, it is important that the pharmacotherapist not only be supportive and encouraging, but remind the patient of the delayed effect of the medication and reiterate the possibility that the dosage may need to be increased. Without such attention and reassurance there is a danger that the patient who experiences an absence of therapeutic benefit particularly in the presence of side effects may discontinue treatment within the first 2 to 4 weeks.

Phone calls. Especially during the early weeks of treatment, the physician must be available to the patient and the parents for telephone calls between appointments for questions about side effects which may occur as medication dosage is increased. Phone calls allow the pharmacotherapist to receive clinical information from the patient about symptoms or medication side effects, make a determination about their significance, and provide an opportunity for immediate management of problems. In addition, they provide the patient with the reassuring knowledge that a concerned and available physician is managing the psychopharmacotherapy. The reassurance provided by such brief calls in everyday clinical practice often makes the difference between a successful outcome and early treatment dropout of a patient who might have responded to the medication. These phone calls can often provide the support necessary to assist the patient in continuing medication despite depressive feelings of hopelessness and discouragement or fears and anxieties stimulated by the occurrence of side effects. It is often reassuring to a patient to know that the physician will be available at a particular time of day to respond to phone calls if necessary. The patient should also be instructed that in the event the pharmacotherapist is not immediately available, there is an emergency number at which to contact a psychiatrist 24 hours a day. In addition, at the outset of the

study, each patient is provided with emergency numbers for contacting the Principal Investigator and Project Coordinator at that site. Phone calls are not to constitute supplementary or adjunctive therapy. The CMAD physician should keep an accurate record of every phone call received from the patient and his/her family. This information should be noted and should include date, time, length of call, content of call, specific and general concerns, and the therapist's response (e.g., advice, instructions, education, and medication adjustments).

<u>Family accessory visits.</u> The clinician will clearly indicate that sessions are primarily for the adolescent, but that input from parents is valued and that parents' concerns will be addressed. Parents will be included in up to 15 minutes of a session at least monthly, up to weekly in the case of urgent concerns on the part of the parent. Parents should be helped to share their observations or concerns in the presence of the adolescent, rather than meeting with the clinician alone, in order to minimize distrust by the adolescent.

These contacts should emphasize open airing of concerns, provide information about affective disorder and pharmacotherapy, and reassure parents that the safety of their son or daughter is being protected. Such intervention may result in increased family support, but active family therapy intervention is not to be conducted during the eight week study.

The parents will also be involved in the four psychoeducational sessions described below.

Clinical deterioration. A clinical management issue of major significance is the referral of unimproved or deteriorating patients for a clinical evaluation. If the patient has shown no improvement or begins to show clinical deterioration after a reasonable therapeutic trial of study medication and further continuation under such circumstance would be detrimental to the patient, a referral should be made for a clinical evaluation to determine whether the patient should be withdrawn from the study. Such clinical evaluations can be done by the PI or a psychiatrist designated by the PI. If the patient is withdrawn from the study, appropriate referral arrangements will be made by research staff. The pharmacotherapist has full responsibility and authority to refer the patient for clinical evaluation at any time regarding the patient's suitability for remaining in the study.

<u>Crisis Management</u>. Treatment of adolescents often requires the therapist to respond to crises which may involve risk of self-destructive or assaultive behavior, intensification of conflict in the family, or disruption of the relationship with the therapist. These possibilities should be anticipated in the initial session and in the four Psychoeducational sessions. Certain general principles should guide the management of such crises. The first priority must be to assess the degree of potential harm to the patient or others and to assure safety. The therapist should take an actively empathic, supportive role rather than being

neutral or distant. One may offer assistance with problem-solving, such as by asking the patient to talk about alternative options and their probable consequences. Simple advice or suggestions may be given. Sustained focus on interpersonal difficulties, e.g. role transitions or disputes other than the crisis itself, on cognitive distortions, or psychodydnamic interpretations are not part of CMAD. A general hierarchy of response, then, beginning with the most universal elements, is:

- 1. Evaluate risk of harm to self or others. Assure safety.
- 2. Empathic listening.
- 3. Assistance with problem-solving.
- 4. Advice or suggestions.

Options for response to crisis include extra sessions, more involvement of parents in sessions, consultation to school, and full or partial hospitalization. None of these interventions requires withdrawal of the subject from the study, as long as the medication protocol can be continued. Such additional interventions should be kept as brief as possible, with the patient returning to the study treatment schedule as soon as possible.

G. Termination

Even though active psychotherapy as such is not provided in the CMAD, a significant doctor-patient relationship will likely develop during the 8 weeks of the study. In light of this, discussion of termination should occur and will likely be an important issue in the last few sessions. A sensitively directed inquiry and guided discussion that permits the patient to express inquiry and guided discussion that permits the patient to express feelings and ideas about having participated in the study, attitude towards the therapist, fears about discontinuing medication, future plans, and possible future therapy needs is essential. Deficiencies in dealing with termination issues can led to instances of "acting out" (e.g., patients abruptly and unilaterally stopping their medications or not returning for tapering sessions). If previously unrecognized or currently unresolved termination issues still remain, an additional session during the tapering phase may be necessary to discuss such issues. However, this is not encouraged as termination issues should be adequately addressed during the final session.

If, at any time during the course of treatment, the patient inquires about continuing treatment beyond the 8-week study period, he/she should be reassured that the appropriate referral will be made if it appears that the patient needs further treatment at the conclusion of the study period.

IV. Maintenance and Continuation Phases

A. Medication and Evaluation Schedule

In most cases, patients who demonstrate a "medication response" will do so between the second and eighth week of treatment. The period after the demonstrated therapeutic response should be considered the maintenance phase.

It is crucial that the patient who is showing a medication response as evidenced by clinical improvement be educated regarding the need to continue medication throughout the entire study period. This should be emphasized especially at the point when the patient begins to show improvement as patients are at high risk for discontinuing treatment shortly after an initial improvement.

In the event that a patient shows a dramatic improvement and develops a state of euphoria or hypomania, it may be necessary to lower the dosage. If this occurs, the therapist should attempt to maintain at least the minimum medication dosage of "x" mg. If the episode progresses to definite mania, it may be necessary to discontinue medication and to withdraw this patient from the study.

The schedule and nature of evaluations in the Continuation Phase should be reviewed prior to the end of the acute treatment study.

B. Evaluation of Response to Treatment

The Symptom, Sign, Side-Effect Checklist will serve as a standard format for assessing symptoms as well as evaluating side effects, and will be completed after every session. Change in the number and intensity of target symptoms of depression and the presence and severity of side effects should be the primary referents for making decisions concerning changes in medication dosage. It is important that increases in the medication dosage be continued as long as any target symptoms of depression remain, since patients who achieve only partial improvement frequently relapse on medication several weeks later.

In the case of patients who fail to improve, the pharmacotherapist and/or the patient may assume that the patient has been receiving a placebo. However, it is important not to make this assumption as some patients may respond slowly, not showing a clinical response until exposed to an adequate blood level for several weeks (blood levels will be determined throughout the study, but will not be available to the clinicians for dosage adjustment). For this reason, it is essential to continue to increase the medication dosage if possible even though improvement has not been achieved. Since and adequate dose may make the difference in

response, it is entirely reasonable and honest to encourage a patient to continue treatment with the expectation of a possible future therapeutic response. In summary, pharmacotherapists should manage medication "as if" every patient were receiving active medication.

V. The Interpersonal Context

A. Therapist Factors

It is essential that pharmacotherapists have sufficient experience with the use of antidepressants to have an appreciation for the importance of adequate dosage as a condition for maximal therapeutic response. The should also be aware of the concept of delayed therapeutic response and its relationship to adequate dosage. Pharmacotherapists should also be familiar with the relative medical importance of side effects and methods for their management. A background of knowledge about, and clinical experience in, the use of antidepressants coupled with confidence in their therapeutic value will help foster a therapeutic relationship that can facilitate patient compliance, prevent premature discontinuation of medication, and contribute to a beneficial outcome.

The importance of this knowledge is highlighted by studies of the treatment-resistant depressions. In examining the reasons for patients' failure to respond to pharmacotherapy combined with supportive psychotherapy, researchers found that at least 50 percent of the patients did not receive an adequate trial of any antidepressant medication because the physician did not prescribe adequate doses of the medication or stopped the medication prematurely due to patient noncompliance or the emergence of side effects of little medical consequences. Furthermore, noncompliance was often a result of lack of an adequate relationship with the physician. For some patients, failure to comply with the treatment regimen was attributed to insufficient information about side effects or about the course of therapeutic effect.

B. Role of Therapist

Of critical importance is the pharmacotherapist's role as physician with primary clinical responsibility for the patient. The pharmacotherapist should function as the patient's physician just as physician would in a nonresearch clinical setting. Pharmacotherapists should not permit the study design, research procedures, or their role as members of a research team to interfere with their role of primary responsibility for the care of the patient. Pharmacotherapists should actively assure the patient and parents of their primary and unwavering commitment to the patient's care. The supportive ad therapeutic engagement of the patient is an integral component of the CMAD. In order to engage the patient rapidly in a positive relationship and inspire confidence in the treatment condition, pharmacotherapists should create an ambiance of warmth and trust and convey a positive and optimistic attitude about the patient's clinical treatment. Ideally pharmacotherapists should be able to communicate relevant clinical information

to the patient in understandable terms, if possible in the patient's own words, and convey their knowledge and experience in the pharmacotherapy of depressive disorders.

Any tendency to administer the pharmacotherapy condition mechanically, to maintain inappropriate distance, or to relate in a perfunctory way is antitherapeutic and must be avoided. The rationalization of antitherapeutic behavior such as distancing by conceptualizing it as consistent with the role of "research therapist" should be considered a breach of doctor-patient responsibility. Neither remoteness nor aloofness in the name of therapeutic neutrality has a place in the CMAD. It is hoped that the pharmacotherapy condition in this study will approximate the best and most effective treatment that could be provided by an eclectic psychiatrist, given the study constraints on active psychotherapeutic intervention.

C. Interpersonal Processes

Although pharmacotherapists should concentrate on target symptoms and side effects, certain interpersonal processes are both permitted and suggested in the CMAD conditions. Clinical management requires the basic keen observational skills, interpersonal sensitivities, and technical interventions that are ideally characteristic of any competent psychiatrist. As described above, flexibility, empathy with both the adolescent and the parents, and active interest are encouraged.

The pharmacotherapist should engage in the types of interpersonal interventions which foster a good doctor-patient relationship, while at the same time avoiding specific interpersonal interactions that would be characterized as formal psychotherapeutic interventions. For example, inquiry into the cognitive, affective, and behavioral-interpersonal realm for the purpose of clarifying the patient's current state or situation is permitted and can be successfully accomplished without utilizing a dynamic, cognitive, behavioral, or other specific organized, systematized psychotherapeutic approach. The separation of these two levels of inquiry and intervention is somewhat arbitrary and may be experienced by the pharmacotherapist as a constraint.

However, it is important that the prohibition on active psychotherapeutic intervention not result in the patient's receiving limited emotional support. The general injunction against "active psychotherapy" should not lead to self-consciousness or rigidity that diminishes the therapist's responsiveness to the patient's immediate need for supportive interaction. In summary, clinically indicated and appropriate supportive psychotherapeutic measures and interventions are sanctioned, whereas interventions related to specific organized systems of psychotherapy are not permitted. See the sample clinical vignettes.

The following sections define several areas of interpersonal process and types of intervention that are permitted within the context of the Clinical Management Condition and several that are not.

- 1. <u>Interpersonal context factors.</u> Depression is an illness in which the patient is frequently anxious and may have negative expectations regarding the treatment intervention and outcome. Because of this, it is critically important to elicit the patient's confidence in the treatment. This can be accomplished through attention to the interpersonal context of the treatment. Research has shown that the medication is more efficacious when it is administered within a supportive interpersonal context. Frequently, the patient will need reassurance to continue to take medication in spite of mild and medically insignificant but anxiety-provoking side effects such as dry mouth and blurred vision. The patient may also need support in the face of criticism by family, friends, or peers who communicate negative attitudes about the medication. The patient's positive and meaningful relationship with the physician is crucial in sustaining medication compliance under adverse or unsupportive psychosocial circumstances. If the patient has trust in the physician, believes in his/her knowledge and competence, and maintains a conviction that the medication will be helpful, the patient will persist in the course of therapy even in the absence of initial improvement.
- 2. <u>Psychological support.</u> Psychological support should be provided by the pharmacotherapist throughout the course of treatment. Conveying a sense of hope and optimism is especially necessary in the earlier phase of treatment when the patient is likely to develop doubts that the treatment will help in the face of an initial lack of improvement. Reassurance may be particularly important if the patient is having medication side effects or physical symptoms of depressive illness. Furthermore, the patient may need special reassurance in the face of criticism of medication use by relatives or friends.
- 3. <u>Instruction</u>, <u>education</u>, <u>and information giving</u>. It is particularly important that, in the first session, the patient be instructed about the characteristics of the medication and the reason that it is given for depression. In addition, there should be some discussion of the notion that depression may be related to a change in brain biochemistry which the medication may help correct. This explanation must be general enough to allow for the possibility that psychotherapeutic treatment can also be effective and the possibility that the type of medication used in the study may not be effective for each individual patient. Physical symptoms of depression and the side effects of the medication should also be discussed.
- 4. <u>Advice.</u> Frequently, patients will ask what they can do to help themselves out of their depression. The pharmacotherapist might give simple suggestions to the patient such as advising increased physical activity (e.g.,

age-appropriate exercise). Patients may also request advice concerning whether to make decisions or to attempt to engage in certain activities during a depressive episode. Simple advice is permitted within the context of the CMAD. For instance, a patient under certain circumstances might be advised to avoid a particular stressful situation or advised to socialize more, depending on the situation. Pharmacotherapists should keep notes on any such direct advise that is given.

5. <u>Ventilation and abreaction</u>. Patients will usually need to describe their depressive feelings at length and share their fears and doubts. Within the limited time frame of the CMAD sessions, patients should be permitted to do this to the extent that it is thought to be of help in sustaining a positive therapeutic relationship.

The following list defines several areas of interpersonal processes and types of intervention which are not permitted within the context of the CMAD:

- 1. Focusing on specific psychological themes, especially interpersonal relationships and cognitive distortions.
- 2. The interpretation of interpersonal events, styles of interpersonal relating, suppressed feelings, or distorted cognition's.
- 3. Interpretations relating to recent losses, secondary gain, and other psychological mechanisms.
- 4. Clarification of the patient's feelings toward others and toward the therapist.
- 5. Specific behavioral instructions or routines other than simple advice about activity such as instructions that the patient should be going out more as he/she shows improvement.
- 6. Explanations of the psychodynamics of depressive conditions (e.g., suppressed anger, shame, and helplessness).
- 7. Any involved interpersonal interactions.

DO'S and DON'T of CMAD

DO'S:

- 1. Speak about current experiences.
- 2. Inquire about feelings.
- 3. Acknowledge understanding of feelings.
- 4. Inquire about events not spontaneously reported.
- 5. Inquire about the patient's thoughts about solving problems
- 6. Express sympathy if misfortunes occur.
- 7. Communicate shared pleasure at positive events.
- 8. Congratulate patient for success.
- 9. Give the patient hope of the likelihood of his/her getting better.

DON'Ts:

- 1. Relate current conflict or attitudes to earlier experiences.
- 2. Draw analogies between behavior toward some people and other, such toward parent and toward friends, siblings, teachers, etc.
- 3. Challenge patient's view of self or others.
- 4. Give specific suggestions for resolving conflict.
- 5. Bring up childhood experiences.
- 6. Bring to the patient's attention that his/her behavior appears to represent specific difficulties, such as fear of failure, fear of rejection, etc.
- 7. Bring to the patient's attention that his/her behavior has intents that he/she is not acknowledging (i.e., punishing parents, getting revenge on friends, trying to prove is generous, etc.).

VI. Psychoeducational Program

All patients and at least one parent - both if possible - will participate in a psychoeducational program consisting of an initial two-session course on Weeks 1 and 2 and review session in Weeks 4 and 6. These will be up to 50 minutes in length.

The program will use the manual Living with Depression: A Survival Manual for Families, developed by Kim Poling, M.S.W., Western Psychiatric Institute and Clinic (1989). The eight sections will be covered in order in the two initial sessions, with the clinician presenting material variably, in the terms understandable to the patient and family, and responding to questions. The manual will be given to the family to read but it is expected that comprehension of the written material will vary. The clinician may answer questions about how the information fits a particular family, but the emphasis will be on sharing information rather than exploring family interactions. Consistent with the CMAD, simple advice can be given (see V. The Interpersonal Context, C.4).

In each of the two review sessions, the clinician will briefly review the outline of the manual and review areas of particular interest and respond to questions. The family and patient are likely to focus on the last three sections: The Family and Depression, Helping The Depressed Person, and Coping with Depression. When family conflicts are presented, the clinician's responses should communicate empathy for the stress of living with a depressed or irritable adolescent, and identification of problematic behaviors or interactions which may be the results of the depression. The family should be helped to be supportive and to avoid critical or pejorative comments, or punitive behavior which results from their frustration.

VII. Pharmacotherapist Training and Adherence Monitoring

Pharmacotherapists will be psychiatrists who have experience with adolescents and with the pharmacotherapy of affective disorders. All will review three videotaped sessions of CMAD and then conduct at least six session, with three different patient, using the model. Audiotapes of three tapes - one per patient - will be rated using the Collaborative Study Psychotherapy Rating Scale (CSPRS-6), an instrument developed by the NIMH Treatment of Depression Collaborative Research Program to assess adherence to the models used in that study, i.e. Cognitive Therapy, Interpersonal Psychotherapy, and Clinical Management.

After agreement by a committee of investigators (), a pharmacotherapist will be accepted for the study.

Continuing adherence will be assessed by reviewing 3 audiotapes from each pharmacotherapist every 6 months, using the CSPRS-6.

The CSPRS-6 is a 96 item instrument developed for rating audiotapes of therapy sessions with depressed adult outpatients. A review of the instrument indicates that it can be used without modification to rate sessions with adolescents. The instrument has scaled to assess Cognitive, Interpersonal and Clinical Management models, Facilitative Conditions (e.g. supportiveness, warmth), Explicit Directiveness, "Tangential" Cognitive and Interpersonal Therapy, and nonspecific strategies (e.g.), the entire instrument will be used to allow a full characterization of the Clinical Management sessions, including the degree of overlap with other models and the extent of the use of nonspecific therapeutic characteristics.

The use of the CSPRS-6 is described in the <u>Raters Manual for the 96-item CSPRS-6</u>. Performance of the instrument and its scale V are reviewed and selection and training of raters for the CSPRS-6 in the <u>Final Report: System for Rating Psychotherapy Audiotapes</u>.

APPENDIX H EXTERNAL REVIEWERS



Blank Case Report Form (CRF)

Project	Protocol	Center	Patient Number
29060	329	0	

SB SmithKline Beecham Pharmaceuticals

CONFIDENTIAL

CASE REPORT FORM

PROTOCOL 29060/329

SCREENING/ELIGIBILITY - BINDER 1

A Multi-Center, Double-Blind, Placebo Controlled Study of Paroxetine and Imipramine in Adolescents with Unipolar Major Depression

Patient Initials Country	
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SMITHKLINE BEECHAM PROTOCOL 29060/329 - SCHEDULE OF PROCEDURES

Assessments	sessments		eline				Acute	Phas	se			Co	ontini	ıatior	ı Pha	se	
11000011101100	Time (weeks)	-1	0	1	2	3	4	5	6	7	8	12	16	20	24	28	32
Informed Consent		•											<u></u>				
Medical History and Physical	Exam	•															
Clinical Laboratory Studies		• 1									•			•			•
Serum Pregnancy		•		• 2						·	ļ						·
ECG		•			•		•		•		•			•			•
Vital Signs		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Hamilton Depression Scale		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Full K-SADS-L		•															•
Affect Section of K-SADS-L			•		•		•		•		•	•	•	•	•	•	
C-GAS		•															
CGI			•	•	•	•	•	•	•	•	•	•	•	•		•	•
SADS-L		•													l		
FH-FHE		•													<u></u>		
Autonomous Functioning Chec	cklist	•									•						•
Self Perception Profile		•									•						•
Sickness Impact Scale		•									•						•
Randomization			•														
Adverse Experiences			•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Supportive Psychotherapy			•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Plasma Sampling for Drug A	nalysis	•					•				•				•		•
Study Medication Record				•	•	•	•	•	•	•	•	•	•	•	•	•	•
Concomitant Medication		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•

Clinical laboratory studies should include a Urine Drug Screen
 On suspicion of pregnancy

GENERAL INSTRUCTIONS

Print clearly in CAPITAL LETTERS using a black ball-point pen and press firmly so that all copies are legible. DO NOT print in shaded areas. Answer all questions on every page.

The plastic writing board in the back of the binder should be used to divide each set of pages before writing on them with a ball-point pen.

<u>Important:</u> Errors should be crossed with a single line and the alteration made as close to the original as possible. All alterations must be printed, initialled and dated.

DATE

Use the following three-letter abbreviations for month:

January :: JAN
February :: FEB
March :: MAR
April :: APR
May :: MAY
June :: JUN
July :: JUL
August :: AUG
September :: SEP
October :: OCT
November :: NOV
December :: DEC

TIME

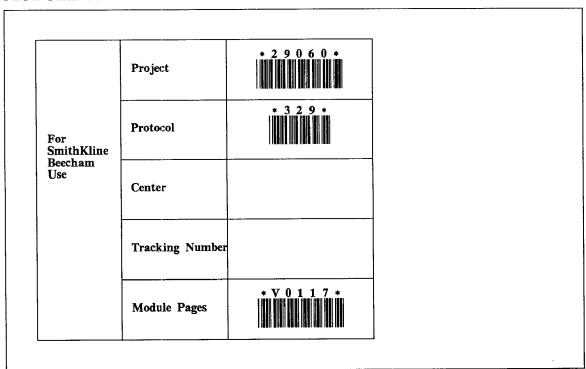
Unless specified otherwise, use the 24 hour clock: 00:00 - 23:59.

Example: $\frac{1 + 5 + 3 + 0}{24 \text{ hr. clock}} = 3:30 \text{ p.m.}$



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MODULE PARAMETERS - SCREENING/ELIGIBILITY







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29060	329	0,0		Screening (Week -1)	day month year	1

					-			
Date of Birth day		month year	Sex	☐ Ma ☐ Fen	le nale			
Race	□ <i>1</i>	White						
		Black						
		Oriental						
		Other - specify:						
AL SIGN	S							
		Sitting	.	Standing				
Weight Height	Blood Pressure Pulse		e Blood Pressure F					
□ lbs □ kg	☐ in☐ cm	(mmHg) systolic diastolic	(beats/ min)	(mmHg) systolic diastolic	(beats/ min)			
		1/1		1/1				
	1 1 1		<u> </u>		1 1 1-			
E CTROC A	DDIOCI) A B.C						
LCIKOCA	KDIOGE							
Were there a	nv clinicall	y significant abnormaliti	ies?					
				Date Per				
Yes	□ No			(day mon	th year			
Record in t	he Significa Il Examinat	nt Medical/Surgical Hist ion section, page 3.	ory					
		,18						

Patient Initials	Country	





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PERSONAL HISTORY

Record the highest level of education for mother and father.
Father Mother
☐ ☐ Graduated JHS
☐ ☐ Graduated HS (do not count G.E.D.)
☐ ☐ Graduated Junior College (A.A.)
☐ ☐ Graduated Senior College (B.A., B.S., B.F.A., etc)
☐ ☐ Completed Masters Degree (M.A., M.S., M.S.W., etc.)
Completed Doctoral, Medical, Law or Comparable Degree
☐ ☐ Dropped out of JHS
□ □ Dropped out of HS
☐ ☐ Dropped out of College
□ □ Received G.E.D.
Record the occupation for mother and father. If retired or deceased, record prior to retirement or death.
Father Mother
☐ ☐ Higher executive, proprietors of large concerns, major professionals
Business managers in large concerns, proprietors of medium-sized
businesses, minor professionals Administrative personnel, owners of small independent businesses,
minor professionals
☐ ☐ ☐ Clerical and sales workers, technicians, owners of little businesses
□ □ Skilled manual employees
☐ ☐ Machine operators, semi-skilled employees
□ □ Unskilled employees
☐ ☐ Not relevant (e.g., was never employed)
Family Composition
2 parents home
Single parent alone Other relative(s) is (are) caretaker
Parent + 1 step-parent Parent + other relative(s) are caretaker
Number of People in Household
Adopted/Natural Offspring
☐ M Adopted ☐ M Natural
School Placement
Regular Ed
Special ED - specify:
•





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SIGNIFICANT MEDICAL/SURGICAL HISTORY AND PHYSICAL EXAMINATION

Is the patient presently suffering from or has he/she ever suffered from any SIGNIFICANT medical or surgical condition?						
 □ No □ Yes						
Diagnosis	Year of First Diagnosis	Past	Current/ Active			
For SB						
For SB						
For SB						
For SB						
For SB						
For SB						
For SB						
For SB						
For SB	1 1 1					
For SB						
For SB	1 1					





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PRIOR MEDICATION

 No Yes → Record details below Where appropriate, medical conditions recorded here must correlate with conditions listed in the Significant Medical History section, utilizing the same terminology. 									
Drug Name	Total Daily Dose	Route	Medical Condition		Start Date *			End Date *	
(Trade Name Preferred)	(e.g., 500 mg)		Condition	day	month	year	day	month year	
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LABORATORY TESTS

Sample Date day month year	For Lab Number SB Code
Attach SBCL laboratory report behind this pa	ge.
Was a urine sample taken and sent to SBCL□ No□ Yes	for drug abuse analysis?
▶ Are there CLINICALLY SIGNIFICANT ABNO	ORMAL laboratory values?
☐ No ☐ Yes → Record the findings and/or of History and Physical Examin	diagnosis in the Significant Medical/Surgical nation section, page 3.

PLASMA SAMPLE - DRUG CONCENTRATION

Was a	a plasma sample obtained for drug concentration?	
	No	
	Yes	





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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 1 OF 3

1.	Depressed Mood (sadness, hopelessness, helpless, worthless)
	 □ 0 = Absent □ 1 = These feeling states indicated only on questioning □ 2 = These feeling states spontaneously reported verbally
	3 = Communicates feeling states non-verbally, i.e., through facial expression, posture, voice and tendency to weep 4 = Patient reports virtually only these feeling states in his/her spontaneous
	verbal and non-verbal communication
2.	Feelings of Guilt
	 □ 1 = Absent □ 1 = Self reproach, feels he/she has let people down □ 2 = Ideas of guilt or rumination over past errors or sinful deeds □ 3 = Present illness is a punishment. Delusions of guilt □ 4 = Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations
_	
3.	Suicide 0 = Absent
	☐ 1 = Feels life is not worth living ☐ 2 = Wishes he/she were dead or any thoughts of possible death to self ☐ 3 = Suicide ideas or gesture ☐ 4 = Attempts at suicide (any serious attempt rates 4)
4.	Insomnia Early
	 □ 0 = No difficulty falling asleep □ 1 = Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour □ 2 = Complains of nightly difficulty falling asleep
5.	Insomnia Middle
	 0 = No difficulty 1 = Patient complains of being restless and disturbed during the night 2 = Waking during the night - getting out of bed rates 2 (except for purposes of voiding)
6.	Insomnia Late
	 0 = No difficulty 1 = Waking in early hours of the morning but goes back to sleep 2 = Unable to fall asleep again if he/she gets out of bed
7.	Work and Activities
	 0 = No difficulty 1 = Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies
	2 = Loss of interest in activity; hobbies or work - either directly reported by patient, or indirectly in listlessness, indecision and vacillation (feels he/she has to push self to work or activities)
	 3 = Decrease in actual time spent in activities or decrease in productivity. 4 = Stopped working because of present illness.





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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 2 OF $\bf 3$

8.	Retardation (slowness of thought and speech, impaired ability to concentrate; decreased motor activity) 0 = Normal speech and thought 1 = Slight retardation at interview 2 = Obvious retardation at interview 3 = Interview difficult 4 = Complete stupor
9.	Agitation
	 □ 0 = None □ 1 = Fidgetiness □ 2 = "Playing with" hands, hair, etc. □ 3 = Moving about, can't sit still □ 4 = Hand wringing, nail-biting, hair-pulling, biting of lips
10.	Anxiety Psychic
	 □ 0 = No difficulty □ 1 = Subjective tension and irritability □ 2 = Worrying about minor matters □ 3 = Apprehensive attitude apparent in face or speech □ 4 = Fears expressed without questioning
11.	Anxiety Somatic (physiological concomitants of anxiety such as: Gastrointestinal (dry mouth, wind, indigestion, diarrhea, cramps, belching), Cardiovascular (palpitations, headaches), Respiratory (hyperventilation, sighing), Urinary frequency, Sweating.
	 □ 0 = Absent □ 1 = Mild □ 2 = Moderate □ 3 = Severe □ 4 = Incapacitating
12.	Somatic Symptoms Gastrointestinal
	 □ 0 = None □ 1 = Loss of appetite but eating. Heavy feelings in abdomen □ 2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms
13.	Somatic Symptoms General
	 □ 0 = None □ 1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability □ 2 = Any clear-cut symptoms rates 2
14.	Genital Symptoms (such as loss of libido and menstrual disturbances)
	 □ 0 = Absent □ 1 = Mild □ 2 = Severe





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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 3 OF $\bf 3$

15.	Hypochondriasis
	□ 0 = Not present □ 1 = Self-absorption (bodily)
	 □ 2 = Preoccupation with health □ 3 = Frequent complaints, requests for help, etc.
	4 = Hypochondriacal delusions
16.	Loss of Weight
	 □ 0 = No weight loss □ 1 = Slight or doubtful loss of weight □ 2 = Obvious or severe loss of weight
17.	Insight
	 □ 0 = Acknowledges being depressed and ill □ 1 = Acknowledges illness but attributes cause to bad food, climate, over-work, virus, need for rest, etc.
	2 = Denies being ill at all
•	HAMD Score (Items 1-17)





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AUTONOMOUS FUNCTIONING CHECKLIST

(mother, father, guardian, other)	Grade in School	لبيا		
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Instructions

The purpose of this checklist is to learn about what your teenager does every day. There are no "right" or "wrong" things for your teenager to do, since teenagers of different ages do many different things. These questions are simply for the purpose of getting an idea of your teenager's daily activity.

When you answer these questions, first, read the question and think about whether or not it describes what you see or have seen your teenager do. You should answer the questions according to what you know your teenager does or does not do rather than what you believe or think he or she could do or could not do.

Second, tell us how the question describes what you teenager does by choosing one of the alternatives "0", "1", "2", "3", or "4" from the scale and circling that number in the space to the right of the item. Here is how to use the rating scale with a sample question.

0	1	2	3	4
Does Not	Does Only	Does About Half	Does Most of	Does Every
Do	Rarely	the Time There is	the Time There is	Time There is
	-	an Opportunity	an Opportunity	an Opportunity

Sample Item. Pick up trash in the yard.

0 1 2 3 4

- 0 Circle "0" if you have never seen your teenager do this, even if he or she may never have had an opportunity. (For example mark "0" if your teenager has never done it, even if you live in an apartment and do not have a yard.)
- 1 Circle "1" if you have seen your teenager do this when there has been a chance, but if there have been many more times that he or she has not done it.
- 2 Circle "2" if your teenager does this about half the time there is a chance, but if he or she does not do it readily or comfortably.
- 3 Circle "3" if there are more times that your teenager does this than does not do it, given the chance, and if he or she does it readily.
- 4 Circle "4" if your teenager does this whenever there is a chance and if he or she does it readily.

Your teenager will not have had the chance to participate in some of the activities the questions described. These items should be answered as "does not do," even though you may feel that your teenager would do it if given the chance. Please circle "0" for questions that describe activities your teenager has **never had the chance** to do.





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Some questions describe things that your teenager may do with help from others. Answer these questions after you think about who has the most responsibility for completing the activity. For example, your teenager may cook the family meals and may be helped by other family members who set the table or chop vegetables. If your teenager is the family member with the most responsibility for cooking every meal that the family eats together, your answer would be "4", which stands for "does every time there is an opporunity." On the other hand, if your teenager helps other family members by doing jobs that they tell him or her to do, and never has the most responsibility for fixing dinner, your answer would be "0", for "does not do."

	0	1	2	3				4	
D	oes Not Do	Does Only Rarely	Does About Half the Time There is an Opportunity	Does M the Time an Oppo	Ther	e is	Tim		ery ere is tunity
Му	teenager:								
1.	Keeps own p makes bed,	personal items and be	elongings in order (for exning and belongings).	ample	0	1	2	3	4
2.		d that does not requ example, cereal, san	ire cooking for himself/dwich).		0	1	2	3	4
3.	Care for his repair, shoe		or example, laundry, simp	ole	0	1	2	3	4
4.			ties (for example, rides b ransportation, drives car).		0	1	2	3	4
5.		d that requires cook e, hamburger, soup).	ing for himself/herself		0	1	2	3	4
6.			dical care for himself/takes own temperature).		0	1	2	3	4
7.			and personal items that example, underwear, toilet	ries).	0	1	2	3	4
8.		nor repair and maint e, changes light bulb	tance in his/her owm envi	ironment	0	1	2	3	4
9.	Shops for an	nd purchases his/her	own groceries.		0	1	2	3	4
10.	Responds to	his/her own medical	l emergency by calling pa	irent.	0	1	2	3	4
11.	Responds to hospital.	his/her own medica	l emergency by calling do	octor or	0	1	2	3	4
12.	Does design living areas yard work).	(for example, clean	tenance chores involving f is, takes out trash, does s	amily imple	0	1	2	3	4





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	0	1.	2	3				4	
Do	Do Do	Does Only Rarely	Does About Half the Time There is an Opportunity	Does M the Time an Oppo	Ther	e is	Tim		ery ere is tunity
13.		tine daily personal, dresses, feeds).	care for another family n	nember.	0	1	2	3	4
14.			gings of another family m, puts away clothing and 1		0	1	2	3	4
15.	Prepares mea	ls for other family	member(s).		0	1	2	3	4
16.	Transports (c	or arranges for trandaily activities.	nsport of) another family	member	0	1	2	3	4
17.		othing and personal her family member	items (that are used on a	a daily	0	1	2	3	4
18.	Shops for an	d purchases family	groceries.		0	1	2	3	4
19.			intenance in family living lbs, hangs picture).	areas	0	1	2	3	4
20.	and maintena		es arrangement for repair usehold needs (for example	, plumbing,	0	1	2	3	4
21.	Responds to problem) by	household emergencealling parent or	cy (for example, stove fire neighbor.	e, plumbing	0	1	2	3	4
22.	problem) by		y (for example, stove fire tment, using fire extinguis) g off water.		0	1	2	3	4
Му	teenager:								
23.	Uses the telp	phone and telephone	e directories.		0	1	2	3	4
24.	Carries out listens to in change).	transactions with saformation, asks qu	ales people (for example, estions, gives payment, rec	ceives	0	1	2	3	4
25.	Uses postal packages).	services (for exam	ple, uses postage, mails le	tters.	0	1	2	3	4
26.	Uses bank (out deposit or withdrawal	slips,	0	1	2	3	4





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	0	1	2	3				4	
De	oes Not Do	Does Only Rarely	Does About Half the Time There is an Opportunity	Does Mo the Time an Oppo	There	e is	Tim	es Eve e The Opport	ere is
27.	Uses travel-r subway).	elated services for	short trips (for example,	taxi, bus	0	1	2	3	4
28.	Uses travel-r train, bus).	elated services for	long trips (for example, a	airline,	0	1	2	3	4
29.	Uses library machine).	services (for examp	ole, checks out books or u	ises Xerox	0	1	2	3	4
30.	Maintains an	d uses his/her own	savings account.		0	1	2	3	4
31.	Maintains an	d uses his/her own	checking or charge accou	nt.	0	1	2	3	4
32.	Maintains ad trims fingers	equate personal care nails and toenails w	e and grooming (for exam then needed)	aple, bathes,	0	1	2	3	4
33.		s/her routine genera e eating, sleeping an	l health and fitness (for end exercise habits).	example,	0	1	2	3	4
34.		ing that is suited to aining, warm clothe	o weather (for example, es in winter).		0	1	2	3	4
35.	unscheduled		himself/herself in everday mple, chooses to watch tel		0	1	2	3	4
36.	Plans activity makes plans	y for his/her long-t for summer vacation	term free time (for examp on, mid-semester vacation)	le,).	0	1	2	3	4
37.		ndships with peers ngs, games, club m	(for example, plans or att eetings).	ends	0	1	2	3	4
38.	example, ke	ademic social obligations appointments for arranged by self of	ations or commitments (for family and peer related or others).	or	0	1	2	3	4
39.		omework assignmen	d commitments (for exampts on time, brings necessar		0	1	2	3	4
40.	arranges for	rtation to and from rides with friends nd schedule).	special activities (for ex- or family or plans care of	ample or	0	1	2	3	4





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	0	1	2	3				4	
Do	oes Not Do	Does Only Rarely	Does About Half the Time There is an Opportunity	Does Mos the Time T an Oppor	here	e is	Time		ery ere is tunity
41.	example, sav	es money for large	n allowance or income (f purchases, pays for routi out running out of money)	ne	0	1	2	3	4
42.	Make long-te selects cours	erm educational and es, investigates coll	/or career plans (for example or technical schools)	nple,	0	1	2	3	4
	n my teenager he chooses to:		how he/she will spend his	s/her unschedu	ıled	free t	ime.		
43.	Listen to mu	sic (for example, r	radio or stereo).		0	1	2	3	4
44.	Read for rela	axation (for exampl	le, books, newspapers)		0	1	2	3	4
45.		or puzzles (for exa- les, computer games	mple, cards, crossword pu s).	zzles,	0	1	2	3	4
46.	Write letters	to friends, relative	es, aquaintances.		0	1	2	3	4
47.	Work on or cooking, col car repair).	take lessons in cra lections, pet care,	fts or hobbies (for examp sewing, model building,	le	0	1	2	3	4
48.	skill (for ex	take lessons that in ample, piano or ot ative writing, foreig	volve a trained artistic or her musical instrument, be an languages).	academic allet,	0	1	2	3	4
49.	Go to the m	ovies, rock concert	s, dances.						
50.	Go to plays,	theater, lectures.			0	1	2	3	4
51.	(for exampl	ities that are relate e, runs a business, rofessional preparat	d to his or her career int works on a computer, pr ion).	erest(s) actices	0	1	2	3	4
52.	Go for wall	:\$.			0	1	2	3	4
53.	Go shopping	, or spend time at	shopping centers or in sh	opping areas.	0	1	2	3	4
54.	Attend club	meetings or other	organized social group me	eetings.	0	1	2	3	4
55.	Work for pa	ay (for example, bak dogs, work at pa	abysit, play in a band, do art-time job, deliver paper	yard s).	0	1	2	3	4





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	0	1	2	3	-	4
D	oes Not Do	Does Only Rarely	Does About Half the Time There is an Opportunity	Does Most of the Time There is an Opportunity	s Time	Every There is cortunity
56.	Clean and/o example, cl household r	ean house, wash or r	ronment or belongings (frepair clothes, wash car,	for 0 1 make	. 2 :	3 4
57.	Work on so make specia	hoolwork (for examp	le, spend extra time on ass projects, spend time	homework, 0 1 in library).	2	3 4
58.	have discus	with family (for exa- sions or casual conve- such as picnics or pa	mple, work on family pressations, attend family rties).	rojects, 0 1	1 2	3 4
On if th	these final it he description	ems, please check "Ye fits your teenager.	es" or "No" in response Check "No" if it does i	to each description.	Check "Ye	es''
Му	teenager:				Ye	es No
59.	Has casual	friendships with teens	agers of opposite sex.			
60.	Has close i	friendships with teena	gers of opposite sex.			
61.	Has casual neighbors,	friendships with adul coaches, scout leaders	its outside the family (fo	or example, teachers,		
62.	Has close ineighbors,	friendships with adult coaches, scout leader	s outside the family (for s).	example, teachers,		
63.	Has casual	friendships with your	nger children.			
64.	Has close	friendships with youn	ger children.			
65.			groups of teenage friends	S.		
66.		friendships.				
67.	Is active i		ized extracurricular group ports team).	p (for example,	[
68.	Has leader example, p	ship position in one operation of the stude	or more organized extrac nt council, captain of th	curricular group (for e sports team).	[
69.		friendship with adult aunt, grandparent).	member of the extended	family (for example	, [
70.	. Works or		r pay or volunteer in an	area of particular	[





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		Yes	No
71.	Works or has worked to earn money by providing a service on a regular scheduled basis (for example, contracts for yard work, dog walking, baby sitting)	Ц	
72.	Works or has worked to earn money by using a special skill (for example, musical performance, typing, tutoring).		
73.	Works or has worked to earn money in a self-or-peer-run organization or business.		
74.	Works or has worked to earn money fundraising for an organization or charity (for example, scouts, church groups, political organizations).		
75.	Does or has done volunteer work without pay for a service, a school or political organization, a social agency, a club, a church, or a hospital.		
76.	Participates or has participated in prevocational (career) or vocational (career) classes or training (for example, any technical training or career development class).		
77.	Has explored career interest by visiting work sites or interviewing people in that job or career.		
78.	Has spent time reading, researching, or "finding out" about a career that particularly interests him/her.		
Com	ments:		
If y beha	ou have any additional information about your teenager's everyday independent or self-vior, use the space below to write your comments. Thank you.	suffici	ent

SS SmithKline Beecham Pharmaceuticals



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WHAT AM I LIKE								
Really True for Me	True	Sample Sentence			Sort of True for Me	Really True for Me		
a		Some teenagers like to go to movies in their spare time	BUT	Other teenagers would rather go to sport events.				
1.		Some teenagers feel that they are just as smart as others their age	BUT	Other teenagers aren't so sure and wonder if they are as smart.				
2.		Some teenagers find it hard to make friends	BUT	For other teenagers it's pretty easy.				
3.		Some teenagers do very well at all kinds of sports	BUT	Other teenagers don't feel that they are very good when it comes to sports.				
4.		Some teenagers are not happy with the way they look	BUT	Other teenagers are happy with the way they look.				
5.		Some teenagers feel that they are ready to do well at a part-time job	BUT	Other teenagers feel that they are not quite ready to handle a part-time job.				
6.		Some teenagers feel that if they are romantically interested in someone, that person will like them back	BUT	Other teenagers worry that when they like someone romantically that person won't like them back.				
7.		Some teenagers usually do the right thing	BUT	Other teenagers often don't do what they know is righ	1 1			
8.		Some teenagers are able to make really close friends.	BUT	Other teenagers find it hard to make really close friends.				
9.		Some teenagers are often disappointed with themselves	BUT	Other teenagers are pretty pleased with themselves.				
10.		Some teenagers are pretty slow in finishing their school work	BUT	Other teenagers can do their school work more quickly				





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Really True for Me	Sort of True for Me				Sort of True for Me	Really True for Me
11.		Some teenagers have a lot of friends	BUT	Other teenagers don't have very many friends.		
12.		Some teenagers think they could do well at just about any new athletic activity	BUT	Other teenagers are afraid they might not do well at a new athletic activity.		
13.		Some teenagers wish their body was different	BUT	Other teenagers like their body the way it is.		
14.		Some teenagers feel that they don't have enough skills to do well at a job	BUT	Other teenagers feel that they do have enough skills to do a job well.		
15.		Some teenagers are not dating the people they are really attracted to	BUT	Other teenagers are dating those people they are attracted to		
16.		Some teenagers often feel guilty about certain things they do	BUT	Other teenagers hardly ever feel guilty about what they do.		
17.		Some teenagers can be trusted to keep secrets that their friends tell them	BUT	Other teenagers have a har time keeping secrets that their friends tell them.	d	
18.		Some teenagers don't like the way they are leading their life	BUT	Other teenagers do like the way they are leading their life.		
19.		Some teenagers do very well at their classwork	BUT	Other teenagers don't do very well at their classwork.		
20.		Some teenagers are very hard to like	BUT	Other teenagers are really easy to like.		
21.		Some teenagers feel that they are better than others their age at sports	BUT	Other teenagers don't feel they can play as well.		
22.		Some teenagers wish their physical appearance was different	BUT	Other teenagers like their physical appearance the way it is.		





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Really True for Me	Sort of True for Me			1	ort of True for Me	Really True for Me
23.		Some teenagers are proud of the work they do on jobs they get paid for	BUT	For other teenagers, getting paid is more important than feeling proud of what they of	lo.	
24.		Some teenagers feel that people their age will be romantically attracted to them	BUT	Other teenagers worry about whether people their age wil be attacted to them.	1	
25.		Some teenagers are usually pleased with the way they act	BUT	Other teenagers are often ashamed of the way they act.		
26.		Some teenagers don't really have a close friend to share things with.	BUT	Other teenagers do have a close friend to share things with.		
27.		Some teenagers are happy with themselves most of the time	BUT	Other teenagers are often not happy with themselves.		
28.		Some teenagers have trouble figuring out the answers in school	BUT	Other teenagers almost always can figure out the answers.		
29.		Some teenagers are popular with others their age	BUT	Other teenagers are not very popular.		
30.		Some teenagers don't do well at new outdoor games	BUT	Other teenagers are good at new outdoor games right away.		
31.		Some teenagers think that they are good looking	BUT	Other teenagers think that they are not very good looking.		
32.		Some teenagers feel like they could do better at work they do pay for	BUT	Other teenagers feel that they are doing really well at work they do pay for.		
33.		Some teenagers feel that they are fun and interesting on a date	BUT	Other teenagers wonder abo how fun and interesting they are on a date.	ut	
34.		Some teenagers do things they know they shouldn't do	BUT	Other teenagers hardly ever do things they know they shouldn't do.		





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Really True	Sort of True				Sort of True	Really True for Me
for Me	for Me	Some teenagers find it hard to make friends they can really trust	BUT	Other teenagers are able to make close friends they can really trust.	for Me	
36.		Some teenagers like the kind of person they are	BUT	Other teenagers often wish they were someone else.		
37.		Some teenagers feel that they are pretty intelligent	BUT	Other teenagers question whether they are intelligent.		
38.		Some teenagers feel that they are socially acceptable	BUT	Other teenagers wished that more people their age accepted them.		
39.		Some teenagers do not feel that they are very athletic	BUT	Other teenagers feel that they are very athletic.		
40.		Some teenagers really like their looks	BUT	Other teenagers wished they looked different.		
41.		Some teenagers feel that it's really important to do the best you can on paying jobs	BUT	Other teenagers feel that getting the job done is what really counts.		
42.		Some teenagers usually don't get asked out by people they would like to date	BUT	Other teenagers do get asked out by people they really want to date.	ed	
43.		Some teenagers usually act the way they know the are supposed to	BUT	Other teenagers often don't act the way they are supposed to.		
44.		Some teenagers don't have a friend that is close enough to share really personal thoughts with	BUT	Other teenagers do have a close friend that they can share personal thoughts and feelings with.	d \square	
45.		Some teenagers are very happy being the way they are	BUT	Other teenagers wish they were different.		





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Introduction					
On the next few pages are statements which describe things people often do when they are not well.					
As you read them, think of yourself today:					
- If a statement describes you TODAY, mark the box under "Yes" (Yes, this statement describes me today).					
- However, if a statement does not describe you TODAY, or does not apply you, mark the box under "No". (No, this statement does not describe me today or does not apply to me).					
For Example:					
"I am not doing any of the shopping that I would usually do."					
- If you have not been doing any shopping for some time, and still are not doing any shopping today, check "YES". (Yes, this statement describes me today).					
- If you are doing your shopping as usual, check "NO" (No this statement does not describe me today or does not apply to me).					
Read and respond to the statements in the order listed. Some of the statements will differ only in a few words, so please read each one carefully. While you may wish to go back to change a response, your first answer is usually best. Please do not read ahead in the questionnaire.					
Please do not discuss the statements with anyone, including family members, while doing the questionnaire.					
Please mark your answers by placing an "X" in the appropriate box like this.					
Thank you for your time and help.					
the left					
How would you describe your present health very good good pair poor very poor					
How would you describe you present quality of life (how things are going for you generally)? Urery good good fair poor very poor					





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		-
A.	These statements describe your sleep and rest this week.	Yes No
	1. I spend much of the day lying down in order to rest.	
	2. I sit for much of the day.	
	3. I am sleeping or dozing much of the time - day and night.	
	4. I lie down more often than my friends during the day in order to rest.	
	5. I sit around half asleep.	
	6. I sleep less at night, for example, I wake up easily, I do not fall asleep for a long time, I keep waking up.	
	7. I sleep or doze more during the day.	
В.	These statements describe your daily work around the house.	Yes No
	 I only do work that I need to do around the house for short periods of time or I rest often. 	
	2. I am doing less of the daily household chores that I would usually do.	Ц Ц
	3. I am not doing any of the daily household chores that I would usually do.	
	4. I am not doing any of the shopping that I would usually do.	
	5. I am not doing any of the cleaning that I would usually do.	
	6. I am not doing any of the clothes washing that I would usually do.	
	the state of the s	
C.	These statements describe your contact with your family and friends today.	Yes No
	1. I am going out less to visit people.	
	2. I am not going out to visit people at all.	
	3. I show less interest in other people's problems, for example, I do not listen when they tell me about their problems. I do not offer to help.	
	4. I am often irritable with those around me, for example, I snap at people or criticize easily.	
	5. I show less affection.	
	6. I take part in fewer social activities than I used to, for example, I go to fewer parties or social events.	





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	7.	I am cutting down the length of visits to friends.	Yes	No
	8.	I avoid having visitors.		
	9.	My sexual activity is decreased.		
	10.	I talk less with those around me.		
	11.	I make demands on other people that they find irritating, for example, I insist that they do things for me, or tell them how to do things.		
	12.	I stay alone much of the time.		
	13.	I am disagreeable with my family, for example, I act spitefully or stubbornly.		
	14.	I frequently get angry with my family, for example, I hit them, scream or throw things at them.		
	15.	I isolate myself as much as I can from the rest of my family.		
	16.	I refuse contact with my family, for example, I turn away from them.		
	17.	I am not joking with my family members as I usually do.		
D.	The	se statements describe your feelings.	Yes	No
	1.	I am confused and start to do more than one thing at a time.		
	2.	I have more minor accidents, for example, I drop things, I trip and fall or bump into things.		
	3.	I react slowly to things that are said or done.		
	4.	I do not finish things I start.		
	5.	I have difficulty reasoning and solving problems, for example, making plans, making decisions, learning new things.		
	6.	I sometimes get confused, for example, I do not know where I am, who is around, or what day it is.		
	7.	I forget a lot, for example, things that happened recently, where I put things, or to keep appointments.		
	8.	I do not keep my attention on any activity for long.	. 🗖	
	9.	I make more mistakes than usual.		
	10.	I have difficulty doing things which involve thought and concentration, for example, paying attention in school or at my job.		





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E.	These statements are about how you talk to other people and write.	Yes	No
	1. I am having trouble writing or typing.	ш	
	2. I am having trouble talking to people.		
	3. I am not comfortable in most social situations like parties.		
	 I speak with difficulty, for example, I get stuck for words, I stutter, I stammer, I slur my words. 		
	5. I do not speak clearly when I am under stress.		
F.	The following statements decribe the activities you usually do in your spare time for relaxation, entertainment or just to pass the time.	Yes	No
	1. I spend shorter periods of time on my hobbies and recreation.		
	2. I am going out and enjoying myself less often.		
	3. I am cutting down on some of my usual inactive pastimes, for example, I watch less TV, play cards less, or read less.		
	4. I am not doing any of my usual inactive pastimes, for example, I watch less TV, play cards less, or read less.		
	5. I am doing more inactive pastimes in place of my other usual activities.		
	6. I am taking part in fewer activities with my friends.		
	 I am cutting down on some of my usual physical recreation or more active pastimes. 		
	8. I am not doing any of my usual physical recreation or more active pastimes.		
			
	Now please look through this questionnaire and make sure that you have read every que	estion.	
	<u>.</u>		





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Subject Version

1. Family Members

Please tell me the first names and ages of your biological mother and father.

Now tell me the names, ages and sexes of all the children born to (Mother's first name) and (Father's first name). Please start with the first born (the oldest) and include yourself in the list.

Now please tell me the names of your children, if any. Please start with the first born (the oldest).

Nam	Mem ber ne ID#	Age (or age at death) 00=<1	Sex	Deceased	Correct Birth Order?
Biologic Mother:	1		Female Male Don't Know	No Yes Don't Know	
Biologic Father:	2		Female Male Don't Know	☐ No ☐ Yes ☐ Don't Know	
Sibling #1:	3		Female Male Don't Know	No Yes Don't Know	
Sibling #2:	4		Female Male Don't Know	No Yes Don't Know	
Sibling #3:	5		Female Male Don't Know	No Yes Don't Know	No Yes Don't Know
Sibling #4:	6		Female Male Don't Know	No Yes Don't Knov	No Yes Don't Know
Sibling #5:	7		Female Male Don't Know		
Child #1:	8		Female Male Don't Kno	+=	
Child #2;	9		Female Male Don't Kno	No Yes Don't Kno	No Yes Don't Know





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0 = NO; 1 = YES; 9 = DON'T KNOW

Now I'd like you to take a pencil or pen and a piece of paper and write down the names as I read them off. (Do so.) Could you read the list back to me? (Check to make sure the list matches yours.) Now I'm going to ask you questions about these people. Looking at the list, can you tell me...

2. Has anyone on the list ever had a serious mental illness, emotional problem, or nervous breakdown? 0 1 9

If no or don't know, go to Q.3

If yes ask: A. Who was that? Anyone else? (until no more names are given)

	0	1	9	,	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9
r	M	oti	her		F	at h	er	S	ib. a	# 1	S	ib.	#2	S	ib.a	#3	S	b.4	# 4	S	ib.a	# 5	CI	uld.	#1	Ch	ild.	#2

3. Has anyone on the list ever seen a psychiatrist, psychologist, social worker, doctor 0 1 9 or other health professional for a psychological or emotional problem?

If no or don't know, go to Q.4

If yes ask: A. Who was that? Anyone else? (until no more names are given)

												9															
Ī	M	ot/	ier	F	ath	er	S	ib. A	# I	S	ib.4	#2	S	ib.a	#3	S	b.4	¥4	S	ib.a	F5	CI	ild.	#1	Ch	ild .	#2

4. Has anyone on the list ever stayed overnight or longer in a hospital or treatment 0 1 9 facility because of any mental or emotional problem?

If no or don't know, go to Q.5

							0 1 9	
Mother	Father	Sib.#1	Sib.#2	Sib.#3	Sib.#4	Sib.4*5	Child#1	Child#2





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0 = NO; 1 = YES; 9 = DON'T KNOW

5. Has anyone on the list ever stayed overnight or longer in a hospital or treatment 0 1 9 facility because of a drug or alcohol problem?

If no or don't know, go to Q.6

If yes ask: A. Who was that? Anyone else? (until no more names are given)

0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9
M	oti	her	F	ath	er	S	ib.a	#1	S	ib.a	# 2	S	ib.a	# 3	S	ib.a	# 4	S	ib.4	r 5	CI	hild	#1	Ch	ild.	#2

6. Has a doctor ever given anyone on the list any medicine for a psychological or 0 1 9 emotional problem?

If no or don't know, go to Q.7

If yes ask: A. Who was that? Anyone else? (until no more names are given)

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	Father	Sib.#1	Sib.#2	Sib.#3	Sib.#4	Sib. at 5	Child#1	Child#2

7. Has anyone on the list ever had difficulty carrying out their usual responsibilities, 0 1 9 such as working, going to school, or taking care of the family or household?

If no or don't know, go to Q.8

If yes ask: A. Who was that? Anyone else? (until no more names are given)

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	Father	Sib.#1	Sib.#2	Sib.#3	Sib.#4	Sib.#5	Child#1	Child #2

B. I don't mean because (you/NAME) were physically ill. Other than that, was anyone UNABLE to carry out their usual responsibilities for a WEEK OR MORE?

If no or don't know, go to Q.8

()	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9
	M	ot h	er	F	at h	er	S	ib.a	#]	S	īb.a	# 2	S	ib.a	# 3	S	ib.a	#4	S	ib.a	# 5	CI	rild	#1	CI	uld	#2





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0 = NO; 1 = YES; 9 = DON'T KNOW

 Did anyone on the list ever feel sad, blue, or depressed for most of the time for two days or more?

If no or don't know, go to Q.9

If yes ask: A. Who was that? Anyone else? (until no more names are given)

0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9
M	oth	er	F	ath	er	S	ib.a	#1	S	ib.;	#2	S	ib. 4	# 3	S	ib.4	£4	S	ib. a	<u>#</u> 5	CI	iild	#1	Ch	ild.	#2

B. Without including times of physical illness, or mourning after a death, did anyone have a period during which they felt sad, blue or depressed that lasted TWO WEEKS OR MORE?

0 1 9

0 1 9

If no or don't know, go to Q.9

If yes ask: C. Who was that? Anyone else? (until no more names are given)

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	Father	Sib.#1	Sib.#2	Sib.#3	Sib.#4	Sib.#5	Child#1	Child#2

9. Did anyone on the list ever have a period of feeling quite tired, having less energy, or not caring about their usual activities?

If no or don't know, go to Note 1

If yes ask: A. Who was that? Anyone else? (until no more names are given)

ı																									-		9
	M	oth	er	F	ath	er	S	ib.a	#1	S	ib.a	# 2	S	ib.a	# 3	S	ib. 4	#4	S	<i>ib.</i> .i	# 5	Ci	uld	#1	Ch	ild.	#2

B. Do not include times of physical illness, or mourning after a death. Other than that, did anyone feel VERY tired MOST of the time, have no energy, or not care about their usual activities, for at least TWO WEEKS?

If no or don't know, go to Note 1

If yes ask: C. Who was that? Anyone else? (until no more names are given)

0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9
M	oth	er	F	at h	er	S	ib.4	* 1	S	ib.4	# 2	S	ib.a	# 3	Si	b. 4	¥4	S	ib.ı	# 5	Ci	tild.	#1	Ch	ild .	#2

Note 1: Say: "I know you know this, but I'm supposed to remind you that ALL of these questions are about whether ANY of these people listed on the page have had any these problems; that is; (names on template)."





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0 = NO; 1 = YES; 9 = DON'T KNOW

10. Did anyone on the list ever have sleep problems, like trouble falling asleep, or waking up too early, or sleeping too much?

0 1 9

If no or don't know, go to Q.11

If yes ask: A. Who was that? Anyone else? (until no more names are given)

	0	1		9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9
Ī	M	ot	he	r	F	at h	er	S	ib. a	# <u>1</u>	S	ib.a	# 2	S	ib.a	# 3	S	b.a	#4	S	ib.4	r5	Ci	uld	#1	Ch	ild,	#2

B. Was it as much as an hour a night for TWO WEEKS OR MORE, and not because of a physical illness?

0 1 9

If no or don't know, go to Q.11

If yes ask: C. Who was that? Anyone else? (until no more names are given)

Ī	0	1		9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9
Ì	M	ot	he.	<i>r</i>	F	ath	er	S	ib. a	# <u>1</u>	S	ib.a	# 2	S	ib.a	# 3	Si	b.a	¥4	S	ib. a	* 5	CI	ild :	#1	Ch	ild .	#2

11. Has anyone on the list ever had a period of feeling extremely happy or high? 0 1 9

If no or don't know, go to Q.12

If yes ask: A. Who was that? Anyone else? (until no more names are given)

	0	1	9	-	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9
Ì	M	oti	ier		F	at h	er	S	ib.4	<i>F1</i>	S	ib.a	#2	S	ib. A	# 3	S	ib. 4	#4	S	ib.i	# 5	Ci	iild	#1	Ch	ild.	#2

B. I mean "high as a kite," so that other people worried about them, or so that it interfered with carrying out normal responsibilities. Has anyone been unusually happy or high, not because of drugs or alcohol, for TWO DAYS OR MORE?

0 1 9

If no or don't know, go to Q.12

0		1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9
	Иo	th	er	F	at h	er	S	ib.4	#]	S	ib.a	# 2	S	ib.a	# 3	Si	b.a	# 4	S	ib.:	* 5	CI	iild	#1	Ch	ild.	#2





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0 = NO; 1 = YES; 9 = DON'T KNOW

12. Has anyone on the list ever had a period in which they were more active or talkative than normal?

If no or don't know, go to Q.13

If yes ask: A. Who was that? Anyone else? (until no more names are given)

	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9
l	M	oth	er	F	ath	er	S	ib.a	<i>‡1</i>	S	ib. a	# 2	S	ib.4	# 3	S	ib.4	# 4	S	ib.i	# 5	CI	uld	#1	Ch	ild.	#2

B. I mean EXTREMELY over-active or talkative, so that people WORRIED 0 1 9 about them, or so that it interfered with carrying out their usual responsibilities. Has anyone been like that, without being under the influence of drugs or alcohol, for at least TWO DAYS?

If no or don't know, go to Q.13

If yes ask: C. Who was that? Anyone else? (until no more names are given)

Ī	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9
	M	oth	er	F	ath	er	S	ib.4	r I	S	ib.4	# 2	S	ib.a	* 3	S	b.a	¥4	S	ib.ı	# 5	CI	iild	#1	Ch	ild,	#2

13. Has anyone on the list ever had a sudden spell or attack in which they felt 0 1 9 frightened or panicked?

If no or don't know, go to Q.14

If yes ask: A. Who was that? Anyone else? (until no more names are given)

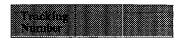
0	1	9	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9
M	oti	hei	r	F	ath	er	S	ib.4	# <u>1</u>	S	ib.a	# 2	S	ib.a	# 3	Si	b.4	£4	S	ib.:i	# 5	CI	iild	#1	Ch	ild ;	#2

B. Has anyone had SEVERAL attacks of EXTREME fear or panic, even though 0 1 9 there was nothing to be afraid of?

If no or don't know, go to Q.14

	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9
l	M	oth	er	F	at h	er	Si	ib.4	<u>* 1</u>	S	ib. a	#2	S	ib.a	#3	S	ib. A	¥4	S	ib.a	# 5	CI	iild	#1	Ch	ild .	#2





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0 = NO; 1 = YES; 9 = DON'T KNOW

14. Has anyone on the list ever had a sudden spell or attack of difficulty breathing or of a rapid heartbeat?

If no or don't know, go to Q.15

If yes ask: A. Who was that? Anyone else? (until no more names are given)

0	1	9	0	1	9	0	1.	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9
M	ot h	er	F	ath	er	S	ib.a	#]	S	ib.a	#2	S	ib.a	#3	S	ib.A	£4	S	ib.a	# 5	CI	uld	#1	Ch	ild.	#2

B. Did the person have SEVERAL such attacks, NOT caused by heart problems, 0 1 9 exercise, or something that would have terrified most people?

If no or don't know, go to Q.15

If yes ask: C. Who was that? Anyone else? (until no more names are given)

												9				<u> </u>			 	-		-					
١	M	ot h	er	F	ath	er	S	ib.a	# 1	S	ib.a	#2	S	ib.4	¥3	S	ib.4	74	S	ib. 4	۴5	CI	rild	#1	Ch	ild.	#2

15. Has anyone on the list ever had a period of at least one month when they were 0 1 9 very tense or nervous and worried?

If no or don't know, go to Q.16

If yes ask: A. Who was that? Anyone else? (until no more names are given)

0		1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9
i	Mc	ot h	er	F	ath	er	S	ib.a	<i>* 1</i>	S	ib.a	#2	S	ib.4	# 3	S	ib.a	‡4	S	ib.	* 5	CI	rild	#1	Ch	ild,	#2

B. Did anyone worry ALMOST EVERY DAY FOR SIX MONTHS OR MORE, about things that other people wouldn't have worried about that much?

If no or don't know, go to Q.16

0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9
M	oti	ter	F	ath	er	S	ib.a	#1	S	ib.a	# 2	S	ib.a	# 3	S	ib.a	#4	S	ib. i	# 5	CI	iild	#1	Ch	ild.	#2





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0 = NO; 1 = YES; 9 = DON'T KNOW

16. Has anyone on the list ever been frightened of going out of the house alone, being in a crowd, standing in lines, going over bridges, or travelling by bus, train or car?

If no or don't know, go to Q.17

If yes ask: A. Who was that? Anyone else? (until no more names are given)

0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9
M	oti	her	F	ath	er	S	ib.4	* <u>1</u>	S	ib.4	# 2	S	ib.a	# 3	S	ib.a	#4	S	ib.i	* 5	CI	iild	#1	Ch	ild.	#2

B. Do not include children who were too young to do these things. Other than that was anyone so frightened that they either COULDN'T do something, or really had to force themselves to do it?

If no or don't know, go to Q.17

If yes ask: C. Who was that? Anyone else? (until no more names are given)

0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9
M	oth	ier	F	at h	er	S	ib, a	# <u>1</u>	S	ib.a	# 2	S	ib.a	# 3	S	ib.a	¥4	S	ibı	# 5	CF	iild	#1	Ch	ild,	#2

17. Has anyone on the list ever been very frightened of heights, animals, insects, or blood?

0 1 9

If no or don't know, go to Q.18

If yes ask: A. Who was that? Anyone else? (until no more names are given)

	0	1		9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9
Ī	M	oti	hei	<i>r</i>	F	at h	er	S	ib.4	* 1	S	ib.a	# 2	S	ib.a	# 3	Si	ib.a	¢4	S	ib.ı	# 5	CI	uld	#1	Ch	ild:	#2

B. Was anyone more frightened than others at their age -- so frightened of something that they tried very hard to AVOID IT?

If no or don't know, go to Q.18

0	1	. 9	,	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9
1	V ot	her		F	at h	er	S	ib.a	# <u> </u>	S	ib.a	# 2	S	ib.a	# 3	S	ib.a	# 4	S	ib.	# 5	Ci	ild	#1	Ch	ild.	#2





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0 = NO; 1 = YES; 9 = DON'T KNOW

18. Has anyone on the list ever gotten very embarrassed when they had to do something that involved other people, such as attend parties or social gatherings, or speak or eat in public?

0 1 9

If no or don't know, go to Note 2

If yes ask: A. Who was that? Anyone else? (until no more names are given)

	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9
ſ	M	oth	er	F	at h	er	S	ib.4	#]	S	ib.a	# 2	S	ib.A	*3	Si	ib.A	t4	S	ib. d	r5	C	uild	#1	Ch	ild.	#2

B. Was anyone so EXTREMELY embarrassed that they COULDN'T DO the things that bothered them, for at least TWO MONTHS?

If no or don't know, go to Note 2

If yes ask: C. Who was that? Anyone else? (until no more names are given)

			<u> </u>			0			-			<u> </u>			<u> </u>			_			_			<u> </u>		
M	oth	er	F	ath	? r	Si	ib.a	#]	S	ib.a	# 2	S	ib.a	F 3	S	ib.#	£4	S	ib.il	# 5	Ch	ild	#1	Ch	ild ,	#2

Note 2: Say: "I want to remind you that all of these questions are about all of the people on the list; that is; (names on template)."

19. Did anyone on the list ever have a habit of checking, counting or cleaning things? 0 1 9

If no or don't know, go to Q.20

If yes ask: A. Who was that? Anyone else? (until no more names are given)

0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9
M	oti	ter	F	ath	er	Si	ib.#	* 1	S	ib.4	# 2	S	ib.a	# 3	S	b.#	r4	S	ib. i	# 5	CI	iild	#1	Ch	ild .	#2

B. Did the person do this over and over again, so much that it interfered with their usual activities?

0 1 9

If no or don't know, go to Q.20

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	Father	Sib.#1	Sib.#2	Sib.#3	Sib.#4	Sib.#5	Child#1	Child #2





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0 = NO; 1 = YES; 9 = DON'T KNOW

20. Has anyone on the list ever had unpleasant, nagging thoughts, such as that they hadn't locked the door, when they really had, or that things were dirty, when they were really clean? 0 1 9

If no or don't know, go to Q.21

If yes ask: A. Who was that? Anyone else? (until no more names are given)

	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9
ĺ	M	oth	er	F	at h	? <i>T</i>	S	ib.z	* I	S	ib.a	# 2	S	ib.a	# 3	Si	b.#	r4	S	ib. i	* 5	CF	ild	#1	Ch	ild,	#2

B. Did these thoughts keep coming back, no matter how hard the person tried to get rid of them?

If no or don't know, go to Q.21

If yes ask: C. Who was that? Anyone else? (until no more names are given)

0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9
M	oth	er	F	ath	er	S	b.	r 1	S	ib.a	# 2	S	ib.a	#3	Si	b.#	ř4	S	ib.i	# 5	CI	iild	#1	Ch	ild.	#2

21. Has anyone on the list ever heard voices, or seen visions, that other people could not see or hear?

0 1 9

If no or don't know, go to Q.22

If yes ask: A. Who was that? Anyone else? (until no more names are given)

	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9
Γ	M	oth	er	F	at h	er	Si	ib.a	# 1	S	ib.i	# 2	S	ib.a	# 3	Si	b.a	r 4	S	ib.i	# 5	Ci	iild	#1	Ch	ild.	#2

B. Don't include experiences caused by alcohol or drugs, or religious
experiences that are common in their religion, or a younger child who had
an imaginary playmate. Other than that, did the person clearly and frequently
hear voices or see visions?

If no or don't know, go to Q.22

0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9
M	ot/	ier	F	at h	er	Si	ib.4	* 1	S	ib.a	# 2	S	ib.a	* 3	Si	b.a	¥4	S	ib.,ı	# 5	Ci	iild	# <u>I</u>	Ch	ild .	#2





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0 = NO; 1 = YES; 9 = DON'T KNOW

22. Has anyone on the list ever believed in things that were very unusual and not true, for example, that people were plotting against them, or that TV programs were sending special messages just to them?

If no or don't know, go to Q.23

If yes ask: A. Who was that? Anyone else? (until no more names are given)

0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9
M	oth	er	F	at he	? <i>T</i>	Si	ib.4	* 1	S	ib.A	# 2	S	ib.a	¥3	Si	b.#	t4	S	ibt	* 5	C	ild	#1	Ch	ild.	#2

B. Don't include beliefs caused by alcohol or drugs, or shared religious beliefs. 0 1 9 Other than that, did the person believe things that were very unusual and not true?

If no or don't know, go to Q.23

If yes ask: C. Who was that? Anyone else? (until no more names are given)

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	Father	Sib.#1	Sib.#2	Sib.#3	Sib.#4	Sib.#5	Child#1	Child#2

23. Did anyone on the list ever have a period in his or her life when they drank 0 1 9 a lot?

If no or don't know, go to Q.24

If yes ask: A. Who was that? Anyone else? (until no more names are given)

Ī	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9
	M	oth	er	F	at h	er	S	ib.4	* 1	S	ib.a	# 2	S	ib.a	# 3	Si	b.A	#4	S	ib.,i	# 5	Ci	iild	#1	Ch	ild.	#2

B. Did the person have a drinking problem, or did people think they had a drinking problem?

If no or don't know, go to Q.24

0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9
M	oth	er	F	at h	er	S	ib.4	# 1	S	ib.a	#2	S	ib.a	# 3	S	ib.a	#4	S	ib.a	# 5	CI	iild	#1	Ch	ild.	#2





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0 = NO; 1 = YES; 9 = DON'T KNOW

24. Did anyone on the list ever have a period in his or her life when they used 0 1 9 illegal drugs regularly?

If no or don't know, go to Q.25

If yes ask: A. Who was that? Anyone else? (until no more names are given)

0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9	0 1 9
Mother	Father	Sib.#1	Sib.#2	Sib.#3	Sib.#4	Sib.#5	Child#1	Child#2

B. Did the person have a drug problem, or did people think they had a drug problem?
0 1 9

If no or don't know, go to Q.25

If yes ask: C. Who was that? Anyone else? (until no more names are given)

0 1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9
Moti	ier	F	at h	e <i>r</i>	S	ib.a	<i>‡1</i>	S	ib.a	# 2	S	ib.a	# 3	Si	b.#	¥4	S	ib.i	# 5	CI	ild	#1	Ch	ild .	#2

25. Has anyone on the list ever been fired from a job, or laid off?

0 1 9

If no or don't know, go to Q.26

If yes ask: A. Who was that? Anyone else? (until no more names are given)

0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9
M	oti	ier	F	ati	er	S	ib.a	#]	S	ib.a	# 2	S	ib.a	# 3	S	ib.a	£4	S	ib.,	# 5	CI	ild	#1	Ch	ild,	#2

B. Was it because their supervisor was not happy with their work, behavior, or attitude?

0 1 9

If no or don't know, go to Q.26

0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9
M	oth	er	F	at h	er	S	ib.a	r1	S	ib.a	# 2	S	ib.a	#3	S	b	£4	S	ib.ı	# 5	CI	iild	#1	Ch	ild,	#2





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0 = NO; 1 = YES; 9 = DON'T KNOW

26. Has anyone on the list ever been put in jail, or arrested or convicted of a crime, other than drunk driving?

If no or don't know, go to Note 3

If yes ask: A. Who was that? Anyone else? (until no more names are given)

0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9
M	oth	ier	F	at h	er	S	ib. x	* 1	S	ib.a	#2	S	ib.a	# 3	S	ib.a	# 4	S	ib. ≉	ľ5	Ci	ild	#1	Ch	ild .	#2

Note 3: Say: "The next few questions are about problems children and teenagers sometimes have. Since we want to know whether anyone on the list ever had the problem in their whole life, please remember to think about whether the adults had the problems when they were young, as well as thinking about whether the youngsters have had it."

27. When they were young, did anyone on the list get upset or frightened when they had to go to school, sleep away from home, or be away from their parents?

If no or don't know, go to Q.28

If yes ask: A. Who was that? Anyone else? (until no more names are given)

0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9
A	fot i	ier	F	ath	er	S	ib.a	# I	S	ib.a	# 2	S	ib.a	# 3	S	ib.a	¥4	S	ib.a	r5	CI	iild	#1	Ch	ild,	#2

B. Was it much more than most children their age?

0 1 9

If no or don't know, go to Q.28

0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9
M	oth	er	F	ath	er	S	ib.a	F1	S	ib.∡	# 2	S	ib.a	# 3	Si	ib.a	# 4	S	ib. i	# 5	CI	ild	#1	Ch	ild.	#2





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28. When they were children, did anyone on the list steal property, skip school, run away from home, or break rules?

0 1 9

If no or don't know, go to Q.29

If yes ask: A. Who was that? Anyone else? (until no more names are given)

	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9
ľ	M	oth	er	F	at h	er	S	ib.,	r I	S	ib.a	#2	S	ib.a	# 3	S	ib. a	# 4	S	ib.a	ř5	CI	iild	#1	Ch	uld.	#2

B. Did the person steal valuable property, skip school a lot, or break a lot of rules, more than other children their age?

0 1 9

If no or don't know, go to Q.29

If yes ask: C. Who was that? Anyone else? (until no more names are given)

0 1 9 0 1 9 0 1 9 0 1 9 0 1 9 0 1 9 0 1 9 0 1 9 0 1 9 0 1 9					1								<u> </u>										+			-		
---	--	--	--	--	---	--	--	--	--	--	--	--	----------	--	--	--	--	--	--	--	--	--	---	--	--	---	--	--

29. In grade school, did anyone on the list fidget, leave their seats when they weren't supposed to, not finish their schoolwork, or not pay attention to the teacher?

0 1 9

If no or don't know, go to Q.30

If yes ask: A. Who was that? Anyone else? (until no more names are given)

						1															-	1		-		
M	oth	er	F	ath	er	S	ib.a	* 1	S	ib.4	# 2	S	ib, a	# 3	S	ib.a	# 4	S	ib.i	# 5	CI	tild.	#1	Ch	ild.	#2

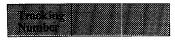
B. Was the person really doing those things all the time, more than other (boys/girls) (his/her) age?

0 1 9

If no or don't know, go to Q.30

	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9
Į	M	oth	ier	F	ath	er	S	ib.a	#]	S	ib.a	# 2	S	ib.,	#3	S	b, a	#4	S	ib.i	# 5	C	hild	#1	C	ild.	#2





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0 = NO; 1 = YES; 9 = DON'T KNOW

30. Has anyone on the list EVER been suspended or expelled from school?

0 1 9

If no or don't know, go to Q.31

If yes ask: A. Who was that? Anyone else? (until no more names are given)

ſ	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9
	M	oth	er	F	ath	er	S	ib. 4	# 1	S	ib.4	# 2	S	ib.a	# 3	Si	b.a	#4	S	ib. 4	! 5	CI	uld	#1	Ch	ild	#2

31. Has anyone on the list EVER tried to kill him or herself, or made a suicide attempt?

0 1 9

If no or don't know, go to Note 4

If yes ask: A. Who was that? Anyone else? (until no more names are given)

0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9	0	1	9
M	oti	her	F	ath	er	S	ib. A	# [S	ib. a	# 2	S	b.4	r3	S	ib.a	# 4	S	ib.4	r 5	Ci	ild	#1	Ch	ild.	#2

B. This may be a painful question, but did the person actually kill him or

0 1 9

If no or don't know, go to Note 4

If yes ask: C. Who was that? Anyone else? (until no more names are given)
I'm sorry. That must be hard to think about.

			ı			Į.						1									_			—		9
M	oth	er	F	at h	er	S	ib.a	#1	S	ib.a	# 2	S	ib.a	# 3	S	ib.a	# 4	S	ib.i	# 5	CI	iild	#1	Ch	ild.	#2

Note 4: Say: "Thank you very much for giving me so much information about your relatives."





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SADS-L

Using the scale below, mark the appropriate box for each term listed below. Complete Onset and Offset dates as applicable.

- 1 = Not present (screen denied)
- 2 = Possible (screen and 1 symptom)
- 3 = Probable (1 criterion short)
- 4 = Definite (meets DSM III criteria)
- 5 = Unknown (no information available)
- 6 = Not Applicable

				Cı	urre	nt				_			P	ast	
	1	2	3	4	5	6	Onset Date (day/mth/yr)	1	2	3	4	5	6	Onset Date (day/mth/yr)	Offset Date (day/mth/yr)
Schizophrenia															
Schizo-affective- manic															
Schizo-affective- depressed															
Other func- tional psychosis															
Major depression							11.11.1								
W psychotic features															
Dysthymia															
Mania															
W psychotic features															
Hypomania															
Cyclothymia															
Recurrent Unipolar															
Bipolar I															
Bipolar II															
Other affective disorder															11111
Simple phobia															1 1 1 1 1 1
Social phobia															1
Agoraphobia														 	
Generalized anxiety															1,1,1,1,1
					_										





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SADS-L

Using the scale below, mark the appropriate box for each term listed below. and Offset dates as applicable.	Complete Onset
1 = Not present (screen denied)	
2 = Possible (screen and 1 symptom)	
3 = Probable (1 criterion short)	

4 = Definite (meets DSM III criteria) 5 = Unknown (no information available)

		6 = Not Applicable Current																	
		-		C	urre	nt								P	ast	-			
	1	2	3	4	5	6	Onset D (day/mth	ate (/yr)	1	2	3	4	5	6	Onset (day/n		Offs (day)	et D mth	ate /yr)
Panic disorder							1 1 1 1									1.1.1		1. 1	
Obsessive- compulsive								1								11.		الـــــــــــــــــــــــــــــــــــ	
Alcohol abuse								Lı							1 1 1			lL	
Drug abuse								1 1									1		
Conduct disorder								با							1 1 1				
Antisocial per- sonality disorder								1								باب	\perp		1.
Attention deficit disorder								ــــــــــــــــــــــــــــــــــــــ									1	1_	
Anorexia nervosa																	1		1_
Bulimia								<u> 1 1 </u>								ىلى	11	1.1	
Separation anxiety															ــــــــــــــــــــــــــــــــــــــ		1		
Post traumatic stress disorder								1.									ا با	1 1	1
Mental retardation																			
Learning disability								ــــــــــــــــــــــــــــــــــــــ								1			1.1
Organic brain disorder		abla						1									1	1_1_	1.
Other psychiatric																	1		
disorder - specify:									_						<u> </u>				
	Current Psychiatric Disorder Psychiatric Disorder			tric			imbe of orma	- 1											
					Yes No			_											
		Yes No Yes No																	





Project	Protocol	Center	Patient Number	Visit	Page
29060	329	0,0		Screening (Week -1)	41

SADS-L

												-	
	None (1)	Thre		A	ssault (3)	Homicide (4)	i	No nforma (5)	tion	ea	ge of rliest navior	Age of earliest assault	Number of assaultive acts
Assaultive Behavior										L			
			•										
	Never hospitaliz (1)	Less 5 da (2	ys		ss than months (3)	Less than 6 months (4)		6 mor or me (5)	ore	info	No rmation (6)	Age of 1st hospital- ization	Number of hospital- izations
Total Psychiatric Hospitalizations													
			•										
	No contact	onsult	rief d of nent	6	months 2 years (3)	2 years or more (4)	i	No informa (5)	ation	ou	of 1st tpatient ontact		
Total Outpatient Treatment]										
													
	None (1)	ation	Thre		Gesture (4)	Attempt (5)		Com- letion (6)	info mat	ion	Age of earliest behavio	t earliest	Number of attempts
Suicidal Behavior]					Ε]			
	Not applicat (living (1)	Natu dea (2	th	Ac	ccidental death (3)	Possible suicide (4)		Defin suic (5	ide	info	No ormation (6)		
Circumstances of Death]				Ì]				
						 -							





[Project	Protocol	Center	Patient Number	Visit	Page
	29060	329	0,0		Screening (Week -1)	42

								-	
<u>DEP</u>	RESSED MOOD Worst Severity of	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	(7) VEX
	Current Episode:	NI	NO	[SLT]	MLD	[<u>wo</u>]	SVK	EAJ	V-CO.
	Duration of Current Episode:	L	」# of we	eks					
2.	Worst Severity of Last Two Weeks:	(0) NI	(1) NO	(2) SLT	MLD	(4) MO	(5) \$VR	(6) EX	(7) VEX
	Frequency:	Day	/s/week						ļ
	Average % time of the day:		」%						
DEF	PRESSED APPEAR	ANCE							
3.	Current Episode:	(0) NI	(1) NO	(2) SLT	MLD	(4) MO	(5) SVR	(6) EX	
4.	Last Two Weeks:	(0) NI	(I) NO	(2) SLT	MLD	(4) MO	(5) SVR	(6) EX	
IDE	AND AND	ANCED							
	UTABILITY AND	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MC	(5) SVR	(6) EX	(7) VEX
5.	Current Episode:	NI			MLD	[MC]	SVK	(EX)	(VEA
	Duration:] # of w		[72 \]	[(4)]	[[5]	[6]	1701
6.	Last Two Weeks:	(0) NI	(1) NO	SLT	MLD	MO	(5) SVR	EX	VEX
	Frequency:	Da	ys/week						
	Average % time of the day:] %						
SEI	PARATION-DEPE	NDENT-	DYSPHOR	<u>RIA</u>					
7.	Current Episode:	(0) NI	(1) NO	(2) OCC	USL	(4) AL'#			
8.	Last Two Weeks:	(0) NI	(1) NO	(2) (OCC	USL	ALW			

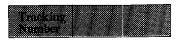




Project	Protocol	Center	Patient Number	Visit	Page
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QUALITY OF DYPS	HORIC M	OOD					2
9. Current Episode:	(0) NI	(I) ND	(2) QUE	(3) DDF	(4) VDF		
10. Last Two Weeks:	(0) NI	(I) ND	QUE	DDF	VDF		
DEGREE OF ASSOC	IATION O	E DEPRE	SSED OR	IRRITAE	LE MOOI	with s	PECIFIC
EVENTS OR PREOC	CUPATIO	NS	JOLE OIL				
11. Current Episode:	(O) 1 <i>N</i>	(1) NAL	(2) MOT	(3) UN	(4) PN		
12. Last Two Weeks:	(0) NI	(I) NAL	(2) MOT	(3) UN	PN		
REACTIVITY OF D	EPRESSED	OR IRR	ITABLE I	MOOD			
							 1
13. Current Episode	(0) NI	(i) VR	(2) FUL	(3) RES	(4) MLD	(5) SLT	UNR
		」% Usu	al % of N	ormal			
14. Last Two Weeks	(0) NI	(1) VR	(2) FUL	(3) RES	(4) MLD	(5) SLT	(6) UNR
		」% Usu	al % of N	ormal (
	L	_] % Ma∷	ximum %	of Normal			
		Number	of hours	good feelin	ig last		
DIURNAL MOOD	ARIATIO	N					
Worse in Morning							
15. Current Episode	(0) NI	(1) NW	MIN	MLD	CW	EXT	
16. Last Two Weeks	(0) NI	NW	MIN	(3) MLD	CW	EXT	
Worse in Afternoon					r-7715	175	
17. Current Episodo		NW	MIN	MLD	CVV	EXT	
18. Last Two Week	(0) S: NI	(I) NW	(2) MIN	(3) MLD	(4) C\V	EXT	





Project	Protocol	Center	Patient Number	Visit	Page
29060	329	0 0		Screening (Week -1)	44

							-	1		
EXCESSIVE INAPPROPRIATE GUILT										
19. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	EXT			
20. Last Two Weeks:	(0)	(I) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	EXT			
Frequency:	Days/W	eek _								
NEGATIVE SELF IMAGE										
21. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT			
-	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT			
22. Last Two Weeks:	NI	[NO]	SEL	MILL	III OL	W 7 12	(22.25)			
FEELING UNLOVED	FORLO	RN								
			F-78-1	[-(a)-1	[7 8.]	[7 <u>6</u>]	F72\T	ļ		
23. Current Episode:	(0) NI	(1)	SLT	(3) MLD	(4) MOD	SVR	(6) EXT			
24. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	MOD	SVR	EXT	ļ		
Frequency:	Days/W	eek [į		
HOPELESSNESS, HEL	PLESSN	ESS, DISC	OURAGE	MENT, PE	SSIMISM					
25. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT			
26. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT			
		·	<u> </u>							
SELF-PITY										
27. Current Episode:	(0) NI	NO NO	OCC	MLD	CON					
28. Last Two Weeks:	(0) NI	(I) NO	(2) OCC	MLD	(4) CON					
ACHES AND PAINS		, <u>.</u>		 781"	785°1	ाक ।	ு			
29. Current Episode:	(0) NI	(1) NO	SLT	(3) MLD	MOE	(5) SVR	EXT			
30. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	MOI	(5) SVR	EXT			





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HYPOCHONDRIASIS							-	
31. Current Episode:32. Last Two Weeks:	(0) NI (0) NX	(1) NO	(2) SLT (2) SLT	(3) MLD MLD	(4) MOD (4) MOD	SVR	(6) EX	
ANHEDONIA, LACK	OF INT	EREST, AP	ATHY, LO	OW MOT	IVATION,	BOREDO	<u>PM</u>	
Combined Overall Ratin	ıg							
33. Current Episode:	(0) NI	(1) NO	(2) SLT	MLD	(4) MO	(5) SVR	(6) EX	
Duration:	L	# of w	/eeks					
34. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	MLD	(4) MO	(5) SVR	(6) EX	
Frequency:	I	Days/week						
Average % time of the day:	ــــا	<u></u>] %						
Differentiating Lack	of Inter	est from A	Inhedonia					
Lack of Interest	(0) NI	[ש]	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
35. Current Episode:	NI (0)	NO (1)	SLT (2)	,	(4)	(5) SVR	(6) EX	
36. Last Two Weeks:	NI	NO	SLT	MLD	мо	SVR	EX	
Anhedonia	ത്ത	[ש]	<u>(2)</u>	[(3)]	[*(4)*]	(5)	[167]	
37. Current Episode:	[N]	NO (I)	SLT	(3) MLD	(4)	SVR	(6) EX	
38. Last Two Weeks:	NI (0)	NO	SLT	MLD	(4) MO	SVR	EX	
FATIGUE, LACK OF ENERGY AND TIREDNESS								
39. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	SVR	(6) EX	
40. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
Frequency:	[_] I	Days/Week						





Project	Protocol	Center	Patient Number	Visit	Page
29060	329	0,0		Screening (Week -1)	46

DIFFICULTY CONCE	NTRATIN	G, INATTI	ENTION, O	OR SLOW	ED THIN	<u>KING</u>	-
41. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
42. Last Two Weeks:	(0) N(I	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
PSYCHOMOTOR AGI	<u>ration</u>						
43. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
44. Last Two Weeks:	(0)	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
Frequency:	Day	s/Week					
MANIFESTATIONS II	CLUDEI);					
Unable to sit still	1 (0)		[72)]	<u> [3</u>]	[-(4) -]	[737]	
45. Current Episo		(1) NPR	DBT	(3) PR	(4) MOD	(5) SVR	
46. Last Two Wee	ks: (0)	(1) NPR	DBT	(3) PR	(4) MOD	(5) SVR	
Pacing							
47. Current Episo	de: (0)	(1) NPR	DBT	(3) PR	SVR	(5) SVR	
48. Last Two Wee	ks: (0)	(1) NPR	DBT	(3) PR	(4) SVR	SVR	:
Hand wringing							
49. Current Episo	de: (0)	(1) NPR	(2) DBT	PR	(4) SVR	(5) SVR	
50. Last Two Wee	ks: (0)	(I) NPR	(2) DBT	PR	(4) SVR	(5) SVR	
Pulling or rubbing	on hair,	clothing, sk	in				
51. Current Episo	de: (0)	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR	
52. Last Two Wee	ks: (0)	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR	
Can't stop talking	talks on	and on					
53. Current Episo	ode: (0)	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR	
54. Last Two Wes	eks: (0)	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR	





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PSYC	CHOMOTOR RETARI	DATION						
55.	Current Episode:	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
56.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
	Frequency:	Day	ys/Week					
MAN	IFESTATIONS INCL	UDED:						
S	lowed Speech							
57.	Current Episode:	(0) NI	(1) NPR	DBT	PR	MOD	SVR	
58.	Last Two Weeks:	(0) NI	(I) NPR	DBT	(3) PR	(4) MOD	(5) SVR	
1	ncreased pauses before	re answei	ring					
59.	Current Episode:	(0) NI	(I) NPR	DBT	PR	(4) MOD	(5) SVR	
60.	Last Two Weeks:	(0) NI	(1) NPR	DBT	PR	(4) MOD	SVR	
1	Low or monotonous spe	ech						
61.	Current Episode:	(0) N1	(I) NPR	DBT	(3) PR	MOD	(5) SVR	
62.	Last Two Weeks:	(0) NI	(1) NPR	DBT	(3) PR	MOD	(5) SVR	
1	Mute or markedly dec	reased ar	nount of s	peech				
63.	Current Episode:	(0) NI	(1) NPR	DBT	PR	(4) MOD	(5) SVR	
64.	Last Two Weeks:	(0) N1	(1) NPR	(2) DBT	PR	(4) MOD	(5) SVR	
	Slowed body movement	3						
65.	Current Episode:	(0) NI	(I) NPR	(2) DBT	PR	(4) MOD	(5) SVR	
66.	Last Two Weeks:	(0) NI	(1) NPR	DBT	PR	(4) MOD	(5) SVR	
	Depressive stupor							
67.	Current Episode:	(0) NI	(I) NPR	(2) DBT	PR	(4) MOD	(5) SVR	
68.	Last Two Weeks:	(0) NI	(1) NPR	DBT	PR	(4) MOD	(5) SVR	





P	Project	Protocol	Center	Patient Number	Visit	Page
2	29060	329	0,0		Screening (Week -1)	48

soc	CIAL WITHDRAW	VAL							
69.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
70.	Last Two Weeks:	NI (0)	NO NO	SLT	(3) MLD	(4) MO	SVR	(6) EX	
REJ	ECTION SENSITI	VITY							
71.	Last Year:	(O)	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX	
72.	Current Episode:	(0)	(1) NO	(2) SLT	(3) MLD	MOD	(5) SVR	(6) EX	
73.	Last Year:	NI (0)	(I) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX	
74.	Current Episode:	N.[{0}	NO (I)	(2) SLT	MLD	MOD	(5) SVR	(6) EX	
SLE	EP PROBLEMS								
75.		lept before	onset of	depression					
76.	Hours s	lept during	the curre	nt episode					
77.	Hours s	lept during	the last t	wo weeks					
ну	PERSOMNIA								,
78.		lent in day	ntime of c	ırrent episo	de				
79.		-		e last two					
80.		-	in current						
81.		_	in last tw						
82.	Current Episode:	(0) NI	(I) NO	(2)	(3)	(4)	(5)	(6)	
83.		F767	(I) NO	(2)	(3)	(4)	(5)	(6)	





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4.	Current Episode: (70) NI	(1) NO	(2)	(3)	(4)	(5)	(6)
5. I	Last Two Weeks: (0) NI	(I)	(2)	(3)	(4)	(5)	(6)
	Frequency:	Nights/Wee	:k				
TYPI	ES OF INSOMNIA						
	Initial Insomnia						
86.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) MLD	(4) MOD	(5) SVR
87.	Last Two Weeks:	(0) NI	(1) NPR	DBT	MLD	MOD MOD	(5) SVR
	Middle Insomnia						
88.	Current Episode:	(0) NI	(1) NPR	DBT	MLD	MOD MOD	(5) SVR
89.	Last Two Weeks:	(0) NI	(1) NPR	DBT	MLD	MOD	(5) SVR
	Terminal Insomnia						
90.	Current Episode:	(0)	(I) NPR	DBT	MLD	MOD	(5) SVR
91.	Last Two Weeks:	(0)	(1) NPR	DBT	MLD	MOD	(3) SVR
	Circadian Reversal						
92.	Current Episode:	(0) NI	NPR	DBT	MLD	MOD	(5) SVR
93.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) MLD	MOD	SVR
	Non-restorative sleep					- 781-1	
94.	Current Episode:	(0) NI	(1) NPR	DBT	MLD	MOD	(5) SVR
95.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) MLD	MOD	(5) SVR
	Daytime sleepiness						
96.	Current Episode:	(0) NI	(I) NPR	DBT	(3) MLD	MOD	(5) SVR
97.	Last Two Weeks:	(Ø) NI	(1) NPR	(2) DBT	(3) MLD	(4) MOD	(5) SVR





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							=	
ANOREXIA			F-785-1		177	[7 5 5]	[-723-]	
98. Current Episode:	(c)	NO (1)	SLT	MLD	MOD	(5) RAR	(6) NVR	
99. Last Two Weeks:	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MOD	(5) RAR	(6) NVR	
WEIGHT LOSS								
100. Current Episode:								
Pounds lost:		lbs.						
Number of Weeks:								
101. Last Two Weeks:								
Pounds lost:		lbs.						
INCREASED APPETIT		1-77-1	[75]	F-73V-1	<u> </u>	F65-1	ראדו	
102. Current Episode:	(0) NI	(1) NO	SLT	(3) MLD	(4) MOD	SVR	(6) EX	
103. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX	
Frequency:	LJ	Days/Weel	C					
STRONG CRAVING I	OR SW	EETS						
104. Current Episode:	(0) NI	(i) ABS	(2) DBT	(3) MLD	(4) MOD	(5) SVR		
105. Last Two Weeks:	(D)	(I) ABS	(2) DBT	(3) MLD	(4) MOD	(5) SVR		
105. Last Two weeks:	[NI	[ABS]	DRI	MLD	MOD	[SVR]		
WEIGHT GAIN								
106. Current Episode:								
Pounds gained:		l lbe						
	,	105.						
Number of Weeks:	-	I						
107. Last Two Weeks:								
Pounds gained:	: L	lbs.						

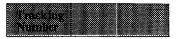




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SUICIDAL IDEATION	<u> </u>							-
108. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	(7) VEX
109. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	(7) VEX
Suicidal Acts - Numbe	r							
110. Current Episode:								
111. Last Two Weeks:								
Suicidal Acts - Serious	ness							
112. Current Episode:	(0)	(1) NO	(2) MIN	(3) DEF	S	4) Er	(5) VS	(6) EXT
113. Last Two Weeks:	(0) NI	(1) NO	(2) MIN	DEF	S	ER	(5) VS	(6) EXT
Medical Lethality								
114. Current Episode	(0) NI	(1) NO	(2) MIN	(3) MLD	M	4) 10	(5) SVR	EXT
115. Last Two Weeks:	(0) NI	(1) NO	(2) MIN	(3) MLD	N.	4) 40	SVR	(6) EXT
Non-Suicidal Physical	Self-De	maging .	Acts					
116. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	N	4) 40	(5) SVR	(6) ACT
117. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	[N	4) 40	(5) SVR	ACT





ſ	Project	Protocol	Center	Patient Number	Visit	Page
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Ç	Onset and Course			
118. ı	Number of Episodes		_	
	Ages of onset and o	offset of	each episode	
119.	Onset	120.	Onset	
	Offset		Offset	
	Weeks		Weeks	
401		122	,	
121.	Onset	122.	Onset	
	Offset		Offset	
	Weeks		Weeks	





Project	Protocol	Center	Patient Number	Visit	Page
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MA	NIC SYNDROME							-	
ELA	TION, EXPANSIV	е моо	<u>D</u>						
1.	Current Episode:	(0) NI	(I)	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
2.	Last Two Weeks:	(0) NI	NO (I)	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
DEC	CREASED NEED F	OR SLE	<u>ep</u>						
3.	Current Episode:	(0) NI	(1) NO	(2) -1	(3) -2	(4) -3	(5)	(6) -4+	
4.	Last Two Weeks:	NI (0)	(1) NO	(2) -1	(3) -2	(4) -3	(5) -4	(6) -4+	
UNI	USUALLY ENERG	<u>ETIC</u>							
5.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) LCH	(4) MOR	(5) MM	(6) UA	
6.	Last Two Weeks:	(0) NI	(I) NO	(2) SLT	(3) LCH	(4) MOR	(5) MM	(6) UA	
INC	REASE IN GOAL	DIRECT	TED ACT	IVITY					
7.	Current Episode:	(5) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX	
8.	Last Two Weeks:	(0) IN	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX	
GR.	ANDIOSITY								
9.	Current Episode:	(0)	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
10.	Last Two Weeks:	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
A (1)	CELERATED, PRE	SSURED	OR INC	REASED	AMOUR	NT OF S	PEECH		
			(I)	(2) SLT	(3) MLD	(4) MO	(3) MKD	(6) EX	
11.	Current Episode:	NI				(4)			
12.	Last Two Weeks:	(0) NI	(1)	(2) SLT	(3) MLD	MO	(5) MKD	(6) EX	





ſ	Project	Protocol	Center	Patient Number	Visit	Page
	29060	329	0,0		Screening (Week -1)	54

RACING THOUGHTS								-	
13. Current Episode:	(0) NI	(I) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	(6) EX		
14. Last Two Weeks:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	(6) EX		
FLIGHT OF IDEAS									
15. Current Episode:	(O) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX		
16. Last Two Weeks:	(0) NI	(I) NO	(2) SLT	MLD	(4) MO	(5) SVR	(6) EX		
POOR JUDGEMENT									
17. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) VS		
18. Last Two Weeks:	(0)	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) VS		
DISTRACTABILITY									
19. Current Episode:	(0)	(1)	(2) SLT	(3) MLD	(4) MO	(5) SVR			
20. Last Two Weeks:	(0) II	NO NO	(2) SLT	(3) MLD	(4) MO	(5) SVR			
MOTOR HYPERACTI	VITY								
21. Current Episode:	(0)	(1) NO	(2) SLT	(3) MLD	(4) MO	(3) MKD	(6) EX		
22. Last Two Weeks:	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX		
Inappropriate laughin	g, jokin	g or punn	uing						
23. Current Episode:	(0) NI	(I) NO	(2) DBT	(3) MLD	(4) MOD				
24. Last Two Weeks:	NI (0)	(I) NO	(2) DBT	(3) MLD	(4) MOD				
Uninhibited people see									
25. Current Episode:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD				
26. Last Two Weeks:	NI (0)	(1) NO	(2) DBT	(3) MLD	(4) MOD	,			





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reased Productivity							-		
Current Episode:	(0) NI	(1) NO	(2) DBT	(3) PRS	(4) SVR				
Last Two Weeks:	(0) NI	(I) NO	(2) DBT	PRS	(4) SVR				
rpened and unusua	lly creat	ive thinki	ing						
Current Episode:	(0) NI	(I) NO	(Z) DBT	(3) PRS	SVR				
Last Two Weeks:	(0) NI	(1) NO	(2) DBT	PRS	(4) SVR				
persexuality									
Current Episode:	(0) NI	(1) NO	(2) DBT	PRS	(4) SVR				
Last Two Weeks:	NI NI	(1)	DBT	PRS	SVR				
LUENCE OF ILLI	CIT DR	UGS OR	ALCOH	<u>OL</u>					
Current Episode:	(0) NA	(1) NVR	(2) SMT	(3) ONL					
Last Two Weeks:	(0) NA	(1) NVR	(2) SMT	(3) ONL					
MBER OF MANIC	PERIO	<u>DS</u>							
	Current Episode: Last Two Weeks: rpened and unusual Current Episode: Last Two Weeks: rersexuality Current Episode: Last Two Weeks: Luence of Illi Current Episode: Last Two Weeks:	Last Two Weeks: Current Episode: C	Current Episode: NI NO Last Two Weeks: NI NO repend and unusually creative thinking Current Episode: NI NO Last Two Weeks: NI NO Current Episode: NI NO Last Two Weeks: NI NO Current Episode: NI NO Last Two Weeks: NI NO Luence Of Illicit Drugs Or Current Episode: NA NYR Last Two Weeks: NA NYR ABER OF MANIC PERIODS	Current Episode: NI NO DBT Last Two Weeks: NI NO DBT repended and unusually creative thinking Current Episode: NI NO DBT Last Two Weeks: NI NO DBT Last Two Weeks: NI NO DBT Current Episode: NI NO DBT Last Two Weeks: NI NO DBT Current Episode: NI NO DBT Current Episode: NI NO DBT Last Two Weeks: NI NO DBT LUENCE OF ILLICIT DRUGS OR ALCOHO Current Episode: NA NVR SMT Last Two Weeks: NA NVR SMT MBER OF MANIC PERIODS	Current Episode: Oi	Current Episode: NI NO DBT PRS SVR Last Two Weeks: NI NO DBT PRS SVR Last Two Weeks: NI NO DBT PRS SVR rpened and unusually creative thinking Current Episode: NI NO DBT PRS SVR Last Two Weeks: NI NO DBT PRS SVR Last Two Weeks: NI NO DBT PRS SVR DBT PRS SVR Current Episode: NI NO DBT PRS SVR DBT PRS SVR DBT PRS SVR Last Two Weeks: NI NO DBT PRS SVR LUENCE OF ILLICIT DRUGS OR ALCOHOL Current Episode: NA NVR SMT ONL Last Two Weeks: NA NVR SMT ONL MBER OF MANIC PERIODS	Current Episode: NI NO DBI PRS SVE Last Two Weeks: NI NO DBI PRS SVE rpened and unusually creative thinking Current Episode: NI NO DBI PRS SVE Last Two Weeks: NI NO DBI PRS SVE Last Two Weeks: NI NO DBI PRS SVE Current Episode: NI NO DBI PRS SVE Last Two Weeks: NI NO DBI PRS SVE LUENCE OF ILLICIT DRUGS OR ALCOHOL Current Episode: NA NVE SMI ONL Last Two Weeks: NA NVE SMI ONL MBER OF MANIC PERIODS	Current Episode: NI NO DBI PRS SVR Last Two Weeks: NI NO DBI PRS SVR (4) CUITENT Episode: NI NO DBI PRS SVR (4) SVR Current Episode: NI NO DBI PRS SVR (4) SVR	Current Episode: Mi





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DIA	GNOSTIC CRITERIA - HYPOMANIC EPISODE
	Onset and Course
36.	Number of Episodes
	Ages of onset and offset of each episode
37.	Onset 38. Onset
	Offset Offset
	Weeks Weeks
DIA	AGNOSTIC CRITERIA - MANIC EPISODE
39.	Onset and Course
	Number of Episodes
	Ages of onset and offset of each episode
40.	Onset 41. Onset
	Offset Offset
	Weeks Weeks





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	PILLO DICORD								-	
	<u>FING DISORD</u> FUSAL TO MA		IN BODY	WEIGH	T					
1.	Lifetime:	(0) NI	(1) NP	(2)	(3)	(4)	(5)	(6)		
ME	THODS OF W	EIGHT	LOSS							
2.	Restriction Lifetime:	(0) NI	(1) NVR	(2) SMT	OFT	(4) ROU				
3.	Only Liquids Lifetime:	(0) NI	(1) NVR	(2) SMT	OFT	(4) ROU				
4.	Vomiting Lifetime:	(0) NI	(I) NVR	(2) SMT	(3) OFT	(4) ROU				
5.	Supressants Lifetime:	(0) NI	(1) NVR	(2) SMT	OFT	(4) ROU				
6.	Laxatives Lifetime:	(0)	(1) NVR	(2) SMT	(3) OFT	(4) ROU				
7.	Diurectics Lifetime:	(0) NI	(I) NVR	(2) SMT	(3) OFT	(4) ROU				
во	DY IMAGE D	ISTURI	BANCE							
8.	Lifetime:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX		
IN'	TENSE AND P	ERSIST	TENT FE	AR OF G	AINING	WEIGH	Т			
9.	Lifetime:	(0) NI	(1) NO	(2)	(3)	(4)	(5)	(6)		
<u>IN</u>	TENSE PREOC	CUPAT	rion wi	тн гоо	D AND I	EATING				
10.	Lifetime:	(0) NI	(I) NO	(2)	(3)	(4)	(5)	(6)		
AN	MENORRHEA									
11.	Age of Mer	narche:								
12.	(0) NI (1		(2) YES							
13.	(0) (1 NI N		YES YES							
L										





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14. Weeks:							-	-	
15. Weeks:									
16. (0) (1) NO	YES								
BULIMIA									
17. Lifetime:	(0)	(I)	(2)	(3)	(4)	(5)	(6)		
18. Eats faster Lifetime:	(0) NI	(1) NVR	(2) SMT	(3) OFT	(4) AS				
19. <i>Uncontrollable</i> Lifetime:	(0) NI	(I) NVR	(2) SMT	(3) OFT	(4) AS				
20. Eats alone Lifetime:	(0) NI	(1) NVR	(2) SMT	(3) OFT	(4) AS				
21. Abdominal Pain Lifetime:	(0) NI	(I) NVR	(2) SMT	(3) OFT	(4) AS				
22. Vomiting Lifetime:	(0) NI	(1) NVR	(2) SMT	(3) OFT	(4) AS				
23. Sleep Lifetime:	(0) NI	(1) NVR	(2) SMT	(3) OFT	(4) AS				
24. Interruption Lifetime:	(0) NI	(1) NVR	(2) SMT	(3) OFT	(4) AS				
25. Depression Lifetime:	(0) NI	(1) NVR	(2) SMT	(3) OFT	(4) AS				
26. Binges:	hoı	ırs							
	,								





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DIAGNOSTIC CRITERIA - ANOREXIA NERVOSA									
Onset and Course									
27. Number of Episodes									
Ages of onset and offset of each episode									
28. Onset 29. Onset									
Offset Offset									
Weeks									
DIAGNOSTIC CRITERIA - BULIMIA NERVOSA									
Onset and Course									
30. Number of Episodes									
Ages of onset and offset of each episode									
31. Onset 32. Onset									
Offset									
Weeks Weeks									





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AN	XIETY DISORDER	<u>s</u>							9	
	ECIFIC PHOBIAS	[((0)]	רשן	□ (2)]	[(3)]	[T4)]	(5)	T671		
1.	Overall Lifetime:	NI	NO	SLT	MLD	МО	SVR	(6) EX		
2.	Flying Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	SVR			
3.	Elevators Lifetime:	(C) NI	(1) NO	DBT	(3) MLD	(4) MO	(5) SVR			
4.	Small Spaces Lifetime:	(c) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR			
5.	Heights Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR			
6.	Dark Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR			
7.	Swimming Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR			
8.	Dogs/animals Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR			
9.	Insects Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR			
10.	Thunderstorms Lifetime:	(0) NI	(I) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR			ļ
11.	Cars/Buses/Trai Lifetime:	ns (0) NI	(I) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR			
12.	Dentist/Doctors Lifetime:	(5)	(1) NO	DBT	(3) MLD	(4) MO	(5) SVR			
13.	Other Lifetime:	(0)	(1) NO	DBT	(3) MLD	(4) MO	(5) SVR			`
<u>DI</u>	AGNOSTIC CRITE	RIA -	SPECIFIC	PHOBI	<u>A</u>					
	Onset and Course									•
14.	Number of Episod	les	لـــا							
	Ages of onset and	l offset o	of each ep	isode						
15.	Onset	1	6. On	set 🗀	ا					
	Offset		Off	fset	_]					
	Weeks	1	We	eks						
		_							_	





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SEP	ARATION ANX	CIETY							-
PRE	EOCCUPATION	WITH TH	OUGHTS	S OF HA	RM TO	PARENT	S		
1.	Lifetime:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
PRE	EOCCUPATION	WITH HA	RM BEI	FALLING	SELF				
2.	Lifetime:	(c)	(I) NO	SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
FEA	AR OF BEING I	HOME AL	ONE						
3.	Lifetime:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
EXC	CESSIVE REAC	TION TO	SEPARA	TION					
4.	Lifetime:	(0) NI	(1) NO	SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
DIE	FICULTY BEIN	NG AWAY	FROM	HOME					
5.	Lifetime:	(0) N/I	(1) NO	SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
HO	MESICKNESS								
6.	Lifetime:	(0)	(1)	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
FE.	AR OF SLEEPI	NG AWAY		HOME					
7.	Lifetime:	(C) 11/1	(1)	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	:
NIC	GHTMARES								
8.	Lifetime:	NI (0)	NO	(2) SLT	MLD	(4) MO	SVR	(6) EX	
SCI	HOOL REFUSA	L/RELUCI	ANCE						
9.	Lifetime:	[VI]	(I) NO	SLT	MLD	(4) MO	(5) SVR	(6) EX	
PH	YSICAL SYMP	TOMS DU	RING SE	PARATI	<u>ON</u>				
10.	Lifetime:	(0) NI	(1) NO	SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
DI.	AGNOSTIC CRI	TERIA - S	SEPARA'	TION AN	XIETY	DISORDE	ER		
	Onset and Cour	se							
11.	Number of Epi	sodes	لــــا	1	2. O	nset		13.	Onset
	Ages of onset	and offset o	of each ep	oisode	0	ffset			Offset
					W	Veeks			Weeks





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PA	NIC DISORDER A	ND AGO	ORAPHO	BIA					-	
1.	Lifetime:	N.	NP	DBT	DPR	6	(5) 3X	(6) DLY		
SP	ONTANEOUS ATTA	ACKS								
2.	Lifetime:	(0) NI	(1) NO	1	2-3	(4)	(5)			
DU	RATION OF SPON	TANEC	US ATT	ACKS						
3.	Lifetime:	(0) NI	20	(2) 10	SOM	(4) MST	(5) ALL			
SIT	TUATIONALLY PR	EDISPO	SED AT	<u> FACKS</u>						
4.	Lifetime:	NI NI	(1) NO	(2) -4	(3)	(4)	(5) 4+			
PH	IOBIA RELATED A	TTACK	<u>s</u>							
5.	Lifetime:	(0) NI	(1) NO	(2)	(3)					
6.	Shortness of Breat Lifetime:	h (0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD				
7.	Pal pitations Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD				
8.	Chest Pains Lifetime:	(0) N(I	(1) NO	(2) DBT	(3) MLD	(4) MOD				
9.	Choking Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD				
10.	Dizziness Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD				
11.	Numbness Lifetime:	(5)	(1) NO	(2) DBT	(3) MLD	(4) MOD				ļ
1	Sweating Lifetime:	(5)	(1) NO	(2) DBT	(3) MLD	MOD				
13.	Trembling Lifetime:	NI (0)	(1) NO	DBT	(3) MLD	MOD				
Į.	Dying Lifetime:	1/I (0)	(1) NO	DBT	(3) MLD	(4) MOD				
15.	Losing Control Lifetime:	(0)	(1) NO	DBT	(3) MLD	(4) MOD				
16.	. Nausea Lifetime:	NI (0)	NO NO	DBT	(3) MLD	(4) MOD				
17.	. Depersonalization Lifetime:	(0)	(1) NO	(2) DBT	(3) MLD	(4) MOD				
18.	. Flashes/Chills Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD				
19	. Most Number of A	ttacks:	i i	na4we	ek period					
20	. Lifetime:	(0) NI	(1) NP	(2) VM	(3) MLD	(4) MO	(5) SVR	(6) EX		





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AG	ORAPHOBIA	WITH PAN	IC DISC	RDER				-
21.	Lifetime:	(0) NI	(1) NO	(2) SLT	MLD	(4) MO	(5) (SVR	(6) EX
<u>AG</u>	ORAPHOBIA	WITHOUT	PANIC :	DISORI	<u>DER</u>			
22.	Lifetime:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
_					nn	***** · ^ -)D	DY A
DIA	Onset and Cou		ANIC I	USORD!	Ages of on			
	-				_			
23.	Number of Ep	oisodes		24.	Onset		25.	Onset
					Offset [Offset
					Weeks			Weeks
DIA	GNOSTIC CR	<u>ITERIA - F</u>	ANIC I	DISORD	ER WITH	AGORAI	PHOBIA	
26.	Onset and Cou	ırse		1	Ages of onse	et and off	set of ea	ch episode
	Number of Ep	oisodes L	لــــا	27.	Onset _	لـــا	28.	Onset
					Offset _			Offset
					Weeks _			Weeks
DIA	GNOSTIC CP	ITERIA - A	AGORA F	'HOBI A	. WITHOU	T HISTO	RY OF	PANIC DISORDER
29.	Onset and Cor				Ages of ons			
	Number of E	pisodes		30.	Onset L		31.	Onset
					Offset L			Offset
					Weeks L			Weeks
			-					





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<u>soc</u> 1.	CIAL PHOBIA Lifetime:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	-			
DIAGNOSTIC CRITERIA - SOCIAL PHOBIA												
2.	2. Onset and Course											
	Number of Episodes											
	Ages of onset and	d offset of	f each ep	isode								
3.	Onset	4	l. Ons	et	J							
	Offset		Off	set	ل							
	Weeks		We	eks								





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								_	
ESSIONS OR	COMPULSIO	<u>ONS</u>						-	
SESSIONS									
Lifetime:	(C) NI	(1) NO	SLT	MLD	(4) MO	SVR	(6) EX		
MPULSIONS									
Lifetime:	(0) NI	(1) NO	SLT	(3) MLD	(4) MO	SVR	(6) EX		
Touching Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD				
Counting Lifetime:	(b) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD				
Washing Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD				
Checking Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD				
Collecting Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	MOD				
Arranging Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD				
Other Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD				
PERSONALIZA	TION OR	DEREAL	<u>IZATI</u> ON	J					
Lifetime:	(0) NI	(1) NO	(2) FLT	OCC	(4) SVL	(5) MRK	(6) FQT		
GNOSTIC CRI	ITERIA - (DBSESSIV	/E-COM	PULSIVI	E DISORI	DER			
	-								
Ages of onset	and offset o	f each ep	isode						
		_		1					
Onset	1.	o. Ons	et						
Offset		Off	set	_					
Weeks		We	eks						
	Lifetime: MPULSIONS Lifetime: Touching Lifetime: Counting Lifetime: Checking Lifetime: Checking Lifetime: Collecting Lifetime: Arranging Lifetime: Other Lifetime: PERSONALIZA Lifetime: Onset and Cou Number of Ep Ages of onset Offset	Lifetime: (C) MPULSIONS Lifetime: (C) MI Touching Lifetime: (C) Life	Lifetime: NI NO MPULSIONS Lifetime: NI NO Touching (0) NI NO Lifetime: NI NO Counting Lifetime: NI NO Counting Lifetime: NI NO Checking Lifetime: NI NO Checking Lifetime: NI NO Collecting (0) NI NO Arranging (Lifetime: Ni	Lifetime:	Lifetime:	Lifetime:	Lifetime: Ni	Lifetime: Ni





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GENE	ERALIZED AN	XIETY DI	SORDER	<u></u>				-			
WOR	RRY										
1.	Lifetime:	(0)	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX			
2.	Lifetime:	(0)	(1) NO	(2) DBT	(3) MLD	(4) MOD					
DIFF	ICULTY CON	FROLLING	G WORR	RIES							
3.	Lifetime:	NI (Q)	(i) NO	(2) SLT	MLD	(4) MO	(5) SVR	(6) EX			
SYM	PTOMS ASSOC	CIATED V	VITH W	ORRY							
4.	Lifetime:	(0) N1	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX			
5.	Onset and Cours Number of Episo	<u>e</u>	<u> </u>	LIZED A	NXIETY	DISORD	<u>JEK</u>				
Ages of onset and offset of each episode											
6.	Onset		7. Ons	set L	J						
6.	Onset			set]						
6.			Off		J						





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POST-TRAUMATIC STRESS DISORDER	-
TRAUMA TO OTHERS	
1. Lifetime:	(5)
TRAUMATIC TO SELF	
2. Lifetime: (0) ND (1) (2) (3) (4) MOD	(5) SVR
INTRUSIVE RECOLLECTIONS OF TRAUMA	
3. Lifetime: $\begin{bmatrix} (0) \\ NI \end{bmatrix}$ $\begin{bmatrix} (1) \\ NO \end{bmatrix}$ $\begin{bmatrix} (2) \\ SLT \end{bmatrix}$ $\begin{bmatrix} (3) \\ MLD \end{bmatrix}$ $\begin{bmatrix} (4) \\ MOD \end{bmatrix}$	(5) SVR EXT
RECURRENT DISTRESSING DREAMS	
4. Lifetime: (0) NO SLT MLD MOD	(5) SVR EXT
SENSE OF RELIVING TRAUMA AND INTENSE DISTRESS A	AT RE-EXPERIENCE
5. Lifetime: (3) (1) (2) (3) (4) (4) (4) (4) (4) (5) (6) (6) (6) (6) (6) (6) (6) (6) (6) (6	(5) SVR (6) EXT
PHYSIOLOGICAL REACTION UPON EXPOSURE	
6. Lifetime: (3) (1) (2) (3) (4) NO SLT MLD MOD	(5) SVR EXT
THOUGHTS, FEELINGS, CONVERSATIONS, ACTIVITIES, PI	LACES OF PEOPLE
7. Lifetime: (5) (1) (2) YES	
NO RECALL OF IMPORTANT ASPECTS OF TRAUMA	
8. Lifetime: (1) (2) (2) (1) (1) (2) (2) (2) (2) (2) (2) (2) (2) (2) (2	
MARKEDLY REDUCED ACTIVITIES/INTEREST	
9. Lifetime: NI NO YES YES	
DETACHMENT, ENSTRANGEMENT, RESTRICTED AFFECT	
10. Lifetime: $\begin{bmatrix} 0 \\ NI \end{bmatrix}$ $\begin{bmatrix} 1 \\ NO \end{bmatrix}$ $\begin{bmatrix} 2 \\ YES \end{bmatrix}$	
SENSE OF FORESHORTENED FUTURE	
11. Lifetime: $\begin{bmatrix} 101 \\ NI \end{bmatrix}$ $\begin{bmatrix} 101 \\ NO \end{bmatrix}$ YES	
SLEEP PROBLEMS	
12. Lifetime: (1) (2) (2) (2) (2) (2) (2) (2) (2) (2) (2	





ĺ	Project	Protocol	Center	Patient Number	Visit	Page
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IRRITABILITY	
13. Lifetime: $\begin{bmatrix} 0 \\ NI \end{bmatrix} \begin{bmatrix} 0 \\ NO \end{bmatrix} \underbrace{ \begin{bmatrix} 0 \\ YES \end{bmatrix}}$	
DIFFICULTY CONCENTRATING	
14. Lifetime: $\begin{bmatrix} 00 \\ NI \end{bmatrix}$ $\begin{bmatrix} 01 \\ NO \end{bmatrix}$ $\underbrace{ \begin{pmatrix} 02 \\ YES \end{pmatrix}}$	
HYPERVIGILENCE	
15. Lifetime: $\begin{bmatrix} (0) \\ NI \end{bmatrix}$ $\begin{bmatrix} (1) \\ NO \end{bmatrix}$ $\begin{bmatrix} (2) \\ YES \end{bmatrix}$	
EXAGGERATED STARTLED RESPONSE	
16. Lifetime: (3) (1) (2) YES	
OVERALL SEVERITY OF POST-TRAUMATIC STRESS DISORDER	
17. Lifetime: (5) (1) (2) (3) (4) (5) (6) (6) NO SLT MLD MOD SVR EXT	
DIAGNOSTIC CRITERIA - POST-TRAUMATIC STRESS DISORDER	
18. Onset and Course	
Number of Episodes	
A CONTRACTOR AND	-
Ages of onset and offset of each episode	
19. Onset 20. Onset	
Offset Offset	
Weeks Weeks	





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ATT	ATTENTION-DEFICIT/HYPERACTIVITY DISORDER											
INA	<u>INATTENTION</u>											
1.	Lifetime:	(0)	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX				
HYPERACTIVITY												
2.	Lifetime:	(0)	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX				
<u>IMI</u>	PULSIVITY											
3.	Lifetime:	(0) NI	(1) NO	SLT	MLD	(4) MO	(5) SVR	(6) EX				
DIA	GNOSTIC CRIT	ERIA - A	TTENTI	ON-DEF	ICIT/HY	PERACI	IVITY I	DISORDER				
4.	Onset and Course	4 .										
٠.	Number of Episo	_	. 1									
	Number of Epise	Jaca										
	Ages of onset an	nd offset o	f each ep	isode								
5.	Onset	i	6. Ons	et L	_							
	Offset		Off	set	_							
	Weeks		We	eks								





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CONDUCT DISORDER/ANTISOCIAL PERSONALITY									
СН	RONIC VIOLA	ATION OF I	RULES A	т номі	E AND/C	OR SCHOOL			
1.	Lifetime:	(C) IM	NO (I)	(2)	(3)	(4)			
SCH	IOOL SUSPEN	ISION/EXPL	LSION						
2.	Lifetime:	(0)	(1) NO	(2) -1	(3) 1+	EXP			
TRU	JANCY								
3.	Lifetime:	(0)	(1) NO	occ	FQT	50%			
PA	THOLOGICAL								
4.	Lifetime:	NI (0)	(1) NO	(2)	(3)	(4)			
<u>STA</u>	YING OUT A								
5.	Lifetime:	MI (9)	(1) NO	(2)	(3)	(4)			
RU	NAWAY OVE								
6.	Lifetime:	141 (0)	(1) NO	(2)	(3) 1+	FQT			
NO:	NAGGRESIVE	STEALING							
7.	Lifetime:	NI (0)	(1) NO	(2)	(3) \$10	\$50			
BU	LLYING								
8.	Lifetime:	NI (0)	(1) NO	(2)	FQT	DLY			
PEI	RSISTENT PH	YSICAL FIG							
9.	Lifetime:	(0) NI	(1) NO	(2)	FQT	(4)			
USI	E OF A WEA								
10.	Lifetime:	NI NI	NVR	CON	(3)	1+			
<u>V</u> A	NDALISM								
11.	Lifetime:	(0) NI	(I) NO	(2)	(3)	(4)			
FIF	RESETTING								
12.	Lifetime:	(0) NI	(1) NO	(2)	(3)	(4)			





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BRE	EAKING AND E	NTERING						-	
13.	Lifetime:	NI NI	(1) NO	(2) -1	(3)	(4)			
<u>AG</u>	GRESSIVE STEA	LING							
14.	Lifetime:	NI	(1) NO	(2) -1	(3)	(4)			
CRI	UELTY TO ANII								
15.	Lifetime:	(b) NI	(1) NO	OCC	(3)	(4)			
PH	YSICAL CRUEL	ry to pi	ERSONS						
16.	Lifetime:	(0) NI	(1) NO	(2)	(3)	(4) 2+			
но	MICIDAL ACTS								
17.	Lifetime:	(0) N(I	(1) NO	GTR	ATT	(4) COM			
FO	RCED SEX		1777	ļq			1787		
18.	Lifetime:	MI (0)	(1) NO	(2)	(3)	(4)	(5) RAP		
	NG ACTIVITIES	_	רמח	[72]]	[(3)]	[
19.	Lifetime:	114	NO (1)	PER	(3) MEM	(4) LDR			
	LINQUENCY	רסח	m	[(2)]	(3)	[747]			
20.	Lifetime:	NI (2)	(1) NO	(2) ARR	(3) CHA	CON			
INC	CARCERATION	[70]	[10]	[(2)]	[(3)]	T457			
21.	Lifetime:	NI (0)	(I) NO	HLD	(3) REF	JAL			
	MMARY RATIN		rm)	[73]	T(3)71	[45]	(5)	ത്ര	
22.	Lifetime:	NI (0)	(1) NO	(2) SLT	MLD	(4) MO	(5) SVR	(6) EX	
	CATOCITIC CINIT	DDI 4 (COMPLIC	T DICOR	DED				
23.	AGNOSTIC CRIT		ONDUC						
23.	Onset and Cours	ĺ	•		and offse	t of each 2	_	1 1	
	Number of Episo	oaes L		24.	Onse	t	2.	5. Onset	
					Offse	et		Offset	
					Weel	KS		Weeks	
1									





ſ	Project	Protocol	Center	Patient Number	Visit	Page
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ANTISOCIAL PERSONALITY DISORDER											
wo	<u>RK</u>										
1.	Lifetime:	(0) NI	(1) NO	(2) MLD	(3) MOD	(4) SVR	(5) EX				
FIN	ANCIAL RESPO	NSIBILIT	<u> </u>								
2.	Lifetime:	(6) NI	(1) NO	(2) MLD	(3) MOD	(4) SVR	(5) EX				
CON	NING										
3.	Lifetime:	NI	MLD	(2) MOD	(3) SVR	(4) EX					
DIS	REGARD FOR S	AFETY (OF SELF	OTHER:	<u>s</u>						
4.	Lifetime:	(b) NI	(I) MLD	(2) MOD	(3) EX						
LAC	CK OF REMORS	<u>E</u>									
5.	Lifetime:	(0) NI	MLD	(2) MOD	(3) EX						
<u>DIA</u>	GNOSTIC CRIT	ERIA - A	ANTISOC	IAL PER	RSONALI	TY DISC	ORDER				
6.	Onset and Course	2									
	Number of Episo	des	لـــــا								
	Ages of onset an	d offset o	f each ep	isode							
7.	Onset		8. Ons	et	_						
	Offset Offset										
Weeks Weeks											
								·~			





ſ	Project	Protocol	Center	Patient Number	Visit	Page
Ì	29060	329	0.0		Screening (Week -1)	73

OPP	OPPOSITIONAL DEFIANT DISORDER												
1.	Lifetime:	(0) NI	(I)	(2) SLT	MLD	(4) MO	(5) SVR	(6) EX		į			
DIA	GNOSTIC CRIT	TERIA - O	PPOSIT	IONAL I)EFIANT	DISORI)ER						
DIA	GIOSTIC CRE	IERIA O	11 0511	IOIVAL I	<u> </u>	DISOIG	<u> </u>						
2.	Onset and Cour	<u>se</u>											
	Number of Epis	sodes L											
	Ages of onset a	and offset of	each ep	isode									
3.	Onset	J 4	· Ons	et	J								
	Offset	_	Off	set]								
	Weeks		We	eks									





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<u>ALCOHO</u>	<u>L</u>								-			
ALCOHO	L ABUSE											
1. Life	etime:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX				
ALCOHO	L DEPENDE	ENCE										
2. Life	etime:	(t) N'I	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX				
DIAGNO	STIC CRITE	DIA – A	тсонот	I. DEPEN	IDENCE							
		ICIA A	ncomo.	D DLI D.	IDEITOE							
3. Onse	t and Course											
Num	ber of Episod	es L										
Ages	of onset and	offset of	f each ep	isode						:		
4. Onset 5. Onset												
0	Offset Offset											
W	Veeks	_	Wee	eks	لــا							
DIAGNO	STIC CRITE	RIA A	LCOHO:	L ABUSE	E							
					-							
6. Onse	t and Course											
Num	ber of Episod	les										
Ages	of onset and	offset o	f each ep	isod e								
7. C	nset L	;	B. Ons	et]							
C	ffset		Off	set	J							
V	Veeks		We	eks								
		8-T-										





Project	Protocol	Center	Patient Number	Visit	Page
29060	329	0,0		Screening (Week -1)	75

<u>DR</u>	<u>ugs</u>								-			
DR	UG ABUSE											
1.	Lifetime:	(5)	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX				
DR	UG DEPENDEN	ICE										
2.	Lifetime:	(0)	(1) NO	(2) MLD	(3) MOD	(4) SVR	(5) EX		i			
DIA	DIAGNOSTIC CRITERIA - SUBSTANCE DEPENDENCE											
3.												
	Number of Episodes											
	Ages of onset and offset of each episode											
4.												
	Offset Offset											
	Weeks											
DI	CNOCTIC ON	TIDI A	TIDOT A N	CE ADI	CID.							
	AGNOSTIC CRI		UBSIAN	CE ABU	<u>SE</u>							
6.	Onset and Cour	rse										
	Number of Epi	sodes										
	Ages of onset	and offset o	f each ep	isode								
7.	Onset		8. Ons	et]							
	Offset		Off	set	J							
	Weeks		Wex	eks								





ſ	Project	Protocol	Center	Patient Number	Visit	Page
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MOTOR TICS 1. Lifetime:													
DISORDERS								-					
TOR TICS													
Lifetime:	(0)	(1) NO	(2) SLT	(3) MLD	(4) MO	SVR	(6) EX						
CAL TICS													
Lifetime:	NI (2)	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX						
MOTOR TICS 1. Lifetime: NI NO SLT MLD MO SVR EX VOCAL TICS 2. Lifetime: NI NO SLT MLD MO SVR EX DIAGNOSTIC CRITERIA - TIC DISORDERS 3. Onset and Course Number of Episodes Ages of onset and offset of each episode 4. Onset Offset Offset Offset													
DIAGNOSTIC CRITERIA - TIC DISORDERS													
DIAGNOSTIC CRITERIA - TIC DISORDERS 3. Onset and Course Number of Episodes													
3. Onset and Course Number of Episodes													
-													
Ages of onset and offset of each episode													
Offset	l	Off	set	J									
Weeks	ا	We	eks										
	Lifetime: CAL TICS Lifetime: CGNOSTIC CRIT Onset and Cours Number of Epise Ages of onset and Onset Lifetime Offset Lifetime:	Lifetime: CAL TICS Lifetime: CIGNOSTIC CRITERIA - T Onset and Course Number of Episodes Ages of onset and offset of the course of the co	Lifetime: NI NO CAL TICS Lifetime: NI NO CAL TICS Lifetime: NI NO CONSTIC CRITERIA - TIC DISC Onset and Course Number of Episodes Ages of onset and offset of each ep Onset	Lifetime: NI NO SLT CAL TICS Lifetime: NI NO SLT CAL TICS Lifetime: NI NO SLT AGNOSTIC CRITERIA - TIC DISORDERS Onset and Course Number of Episodes Ages of onset and offset of each episode Onset Onset Offset Offset Offset Offset Offset Offset Offset Offset Offset Offset Offset Offset Offset Offset Offset Offset Offset Offset Offset Offset Offset Offset Offset Offset Offset Offset Offset Offset Offset Offset Offset Offset Offset Offset Offset Offset Offset Offset Offset Offset Offset Offset Offset Offset Offset Offset Offset Offset Offs	Lifetime: NI NO SLT MLD CAL TICS Lifetime: NI NO SLT MLD CAL TICS Lifetime: NI NO SLT MLD AGNOSTIC CRITERIA - TIC DISORDERS Onset and Course Number of Episodes Ages of onset and offset of each episode Onset Onset Onset Offset Offset	Lifetime: NI NO SLT MLD MO CAL TICS Lifetime: NI NO SLT MLD MO CAL TICS Lifetime: NI NO SLT MLD MO AGNOSTIC CRITERIA - TIC DISORDERS Onset and Course Number of Episodes	Lifetime: NI NO SLT MLD MO SVR CAL TICS Lifetime: NI NO SLT MLD MO SVR CAL TICS Lifetime: NI NO SLT MLD MO SVR AGNOSTIC CRITERIA - TIC DISORDERS Onset and Course Number of Episodes Ages of onset and offset of each episode Onset Onset Offset O	Lifetime: NI NO SLT MLD MO SVR EX CAL TICS Lifetime: NI NO SLT MLD MO SVR EX CAL TICS Lifetime: NI NO SLT MLD MO SVR EX CONSTIC CRITERIA - TIC DISORDERS Onset and Course Number of Episodes	Lifetime: NI NO SLT MLD MO SVR EX CAL TICS Lifetime: NI NO SLT MLD MO SVR EX CAL TICS Lifetime: NI NO SLT MLD MO SVR EX AGNOSTIC CRITERIA - TIC DISORDERS Onset and Course Number of Episodes Ages of onset and offset of each episode Onset Offset Offset	Lifetime:			





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PSY(CHOTIC SYN	<u>MPTOMOLOG</u>	<u>Y</u>		
COM	MAND HA	LLUCINATIO	NS		
1.	Lifetime:	(0) NI	(1) ABS	(2) SUS	(3) DEF
CON	VERSING V	OICES			
2.	Lifetime:	(0) N(I	(1) ABS	(2) SUS	(3) DEF
PER	SECUTORY	HALLUCINA	ΓΙΟΝS		
3.	Lifetime:	(0) II <u>M</u>	(1) ABS	(2) SUS	(3) DEF
COM	MMENTING	VOICE			
4.	Lifetime:	(0)	(I) ABS	(2) SUS	(3) DEF
REL	LIGIOUS HA	LLUCINATIO	<u>NS</u>		
5.	Lifetime:	(5)	(1) ABS	(2) SUS	(3) DEF
	OUGHTS ALC			<u> </u>	
6.	Lifetime:	(0) NI	(1) ABS	(2) SUS	(3) DEF
		L HALLUCIN			
7.	Lifetime:	(0) NI	(I) ABS	(2) SUS	DEF
LOC	CATION OF	AUDITORY I			<u>NS</u>
8.	Lifetime:	(<u>0</u>)	(1) ABS	(2) SUS	(3) DEF
9.	Lifetime:	(0)	(I) ABS	(2) SUS	(3) DEF
10.	Lifetime:	(0) NI	(I) ABS	(2)	(3) DEF
			[YR2]	SUS	ואמטן
VIS	SUAL HALLI	UCINATIONS	1.00	[- []	(7 5 \-)
11.	Lifetime:	NI (0)	(1) ABS	SUS	DEF
TA	CTILE HALI	LUCINATIONS	<u>s</u>		
12.	Lifetime:	NI (0)	(1) ABS	(2) SUS	(3) DEF
OL	FACTORY H	IALLUCINATI	ONS		
13.	Lifetime:	(0) NI	(1) ABS	(2) SUS	(3) DEF
14	T : 6 . 4:		[0]	[2]	(3)
14.	Lifetime:	NI	ABS	sus	DEF





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HYPNAGOGIC OR HYPNAPOMPIC HALLUCINATION 1. Lifetime: (7) (3) (2) (2) (3) (3) (4) (4) (4) (4) (4) (4) (4) (4) (4) (4	<u>vs</u>			
1. Lifetime: NI ABS SUS DEF				
2. Lifetime: (6) (1) (2) (3) DEF				
3. Lifetime: (6) (1) (2) (3) DEF				
ILLUSIONS				
4. Lifetime: (0) (1) (2) (3) (3) (2) (5) (4) (5) (6) (7) (7) (7) (7) (7) (7) (7) (7) (7) (7				
EIDETIC IMAGERY				Ì
5. Lifetime: (0) (1) (2) (3) (2) (5) (1) (1) (2) (3) (4) (4) (4) (4) (4) (4) (4) (4) (4) (4				
ELABORATED FANTASIES				
6. Lifetime: (1) (2) (3) (B) (B) (C) (C) (C) (C) (C) (C) (C) (C) (C) (C				
IMAGINARY COMPANIONS				
7. Lifetime: (1) (2) (3) (3) (4) (4) (4) (5) (6) (6) (7) (7) (7) (7) (7) (7) (7) (7) (7) (7				
CHARACTERISTICS OF PSYCHOPATHOLOGICALLY	MEANING	FUL HA	LLUCINATIO	<u>NS</u>
FREQUENCY				
8. Lifetime: (0) (1) (2) (3) NO SUS -5	SOM	(5) LOT	(6) DLY	
SEVERITY				
9. Lifetime: (3) (1) (2) (3) DBF	GEN	(5) CNV	(6) ACT	
THEMATIC CONSISTENCY WITH MOOD DISORDER	<u>L</u>			
DEPRESSION (0) (1) (2) (3) 10. Lifetime: NI NO Pos COM				
MANIA (0) (1) (2) (3) 11. Lifetime: NI NO POS COM				
	_			
TEMPORAL CONSISTENCY WITH MOOD DISORDE	<u>R</u>			
DEPRESSION (1) (2) (3) 12. Lifetime: NI NO SUS POS				
MANIA 13. Lifetime: (0) (1) (2) (3) (3) (5) (5) (6) (1) (6) (7) (1) (1) (1) (1) (1) (1) (1) (1) (1) (1				





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	JSIONS OF	REFERENCE				
<u>JEL.</u> 1.	Lifetime:	(0)	(I) ABS	(2) NON	(3) SUS	(4) DEF
		BEING CON			FLUENC	ED
2.	Lifetime:	(0) N(I	(I) ABS	(2) NON	(3) SUS	(4) DEF
DEL	USIONS THA	AT PEOPLE	CAN RE	AD HIS	MIND	
3.	Lifetime:	(0) NI	(I) ABS	(2) NON	SUS	(4) DEF
THO	UGHT BRO	ADCASTING				
4.	Lifetime:	NI (2)	(I) ABS	(2) NON	(3) SUS	DEF
THO	UGHT INSE	RTION				
5.	Lifetime:	(0)	(1) ABS	(2) NON	SUS	(4) DEF
тно	UGHT WIT	HDRAWAL				
6.	Lifetime:	(0)	(i) ABS	(2) NON	SUS	(4) DEF
<u>DE</u> L	USIONS OF	GUILT OR S	SIN			
7.	Lifetime:	NI (0)	(1) ABS	(2) NON	SUS	(4) DEF
DEL	USIONS OF	INFLUENCE	<u>-</u>			
8.	Lifetime:	(0) NI	(1) ABS	(2) NON	SUS	(4) DEF
PER	SECUTORY	DELUSIONS				
9.	Lifetime:	(0) NI	(I) ABS	NON	SUS	DEF
GUI	ILT RELATE	D PERSECUT	ORY D	ELUSION	IS	
10.	Lifetime:	(0) NI	(1) ABS	(2) NON	SUS	DEF
SON	MATIC DEL					
11.	Lifetime:	(0) NI	(1) ABS	(2) NON	SUS	(4) DEF
GU	ILT RELATI	ED SOMATIC				
12.	Lifetime:	(0) NI	(I) ABS	(2) NON	SUS	(4) DEF

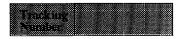




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NIH	ILISTIC DE	LUSIONS						-	
13.	Lifetime:	(0) 1 <u>N</u>	(I) ABS	(2) NON	SUS	(4) DEF			
GUI	LT RELATE	D NIHILISTIC	C DELU	SIONS					
14.	Lifetime:	(6) NI	(1) ABS	(2) NON	(3) SUS	(4) DEF			
GRA	ANDIOSE DE	LUSIONS							
15.	Lifetime:	(0) NI	(1) ABS	(2) NON	SUS	(4) DEF			
SUB	CULTURAL	OR FAMILY	DELUS	IONS					
16.	Lifetime:	NI (0)	(I) DEF	(2) LIK	(3) ALL				
SEV	ERITY OF	DELUSIONS_C	OF ANY	TYPE					
17.	Lifetime:	NI (2)	(1) NO	(2) SUS	PST	(4) GEN	(5) SIG	(6) ACT	
SEN	SORIUM W	HILE DELUD	ED						
18.	Lifetime:	NI (0)	(I) DEL	(2) PLX	(3) ALW				
<u>THI</u>	EMATIC CO	NSISTENCY V	WITH M	IOOD DI	SORDER				
DEI	PRESSION								
19.	Lifetime:	NI	(1) NO	(2) POSS	COM				
MA	NIA			F-ZeV-1					
20.	Lifetime:	NI (0)	(1) NO	POSS	(3) COM				
TEN	MPORAL CO	NSISTENCY	WITH I	MOOD D	ISORDER	:			
DE	PRESSION								
21.	Lifetime:	NI (0)	(1) NO	(2) SUS	POS				
MA	NIA	<u>∟</u> ∞1	1007	172)	[(3)]				
22.	Lifetime:	NI (0)	(I) NO	(2) SUS	POS				
BIZ	ARRENESS	OF DELUSIO							
23.	Lifetime:	(0) NI	(1) NO	(2) SLT	MLD	(4) MOD	SVR	(6) EX	
MU	J LTIPLE DE	LUSIONS							
24.	Lifetime:	(0) NI	(1) ABS	SUS	DEF				





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29060	329	0 0		Screening (Week -1)	81

FOR	MAL THOUG	HT DISORI	ER						<u></u>	
SEN	TENCE INCO	HERENCE								
1.	Lifetime:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX		
2.	Observed:	(0) N[(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX		
DER	AILMENT									
3.	Lifetime:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX		
4.	Observed:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX		
ILL	OGICAL THIN	NKING								
5.	Lifetime:	(C) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX		
6.	Observed:	(C) NI	(1) NO	(2) SLT	(3) MLD	MOD	(5) SVR	(6) EX		
POV	ERTY OF CO	ONTENT OF	SPEECI	<u> </u>						
7.	Lifetime:	(t) NI	NO (I)	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX		
8.	Observed:	NI NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX		
NEC	LOGISMS									
9.	Lifetime:	(0) NI	(1) ABS	(2) SLT	(3) MLD	(4) MOD	(5) 20%	(6) JAR		
10.	Observed:	(0) NI	(1) ABS	(2) SLT	(3) MLD	(4) MOD	(5) 20%	JAR		
PRE	SSURE OF SI	PEECH								
11.	Lifetime:	[(0)]	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX		
12.	Observed:	NI NI	(I) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX		
	, , , , , , , , , , , , , , , , , , , 	·····								





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KIDDIE-SADS-LIFETIME - SCORING FORM

OBSE	RVATIONAL	ITEMS						-	
INA	PROPRIATE	AFFECT							
1.	Observed:	(0)	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX	
BLU	NTED AFFEC	<u>T</u>							
2.	Observed:	(0) NI	(1) NO	(2) SLT	MLD	(4) MOD	(5) SVR	(6) EX	
CAT	ATONIC MO	TOR BEHA	<u>VIOR</u>						
3.	Observed:	(6) N(I	(1) ABS	(2) DBT	(3) MM	(4) SVR			
4.	Observed:	NI NI	(I) ABS	(2) DBT	(3) MM	(4) SVR			
5.	Observed:	MI (2)	(I) ABS	(2) DBT	(3) MM	SVR			
6.	Observed:	(0)	(I) ABS	(2) DBT	(3) MM	(4) \$VR			
7.	Observed:	(0)	(I) ABS	(2) DBT	(3) MM	SVR			
BIZA	ARRENESS								
8.	Observed:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX	
9.	Observed:	[NI	(I) ABS	(2) DBT	(3) PST	(4) SVR			
10.	Observed:	[0] [0]	(1) ABS	(2) DBT	(3) PST	(4) SVR			
11.	Observed:	(0) [N]	(1) ABS	(2) DBT	(3) PST	(4) SVR			
12.	Observed:	(0) VG	(1) G	(2) OF	(3) P	(4) VP			





Project	Protocol	Center	Patient Number	Visit	Page
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KIDDIE-SADS-LIFETIME - SCORING FORM

DIAGNOSTIC CRITERIA - SCHIZOPHRENIA	-
1. Onset and Course	
Number of Episodes	
Ages of onset and offset of each episode	
2. Onset 3. Onset	
Offset Offset	
Weeks Weeks	
DIAGNOSTIC CRITERIA - SCHIZOAFFECTIVE DISORDER	
4. Onset and Course	3
Number of Episodes	
Ages of onset and offset of each episode	
5. Onset 6. Onset	
Offset Offset	
Weeks Weeks	
DIAGNOSTIC CRITERIA - BRIEF PSYCHOTIC DISORDER	
7. Onset and Course	
Number of Episodes	
Ages of onset and offset of each episode	
8. Onset 9. Onset	
Offset Offset	
Weeks Weeks	
	ALC:





ſ	Project	Protocol	Center	Patient Number	Visit	Page
Ì	29060	329	0 0		Screening (Week -1)	84

KIDDIE-SADS-LIFETIME - SCORING FORM

DIA	AGNOSTIC CRITERIA - DE	LUSIONAL DISORDER
10.	Onset and Course	
	Number of Episodes	ب
	Ages of onset and offset of	each episode
11.	Onset 12.	Onset
	Offset	Offset
	Weeks	Weeks

KIDDY-GAS (C-GAS)

1. Current Episode:	100 91	90- 81	80- 71	70- 61	60- 51	50- 41	40- 31	30- 21	20- 11	10-
2. Last Two Weeks:	100- 91	90- 81	80- 71	70- 61	60 51	50- 41	40- 31	30- 21	20- 11	10-1





Project	Protocol	Center	Patient Number	Visit	Visit Date	Page
29060	329	0,0		Eligibility Determination	day month year	85

VITAL SIGNS

Weight		Sitting		Standing	
☐ lbs ☐ kg	Blood F (mm systolic		Pulse (beats/ min)	Pressure nHg) diastolic	Pulse (beats/ min)
[4]	1	/1 , ,		/	, ,

ADVERSE EXPERIENCES / CONCOMITANT MEDICATION

	nt: "Do you feel different in any way since starting the treatment or since the la
_	Yes No
	Record in the Adverse Experience section, page
as	there been any change in concomitant medication since the last visit?
	Yes Do
ſ	Record in the Concomitant Medication section, page





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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 1 OF $\bf 3$

1.	Depressed Mood (sadness, hopelessness, helpless, worthless)
	 □ 0 = Absent □ 1 = These feeling states indicated only on questioning □ 2 = These feeling states spontaneously reported verbally □ 3 = Communicates feeling states non-verbally, i.e., through facial expression, posture, voice and tendency to weep □ 4 = Patient reports virtually only these feeling states in his/her spontaneous verbal and non-verbal communication
2.	Feelings of Guilt
	 □ 0 = Absent □ 1 = Self reproach, feels he/she has let people down □ 2 = Ideas of guilt or rumination over past errors or sinful deeds □ 3 = Present illness is a punishment. Delusions of guilt □ 4 = Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations
3.	Suicide
	 □ 0 = Absent □ 1 = Feels life is not worth living □ 2 = Wishes he/she were dead or any thoughts of possible death to self □ 3 = Suicide ideas or gesture □ 4 = Attempts at suicide (any serious attempt rates 4)
4.	Insomnia Early
	 □ 0 = No difficulty falling asleep □ 1 = Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour □ 2 = Complains of nightly difficulty falling asleep
5.	Insomnia Middle
	 □ 0 = No difficulty □ 1 = Patient complains of being restless and disturbed during the night □ 2 = Waking during the night - getting out of bed rates 2 (except for purposes of voiding)
6.	Insomnia Late
	 □ 0 = No difficulty □ 1 = Waking in early hours of the morning but goes back to sleep □ 2 = Unable to fall asleep again if he/she gets out of bed
7.	Work and Activities
	 □ 0 = No difficulty □ 1 = Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies □ 2 = Love of interest in activities babbies or work = either directly reported by regions
	2 = Loss of interest in activity; hobbies or work - either directly reported by patient, or indirectly in listlessness, indecision and vacillation (feels he/she has to push self to work or activities)
	 □ 3 = Decrease in actual time spent in activities or decrease in productivity. □ 4 = Stopped working because of present illness.





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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 2 OF $\bf 3$

,	8.	Retardation (slowness of thought and speech, impaired ability to concentrate; decreased motor activity)
		 □ 0 = Normal speech and thought □ 1 = Slight retardation at interview □ 2 = Obvious retardation at interview □ 3 = Interview difficult □ 4 = Complete stupor
	9.	Agitation
		 □ 0 = None □ 1 = Fidgetiness □ 2 = "Playing with" hands, hair, etc. □ 3 = Moving about, can't sit still □ 4 = Hand wringing, nail-biting, hair-pulling, biting of lips
1	0.	Anxiety Psychic
		 □ 0 = No difficulty □ 1 = Subjective tension and irritability □ 2 = Worrying about minor matters □ 3 = Apprehensive attitude apparent in face or speech □ 4 = Fears expressed without questioning
1	1.	Anxiety Somatic (physiological concomitants of anxiety such as: Gastrointestinal (dry mouth, wind, indigestion, diarrhea, cramps, belching), Cardiovascular (palpitations, headaches), Respiratory (hyperventilation, sighing), Urinary frequency, Sweating.
		 □ 0 = Absent □ 1 = Mild □ 2 = Moderate □ 3 = Severe □ 4 = Incapacitating
1	.2.	Somatic Symptoms Gastrointestinal
		 □ 0 = None □ 1 = Loss of appetite but eating. Heavy feelings in abdomen □ 2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms
1	l 3.	Somatic Symptoms General
		 □ 0 = None □ 1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability □ 2 = Any clear-cut symptoms rates 2
1	L4.	Genital Symptoms (such as loss of libido and menstrual disturbances)
		 □ 0 = Absent □ 1 = Mild □ 2 = Severe





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HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 3 OF 3

15.	Hypochondriasis
	 □ 0 = Not present □ 1 = Self-absorption (bodily) □ 2 = Preoccupation with health □ 3 = Frequent complaints, requests for help, etc. □ 4 = Hypochondriacal delusions
16.	Loss of Weight
	 □ 0 = No weight loss □ 1 = Slight or doubtful loss of weight □ 2 = Obvious or severe loss of weight
17.	Insight
	 0 = Acknowledges being depressed and ill 1 = Acknowledges illness but attributes cause to bad food, climate, over-work, virus, need for rest, etc.
	☐ 2 = Denies being ill at all
•	HAMD Score (Items 1-17)





Project	Protocol	Center	Patient Number	Visit	Page
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								-	
<u>DEP</u>	RESSED MOOD								
1.	Worst Severity of Current Episode:	(0) NI	(1) NO	SLT	MLD	(4) MO	(5) SVR	(6) EX	(7) VEX
	Duration of Current Episode:		# of we	æks					
2.	Worst Severity of Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	(7) VE
	Frequency:	Day	s/week						
	Average % time of the day:	<u> </u>	%						
<u>DEP</u>	RESSED APPEAR	ANCE							
		ത	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
3.	Current Episode:	NI	[1.0]						
3. 4.	Current Episode: Last Two Weeks:	(0) NI	NO NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
4.	_	(0) NI		(2) SLT		(4) MO	SVR	(6) EX	
4.	Last Two Weeks:	(0) NI		(2) SLT		(4) MO	(5) SVR	(6) EX	
4. <u>IRR</u>	Last Two Weeks:	ANGER	(I) NO	SLT (2) SLT (2) SLT	MLD MLD	(4) MO	SVR (3) SVR	(6) EX	VI
4. <u>IRR</u>	Last Two Weeks: EITABILITY AND Current Episode:	NI ANGER	(I) NO	SLT	MLD.	мо	SVR	[EX]	VI VI
4. <u>IRR</u> 5.	Last Two Weeks: EITABILITY AND Current Episode: Duration:	ANGER (0) NI (0) NI	(I) NO	SLT (2) SLT (2) SLT	MLD MLD	(4) MO	SVR (3) SVR	(6) EX	VI
4. <u>IRR</u> 5.	Last Two Weeks: EITABILITY AND Current Episode: Duration: Last Two Weeks:	ANGER (0) NI (0) NI	(I) NO WO # of w	SLT (2) SLT (2) SLT	MLD MLD	(4) MO	SVR (3) SVR	(6) EX	<u>v</u> i
4. IRR 5.	Last Two Weeks: CITABILITY AND Current Episode: Duration: Last Two Weeks: Frequency: Average % time	ANGER ON NI Da	# of w NO ys/week	SLT (2) SLT (2) SLT	MLD MLD	(4) MO	SVR (3) SVR	(6) EX	<u>v</u>
4. IRR 5.	Last Two Weeks: Current Episode: Duration: Last Two Weeks: Frequency: Average % time of the day:	ANGER ON NI Da	# of w NO ys/week	SLT (2) SLT (2) SLT	MLD MLD	(4) MO	SVR (3) SVR	(6) EX	<u>[v</u>





1	Project	Protocol	Center	Patient Number	Visit	Page
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OUA	LITY OF DYPSH	ORIC MO	OD					~
9.	Current Episode:	(0) NI	(1) ND	(2) QUE	(3) DDF	(4) VDP		
	-	(0) NI	(I) ND	[(2)]	(3)	(4) VDF		
10.	Last Two Weeks:	NI	ND	QUE	DDF	VDF]		
DEC	REE OF ASSOCIA	TION OF	DEPRES	SED OR 1	RRITABI	E MOOD	WITH SP	ECIFIC
EVE	NTS OR PREOCC	UPATION	S	OLL OLL				
11.	Current Episode:	(0) NI	(1) NAL	(2) MOT	(3) UN	(4) PN		
12.	Last Two Weeks:	(0) NI	(I) NAL	(2) MOT	(3) UN	(4) PN		
14.	Last 1 WO WOODS.	[NI]	WAL	faro ti	<u> </u>	لنفف		
REA	CTIVITY OF DE	PRESSED	OR IRRI	TABLE M	<u>00D</u>			
13.		(0) NI	(I) VR	(2) FUL	(3) RES	(4) MLD	(5) SLT	(6) UNR
13.	Current Episode:	NI				THE .	[521]	
				% of No		[-(4)]	[[5]]	ா
14.	Last Two Weeks:	(0)	(I) VR	FUL	(3) RES	MLD	SLT	UNR
			% Usua	1 % of No	rmal			
			% Maxi	mum % of	Normal			
			Number	of hours g	ood feeling	last		
DII	JRNAL MOOD VA	DIATION	т					
		LICIATIO						
	rse in Morning	(0) NI	(1)	(2) MIN	(3) MLD	(4) CW	(5) EXT	
15.	Current Episode:		NW (I)	(MIN)		(4) cw	(5) EXT	
16.	Last Two Weeks:	(0) NI	NW	MIN	MLD	[CW]	EXT	
Wo	rse in Afternoon a	nd/or Eve					**************************************	
17.	Current Episode:	(0) NI	(I) NW	MIN	(3) MLD	CW (4)	EXT	
18.	Last Two Weeks:	(0) NI	(I) NW	(2) MIN	(3) MLD	CW	EXT	





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EXCESSIVE INAPPRO	OPRIATE	GUILT					-					
19. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	MOD	(5) SVR	(6) EXT					
20. Last Two Weeks:	(0) N1	(I) NO	SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT					
Frequency:	Days/Wo	eek [
NEGATIVE SELF IMAGE												
21. Current Episode:	(0) NI	NO NO	(2) SLT	(3) MLD	(4) MOD	SVR	(6) EXT					
22. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT					
FEELING UNLOVED	/FORLO	RN										
23. Current Episode:	(0) NI	(I) NO	(2) SLT	MLD	(4) MOD	(5) SVR	(6) EXT					
24. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	MLD	(4) MOD	SVR	(6) EXT					
Frequency:	Days/W	eek [
HOPELESSNESS, HE	LPLESSN	ESS, DISC	OURAGE	MENT, PE	SSIMISM			-				
25. Current Episode:	(0) MI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT					
26. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT					
SELF-PITY												
27. Current Episode:	(0)	(I) NO	OCC	MLD	CON							
28. Last Two Weeks:	(0) NI	(1) NO	OCC	MLD	(4) CON							
ACHES AND PAINS	=			r aci	- 735 	ראין	· T&T					
29. Current Episode:		(1) NO	SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT					
30. Last Two Weeks:	(0) NI	NO	SLT	(3) MLD	MOD	(5) SVR	(6) EXT					





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HYPOCHONDRIASIS							-			
31. Current Episode:	(0) N.I.	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX			
32. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX			
ANHEDONIA, LACK	OF INT	EREST, AP	ATHY, L	OW MOT	IVATION,	BOREDO	<u> </u>			
Combined Overall Rati	ng									
33. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX			
Duration:	L] # of w	reeks							
34. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX			
Frequency:	D	ays/week								
Average % time of the day:		%								
Differentiating Lack	of Inter	est from A	nhedonia							
Lack of Interest	[(0)]	[תו]	(2)	(3) MLD	(4) MQ	(5) SVR	(6) EX			
35. Current Episode:	N1 (0)	NO	(2) SLT		<u>MO</u>]		[EX]			
36. Last Two Weeks:	(0) N(I	NO	SLT	MLD	МО	(5) SVR	EX			
Anhedonia										
37. Current Episode:	(0) NI	(1) NO	SLT	MLD	(4) MO	(5) SVR	(6) EX			
38. Last Two Weeks:	NI (2)	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX			
FATIGUE, LACK OF ENERGY AND TIREDNESS										
39. Current Episode:	(0)	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX			
40. Last Two Weeks:	I/I (0)	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX			
Frequency:		ays/Week								





Project	Protocol	Center	Patient Number	Visit	Page
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DIF	FICULTY CONCENTRA	ATING	, INATTE	ENTION, O	OR SLOW	ED THIN	KING	-
41.	Current Episode: (6) NI]	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
42.	Last Two Weeks: (6)]	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
PSY	CHOMOTOR AGITAT	<u>ION</u>						
43.	Current Episode: (0)]	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
44.	Last Two Weeks: (0)]	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
	Frequency:	Days	/Week					
MA	NIFESTATIONS INCL	J DED :						
	Unable to sit still							
45.	Current Episode:	(0) NI	(I) NPR	(2) DBT	PR	(4) MOD	(5) SVR	
46.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR	
	Pacing							
47.	Current Episode:	(0) NI	(1) NPR	DBT	(3) PR	SVR	(5) SVR	
48.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR	
	Hand wringing							
49.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR	
50.	Last Two Weeks:	(0) NI	(1) NPR	DBT	(3) PR	(4) SVR	(5) SVR	
Ì	Pulling or rubbing on i	hair c	lothing.sk	in				
	•	(0) NI	(I) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR	
51.	Current Episode:							:
52.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR	
	Can't stop talking, talk	s on c	and on					
53.	Current Episode:	(0) NI	(1) NPR	DBT	(3) PR	SVR	(5) SVR	
54.	Last Two Weeks:	(0) NI	(I) NPR	DBT	PR	(4) SVR	(5) SVR	!
1								





Project	Protocol	Center	Patient Number	Visit	 Page
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PSYC	CHOMOTOR RETARD	ATION						-
55.	Current Episode:	(0) NI	NO NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
56.	Last Two Weeks:	(0) NI	(I) NO	SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
	Frequency:	Day	/s/Week					
MAN	IFESTATIONS INCL	U DED :						
5	Slowed Speech							
57.	Current Episode:	(0) NI	(I) NPR	DBT	PR	(4) MOD	(5) SVR	
58.	Last Two Weeks:	NI NI	(I) NPR	DBT	PR	(4) MOD	(5) SVR	
j	Increased pauses befor	е алзжеі	ring					
59.	Current Episode:	(0) NI	(I) NPR	DBT	PR	MOD	(5) SVR	
60.	Last Two Weeks:	(0) NI	NPR	DBT	(3) PR	MOD	(5) SVR	
	Low or monotonous spe							
61.	Current Episode:	(0) NI	(1) NPR	DBT	PR	(4) MOD	(5) SVR	
62.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	PR	(4) MOD	(5) SVR	
	Mute or markedly deci	reased ar	nount of s	peech				
63.	Current Episode:	(0)	(1) NPR	DBT	(3) PR	MOD	(5) SVR	
64.	Last Two Weeks:	(0) NI	(I) NPR	(2) DBT	PR	(4) MOD	SVR	
	Slowed body movement	s						
65.	Current Episode:	(0) NI	(1) NPR	DBT	PR	(4) MOD	(5) SVR	
66.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	MOD	(5) SVR	
	Depressive stupor							
67.	Current Episode:	(0) NI	(1) NPR	(2) DBT	PR	(4) MOD	SVR	
68.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	PR	(4) MOD	(5) SVR	





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<u>SOC</u> 69. 70.	Current Episode: Last Two Weeks:	AL (O) NI (N)	(1) NO	(2) SLT (2) SLT	(3) MLD (3) MLD	(4) MO	(5) SVR (5) SVR	(6) EX	
<u>REJ</u>	ECTION SENSITI	<u>VITY</u>							
71.	Last Year:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX	
72.	Current Episode:	(0) NI	(I) NO	SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX	
73.	Last Year:	(0) NI	(I) NO	SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX	
74.	Current Episode:	NI (C)	(1) NO	SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX	
	EP PROBLEMS			1					
75. 76.		_	onset of o						
77.			the last t						
,,,	1.00.0 0.	op t							
<u>нү</u>	PERSOMNIA								
78.	Hours sl	ept in day	time of cu	ırrent episo	de				
79.	Hours sl	ept in day	time in the	e last two	weeks				
80.	Hours ly	ing down	in current	episode					
81.	Hours ly	ying down	in last tw	o weeks					
82.	Current Episode:	(0) NI	(1) NO	(2)	(3)	(4)	(5)	(6)	
83.	Last Two Weeks:	(0)	(1) NO	(2)	(3)	(4)	(5)	(6)	





Project	Protocol	Center	Patient Number	Visit	Page
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NISC	OMNIA_						-
84.	Current Episode: (6)	(1) NO	(2)	(3)	(4)	(5)	(6)
	Last Two Weeks: (6)	(I) NO	(2)	(3)	(4)	(5)	(6)
03.		Nights/Wee	لـــــ	(37)			
	riequency.	111611137 11 00	•				
TYP	ES OF INSOMNIA						
	Initial Insomnia	ריאניין	1-75-1		17517		1787°1
86.	Current Episode:	(0) NI	(1) NPR	DBT	(3) MLD	(4) MOD	(5) SVR
87.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	MLD	MOD	SVR
	Middle Insomnia					P	
88.	Current Episode:	(0) NI	(1) NPR	DBT	MLD	MOD MOD	(5) SVR
89.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) MLD	(4) MOD	(5) SVR
	Terminal Insomnia						
90.	Current Episode:	(0) NI	(1) NPR	(2) DBT	MLD	(4) MOD	(5) SVR
91.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) MLD	MOD	(5) SVR
	Circadian Reversal						
92.	Current Episode:	(0) NI	(I) NPR	DBT	MLD	MOD MOD	(5) SVR
93.	Last Two Weeks:	(0)	(I) NPR	(2) DBT	MLD	MOD MOD	(5) SVR
	Non-restorative sleep						
94.	Current Episode:	(O) NI	(I) NPR	DBT	MLD	MOD	(5) SVR
95.	Last Two Weeks:	(0) NI	(I) NPR	DBT	(3) MLD	(4) MOD	(5) SVR
	Daytime sleepiness						
96.	Current Episode:	(0) NI	NPR	DBT	MLD	MOD	SVR
97.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	MLD	MOD	(5) SVR





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							-	
ANOREXIA	רוסדיו	[m]	[72]	(3) MLD	(4) MOD	(5) RAR	(6) NVR	
98. Current Episode:	(0) NI	NO NO	SLT					
99. Last Two Weeks:	(0) NI	NO NO	SLT	(3) MLD	(4) MOD	(5) RAR	(6) NVR	
WEIGHT LOSS								
100. Current Episode:								
Pounds lost:		lbs.						
Number of Weeks:	لــــا							
101. Last Two Weeks:								:
Pounds lost:	لـــا	lbs.						
INCREACED ADDREST	ישר							
INCREASED APPETIT	(D) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX	
102. Current Episode:					MOD MOD	(5) SVR	(6) EX	
103. Last Two Weeks:	NI (0)	(1) NO	(2) SLT	(3) MLD	мор	SVR	EX	
Frequency:		Days/Week						
STRONG CRAVING F	OR SV	VEETS						
104 Commit Emission	[N]	(1) ABS	(2) DBT	(3) MLD	(4) MOD	(5) SVR		
104. Current Episode:	(0) NI	(1) ABS	(2) DBT	(3) MLD	(4) MOD	(5) SVR		
105. Last Two Weeks:	NI	[ABS]	DRI	MLD	МОП	SVK		
WEIGHT GAIN								
106. Current Episode:								
Pounds gained:		lbs.						
Number of Weeks:	<u> </u>	_						
107. Last Two Weeks:								
Pounds gained:	: [」lbs.						
					·————			





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SUICIDAL IDEATION	<u> </u>							-
108. Current Episode:	(0) I.N	ио (1)	SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	VEX
109. Last Two Weeks:	(0) NI	(I)	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	(7) VEX
Suicidal Acts – Numbe	r							
110. Current Episode:								
111. Last Two Weeks:	لــــا							
Suicidal Acts – Serious	sness							
112. Current Episode:	(C)	(1) NO	(2) MIN	(3) DEF	s	(4) ER	(5) VS	(6) EXT
113. Last Two Weeks:	(0) IN	(1) NO	(2) MIN	(3) DEF	S	(4) ER	(5) VS	(6) EXT
Medical Lethality								
114. Current Episode	(6) NI	(I) NO	(2) MIN	(3) MLD	[]	(4) (10)	(5) SVR	(6) EXT
115. Last Two Weeks:	(0) NI	(I) NO	(2) MIN	(3) MLD		(4) MO	SVR	EXT
Non-Suicidal Physical	Self-De	emaging .	Acts					
116. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD		(4) MO	(5) SVR	(6) ACT
117. Last Two Weeks:	(0)	(1) NO	(2) SLT	(3) MLD		(4) MO	(5) SVR	(6) ACT





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DIAC	GNOSTIC CRITERIA	- MAJ	OR DEPRESSIVE EPISODE	
	Onset and Course			
118.	Number of Episodes			
	Ages of onset and or	ffset of	each episode	
119.	Onset	120.	Onset	
	Offset		Offset	
	Weeks		Weeks	
121.	Onset	122.	Onset)
	Offset		Offset	
	Weeks		Weeks	
				. •





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<u>MA</u>	NIC SYNDROME							-
ELA	TION, EXPANSIV	E MOO	<u>D</u>					
1.	Current Episode:	(0) N	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
2.	Last Two Weeks:	(0) NI	(I)	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
DEC	REASED NEED F	OR SLE	<u>EP</u>					
3.	Current Episode:	(0) NI	(1) NO	(2) -1	(3) -2	(4) -3	(5)	(6) -4+
4.	Last Two Weeks:	(0) NI	(1) NO	(2) -1	(3) -2	(4) -3	(5) -4	(6) -4+
UNI	USUALLY ENERG	ETIC						
5.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) LCH	(4) MOR	(5) MM	(6) UA
6.	Last Two Weeks:	(C)	(1) NO	(2) SLT	(3) LCH	MOR	(5) MM	(6) UA
INC	REASE IN GOAL	DIREC	TED ACT	IVITY				
7.	Current Episode:	(0) NI	(1) NO	SLT	MLD	(4) MO	(5) MKD	(6) EX
8.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	MLD	(4) MO	(5) MKD	(6) EX
<u>GR</u>	ANDIOSITY							
9.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
10.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
AC	CELERATED, PRE	SSURED	OR INC	REASED	AMOU	NT OF S	PEECH	
11.	Current Episode:	(2)	(1) NO	SLT	(3) MLD	(4) MO	(5) MKD	(6) EX
12.	Last Two Weeks:	(0)	NO	SLT	MLD	(4) MO	MKD	(6) EX

SS SmithKline Beecham Pharmaceuticals



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										 _
RAC	ING THOUGHTS								-	
13.	Current Episode:	(0) N:	(I) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	(6) EX		
14.	Last Two Weeks:	(0)	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	(6) EX		
<u>FLI</u>	GHT OF IDEAS									
15.	Current Episode:	(0)	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX		
16.	Last Two Weeks:	(C)	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX		
<u>PO</u> (OR JUDGEMENT									
17.	Current Episode:	(6) NI	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) VS		
18.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) VS		
DIS	TRACTABILITY									į
19.	Current Episode:	(0) N/I	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR			
20.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	MLD	(4) MO	(5) SVR			ĺ
MC	OTOR HYPERACT	VITY								
21.	Current Episode:	(2)	(1)	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX		
22.	Last Two Weeks:	NI (0)	NO (1)	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX		
In	appropriate laughin	g, jokinį	g or puns	iing						
23.	Current Episode:	(0) NI	(I) NO	(2) DBT	(3) MLD	(4) MOD				
24.	Last Two Weeks:]VI (0)	(1) NO	(2) DBT	(3) MLD	MOD				
Un	unhibited people se	eking, gi	egarious							
25.	Current Episode:	(0) NI	NO NO	(2) DBT	(3) MLD	MOD				ļ
26.	Last Two Weeks:	(0) NI	(I) NO	DBT	MLD	(4) MOD				

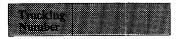




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[nc.	reased Productivity								-	-	-	-	-	-
27.	Current Episode:	NI (0)	(1) NO	(2) DBT	PRS	SVR								
28.	Last Two Weeks:	(0)	(1) NO	(2) DBT	PRS	(4) SVR								
Sho	rpened and unusua	lly creat	ive thinki	ng										
29.	Current Episode:	(5)	(1) NO	(2) DBT	PRS	(4) SVR								
30.	Last Two Weeks:	1/1 (0)	(I) NO	DBT	PRS	SVR								
Ну	persexuality													
31.	Current Episode:	NI (0)	(1) NO	(2) DBT	(3) PRS	(4) SVR								
32.	Last Two Weeks:	(0) NI	(I) NO	(2) DBT	PRS	SVR								
<u>INI</u>	FLUENCE OF ILLI	CIT DE	RUGS OR	ALCOH	<u>OL</u>									
33.	Current Episode:	(0) NA	(1) NVR	(2) SMT	(3) ONL									
34.	Last Two Weeks:	(0) NA	(1) NVR	(2) SMT	(3) ONL									
<u>NU</u> 35.	MBER OF MANIC	PERIC	<u>ODS</u>											





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DIA	GNOSTIC CRITERIA - HYPOMANIC EPISODE
	Onset and Course
36.	Number of Episodes
	Ages of onset and offset of each episode
37.	Onset 38. Onset
	Offset Offset
	Weeks Weeks
DIA	AGNOSTIC CRITERIA - MANIC EPISODE
39.	Onset and Course
	Number of Episodes
	Ages of onset and offset of each episode
40.	Onset 41. Onset
	Offset Offset
	Weeks Weeks





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ELIGIBILITY CHECKLIST

	sion criteria		
If any	of the following statements are answered 'No', the patient is not eligible for	the stud	iy. N
1.	Has the patient and legal guardian signed an informed consent?		
2.	Is the patient an adolescent between the ages of 12 years 0 month and 18 years 11 months inclusive?	P	
3.	Is the patient currently in an episode of major depression (DSM-III-R) for at least 8 weeks?	P	
4.	Does the patient have a score of \geq 12 on the 17-item Hamilton Depression Scale (Screening visit <u>and</u> Eligibility Determination visit, pages 8 and 88)?	7	
5.	Is the patient medically healthy as determined by physical examination, medical history and laboratory screening (pages 3 and 5)?	7	
6.	Does the patient have an IQ \geq 80 by Peabody Picture Vocabulary Test?	中	
7.	Is the patient male, or if female and sexually active, is the patient using a reliable method of contraception (oral contraception, surgical sterilization, I.U.D., diaphragm in conjunction with spermicidal foam amd condom on partners)?		
	ision criteria		
II an	y of the following statements are answered 'Yes', the patient is <u>not eligible</u> for	the stu Yes	idy. ľ
	Does the patient have or have had a DSM-III-R diagnosis of bipolar disorder, schizo-affective disorder, anorexia, bulimia, alcohol or drug abuse/dependence, obsessive/compulsive disorder, autism/pervasive mental disorder, or organic psychiatric disorder?		ldy.
	Does the patient have or have had a DSM-III-R diagnosis of bipolar disorder, schizo-affective disorder, anorexia, bulimia, alcohol or drug abuse/dependence, obsessive/compulsive disorder, autism/pervasive mental disorder, or organic psychiatric disorder?	Yes	ldy.
1.	Does the patient have or have had a DSM-III-R diagnosis of bipolar disorder, schizo-affective disorder, anorexia, bulimia, alcohol or drug abuse/dependence, obsessive/compulsive disorder, autism/pervasive mental disorder, or organic psychiatric disorder? Does the patient have a current diagnosis (within 12 months) of post traumatic stress disorder (DSM-III-R)?	Yes	ldy.
1.	Does the patient have or have had a DSM-III-R diagnosis of bipolar disorder, schizo-affective disorder, anorexia, bulimia, alcohol or drug abuse/dependence, obsessive/compulsive disorder, autism/pervasive mental disorder, or organic psychiatric disorder? Does the patient have a current diagnosis (within 12 months) of post traumatic stress disorder (DSM-III-R)? Has the patient been adequately treated with anti-depressants within 6 months prior to beginning this study (page 4)?	Yes	ldy.
 2. 3. 	Does the patient have or have had a DSM-III-R diagnosis of bipolar disorder, schizo-affective disorder, anorexia, bulimia, alcohol or drug abuse/dependence, obsessive/compulsive disorder, autism/pervasive mental disorder, or organic psychiatric disorder? Does the patient have a current diagnosis (within 12 months) of post traumatic stress disorder (DSM-III-R)? Has the patient been adequately treated with anti-depressants within 6 months prior to beginning this study (page 4)? Has the patient ever had suicidal ideation with a definite plan, or made a suicide attempt within the current episode, or ever made a suicide attempt by medication overdose? Has the patient any medical illness which would contraindicate the use of heterocyclic antidepressants (e.g., cardiovascular disease)?	Yes	Idy.
 2. 3. 4. 	Does the patient have or have had a DSM-III-R diagnosis of bipolar disorder, schizo-affective disorder, anorexia, bulimia, alcohol or drug abuse/dependence, obsessive/compulsive disorder, autism/pervasive mental disorder, or organic psychiatric disorder? Does the patient have a current diagnosis (within 12 months) of post traumatic stress disorder (DSM-III-R)? Has the patient been adequately treated with anti-depressants within 6 months prior to beginning this study (page 4)? Has the patient ever had suicidal ideation with a definite plan, or made a suicide attempt within the current episode, or ever made a suicide attempt by medication overdose? Has the patient any medical illness which would contraindicate the use of heterocyclic antidepressants (e.g., cardiovascular disease)?	Yes	.dy.
1. 2. 3. 4. 5. 6.	Does the patient have or have had a DSM-III-R diagnosis of bipolar disorder, schizo-affective disorder, anorexia, bulimia, alcohol or drug abuse/dependence, obsessive/compulsive disorder, autism/pervasive mental disorder, or organic psychiatric disorder? Does the patient have a current diagnosis (within 12 months) of post traumatic stress disorder (DSM-III-R)? Has the patient been adequately treated with anti-depressants within 6 months prior to beginning this study (page 4)? Has the patient ever had suicidal ideation with a definite plan, or made a suicide attempt within the current episode, or ever made a suicide attempt by medication overdose? Has the patient any medical illness which would contraindicate the use of heterocyclic antidepressants (e.g., cardiovascular disease)? Is the patient currently using (1) psychotropic medications including anticonyulsants, anxiolytics, neuroleptics, lithium carbonate, (2) illicit drugs	Yes	I I
1. 2. 3. 4. 5. 6.	Does the patient have or have had a DSM-III-R diagnosis of bipolar disorder, schizo-affective disorder, anorexia, bulimia, alcohol or drug abuse/dependence, obsessive/compulsive disorder, autism/pervasive mental disorder, or organic psychiatric disorder? Does the patient have a current diagnosis (within 12 months) of post traumatic stress disorder (DSM-III-R)? Has the patient been adequately treated with anti-depressants within 6 months prior to beginning this study (page 4)? Has the patient ever had suicidal ideation with a definite plan, or made a suicide attempt within the current episode, or ever made a suicide attempt by medication overdose? Has the patient any medical illness which would contraindicate the use of heterocyclic antidepressants (e.g., cardiovascular disease)? Is the patient currently using (1) psychotropic medications including anticonvulsants, anxiolytics, neuroleptics, lithium carbonate, (2) illicit drugs as documented by a drug screen with two weeks of starting the study (page Does the patient have evidence of organic brain disease, epilepsy or mental	Yes	dy.





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QUALIFICATION FOR ENTRY TO DOUBLE-BLIND PHASE

Does the patie and exclusion	nt qualify to enter the double-blind phase of the study, i.e., are the inclusion criteria listed on page 104 satisfied?
□ No -	the patient does not qualify for entry
1.	Complete page 106 (concomitant medication) and page 107 (adverse experience) if the patient has taken any medication or reported an adverse experience during the screening phase.
:	Note: These pages are to be completed only for patients who will not enter the double-blind phase.
☐ Yes -	the patient does qualify for entry
1.	Dispense the Week 1 study medication card.
2.	Detach the tear off label from the Week 1 card and affix the label to the Week 1 Label page (page 113) in Binder 2. Also record the start date in the Study Medication Record on page 112 in Binder 2.
	The drug code on the randomization label must be identical to the Patient Number preprinted in the Patient Number box atop of pages 108-232 in Binder 2. To ensure that this Patient Number is properly referenced to the Tracking Number of the Screening/Eligibility pages of this case report form record the pre-printed Patient Number from the top of page 108 (Binder 2) in the space below and again on page 1 (Binder 1-in the page header) of the case report form.
	Patient Number
3.	If the patient is entering the double-blind phase and had an adverse experience during the screening procedures, the experience must be recorded in the adverse experience section (pages 226-231). Additionally, if the patient has taken any medication, either over the counter or prescription, during the screening procedures, these must be recorded in the concomitant medication section (pages 224-225).
I certify that (pages 1-107)	t I have reviewed the screening/eligiblity data in the case report form and that all information is complete and accurate.
	Signature





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CONCOMITANT MEDICATION -> SCREENING FAILURES ONLY

	Where appropriate, medical conditions should be recorded on the Adverse Experiences form utilizing the same terminology.										
Drug Name (Trade name preferred)	me Dose		Medical Condition	Start Date★	End Date * or Continuation (mark box)						
				day month year	day month year						
or B											
For SB											
or B											
or B											
or B											
//											
For SB											
3D				1	, , [
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ADVERSE EXPERIENCE --> SCREENING FAILURES ONLY

Record follow treatm	l in standard medi ing direct question tent or since the la	cal terminology any ad to patient: "Do you f ast visit?" Mark appro	verse experience observe eel different in any way priate boxes (one experi	d or elicited by the y since starting the ence per column).		
Experience	-					
For Smith!	∐ine Beecham					
Date Starte	ed	day month year	day month year	day month year		
Date Stopp	ed	day month year	day month year	day month year		
than	tion if less 24 hours	hours minutes	hours minutes	hours minutes		
Expe	rience continuing rience continuing id of study					
Course	Continuous? - if no, number of episodes	☐ Yes ☐ No - ☐	☐ Yes ☐ No - ☐	☐ Yes ☐ No - ☐		
Intensity	1 Mild 2 Moderate 3 Severe					
Action Taken on Study Medication	1 None 2 Dose decreased 3 Dose increased 4 Drug stopped					
Suspected Relationship To Study Medication	unrelated					
Corrective Therapy	If yes, record on Concomitant Medication form	☐ Yes ☐ No	☐ Yes	☐ Yes		
adverse expedefinitions	sider this a serious erience by the on previous page?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No		
If yes to SB within	, report experience by telephone 24 hours	AE Number	AE Number	AE Number		
Investigator	's Signature			complete Form D		

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Page 16 - Self-Perception for Adolescents

Page 20 - Sickness Impact Profile

Page 24 - Family History

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CONFIDENTIAL

CASE REPORT FORM

PROTOCOL 29060/329

ACUTE PHASE - BINDER 2

A Multi-Center, Double-Blind, Placebo Controlled Study of Paroxetine and Imipramine in Adolescents with Unipolar Major Depression

Patient	Initials	Country	

GENERAL INSTRUCTIONS

Print clearly in CAPITAL LETTERS using a black ball-point pen and press firmly so that all copies are legible. DO NOT print in shaded areas. Answer all questions on every page.

The plastic writing board in the back of the binder should be used to divide each set of pages before writing on them with a ball-point pen.

<u>Important:</u> Errors should be crossed with a single line and the alteration made as close to the original as possible. All alterations must be printed, initialled and dated.

DATE

Use the following three-letter abbreviations for month:

January = JAN February = **FEB** = MAR = APR March April May = MAY = JUN June = JUL July August = AUG September = SEP = OCT October November = NOV December = DEC

TIME

Unless specified otherwise, use the 24 hour clock: 00:00 - 23:59.

Example: $\frac{1}{24} \frac{5}{10} \frac{3}{10} = 3:30 \text{ p.m.}$

SMITHKLINE BEECHAM PROTOCOL 29060/329 - SCHEDULE OF PROCEDURES

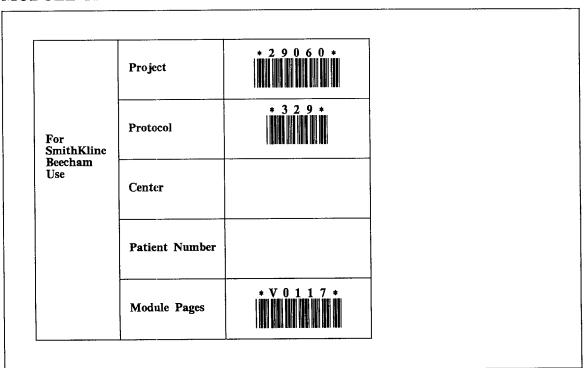
Assessments		Base	line			A	cute	Phas	ie			Co	ntinu	ation	Pha	se	
Assessments	Time (weeks)	-1	0	1_	2	3	4	5	6	7	8	12	16	20	24	28	32
Informed Consent		•															
Medical History and Physical	Exam	•															<u> </u>
Clinical Laboratory Studies		• 1									•			•			•
Serum Pregnancy		•		• 2													
ECG		•			•		•		•		•		<u> </u>	•	ļ		•
Vital Signs		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Hamilton Depression Scale		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Full K-SADS-L		•											_				•
Affect Section of K-SADS-L			•		•		•	ļ	•	ļ <u>.</u>	•	•	•	•	•	•	<u> </u>
C-GAS		•								<u> </u>	<u> </u>		ļ	<u> </u>			<u> </u>
CGI			•	•	•	•	•	•	•	•	•	•	•	•	<u> </u>	•	<u> </u>
SADS-L		•													ļ	<u> </u>	
FH-FHE		•		<u> </u>									<u> </u>	-		ļ	<u> </u>
Autonomous Functioning Chec	klist	•		<u> </u>							•	ļ	ļ				lacksquare
Self Perception Profile		•				<u> </u>					•	<u> </u>			ļ	ļ	•
Sickness Impact Scale		•				<u> </u>					•		ļ	ļ	-		•
Randomization			•						ļ	<u> </u>			_	ļ		ļ	<u> </u>
Adverse Experiences			•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Supportive Psychotherapy			•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Plasma Sampling for Drug A	nalysis	•					•	<u> </u>			•		<u> </u>		•	ļ	•
Study Medication Record				•	•	•	•	•	•	•	•	•	•	•	•	•	•
Concomitant Medication		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•

Clinical laboratory studies should include a Urine Drug Screen
 On suspicion of pregnancy

S SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit	
29060	329	0.0		Acute Phase	

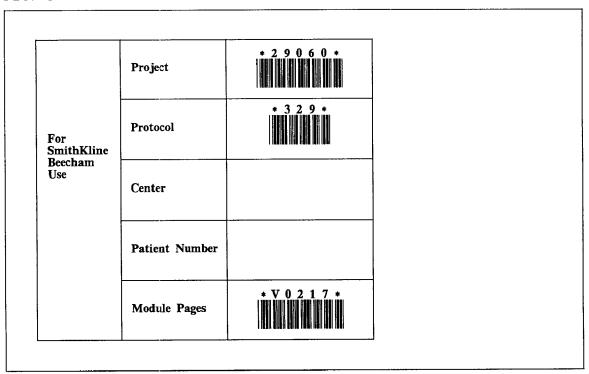
MODULE PARAMETERS - SCREENING/ELIGIBILITY



SmrthKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit	
29060	329	0 0		Acute Phase	

MODULE PARAMETERS - WEEK 1



6

ſ	Project	Protocol	Center	Patient Number	Visit	Visit Date	Page
	29060	329	0.0		Acute Phase Week 1	day month year	108

TRA	CK	ING	NIIN	ABER	
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Enter the Tracking Number from the top of page 107.	Tracking Number	-

VITAL SIGNS

Weight ☐ lbs ☐ kg	Sittin	Standing			
	Blood Pressur (mmHg) systolic dia	Pulse (beats/stolic min)	Blood P (mm systolic		Pulse (beats/ min)

ADVERSE EXPERIENCES / CONCOMITANT MEDICATION

Have	any adverse experiences been observed or elicited by the following direct question to the
patier	nt: "Do you feel different in any way since starting the treatment or since the last v
	☐ Yes ☐ No
_	
ļ	Record in the Adverse Experience section
Has	there been any change in concomitant medication since the last visit?
	☐ Yes ☐ No
ſ	Record in the Concomitant Medication section

CLINICAL GLOBAL IMPRESSIONS - GLOBAL IMPROVEMENT

reau	nent. 1t chan	Compared to his/her condition a med?	t aumission to the study, no	ow Much has the
•				
[∃ 1 =	Very much improved		
[□ 2 =	Much improved		
[□ 3 =	Minimally improved		
[□ 4 =	No change		
[□ 5 =	Minimally worse		
[□ 6:	Much worse		
	7:	Very much worse		

Project	Protocol	Center	Patient Number	Visit	Page
29060	329	0.0		Acute Phase Week 1	109

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 1 OF 3

1.	Depressed Mood (sadness, hopelessness, helpless, worthless) 0 = Absent 1 = These feeling states indicated only on questioning 2 = These feeling states spontaneously reported verbally 3 = Communicates feeling states non-verbally, i.e., through facial expression, posture, voice and tendency to weep
	4 = Patient reports virtually only these feeling states in his/her spontaneous verbal and non-verbal communication
2.	Feelings of Guilt
	 □ 1 = Absent □ 1 = Self reproach, feels he/she has let people down □ 2 = Ideas of guilt or rumination over past errors or sinful deeds □ 3 = Present illness is a punishment. Delusions of guilt □ 4 = Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations
3.	Suicide
	 □ 0 = Absent □ 1 = Feels life is not worth living □ 2 = Wishes he/she were dead or any thoughts of possible death to self □ 3 = Suicide ideas or gesture □ 4 = Attempts at suicide (any serious attempt rates 4)
4.	Insomnia Early
	 □ 0 = No difficulty falling asleep □ 1 = Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour □ 2 = Complains of nightly difficulty falling asleep
5.	Insomnia Middle
	 0 = No difficulty 1 = Patient complains of being restless and disturbed during the night 2 = Waking during the night - getting out of bed rates 2 (except for purposes of voiding)
6.	Insomnia Late
	 0 = No difficulty 1 = Waking in early hours of the morning but goes back to sleep 2 = Unable to fall asleep again if he/she gets out of bed
7.	Work and Activities
	 □ 0 = No difficulty □ 1 = Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies
	2 = Loss of interest in activity; hobbies or work - either directly reported by patient, or indirectly in listlessness, indecision and vacillation (feels he/she has to push self to work or activities)
	 □ 3 = Decrease in actual time spent in activities or decrease in productivity. □ 4 = Stopped working because of present illness.

Signature State Signature Signature

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0,0		Acute Phase Week 1	8.5	110

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 2 OF 3

8.	Retardation (slowness of thought and speech, impaired ability to concentrate; decreased motor activity)
	 □ 0 = Normal speech and thought □ 1 = Slight retardation at interview □ 2 = Obvious retardation at interview □ 3 = Interview difficult □ 4 = Complete stupor
9.	Agitation
	 □ 0 = None □ 1 = Fidgetiness □ 2 = "Playing with" hands, hair, etc. □ 3 = Moving about, can't sit still □ 4 = Hand wringing, nail-biting, hair-pulling, biting of lips
10.	Anxiety Psychic
	 □ 0 = No difficulty □ 1 = Subjective tension and irritability □ 2 = Worrying about minor matters □ 3 = Apprehensive attitude apparent in face or speech □ 4 = Fears expressed without questioning
11.	Anxiety Somatic (physiological concomitants of anxiety such as: Gastrointestinal (dry mouth, wind, indigestion, diarrhea, cramps, belching), Cardiovascular (palpitations, headaches), Respiratory (hyperventilation, sighing), Urinary frequency, Sweating.
	 □ 0 = Absent □ 1 = Mild □ 2 = Moderate □ 3 = Severe □ 4 = Incapacitating
12.	Somatic Symptoms Gastrointestinal
·	 □ 0 = None □ 1 = Loss of appetite but eating. Heavy feelings in abdomen □ 2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms
13.	Somatic Symptoms General
	 □ 0 = None □ 1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability □ 2 = Any clear-cut symptoms rates 2
14.	Genital Symptoms (such as loss of libido and menstrual disturbances)
	 □ 0 = Absent □ 1 = Mild □ 2 = Severe

Project	Protocol	Center	Patient Number	Visit	Page
29060	329	0 0		Acute Phase Week 1	111

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 3 OF 3 $\,$

15.	Hypochondriasis
	 □ 0 = Not present □ 1 = Self-absorption (bodily) □ 2 = Preoccupation with health □ 3 = Frequent complaints, requests for help, etc. □ 4 = Hypochondriacal delusions
16.	Loss of Weight
	 □ 0 = No weight loss □ 1 = Slight or doubtful loss of weight □ 2 = Obvious or severe loss of weight
17.	Insight
	 0 = Acknowledges being depressed and ill 1 = Acknowledges illness but attributes cause to bad food, climate, over-work, virus, need for rest, etc.
	□ 2 = Denies being ill at all
• !	HAMD Score (Items 1-17)

Project	Protocol	Center	Patient Number	Visit	Page
29060	329	0 0		Acute Phase Week 1	112

STUDY MEDICATION RECORD

Start Date lay month year	End Date day month year	Dose Level	Number of Capsules Daily	
t I	1	1	2	

STUDY MEDICATION DOSING CHANGES

☐ Yes —		_		
	Reminder:	Changes i	in dose constitu	te deviation from the protocol.
Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily	Reason for Dose Change

STUDY MEDICATION COMPLIANCE

Capsules Dispensed (A)	Capsules Returned (B)	Capsules Taken (A - B)	Since	% Compliance		
20						
	ance = - npliance mu	(2 x da	of capsules ys since las 0% and \(\leq \)	st visit) x	100	
Has the pa	tient been	non-compli	iant?			•
	s 🗆 1	No				

Project	Protocol	Center	Patient Number	Visit	Page
29060	329	0,0		Acute Phase Week 1	113

STUDY MEDICATION LABEL

			Attach label here		
-					
	•	Enter patient number (drug code as listed on clinical supplies)		Important:	The drug code on the study medication label must be identical to the preprinted Patient Number above.

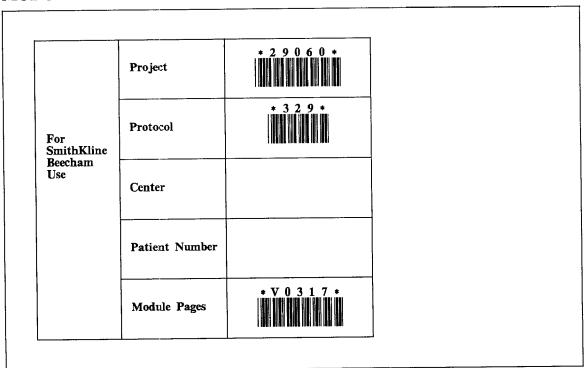
STUDY MEDICATION DISPENSING

Record study medication information for Week 2 in the Study Medication Record, page 131. Attach label to page 132. Record number of capsules dispensed on page 131.

Reminder: The drug code on the study medication label must be identical to the preprinted Patient Number above.

Project	Protocol	Center	Patient Number	Visit	
29060	329	0.0		Acute Phase	

MODULE PARAMETERS - WEEK 2



Project	Protocol	Center	Patient Number	Visit		V	isit Dat	e	Page
29060	329	0,0		Acute Phase Week 2	A	day	month	year	114

VITAL SIGNS

Weight		Sitting			Standing	
Weight □ lbs □ kg	Blood I (ınn systolic	Pressure 1Hg) diastolic	Pulse (beats/ min)		Pressure nHg) diastolic	Pulse (beats/ min)
	, , ,	/	4 1	, , 1	/	

ADVERSE EXPERIENCES / CONCOMITANT MEDICATION

atie	any adverse experiences been observed or elicited by the following direct question to ent: "Do you feel different in any way since starting the treatment or since the las
	□ Yes □ No
	Record in the Adverse Experience section
	Record in the Adverse Experience section
łas	there been any change in concomitant medication since the last visit?
	□ Yes □ No
	Record in the Concomitant Medication section

CLINICAL GLOBAL IMPRESSIONS - GLOBAL IMPROVEMENT

atient		Compared to his/her condition at admission to the study, how much has the nged?
	1 :	= Very much improved
		= Much improved
	3 :	= Minimally improved
	4	= No change
	5 :	= Minimally worse
	6	= Much worse
$\overline{}$	7	= Very much worse

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0 0		Acute Phase Week 2	134	115

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 1 OF 3 $\,$

1	l.	Depressed Mood (sadness, hopelessness, helpless, worthless) 0 = Absent 1 = These feeling states indicated only on questioning 2 = These feeling states spontaneously reported verbally 3 = Communicates feeling states non-verbally, i.e., through facial expression, posture, voice and tendency to weep 4 = Patient reports virtually only these feeling states in his/her spontaneous verbal and non-verbal communication
2	2.	Feelings of Guilt
		 □ 0 = Absent □ 1 = Self reproach, feels he/she has let people down □ 2 = Ideas of guilt or rumination over past errors or sinful deeds □ 3 = Present illness is a punishment. Delusions of guilt □ 4 = Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations
	3.	Suicide
		 □ 0 = Absent □ 1 = Feels life is not worth living □ 2 = Wishes he/she were dead or any thoughts of possible death to self □ 3 = Suicide ideas or gesture □ 4 = Attempts at suicide (any serious attempt rates 4)
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		 0 = No difficulty 1 = Waking in early hours of the morning but goes back to sleep 2 = Unable to fall asleep again if he/she gets out of bed
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		2 = Loss of interest in activity; hobbies or work - either directly reported by patient, or indirectly in listlessness, indecision and vacillation (feels he/she has to push self to work or activities)
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Project	Protocol	Center	Patient Number	Visit	Page
29060	329	0 0		Acute Phase Week 2	116

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 2 OF 3

8.	Retardation (slowness of thought and speech, impaired ability to concentrate; decreased motor activity) 0 = Normal speech and thought 1 = Slight retardation at interview 2 = Obvious retardation at interview 3 = Interview difficult 4 = Complete stupor
9.	Agitation
	 □ 0 = None □ 1 = Fidgetiness □ 2 = "Playing with" hands, hair, etc. □ 3 = Moving about, can't sit still □ 4 = Hand wringing, nail-biting, hair-pulling, biting of lips
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	 □ 0 = No difficulty □ 1 = Subjective tension and irritability □ 2 = Worrying about minor matters □ 3 = Apprehensive attitude apparent in face or speech □ 4 = Fears expressed without questioning
11.	Anxiety Somatic (physiological concomitants of anxiety such as: Gastrointestinal (dry mouth, wind, indigestion, diarrhea, cramps, belching), Cardiovascular (palpitations, headaches), Respiratory (hyperventilation, sighing), Urinary frequency, Sweating.
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12.	Somatic Symptoms Gastrointestinal
	 □ 0 = None □ 1 = Loss of appetite but eating. Heavy feelings in abdomen □ 2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms
13.	Somatic Symptoms General
	 □ 0 = None □ 1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability □ 2 = Any clear-cut symptoms rates 2
14.	Genital Symptoms (such as loss of libido and menstrual disturbances)
	 □ 0 = Absent □ 1 = Mild □ 2 = Severe

Project	Protocol	Center	Patient Number	Visit	Page
29060	329	0,0		Acute Phase Week 2	117

HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 3 OF 3 $\,$

15.	Hypochondriasis
	 □ 0 = Not present □ 1 = Self-absorption (bodily) □ 2 = Preoccupation with health □ 3 = Frequent complaints, requests for help, etc. □ 4 = Hypochondriacal delusions
16.	Loss of Weight
	 □ 0 = No weight loss □ 1 = Slight or doubtful loss of weight □ 2 = Obvious or severe loss of weight
17.	Insight
	 □ 0 = Acknowledges being depressed and ill □ 1 = Acknowledges illness but attributes cause to bad food, climate, over-work, virus, need for rest, etc. □ 2 = Denies being ill at all
	☐ 2 = Denies being ill at all
•	HAMD Score (Items 1-17)

Γ	Project	Protocol	Center	Patient Number	Visit	Page
	29060	329	0 0		Acute Phase Week 2	118

DEF	PRESSED MOOD							-	
1.	Worst Severity of Current Episode:	(0) NI	(1) NO	SLT	MLD	(4) MO	(5) SVR	(6) EX	VEX
	Duration of Current Episode:		# of we	æks					
2.	Worst Severity of Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	(7) VEX
	Frequency:	Days	s/week						
	Average % time of the day:		%						
DEI	PRESSED APPEAR	ANCE							
3.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
4.	Last Two Weeks:	(0) NI	(1) NO	SLT	(3) MLD	(4) MO	SVR	(6) EX	
IRE	RITABILITY AND	ANGER							
5.	Current Episode:	(0) NI	(1) NO	SLT	MLD	(4) MO	(5) SVR	(6) EX	(7) VEX
	Duration:		# of w	eeks					
6.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	(7) VEX
	Frequency:	Day	s/week						
	Average % time of the day:]%						
SEI	PARATION-DEPE	NDENT-D	YSPHOR	<u>IA</u>					
7.	Current Episode:	(0) NI	NO	(2) OCC	(3) USL	(4) ALW			
8.	Last Two Weeks:	(0)	(1) NO	OCC	USL	ALW			
i .									

Ī	Project	Protocol	Center	Patient Number	Visit		Page
	29060	329	0 0		Acute Phase Week 2	4	119

OTIA	LITY OF DYPSH	ORIC MO	OD					-
9.	Current Episode:	[0] NI	(I) ND	(2) QUE	(3) DDF	(4) VDF		
	-	(0) NI	(I) ND	(2)	(3)	(4) VDF		
10.	Last Two Weeks:	NI	ND	QUE	DDF	VDF]		
DEC	REE OF ASSOCIA	ATION OF	DEPRES	SED OR 1	RRITARI	E MOOD	WITH SP	ECIFIC
EVE	NTS OR PREOCC	UPATION	S	OLD OR				
11.	Current Episode:	(0) NI	(1) NAL	(2) MOT	(3) UN	PN		
12.	Last Two Weeks:	(0) NI	(1) NAL	(2) MOT	(3) UN	(4) PN		
	· -	يتنيا	<u></u>					
REA	CTIVITY OF DE	PRESSED	OR IRRIT	TABLE M	OOD			
13.	Current Episode:	(0) NI	(1) VR	(2) FUL	(3) RES	(4) MLD	(5) SLT	(6) UNR
	Current Episode.	! !		% of No				
		<u>~~~</u>				(4) MLD	(5) SLT	(6) UNR
14.	Last Two Weeks:	(0) NI	(1) VR	FUL	(3) RES	MLD	SLT	UNR
				1 % of No				
		1	% Maxi	mum % of	Normal			
			Number	of hours g	ood feeling	last		
DIU	RNAL MOOD VA	ARIATION	1					
-	rse in Morning		•					
15.	Current Episode:	(0) NI	(1) NW	(2) M1N	(3) MLD	(4) CW	(5) EXT	
	Last Two Weeks:	(0) NI	(1) NW	(2) MIN	(3) MLD	(4) CW	(5) EXT	
10.	Last Iwo Weeks:	NI	ΓΩM.	MILE	EATT D	5	<u> </u>	
Wo	rse in Afternoon a	nd/or Eve		[7(2)]	□ (3)□	[747]	[3]	
17.	Current Episode:	NI	(I) NW	(2) MIN	MLD	cw	EXT	
18.	Last Two Weeks:	(0) NI	(I) NW	MIN	(3) MILD	CW	EXT	

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0.0		Acute Phase Week 2	64	120

EXCESSIVE INAPPRO	OPRIATE	GUILT					-
19. Current Episode:	(C)	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
20. Last Two Weeks:	(c)	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
Frequency:	Days/Wo	eek _					
NEGATIVE SELF IM.	AGE						
21. Current Episode:	(C)	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
22. Last Two Weeks:	(C) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
FEELING UNLOVED	'FORLOF	<u>en</u>					
23. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
24. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
Frequency:	Days/W	eek [
					~~~~		
HOPELESSNESS, HEL	PLESSNE	SS, DISC	OURAGEN	1ENT, PE	<u>SSIMISM</u>		
25. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
26. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	MLD	(4) MOD	(5) SVR	(6) EXT
SELF-PITY							
27. Current Episode:	(0) NI	(1) NO	(2) OCC	(3) MLD	(4) CON		
28. Last Two Weeks:	(0) NI	(1) NO	(2) occ	(3) MLD	(4) CON		
	<u> </u>	لكنما	<del>Leaniel</del>	L,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,			
ACHES AND PAINS	propyletone						
29. Current Episode:	(0) NI	(1) NO	(2) SLT	MLD	(4) MOD	(5) SVR	EXT
30. Last Two Weeks:	(0)	(1)	SLT	(3) MLD	MOD	SVR	EXT

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0 0		Acute Phase Week 2	84	121

								$\overline{}$
HYPOCHONDRIASIS							-	
31. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	SVR	(6) EX	
32. Last Two Weeks:	(0) N1	(1) NO	SLT	MLD	(4) MOD	(5) SVR	EX	
ANHEDONIA, LACK	OF INT	PDEST AD	ATHV I	OW MOT	IVATION	ROREDO	M	
ANHEDONIA, LACK	OF INT	ERESI, AI	AIIII, D	011 11101	VAIION	DOIGEDO	111	1
Combined Overall Ratio	-				<del></del> 1	1 7 EV 1		
33. Current Episode:	(0) N1	(I)	(2) SLT	MLD	(4) MO	(5) SVR	(6) EX	
Duration:		# of w	eeks					
34. Last Two Weeks:	(0) NI	(1) NO	SLT	MLD	(4) MO	(5) SVR	(6) EX	
Frequency:	L_ D	ays/week						
Average % time of the day:		]%						:
Differentiating Lack	of Inter	est from A	nhedonia					
Lack of Interest			l-ray-1	I-753-1	<del></del> -	L-87-1	17671	
35. Current Episode:	(t) NI	NO (1)	SLT	(3) MLD	(4) MO	SVR	(6) EX	
36. Last Two Weeks:	(0) N1	(I) NO	SLT	MLD	(4) MO	SVR	(6) EX	
Anhedonia								
37. Current Episode:	(0) NI	NO NO	SLT	MLD	MO	(5) SVR	(6) EX	
38. Last Two Weeks:	(0) NI	(I) NO	SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
FATIGUE, LACK OF	ENERG	Y AND TI	REDNESS					
39. Current Episode:	(0) NI	(l) NO	SLT	MLD	(4) MO	SVR	(6) EX	
40. Last Two Weeks:	(D)	NO NO	SLT	(3) MLD	(4) MO	SVR	(6) EX	
Frequency:	D	ays/Week					- •	

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0,0		Acute Phase Week 2	114	122

DIF	FICULTY CONCENTR	ATIN(	G, INATTI	ENTION, O	OR SLOW	ED THIN	KING	-				
41.	Current Episode: (5)		(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX				
42.	Last Two Weeks:		(i) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX				
PSY	CHOMOTOR AGITAT	<u>'ION</u>										
43.	43. Current Episode: (1) NO (2) (3) (4) (5) (6) SVR EX											
44.	Last Two Weeks:	7	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX				
	Frequency:	Days	/Week									
MA	NIFESTATIONS INCL	UDED:										
	Unable to sit still											
45.	Current Episode:	(0) NI	(1) NPR	DBT	PR	(4) MOD	(5) SVR					
46.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR					
	Pacing											
47.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR					
48.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR					
	Hand wringing											
49.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR					
50.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	SVR	(5) SVR					
	Pulling or rubbing on	hair.c	lothing, sk	in								
51.	Current Episode:	(0) NI	(I) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR					
52.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR					
	Can't stop talking, tali	ks on a	und on									
53.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR					
53. 54.	Last Two Weeks:	(0) NI	(I) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR					
<b>5</b> -10		141	[111.16]	[DBI]	14	(318)	[3VK]					

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0,0		Acute Phase Week 2	94	123

							****
CHOMOTOR RETARI	DATION						-
Current Episode:	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
Frequency:	Day	ys/Week					
IFESTATIONS INCL	U <b>DED</b> :						
lowed Speech							
Current Episode:	(0) NI	(1) NPR	DBT	PR	MOD	(5) SVR	
Last Two Weeks:	(0) NI	(1) NPR	DBT	(3) PR	MOD	(5) SVR	
ncreased pauses befor	e answei	ring					
Current Episode:	(0) NI	(1) NPR	DBT	(3) PR	(4) MOD	(5) SVR	
Last Two Weeks:	(0) NI	(1) NPR	DBT	PR	(4) MOD	(5) SVR	
ow or monotonous spe							
Current Episode:		NPR			MOD		
Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	PR	MOD	(5) SVR	
Aute or markedly deci	eased an	nount of s	peech				
Current Episode:	(0) NI	(1) NPR	(2) DBT	PR	(4) MOD	(5) SVR	
Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR	
lowed body movement.	5						
Current Episode:	(0) NI	(I) NPR	(2) DBT	PR	(4) MOD	SVR	
Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	PR	(4) MOD	(5) SVR	
Depressive stupor							
Current Episode:	(0) NI	(I) NPR	(2) DBT	PR	(4) MOD	(5) SVR	
Last Two Weeks:	(0) NI	(I) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR	
	Current Episode:  Last Two Weeks:  Frequency:  IFESTATIONS INCLU-  Flowed Speech  Current Episode:  Last Two Weeks:  Increased pauses be for  Current Episode:  Last Two Weeks:  Low or monotonous speech  Current Episode:  Last Two Weeks:  Increased pauses be for  Current Episode:  Last Two Weeks:  Current Episode:  Last Two Weeks:  Illowed body movement:  Current Episode:  Last Two Weeks:  Current Episode:  Last Two Weeks:	Last Two Weeks: ONI  Frequency: Day  IFESTATIONS INCLUDED:  Illowed Speech  Current Episode: NI  Last Two Weeks: NI  Illowed body movements  Current Episode: NI  Last Two Weeks: NI  Illowed body movements  Current Episode: NI  Last Two Weeks: NI  Illowed body movements  Current Episode: NI  Last Two Weeks: NI  Illowed body movements  Current Episode: NI  Last Two Weeks: NI  Depressive stupor  Current Episode: NI  Current Episode: NI	Current Episode: NI NO  Last Two Weeks: NI NO  Frequency: Days/Week  IFESTATIONS INCLUDED:  Iowed Speech  Current Episode: NI NPR  Last Two Weeks: NI NPR  Current Episode: NI NPR  Current Episode: NI NPR  Last Two Weeks: NI NPR  Last Two Weeks: NI NPR  Last Two Weeks: NI NPR  Current Episode: NI NPR  Last Two Weeks: NI NPR  Current Episode: NI NPR  Last Two Weeks: NI NPR  Last Two Weeks: NI NPR  Current Episode: NI NPR	Current Episode: NI NO SET  Last Two Weeks: NI NO SET  Frequency: Days/Week  IFESTATIONS INCLUDED:  Illowed Speech  Current Episode: NI NPR DBT  Last Two Weeks: NI NPR DBT  Current Episode: NI NPR DBT  Last Two Weeks: NI NPR DBT  Last Two Weeks: NI NPR DBT  Current Episode: NI NPR DBT  Last Two Weeks: NI NPR DBT  Current Episode: NI NPR DBT  Current Episode: NI NPR DBT  Current Episode: NI NPR DBT	Current Episode: NI NO SIT MLD  Last Two Weeks: OO NI NO SIT MLD  Frequency: Days/Week  IFESTATIONS INCLUDED:  Ilowed Speech  Current Episode: NI NPR DBT PR  Last Two Weeks: NI NPR DBT PR  Current Episode: NI NPR DBT PR  Last Two Weeks: NI NPR DBT PR  Current Episode: NI NPR DBT PR  Last Two Weeks: NI NPR DBT PR  Last Two Weeks: NI NPR DBT PR  Current Episode: NI NPR  Current Episode: NI NPR  Curr	Current Episode: NI NO SIT MID MO  Last Two Weeks: NI NO SIT MID MO  Frequency: Days/Week  IFESTATIONS INCLUDED:  Ilowed Speech  Current Episode: NI NPR DBT PR MOD  Last Two Weeks: NI NPR DBT PR MOD  Current Episode: NI NPR DBT PR MOD  Last Two Weeks: NI NPR DBT PR MOD  Current Episode: NI NPR DBT PR MOD  Last Two Weeks: NI NPR DBT PR MOD  Last Two Weeks: NI NPR DBT PR MOD  Current Episode: NI NPR DBT PR MOD  Last Two Weeks: NI NPR DBT PR MOD  Last Two Weeks: NI NPR DBT PR MOD  Last Two Weeks: NI NPR DBT PR MOD  Cow or monotonous speech  Current Episode: NI NPR DBT PR MOD  Last Two Weeks: NI NPR DBT PR MOD  Current Episode: NI NPR DBT PR MOD  Last Two Weeks: NI NPR DBT PR MOD  Current Episode: NI NPR DBT PR MOD  Current Episode: NI NPR DBT PR MOD  Depressive stupor  Current Episode: NI NPR DBT PR MOD	Current Episode: Ni No SiT MALD MO SYR  Last Two Weeks: Ni No SiT MALD MO SYR  Frequency: Days/Week  IFESTATIONS INCLUDED:  Illowed Speech  Current Episode: Ni NPR DBT PR MOD SYR  Last Two Weeks: Ni NPR DBT PR MOD SYR  Last Two Weeks: Ni NPR DBT PR MOD SYR  Current Episode: Ni NPR DBT PR MOD SYR  Last Two Weeks: Ni NPR DBT PR MOD SYR  Last Two Weeks: Ni NPR DBT PR MOD SYR  Current Episode: Ni NPR DBT PR MOD SYR  Current Episode: Ni NPR DBT PR MOD SYR  Cow or monotonous speech  Current Episode: Ni NPR DBT PR MOD SYR  Last Two Weeks: Ni NPR DBT PR MOD SYR  Last Two Weeks: Ni NPR DBT PR MOD SYR  Last Two Weeks: Ni NPR DBT PR MOD SYR  Current Episode: Ni NPR DBT PR MOD SYR  Last Two Weeks: Ni NPR DBT PR MOD SYR  Last Two Weeks: Ni NPR DBT PR MOD SYR  Last Two Weeks: Ni NPR DBT PR MOD SYR  Last Two Weeks: Ni NPR DBT PR MOD SYR  Last Two Weeks: Ni NPR DBT PR MOD SYR  Last Two Weeks: Ni NPR DBT PR MOD SYR  Last Two Weeks: Ni NPR DBT PR MOD SYR  Last Two Weeks: Ni NPR DBT PR MOD SYR  Last Two Weeks: Ni NPR DBT PR MOD SYR  Last Two Weeks: Ni NPR DBT PR MOD SYR  Last Two Weeks: Ni NPR DBT PR MOD SYR  Last Two Weeks: Ni NPR DBT PR MOD SYR  Last Two Weeks: Ni NPR DBT PR MOD SYR  Last Two Weeks: Ni NPR DBT PR MOD SYR  Last Two Weeks: Ni NPR DBT PR MOD SYR  Last Two Weeks: Ni NPR DBT PR MOD SYR  Last Two Weeks: Ni NPR DBT PR MOD SYR  Current Episode: Ni NPR DBT PR MOD SYR  Last Two Weeks: Ni NPR DBT PR MOD SYR  Depressive stupor  Current Episode: Ni NPR DBT PR MOD SYR

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XIDI	JIE GADG LII	C TO I TIATI	ALLI	CIIVE	LIVILLI	CHILOIT	50.	OMILIO	1 OIL
soc	IAL WITHDRAW	AL				,			
69.	Current Episode:	(5) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
70.	Last Two Weeks:	(5)	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
<u>REJ</u>	ECTION SENSITI	<u>VITY</u>							
71.	Last Year:	NI (0)	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX	
72.	Current Episode:	NI (0)	(1) NO	SLT	MLD	MOD	SVR	(6) EX	
73.	Last Year:	)/I (0)	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX	
74.	Current Episode:	NI (0)	(1) NO	SLT	MLD	(4) MOD	(5) SVR	(6) EX	
SLE	EP PROBLEMS								
75.	Hours sle	ept before	onset of d	epression					
76.	Hours sl	ept during	the curren	t episode					
77.	Hours sl	ept during	the last tv	vo weeks					
<u>HY</u>	PERSOMNIA								
78.	Hours sl	ept in dayt	ime of cu	rrent episod	е				
79.	Hours sl	ept in dayt	ime in the	: last two v	veeks				
80.	Hours ly	ing down	n current	episode					
81.	Hours ly	ring down	n last two	weeks					
82.	Current Episode:	(0) NI	NO	(2)	(3)	(4)	(5)	(6)	
83.	Last Two Weeks:	(0)	(1)	(2)	(3)	(4)	(5)	(6)	

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NSON	INIA						
4. (	Current Episode: (C)	(I) NO	(2)	(3)	(4)	(5)	(6)
5. L	ast Two Weeks: (C)	(I) NO	(2)	(3)	(4)	(5)	(6)
	Frequency:	Nights/Wee	:k				
TYPE	S OF INSOMNIA						
	Initial Insomnia						
86.	Current Episode:	(0)	(I) NPR	DBT	(3) MLD	MOD	(5) SVR
87.	Last Two Weeks:	(0) NI	(I) NPR	(2) DBT	MLD	(4) MOD	(5) SVR
	Middle Insomnia						
88.	Current Episode:	(0)	(1) NPR	DBT	(3) MLD	MOD	(5) SVR
89.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	MLD	MOD	(5) SVR
	Terminal Insomnia						r-725
90.	Current Episode:		(I) NPR	DBT	MLD	MOD	(5) SVR
91.	Last Two Weeks:	(0) NI	(1) NPR	DBT	MLD	MOD MOD	SVR
	Circadian Reversal						[780-]
92.	Current Episode:	(0) NI	(I) NPR	DBT	(3) MLD	MOD	(5) SVR
93.	Last Two Weeks:	(0) N1	NPR	DBT	MLD	(4) MOD	SVR
	Non-restorative sleep				1 <del>77</del> 771	<del></del>	
94.	Current Episode:	(0) NI	(1) NPR	DBT	MLD	(4) MOD	(5) SVR
95.	Last Two Weeks:	(O)	(I) NPR	DBT	(3) MLD	(4) MOD	(5) SVR
	Daytime sleepiness				<del>- /2/-1</del>		
96.	Current Episode	(0) NI	(1) NPR	DBT	MLD	MOD	(5) SVR
97.	Last Two Weeks	(0) NI	(I) NPR	(2) DBT	MLD	MOD	(5) SVR

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						-
رق	(m)	(2)	(3)	(4)	(5)	(6) NVR
NI	NO	SLT	MLD	MOD	RAR	(6) NVR
لـــا	lbs.					
لـــا	lbs.					
TE_						
(0)	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
[N]	(1) NO	(2) SLT	MLD	(4) MOD	(5) SVR	(6) EX
	Days/Week					
FOR SW	<u>EETS</u>					
NI (0)	(1) ABS	(2) DBT	(3) MLD	(4) MOD	(5) SVR	
(0) NI	(1) ABS	(2) DBT	(3) MLD	(4) MOD	(5) SVR	
	lbs.					
: []	lbs.					
	TE  (0) NI  (0) NI  FOR SW	IDS.  IDS.	(0) NI (1) (2) SLT    lbs.     lbs.	(3)	TE	(6) NI NO SLT MLD MOD RAR

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SUICIDAL IDEATION	1						-	
108. Current Episode:	(0)	(1) NO	(2) SLT	(3) MLD	(4) MO SVR	(6) EX	VEX	
109. Last Two Weeks:	10) NI	(I) NO	(2) SLT	(3) MLD	(4) MO SVR	(6) EX	(7) VEX	
Suicidal Acts - Numbe	er.							
110. Current Episode:								
111. Last Two Weeks:	لــــا							
Suicidal Acts - Seriou	sness							
112. Current Episode:	)/I (0)	(1) NO	(2) MIN	(3) DEF	(4) SER	(5) VS	(6) EXT	
113. Last Two Weeks:	)AI (0)	(1) NO	(2) MIN	(3) DEF	(4) SER	(5) VS	(6) EXT	
Medical Lethality								
114. Current Episode	NI NI	(1) NO	(2) MIN	(3) MLD	(4) MO	(5) SVR	(6) EXT	
115. Last Two Weeks:	NI NI	(1) NO	(2) MIN	(3) MLD	(4) MO	SVR	EXT	
Non-Suicidal Physical	Self-De	emaging .	Acts					
116. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) ACT	
117. Last Two Weeks:	(0)  NI	NO NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) ACT	

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	NIC SYNDROME	E MOO	ın.						-	
ELA	TION, EXPANSIV	E MOO	<u>עי</u>							
1.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX		
2.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX		
DEC	CREASED NEED F	OR SLE	<u>EP</u>							
3.	Current Episode:	(0) NI	(1) NO	(2) -1	(3) -2	(4) -3	( <u>5)</u> -4	(6) -4+		
4.	Last Two Weeks:	(0) NI	(i) NO	(2) -1	(3) -2	(4) -3	(5) -4	(6) -4+		
UNI	USUALLY ENERG	<u>etic</u>								
5.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) LCH	(4) MOR	(5) MM	(6) UA		
6.	Last Two Weeks:	(0) NII	(1) NO	(2) SLT	(3) LCH	(4) MOR	(5) MM	(6) UA		
INC	REASE IN GOAL	DIREC	TED ACT	CIVITY						
7.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX		
8.	Last Two Weeks:	(0) NI	NO (I)	(2) SLT	MLD	(4) MO	(5) MKD	(6) EX		
<u>GR</u>	ANDIOSITY									
9.	Current Episode:	(0) (0)	(1)	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX		
10.	Last Two Weeks:	(0)	NO (1)	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX		
AC	CELERATED, PRE	SSURED	OR INC	REASED	AMOUN	NT OF S	PEECH			
11.	Current Episode:	(0)	(I) NO	(2) SLT	MLD	(4) MO	(5) MKD	(6) EX		
12.	Last Two Weeks:	NI (0)	NO (I)	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX		

### SMITHKline Beecham Pharmaceuticals

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RACING THOUGHTS								-	
13. Current Episode:	(0) N:I	(I) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	(6) EX		
14. Last Two Weeks:	(0) NI	(I) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	(6) EX		
FLIGHT OF IDEAS									
15. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX		
16. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX		
POOR JUDGEMENT									
17. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) VS		
18. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) VS		
DISTRACTABILITY									
19. Current Episode:	NI (C)	(1) NO	(2) SLT	MLD	(4) MO	(5) SVR			
20. Last Two Weeks:	NI NI	NO NO	(2) SLT	(3) MLD	(4) MO	(5) SVR			
MOTOR HYPERACTI	VITY								
21. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX		
22. Last Two Weeks:	(0) IN	(1)	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX		
Inappropriate laughin	g, jokin	g or puns	iing						
23. Current Episode:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD				
24. Last Two Weeks:	(0) NI	(I) NO	(2) DBT	(3) MLD	(4) MOD				
Uninhibited people sec	eking, gi	egarious							
25. Current Episode:	(0)	(1) NO	(2) DBT	MLD	(4) MOD				
26. Last Two Weeks:	(5) IM	(1) NO	(2) DBT	(3) MLD	MOD				

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Inc	reased Productivity						
27.	Current Episode:	(0) NI	(1) NO	DBT	PRS	(4) SVR	
28.	Last Two Weeks:	(0)	(1) NO	(2) DBT	PRS	(4) SVR	
Sha	r pened and unusua	ilv creat	ive thinki	'nσ			
	- F	.,		0			
29.	Current Episode:	NI (0)	NO (1)	DBT	PRS	(4) SVR	
30.	Last Two Weeks:	[NI]	(1) NO	(2) DBT	PRS	SVR	
Ηv	persexuality						
	po, someony						
31.	Current Episode:	NI (0)	(1) NO	DBT	PRS	(4) SVR	
32.	Last Two Weeks:	(0)	(I) NO	(2) DBT	(3) PRS	SVR	
INF	LUENCE OF ILLI	CIT DR	UGS OR	ALCOH	<u>OL</u>		
33.	Current Episode:	(0) NA	(I) NVR	(2) SMT	(3) ONL		
34.	Last Two Weeks:	(0) NA	(I) NVR	(2) SMT	ONL		
NU:	MBER OF MANIC	PERIO	DS				
35.							

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#### STUDY MEDICATION RECORD

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily	
. 1		2		

#### STUDY MEDICATION DOSING CHANGES

☐ Yes — Indicate change(s) below	,	ny investigator pre-	scribea cn	anges in study	medication since the last visit
Reminder: Changes in dose constitute deviation from the protocol.  Start Date End Date Dose Capsules	□ No		(3.1.1		
Start Date End Date Dose Number of Capsules	□ Yes —	—▶ Indicate cha	nge(s) belo	0W	
Start Date End Date Dose Capsules		<b>.</b>	CI -		to desiration from the nuctocal
Start Date   End Date   Dose   Capsules		Reminder:	Changes	in dose constitu	te deviation from the protocol.
Start Date   End Date   Dose   Capsules					
				N 1 e	
	Start Date	End Date	Dose		
				Capsules	Reason for Dose Change
				Capsules	Reason for Dose Change
				Capsules	Reason for Dose Change

#### STUDY MEDICATION COMPLIANCE

Capsules Dispensed (A)	Capsules Returned (B)	Capsules Taken (A - B)	Days Since Last Visit	% Compliance		
20						
Compli Cor			nys since last $0\%$ and $\leq 1$	st visit)	100	
Has the pa	tient been	non-compli	lant?			
	s 🗆 1	No				

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ST	TIDY	M	TO:	CA'	LIUN	T.4	<b>ABEL</b>

	Attach label here	
,		_
Enter patient number (drug code as listed on clinical supplies)	<u>I</u>	mportant: The drug code on the study medication label must be identical to the preprinted Patient Number above.

#### **ELECTROCARDIOGRAM**

for interpret	ardiogram performed and sent to a central reader ation?	Date Performed (day month year)
☐ Yes	□ No	(US) AND

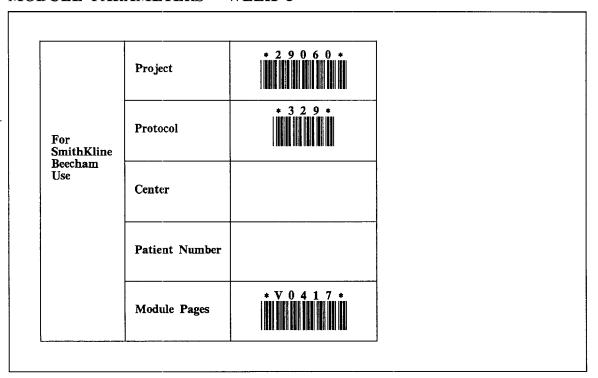
#### STUDY MEDICATION DISPENSING

Record study medication information for Week 3 in the Study Medication Record, page 137. Attach label to page 138. Record number of capsules dispensed on page 137.

<u>Reminder:</u> The drug code on the study medication label must be identical to the preprinted Patient Number above.

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#### **MODULE PARAMETERS - WEEK 3**



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#### **VITAL SIGNS**

Weight □ lbs □ kg	Sitting			Standing			
	Blood P (mm systolic		Pulse (beats/ min)		Pressure nHg) diastolic	Pulse (beats/ min)	
[4]	1/	,	1 1	, , ,	/1 , ,	1 1	

#### ADVERSE EXPERIENCES / CONCOMITANT MEDICATION

Record in the Adverse Experience section	tient: "Do you	□ No
Record in the Adverse Experience section		
	Record in th	e Adverse Experience section
s there been any change in concomitant medication since the last visit?	is there been ar	ny change in concomitant medication since the last visit?
s there been any <u>change</u> in concomitant medication since the last visit?    Yes   No		

#### CLINICAL GLOBAL IMPRESSIONS - GLOBAL IMPROVEMENT

	ent. Compared to his/her condition at admission to the study, how changed?	much has the
patient	changeu.	
	1 = Very much improved	
	2 = Much improved	
	3 = Minimally improved	
	4 = No change	
	5 = Minimally worse	
	6 = Much worse	
	7 = Very much worse	

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# HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 1 OF 3 $\,$

1.	Depressed Mood (sadness, hopelessness, helpless, worthless)
	☐ 1 = These feeling states indicated only on questioning ☐ 2 = These feeling states spontaneously reported verbally ☐ 3 = Communicates feeling states non-verbally, i.e., through facial expression, posture, voice and tendency to weep ☐ 4 = Patient reports virtually only these feeling states in his/her spontaneous verbal and non-verbal communication
2.	Feelings of Guilt
	<ul> <li>□ 0 = Absent</li> <li>□ 1 = Self reproach, feels he/she has let people down</li> <li>□ 2 = Ideas of guilt or rumination over past errors or sinful deeds</li> <li>□ 3 = Present illness is a punishment. Delusions of guilt</li> <li>□ 4 = Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations</li> </ul>
3.	Suicide
	<ul> <li>□ 0 = Absent</li> <li>□ 1 = Feels life is not worth living</li> <li>□ 2 = Wishes he/she were dead or any thoughts of possible death to self</li> <li>□ 3 = Suicide ideas or gesture</li> <li>□ 4 = Attempts at suicide (any serious attempt rates 4)</li> </ul>
4.	Insomnia Early
	<ul> <li>□ 0 = No difficulty falling asleep</li> <li>□ 1 = Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour</li> <li>□ 2 = Complains of nightly difficulty falling asleep</li> </ul>
5.	Insomnia Middle
	<ul> <li>□ 0 = No difficulty</li> <li>□ 1 = Patient complains of being restless and disturbed during the night</li> <li>□ 2 = Waking during the night - getting out of bed rates 2 (except for purposes of voiding)</li> </ul>
6.	Insomnia Late
	<ul> <li>□ 0 = No difficulty</li> <li>□ 1 = Waking in early hours of the morning but goes back to sleep</li> <li>□ 2 = Unable to fall asleep again if he/she gets out of bed</li> </ul>
7.	Work and Activities
	<ul> <li>0 = No difficulty</li> <li>1 = Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies</li> </ul>
	2 = Loss of interest in activity; hobbies or work - either directly reported by patient, or indirectly in listlessness, indecision and vacillation (feels he/she has to push self to work or activities)
	<ul> <li>3 = Decrease in actual time spent in activities or decrease in productivity.</li> <li>4 = Stopped working because of present illness.</li> </ul>

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# HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 2 OF 3 $\,$

8.	Retardation (slowness of thought and speech, impaired ability to concentrate; decreased motor activity)
	<ul> <li>□ 0 = Normal speech and thought</li> <li>□ 1 = Slight retardation at interview</li> <li>□ 2 = Obvious retardation at interview</li> <li>□ 3 = Interview difficult</li> <li>□ 4 = Complete stupor</li> </ul>
9.	Agitation
	<ul> <li>□ 0 = None</li> <li>□ 1 = Fidgetiness</li> <li>□ 2 = "Playing with" hands, hair, etc.</li> <li>□ 3 = Moving about, can't sit still</li> <li>□ 4 = Hand wringing, nail-biting, hair-pulling, biting of lips</li> </ul>
10.	Anxiety Psychic
	<ul> <li>□ 0 = No difficulty</li> <li>□ 1 = Subjective tension and irritability</li> <li>□ 2 = Worrying about minor matters</li> <li>□ 3 = Apprehensive attitude apparent in face or speech</li> <li>□ 4 = Fears expressed without questioning</li> </ul>
11.	Anxiety Somatic (physiological concomitants of anxiety such as: Gastrointestinal (dry mouth, wind, indigestion, diarrhea, cramps, belching), Cardiovascular (palpitations, headaches), Respiratory (hyperventilation, sighing), Urinary frequency, Sweating.
	<ul> <li>□ 0 = Absent</li> <li>□ 1 = Mild</li> <li>□ 2 = Moderate</li> <li>□ 3 = Severe</li> <li>□ 4 = Incapacitating</li> </ul>
12.	Somatic Symptoms Gastrointestinal
	<ul> <li>□ 0 = None</li> <li>□ 1 = Loss of appetite but eating. Heavy feelings in abdomen</li> <li>□ 2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms</li> </ul>
13.	Somatic Symptoms General
	<ul> <li>□ 0 = None</li> <li>□ 1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability</li> <li>□ 2 = Any clear-cut symptoms rates 2</li> </ul>
14.	Genital Symptoms (such as loss of libido and menstrual disturbances)
	<ul> <li>□ 0 = Absent</li> <li>□ 1 = Mild</li> <li>□ 2 = Severe</li> </ul>

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### HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 3 OF 3

15. Hypochondriasis	
<ul> <li>□ 0 = Not present</li> <li>□ 1 = Self-absorption (bodily)</li> <li>□ 2 = Preoccupation with health</li> <li>□ 3 = Frequent complaints, requests for help, etc.</li> <li>□ 4 = Hypochondriacal delusions</li> </ul>	
16. Loss of Weight	
<ul> <li>□ 0 = No weight loss</li> <li>□ 1 = Slight or doubtful loss of weight</li> <li>□ 2 = Obvious or severe loss of weight</li> </ul>	
17. Insight	
<ul> <li>□ 0 = Acknowledges being depressed and ill</li> <li>□ 1 = Acknowledges illness but attributes cause to bad food, climate, over-work, virus need for rest, etc.</li> <li>□ 2 = Denies being ill at all</li> </ul>	,
HAMD Score (Items 1-17)	

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#### STUDY MEDICATION RECORD

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily		
		3			

#### STUDY MEDICATION DOSING CHANGES

	Have there been a	ny investigator pre	scribed ch	anges in study	medication since the last visit?
	□ No				
	☐ Yes —	→ Indicate cha	nge(s) belo	ow	
İ		Reminder:	Changes i	in dose constitu	te deviation from the protocol.
	Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily	Reason for Dose Change
				Capsules	Reason for Dose Change

#### STUDY MEDICATION COMPLIANCE

Capsules Dispensed (A)	Capsules Returned (B)	Capsules Taken (A - B)	Days Since Last Visit	% Compliance		
30						
,	ance = - npliance mi		ys since las $0\%$ and $\leq 1$			
₩ Con	•					
,	tient been	non-compli	ant?			

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#### STUDY MEDICATION LABEL

				_
		Attach label here		
•	Enter patient number (drug code as listed on clinical supplies)		Important:	The drug code on the study medication label must be identical to the preprinted Patient Number above.

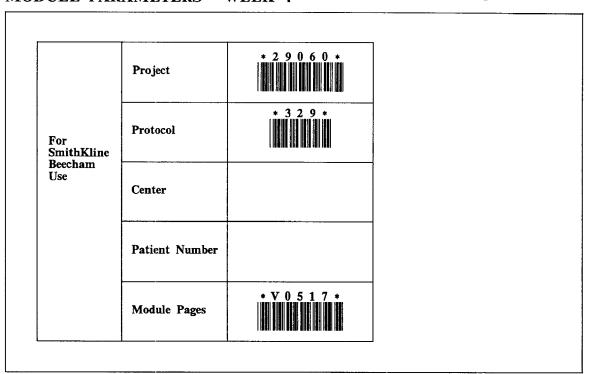
#### STUDY MEDICATION DISPENSING

Record study medication information for Week 4 in the Study Medication Record, page 156. Attach label to page 157. Record number of capsules dispensed on page 156.

Reminder: The drug code on the study medication label must be identical to the preprinted Patient Number above.

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#### **MODULE PARAMETERS - WEEK 4**



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Weight	Sitting		Standing	
☐ lbs ☐ kg	Blood Pressure (mmHg) systolic diastolic	Pulse (beats/ min)	Blood Pressure (mmHg) systolic diastolic	Pulse (beats/ min)
	1/1			

#### ADVERSE EXPERIENCES / CONCOMITANT MEDICATION

Have any adverse experiences been observed or elicited by the following direct question to the patient: "Do you feel different in any way since starting the treatment or since the last visi
☐ Yes ☐ No
Record in the Adverse Experience section
Has there been any change in concomitant medication since the last visit?
☐ Yes ☐ No
Record in the Concomitant Medication section

#### CLINICAL GLOBAL IMPRESSIONS - GLOBAL IMPROVEMENT

Rate the treatmen patient c	total improvement whether or not, in your judgment, it is due entirely to drug at. Compared to his/her condition at admission to the study, how much has the changed?
	1 = Very much improved
	2 = Much improved
	3 = Minimally improved
	4 = No change
	5 = Minimally worse
	6 = Much worse
	7 = Very much worse

#### PLASMA SAMPLE - DRUG CONCENTRATION

Was a plasma sam	ple obtained for drug concentration	n?	
☐ Yes	□ No		

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## HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 1 OF 3 $\,$

1.	Depressed Mood (sadness, hopelessness, helpless, worthless)    0 = Absent  1 = These feeling states indicated only on questioning  2 = These feeling states spontaneously reported verbally  3 = Communicates feeling states non-verbally, i.e., through facial expression, posture, voice and tendency to weep  4 = Patient reports virtually only these feeling states in his/her spontaneous verbal and non-verbal communication
2.	Feelings of Guilt
	<ul> <li>□ 0 = Absent</li> <li>□ 1 = Self reproach, feels he/she has let people down</li> <li>□ 2 = Ideas of guilt or rumination over past errors or sinful deeds</li> <li>□ 3 = Present illness is a punishment. Delusions of guilt</li> <li>□ 4 = Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations</li> </ul>
3.	Suicide
	<ul> <li>□ 0 = Absent</li> <li>□ 1 = Feels life is not worth living</li> <li>□ 2 = Wishes he/she were dead or any thoughts of possible death to self</li> <li>□ 3 = Suicide ideas or gesture</li> <li>□ 4 = Attempts at suicide (any serious attempt rates 4)</li> </ul>
4.	Insomnia Early
	<ul> <li>□ 0 = No difficulty falling asleep</li> <li>□ 1 = Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour</li> <li>□ 2 = Complains of nightly difficulty falling asleep</li> </ul>
5.	Insomnia Middle
	<ul> <li>□ 0 = No difficulty</li> <li>□ 1 = Patient complains of being restless and disturbed during the night</li> <li>□ 2 = Waking during the night - getting out of bed rates 2 (except for purposes of voiding)</li> </ul>
6.	Insomnia Late
	<ul> <li>□ 0 = No difficulty</li> <li>□ 1 = Waking in early hours of the morning but goes back to sleep</li> <li>□ 2 = Unable to fall asleep again if he/she gets out of bed</li> </ul>
7.	Work and Activities
	<ul> <li>□ 0 = No difficulty</li> <li>□ 1 = Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies</li> <li>□ 2 = Loss of interest in activity; hobbies or work - either directly reported by patient, or indirectly in listlessness, indecision and vacillation (feels he/she has to push self to work or activities)</li> </ul>
	☐ 3 = Decrease in actual time spent in activities or decrease in productivity. ☐ 4 = Stopped working because of present illness.

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# HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 2 OF 3

8.	Retardation (slowness of thought and speech, impaired ability to concentrate; decreased motor activity)
	<ul> <li>□ 0 = Normal speech and thought</li> <li>□ 1 = Slight retardation at interview</li> <li>□ 2 = Obvious retardation at interview</li> <li>□ 3 = Interview difficult</li> <li>□ 4 = Complete stupor</li> </ul>
9.	Agitation
	<ul> <li>□ 0 = None</li> <li>□ 1 = Fidgetiness</li> <li>□ 2 = "Playing with" hands, hair, etc.</li> <li>□ 3 = Moving about, can't sit still</li> <li>□ 4 = Hand wringing, nail-biting, hair-pulling, biting of lips</li> </ul>
10.	Anxiety Psychic
	<ul> <li>□ 0 = No difficulty</li> <li>□ 1 = Subjective tension and irritability</li> <li>□ 2 = Worrying about minor matters</li> <li>□ 3 = Apprehensive attitude apparent in face or speech</li> <li>□ 4 = Fears expressed without questioning</li> </ul>
11.	Anxiety Somatic (physiological concomitants of anxiety such as: Gastrointestinal (dry mouth, wind, indigestion, diarrhea, cramps, belching), Cardiovascular (palpitations, headaches), Respiratory (hyperventilation, sighing), Urinary frequency, Sweating.
	<ul> <li>□ 0 = Absent</li> <li>□ 1 = Mild</li> <li>□ 2 = Moderate</li> <li>□ 3 = Severe</li> <li>□ 4 = Incapacitating</li> </ul>
12.	Somatic Symptoms Gastrointestinal
	<ul> <li>□ 0 = None</li> <li>□ 1 = Loss of appetite but eating. Heavy feelings in abdomen</li> <li>□ 2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms</li> </ul>
13.	Somatic Symptoms General
	<ul> <li>□ 0 = None</li> <li>□ 1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability</li> <li>□ 2 = Any clear-cut symptoms rates 2</li> </ul>
14.	Genital Symptoms (such as loss of libido and menstrual disturbances)
	<ul> <li>□ 0 = Absent</li> <li>□ 1 = Mild</li> <li>□ 2 = Severe</li> </ul>

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# HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 3 OF 3

15.	Hypochondriasis
	<ul> <li>□ 0 = Not present</li> <li>□ 1 = Self-absorption (bodily)</li> <li>□ 2 = Preoccupation with health</li> <li>□ 3 = Frequent complaints, requests for help, etc.</li> <li>□ 4 = Hypochondriacal delusions</li> </ul>
16.	Loss of Weight
	<ul> <li>□ 0 = No weight loss</li> <li>□ 1 = Slight or doubtful loss of weight</li> <li>□ 2 = Obvious or severe loss of weight</li> </ul>
17.	Insight
	<ul> <li>0 = Acknowledges being depressed and ill</li> <li>1 = Acknowledges illness but attributes cause to bad food, climate, over-work, virus, need for rest, etc.</li> </ul>
	2 = Denies being ill at all
<b>•</b> [	HAMD Score (Items 1-17)

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	RESSED MOOD Worst Severity of	(0)	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	(7) VEX
	Current Episode:	<u>INI</u>	[NO]	SLI	MLD	[MO]	[348]	LEA	<u>V-L</u>
	Duration of Current Episode:	<u> </u>	# of we	æks					
2.	Worst Severity of Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	(7) VEX
	Frequency:	Days	s/week						
	Average % time of the day:	<u> </u>	<b>]</b> %						
<u>DEP</u>	RESSED APPEAR	ANCE							
3.	Current Episode:	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
4.	Last Two Weeks:	(0) N1	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
<u>IRR</u>	ITABILITY AND						F-787-1		- C
5.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	VE
	Duration:		」# of w	eeks					
6.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	MLD	(4) MO	(5) SVR	(6) EX	VE
	Frequency:	Day	/s/week						
	Average % time of the day:		<u>J</u> %						
SEF	PARATION-DEPE	NDENT-I	YSPHOR	l <u>A</u>					
7.	Current Episode:	(0) NI	NO NO	(2) OCC	(3) USL	(4) ALW			
8.	Last Two Weeks:	(0) NI	(1) NO	OCC	USL	ALW			

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QUALITY OF DYPSH	ORIC MO	OD					-
9. Current Episode:	(0) NI	(1) ND	(2) QUE	(3) DDF	(4) VDF		
10. Last Two Weeks:	(0) NI	(1) ND	(2) QUE	(3) DDF	(4) VDF		
DEGREE OF ASSOCIA	TION OF	DEBBES	SED OD I	DDITARI	F MOOD	WITH SP	FCIFIC
EVENTS OR PREOCC			JED OK I	KKITADU	L MOOD	***************************************	<u>Lonro</u>
11. Current Episode:	(0) NI	(1) NAL	(2) MOT	(3) UN	PN PN		
12. Last Two Weeks:	(0) NI	(1) NAL	(2) MOT	(3) UN	(4) PN		
REACTIVITY OF DE	PRESSED (	OR IRRIT	CABLE MO	OOD			
KEACHVIII OF BEI	TELOGER	010 221102		<u> </u>			
13. Current Episode:	(0) NI	(I) VR	FUL.	RES	MLD	(5) SLT	(6) UNR
		% Usual	% of Nor	mal			
14. Last Two Weeks:	(0) NI	(I) VR	FUL	(3) RES	MLD	SLT	(6) UNR
	لــــا	% Usual	% of Nor	mal			
		% Maxii	num % of	Normal			
		Number of	of hours go	od feeling	last		
DIURNAL MOOD VA	RIATION						
Worse in Morning							
15. Current Episode:	(0) NI	(1) NW	MIN	(3) MLD	CW	EXT	
16. Last Two Weeks:	(0) NI	(1) NW	(2) MIN	(3) MLD	(4) CW	(5) EXT	
Worse in Afternoon a	nd/or Eve	ning					
17. Current Episode:	(0) NI	(I) NW	(2) MIN	MLD	(4) CW	EXT	
18. Last Two Weeks:	(0) NI	(I) NW	(2) MIN	(3) MLD	(4) CW	(5) EXT	

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EXCESSIVE INAPPRO	PRIATE	GUILT					***
19. Current Episode:	(0) NI	(I) NO	SLT	(3) MLD	(4) MOD	(5) SVR	EXT
20. Last Two Weeks:	NI (C)	(I) NO	SLT	(3) MLD	(4) MOD	(5) SVR	EXT
Frequency:	Days/Wo	eek					
NEGATIVE SELF IM.	<u>AGE</u>						3
21. Current Episode:	(6) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
22. Last Two Weeks:	(6) N1	(1) NO	SLT	MLD	MOD	(5) SVR	EXT
FEELING UNLOVED	'FORLOI	<u>RN</u>					
23. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
24. Last Two Weeks:	(0) NI	(1) NO	SLT	MLD	MOD	SVR	(6) EXT
Frequency:	Days/W	eek					
HOPELESSNESS, HEL	PLESSN	ESS, DISC	OURAGEN	MENT, PE	SSIMISM		
25. Current Episode:	(0) [11]	(I) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
26. Last Two Weeks:	(0)	(I) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	EXT
SELF-PITY							
27. Current Episode:	(0) NI	(1) NO	(2) OCC	(3) MLD	(4) CON		
28. Last Two Weeks:	(0) NI	(1) NO	(2) OCC	(3) MLD	(4) CON		
ACHES AND PAINS							
29. Current Episode:	(0) NI	NO NO	(2) SLT	MLD	(4) MOD	(5) SVR	EXT
30. Last Two Weeks:	NI	NO NO	SLT	MLD	MOD	(5) SVR	EXT

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HYPOCHONDRIASIS									
31. Current Episode:	(0) NI	(1) NO	(2) SLT	MLD	(4) MOD	(5) SVR	(6) EX		
32. Last Two Weeks:	(0)	(1) NO	(2) SLT	MLD	MOD	(5) SVR	(6) EX		
ANHEDONIA, LACK	OF INT	EREST, AF	PATHY, L	ом мот	IVATION,	BOREDO	<u>om</u>		
Combined Overall Ratio	ng								
33. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX		
Duration:		# of w	veeks						
34. Last Two Weeks:	NI (0)	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX		
Frequency:	D	ays/week							
Average % time of the day:	1	] %							
Differentiating Lack	of Inter	est from A	Inhedonia						
Lack of Interest		[100]	C ec.	17371	[(4)]	רמון	[(6)]		
35. Current Episode:	(0)	NO	SLT	MLD	МО	SVR	EX		
36. Last Two Weeks:	NI (0)	(1) NO	SLT	(3) MLD	(4) MO	(5) SVR	(6) EX		
Anhedonia									
37. Current Episode:	1/1	(I)	SLT	(3) MLD	(4) MO	SVR	(6) EX		
38. Last Two Weeks:	(0)	(I) NO	SLT	(3) MLD	(4) MO	(5) SVR	(6) EX		
FATIGUE, LACK OF ENERGY AND TIREDNESS									
39. Current Episode:	[N]	(1) NO	(2) SLT	MLD	(4) MO	(5) SVR	(6) EX		
40. Last Two Weeks:	(0)	(1) NO	(2) SLT	(3) MLD	MO	(5) SVR	(6) EX		
Frequency:	D	ays/Week							

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DIF	FICULTY CONCENTR	ATING	G, INATTI	ENTION, O	OR SLOW	ED THIN	KING	-
41.	Current Episode: (6) N		(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
42.	Last Two Weeks:		(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
PSY	CHOMOTOR AGITAT	<u>'ION</u>						
43.	Current Episode:		(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
44.	Last Two Weeks:	7	NO NO	SLT	(3) MLD	(4) MO	SVR	(6) EX
	Frequency:	Days	/Week					
MA	NIFESTATIONS INCL	UDED:	:					
	Unable to sit still							İ
45.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR	
46.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR	
	Pacing							
47.	Current Episode:	(0) NI	(1) NPR	(2) DBT	PR	SVR	(5) SVR	
48.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR	
	Hand wringing							
49.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR	
50.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR	
	Pulling or rubbing on	hair, c	lothing, sk	in				
51.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR	
52.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR	
	Can't stop talking, tali	ks on a	and on					
53.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) \$VR	(5) SVR	
54.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR	

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								_
PSYC	HOMOTOR RETARI	DATION						
55.	Current Episode:	(0)	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
56.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
	Frequency:	Day	ys/Week					
MANI	FESTATIONS INCL	UDED:						
Si	lowed Speech							
57.	Current Episode:	(0) NI	(1) NPR	DBT	PR	MOD	SVR	
58.	Last Two Weeks:	(0) NI	(1) NPR	DBT	(3) PR	(4) MOD	(5) SVR	
Iı	ncreased pauses befor	re answei	ring					
59.	Current Episode:	(0) NI	(1) NPR	DBT	PR	(4) MOD	SVR	
60.	Last Two Weeks:	(0) NI	(I) NPR	(2) DBT	PR	MOD	(5) SVR	
L	ow or monotonous spe	ech						
61.	Current Episode:	(0) N1	(I) NPR	(2) DBT	PR	(4) MOD	(5) SVR	
62.	Last Two Weeks:	(O) NI	(1) NPR	(2) DBT	PR	(4) MOD	(5) SVR	
M	fute or markedly deci	reased an	nount of s	peech				
63.	Current Episode:	(0) NI	(1) NPR	DBT	PR	(4) MOD	(5) SVR	
64.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	PR	(4) MOD	(5) SVR	
S	lowed body movement	s						
65.	Current Episode:	(0) NI	(I) NPR	DBT	PR	(4) MOD	(5) SVR	
66.	Last Two Weeks:	(0) NI	(1) NPR	DBT	PR	(4) MOD	(5) SVR	
I	epressive stupor							
67.	Current Episode:	(0) NI	(1) NPR	DBT	PR	(4) MOD	(5) SVR	
68.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR	

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SOCI	AL WITHDRAW	AL						_	
69.	Current Episode:	(0) IN	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
70. I	Last Two Weeks:	111	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
REJE	CTION SENSITI	<u>VITY</u>							
71.	Last Year:	(c) IM	(I) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX	
2. (	Current Episode:	(0) NI	(1) NO	SLT	(3) MLD	MOD	(5) SVR	(6) EX	
3.	Last Year:	(0)	(I) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX	
l. (	Current Episode:	и <u>г</u> (0)	(1) NO	SLT	MLD	(4) MOD	(5) SVR	(6) EX	
<u>.ee</u>	P PROBLEMS								
5.	Hours sle	ept before	onset of d	lepression					
<b>.</b>	Hours sle	ept during	the curren	t episode					
•	Hours sl	ept during	the last to	wo weeks					
YPI	ERSOMNIA								
3.	Hours sl	ept in dayt	ime of cu	rrent episod	9				
<b>)</b> .	Hours sl	ept in dayt	ime in the	last two w	eeks				
0.	Hours ly	ring down i	n current	episode					
1.	Hours ly	ring down i	n last two	weeks					
2.	Current Episode:	(0)  NI	NO NO	(2)	(3)	(4)	(5)	(6)	
3.	Last Two Weeks:	.V1 .00	(1) NO	(2)	(3)	(4)	(5)	(6)	
								4	
									3

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NSO	MNIA						
4.	Current Episode: (0) NI	(I) NO	(2)	(3)	(4)	(5)	(6)
5. L	ast Two Weeks: (5)	(1) NO	(2)	(3)	(4)	(5)	(6)
	Frequency:	Nights/Wea	ek				
TYPE	ES OF INSOMNIA						
	Initial Insomnia						
86.	Current Episode:	(0) NI	(1) NPR	DBT	(3) MLD	(4) MOD	(5) SVR
87.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) MLD	MOD	(5) SVR
	Middle Insomnia						
88.	Current Episode:	(0) NI	(1) NPR	(2) DBT	MLD	MOD	(5) SVR
89.	Last Two Weeks:	(0) NI	(1) NPR	DBT	(3) MLD	(4) MOD	(5) SVR
	Terminal Insomnia						
90.	Current Episode:	NI (0)	(I) NPR	DBT	(3) MLD	MOD MOD	(5) SVR
91.	Last Two Weeks:	(0) NI	(I) NPR	DBT	(3) MLD	(4) MOD	SVR
	Circadian Reversal						
92.	Current Episode:	(0) NI	(1) NPR	DBT	MLD	MOD	(5) SVR
93.	Last Two Weeks:	(0) N1	(1) NPR	DBT	MLD	MOD MOD	(5) SVR
	Non-restorative sleep					<del></del>	[-70-]
94.	Current Episode:	(0) NI	(1) NPR	DBT	MLD	MOD	(5) SVR
95.	Last Two Weeks:	(0) NI	(I) NPR	DBT	(3) MLD	MOD	(5) SVR
	Daytime sleepiness						
96.	Current Episode:	(0) NI	(1) NPR	DBT	MLD	MOD	(5) SVR
97.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) MLD	(4) MOD	(5) SVR

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ANOREXIA  98. Current Episode:  99. Last Two Weeks:	(0) NI (0)	(I) NO	(2) SLT (2) SLT	(3) MLD (3) MLD	(4) MOD (4) MOD	(5) RAR (5) RAR	(6)  NVR (6)  NVR
WEIGHT LOSS							
100. Current Episode:							
Pounds lost:		lbs.					
Number of Weeks:	L						
101. Last Two Weeks:							
Pounds lost:	لـــا	lbs.					
INCREASED APPETIT	ΓE						
102. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
103. Last Two Weeks:	(0) NI	(I)	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
Frequency:	LJ	Days/Wee					
-							
STRONG CRAVING I	OR SW	<u>EETS</u>					
104. Current Episode:	NI (0)	(I) ABS	(2) DBT	MLD	(4) MOD	(5) SVR	
105. Last Two Weeks:	(0) NI	(1) ABS	(2) DBT	(3) MLD	(4) MOD	(5) SVR	
WEIGHT GAIN							
106. Current Episode:	:						
Pounds gained:		lbs.					
Number of Weeks	: []						
107. Last Two Weeks							
Pounds gained	: []	lbs.					

	Project	Protocol	Center	Patient Number	Visit		Page
Ì	29060	329	0 0		Acute Phase Week 4	16	152

SUICIDAL IDEATION	<u> </u>							-
108. Current Episode:	(C) NI	(I)	(Z) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	(7) VEX
109. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	VEX
Suicidal Acts – Numbe	r							
110. Current Episode:	لــــا							
111. Last Two Weeks:								
Suicidal Acts - Seriou	sness							
112. Current Episode:	(0) NI	(I) NO	(2) MIN	DEF	Si	ER	(5) VS	EXT
113. Last Two Weeks:	(0) NI	(1) NO	(2) MIN	(3) DEF	S	4) ER	(5) VS	EXT
Medical Lethality								
114. Current Episode	(O)	(1) NO	(2) MIN	(3) MLD	(A	4) 10	(5) SVR	(6) EXT
115. Last Two Weeks:	(0)	(I)	(2) MIN	(3) MLD	<u></u>	4) 10	(5) SVR	EXT
Non-Suicidal Physical	Self-D	emaging .	Acts					
116. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	N	4) 1O	(5) SVR	(6) ACT
117. Last Two Weeks:	[N] (0)	(1) NO	(2) SLT	(3) MLD	[N	4) 40	(5) SVR	(6) ACT

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МА	NIC SYNDROME								-	
	TION, EXPANSIV	E MOO	<u>D</u>							
1.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX		
2.	Last Two Weeks:	(0)	(I) NO	(2) SLT	(3) MLD	MO	(5) SVR	(6) EX		
DEC	CREASED NEED F	OR SLE	EP		,					
3.	Current Episode:	(0) NI	(1) NO	(2) -1	(3)	(4) -3	(5) ~4	(6) -4+		
4.	Last Two Weeks:	[11] (0)	(1) NO	(2) -1	(3) -2	(4) -3	(5) -4	(6) -4+		
UNI	UNUSUALLY ENERGETIC									
5.	Current Episode:	)/[ (0)	(1) NO	(2) SLT	(3) LCH	(4) MOR	(5) MM	(6) UA		
6.	Last Two Weeks:	(0)	(I) NO	(2) SLT	LCH	(4) MOR	(5) MM	(6) UA		
INC	INCREASE IN GOAL DIRECTED ACTIVITY									
7.	Current Episode:	NI (0)	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX		
8.	Last Two Weeks:	NI (0)	(1) NO	(2) SLT	MLD	(4) MO	(5) MKD	(6) EX		
GR	ANDIOSITY									
9.	Current Episode:	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX		
10.	Last Two Weeks:	(0)	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX		
ACC	CELERATED, PRE	SSURED	OR INC	REASED	AMOU	NT OF S	PEECH			
11.	Current Episode:	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX		
12.	Last Two Weeks:	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) MKE	(6) EX		
							<del></del>			

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DDIE SHES EN	LORALV	1 1 1 1 1 1	LOII					
RACING THOUGHTS							-	
13. Current Episode:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	(6) EX	
14. Last Two Weeks:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	(6) EX	
FLIGHT OF IDEAS								
15. Current Episode:	(O) NI	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
16. Last Two Weeks:	(0) NI	(I)	(2) SLT	MLD	(4) MO	SVR	(6) EX	
POOR JUDGEMENT								
17. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) VS	
18. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) VS	
DISTRACTABILITY								
19. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR		
20. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR		
MOTOR HYPERACTI	VITY							
21. Current Episode:	(0)	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX	
22. Last Two Weeks:	(5)	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX	
Inappropriate laughin	g, jokin	g or puni	ning					
23. Current Episode:	(0)	(1) NO	DBT	(3) MLD	(4) MOD			
24. Last Two Weeks:	(0)	NO NO	(2) DBT	(3) MLD	MOD			
Uninhibited people sec	eking, gi	regarious						
25. Current Episode:	(0)	(1) NO	(2) DBT	MLD	(4) MOD			
26. Last Two Weeks:	NI  (0)	NO (I)	(2) DBT	(3) MLD	MOD			

Project	Protocol	Center	Patient Number	Visit	Page
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reased Productivity	-							_	
Current Episode:	(0) NI	(I) NO	(2) DBT	PRS	(4) SVR				
Last Two Weeks:	(0) NI	NO NO	(2) DBT	PRS	(4) SVR				
or pened and unusua	ily creat	ive thinki	ng						
Current Episode:	(0) N(I	NO NO	(2) DBT	(3) PRS	SVR				
Last Two Weeks:	(0) NI	(1) NO	(2) DBT	(3) PRS	(4) SVR				
persexuality									
Current Episode:	(0) NI	(I) NO	(2) DBT	(3) PRS	(4) SVR				
Last Two Weeks:	(0) NI	NO NO	(2) DBT	(3) PRS	(4) SVR				
LUENCE OF ILLI	CIT DR	UGS OR	ALCOH	<u>OL</u>					
Current Episode:	(0) NA	(1) NVR	(2) SMT	(3) ONL					
Last Two Weeks:	(0) NA	(1) NVR	(2) SMT	ONL					
MBER OF MANIO	PERIO	DDS							
	Current Episode: Last Two Weeks:  Typened and unusual Current Episode: Last Two Weeks:  Persexuality Current Episode: Last Two Weeks:  Current Episode: Last Two Weeks:  Current Episode: Last Two Weeks:	Last Two Weeks:  Current Episode:  Last Two Weeks:  Current Episode:  Last Two Weeks:  Current Episode:  NI  Persexuality  Current Episode:  Last Two Weeks:  Current Episode:  Last Two Weeks:  Current Episode:   Current Episode: NI NO  Last Two Weeks: NI NO  Current Episode: NI NO  Current Episode: NI NO  Last Two Weeks: NI NO  Last Two Weeks: NI NO  Current Episode: NI NO  Last Two Weeks: NI NO  Persexuality  Current Episode: NI NO  Current Episode: NI NVR   Current Episode: NI NO DBT  Last Two Weeks: NI NO DBT  Current Episode: NI NO DBT  Current Episode: NI NO DBT  Last Two Weeks: NI NO DBT  Last Two Weeks: NI NO DBT  Last Two Weeks: NI NO DBT  Current Episode: NI NO DBT  Last Two Weeks: NI NO DBT  Current Episode: NI NO DBT  Current Episode: NI NO DBT  Current Episode: NI NO DBT  Last Two Weeks: NI NO DBT  Current Episode: NI NO DBT  Current	Current Episode:    NI	Current Episode: NI NO DBI PRS SVR  Last Two Weeks: NI NO DBI PRS SVR  Trend and unusually creative thinking  Current Episode: NI NO DBI PRS SVR  Last Two Weeks: NI NO DBI PRS SVR  Last Two Weeks: NI NO DBI PRS SVR  Last Two Weeks: NI NO DBI PRS SVR  Persexuality  Current Episode: NI NO DBI PRS SVR  Last Two Weeks: NI NO DBI PRS SVR  Current Episode: NI NVR SMI ONL   Current Episode: NI NO DBT PRS SVR  Last Two Weeks: NI NO DBT PRS SVR  urpened and unusually creative thinking  Current Episode: NI NO DBT PRS SVR  Last Two Weeks: NI NO DBT PRS SVR  Last Two Weeks: NI NO DBT PRS SVR  Last Two Weeks: NI NO DBT PRS SVR  persexuality  Current Episode: NI NO DBT PRS SVR  Last Two Weeks: NI NO DBT PRS SVR  PLUENCE OF ILLICIT DRUGS OR ALCOHOL  Current Episode: NA NVR SMT ONL  Last Two Weeks: NA NVR SMT ONL  MBER OF MANIC PERIODS	Current Episode: NI NO DBI PRS SVE  Last Two Weeks: NI NO DBI PRS SVE  Last Two Weeks: NI NO DBI PRS SVE  Current Episode: NI NO DBI PRS SVE  Last Two Weeks: NI NO DBI PRS SVE  Current Episode: NI NO DBI PRS SVE  Last Two Weeks: NI NO DBI PRS SVE  Current Episode: NI NO DBI PRS SVE	Current Episode:    No			

Project	Protocol	Center	Patient Number	Visit	Page
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#### STUDY MEDICATION RECORD

Start Date lay month year	End Date day month year	Dose Level	Number of Capsules Daily	
		4		

#### STUDY MEDICATION DOSING CHANGES

□ No				medication since the last visit
☐ Yes ——	→ Indicate cha	nge(s) belo	O₩	
	Reminder:	Changes	in dose constitu	te deviation from the protocol.
Start Date	End Date	Dose Level	Number of Capsules Daily	Reason for Dose Change
day month year	day month year	Lictor	Dairy	

#### STUDY MEDICATION COMPLIANCE

Capsules Dispensed (A)	Capsules Returned (B)	Capsules Taken (A - B)	Days Since Last Visit	% Compliance		
40						
Cor	•	ust be $\geq$ 8	nys since las	st visit)	100	
Has the pa	tient been	non-compli	iant?			

Project	Protocol	Center	Patient Number	Visit	Page
29060	329	0.0		Acute Phase Week 4	157

UD	Y MEDICATION	LABEL		
		Attach label here		
•	Enter patient number (drug code as listed on clinical supplies)	<u>Im</u>	portant:	The drug code on the study medication label must be identito the preprinted Patient Numabove.
ÆC	CTROCARDIOGRA	ιM		
Wa for	as electrocardiogram peri	formed and sent to a centra	al reade	Date Performed (day month year)

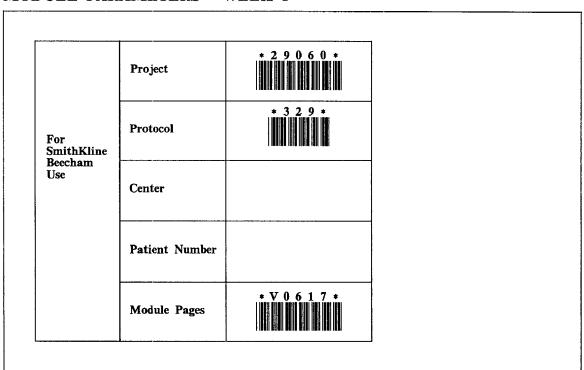
#### STUDY MEDICATION DISPENSING

Record study medication information for Week 5 in the Study Medication Record, page 162. Attach label to page 163. Record number of capsules dispensed on page 162.

Reminder: The drug code on the study medication label must be identical to the preprinted Patient Number above.

Project	Protocol	Center	Patient Number	Visit	
29060	329	0.0		Acute Phase	

#### **MODULE PARAMETERS - WEEK 5**



Project	Protocol	Center	Patient Number	Visit	Visit Date	Page
29060	329	0,0		Acute Phase Week 5	day month year	158

#### **VITAL SIGNS**

*** * 1 .	Sitting		Standing	
Weight □ lbs □ kg	Blood Pressure (mmHg) systolic diastolic	Pulse (beats/ min)	Blood Pressure (mmHg) systolic diastolic	Pulse (beats/ min)
	. ,  /		1/1	

#### ADVERSE EXPERIENCES / CONCOMITANT MEDICATION

Have	any adverse experiences been observed or elicited by the following direct question to the nt: "Do you feel different in any way since starting the treatment or since the last vis
patiei	nt: "Do you feel different in any way since starting the treatment of since the last vis
	☐ Yes ☐ No
ſ	Record in the Adverse Experience section
L	
Has	there been any change in concomitant medication since the last visit?
	□ Yes □ No
	T
[	Record in the Concomitant Medication section
L	

#### CLINICAL GLOBAL IMPRESSIONS - GLOBAL IMPROVEMENT

reatme	nt. Cor	mprovement whether or not, in your judgment, it is due entirely to drug npared to his/her condition at admission to the study, how much has the
patient	changed	?
	1 = V	ery much improved
	2 = M	luch improved
	3 = M	(inimally improved
	4 = N	o change
	5 = M	linimally worse
	6 = M	Iuch worse
	7 = V	ery much worse

Project	Protocol	Center	Patient Number	Visit	Page
29060	329	0 0		Acute Phase Week 5	159

# HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 1 OF $\bf 3$

	-
1.	Depressed Mood (sadness, hopelessness, helpless, worthless)
	<ul> <li>□ 1 = These feeling states indicated only on questioning</li> <li>□ 2 = These feeling states spontaneously reported verbally</li> <li>□ 3 = Communicates feeling states non-verbally, i.e., through facial expression, posture, voice and tendency to weep</li> <li>□ 4 = Patient reports virtually only these feeling states in his/her spontaneous verbal and non-verbal communication</li> </ul>
2.	Feelings of Guilt
	<ul> <li>□ 0 = Absent</li> <li>□ 1 = Self reproach, feels he/she has let people down</li> <li>□ 2 = Ideas of guilt or rumination over past errors or sinful deeds</li> <li>□ 3 = Present illness is a punishment. Delusions of guilt</li> <li>□ 4 = Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations</li> </ul>
3.	Suicide
	<ul> <li>□ 0 = Absent</li> <li>□ 1 = Feels life is not worth living</li> <li>□ 2 = Wishes he/she were dead or any thoughts of possible death to self</li> <li>□ 3 = Suicide ideas or gesture</li> <li>□ 4 = Attempts at suicide (any serious attempt rates 4)</li> </ul>
4.	Insomnia Early
	<ul> <li>□ 0 = No difficulty falling asleep</li> <li>□ 1 = Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour</li> <li>□ 2 = Complains of nightly difficulty falling asleep</li> </ul>
5.	Insomnia Middle
	<ul> <li>□ 0 = No difficulty</li> <li>□ 1 = Patient complains of being restless and disturbed during the night</li> <li>□ 2 = Waking during the night - getting out of bed rates 2 (except for purposes of voiding)</li> </ul>
6.	Insomnia Late
	<ul> <li>0 = No difficulty</li> <li>1 = Waking in early hours of the morning but goes back to sleep</li> <li>2 = Unable to fall asleep again if he/she gets out of bed</li> </ul>
7.	Work and Activities
	<ul> <li>□ 0 = No difficulty</li> <li>□ 1 = Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies</li> </ul>
	2 = Loss of interest in activity; hobbies or work - either directly reported by patient, or indirectly in listlessness, indecision and vacillation (feels he/she has to push self to work or activities)
	<ul> <li>3 = Decrease in actual time spent in activities or decrease in productivity.</li> <li>4 = Stopped working because of present illness.</li> </ul>

Project	Protocol	Center	Patient Number	Visit	Page
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# HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 2 OF 3 $\,$

8.	Retardation (slowness of thought and speech, impaired ability to concentrate; decreased motor activity)  0 = Normal speech and thought 1 = Slight retardation at interview 2 = Obvious retardation at interview 3 = Interview difficult 4 = Complete stupor
9.	Agitation  O = None  1 = Fidgetiness  2 = "Playing with" hands, hair, etc.  3 = Moving about, can't sit still  4 = Hand wringing, nail-biting, hair-pulling, biting of lips
10.	Anxiety Psychic  0 = No difficulty 1 = Subjective tension and irritability 2 = Worrying about minor matters 3 = Apprehensive attitude apparent in face or speech 4 = Fears expressed without questioning
11.	Anxiety Somatic (physiological concomitants of anxiety such as: Gastrointestinal (dry mouth, wind, indigestion, diarrhea, cramps, belching), Cardiovascular (palpitations, headaches), Respiratory (hyperventilation, sighing), Urinary frequency, Sweating.  □ 0 = Absent □ 1 = Mild □ 2 = Moderate □ 3 = Severe □ 4 = Incapacitating
12.	Somatic Symptoms Gastrointestinal  0 = None 1 = Loss of appetite but eating. Heavy feelings in abdomen 2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms
13.	Somatic Symptoms General  O = None  Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability  2 = Any clear-cut symptoms rates 2
14.	Genital Symptoms (such as loss of libido and menstrual disturbances)  □ 0 = Absent □ 1 = Mild □ 2 = Severe

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0 0		Acute Phase Week 5	87	161

# HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 3 OF 3 $\,$

15. Hypochondriasis
<ul> <li>□ 0 = Not present</li> <li>□ 1 = Self-absorption (bodily)</li> <li>□ 2 = Preoccupation with health</li> <li>□ 3 = Frequent complaints, requests for help, etc.</li> <li>□ 4 = Hypochondriacal delusions</li> </ul>
16. Loss of Weight
□ 0 = No weight loss □ 1 = Slight or doubtful loss of weight □ 2 = Obvious or severe loss of weight
17. Insight
<ul> <li>□ 0 = Acknowledges being depressed and ill</li> <li>□ 1 = Acknowledges illness but attributes cause to bad food, climate, over-work, virus, need for rest, etc.</li> <li>□ 2 = Denies being ill at all</li> </ul>
HAMD Score (Items 1-17)

Project	Protocol	Center	Patient Number	Visit	Page
29060	329	0 0		Acute Phase Week 5	162

#### STUDY MEDICATION RECORD

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily		
	<u> </u>				

#### STUDY MEDICATION DOSING CHANGES

☐ No ☐ Yes	 Indicate cha	_		te deviation from the protocol
Start I	 End Date day month year	Dose Level	Number of Capsules Daily	Reason for Dose Change

#### STUDY MEDICATION COMPLIANCE

Capsules Dispensed (A)	Capsules Returned (B)	Capsules Taken (A - B)	Days Since Last Visit	% Compliance			
Co	iance =	$\langle N \star X \rangle$ ust be $\geq 8$		ast visit) X	100	* _N =	number of capsules daily (see above)
Has the pa	atient been	non-compl	iant?				

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0 0		Acute Phase Week 5	67	163

#### STUDY MEDICATION LABEL

			7913		
			Attach label here		
,				<b>_</b>	
-	•	Enter patient number (drug code as listed on clinical supplies)		Important:	The drug code on the study medication label must be identical to the preprinted Patient Number above.

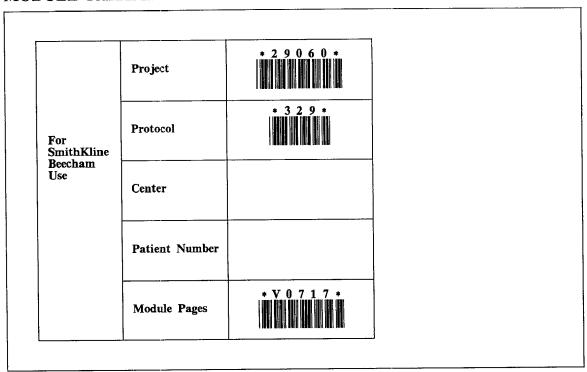
#### STUDY MEDICATION DISPENSING

Record study medication information for Week 6 in the Study Medication Record, page 181. Attach label to page 182. Record number of capsules dispensed on page 181.

Reminder: The drug code on the study medication label must be identical to the preprinted Patient Number above.

Project	Protocol	Center	Patient Number	Visit	
29060	329	0		Acute Phase	

#### **MODULE PARAMETERS - WEEK 6**



Project	Protocol	Center	Patient Number	Visit		V	isit Dat	te	Page
29060	329	0 0		Acute Phase Week 6	12	day	month	year	164

#### **VITAL SIGNS**

Weight		Sitting			Standing			
Weight ☐ Ibs ☐ kg	Blood P (mm systolic		Pulse (beats/ min)	Blood F (mrr systolic		Pulse (beats/ min)		
,   .	1 1/	<u>'</u>			/  , ,	1 1		

#### ADVERSE EXPERIENCES / CONCOMITANT MEDICATION

-	feel different in any way since starting the treatment or since the la
Yes	□ No
Record in th	ne Adverse Experience section
as there been a	ny change in concomitant medication since the last visit?
as there been a	ny <u>change</u> in concomitant medication since the last visit?

#### CLINICAL GLOBAL IMPRESSIONS - GLOBAL IMPROVEMENT

reatme oatient		Compared to his/her condition at admission to the study, how much has the
aticiit	CHAI	gcu.
	1 =	· Very much improved
	2 =	Much improved
	3 =	Minimally improved
	4 =	No change
	5 =	Minimally worse
	6 =	Much worse
	7 -	= Very much worse

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0 0		Acute Phase Week 6	118	165

# HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 1 OF $\bf 3$

1.	Depressed Mood (sadness, hopelessness, helpless, worthless)  0 = Absent 1 = These feeling states indicated only on questioning 2 = These feeling states spontaneously reported verbally 3 = Communicates feeling states non-verbally, i.e., through facial expression, posture, voice and tendency to weep 4 = Patient reports virtually only these feeling states in his/her spontaneous verbal and non-verbal communication
2.	Feelings of Guilt
	□ 0 = Absent □ 1 = Self reproach, feels he/she has let people down □ 2 = Ideas of guilt or rumination over past errors or sinful deeds □ 3 = Present illness is a punishment. Delusions of guilt □ 4 = Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations
3.	Suicide
	<ul> <li>□ 0 = Absent</li> <li>□ 1 = Feels life is not worth living</li> <li>□ 2 = Wishes he/she were dead or any thoughts of possible death to self</li> <li>□ 3 = Suicide ideas or gesture</li> <li>□ 4 = Attempts at suicide (any serious attempt rates 4)</li> </ul>
4.	Insomnia Early
	<ul> <li>□ 0 = No difficulty falling asleep</li> <li>□ 1 = Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour</li> <li>□ 2 = Complains of nightly difficulty falling asleep</li> </ul>
5.	Insomnia Middle
	<ul> <li>0 = No difficulty</li> <li>1 = Patient complains of being restless and disturbed during the night</li> <li>2 = Waking during the night - getting out of bed rates 2 (except for purposes of voiding)</li> </ul>
6.	Insomnia Late
	<ul> <li>0 = No difficulty</li> <li>1 = Waking in early hours of the morning but goes back to sleep</li> <li>2 = Unable to fall asleep again if he/she gets out of bed</li> </ul>
7.	Work and Activities
	<ul> <li>0 = No difficulty</li> <li>1 = Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies</li> </ul>
	2 = Loss of interest in activity; hobbies or work - either directly reported by patient, or indirectly in listlessness, indecision and vacillation (feels he/she has to push self to work or activities)
	<ul> <li>3 = Decrease in actual time spent in activities or decrease in productivity.</li> <li>4 = Stopped working because of present illness.</li> </ul>

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8.	Retardation (slowness of thought and speech, impaired ability to concentrate; decreased motor activity)  0 = Normal speech and thought 1 = Slight retardation at interview 2 = Obvious retardation at interview 3 = Interview difficult 4 = Complete stupor
9.	Agitation
	<ul> <li>□ 0 = None</li> <li>□ 1 = Fidgetiness</li> <li>□ 2 = "Playing with" hands, hair, etc.</li> <li>□ 3 = Moving about, can't sit still</li> <li>□ 4 = Hand wringing, nail-biting, hair-pulling, biting of lips</li> </ul>
10.	Anxiety Psychic
	<ul> <li>□ 0 = No difficulty</li> <li>□ 1 = Subjective tension and irritability</li> <li>□ 2 = Worrying about minor matters</li> <li>□ 3 = Apprehensive attitude apparent in face or speech</li> <li>□ 4 = Fears expressed without questioning</li> </ul>
11.	Anxiety Somatic (physiological concomitants of anxiety such as: Gastrointestinal (dry mouth, wind, indigestion, diarrhea, cramps, belching), Cardiovascular (palpitations, headaches), Respiratory (hyperventilation, sighing), Urinary frequency, Sweating.
	<ul> <li>□ 0 = Absent</li> <li>□ 1 = Mild</li> <li>□ 2 = Moderate</li> <li>□ 3 = Severe</li> <li>□ 4 = Incapacitating</li> </ul>
12.	Somatic Symptoms Gastrointestinal
	<ul> <li>□ 0 = None</li> <li>□ 1 = Loss of appetite but eating. Heavy feelings in abdomen</li> <li>□ 2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms</li> </ul>
13.	Somatic Symptoms General
	<ul> <li>□ 0 = None</li> <li>□ 1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability</li> <li>□ 2 = Any clear-cut symptoms rates 2</li> </ul>
14.	Genital Symptoms (such as loss of libido and menstrual disturbances)
	<ul> <li>□ 0 = Absent</li> <li>□ 1 = Mild</li> <li>□ 2 = Severe</li> </ul>

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15.	Hypochondriasis
	<ul> <li>□ 0 = Not present</li> <li>□ 1 = Self-absorption (bodily)</li> <li>□ 2 = Preoccupation with health</li> <li>□ 3 = Frequent complaints, requests for help, etc.</li> <li>□ 4 = Hypochondriacal delusions</li> </ul>
16.	Loss of Weight
	<ul> <li>□ 0 = No weight loss</li> <li>□ 1 = Slight or doubtful loss of weight</li> <li>□ 2 = Obvious or severe loss of weight</li> </ul>
17.	Insight
	<ul> <li>□ 0 = Acknowledges being depressed and ill</li> <li>□ 1 = Acknowledges illness but attributes cause to bad food, climate, over-work, virus, need for rest, etc.</li> </ul>
	☐ 2 = Denies being ill at all
• [	HAMD Score (Items 1-17)

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DEPRESSED MOOD  1. Worst Severity of Current Episode:											
Duration of Current Episode: # of weeks  2. Worst Severity of Last Two Weeks: Will No SULT MILD MO SYR EX VEX Frequency: Days/week  Average % time of the day: %  DEPRESSED APPEARANCE  3. Current Episode: Will No SULT MILD MC SYR EX  4. Last Two Weeks: Will No SULT MILD MC SYR EX  IRRITABILITY AND ANGER  5. Current Episode: Will No SULT MILD MC SYR EX  Duration: # of weeks  6. Last Two Weeks: Will NO SULT MILD MC SYR EX  Frequency: Days/week  Average % time of the day: %  SEPARATION-DEPENDENT-DYSPHORIA  7. Current Episode: Will NO GCC USL ALW	DEP	RESSED MOOD							-		
Current Episode:	1.		(O) NI	(1) NO	(2) SLT		(4) MO	(5) SVR	(6) EX	VEX	
Last Two Weeks:   NI				# of we	æks						
Average % time of the day: %  DEPRESSED APPEARANCE  3. Current Episode: 100	2.		(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	(7) VEX	
DEPRESSED APPEARANCE  3. Current Episode: NI NO SIT MID MO SVR EX  4. Last Two Weeks: NI NO SIT MID MO SVR EX  IRRITABILITY AND ANGER  5. Current Episode: NI NO SIT MID MO SVR EX  Duration: # of weeks  6. Last Two Weeks: NI NO SIT MID MO SVR EX  Frequency: Days/week  Average % time of the day: %  SEPARATION-DEPENDENT-DYSPHORIA  7. Current Episode: NI NO COC USL ALW		Frequency:	Days	/week						ļ	
3. Current Episode: NI NO SIT MID MO SYR EX  4. Last Two Weeks: NI NO SIT MID MO SYR EX  IRRITABILITY AND ANGER  5. Current Episode: NI NO SIT MID MO SYR EX  Duration: # of weeks  6. Last Two Weeks: NI NO SIT MID MO SYR EX  Frequency: Days/week  Average % time of the day: %  SEPARATION-DEPENDENT-DYSPHORIA  7. Current Episode: NI NO OCC USL ALW  A Last Two Weeks: NI NO OCC USL ALW  3. (4) SYR EX  (6) SYR (6) SYR (6) SYR EX  (7) TO SYR EX  (6) SYR EX  (7) TO SYR EX  (7) TO SYR EX  (7) TO SYR EX  (7) TO SYR EX  (8) TO SYR EX  (8) TO SYR EX  (9) TO SYR EX  (17) TO SYR EX				%							
4. Last Two Weeks:	DEI	PRESSED APPEAR	ANCE								
IRRITABILITY AND ANGER   (1)	3.	Current Episode:	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MO	SVR			
5. Current Episode: (3) (1) (2) (3) (4) (4) (5) (5) (6) (7) (7) (8) (8) (8) (8) (8) (8) (8) (8) (8) (8	4.	Last Two Weeks:	(0) NI	NO NO	SLT		(4) MC	(5) SVR	(6) EX		
5. Current Episode: (3) (1) (2) (3) (4) (4) (5) (6) (7) (7) (7) (8) (8) (8) (8) (8) (8) (8) (8) (8) (8											
Duration: # of weeks  6. Last Two Weeks: NI NO SLT MLD MO SVR EX VEX  Frequency: Days/week  Average % time of the day: %  SEPARATION-DEPENDENT-DYSPHORIA  7. Current Episode: NI NO OCC USL ALW	IRI	RITABILITY AND	ANGER								
6. Last Two Weeks: NI NO SLT MID MO SVR EX VEX  Frequency: Days/week  Average % time of the day: %  SEPARATION-DEPENDENT-DYSPHORIA  7. Current Episode: NI NO OCC USL ALW	5.	Current Episode:	(0) NI	(1) NO	(2) SLT	MLD	(4) MO	(5) SVR	(6) EX	(7) VEX	
6. Last Two Weeks: NI NO SIT MID MO SVR EX VEX  Frequency: Days/week  Average % time of the day: %  SEPARATION-DEPENDENT-DYSPHORIA  7. Current Episode: NI NO OCC USL ALW		Duration:		」# of w	eeks						
Average % time of the day:  SEPARATION-DEPENDENT-DYSPHORIA  7. Current Episode: (0) (1) (2) (3) (4) (4) (4) (4) (4) (4) (4) (4) (4) (4	6.	Last Two Weeks:	(0) NI	(1) NO	SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	(7) VEX	
of the day:  SEPARATION-DEPENDENT-DYSPHORIA  7. Current Episode: (0) (1) (2) (3) (4) (4) (4) (4) (4) (4) (4) (4) (4) (4		Frequency:	Day	rs/week							
7. Current Episode: (0) NO OCC USL (4) ALW				<b>」%</b>							
	SEPARATION-DEPENDENT-DYSPHORIA										
8. Last Two Weeks: (8) (1) (2) (3) (4) (4) (4) (5) (6) (1) (6) (1) (6) (1) (6) (1) (6) (1) (6) (1) (1) (1) (1) (1) (1) (1) (1) (1) (1	7.	Current Episode:	(0) NI	(1) NO	(2) OCC	(3) USL	(4) ALW				
	8.	Last Two Weeks:	(0) NI	(1) NO	OCC	USL	(4) ALW				

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OTT A	LITY OF DVDCU	ODIC MO	OD					
	LITY OF DYPSH			(2)	(3)	(4) VDF		
9.	Current Episode:	(0) NI	(1) ND	QUE	(3) DDF			
10.	Last Two Weeks:	(0) NI	(I) ND	(2) QUE	DDF	(4) VDP		
DEG.	REE OF ASSOCIA	TION OF	<u>' DEPRES</u> S	SED OR I	RRITABL	E MOOD	WITH SP	ECIFIC
<u> </u>	110 011 110000	[ (0) ]	(I) NAL	(2) MOT	(3) UN	(4) PN		
11.	Current Episode:	NI						
12.	Last Two Weeks:	(0) NI	(I) NAL	(2) MOT	(3) UN	PN		
<b>D</b> E :	CHITTIME OF THE	DDECCE	מת מת	CADIE 14	OOD			
REA	CTIVITY OF DE	PRESSED	OK IKKI	ABLE W	<u>00D</u>			
13.	Current Episode:	(0)	(1) VR	FUL	(3) RES	(4) MLD	SLT	(6) UNR
	_		% Usual	% of No	rmal			
14.	Last Two Weeks:	(0) NI	(1) VR	(2) FUL	(3) RES	MLD	(5) SLT	(6) UNR
	Last Two Woods.	I I		1 % of No		MILL.	Gen	
		<u> </u>		mum % of				
		لـــا	Number	of hours go	ood feeling	last		
DIU	RNAL MOOD VA	RIATION	Ī					
Wor	rse in Morning							
15.	Current Episode:	(0) NI	(I) NW	(2) MIN	(3) MLD	CW CW	(5) EXT	
16.	Last Two Weeks:	(0) NI	(1) NW	(2) MIN	(3) MLD	CW (4)	(5) EXT	
			_					
Wo	rse in Afternoon a	nd/or Eve □∞□	ning	(2)	[(3)]	[-(4)-]	(5) EXT	
17.	Current Episode:	NI	NW	MIN	MLD	(4) (cw		
18.	Last Two Weeks:	(0) NI	NW	(2) MIN	MLD	(4) C:W	EXT	

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EXCESSIVE INAPPRO	PRIATE	GUILT			1/- 11		ar .
19. Current Episode:	(C) 114	(I) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
20. Last Two Weeks:	(c)	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	EXT
Frequency:	Days/Wo	eek _					
NEGATIVE SELF IM.	AGE						
21. Current Episode:	(0)	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
22. Last Two Weeks:	(O)	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
FEELING UNLOVED	'FORLOF	<u>en</u>					
23. Current Episode:	(O)	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
24. Last Two Weeks:	(0)	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
Frequency:	Days/W	eek [					
HOPELESSNESS, HEL	PLESSNE	SS, DISC	OURAGEN	MENT, PE	SSIMISM		
25. Current Episode:	) NI (0)	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
26. Last Two Weeks:	NI (0)	NO NO	SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT
SELF-PITY							
27. Current Episode:	(0)	(1) NO	(2) OCC	(3) MLD	(4) CON		
28. Last Two Weeks:	(0) NI	(I)	(2) OCC	(3) MLD	(4) CON		
201 200 200 00000	[_111_]	[HO]			[]		
ACHES AND PAINS							
29. Current Episode:	(0) NI	NO (1)	(2) SLT	MLD	MOD	svr	EXT
30. Last Two Weeks:	(0)	NO (1)	(2) SLT	(3) MLD	(4) MOD	SVR	EXT

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HYPOCHONDRIASIS											
31. Current Episode:	(O) NI	(I)	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX				
32. Last Two Weeks:	(O) NI	(1) NO	SLT	MLD	MOD	(5) SVR	(6) EX				
ANHEDONIA, LACK OF INTEREST, APATHY, LOW MOTIVATION, BOREDOM											
Combined Overall Ratio		<u> </u>									
33. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX				
Duration:	<u> </u>	# of w	reeks								
34. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX				
Frequency:	D	ays/week									
Average % time of the day:		] %									
Differentiating Lack	of Inter	est from A	nhedonia								
Lack of Interest	f-701-1	רמח	[ <del>-</del> (2)]	(3) 1	[4]]	(5) SVR	(6)				
35. Current Episode:	NI (O)	(I) NO	(2) SLT	MLD	(4) MO		[EX]				
36. Last Two Weeks:	1/1 (0)	NO	SLT	(3) MLD	МО	SVR	(6) EX				
Anhedonia			(-78V-1	[	ran-1	<del>- 785 -</del> 1	[757]				
37. Current Episode:	(0) NI	NO (1)	SLT	MLD	(4) MO	SVR	(6) EX				
38. Last Two Weeks:	(0)	NO NO	SLT	MLD	(4) MO	(5) SVR	(6) EX				
FATIGUE, LACK OF ENERGY AND TIREDNESS											
39. Current Episode:	(0) NI	(1) NO	SLT	(3) MLD	(4) MO	(5) SVR	(6) EX				
40. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX				
Frequency:	L_ D	ays/Week									

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,								-		
DIFFICULTY CONCENTRATING, INATTENTION, OR SLOWED THINKING										
41.	Current Episode: N	)) 	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX		
42.	Last Two Weeks:		(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX		
	Last 1 we weeks	1.)	[NO]	SLI	MLD	[MO]	[SVK]	(EX)		
<b>PSY</b>	CHOMOTOR AGITAT	TION								
43.	Current Episode: N	27	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX		
			(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX		
44.	Last Two Weeks:	1	NO	SLT	MLD	МО	SVR	EX		
	Frequency:	□ Days	/Week							
MA	NIFESTATIONS INCL	UDED:	:							
	Unable to sit still									
45.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR	1		
46.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR			
40.	Last 1 wo weeks.	INT.	III K	[221]	115	MOD	0110			
	Pacing									
47.	Current Episode:	(0) NI	(I) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR			
48.	Last Two Weeks:	(0) NI	(I) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR			
	<b></b>					-				
	Hand wringing	F-785-1	1-25-1	l-zavi			[-7 <del>21</del> -]			
49.	Current Episode:	(0) NI	(1) NPR	DBT	(3) PR	(4) SVR	SVR			
50.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR			
				_						
	Pulling or rubbing on	_								
51.	Current Episode:	(0) NI	(I) NPR	DBT	(3) PR	(4) SVR	(5) SVR			
52.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR			
							-			
	Can't stop talking, tal			I 75.	l-ray-4					
53.	Current Episode:	(0)	(1) NPR	DBT	(3) PR	(4) SYR	(5) SVR			
54.	Last Two Weeks:	(0) NI	(I) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR			

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ועעו	E DADO ELLE	. IIVXIJ I	HILDO.		1112011			
PSYC	HOMOTOR RETARI	DATION						_
55.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
56.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
	Frequency:	Day	ys/Week					
MANI	IFESTATIONS INCL	UDED:						
S	lowed Speech							
57.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR	
58.	Last Two Weeks:	(0) NI	(I) NPR	(2) DBT	PR	(4) MOD	(5) SVR	
I	ncreased pauses befo	re answei						
59.	Current Episode:	(0) NI	(1) NPR	(2) DBT	PR	(4) MOD	(5) SVR	
60.	Last Two Weeks:	NI (0)	(1) NPR	(2) DBT	PR	(4) MOD	(5) SVR	
L	ow or monotonous sp	eech						
61.	Current Episode:	(0) NI	(I) NPR	(2) DBT	PR	(4) MOD	(5) SVR	
62.	Last Two Weeks:	(0) NI	(i) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR	
λ	Aute or markedly dec	reased as	nount of s	peech				
63.	Current Episode:	(0) NI	(I) NPR	DBT	PR	(4) MOD	(5) SVR	
64.	Last Two Weeks:	(0) NI	(I) NPR	(2) DBT	(3) PR	MOD	(5) SVR	
s	lowed body movement							
65.	Current Episode:	(0) NI	(1) NPR	DBT	PR	(4) MOD	(5) SVR	
66.	Last Two Weeks:	(0)	(1) NPR	(2) DBT	PR	(4) MOD	(5) SVR	
1	Depressive stupor							
67.	Current Episode:	(O) NI	(1) NPR	DBT	PR	MOD	SVR	
68.	Last Two Weeks:	(0) 1N	(I) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR	

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ZIVI	JIE SADS EII	F. 173 JE 1141			DVAL	CHILO		OMITYO	I OILIV		
SOC	IAL WITHDRAW	'AL									
69.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX			
70.	Last Two Weeks:	(0) NI	(1) NO	SLT	(3) MLD	(4) MO	(5) SVR	(6) EX			
<u>REJ</u>	ECTION SENSITI	<u>VITY</u>									
71.	Last Year:	NI NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX			
72.	Current Episode:	(6) NI	(I)	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX	ĺ		
73.	Last Year:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX			
74.	Current Episode:	(0) NI	NO (I)	(2) SLT	MLD	(4) MOD	(5) SVR	(6) EX			
SLE	EP PROBLEMS										
75.	Hours sl	ept before	onset of	depression					ļ		
76.	Hours sl	ept during	the curre	nt episode							
77.	Hours sl	ept during	the last t	wo weeks							
HY	PERSOMNIA										
78.	Hours sl	ept in day	time of cu	rrent episo	de						
79.	Hours sl	lept in day	time in the	e last two	weeks						
80.	Hours ly	ing down	in current	episode							
81.	81. Hours lying down in last two weeks										
82.	Current Episode:	(0) NI	(I) NO	(2)	(3)	(4)	(5)	(6)			
83.	Last Two Weeks:	(5) NI	(I) NO	(2)	(3)	(4)	(5)	(6)			

## SS SmithKline Beecham Pharmaceuticals

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NSOM	INIA						
<b>1.</b> C	urrent Episode: (5)	(1) NO	(2)	(3)	(4)	(5)	(6)
5. La	st Two Weeks: [5]	(1) NO	(2)	(3)	(4)	(5)	(6)
	Frequency:	Nights/Wee	:k				
TYPES	OF INSOMNIA						
1	nitial Insomnia						
86.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) MLD	MOD	(5) SVR
87.	Last Two Weeks:	(0) NI	(I) NPR	(2) DBT	MLD	MOD	(5) SVR
j	Middle Insomnia						
88.	Current Episode:	(0) NI	(I) NPR	DBT	MLD	MOD	(5) SVR
89.	Last Two Weeks:	(0) NI	(1) NPR	DBT	MLD	(4) MOD	(5) SVR
2	Terminal Insomnia						
90.	Current Episode:	(0) NI	(1) NPR	DBT	MLD	MOD MOD	(5) SVR
91.	Last Two Weeks:	(0) NI	(I) NPR	(2) DBT	MLD	(4) MOD	SVR
(	Circadian Reversal						
92.	Current Episode:	(0) NI	(1) NPR	DBT	MLD	MOD	SVR
93.	Last Two Weeks:	(0) NI	(I) NPR	(2) DBT	MLD	MOD	SVR
	Non-restorative sleep						
94.	Current Episode:	(0) N1	(I) NPR	DBT	MLD	MOD	(5) SVR
95.	Last Two Weeks:	(O) NI	NPR	DBT	MLD	(4) MOD	SVR
	Daytime sleepiness						
96.	Current Episode:	(0) N1	(1) NPR	DBT	MLD	MOD	(5) SVR
97.	Last Two Weeks:	(0) NI	(I) NPR	DBT	(3) MLD	(4) MOD	(5) SVR

## SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit	Page
29060	329	0,0		Acute Phase Week 6	176

98. Current Episode: 99. Last Two Weeks:	(0) NI (0)	(I) NO	(2) SLT	(3) MLD	(4) MOD (4) MOD	(5) RAR (5) RAR	(6) NVR (6) NVR
WEIGHT LOSS  100. Current Episode:  Pounds lost:	لـــا	lbs.					
Number of Weeks:  101. Last Two Weeks:  Pounds lost:		lbs.					
INCREASED APPETIT	(0)	(I) NO	(2) SLT (2) SLT	(3) MLD MLD	(4) MOD (4) MOD	(5) SVR (5) SVR	(6) EX (6) EX
103. Last Two Weeks:  Frequency:		Days/Weel		MLD	мод	[SVR]	[EX]
STRONG CRAVING F	OR SW	<u>EETS</u>					
<ul><li>104. Current Episode:</li><li>105. Last Two Weeks:</li></ul>	(0) NI	(I) ABS	(2) DBT (2) DBT	(3) MLD MLD	(4) MOD (4) MOD	(5) SVR (5) SVR	
WEIGHT GAIN							
106. Current Episode:							
Pounds gained:		lbs.					
Number of Weeks:							
107. Last Two Weeks:							
Pounds gained:		lbs.					

### SS SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit	Page
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SUICIDAL IDEATION	т							
SUICIDAL IDEATION	_							
108. Current Episode:	(0) NI	NO	SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	(7) VEX
109. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	(7) VEX
Suicidal Acts - Numbe	r							
110. Current Episode:	لــــا							
111. Last Two Weeks:	لـــا							
Suicidal Acts - Serious	sness							
112. Current Episode:	(0) NI	(1) NO	(2) MIN	(3) DEF	(4 SE	R	(5) VS	(6) EXT
113. Last Two Weeks:	(0) NI	(1) NO	(2) MIN	(3) DEF	SE	R.	(5) VS	(6) EXT
Medical Lethality								
114. Current Episode	(0) NI	(1) NO	(2) MIN	(3) MLD	(4 M	0	(5) SVR	EXT
115. Last Two Weeks:	(0) NI	(I) NO	(2) MIN	(3) MLD	(4 M	0	SVR	(6) EXT
Non-Suicidal Physical	Self-De	maging 1	Acts					
116. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4 M	0	(5) SVR	(6) ACT
117. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4 M	0	(5) SVR	(6) ACT

## SS SmithKline Beecham Pharmaceuticals

Proje	ect	Protocol	Center	Patient Number	Visit		Page
2900	50	329	0,0		Acute Phase Week 6	18	178

									-	
MAN	SIC SYNDROME									
ELA	ΓΙΟΝ, EXPANSIV	E MOO	D							
1.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX		
2.	Last Two Weeks:	(0)	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX		
24	Last 1 wo weeks.	[141]	[NO]	SLI	MED	[MO]	SYK	LEAT		
DECI	REASED NEED FO	OR SLE	<u>EP</u>							
3.	Current Episode:	(Q)	(I) NO	(2) -1	(3)	(4) -3	(5) -4	(6) -4+		
4.	Last Two Weeks:	(0) NI	(1) NO	(2) -1	(3)	(4) -3	(5)	(6) -4+		
		737	(NO)		<u> </u>	رت	<u> </u>	ر الم		
<u>UNU</u>	SUALLY ENERG	ETIC								
5.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) LCH	(4) MOR	(5) MM	(6) UA		
	Last Two Weeks:	(0)	(1) NO	(2) SLT	(3) LCH	(4) MOR	(5) MM	(6) UA		
•	Lust 1 wo weeks.	1 141	[NO]	SELI	<u> </u>	MON	[MIM]	LUA		
INCE	REASE IN GOAL	DIRECT	TED ACT	IVITY						
7.	Current Episode:	(0) (0)	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX		
	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX		
0.	Last 1 wo weeks.	[NI]	NO	SLI	MLU	[MO]	MKL	[[6]		
GRA	NDIOSITY									
9.	Current Episode:	(0) (0)	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX		
	Last Two Weeks:	(0)	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX		
10.	Last I wo weeks:	[NI]	[NO]	[SLT]	MLD	[MO]	SVR	[EX]		
ACC	ELERATED, PRES	SSURED	OR INC	REASED	AMOUN	NT OF S	PEECH			
11.	Current Episode:	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX		
		(0)	(I) NO	(2) SLT	(3) MLD	(4) MO	(5)	(6) EX		
12.	Last Two Weeks:	[NI]	ИО	SLT	MLD	[MO]	MKD	EX		

# SB SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0 0		Acute Phase Week 6	88	179

									UKIV
RA	CING THOUGHTS	_						-	
13.	Current Episode:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	(6) EX	
14.	Last Two Weeks:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	(6) EX	
FLI	GHT OF IDEAS								
15.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
16.	Last Two Weeks:	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
PO	OR JUDGEMENT								
17.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) VS	
18.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) VS	
DIS	TRACTABILITY								
19.	Current Episode:	NI NI	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR		
20.	Last Two Weeks:	NI (0)	NO (I)	SLT	MLD	(4) MO	(5) SVR		
MO	TOR HYPERACTI	VITY							
21.	Current Episode:	(0)	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX	
22.	Last Two Weeks:	(0) NI	NO (1)	(2) SLT	(3) MLD	(4) MO	(S) MKD	(6) EX	
Ina	ppropriate laughing	g, joking	g or punn	ing					
23.	Current Episode:	(0) NI	NO (1)	DBT	(3) MLD	(4) MOD			
24.	Last Two Weeks:	(0)	(1) NO	DBT	(3) MLD	(4) MOD			
Uni	nhibited people see	king, gr	egarious						
25.	Current Episode:	(O)	(1) NO	DBT	(3) MLD	(4) MOD			
26.	Last Two Weeks:	NI (0)	NO NO	DBT	(3) MLD	(4) MOD			

## S Smith Kline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit	Page
29060	329	0,0		Acute Phase Week 6	180

Inc	reased Productivity					-	
27.	Current Episode:	(0) NI	(I) NO	(2) DBT	PRS	SVR	
28.	Last Two Weeks:	(0) NI	(1) NO	(2) DBT	(3) PRS	SVR	
Sha	r pened and unusua	ily creat	ive thinki	ng			
29.	Current Episode:	(0) NI	(1) NO	(2) DBT	(3) PRS	(4) SVR	
30.	Last Two Weeks:	(0)	NO NO	(2) DBT	PRS	(4) SVR	
Ну	persexuality						
31.	Current Episode:	(0) NI	(I)	(2) DBT	(3) PRS	(4) SVR	
32.	Last Two Weeks:	(0)	NO NO	DBT	PRS	SVR	
INF	LUENCE OF ILLI	CIT DR	UGS OR	ALCOH	OL		
22.12							
33.	Current Episode:	(0) NA	(1) NVR	(2) SMT	ONL		
34.	Last Two Weeks:	(0) NA	(1) NVR	(2) SMT	ONL		
NU	MBER OF MANIC	PERIO	DDS				
35.							

## SS SmrthKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit	Page
29060	329	0,0		Acute Phase Week 6	181

#### STUDY MEDICATION RECORD

r of les y

#### STUDY MEDICATION DOSING CHANGES

Have there been a	ny investigator pre	scribed ch	nanges in study	medication since the last visit?
□ No	-J			
☐ Yes —	→ Indicate cha	nge(s) bel	ow	
	D	C'l		
	Reminder:	Changes	in dose constiti	ite deviation from the protocol.
Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily	Reason for Dose Change
			Capsules	Reason for Dose Change

#### STUDY MEDICATION COMPLIANCE

Capsules Dispensed (A)	Capsules Returned (B)	Capsules Taken (A - B)	Days Since Last Visit	% Compliance			
, •	ance = -	(N <b>★</b> x 0	of capsules days since I	ast visit) x	100	* _N =	number of capsules dail (see above)
Has the pa	tient been	non-compli	ant?				

## SmithKline Beecham Pharmaceuticals

	Project	Protocol	Center	Patient Number	Visit	Page
****	29060	329	0.0		Acute Phase Week 6	182

STUDY MEDICATION LA	STUDY	MEDICATION	LABEL
---------------------	-------	------------	-------

		Attach label here		
•	Enter patient number (drug code as listed on clinical supplies)		Important:	The drug code on the study medication label must be identical to the preprinted Patient Number above.

#### **ELECTROCARDIOGRAM**

for interpreta	ardiogram performed and sent to a central reader ation?	Date Performed (day month year)
☐ Yes	□ No	(auj month jour)

#### STUDY MEDICATION DISPENSING

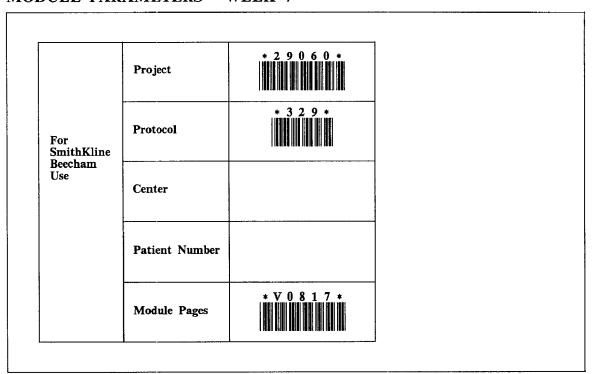
Record study medication information for Week 7 in the Study Medication Record, page 187. Attach label to page 188. Record number of capsules dispensed on page 187.

Reminder: The drug code on the study medication label must be identical to the preprinted Patient Number above.

### SmrthKline Beecham Pharmaceuticals

Projec	Protocol	Center	Patient Number	Visit	
29060	329	0,0		Acute Phase	

#### **MODULE PARAMETERS - WEEK 7**



### SmrthKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit	Visit Date	Page
29060	329	0.0		Acute Phase Week 7	day month year	183

#### **VITAL SIGNS**

Weight	Sitting		Standing			
weight □ lbs □ kg	Pressure mHg) diastolic	Pulse (beats/ min)	Blood I (mn systolic	Pressure nHg) diastolic	Pulse (beats/ min)	
	/			/  , ,		

#### ADVERSE EXPERIENCES / CONCOMITANT MEDICATION

Have	any adverse experiences been observed or elicited by the following direct question to the
patie	nt: "Do you feel different in any way since starting the treatment or since the last visi
	☐ Yes ☐ No
	Record in the Adverse Experience section
ı	
Has	there been any change in concomitant medication since the last visit?
	☐ Yes ☐ No
	Record in the Concomitant Medication section

#### CLINICAL GLOBAL IMPRESSIONS - GLOBAL IMPROVEMENT

treat patie			Compared to his/her condition at admission to the study, how much has th
MIIC	ii c	пац	500.
		1 =	Very much improved
	3	2 =	Much improved
[		3 =	Minimally improved
		4 =	No change
	1	5 =	Minimally worse
		6 =	Much worse
	=	7 =	Very much worse

## SS SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0,0		Acute Phase Week 7	00	184

# HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 1 OF 3

1.	Depressed Mood (sadness, hopelessness, helpless, worthless)  0 = Absent 1 = These feeling states indicated only on questioning 2 = These feeling states spontaneously reported verbally 3 = Communicates feeling states non-verbally, i.e., through facial expression, posture, voice and tendency to weep 4 = Patient reports virtually only these feeling states in his/her spontaneous verbal and non-verbal communication
2.	Feelings of Guilt
	<ul> <li>□ 0 = Absent</li> <li>□ 1 = Self reproach, feels he/she has let people down</li> <li>□ 2 = Ideas of guilt or rumination over past errors or sinful deeds</li> <li>□ 3 = Present illness is a punishment. Delusions of guilt</li> <li>□ 4 = Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations</li> </ul>
3.	Suicide
	<ul> <li>□ 0 = Absent</li> <li>□ 1 = Feels life is not worth living</li> <li>□ 2 = Wishes he/she were dead or any thoughts of possible death to self</li> <li>□ 3 = Suicide ideas or gesture</li> <li>□ 4 = Attempts at suicide (any serious attempt rates 4)</li> </ul>
4.	Insomnia Early
	<ul> <li>□ 0 = No difficulty falling asleep</li> <li>□ 1 = Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour</li> <li>□ 2 = Complains of nightly difficulty falling asleep</li> </ul>
5.	Insomnia Middle
	<ul> <li>□ 0 = No difficulty</li> <li>□ 1 = Patient complains of being restless and disturbed during the night</li> <li>□ 2 = Waking during the night - getting out of bed rates 2 (except for purposes of voiding)</li> </ul>
6.	Insomnia Late
	<ul> <li>□ 0 = No difficulty</li> <li>□ 1 = Waking in early hours of the morning but goes back to sleep</li> <li>□ 2 = Unable to fall asleep again if he/she gets out of bed</li> </ul>
7.	Work and Activities
	<ul> <li>□ 0 = No difficulty</li> <li>□ 1 = Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies</li> <li>□ 2 = Loss of interest in activity; hobbies or work - either directly reported by patient, or indirectly in listlessness, indecision and vacillation (feels he/she has to push self to work or activities)</li> </ul>
	<ul> <li>3 = Decrease in actual time spent in activities or decrease in productivity.</li> <li>4 = Stopped working because of present illness.</li> </ul>

### SSS SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0 0		Acute Phase Week 7	80	185

# HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 2 OF 3

8.	Retardation (slowness of thought and speech, impaired ability to concentrate; decreased motor activity)  □ 0 = Normal speech and thought
	☐ 1 = Slight retardation at interview ☐ 2 = Obvious retardation at interview ☐ 3 = Interview difficult ☐ 4 = Complete stupor
9.	Agitation
	<ul> <li>□ 0 = None</li> <li>□ 1 = Fidgetiness</li> <li>□ 2 = "Playing with" hands, hair, etc.</li> <li>□ 3 = Moving about, can't sit still</li> <li>□ 4 = Hand wringing, nail-biting, hair-pulling, biting of lips</li> </ul>
10.	Anxiety Psychic
	<ul> <li>□ 0 = No difficulty</li> <li>□ 1 = Subjective tension and irritability</li> <li>□ 2 = Worrying about minor matters</li> <li>□ 3 = Apprehensive attitude apparent in face or speech</li> <li>□ 4 = Fears expressed without questioning</li> </ul>
11.	Anxiety Somatic (physiological concomitants of anxiety such as: Gastrointestinal (dry mouth, wind, indigestion, diarrhea, cramps, belching), Cardiovascular (palpitations, headaches), Respiratory (hyperventilation, sighing), Urinary frequency, Sweating.
	<ul> <li>□ 0 = Absent</li> <li>□ 1 = Mild</li> <li>□ 2 = Moderate</li> <li>□ 3 = Severe</li> <li>□ 4 = Incapacitating</li> </ul>
12.	Somatic Symptoms Gastrointestinal
	<ul> <li>□ 0 = None</li> <li>□ 1 = Loss of appetite but eating. Heavy feelings in abdomen</li> <li>□ 2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms</li> </ul>
13.	Somatic Symptoms General
	<ul> <li>□ 0 = None</li> <li>□ 1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability</li> <li>□ 2 = Any clear-cut symptoms rates 2</li> </ul>
14.	Genital Symptoms (such as loss of libido and menstrual disturbances)
	<ul> <li>□ 0 = Absent</li> <li>□ 1 = Mild</li> <li>□ 2 = Severe</li> </ul>

## SSS SmrthKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0 0		Acute Phase Week 7	62	186

# HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 3 OF 3

15. Hypochondriasis
$ \Box 0 = \text{Not present}  \Box 1 = \text{Self-absorption (bodily)} $
2 = Preoccupation with health
<ul> <li>3 = Frequent complaints, requests for help, etc.</li> <li>4 = Hypochondriacal delusions</li> </ul>
16. Loss of Weight
0 = No weight loss
<ul> <li>1 = Slight or doubtful loss of weight</li> <li>2 = Obvious or severe loss of weight</li> </ul>
17. Insight
0 = Acknowledges being depressed and ill
1 = Acknowledges illness but attributes cause to bad food, climate, over-work, virus, need for rest, etc.
2 = Denies being ill at all
HAMD Score (Items 1-17)

## S SmithKline Beecham Pharmaceuticals

	Project	Protocol	Center	Patient Number	Visit	Page
	29060	329	0,0		Acute Phase Week 7	187

#### STUDY MEDICATION RECORD

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily		

#### STUDY MEDICATION DOSING CHANGES

□ No				medication since the last visit
☐ Yes —	→ Indicate cha	nge(s) belo	ow	
	nidam	Changes	in doso constitu	te deviation from the protocol
	Reminder:	Changes	m dose constitu	ic deviation from the protocol
Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily	Reason for Dose Change
Start Date day month year			Capsules	Reason for Dose Change
			Capsules	Reason for Dose Change

### STUDY MEDICATION COMPLIANCE

Capsules Dispensed (A)	Capsules Returned (B)	Capsules Taken (A - B)	Days Since Last Visit	% Compliance			
-	ance = -	(N <b>★</b> x	of capsules days since l 0% and $\leq$ 1	ast visit)	100	* _N =	number of capsules dail (see above)
Has the pa	tient been	non-compli	iant?				
□ Ye		No					

## SB SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit	Pag	zе
29060	329	0,0		Acute Phase Week 7	188	8

#### STUDY MEDICATION LABEL

				_
-	Atta	ach label here		
	Enter patient number (drug code as listed on clinical supplies)		Important:	The drug code on the study medication label must be identical to the preprinted Patient Number above.

#### STUDY MEDICATION DISPENSING

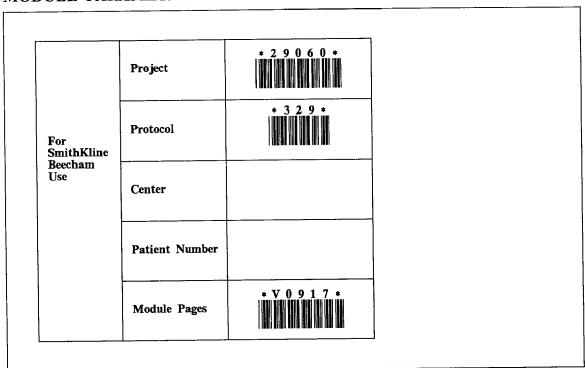
Record study medication information for Week 8 in the Study Medication Record, page 222. Attach label to page 223. Record number of capsules dispensed on page 222.

Reminder: The drug code on the study medication label must be identical to the preprinted Patient Number above.

## S SmithKline Beecham Pharmaceuticals

Г	Project	Protocol	Center	Patient Number	Visit	
	29060	329	0,0		Acute Phase	

#### **MODULE PARAMETERS - WEEK 8**



### SB SmithKline Beecham Pharmaceuticals

Pro	ject	Protocol	Center	Patient Number	Visit	Visit Date	Page
290	)60	329	0,0		Acute Phase Week 8	day month year	189

VITAL.	SIGNS
--------	-------

	Sitting			Standing			
Weight □ lbs □ kg		Pressure nHg) diastolic	Pulse (beats/ min)		Pressure nHg) diastolic	Pulse (beats/ min)	

#### ADVERSE EXPERIENCES / CONCOMITANT MEDICATION

Have paties	any adverse experiences been observed or elicited by the following direct question to t nt: "Do you feel different in any way since starting the treatment or since the last v
•	☐ Yes ☐ No
	Record in the Adverse Experience section
Has	there been any change in concomitant medication since the last visit?
	☐ Yes ☐ No
ſ	Record in the Concomitant Medication section

### CLINICAL GLOBAL IMPRESSIONS - GLOBAL IMPROVEMENT

Rate the	e tota	al improvement whether or not, in your judgment, it is due entirely to drug
treatmer	nt. (	Compared to his/her condition at admission to the study, now much has the
patient	cnan;	geu:
	1 =	Very much improved
	2 =	Much improved
	3 =	Minimally improved
		No change
		Minimally worse
		Much worse
	-	Very much worse

### PLASMA SAMPLE - DRUG CONCENTRATION

Was a plasma samp	le obtained for drug concentration?
☐ Yes	□ No

# ST SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page	
29060	329	0 0		Acute Phase Week 8	10	 190	l

# HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 1 OF $\bf 3$

	1.	Depressed Mood (sadness, hopelessness, helpless, worthless)  0 = Absent 1 = These feeling states indicated only on questioning 2 = These feeling states spontaneously reported verbally 3 = Communicates feeling states non-verbally, i.e., through facial expression, posture, voice and tendency to weep 4 = Patient reports virtually only these feeling states in his/her spontaneous verbal and non-verbal communication
	2.	Feelings of Guilt
		□ 0 = Absent □ 1 = Self reproach, feels he/she has let people down □ 2 = Ideas of guilt or rumination over past errors or sinful deeds □ 3 = Present illness is a punishment. Delusions of guilt □ 4 = Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations
ı	3.	Suicide
		<ul> <li>□ 0 = Absent</li> <li>□ 1 = Feels life is not worth living</li> <li>□ 2 = Wishes he/she were dead or any thoughts of possible death to self</li> <li>□ 3 = Suicide ideas or gesture</li> <li>□ 4 = Attempts at suicide (any serious attempt rates 4)</li> </ul>
	4.	Insomnia Early
		<ul> <li>□ 0 = No difficulty falling asleep</li> <li>□ 1 = Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour</li> <li>□ 2 = Complains of nightly difficulty falling asleep</li> </ul>
Ì	5.	Insomnia Middle
		<ul> <li>□ 0 = No difficulty</li> <li>□ 1 = Patient complains of being restless and disturbed during the night</li> <li>□ 2 = Waking during the night - getting out of bed rates 2 (except for purposes of voiding)</li> </ul>
	6.	Insomnia Late
		<ul> <li>0 = No difficulty</li> <li>1 = Waking in early hours of the morning but goes back to sleep</li> <li>2 = Unable to fall asleep again if he/she gets out of bed</li> </ul>
	7.	Work and Activities
		<ul> <li>□ 0 = No difficulty</li> <li>□ 1 = Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies</li> </ul>
		2 = Loss of interest in activity; hobbies or work - either directly reported by patient, or indirectly in listlessness, indecision and vacillation (feels he/she has to push self to work or activities)
İ		<ul> <li>3 = Decrease in actual time spent in activities or decrease in productivity.</li> <li>4 = Stopped working because of present illness.</li> </ul>

# SB SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0.0		Acute Phase Week 8	10	191

# HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 2 OF $\bf 3$

8.	Retardation (slowness of thought and speech, impaired ability to concentrate; decreased motor activity)  □ 0 = Normal speech and thought □ 1 = Slight retardation at interview □ 2 = Obvious retardation at interview □ 3 = Interview difficult
	4 = Complete stupor
9.	Agitation
	<ul> <li>□ 0 = None</li> <li>□ 1 = Fidgetiness</li> <li>□ 2 = "Playing with" hands, hair, etc.</li> <li>□ 3 = Moving about, can't sit still</li> <li>□ 4 = Hand wringing, nail-biting, hair-pulling, biting of lips</li> </ul>
10.	Anxiety Psychic
	<ul> <li>□ 0 = No difficulty</li> <li>□ 1 = Subjective tension and irritability</li> <li>□ 2 = Worrying about minor matters</li> <li>□ 3 = Apprehensive attitude apparent in face or speech</li> <li>□ 4 = Fears expressed without questioning</li> </ul>
11.	Anxiety Somatic (physiological concomitants of anxiety such as: Gastrointestinal (dry mouth, wind, indigestion, diarrhea, cramps, belching), Cardiovascular (palpitations, headaches), Respiratory (hyperventilation, sighing), Urinary frequency, Sweating.
	<ul> <li>□ 0 = Absent</li> <li>□ 1 = Mild</li> <li>□ 2 = Moderate</li> <li>□ 3 = Severe</li> <li>□ 4 = Incapacitating</li> </ul>
12.	Somatic Symptoms Gastrointestinal
	<ul> <li>□ 0 = None</li> <li>□ 1 = Loss of appetite but eating. Heavy feelings in abdomen</li> <li>□ 2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms</li> </ul>
13.	Somatic Symptoms General
	<ul> <li>□ 0 = None</li> <li>□ 1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability</li> <li>□ 2 = Any clear-cut symptoms rates 2</li> </ul>
14.	Genital Symptoms (such as loss of libido and menstrual disturbances)
	<ul> <li>□ 0 = Absent</li> <li>□ 1 = Mild</li> <li>□ 2 = Severe</li> </ul>

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# HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 3 OF $\bf 3$

15.	Hypochondriasis
	<ul> <li>□ 0 = Not present</li> <li>□ 1 = Self-absorption (bodily)</li> <li>□ 2 = Preoccupation with health</li> <li>□ 3 = Frequent complaints, requests for help, etc.</li> <li>□ 4 = Hypochondriacal delusions</li> </ul>
16.	Loss of Weight
	<ul> <li>□ 0 = No weight loss</li> <li>□ 1 = Slight or doubtful loss of weight</li> <li>□ 2 = Obvious or severe loss of weight</li> </ul>
17.	Insight
	<ul> <li>□ 0 = Acknowledges being depressed and ill</li> <li>□ 1 = Acknowledges illness but attributes cause to bad food, climate, over-work, virus, need for rest, etc.</li> <li>□ 2 = Denies being ill at all</li> </ul>
	☐ 2 = Denies being ill at all
<b>•</b> 1	HAMD Score (Items 1-17)

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#### AUTONOMOUS FUNCTIONING CHECKLIST

Grade in School		Informant (mother, father, guardian, other)
-----------------	--	---------------------------------------------

#### Instructions

The purpose of this checklist is to learn about what your teenager does every day. There are no "right" or "wrong" things for your teenager to do, since teenagers of different ages do many different things. These questions are simply for the purpose of getting an idea of your teenager's daily activity.

When you answer these questions, first, read the question and think about whether or not it describes what you see or have seen your teenager do. You should answer the questions according to what you know your teenager does or does not do rather than what you believe or think he or she could do or could not do.

**Second**, tell us how the question describes what you teenager does by choosing one of the alternatives "0", "1", "2", "3", or "4" from the scale and circling that number in the space to the right of the item. Here is how to use the rating scale with a sample question.

0	1	2	3	4
Does Not Do	Does Only Rarely	Does About Half the Time There is an Opportunity	Does Most of the Time There is an Opportunity	Does Every Time There is an Opportunity

#### Sample Item. Pick up trash in the yard.

- 0 1 2 3 4
- 0 Circle "0" if you have never seen your teenager do this, even if he or she may never have had an opportunity. (For example mark "0" if your teenager has never done it, even if you live in an apartment and do not have a yard.)
- 1 Circle "1" if you have seen your teenager do this when there has been a chance, but if there have been many more times that he or she has not done it.
- 2 Circle "2" if your teenager does this about half the time there is a chance, but if he or she does not do it readily or comfortably.
- 3 Circle "3" if there are more times that your teenager does this than does not do it, given the chance, and if he or she does it readily.
- 4 Circle "4" if your teenager does this whenever there is a chance and if he or she does it readily.

Your teenager will not have had the chance to participate in some of the activities the questions described. These items should be answered as "does not do," even though you may feel that your teenager would do it if given the chance. Please circle "0" for questions that describe activities your teenager has **never had the chance** to do.

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#### AUTONOMOUS FUNCTIONING CHECKLIST

Some questions describe things that your teenager may do with help from others. Answer these questions after you think about who has the most responsibility for completing the activity. For example, your teenager may cook the family meals and may be helped by other family members who set the table or chop vegetables. If your teenager is the family member with the most responsibility for cooking every meal that the family eats together, your answer would be "4", which stands for "does every time there is an opporunity." On the other hand, if your teenager helps other family members by doing jobs that they tell him or her to do, and never has the most responsibility for fixing dinner, your answer would be "0", for "does not do."

	0	1	2		3		Does Every			
D	oes Not Do	Does Only Rarely	Does About Half the Time There is an Opportunity	e is the Time There i			Tim	e The		
Му	teenager:						•			
1.	Keeps own p makes bed,	ersonal items and be puts away own cloth	elongings in order (for exing and belongings).	kample	0	1	2	3	4	
2.	Prepares foo herself (for	d that does not requiexample, cereal, san		0	1	2	3	4		
3.	Care for his/her own clothing (for example, laundry, simple repair, shoe cleaning)							3	4	
4.	Travels to and from daily activities (for example, rides bike or walks, takes bus, arranges for transportation, drives car).							3	4	
5.		repares food that requires cooking for himself/herself of example, hamburger, soup).						3	4	
6.			lical care for himself/takes own temperature).		0	1	2	3	4	
7.	Purchases hi are used on	s/her own clothing a a daily basis (for e	and personal items that example, underwear, toile	tries).	0	1	2	3	4	
8.		nor repair and maint e, changes light bulb	ance in his/her owm env	rironment	0	1	2	3	4	
9.	Shops for an	nd purchases his/her	own groceries.		0	1	2	3	4	
10.	Responds to	his/her own medical	l emergency by calling p	arent.	0	1	2	3	4	
11.	Responds to hospital.	Responds to his/her own medical emergency by calling doctor or hospital.						3	4	
12.	Does designativing areas yard work).	gnated household maintenance chores involving family eas (for example, cleans, takes out trash, does simple k).			0	1	2	3	4	

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	0	1	2	3				4	_
Do	oes Not Do	Does Only Rarely	Does About Half the Time There is an Opportunity	Does Mo the Time an Oppor	There	is	Doe Time an C	re is	
13.	Performs rout (for example,	ine daily personal o dresses, feeds).	care for another family n	nember.	0	1	2	3	4
14.	Keeps persona order (for ex	l items and belongi ample, makes bed,	ings of another family mo	ember in belongings).	0	1	2	3	4
15.	Prepares meal	Prepares meals for other family member(s).					2	3	4
16.	Transports (or arranges for transport of) another family member to and from daily activities.					1	2	3	4
17.	Purchases clothing and personal items (that are used on a daily basis) for other family members.					1	2	3	4
18.	Shops for and	l purchases family	groceries.		0	1	2	3	4
19.	Performs min	or repairs and mair, changes light bulb	ntenance in family living os, hangs picture).	areas	0	1	2	3	4
20.	and maintena	naintains (or makes nce of) major hous lectrical wiring).	arrangement for repair schold needs (for example	e, plumbing,	0	1	2	3	4
21.	Responds to problem) by	household emergency calling parent or n	y (for example, stove fir neighbor.	e, plumbing	0	1	2	3	4
22.	problem) by	ousehold emergency calling fire departs r service or shuting	(for example, stove fire ment, using fire extinguis off water.	e, plumbing ther, or	0	1	2	3	4
Му	teenager:								
23.	Uses the telp	phone and telephone	directories.		0	1	2	3	4
24.	<ol> <li>Carries out transactions with sales people (for example, listens to information, asks questions, gives payment, receives change).</li> </ol>				0	1	2	3	4
25.	Uses postal packages).	services (for examp	ole, uses postage, mails le	etters.	0	1	2	3	4
26.	Uses bank (		out deposit or withdrawal	slips,	0	1	2	3	4

# SM SmrthKline Beecham Pharmaceuticals

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	0	1	2	3				4	
D	oes Not Do	Does Only Rarely	Does About Half the Time There is an Opportunity	Does M the Time an Oppo	Ther	e is			
27.	Uses travel-r subway).	elated services for	short trips (for example,	taxi, bus	0	1	2	3	4
28.	Uses travel-retrain, bus).	elated services for	ong trips (for example,	airline,	0	1	2	3	4
29.	Uses library machine).	ses library services (for example, checks out books or uses Xerox nachine).							4
30.	Maintains and	d uses his/her own		o	1	2	3	4	
31.	Maintains and	d uses his/her own	ınt.	o	1	2	3	4	
32.		Maintains adequate personal care and grooming (for example, bathes, 0 trims fingernails and toenails when needed)							4
33.	Maintains his has adequate	her routine general eating, sleeping and	health and fitness (for education described health).	example,	0	1	2	3	4
34.		ng that is suited to aining, warm clother	weather (for example, in winter).		0	1	2	3	4
35.	unscheduled		imself/herself in everday ple, chooses to watch tel	evision	0	1	2	3	4
36.	Plans activity makes plans	for his/her long-te for summer vacatio	rm free time (for examp n, mid-semester vacation)	le,	0	1	2	3	4
37.	Initiates frien parties, outin	dships with peers (sigs, games, club me	for example, plans or attentions.	ends	0	1	2	3	4
38.	example, kee	demic social obligat ps appointments for arranged by self or	tions or commitments (for family and peer related to others).	r	0	1	2	3	4
39.	Meets academ completes hos supplies to c	mework assignments	commitments (for example on time, brings necessar	le, 'y	0	1	2	3	4
40.	Plan transport arranges for bus route and	rides with friends of	special activities (for exa or family or plans care o	mple r	0	1	2	3	4

# S SmithKline Beecham Pharmaceuticals

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	0	1	2	3			-	4	
Do	Do Do	Does Only Rarely	Does About Half the Time There is an Opportunity	Does Mosthe Time Tan Oppor	here	is	Time	s Eve e The pport	re is
<b>1</b> 1.	example, sav-	es money for large	n allowance or income (f purchases, pays for routi ut running out of money)	ne	0	1	2	3	4
42.	Make long-te selects cours	rm educational and, es, investigates coll	or career plans (for example eges or technical schools)	nple,	0	1	2	3	4
	n my teenager he chooses to:		how he/she will spend his	s/her unschedu	ıled	free t	ime.		
43.	Listen to mu	sic (for example, ra	adio or stereo).		0	1	2	3	4
44.	4. Read for relaxation (for example, books, newspapers) 0						2	3	4
45.	Play games or puzzles (for example, cards, crossword puzzles, 0 1 jigsaw puzzles, computer games).						2	3	4
46.	Write letters	to friends, relative	s, aquaintances.		0	1	2	3	4
47.	Work on or cooking, col car repair).	take lessons in crail lections, pet care, s	fts or hobbies (for examp sewing, model building,	le	0	1	2	3	4
48.	skill (for ex	ake lessons that invample, piano or other writing, foreign	volve a trained artistic or ner musical instrument, be n languages).	academic allet,	0	1	2	3	4
49.	Go to the m	ovies, rock concerts	s, dances.						
50.	Go to plays,	theater, lectures.			0	1	2	3	4
51.	(for example	ities that are related e, runs a business, rofessional preparati	i to his or her career int works on a computer, pron).	erest(s) actic <del>e</del> s	0	1	2	3	4
52.	Go for walk	S.			0	1	2	3	4
53.	Go shopping, or spend time at shopping centers or in shopping areas.					1	2	3	4
54.	Attend club	meetings or other	meetings or other organized social group meetings. 0 1					3	4
55.	Work for pa	ay (for example, bak dogs, work at pa	bysit, play in a band, do rt-time job, deliver paper:	yard s).	0	1	2	3	4

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	(	)	1	2	3		4		
		Not Oo	Does Only Rarely	Does About Half the Time There is an Opportunity	Does Most of the Time There i an Opportunity	s Tir	Does Every Time There an Opportun		
56	e		n house, wash or r	ronment or belongings (fepair clothes, wash car,		1 2	3	4	
57			•	le, spend extra time on lass projects, spend time		1 2	3	4	
58	h	ave discussion		mple, work on family pr crsations, attend family rties).	ojects, 0	1 2	3	4	
Or if	the	se final item description f	s, please check "Ye its your teenager.	es" or "No" in response Check "No" if it does n	to each description.	Check	"Yes"		
M	y tee	nager:					Yes	No	
59	). н	as casual fr	iendships with teens	agers of opposite sex.					
60	). H	as close frie	endships with teenag	gers of opposite sex.					
6			iendships with adul aches, scout leaders	ts outside the family (for	r example, teachers,				
62			endships with adults aches, scout leaders	s outside the family (for s).	example, teachers,				
6	3. H	as casual fr	iendships with your	nger children.					
64	4. H	las close frie	endships with young	ger children.					
6:				groups of teenage friends					
		las many fri	•	- <del>-</del>					
	7. I	s active in o		zed extracurricular group	(for example,				
6	8. I	Ias leadershi example, pre	p position in one o sident of the studer	or more organized extract nt council, captain of the	arricular group (for sports team).				
6			endship with adult nt, grandparent).	member of the extended	family (for example	,			
7		Works or has		pay or volunteer in an	area of particular				

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		Yes	No
71.	Works or has worked to earn money by providing a service on a regular scheduled basis (for example, contracts for yard work, dog walking, baby sitting)		
72.	Works or has worked to earn money by using a special skill (for example, musical performance, typing, tutoring).		
73.	Works or has worked to earn money in a self-or-peer-run organization or business.		
74.	Works or has worked to earn money fundraising for an organization or charity (for example, scouts, church groups, political organizations).		
75.	Does or has done volunteer work without pay for a service, a school or political organization, a social agency, a club, a church, or a hospital.		
76.	Participates or has participated in prevocational (career) or vocational (career) classes or training (for example, any technical training or career development class).		
77.	Has explored career interest by visiting work sites or interviewing people in that job or career.		
78.	Has spent time reading, researching, or "finding out" about a career that particularly interests him/her.		
	ments:		<b>-</b>
	ou have any additional information about your teenager's everyday independent or self- vior, use the space below to write your comments. Thank you.	Suffici	епі

## SB SmithKline Beecham Pharmaceuticals

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		WHAT	AMI	LIKE	-	
Really True for Me	Sort of True for Me	Samp	le Sentene	се	Sort of True for Me	Really True for Me
a		Some teenagers like to go to movies in their spare time	BUT	Other teenagers would rather go to sport events.		
1.		Some teenagers feel that they are just as smart as others their age	BUT	Other teenagers aren't so sure and wonder if they are as smart.		
2.		Some teenagers find it hard to make friends	BUT	For other teenagers it's pretty easy.		
з. 🗌		Some teenagers do very well at all kinds of sports	BUT	Other teenagers don't feel that they are very good when it comes to sports.		
4.		Some teenagers are not happy with the way they look	BUT	Other teenagers are happy with the way they look.		
5.		Some teenagers feel that they are ready to do well at a part-time job	BUT	Other teenagers feel that they are not quite ready to handle a part-time job.		
6.		Some teenagers feel that if they are romantically interested in someone, that person will like them back	BUT	Other teenagers worry that when they like someone romantically that person won't like them back.		
7.		Some teenagers usually do the right thing	BUT	Other teenagers often don't do what they know is right	. 🗆	
8.		Some teenagers are able to make really close friends.	BUT	Other teenagers find it hard to make really close friends.		
9.		Some teenagers are often disappointed with them- selves	BUT	Other teenagers are pretty pleased with themselves.		
10.		Some teenagers are pretty slow in finishing their school work	BUT	Other teenagers can do their school work more quickly		

## SS SmithKline Beecham Pharmaceuticals

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Really True for Me	Sort of True for Me			•	Sort of True for Me	Really True for Me
11.		Some teenagers have a lot of friends	BUT	Other teenagers don't have very many friends.		
12.		Some teenagers think they could do well at just about any new athletic activity	BUT	Other teenagers are afraid they might not do well at a new athletic activity.		
13.		Some teenagers wish their body was different	BUT	Other teenagers like their body the way it is.		
14.		Some teenagers feel that they don't have enough skills to do well at a job	BUT	Other teenagers feel that they do have enough skills to do a job well.		
15.		Some teenagers are not dating the people they are really attracted to	BUT	Other teenagers are dating those people they are attracted to		
16.		Some teenagers often feel guilty about certain things they do	BUT	Other teenagers hardly ever feel guilty about what they do.		
17.		Some teenagers can be trusted to keep secrets that their friends tell them	BUT	Other teenagers have a hard time keeping secrets that their friends tell them.	i 🗌	
18.		Some teenagers don't like the way they are leading their life	BUT	Other teenagers do like the way they are leading their life.		
19.		Some teenagers do very well at their classwork	BUT	Other teenagers don't do very well at their classwork.		
20.		Some teenagers are very hard to like	BUT	Other teenagers are really easy to like.		
21.		Some teenagers feel that they are better than others their age at sports	BUT	Other teenagers don't feel they can play as well.		
22.		Some teenagers wish their physical appearance was different	BUT	Other teenagers like their physical appearance the way it is.		

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Really True for Me	Sort of True for Me			Sort of True for Me	Really True for Me
23.		Some teenagers are proud of the work they do on jobs they get paid for	BUT	For other teenagers, getting paid is more important than feeling proud of what they do.	
24.		Some teenagers feel that people their age will be romantically attracted to them	BUT	Other teenagers worry about whether people their age will be attacted to them.	
25.		Some teenagers are usually pleased with the way they act	BUT	Other teenagers are often ashamed of the way they act.	
26.		Some teenagers don't really have a close friend to share things with.	BUT	Other teenagers do have a close friend to share things with.	
27.		Some teenagers are happy with themselves most of the time	BUT	Other teenagers are often not happy with themselves.	
28.		Some teenagers have trouble figuring out the answers in school	BUT	Other teenagers almost always can figure out the answers.	
29.		Some teenagers are popular with others their age	BUT	Other teenagers are not very popular.	
30.		Some teenagers don't do well at new outdoor games	BUT	Other teenagers are good at new outdoor games right away.	
31.		Some teenagers think that they are good looking	BUT	Other teenagers think that they are not very good looking.	
32.		Some teenagers feel like they could do better at work they do pay for	BUT	Other teenagers feel that they are doing really well at work they do pay for.	
33.		Some teenagers feel that they are fun and interesting on a date	BUT	Other teenagers wonder about how fun and interesting they are on a date.	
34.		Some teenagers do things they know they shouldn't do	BUT	Other teenagers hardly ever do things they know they shouldn't do.	

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Really True	Sort of True				Sort of True for Me	Really True for Me
35	for Me	Some teenagers find it hard to make friends they can really trust	BUT	Other teenagers are able to make close friends they can really trust.	IOI MIC	IOI IVIE
36.		Some teenagers like the kind of person they are	BUT	Other teenagers often wish they were someone else.		
37.		Some teenagers feel that they are pretty intelligent	BUT	Other teenagers question whether they are intelligent.		
38.		Some teenagers feel that they are socially acceptable	BUT	Other teenagers wished that more people their age accepted them.		
39.		Some teenagers do not feel that they are very athletic	BUT	Other teenagers feel that they are very athletic.		
40.		Some teenagers really like their looks	BUT	Other teenagers wished they looked different.		
41.		Some teenagers feel that it's really important to do the best you can on paying jobs	BUT	Other teenagers feel that getting the job done is what really counts.		
42.		Some teenagers usually don't get asked out by people they would like to date	BUT	Other teenagers do get aske out by people they really want to date.	d	
43.		Some teenagers usually act the way they know the are supposed to	BUT	Other teenagers often don't act the way they are supposed to.		
44.		Some teenagers don't have a friend that is close enough to share really personal thoughts with	BUT	Other teenagers do have a close friend that they can share personal thoughts and feelings with.		
45.		Some teenagers are very happy being the way they are	BUT	Other teenagers wish they were different.		

# S SmithKline Beecham Pharmaceuticals

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Introduction							
On the next few pages are statements which describe things people often do when they are not well.							
As you read them, think of yourself today:							
- If a statement describes you TODAY, mark the box under "Yes" (Yes, this statement describes me today).							
- However, if a statement does not describe you TODAY, or does not apply you, mark the box under "No". (No, this statement does not describe me today or does not apply to me).							
For Example:							
"I am not doing any of the shopping that I would usually do."							
- If you have not been doing any shopping for some time, and still are not doing any shopping today, check "YES". (Yes, this statement describes me today).							
- If you are doing your shopping as usual, check "NO" (No this statement does not describe me today or does not apply to me).							
Read and respond to the statements in the order listed. Some of the statements will differ only in a few words, so please read each one carefully. While you may wish to go back to change a response, your first answer is usually best. Please do not read ahead in the questionnaire.							
Please do not discuss the statements with anyone, including family members, while doing the questionnaire.							
Please mark your answers by placing an "X" in the appropriate box like this.							
Thank you for your time and help.							
How would you describe your present health							
very good good fair poor very poor							
How would you describe you present quality of life (how things are going for you generally)?							
☐ very good ☐ good ☐ fair ☐ poor ☐ very poor							

# SSS SmithKline Beecham Pharmaceuticals

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		+
A.	These statements describe your sleep and rest this week.	Yes No
	1. I spend much of the day lying down in order to rest.	
	2. I sit for much of the day.	
	3. I am sleeping or dozing much of the time - day and night.	
	4. I lie down more often than my friends during the day in order to rest.	
	5. I sit around half asleep.	
	6. I sleep less at night, for example, I wake up easily, I do not fall asleep for a long time, I keep waking up.	
	7. I sleep or doze more during the day.	
В.	These statements describe your daily work around the house.	Yes No
}	1. I only do work that I need to do around the house for short periods of time or I rest often.	
	2. I am doing less of the daily household chores that I would usually do.	
	3. I am not doing any of the daily household chores that I would usually do.	
	4. I am not doing any of the shopping that I would usually do.	
	5. I am not doing any of the cleaning that I would usually do.	
	6. I am not doing any of the clothes washing that I would usually do.	
C.	These statements describe your contact with your family and friends today.	Yes No
	1. I am going out less to visit people.	
	2. I am not going out to visit people at all.	
	<ol> <li>I show less interest in other people's problems, for example, I do not listen when they tell me about their problems. I do not offer to help.</li> </ol>	
	<ol> <li>I am often irritable with those around me, for example, I snap at people or criticize easily.</li> </ol>	
	5. I show less affection.	
	6. I take part in fewer social activities than I used to, for example, I go to fewer parties or social events.	

## SB SmithKline Beecham Pharmaceuticals

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			<b>37</b>	NT.
	7.	I am cutting down the length of visits to friends.	Yes ☐	No
	8.	I avoid having visitors.		
	9.	My sexual activity is decreased.		
	10.	I talk less with those around me.		
	11.	I make demands on other people that they find irritating, for example, I insist that they do things for me, or tell them how to do things.		
	12.	I stay alone much of the time.		
	13.	I am disagreeable with my family, for example, I act spitefully or stubbornly.		
	14.	I frequently get angry with my family, for example, I hit them, scream or throw things at them.		
	15.	I isolate myself as much as I can from the rest of my family.		
	16.	I refuse contact with my family, for example, I turn away from them.		
	17.	I am not joking with my family members as I usually do.		
D.	The	se statements describe your feelings.	Yes	No
D.	Thes	se statements describe your feelings.  I am confused and start to do more than one thing at a time.	Yes	No
D.	1.	-	Yes	No
D.	1.	I am confused and start to do more than one thing at a time.  I have more minor accidents, for example, I drop things, I trip and fall or	Yes	No
D.	1. 2.	I am confused and start to do more than one thing at a time.  I have more minor accidents, for example, I drop things, I trip and fall or bump into things.	Yes	No
D.	<ol> <li>2.</li> <li>3.</li> </ol>	I am confused and start to do more than one thing at a time.  I have more minor accidents, for example, I drop things, I trip and fall or bump into things.  I react slowly to things that are said or done.  I do not finish things I start.	Yes	No □ □ □
D.	<ol> <li>2.</li> <li>3.</li> <li>4.</li> </ol>	I am confused and start to do more than one thing at a time.  I have more minor accidents, for example, I drop things, I trip and fall or bump into things.  I react slowly to things that are said or done.  I do not finish things I start.  I have difficulty reasoning and solving problems, for example, making plans,	Yes	<b>N</b> • □ □ □ □ □ □
D.	<ol> <li>2.</li> <li>3.</li> <li>4.</li> <li>5.</li> </ol>	I am confused and start to do more than one thing at a time.  I have more minor accidents, for example, I drop things, I trip and fall or bump into things.  I react slowly to things that are said or done.  I do not finish things I start.  I have difficulty reasoning and solving problems, for example, making plans, making decisions, learning new things.  I sometimes get confused, for example, I do not know where I am, who is	Yes	
D.	1. 2. 3. 4. 5.	I am confused and start to do more than one thing at a time.  I have more minor accidents, for example, I drop things, I trip and fall or bump into things.  I react slowly to things that are said or done.  I do not finish things I start.  I have difficulty reasoning and solving problems, for example, making plans, making decisions, learning new things.  I sometimes get confused, for example, I do not know where I am, who is around, or what day it is.  I forget a lot, for example, things that happened recently, where I put things,	Yes	
D.	1. 2. 3. 4. 5. 6.	I am confused and start to do more than one thing at a time.  I have more minor accidents, for example, I drop things, I trip and fall or bump into things.  I react slowly to things that are said or done.  I do not finish things I start.  I have difficulty reasoning and solving problems, for example, making plans, making decisions, learning new things.  I sometimes get confused, for example, I do not know where I am, who is around, or what day it is.  I forget a lot, for example, things that happened recently, where I put things, or to keep appointments.	Yes	

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E.	These statements are about how you talk to other people and write.	Yes	No	
	1. I am having trouble writing or typing.	Ш	لــا	
	2. I am having trouble talking to people.			
	3. I am not comfortable in most social situations like parties.			
	4. I speak with difficulty, for example, I get stuck for words, I stutter, I stammer, I slur my words.			
	5. I do not speak clearly when I am under stress.			
F.	The following statements decribe the activities you usually do in your spare time for relaxation, entertainment or just to pass the time.	Yes	No	
	1. I spend shorter periods of time on my hobbies and recreation.			
	2. I am going out and enjoying myself less often.			
	3. I am cutting down on some of my usual inactive pastimes, for example, I watch less TV, play cards less, or read less.			
	4. I am not doing any of my usual inactive pastimes, for example, I watch less TV, play cards less, or read less.			
	5. I am doing more inactive pastimes in place of my other usual activities.			
	6. I am taking part in fewer activities with my friends.			
	<ol> <li>I am cutting down on some of my usual physical recreation or more active pastimes.</li> </ol>			
	8. I am not doing any of my usual physical recreation or more active pastimes.			
N	low please look through this questionnaire and make sure that you have read every ques	stion.		
T	hank you once again for your help.			

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<u>DEF</u> 1.	PRESSED MOOD  Worst Severity of	ן מסין	m	[ <del>-(2)</del> ]	[(3)]	[747]	[T5]]	[76]	[ <del>(7)</del>
1.	Current Episode:	NI	NO	SLT	MLD	мо	SVR	EX	VEX
	Duration of Current Episode:		∫# of w	eeks					
2.	Worst Severity of Last Two Weeks:	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	(7) VEX
	Frequency:	Day	s/week						
	Average % time of the day:		<b>]</b> %						
DEF	PRESSED APPEAR	ANCE							
3.	Current Episode:	(0)	(I) NO	SLT	MLD	(4) MO	SVR	(6) EX	
4.	Last Two Weeks:	(0) NI	(I) NO	SLT	MLD	(4) MO	(5) SVR	(6) EX	
IRR	RITABILITY AND	ANGER							
5.	Current Episode:	(0) NI	(1) NO	(2) SLT	MLD	(4) MO	(5) SVR	(6) EX	(7) VEX
	Duration:		」# of w						
6.	Last Two Weeks:	(0) NI	NO NO	SLT	MLD	(4) MO	(5) SVR	(6) EX	(7) VEX
	Frequency:	Day	s/week						
	Average % time of the day:		<b>」%</b>						
SEF	PARATION-DEPEN	IDENT-D	YSPHOR	<u>IA</u>					
7.	Current Episode:	(0) NI	NO (I)	(2) OCC	(3) USL	(4) ALW			
8.	Last Two Weeks:	(0) NI	NO (I)	occ	USL	ALW			

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OUA	LITY OF DYPSH	ORIC MO	ЮD					-
9.	Current Episode:	(0) NI	(I) ND	(2) QUE	(3) DDF	(4) VDF		
10.	Last Two Weeks:	(0) NI	(1) ND	(2) QUE	(3) DDF	(4) VD:		
		(M)	(ND)	QUL	<i>551</i>	(12.		
	REE OF ASSOCIA			SED OR I	RRITABL	E MOOD	WITH SP	ECIFIC
EVE	NTS OR PREOCC	UPATION	<u>3</u>					
11.	Current Episode:	(0) NI	(1) NAL	MOT	UN	PN		
12.	Last Two Weeks:	(0) NI	(I) NAL	(2) MOT	(3) UN	(4) PN		
			OR IRRE	CADID 36	000			
REA	CTIVITY OF DE	PRESSED	OK IRRIT	ABLE M	ססח			
13.	Current Buisades	(0) NI	(1) VR	(2) FUL	(3) RES	(4) MLD	(5) SLT	(6) UNR
	Current Episode:		لمن		لمست	<u></u>		<del></del>
		لــــا	% Usual	% of Nor	mal			
14.	Last Two Weeks:	(0) NI	(1) VR	FUL	(3) RES	MLD	(5) SLT	(6) UNR
		لــــا	% Usual	l % of No	rmal			
			% Maxi	mum % of	Normal			
			Number	of hours go	ood feeling	last		
חוות	RNAL MOOD VA	DIATION	I					
		KIATION	•					
Wor	se in Morning	<u>⊤</u> ∞1	[0]	(2)	[(3)]	[47]	(5)	
15.	Current Episode:	(0) NI	NW	MIN	MLD	(4) CW	EXT	
16.	Last Two Weeks:	(0) NI	(I) NW	(2) MIN	MLD	CW CW	(5) EXT	
Wor	rse in Afternoon a	nd/or Eve	ning					
17.	Current Episode:	(0) NI	(1) NW	(2) MIN	(3) MLD	(4) CW	(5) EXT	
		(O) ]	[707]	(2)	(3)	(4)	(5) EXT	

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EXCESSIVE INAPPRO	PRIATE	GUILT					ur-	
19. Current Episode:	(0)	(I) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT	
20. Last Two Weeks:	(0)	(1) NO	SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT	
Frequency:	Days/We	eek [						
NEGATIVE SELF IM	<u>AGE</u>							
21. Current Episode:	(0)	(1) NO	(2) ) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT	
22. Last Two Weeks:	(0) NI	(1) NO	SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT	
FEELING UNLOVED	'FORLOF	<u>en</u>						
23. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT	
24. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	MOD	(5) SVR	(6) EXT	
Frequency:	Days/W	eek [						
			07:D + 0D3	(D) III DD	0013 4103 4			
HOPELESSNESS, HEL	PLESSNI	ess, bisc	OURAGEN	AENI, PE	921W19W			
25. Current Episode:	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	EXT	
26. Last Two Weeks:	(0) NI	NO NO	(2) SLT	MLD	MOD	SVR	EXT	
SELF-PITY								
27. Current Episode:	(0)	(1) NO	(2) OCC	(3) MLD	(4) CON			
28. Last Two Weeks:	(0)	(1) NO	(2) occ	(3) MLD	(4) CON			
20. 201 110 110023.	[NI]	[NO]	man					
ACHES AND PAINS								
29. Current Episode:	(0) NI	(1) NO	(2) SLT	MLD	MOD	(5) SVR	EXT	
30. Last Two Weeks:	(0) NI	NO NO	SLT	(3) MLD	MOD	(5) SVR	EXT	

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HYPOCHONDRIASIS							-
31. Current Episode:	(0)	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
32. Last Two Weeks:	(0) NI	NO NO	(2) SLT	(3) MLD	MOD	(5) SVR	(6) EX
ANHEDONIA, LACK	OF INT	EREST. AF	PATHY. 14	OW MOT	IVATION.	BOREDO	м
Combined Overall Ratio			,		<u> </u>		
33. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
Duration:	L	# of w	veeks				
34. Last Two Weeks:	(0) 11	(I)	(2) SLT	MLD	(4) MO	(5) SVR	(6) EX
Frequency:	D	ays/week					
Average % time of the day:	<u> </u>	<b>∟</b> ]%					
Differentiating Lack	of Inter	est from A	nhedonia				
Lack of Interest	[ത]	רשין	(2)	F7807	<u>  [</u>	ristra -	[6]
35. Current Episode:	NI	NO	SLT	MLD	(4) MO	SVR	(6) EX
36. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
Anhedonia							
37. Current Episode:	(0) NI	NO (I)	SLT	MLD	(4) MO	SVR	(6) EX
38. Last Two Weeks:	(0) NI	(1) NO	SLT	MLD	(4) MO	(5) SVR	(6) EX
FATIGUE, LACK OF	ENERG	Y AND TI	<u>redness</u>				
39. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
40. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
Frequency:	∐ D	ays/Week					

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			<del></del>					
DIF	FICULTY CONCENTR	ATIN	G, INATTE	ENTION, C	OR SLOW	ED THIN	KING	
41.	Current Episode: N	<u> </u>	(i) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
42.	Last Two Weeks:	) I	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
PSY	CHOMOTOR AGITAT	CION						
43.	Current Episode: N		(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
44.	Last Two Weeks:	) I	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
	Frequency:	] Days	/Week					
MA	NIFESTATIONS INCL	UDED	:					
	Unable to sit still							
45.	Current Episode:	(0) NI	(1) NPR	DBT	PR	(4) MOD	(5) SVR	
46.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR	
	Pacing							
47.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR	
48.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR	
	Hand wringing							
49.	Current Episode:	(0) NI	(1) NPR	(2) DBT	PR	(4) SVR	(5) SVR	1 1
50.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR	
	Pulling or rubbing on	hair.	lothing sk	in				
51.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR	
52.	Last Two Weeks:	(0) NI	(I) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR	
	Can't stop talking, tal	ks on	and on					
		(0)	[(1)]	(2)	(3) PR	(4) SVR	(5) SVR	-
53.	Current Episode:	NI_	NPR (I)	(2)				
54.	Last Two Weeks:	(0) NI	NPR	DBT	(3) PR	(4) SVR	(5) SVR	

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ועעו	E DIEDO EILEI							
PSYC	HOMOTOR RETARI	DATION						-
55.	Current Episode:	(0) NI	(I)	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
56.	Last Two Weeks:	(0)	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
	Frequency:	Da	ys/Week					
MANI	FESTATIONS INCL	UDED:						
S	lowed Speech							
57.	Current Episode:	NI NI	(1) NPR	DBT	(3) PR	MOD	(5) SVR	
58.	Last Two Weeks:	NI (0)	(1) NPR	(2) DBT	PR	MOD	(5) SVR	
I	ncreased pauses befor		ring					
59.	Current Episode:	NI NI	(1) NPR	(2) DBT	PR	(4) MOD	(5) SVR	
60.	Last Two Weeks:	(0) NI	(1) NPR	DBT	(3) PR	(4) MOD	(5) SVR	
L	ow or monotonous spe	ech						
61.	Current Episode:	(0) NI	(1) NPR	(2) DBT	PR	(4) MOD	(5) SVR	
62.	Last Two Weeks:	(0) NI	(I) NPR	(2) DBT	PR	MOD	(5) SVR	
A	(ute or markedly dec	reased as	nount of s	peech				
63.	Current Episode:	(0) NI	(I) NPR	(2) DBT	PR	(4) MOD	(5) SVR	
64.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	PR	MOD	(5) SVR	
s	lowed body movement							
65.	Current Episode:	(0) NI	(I) NPR	DBT	(3) PR	MOD	(5) SVR	
66.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR	
1	Depressive stupor							
67.	Current Episode:	(O) NI	(I) NPR	DBT	(3) PR	(4) MOD	(5) SVR	
68.	Last Two Weeks:	(0) NI	(I) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR	

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soc	CIAL WITHDRAW	AL_							
69.	Current Episode:	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
70.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
ומומו	IECTION CENCITI	<b>.</b> ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,							
KE	ECTION SENSITI								
71.	Last Year:	(0)	NO NO	SLT	MLD	(4) MOD	(5) SVR	(6) EX	
72.	Current Episode:	MI (0)	NO NO	SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX	
73.	Last Year:	(0)	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX	
74.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX	
SLE	EP PROBLEMS								
75.	Hours sle	ept before	onset of	depression					
76.	Hours sle	ept during	the curren	nt episode					
77.	Hours sle	ept during	the last t	wo weeks					
<u>HY</u>	PERSOMNIA_								٠
78.	Hours sle	ept in day	time of cu	rrent episo	de				
79.	Hours sle	ept in day	time in the	e last two	weeks				
80.	Hours ly	ing down	in current	episode					
81.	∐ Hours ly	ing down	in last tw	o weeks					
82.	Current Episode:	(0) NI	(1) NO	(2)	(3)	(4)	(5)	(6)	
83.	Last Two Weeks:	(0)	(1) NO	(2)	(3)	(4)	(5)	(6)	=
i									

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							-
INSC	<u>OMNIA</u>			F	<b></b>		
34.	Current Episode: (0) NI	(1)	(2)	(3)	(4)	(5)	(6)
35.	Last Two Weeks: (0)	(1) NO	(2)	(3)	(4)	(5)	(6)
	Frequency:	Nights/Wee	:k				
ТҮР	ES OF INSOMNIA						
	Initial Insomnia						
86.	Current Episode:	(0) NI	(1) NPR	(2) DBT	MLD	(4) MOD	SVR
87.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	MLD	MOD	(5) SVR
	Middle Insomnia						
88.	Current Episode:	(0) NI	(1) NPR	DBT	(3) MLD	MOD	(5) SVR
89.	Last Two Weeks:	(0) NI	(I) NPR	(2) DBT	MLD	(4) MOD	(5) SVR
	Terminal Insomnia						
90.	Current Episode:	(O) NI	(I) NPR	DBT	MLD	MOD	(5) SVR
91.	Last Two Weeks:	(0) NI	NPR	DBT	MLD	(4) MOD	(5) SVR
	Circadian Reversal						
92.	Current Episode:	(O) NI	(I) NPR	DBT	MLD	MOD	(5) SVR
93.	Last Two Weeks:	(0) NI	(1) NPR	DBT	MLD	MOD	(5) SVR
	Non-restorative sleep						
94.	Current Episode:	(0) NI	(I) NPR	(2) DBT	MLD	MOD	(5) SVR
95.	Last Two Weeks:	(0) NI	(I) NPR	DBT	(3) MLD	MOD	(5) SVR
	Daytime sleepiness						
96.	Current Episode:	NI	(I) NPR	DBT	MLD	MOD	(5) SVR
97.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	MLD	MOD	(5) SVR

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98. Current Episode: 99. Last Two Weeks:	(0) NI	NO NO	(2) SLT (2) SLT	(3) MLD (3) MLD	(4) MOD (4) MOD	(5) RAR (5) RAR	(6) NVR (6) NVR
WEIGHT LOSS  100. Current Episode:							
Pounds lost: Number of Weeks:		lbs.					
101. Last Two Weeks:  Pounds lost:		lbs.					
INCREASED APPETIT	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
103. Last Two Weeks:  Frequency:	NI (0)	(1) NO Days/Weel	(2) SLT	MLD	MOD	SVR	EX
STRONG CRAVING F							
104. Current Episode: 105. Last Two Weeks:	(0) NI	(I) ABS	DBT (2)	(3) MLD (3) MLD	(4) MOD (4) MOD	(5) SVR (5) SVR	
WEIGHT GAIN  106. Current Episode:							
Pounds gained: Number of Weeks:		lbs.					
107. Last Two Weeks:  Pounds gained:		lbs.					

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SUICIDAL IDEATION	I							
108. Current Episode:	(0)	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	(7) VEX
109. Last Two Weeks:	(0)	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	(7) VEX
Suicidal Acts - Numbe	r							
110. Current Episode:								
111. Last Two Weeks:								
Suicidal Acts - Serious	sness							
112. Current Episode:	(0)	(1) NO	(2) MIN	(3) DEF	(4) SER	]	(5) VS	(6) EXT
113. Last Two Weeks:	(0) NI	(1) NO	(2) MIN	(3) DEF	SER		(5) VS	(6) EXT
Medical Lethality								
114. Current Episode	(0) NI	(I) NO	(2) MIN	(3) MLD	(4) MO		(5) SVR	(6) EXT
115. Last Two Weeks:	(0) NI	(1) NO	(2) MIN	(3) MLD	(4) MO	]	SVR	(6) EXT
Non-Suicidal Physical	Self-De	emaging .	Acts					
116. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO		(5) SVR	(6) ACT
117. Last Two Weeks:	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MO		(5) SVR	ACT
						,		

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				-,-				
ANIC SYNDROME	T. 1400	. To						
ATION, EXPANSIV			[ <del>[</del> 2]]	[3]	[747]	(5) SVR	(6) EX	
. Current Episode:	(0) NI	NO (1)	(2) SLT	MLD	(4) MO			
. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
ECREASED NEED F	OR SLE	EP						
Current Episode:	NI (0)	(I) NO	(2) -1	(3) -2	(4) -3	(5)	(6) -4+	
Last Two Weeks:	(0)	(1) NO	(2) -1	(3) -2	(4) -3	(5)	(6) -4+	
			<u> </u>			<del></del>	<del></del>	
NUSUALLY ENERG						1787	F767	
. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) LCH	(4) MOR	(5) MM	(6) UA	
Last Two Weeks:	NI NI	(1) NO	SLT	LCH	(4) MOR	(5) MM	(6) UA	
CREASE IN GOAL	DIREC	TED ACT	IVITV					
	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX	
7. Current Episode:	<del></del>				(4) MO	(5) MKD	(6) EX	
3. Last Two Weeks:	(0) NI	NO (I)	(2) SLT	MLD	МО	MKD	EX	
RANDIOSITY								
9. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
0. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
					· · · · · ·	DDECTY		
ACCELERATED, PRE							ല്ക്	
1. Current Episode:	(0) NI	(1) NO	SLT	(3) MLD	(4) MO	(5) MKD	(6) EX	
12. Last Two Weeks:	(0) NI	NO NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX	

ſ	Project	Protocol	Center	Patient Number	Visit	Page
	29060	329	0 0		Acute Phase Week 8	219

IDDIE-SADS-EII	· IS I IIV		recii	V 15 15 V	ALUA		- SCORING	rokiv.
RACING THOUGHTS							-	
13. Current Episode:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	(6) EX	
14. Last Two Weeks:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	(6) EX	
FLIGHT OF IDEAS								
15. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
16. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
POOR JUDGEMENT								
17. Current Episode:	(0) NI	NO NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) VS	
18. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) VS	
DISTRACTABILITY								
19. Current Episode:	(0)	(1) NO	(2) SLT	MLD	(4) MO	(5) SVR		
20. Last Two Weeks:	(0)	NO (1)	(2) SLT	MLD	(4) MO	(5) SVR		
MOTOR HYPERACTI	VITY							
21. Current Episode:	(0) NI	NO NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX	
22. Last Two Weeks:	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX	
Inappropriate laughin								
23. Current Episode:	(0) NI	(1) NO	(2) DBT	(3) MLD	MOD			ţ
24. Last Two Weeks:	(0) NI	(1) NO	DBT	(3) MLD	(4) MOD			
Uninhibited people see								
25. Current Episode:	NI NI	(I) NO	(2) DBT	(3) MLD	(4) MOD			
26. Last Two Weeks:	(0) NI	(I) NO	DBT	(3) MLD	(4) MOD			-

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0,0		Acute Phase Week 8	10	220

Inci	reased Productivity						
27.	Current Episode:	(0) NI	(1) NO	DBT	PRS	SVR	
28.	Last Two Weeks:	(0) NI	NO (1)	(2) DBT	PRS	SVR	
Sha	rpened and unusua	ily creat	ive thinki	ng			
29.	Current Episode:	(0) NI	(1) NO	(2) DBT	PRS	(4) SVR	
30.	Last Two Weeks:	(0)	(1) NO	(2) DBT	(3) PRS	(4) SVR	
Ну	persexuality						
31.	Current Episode:	(0) 1N	(I) NO	(2) DBT	(3) PRS	(4) SVR	
32.	Last Two Weeks:	(0)	(I) NO	(2) DBT	PRS	SVR	
<u>INF</u>	LUENCE OF ILLI	CIT DR	UGS OR	ALCOH	<u>ol</u>		
33.	Current Episode:	(0) NA	(1) NVR	(2) SMT	(3) ONL		
34.	Last Two Weeks:	(0) NA	(1) NVR	(2) SMT	(3) ONL		
NU!	MBER OF MANIC	PERIC	<u>DDS</u>				
35.							

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0 0		Acute Phase Week 8	16	 221

### LABORATORY TESTS

Sample Date day month year	For Lab Number SB Code
Attach SBCL laboratory report behind this page.	
Are there CLINICALLY SIGNIFICANT ABNOR	MAL laboratory values?
☐ No ☐ Yes —→ Record the findings and/or dia	gnosis in the Adverse Experiences.

Project	Protocol	Center	Patient Number	Visit	Page
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#### STUDY MEDICATION RECORD

d	Start Date ay month year	End Date day month year	Dose Level	Number of Capsules Daily

#### STUDY MEDICATION DOSING CHANGES

<ul><li>□ No</li><li>□ Yes</li></ul>	→ Indicate cha	(-) 1-1		
		inge(s) bei	ow wo	
		_		
	Reminder:	Changes i	in dose constitu	e deviation from the protocol
Start Date End Date		Dose	Number of Capsules	
			Capsules	
Start Date day month year	End Date day month year	Dose Level		Reason for Dose Change
			Capsules	Reason for Dose Change
			Capsules	Reason for Dose Change

#### STUDY MEDICATION COMPLIANCE

Capsules Dispensed (A)	Capsules Returned (B)	Capsules Taken (A - B)	Days Since Last Visit	% Compliance			
	ance = -	(N <b>★</b> x 0	of capsules days since 1	ast visit) x	100	* _N =	number of capsules dail (see above)
Has the pa	tient been	non-com pli	ant?				
	. 🗆 1	No					

Date Performed y month ye

year)

# ST SmithKline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit	Page
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STUD	Y MEDICATION	LABEL			
		Attach lab	el here		
•	Enter patient number (drug code as listed on clinical supplies)			Important:	The drug code on the study medication label must be identical to the preprinted Patient Number above.

#### STUDY MEDICATION DISPENSING

☐ No

☐ Yes

Was electrocardiogram performed and sent to a central reader for interpretation?

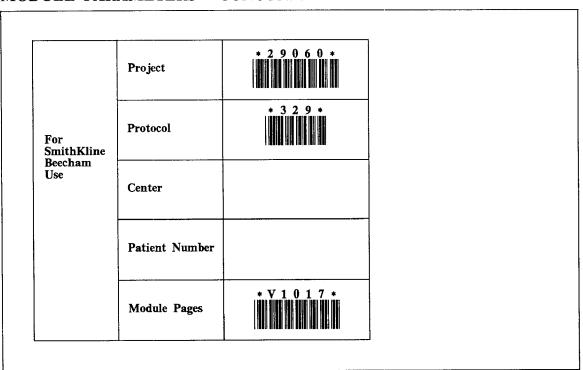
Record study medication information for Weeks 9-12 in the Study Medication Record, page 250 in Binder 3. Attach label to page 251. Record number of capsules dispensed on page 250.

Reminder: The drug code on the study medication label must be identical to the preprinted Patient Number above.

# Signath Kline Beecham Pharmaceuticals

Project	Protocol	Center	Patient Number	Visit	
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### MODULE PARAMETERS - CONCOMITANT MEDICATION



Project	Protocol	Center	Patient Number	Page
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#### CONCOMITANT MEDICATION

			Γ		End Date ★		
Drug Name (Trade name preferred)	Total Daily Dose (e.g., 500 mg)	Route	Medical Condition	Start Date*	or Continuation (mark box)		
				day month year	day month year		
Cor							
SB				, ,			
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SB				1 1			
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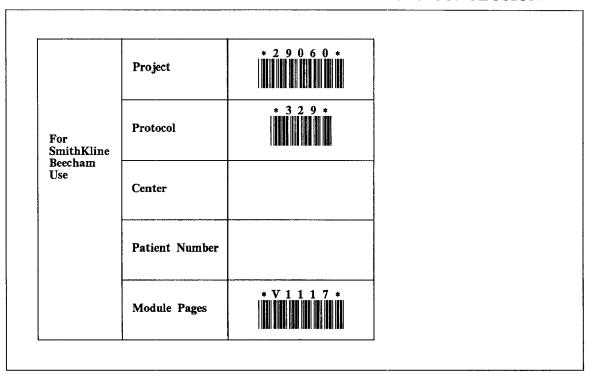
Project	Protocol	Center	Patient Number	Page
29060	329	0 0		225

### CONCOMITANT MEDICATION (CONTINUED)

Drug Name (Trade name preferred)	Total Daily Dose (e.g., 500 mg)	Dose Route Medical Condition		Start Date★	End Date ★ or Continuation (mark box)		
preferred/	,			day month year	day month year		
For SB							
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For SR							
For SB * State dat	es as precisely a	ıs poss	ible.				

Project	Protocol	Center	Patient Number	Visit	
29060	329	0,0		Acute Phase	

#### MODULE PARAMETERS - ADVERSE EXPERIENCES/CONCLUSION



Project	Protocol	Center	Patient Number	Page
29060	329	0.0		226

folloy	Record in standard medical terminology any adverse experience observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit?" Mark appropriate boxes (one experience per column).							
Experience								
For Smith	Kline Beecham							
Date Start	ed	day mon	th year	day mon	th year	day mont	h year	
Date Stopp	oed	day mon	th year	day mon	th year	day mont	h year	
than	tion if less 24 hours	hours min	utes	hours min	nutes	hours min	utes	
Experience continuing Experience continuing at end of study								
Course	Continuous? - if no, number of episodes	☐ Yes ☐ No -		☐ Yes ☐ No -		☐ Yes ☐ No -		
Intensity	<ul><li>1 Mild</li><li>2 Moderate</li><li>3 Severe</li></ul>							
Action Taken on Study Medication	1 None 2 Dose decreased 3 Dose increased 4 Drug stopped							
Suspected Relationship To Study Medication	1 Related 2 Possibly related 3 Probably unrelated 4 Unrelated							
Corrective Therapy	If yes, record on Concomitant Medication form		Yes No		Yes No		Yes No	
Do you consider this a serious adverse experience by the definitions on previous page?			Yes No		Yes No		Yes No	
to SB within	report experience by telephone 24 hours	AE Number		AE Number		AE Number		
Investigator'	s Signature					If patient		

Project	Protocol	Center	Patient Number	Page
29060	329	0,0		227

follow	Record in standard medical terminology any adverse experience observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit?" Mark appropriate boxes (one experience per column).							
Experience								
For Smith	Kline Beecham							
Date Start	ed	day month year	day month year	day month year				
Date Stopp		day month year	day month year	day month year				
than	tion if less 24 hours rience continuing	hours minutes	hours minutes	hours minutes				
Expe	rience continuing id of study							
Course	Continuous? - if no, number of episodes	☐ Yes☐ No -	☐ Yes ☐ No - ☐	☐ Yes ☐ No - ☐				
Intensity	<ul><li>1 Mild</li><li>2 Moderate</li><li>3 Severe</li></ul>							
Action Taken on Study Medication	<ol> <li>None</li> <li>Dose decreased</li> <li>Dose increased</li> <li>Drug stopped</li> </ol>							
Suspected Relationship To Study Medication	3 Probably unrelated							
Corrective Therapy	4 Unrelated  If yes, record on Concomitant Medication form	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No				
adverse expe	sider this a serious erience by the on previous page? , report experience	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No				
to SB within	by telephone 24 hours	AE Number	AE Number	AE Number				
Investigator	's Signature			If patient died, complete Form D				

Project	Protocol	Center	Patient Number	Page
29060	329	0,0		228

Record in standard medical terminology any adverse experience observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit?" Mark appropriate boxes (one experience per column).							
Experience							
For Smith	Kline Beecham						
Date Starte	ed	day month year	day month year	day month year			
Date Stopp		day month year	day month year	day month year			
Duration if less than 24 hours  Experience continuing		hours minutes	hours minutes	hours minutes			
Experience continuing at end of study							
Course	Continuous? - if no, number of episodes	☐ Yes ☐ No -	☐ Yes ☐ No -	☐ Yes ☐ No -			
Intensity	1 Mild 2 Moderate 3 Severe						
Action Taken on Study	1 None 2 Dose decreased 3 Dose increased						
Medication	4 Drug stopped  1 Related						
Suspected Relationship To Study Medication	2 Possibly related 3 Probably unrelated						
Corrective Therapy	4 Unrelated  If yes, record on Concomitant Medication form	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No			
adverse expe	sider this a serious erience by the on previous page?	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No			
to SB	report experience by telephone 24 hours	AE Number	AE Number	AE Number			
Investigator	's Signature			If patient died, complete Form D			

Project	Protocol	Center	Patient Number	Page
29060	329	0,0		229

Record follow treatm	l in standard medi ing direct question tent or since the la	cal terminology a to patient: "Do ast visit?" Mark	any ad you fo appro	verse experien eel different i priate boxes (	ice observe n any wa one experi	d or elicited by since startinence per colun	y the g the nn).
Experience	-						
For Smithl	Cline Beecham						
Date Starte	ed	day month	year	day month	h year	day month	year
Date Stopp		day month	year	day montl	h year	day month	year
than	tion if less 24 hours rience continuing	hours minutes	}	hours minu	utes	hours minu	tes
Expe	rience continuing ad of study						
Course	Continuous? - if no, number of episodes	☐ Yes ☐ No - ☐		<ul><li>☐ Yes</li><li>☐ No -</li></ul>		☐ Yes ☐ No -	
Intensity	1 Mild 2 Moderate 3 Severe						
Action Taken on Study Medication	1 None 2 Dose decreased 3 Dose increased						
Suspected Relationship To Study	3 Probably						
Medication	unrelated 4 Unrelated If yes, record				Yes		Yes
Corrective Therapy	on Concomitant Medication form	☐ Ye			No		No
adverse exp definitions	sider this a serious erience by the on previous page? , report experience	□ No		1	Yes No		Yes No
to SB within	by telephone 24 hours	AE Number		AE Number		AE Number	
	's Signature					If patient complete I	died, Form D

Project	Protocol	Center	Patient Number	Page
29060	329	0,0		230

Record in standard medical terminology any adverse experience observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit?" Mark appropriate boxes (one experience per column).							
Experience							
For Smith	Kline Beecham						
Date Start	ed	day month year	day month year	day month year			
Date Stopp	oed	day month year	day month year	day month year			
than	tion if less 24 hours	hours minutes	hours minutes	hours minutes			
Experience continuing Experience continuing at end of study							
Course	Continuous? - if no, number of episodes	☐ Yes ☐ No - ☐	☐ Yes ☐ No - ☐	☐ Yes ☐ No - ☐			
Intensity	<ul><li>1 Mild</li><li>2 Moderate</li><li>3 Severe</li></ul>						
Action Taken on Study Medication	1 None 2 Dose decreased 3 Dose increased 4 Drug stopped						
Suspected Relationship To Study Medication	1 Related 2 Possibly related 3 Probably unrelated 4 Unrelated						
Corrective Therapy	If yes, record on Concomitant Medication form	☐ Yes	☐ Yes	☐ Yes			
Do you consider this a serious adverse experience by the definitions on previous page?		□ No	☐ Yes ☐ No	☐ Yes ☐ No			
to SB within	report experience by telephone 24 hours	AE Number	AE Number	AE Number			
Investigator	's Signature			If patient died,			

Project	Protocol	Center	Patient Number	Page
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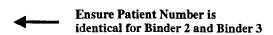
Recor follow treats	d in standard med ving direct question nent or since the	lical terminology any ac n to patient: "Do you f last visit?" Mark appro	lverse experience observ feel different in any wa opriate boxes (one exper	ed or elicited by the y since starting the ience per column).
Experience				
For Smith	Kline Beecham			
Date Start	ed	day month year	day month year	day month year
Date Stopped		day month year	day month year	day month year
than	tion if less 24 hours rience continuing	hours minutes	hours minutes	hours minutes
Expe	rience continuing id of study			
Course	Continuous? - if no, number of episodes	☐ Yes ☐ No - ☐	☐ Yes ☐ No - ☐	☐ Yes ☐ No -
Intensity	<ol> <li>Mild</li> <li>Moderate</li> <li>Severe</li> </ol>			
Action Taken on Study Medication	<ol> <li>None</li> <li>Dose decreased</li> <li>Dose increased</li> <li>Drug stopped</li> </ol>			
Suspected Relationship To Study Medication	1 Related 2 Possibly related 3 Probably unrelated			
Corrective Therapy	4 Unrelated  If yes, record on Concomitant Medication form	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
adverse expe definitions o	sider this a serious rience by the n previous page? report experience	□ Yes □ No	☐ Yes ☐ No	☐ Yes ☐ No
to SB within	by telephone 24 hours	AE Number	AE Number	AE Number
Investigator'	s Signature			If patient died,

Project	Protocol	Center	Patient Number	Page
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## ACUTE PHASE CONCLUSION

	o to Binder 3 - Ensure the preprinted Patient Number is identical o the Patient Number assigned in this phase.
□ No	o the Patient Number assigned in the Patient
<b>♦</b> If '	No', mark the ONE most appropriate category
1	☐ Adverse experience (complete Adverse Experience section)
2	☐ Lack of efficacy
3	☐ Deviation from protocol (including non-compliance)
4	☐ Lost to follow-up
6	☐ Termination by sponsor
1 1	
7	☐ Other
	ason for withdrawal:
Comments on re	ason for withdrawal:
Comments on re	eason for withdrawal: sit day month year
Date of Last Vi	sit day month year

Project	Protocol	Center	Patient Number
29060	329	0	



### **CONFIDENTIAL**

### CASE REPORT FORM

PROTOCOL 29060/329

### **CONTINUATION PHASE - BINDER 3**

A Multi-Center, Double-Blind, Placebo Controlled Study of Paroxetine and Imipramine in Adolescents with Unipolar Major Depression

Patient Initials Country	
--------------------------	--

### **GENERAL INSTRUCTIONS**

Print clearly in CAPITAL LETTERS using a black ball-point pen and press firmly so that all copies are legible. DO NOT print in shaded areas. Answer all questions on every page.

The plastic writing board in the back of the binder should be used to divide each set of pages before writing on them with a ball-point pen.

Errors should be crossed with a single line and the alteration made as close to the original as possible. All alterations must be printed, initialled and dated.

#### DATE

Use the following three-letter abbreviations for month:

= JAN January February = FEB = MARMarch = APR April = MAY May = JUN June July = JUL = AUG August September = SEP = OCT October November = NOV December = DEC

Example:  $\begin{bmatrix} 0 & 1 & J & A & N & 9 & 3 \\ day & month & year \end{bmatrix}$  = 1st January 1993

#### TIME

Unless specified otherwise, use the 24 hour clock: 00:00 - 23:59.

Example:  $\frac{ | 1 | 5 | 3 | 0 }{ 24 \text{ hr. clock} } = 3:30 \text{ p.m.}$ 

#### ADVERSE EXPERIENCE DEFINITIONS

#### INTENSITY

Mild

Adverse experience which is easily tolerated.

Moderate

Adverse experience sufficiently discomforting to interfere with daily activity.

Severe

Adverse experience which prevents normal everyday activities.

#### SUSPECTED RELATIONSHIP TO STUDY MEDICATION

Related

There is a direct cause and effect relationship between the adverse

experience and the study drug.

Possibly Related

A direct cause and effect relationship between the drug and the adverse experience has not been demonstrated but is possible or likely.

Probably Unrelated

Cause and effect relationship between the drug and the adverse

experience has not been demonstrated, is improbable but not impossible.

Unrelated

The adverse experience is definitely not related to the test drug.

#### SERIOUS ADVERSE EXPERIENCE

A serious adverse experience is any experience which:

- Is fatal
- Is life threatening
- Is permanently or temporarily disabling
- Is incapacitating
- Results in hospitalization
- Prolongs a hospital stay
- Is associated with congenital abnormality, carcinoma or overdose

In addition, any experience which the investigator regards as serious or which would suggest any significant hazard, contraindication, side effect or precaution that may be associated with the use of the drug should be reported as a serious experience.

- Use each form for a maximum of three experiences.
- All questions on the Adverse Experience form should be completed.

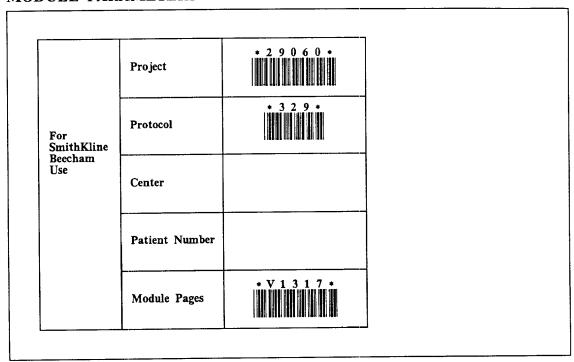
### SMITHKLINE BEECHAM PROTOCOL 29060/329 - SCHEDULE OF PROCEDURES

Assessments	Bas	eline			,	Acute	Pha	se			C	ntinı	uation	ı Pha	ıse	
Time (weeks)	-1	0	1	2	3	4	5	6	7	8	12	16	20	24	28	32
Informed Consent	•						ļ									
Medical History and Physical Exam	•															
Clinical Laboratory Studies	• 1									•			•			•
Serum Pregnancy	•		• 2													
ECG	•			•		•		•		•			•			•
Vital Signs	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Hamilton Depression Scale	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Full K-SADS-L	•															•
Affect Section of K-SADS-L		•		•		•		•		•	•	•	•	•	•	
C-GAS	•															
CGI		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
SADS-L	•															
FH-FHE	•															
Autonomous Functioning Checklist	•									•						•
Self Perception Profile	•									•						•
Sickness Impact Scale	•									•						•
Randomization		•														
Adverse Experiences		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Supportive Psychotherapy		•	•	•	•	•	•	•	•	•	•	•	•	•	•	•
Plasma Sampling for Drug Analysis	•					•				•				•		•
Study Medication Record			•	•	•	•	•	•	•	•	•	•	•	•	•	•
Concomitant Medication	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•	•

Clinical laboratory studies should include a Urine Drug Screen
 On suspicion of pregnancy

Project	Protocol	Center	Patient Number	Visit	
29060	329	0,0		Continuation Phase	

### **MODULE PARAMETERS - WEEK 12**



Project	Protocol	Center	Patient Number	Visit	Visit Date	Page
29060	329	0 0		Continuation Phase Week 12	day month year	233

### **VITAL SIGNS**

TT		Sitting		Standing					
Weight □ lbs □ kg		Blood Pressure (mmHg) systolic diastolic			Pressure nHg) diastolic	Pulse (beats/ min)			
. [4]	1	/			/  , ,				

## ADVERSE EXPERIENCES / CONCOMITANT MEDICATION

Have patie	e any adverse experiences been observed or elicited by the following direct question to the ent: "Do you feel different in any way since starting the treatment or since the last visit"
	☐ Yes ☐ No
	Record in the Adverse Experience section
Has	there been any change in concomitant medication since the last visit?
	Yes  No
	Record in the Concomitant Medication section

# CLINICAL GLOBAL IMPRESSIONS - GLOBAL IMPROVEMENT

treatn	ent.	otal improvement whether or not, in your judgment, it is due enting Compared to his/her condition at admission to the study, how managed?	luch has the
='		anged?	
	1	= Very much improved	
	2	= Much improved	
Ē	3	= Minimally improved	
	] 4	= No change	
	5	= Minimally worse	
Г	6	= Much worse	
_		= Very much worse	

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# HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 1 OF 3

1.	Depressed Mood (sadness, hopelessness, helpless, worthless)
	2 = These feeling states spontaneously reported verbally 3 = Communicates feeling states non-verbally, i.e., through facial
	expression, posture, voice and tendency to weep  4 = Patient reports virtually only these feeling states in his/her spontaneous verbal and non-verbal communication
2.	Feelings of Guilt
	<ul> <li>□ 0 = Absent</li> <li>□ 1 = Self reproach, feels he/she has let people down</li> <li>□ 2 = Ideas of guilt or rumination over past errors or sinful deeds</li> <li>□ 3 = Present illness is a punishment. Delusions of guilt</li> <li>□ 4 = Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations</li> </ul>
3.	Suicide
	<ul> <li>□ 0 = Absent</li> <li>□ 1 = Feels life is not worth living</li> <li>□ 2 = Wishes he/she were dead or any thoughts of possible death to self</li> <li>□ 3 = Suicide ideas or gesture</li> <li>□ 4 = Attempts at suicide (any serious attempt rates 4)</li> </ul>
4.	Insomnia Early
	<ul> <li>□ 0 = No difficulty falling asleep</li> <li>□ 1 = Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour</li> <li>□ 2 = Complains of nightly difficulty falling asleep</li> </ul>
5.	Insomnia Middle
	<ul> <li>0 = No difficulty</li> <li>1 = Patient complains of being restless and disturbed during the night</li> <li>2 = Waking during the night - getting out of bed rates 2 (except for purposes of voiding)</li> </ul>
_	To a contract Today
6.	Insomnia Late
6.	☐ 0 = No difficulty ☐ 1 = Waking in early hours of the morning but goes back to sleep ☐ 2 = Unable to fall asleep again if he/she gets out of bed
	☐ 0 = No difficulty ☐ 1 = Waking in early hours of the morning but goes back to sleep
	□ 0 = No difficulty □ 1 = Waking in early hours of the morning but goes back to sleep □ 2 = Unable to fall asleep again if he/she gets out of bed  Work and Activities □ 0 = No difficulty □ 1 = Thoughts and feelings of incapacity, fatigue or weakness related to activities;
	□ 0 = No difficulty □ 1 = Waking in early hours of the morning but goes back to sleep □ 2 = Unable to fall asleep again if he/she gets out of bed  Work and Activities □ 0 = No difficulty □ 1 = Thoughts and feelings of incapacity, fatigue or weakness related to activities;

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	1
8.	Retardation (slowness of thought and speech, impaired ability to concentrate; decreased motor activity)
	<ul> <li>□ 0 = Normal speech and thought</li> <li>□ 1 = Slight retardation at interview</li> <li>□ 2 = Obvious retardation at interview</li> <li>□ 3 = Interview difficult</li> <li>□ 4 = Complete stupor</li> </ul>
9.	Agitation
	<ul> <li>□ 0 = None</li> <li>□ 1 = Fidgetiness</li> <li>□ 2 = "Playing with" hands, hair, etc.</li> <li>□ 3 = Moving about, can't sit still</li> <li>□ 4 = Hand wringing, nail-biting, hair-pulling, biting of lips</li> </ul>
10.	Anxiety Psychic
	<ul> <li>□ 0 = No difficulty</li> <li>□ 1 = Subjective tension and irritability</li> <li>□ 2 = Worrying about minor matters</li> <li>□ 3 = Apprehensive attitude apparent in face or speech</li> <li>□ 4 = Fears expressed without questioning</li> </ul>
11.	Anxiety Somatic (physiological concomitants of anxiety such as: Gastrointestinal (dry mouth, wind, indigestion, diarrhea, cramps, belching), Cardiovascular (palpitations, headaches), Respiratory (hyperventilation, sighing), Urinary frequency, Sweating.
	<ul> <li>□ 0 = Absent</li> <li>□ 1 = Mild</li> <li>□ 2 = Moderate</li> <li>□ 3 = Severe</li> <li>□ 4 = Incapacitating</li> </ul>
12.	Somatic Symptoms Gastrointestinal
	<ul> <li>□ 0 = None</li> <li>□ 1 = Loss of appetite but eating. Heavy feelings in abdomen</li> <li>□ 2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms</li> </ul>
13.	Somatic Symptoms General
	<ul> <li>□ 0 = None</li> <li>□ 1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability</li> <li>□ 2 = Any clear-cut symptoms rates 2</li> </ul>
14.	Genital Symptoms (such as loss of libido and menstrual disturbances)
	<ul> <li>□ 0 = Absent</li> <li>□ 1 = Mild</li> <li>□ 2 = Severe</li> </ul>

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15.	Hypochondriasis
	<ul> <li>□ 0 = Not present</li> <li>□ 1 = Self-absorption (bodily)</li> </ul>
	2 = Preoccupation with health
	☐ 3 = Frequent complaints, requests for help, etc. ☐ 4 = Hypochondriacal delusions
16.	Loss of Weight
	0 = No weight loss
	☐ 1 = Slight or doubtful loss of weight ☐ 2 = Obvious or severe loss of weight
17	
17.	Insight
	<ul> <li>□ 0 = Acknowledges being depressed and ill</li> <li>□ 1 = Acknowledges illness but attributes cause to bad food, climate, over-work, virus,</li> </ul>
	need for rest, etc.
	2 = Denies being ill at all
•	HAMD Score (Items 1-17)

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RESSED MOOD  Worst Severity of Current Episode:	(0) NI	(I) NO	(2) SLT	MLD	(4) MO	(5) SVR	(6) EX	(7) VEX
Duration of Current Episode:		# of we	eks					
Worst Severity of Last Two Weeks:	(0) NI	(I) NO	(2) SLT	MLD	(4) MO	(5) SVR	(6) EX	(7) VEX
Frequency:	Days	s/week						
Average % time of the day:		] %						
PRESSED APPEAR	ANCE							
Current Episode:	(0) NI	(1) NO	SLT	MLD	(4) MO	(5) SVR	(6) EX	
Last Two Weeks:	(0) NI	NO NO	SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
RITABILITY AND	ANGER							
Current Episode:	(0) NI	NO NO	(2) SLT	MLD	(4) MO	(5) SVR	(6) EX	(7) VEX
Duration:		」# of w	eeks					
Last Two Weeks:	(0) NI	NO NO	(2) SLT	MLD	(4) MO	(5) SVR	(6) EX	VEX
Frequency:	∐ Day	/s/week						
Average % time of the day:		<b>%</b>						
PARATION-DEPE	NDENT-I	YSPHOR	<u>UA</u>					
Current Episode:	(0) NI	(1) NO	(2) OCC	(3) USL	(4) ALW			
Last Two Weeks:	(0) NI	(1) NO	occ	USL	(4) ALW			
	Worst Severity of Current Episode:  Duration of Current Episode:  Worst Severity of Last Two Weeks:  Frequency:  Average % time of the day:  PRESSED APPEAR  Current Episode:  Last Two Weeks:  RITABILITY AND  Current Episode:  Duration:  Last Two Weeks:  Frequency:  Average % time of the day:  PARATION-DEPE	Worst Severity of Current Episode:  Duration of Current Episode:  Worst Severity of Last Two Weeks:  Frequency:  Day:  Average % time of the day:  PRESSED APPEARANCE  Current Episode:  Last Two Weeks:  NI  RITABILITY AND ANGER  Current Episode:  Duration:  Duration:  Last Two Weeks:  NI  Frequency:  Day:  Average % time of the day:  PARATION-DEPENDENT-I  Current Episode:  OOD NI  Day:  PARATION-DEPENDENT-I  Current Episode:  OOD NI  Current Episode:  OOD NI  Current Episode:  OOD NI  OOD NI  Current Episode:  OOD NI  OOD NI  Current Episode:  OOD NI  OOD NI  Current Episode:  OOD NI  OOD NI  Current Episode:  OOD NI  OOD NI  OOD NI  OOD NI  OOD NI  OOD NI  OOD NI  OOD NI  OOD NI  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day:  Last Two Weeks:  NI NO SLT  PRESSED APPEARANCE  Current Episode:  NI NO SLT  Last Two Weeks:  NI NO SLT  RITABILITY AND ANGER  Current Episode:  Duration:  Duration:  Frequency:  Days/week  Average % time of the day:  Duration:  Frequency:  Days/week  Average % time of the day:  PARATION-DEPENDENT-DYSPHORIA  Current Episode:  NI NO SLT  (2) (2) (2) (3) (4) (5) (5) (6) (7) (7) (7) (7) (7) (7) (7) (7) (7) (7	Worst Severity of Current Episode:  Duration of Current Episode:  Worst Severity of Last Two Weeks:  Worst Severity of Last Two Weeks:  Worst Severity of Last Two Weeks:  NI NO SIT MILD  Frequency:  Days/week  Average % time of the day:  Current Episode:  NI NO SIT MILD  Current Episode:  NI NO SIT MILD  Current Episode:  NI NO SIT MILD  Current Episode:  NI NO SIT MILD  Current Episode:  NI NO SIT MILD  Current Episode:  NI NO SIT MILD  Current Episode:  NI NO SIT MILD  Current Episode:  Duration:  Frequency:  Days/week  Average % time of the day:  PARATION-DEPENDENT-DYSPHORIA  Current Episode:  NI NO COCC USE	Worst Severity of Current Episode:  Duration of Current Episode:  Worst Severity of Last Two Weeks:  NI NO SLT MLD MO  PRESSED APPEARANCE  Current Episode:  NI NO SLT MLD MO  RITABILITY AND ANGER  Current Episode:  On NI NO SLT MLD MO  RITABILITY AND ANGER  Current Episode:  NI NO SLT MLD MO  RITABILITY AND ANGER  Current Episode:  On NI NO SLT MLD MO  RITABILITY AND ANGER  Current Episode:  On NI NO SLT MLD MO  Frequency:  Days/week  Average % time of the day:  PARATION-DEPENDENT-DYSPHORIA  Current Episode:  On NI NO OCC USL ALW	Worst Severity of Current Episode:  Duration of Current Episode:  Worst Severity of Current Episode:  Worst Severity of Last Two Weeks:  No Sur Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Mo Syr Milb Milb Mo Syr Milb Milb Mo Syr Milb Milb Milb Milb Milb Milb Milb Milb	Worst Severity of Current Episode:

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							···
QUALITY OF DYPSH	ORIC MO	OD					<u>-</u> -
9. Current Episode:	(0) NI	(I) ND	(2) QUE	(3) DDF	(4) VDF		:
10. Last Two Weeks:	(0) NI	(1) ND	QUE	DDF	(4) VDF		
DEGREE OF ASSOCIA	ATION OF	DEPRES	SED OR I	RRITABL	E MOOD	WITH SP	ECIFIC
EVENTS OR PREOCO	UPATION	<u>S</u>					_
11. Current Episode:	(0) NI	(I) NAL	(2) MOT	(3) UN	(4) PN		
12. Last Two Weeks:	(0) NI	(I) NAL	(2) MOT	(3) UN	(4) PN		
REACTIVITY OF DE	PRESED	OR IRRIT	ABLE MO	OOD			
13. Current Episode:	(0) NI	VR	FUL	RES	(4) MLD	SLT	(6) UNR
		% Usual	% of Nor	mal			
14. Last Two Weeks:	(0)	VR	FUL.	RES	MLD	(5) SLT	UNR
			% of No				
			mum % of				
		Number of	of hours go	ood feeling	last		
DIURNAL MOOD VA	ARIATION						
Worse in Morning							
15. Current Episode:	(0) NI	NW	MIN	MLD	(4) CW	EXT	
16. Last Two Weeks:	(0) NI	(I) NW	MIN	MLD	CW	EXT	
Worse in Afternoon a							
17. Current Episode:	(0) NI	NW (1)	(2) MIN	MLD	CW CW	EXT	- '
18. Last Two Weeks:	(0)	(I) NW	MIN	MLD	(4) CW	EXT	

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EXCESSIVE INAPPRO	PRIATE	GUILT					en."	
19. Current Episode:	(0) NI	NO (1)	SLT	(3) MLD	(4) MOD	SVR	EXT	
20. Last Two Weeks:	(0) NI	NO NO	SLT	MLD	MOD	(5) SVR	EXT	
Frequency:	Days/We	ek _						
NEGATIVE SELF IM	<u>AGE</u>			0				
21. Current Episode:	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT	
22. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT	
FEELING UNLOVED,	/FORLO	<u>en</u>						
22	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT	ļ
23. Current Episode:	(0) NI	(I)	(2) SLT	(3) MLD	(4) MOD	(3) SVR	(6) EXT	
24. Last Two Weeks:  Frequency:	Days/W		[361]	HILL	<u> </u>	<u> </u>	2717	
Frequency.	Days! W	<b>ω</b> . [						
HOPELESSNESS, HEL	PLESSNI	ESS, DISC	OURAGEN	MENT, PE	<u>SSIMISM</u>			
25. Current Episode:	(0)	(I) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT	
25. Current Episode: 26. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT	
	[11]	<u> </u>	[321]					
SELF-PITY								
27. Current Episode:	(0) NI	(1) NO	(2) OCC	(3) MLD	CON			
28. Last Two Weeks:	(O) NI	(1) NO	(2) OCC	MLD	CON			
ACTIEC AND DAINE								
ACHES AND PAINS	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT	
29. Current Episode:	(0) NI	(I)	(2)   SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT	
30. Last Two Weeks:	NI	וטאן	arı,	INITIA	<u> </u>	2.75		

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HYPOCHONDRIASIS							er T	
31. Current Episode:	(0) NI	(1) NO	(2) SLT	MLD	(4) MOD	(5) SVR	(6) EX	
32. Last Two Weeks:	(0) NI	NO NO	SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX	
ANHEDONIA, LACK	OF INT	EREST, AP	ATHY, L	OW MOT	IVATION,	BOREDO	M	
Combined Overall Ratio		····	<u> </u>				_	
33. Current Episode:	(0) NI	(1) NO	SLT	MLD	(4) MO	SVR	(6) EX	
Duration:	L	# of w	veeks					
34. Last Two Weeks:	(0) NI	(1) NO	SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
Frequency:	I	Days/week						
Average % time of the day:	<u></u>	<u></u> %						
Differentiating Lack	of Inter	rest from A	Inhedonia					
Lack of Interest	TOT	[ <del>-</del> 00]	(2)	(3)	[T47]	[1(5)]	ாரை	
35. Current Episode:	NI	NO	SLT	MLD	<u>MO</u>	SVR	EX	
36. Last Two Weeks:	(0)	(1) NO	SLT	MLD	мо	SVR	(6) EX	
Anhedonia								
37. Current Episode:	(0) NI	NO NO	SLT	MLD	(4) MO	SVR	(6) EX	
38. Last Two Weeks:	(0) NI	(I) NO	SLT	(3) MLD	(4) MO	SVR	(6) EX	
FATIGUE, LACK OF	ENERG	Y AND TI	REDNESS					
39. Current Episode:	(0) NI	(I)	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
40. Last Two Weeks:	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
Frequency:	I	Days/Week						

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DIF	DIFFICULTY CONCENTRATING, INATTENTION, OR SLOWED THINKING										
41.	Current Episode: (0) NI	N N	0	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX			
42.	Last Two Weeks: (0) NI	N N	0	(2) SLT	(3) MLD	(4) MO	SVR	(6) EX			
PSY	CHOMOTOR AGITATI	<u>:ON</u>						:			
43.	Current Episode: NI		(O	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX			
	Last Two Weeks: NI		10	SLT	(3) MLD	(4) MO	(5) SVR	(6) EX			
	Frequency:	Days/W	eek								
MA	NIFESTATIONS INCLU	J <b>DED</b> :									
	Unable to sit still										
45.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR				
46.	Last Two Weeks:	(0) NI	(I) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR				
	Basina										
	Pacing	י הארן	Lun	<del>  1751  </del>	[(3)]	(4)	ाडा ।	1			
47.	Current Episode:	(0) NI	(I) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR				
48.	Last Two Weeks:	(0) NI	(I) NPR	DBT	(3) PR	SVR	(5) SVR				
	Hand wringing										
49.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	SVR	SVR				
50.	Last Two Weeks:	(0) NI	(I) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR	]			
	Pulling or rubbing on i	iair clas	hino •1	in							
					[(3)]	(4)	(5)	1			
51.	Current Episode:	NI (0)	(1) NPR	(2) DBT		SVR	(5) SVR				
52.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	PR	(4) SVR	(5) SVR	7			
	Can't stop talking, talk	s on and	! on								
53.	Current Episode:	(0) NI	(I) NPR	(2) DBT	(3) PR	SVR	(5) SVF	1			
54.	Last Two Weeks:	(0) NI	(1) NPR	DBT	(3) PR	(4) SVR	(5) SVI				

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PSYC	CHOMOTOR RETARI	DATION					-		
55.	Current Episode:	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
56.	Last Two Weeks:	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
	Frequency:	Day	ys/Week						
MAN	HIFESTATIONS INCL	UDED:							
3	Slowed Speech								
57.	Current Episode:	NI	NPR	DBT	PR	MOD	SVR		
58.	Last Two Weeks:	(0) NI	(1) NPR	DBT	PR	MOD	(5) SVR		
1	Increased pauses before								
59.	Current Episode:	(0) NI	NPR	DBT	PR	MOD	(5) SVR		
60.	Last Two Weeks:	(0) NI	(I) NPR	DBT	PR	(4) MOD	(5) SVR		
1	Low or monotonous spe	ech							
61.	Current Episode:	(0) NI	(I) NPR	DBT	PR	(4) MOD	SVR		
62.	Last Two Weeks:	(0) NI	(1) NPR	DBT	(3) PR	(4) MOD	(5) SVR		
1	Mute or markedly dec	reased an	nount of s	peech					•
63.	Current Episode:	(0) NI	(I) NPR	DBT	PR	(4) MOD	(5) SVR		
64.	Last Two Weeks:	(0) NI	(I) NPR	(2) DBT	PR	(4) MOD	SVR		
	Slowed body movement	:s							
65.	Current Episode:	(0) NI	(I) NPR	DBT	(3) PR	MOD	SVR		
66.	Last Two Weeks:	(0) NI_	(1) NPR	DBT	PR	MOD	(5) SVR		
	Depressive stupor								
67.	Current Episode:	(0) NI	(1) NPR	(2) DBT	PR	(4) MOD	(5) SVR		
68.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR		
vo.	2001 1 110 1100231	141	[HEK]	וומכו	ندعا		(VIA)		

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SOCIAL WITHDRAWA	ΛΙ					_'
		[727]	[(3)]	[47]	<b>[</b> (5)]	[767]
69. Current Episode:	(I) NI NO	SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
70. Last Two Weeks:	(0) NI NO	(2) SLT	(3) MLD	(4) MO	SVR	(6) EX
REJECTION SENSITIV						
71. Last Year:	(0) NI NO	(2) SLT	(3) MLD	MOD	SVR	(6) EX
72. Current Episode:	(0) NI NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
73. Last Year:	(0) NI NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
74. Current Episode:	(0) NI NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
SLEEP PROBLEMS						
75. Hours sle	ot before onset of	depression				
76. Hours sle	ot during the curre	ent episode				
77. Hours sle	pt during the last	two weeks				
HYPERSOMNIA						
78. Hours sle	pt in daytime of c	urrent episo	de			
79. L Hours sle	pt in daytime in th	he last two	weeks			
80. L Hours lyin	ng down in curren	t episode				
81. Hours lyin	ng down in last tv	vo weeks				
93 Ournet British	(0) NI NO	(2)	(3)	(4)	(5)	(6)
82. Current Episode:				<u> </u>		
83. Last Two Weeks:	(0) NI NO	(2)	(3)	(4)	(5)	(6)

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INCO	MANUA A					· · ·	×*
1NSO 84.	MNIA  Current Episode: (0) NI	(I) NO	(2)	(3)	(4)	(5)	(6)
	Last Two Weeks: (6) NI	(I) NO	(2)	(3)	(4)	(5)	(6)
	Frequency:	Nights/Wee	k				
TYP	ES OF INSOMNIA						
	Initial Insomnia						
86.	Current Episode:	(0) NI	(1) NPR	DBT	MLD	(4) MOD	SVR
87.	Last Two Weeks:	(0)	(I) NPR	DBT	MLD	MOD MOD	(5) SVR
	Middle Insomnia						men.
88.	Current Episode:	(0) NI	(I) NPR	DBT	MLD	MOD	SVR
89.	Last Two Weeks:	NI	(1) NPR	DBT	MLD	MOD	SVR
	Terminal Insomnia						·
90.	Current Episode:	(0) NI	(I) NPR	DBT	MLD	MOD	SVR
91.	Last Two Weeks:	(0) NI	NPR	DBT	(3) MLD	MOD	SVR
	Circadian Reversal			-		<del>- 787 1</del>	<del></del>
92.	Current Episode:	NI NI	(I) NPR	DBT	MLD	(4) MOD	SVR
93.	Last Two Weeks:	NI (0)	(1) NPR	(2) DBT	MLD	(4) MOD	SVR
	Non-restorative sleep			[78]	F-127-1	<b>□74</b> 11	785
94.	Current Episode:	(0) NI	(I) NPR	(2) DBT	MLD	MOD	(5) SVR
95.	Last Two Weeks:	(0) NI	(1) NPR	DBT	(3) MLD	MOD	SVR
	Daytime sleepiness	(TO)	<u> [m]</u>	17277		<u> </u>	(5) SVR
96.	Current Episode:	(0) NI	(1) NPR	(2) DBT	MLD (3)	(4) MOD	<del></del>
97.	Last Two Weeks:	NI (0)	NPR	DBT	MLD	MOD	SVR

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ANOREXIA  98. Current Episode:  99. Last Two Weeks:	(0) NI (0)	(I) NO	(2) SLT (2) SLT	(3) MLD (3) MLD	(4) MOD (4) MOD	(5) RAR (5) RAR	(6) NVR (6) NVR
WEIGHT LOSS  100. Current Episode: Pounds lost: Number of Weeks: 101. Last Two Weeks: Pounds lost:							
INCREASED APPETIT  102. Current Episode:  103. Last Two Weeks:  Frequency:	(0) NI (0) NI (1)	(1) NO (1) NO Days/Weel	(2) SLT (2) SLT	(3) MLD MLD	MOD MOD	(5) SVR (3) SVR	(6) EX
STRONG CRAVING F  104. Current Episode:  105. Last Two Weeks:	(0) NI	EETS (1) ABS	(2) DBT (2) DBT	(3) MLD (3) MLD	(4) (MOD (MOD	(5)  SVR   (5)  SVR	
WEIGHT GAIN  106. Current Episode: Pounds gained: Number of Weeks: 107. Last Two Weeks:		lbs.					
Pounds gained:	: [	lbs.					

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								<del></del>
SUICIDAL IDEATION	<u>I</u>							
108. Current Episode:	(O) NI	NO	SLT	MLD	(4) MO	(5) SVR	(6) EX	(7) VEX
109. Last Two Weeks:	(0) NI	(I) NO	(2) SLT	MLD	(4) MO	(5) SVR	(6) EX	VEX
Suicidal Acts - Numbe	r							
110. Current Episode:								
111. Last Two Weeks:								
Suicidal Acts – Seriou	sness							
112. Current Episode:	(0) NI	(1) NO	(2) MIN	(3) DEF	(4 SE	R R	(5) VS	EXT
113. Last Two Weeks:	(0) NI	(1) NO	(2) MIN	(3) DEF	SE	R	(5) VS	(6) EXT
Medical Lethality								
114. Current Episode	(0) NI	NO (1)	MIN	MLD	(4 M	0	SVR	(6) EXT
115. Last Two Weeks:	(0) NI	(I) NO	MIN	(3) MLD	(4 M	0	(5) SVR	(6) EXT
Non-Suicidal Physical	Self-De	emaging .	Acts					
116. Current Episode:	(0)	(1) NO	(2) SLT	(3) MLD		0	(5) SVR	(6) ACT
117. Last Two Weeks:	(O)	(I) NO	(2) SLT	(3) MLD	(4 M	0	(5) SVR	(6) ACT

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						<del></del>			
MANIC SYNDROME	<u>.</u>								
ELATION, EXPANSI	VE MOO	<u>D</u>							
1. Current Episode:	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX		
2. Last Two Weeks:	(0) NI	NO NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX		
DECREASED NEED	FOR SLE	<u>EP</u>							
3. Current Episode:	(0) NI	(1) NO	(2) -1	(3) -2	(4) -3	(5)	(6) -4+		
4. Last Two Weeks:	(O) NI	(1) NO	(2) -1	(3) -2	(4) -3	(5) -4	(6) -4+		
UNUSUALLY ENERG	GETIC								
5. Current Episode:	NI (Q)	(I) NO	(2) SLT	(3) LCH	(4) MOR	(5) MM	(6) UA		
6. Last Two Weeks:	(0)	(1) NO	(2) SLT	LCH	MOR	(5) MM	(6) UA		
INCREASE IN GOAL	L DIREC	TED ACT	IVITY						
7. Current Episode:	(0) NI	(I) NO	(2) SLT	MLD	(4) MO	(5) MKD	(6) EX		
8. Last Two Weeks:	(0) NI	(I) NO	(2) SLT	MLD	(4) MO	(5) MKD	(6) EX		
GRANDIOSITY									
9. Current Episode:	(0) NI	(I) NO	(2) SLT	MLD	(4) MO	(5) SVR	(6) EX		
10. Last Two Weeks:	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX		
ACCELERATED, PR	ESSURED	OR INC	CREASED	AMOU	NT OF S	PEECH			
11. Current Episode:	(0) NI	NO NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX		
12. Last Two Weeks:	(0) NI	(I) NO	SLT	MLD	(4) MO	(5) MKD	(6) EX		
							_	-	

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RACING THOUGHT	<u>'S</u>							<i>⊒</i>	
13. Current Episode	(0) NI	(I)	(2) DBT	(3) MLD	(4) MO	(5) \$VR	(6) EX		
14. Last Two Weeks	: (0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	(6) EX		
FLIGHT OF IDEAS	_								
15. Current Episode	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX		
16. Last Two Weeks	s: (0)	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX		
POOR JUDGEMEN	<u>r</u>								
17. Current Episode	e: (0)	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) VS		
18. Last Two Weeks	s: (0)	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) VS		
DISTRACTABILITY	<u>.</u>								
19. Current Episode	e: (0)	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR			
20. Last Two Week	s: (0) NI	NO NO	(2) SLT	MLD	(4) MO	(5) SVR			
MOTOR HYPERAC	TIVITY								
21. Current Episod	e: (0) NI	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX		
22. Last Two Week	s: (0)	NO NO	(2) SLT	(3) MLD	(4) MO	MKD	(6) EX		
Inappropriate laug	hing, jokin								
23. Current Episod		NO NO	DBT	(3) MLD	MOD				
24. Last Two Week	(S: NI	NO (1)	DBT	MLD	MOD				
Uninhibited people	seeking, g								
25. Current Episod		(I) NO	DBT	MLD	(4) MOD				
26. Last Two Week	(S: (0)	(I) NO	DBT	(3) MLD	MOD		<u></u>		

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Inci	reased Productivity					
27.	Current Episode:	(0) NI	NO NO	DBT	PRS	SVR
28.	Last Two Weeks:	(0) NI	(I) NO	DBT	PRS	SVR
Sha	rpened and unusual	lly creat	ive thinki	ng		
29.	Current Episode:	(0) NI	(1)	(2) DBT	(3) PRS	(4) SVR
30.	Last Two Weeks:	(0) NI	(1) NO	(2) DBT	PRS	(4)] SVR
Ну	persexuality					
31.	Current Episode:	(0) NI	(1) NO	(2) DBT	PRS	SVR
32.	Last Two Weeks:	(0) NI	(I) NO	DBT	PRS	SVR
INF	LUENCE OF ILL	CIT DR	ugs or	ALCOH	<u>OL</u>	
33.	Current Episode:	(0) NA	(1) NVR	(2) SMT	(3) ONL	
34.	Last Two Weeks:	(0) NA	(1) NVR	(2) SMT	ONL	
NU	MBER OF MANIC	PERIO	DS			
35.						

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#### STUDY MEDICATION RECORD

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily	
. 1				

#### STUDY MEDICATION DOSING CHANGES

<ul><li>□ No</li><li>□ Yes ——</li></ul>	→ Indicate cha			
LJ res ——		mac(c) hold	O. W	
	Indicate cha	mge(2) per	UW	
	Reminder:	Changes	in dose constitu	e deviation from the protocol
	Reminuel:	Cuanges	in dose constitu	c actiation from the protocol
			Number of	
Start Date	End Date	Dose	Number of Capsules	Day Change
Start Date day month year	End Date day month year	Dose Level		Reason for Dose Change
			Capsules	Reason for Dose Change

#### STUDY MEDICATION COMPLIANCE

Capsules Dispensed (A)	Capsules Returned (B)	Capsules Taken (A - B)	Days Since Last Visit	% Compliance			
Con	tient been	$(N \times x)$ ust be $\geq 8$	of capsules days since l  o and  ident for two	ast visit) x	100	*N=	number of capsules dail (see above)

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#### STUDY MEDICATION LABEL

	EDICATION	EABEE		Ψ
		Attach label here		
		Attach label here		
		Attach label here		
		Attach label here		
<b>▶</b> Enter	patient number	(drug code as listed on clin	ical supplies)	

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#### STUDY MEDICATION DISPENSING

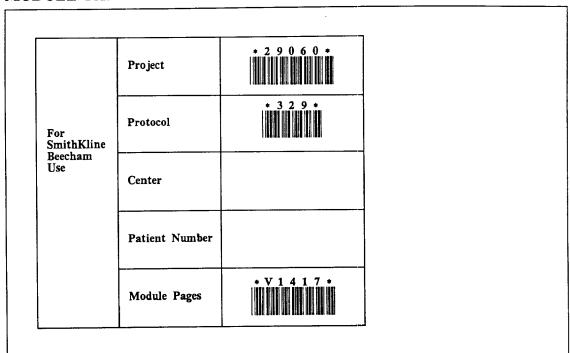
Record study medication information for Weeks 13-16 in the Study Medication Record, page 270. Attach label(s) to page 271. Record number of capsules dispensed on page 270.

<u>Reminder:</u> The drug code on the study medication label must be identical to the preprinted Patient Number above.

### SMITHKline Beecham Pharmaceuticals

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### MODULE PARAMETERS - WEEK 16



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#### **VITAL SIGNS**

VI7 - ! - l- 4		Sitting		Standing	
Weight □ lbs □ kg	Blood P (mm systolic		Pulse (beats/ min)	Pressure nHg) diastolic	Pulse (beats/ min)
	1	/  , ,	. 1	/	1 1

#### ADVERSE EXPERIENCES / CONCOMITANT MEDICATION

atien	t: "Do you feel different in any way since starting the treatment or since the la	ıst
	☐ Yes ☐ No	
	Record in the Adverse Experience section	
Has t	here been any change in concomitant medication since the last visit?	
	☐ Yes ☐ No	
Г	Record in the Concomitant Medication section	

#### CLINICAL GLOBAL IMPRESSIONS - GLOBAL IMPROVEMENT

treatment. Compared to his/her condition at admissipatient changed?	ion to the study, now much has the
☐ 1 = Very much improved	
☐ 2 = Much improved	
3 = Minimally improved	
☐ 4 = No change	
☐ 5 = Minimally worse	
☐ 6 = Much worse	
☐ 7 = Very much worse	· · · · · ·

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## HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 1 OF $\bf 3$

	1.	Depressed Mood (sadness, hopelessness, helpless, worthless)
		$\bigcirc$ 0 = Absent
		1 = These feeling states indicated only on questioning
		2 = These feeling states spontaneously reported verbally
		3 = Communicates feeling states non-verbally, i.e., through facial expression, posture, voice and tendency to weep
		4 = Patient reports virtually only these feeling states in his/her spontaneous
		verbal and non-verbal communication
	2.	Feelings of Guilt
		$\bigcirc$ 0 = Absent
		1 = Self reproach, feels he/she has let people down
		<ul> <li>2 = Ideas of guilt or rumination over past errors or sinful deeds</li> <li>3 = Present illness is a punishment. Delusions of guilt</li> </ul>
		4 = Hears accusatory or denunciatory voices and/or experiences
		threatening visual hallucinations
	3.	Suicide
		□ 0 = Absent
		1 = Feels life is not worth living
		2 = Wishes he/she were dead or any thoughts of possible death to self
		☐ 3 = Suicide ideas or gesture
		4 = Attempts at suicide (any serious attempt rates 4)
	4.	Insomnia Early
		□ 0 = No difficulty falling asleep
		1 = Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour
		☐ 2 = Complains of nightly difficulty falling asleep
	5.	Insomnia Middle
		0 = No difficulty
		1 = Patient complains of being restless and disturbed during the night
		2 = Waking during the night - getting out of bed rates 2 (except for
		purposes of voiding)
	6.	Insomnia Late
		□ 0 = No difficulty
		1 = Waking in early hours of the morning but goes back to sleep
		2 = Unable to fall asleep again if he/she gets out of bed
	7.	Work and Activities
		0 = No difficulty
		1 = Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies
		2 = Loss of interest in activity; hobbies or work - either directly reported by patient, or indirectly in listlessness, indecision and vacillation (feels he/she has to push
		self to work or activities)
ĺ		☐ 3 = Decrease in actual time spent in activities or decrease in productivity.
1		4 = Stopped working because of present illness.

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# HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 2 OF 3

8.	Retardation (slowness of thought and speech, impaired ability to concentrate; decreased motor activity)  0 = Normal speech and thought 1 = Slight retardation at interview 2 = Obvious retardation at interview 3 = Interview difficult
	4 = Complete stupor
9.	Agitation
	<ul> <li>□ 1 = Fidgetiness</li> <li>□ 2 = "Playing with" hands, hair, etc.</li> <li>□ 3 = Moving about, can't sit still</li> <li>□ 4 = Hand wringing, nail-biting, hair-pulling, biting of lips</li> </ul>
10.	Anxiety Psychic
	<ul> <li>□ 0 = No difficulty</li> <li>□ 1 = Subjective tension and irritability</li> <li>□ 2 = Worrying about minor matters</li> <li>□ 3 = Apprehensive attitude apparent in face or speech</li> <li>□ 4 = Fears expressed without questioning</li> </ul>
11	Anxiety Somatic (physiological concomitants of anxiety such as: Gastrointestinal (dry mouth, wind, indigestion, diarrhea, cramps, belching), Cardiovascular (palpitations, headaches), Respiratory (hyperventilation, sighing), Urinary frequency, Sweating.
	<ul> <li>□ 0 = Absent</li> <li>□ 1 = Mild</li> <li>□ 2 = Moderate</li> <li>□ 3 = Severe</li> <li>□ 4 = Incapacitating</li> </ul>
12	. Somatic Symptoms Gastrointestinal
	<ul> <li>□ 0 = None</li> <li>□ 1 = Loss of appetite but eating. Heavy feelings in abdomen</li> <li>□ 2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms</li> </ul>
13	. Somatic Symptoms General
	<ul> <li>□ 0 = None</li> <li>□ 1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability</li> <li>□ 2 = Any clear-cut symptoms rates 2</li> </ul>
14	Genital Symptoms (such as loss of libido and menstrual disturbances)
	□ 0 = Absent □ 1 = Mild □ 2 = Severe

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# HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 3 OF 3

15.	Hypochondriasis
	<ul> <li>□ 0 = Not present</li> <li>□ 1 = Self-absorption (bodily)</li> <li>□ 2 = Preoccupation with health</li> <li>□ 3 = Frequent complaints, requests for help, etc.</li> <li>□ 4 = Hypochondriacal delusions</li> </ul>
16.	Loss of Weight
	<ul> <li>□ 0 = No weight loss</li> <li>□ 1 = Slight or doubtful loss of weight</li> <li>□ 2 = Obvious or severe loss of weight</li> </ul>
17.	Insight
	<ul> <li>□ 0 = Acknowledges being depressed and ill</li> <li>□ 1 = Acknowledges illness but attributes cause to bad food, climate, over-work, virus, need for rest, etc.</li> <li>□ 2 = Denies being ill at all</li> </ul>
	•
•	HAMD Score (Items 1-17)

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DEP	RESSED MOOD							<u></u>	
1.	Worst Severity of Current Episode:	(0) NI	NO NO	SLT	MLD	(4) MO	(5) SVR	(6) EX	(7) VEX
	Duration of Current Episode:	L	」# of wo	<del>ec</del> ks					
2.	Worst Severity of Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	(7) VEX
	Frequency:	∐ Day	s/week						
	Average % time of the day:		<b>」%</b>						
<u>DEI</u>	PRESSED APPEAR	ANCE							
3.	Current Episode:	(0) NI	NO NO	(2) SLT	MLD	(4) MO	SVR	(6) EX	
4.	Last Two Weeks:	(0) NI	NO NO	SLT	MLD	(4) MO	(5) SVR	(6) EX	
IRF	RITABILITY AND	ANGER							
5.	Current Episode:	(0) NI	(I) NO	SLT	MLD	(4) MO	(5) SVR	(6) EX	(7) VE
	Duration:	L	」# of w						
6.	Last Two Weeks:	(0) NI	(1) NO	SLT	MLD	(4) MO	(5) SVR	(6) EX	(7) VE:
	Frequency:	∐ Da	ys/week						
	Average % time of the day:	ــــــــــــــــــــــــــــــــــــــ							
SEI	PARATION-DEPE	NDENT-I	DYSPHOR	<u>lia</u>					
7.	Current Episode:	(0)	(1) NO	(2) OCC	(3) USL	(4) ALW			
8.		(0)	(I) NO	OCC	USL	(4) ALW			
-	Last Two Weeks:	NI	NO	(000)	0001				
	Last Two Weeks:	NI]	NO	(000)	[032]				

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QUALITY OF DYPSH	IORIC MO	OOD					er.
9. Current Episode:	(0) NI	(I) ND	QUE	DDF	(4) VDF		
10. Last Two Weeks:	(0) NI	(1) ND	QUE	DDF	(4) VDF		
DEGREE OF ASSOCI	ΑΤΙΟΝ ΟΙ	F DEPRES	SED OR	IRRITAR	LE MOOD	WITH S	PECIFIC
EVENTS OR PREOCO			OLD OR		<u> </u>	,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	<u> </u>
11. Current Episode:	(0) NI	(1) NAL	(2) MOT	UN	PN		
12. Last Two Weeks:	(0) NI	(I) NAL	(2) MOT	(3) UN	(4) PN		
REACTIVITY OF DE	PRESSED	OR IRRI	TABLE M	100D			
			[2]	(3)	f TZO I	1757	ראדו
13. Current Episode:	(0) NI	(I) VR	FUL	RES	(4) MLD	SLT	UNR
		% Usual	1 % of No	ormal			
14. Last Two Weeks:	(0) NI	VR	FUL.	(3) RES	MLD	(5) SLT	UNR
		% Usua	1 % of No	ormal			
		% Maxi	mum % o	f Normal			
	لــا	Number	of hours g	good feeling	g last		
DIURNAL MOOD VA	ARIATION	Ţ					
Worse in Morning							
15. Current Episode:	(O) NI	(1) NW	MIN	MLD	CW	EXT	
16. Last Two Weeks:	(0) NI	(1) NW	MIN	MLD	CW	EXT	
Worse in Afternoon a	nd/or Eve	ning					
17. Current Episode:	(0) NI	(I) NW	MIN	MLD	CW	EXT	
18. Last Two Weeks:	(0) NI	NW	(2) MIN	MLD	CW	EXT	

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EXCESSIVE INAPPRO	PRIATE	GUILT					-°	
19. Current Episode:	(0) NI	NO NO	SLT	MLD	(4) MOD	SVR	(6) EXT	
20. Last Two Weeks:	(0) NI	NO (I)	SLT	MLD	MOD	SVR	EXT	
Frequency:	Days/We	eek _						
NEGATIVE SELF IM	<u>age</u>							
21. Current Episode:	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT	
22. Last Two Weeks:	(0) NI	NO	SLT	(3) MLD	MOD	(5) SVR	(6) EXT	
FEELING UNLOVED	FORLOF	<u>en</u>						
23. Current Episode:	(0) NI	NO NO	SLT	(3) MLD	MOD	(5) SVR	EXT	
24. Last Two Weeks:	(0) NI	NO NO	SLT	(3) MLD	MOD	(5) SVR	(6) EXT	
Frequency:	Days/W	eek [						
HOPELESSNESS, HEL	PLESSNI	ess, disc	OURAGE	MENT, PE	SSIMISM			
25. Current Episode:	(0)	(I) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT	
26. Last Two Weeks:	(0) NI	(1) NO	SLT	(3) MLD	MOD	(5) SVR	EXT	
SELF-PITY								
27. Current Episode:	(0) NI	(1) NO	(2) OCC	(3) MLD	CON			
28. Last Two Weeks:	(0) NI	(1) NO	occ	MLD	CON			
ACHES AND PAINS								
29. Current Episode:	(e) NI	(I)	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT	
30. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT	

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HYPOCHONDRIASIS							-
31. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
32. Last Two Weeks:	(0) NI	(1) NO	SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX
ANHEDONIA, LACK	OF INT	EREST AP	ATHV. 14	OW MOT	IVATION.	BOREDO	M
		SKESI, AI	AIIII, L	JW 1011	i v Airory	DOILLDO	112
Combined Overall Ratio	_				r	<del>- 700 -</del>	
33. Current Episode:	(0) NI	(1) NO	SLT	MLD	(4) MO	(5) SVR	(6) EX
Duration:	ــــــا	# of w	reeks				
34. Last Two Weeks:	(0) NI	(1) NO	SLT	MLD	(4) MO	(5) SVR	(6) EX
Frequency	L D	ays/week					
Average % time of the day:	I .	<b></b>					
Differentiating Lack	of Inter	est from A	nhedonia				
Lack of Interest			t-185-3	1-797-1	-78 <del>-</del> 7	LT83-1	F7651
35. Current Episode:	(O) NI	(1) NO	SLT	MLD	(4) MO	svr	EX
36. Last Two Weeks:	(O) NI	NO	SLT	MLD	(4) MO	SVR	(6) EX
Anhedonia							
37. Current Episode:	(0) NI	NO (1)	SLT	(3) MLD	(4) MO	SVR	(6) EX
38. Last Two Weeks:	(0) NI	(1) NO	SLT	MLD	(4) MO	(5) SVR	(6) EX
FATIGUE, LACK OF	ENERG	V AND TI	REDNESS				
FAIIGUE, LACK OF	LIVERG	I ALID II	11111111111				
39. Current Episode:	(0) NI	(I) NO	SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
40. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
Frequency:	D	ays/Week					

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DIF	FICULTY CONCENTI	RATING	, INATTE	NTION, C	OR SLOW	ED THINE	KING	=
41.	Current Episode:	0)	(1) NO	SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
42.	Last Two Weeks:	0)	NO (1)	SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
PSY	CHOMOTOR AGITA	TION						
43.	Current Episode:	0) 	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
		(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
	Frequency:	_ Days	/Week					
MA	NIFESTATIONS INC	LUDED:	:					
	Unable to sit still							
45.	Current Episode:	(0) NI	(I) NPR	DBT	(3) PŘ	(4) MOD	(5) SVR	
46.	Last Two Weeks:	(0) NI	(I) NPR	DBT	(3) PR	(4) MOD	(5) SVR	
								1
	Pacing				CT.	r <del>an</del> a	( <del>787</del> 1	
47.	Current Episode:		(1) NPR	DBT	(3) PR	(4) SVR	(5) SVR	
48.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR	
	Hand wringing							
49.	Current Episode:	(0) NI	(1) NPR	DBT	(3) PR	(4) SVR	(5) SVR	
50.	Last Two Weeks	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR	
	Pulling or rubbing or	n hair, c	clothing, sk	in				
51.	Current Episode	(0) NI	(1) NPR	(2) DBT	PR	(4) SVR	(5) SVR	,
52.	Last Two Weeks	(0) NI	(I) NPR	(Z) DBT	(3) PR	(4) SVR	(5) SVR	
	Can't stop talking, to	ilks on	and on					
53.	Current Episode	(0) NI	(1) NPR	(2) DBT	(3) PR	SVR	(5) SVR	
54.	Last Two Weeks	(0) NI	(1) NPR	(Z) DBT	(3) PR	(4) SVR	(5) SVR	
l								

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								1
PSYCI	HOMOTOR RETARD	ATION					÷	
55.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
56.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
	Frequency:	Day	s/Week					İ
MANI	FESTATIONS INCLU	J <b>DED</b> :						
SI	lowed Speech							
57.	Current Episode:	(0) NI	NPR	DBT	(3) PR	MOD	(5) (SVR	
58.	Last Two Weeks:	(0) NI	(I) NPR	DBT	PR	MOD	(5) SVR	
I	ncreased pauses befor	e answer	ing					
59.	Current Episode:	NI NI	(I) NPR	DBT	PR	MOD	SVR	
60.	Last Two Weeks:	(O) NI	NPR	(2) DBT	PR	(4) MOD	SVR	
L	ow or monotonous spe				(77V-1	[78]	ारी ।	:
61.	Current Episode:	(0) NI	(I) NPR	DBT	(3) PR	MOD	(5) SVR	
62.	Last Two Weeks:	(0) NI	(1) NPR	DBT	PR	MOD	(S) SVR	
A	Aute or markedly dec	reased an	nount of s	peech				
63.	Current Episode:	(0) NI	(I) NPR	DBT	PR	(4) MOD	SVR	
64.	Last Two Weeks:	(0) IN	(1) NPR	(2) DBT	PR	(4) MOD	(5) SVR	
s	Slowed body movement	:5						
65.	Current Episode:	(0) NI	(1) NPR	DBT	(3) PR	(4) MOD	(5) SVR	
66.	Last Two Weeks:	(0) NI	(1) NPR	DBT	(3) PR	MOD	SVR	
	Depressive stupor							
67.	Current Episode:	(0) NI	(I) NPR	(2) DBT	PR	MOD	SVR	
68.	Last Two Weeks:	(0)	(I) NPR	(2) DBT	PR	(4) MOD	(5) SVR	

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SOC	IAL WITHDRAW	AL						÷	
69.	Current Episode:	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
70.	Last Two Weeks:	(0) NI	NO (I)	SLT	MLD	(4) MO	(5) SVR	(6) EX	
<u>REJ</u>	ECTION SENSITI	VITY							
71.	Last Year:	(0)	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX	
72.	Current Episode:	(0) NI	(I) NO	SLT	MLD	MOD	SVR	(6) EX	
73.	Last Year:	(0) NI	(1) NO	SLT	(3) MLD	(4) MOD	SVR	(6) EX	
74.	Current Episode:	(0) NI	(I) NO	SLT	MLD	MOD	(5) SVR	(6) EX	
CT 17	EP PROBLEMS								İ
SLE									
75.		-	onset of						
76.	Hours s	iept during	the curren	nt episode					
77.	Hours s	lept during	the last t	wo weeks					
<u>HY</u>	PERSOMNIA								:
78.	Hours s	lept in da	ytime of cu	irrent episo	dė				
79.	Hours s	lept in day	ytime in th	e last two	weeks				
80.	Hours 1	ying down	in current	episode					
81.	Hours 1	ying down	in last tw	o weeks					
82.	Current Episode:	(0) NI	(I)	(2)	(3)	(4)	(5)	(6)	
83.	Last Two Weeks:	(0) NI	(1) NO	(2)	(3)	(4)	(5)	(6)	

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			······································				-
INSOM	INIA						
84.	Current Episode: (0)	(1) NO	(2)	(3)	(4)	(5)	(6)
85. L	ast Two Weeks: (0) NI	(1)	(2)	(3)	(4)	(5)	(6)
	Frequency:	Nights/Wee	k				
en i n	a or ingolouia						
	S OF INSOMNIA						
	Initial Insomnia	(0) NI	(I) NPR	(2) DBT	(3) MLD	(4) MOE	(5) SVR
86.	Current Episode:		(I)				
87.	Last Two Weeks:	(0) NI	NPR	DBT	MLD	MOD	SVR
	Middle Insomnia				F-76-7	<del>  [65]</del>	r <del>(S)</del> 1
88.	Current Episode:	NI (0)	(I) NPR	DBT	MLD	MOD	SVR
89.	Last Two Weeks:	(0) NI	(1) NPR	DBT	MLD	MOE	(5) SVR
	Terminal Insomnia						
90.	Current Episode:	(0) NI	(I) NPR	(2) DBT	MLD	MOD	SVR
91.	Last Two Weeks:	(0) NI	(1) NPR	DBT	MLD	(4) MOD	SVR
	Circadian Reversal						
92.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) MLD	MOD	(5) SVR
93.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) MLD	MOD	(5) SVR
İ	Non-restorative sleep						
		(0) NI	(1) NPR	(2) DBT	(3) MLD	(4) MOD	(5) SVR
94.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) MLD	(4) MOD	(5) SVR
95.	Last Two Weeks:	NI	[NPK]	ត្រែព	MILL	mos	لخبيت
	Daytime sleepiness	டனா	רמח	[CD]	(3) MLD	(4) MOD	(5) SVR
96.	Current Episode:	(0) NI	(I) NPR	DBT			
97.	Last Two Weeks:	(0) NI	(I) NPR	DBT	MLD	MOD	SVR

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ANOREXIA  98. Current Episode:  99. Last Two Weeks:	(0) NI (0)	(I) NO	(2) SLT (2) SLT	(3) MLD MLD	(4) MOD MOD	(3) RAR (5) RAR	(6) NVR (6) NVR
WEIGHT LOSS  100. Current Episode:  Pounds lost:	لـــا	lbs.					
Number of Weeks:  101. Last Two Weeks:  Pounds lost:		lbs.					
102. Current Episode: 103. Last Two Weeks: Frequency:	(0) NI (0) NI	(1) NO NO Days/Wee	(2) SLT (2) SLT	(3) MLD (3) MLD	(4) MOD (4) MOD	(5) SVR (5) SVR	(6) EX (6) EX
STRONG CRAVING			<u>[2]</u>	r <del>a</del> n	[T4)T	(5) SVR	
<ul><li>104. Current Episode:</li><li>105. Last Two Weeks:</li></ul>	(0) NI (0)	ABS	(2) DBT (2) DBT	(3) MLD (3) MLD	(4) MOD MOD	SVR SVR	
WEIGHT GAIN  106. Current Episode  Pounds gained  Number of Weeks  107. Last Two Weeks	:						
Pounds gained	<u>:</u>	lbs.					

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				· · · · · · · · · · · · · · · · · · ·				
SUICIDAL IDEATION	-							<i>-</i>
108. Current Episode:	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MO	SVR	(6) EX	vex
109. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	(7) VEX
Suicidal Acts – Numbe	r							
110. Current Episode:								
111. Last Two Weeks:								
Suicidal Acts – Seriou	sness							
112. Current Episode:	(0) NI	(I)	(2) MIN	(3) DEF		SER	(5) VS	EXT
113. Last Two Weeks:	(0) NI	(I)	(2) MIN	(3) DEF	]	SER.	(5) V\$	(6) EXT
Medical Lethality								
114. Current Episode	(0) NI	(1) NO	(2) MIN	(3) MLD	]	(4) MO	(5) SVR	(6) EXT
115. Last Two Weeks:	(0) NI	(1) NO	(2) MIN	(3) MLT	]	(4) MO	SVR	(6) EXT
Non-Suicidal Physica	! Self-D	emaging	Acts					
116. Current Episode:	(0) N1	(I) NO	(2) SLT	(3) MLI		(4) MO	(5) SVR	ACT
117. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLI	<u></u>	(4) MO	(5) SVR	ACT
		<del></del>						

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			·					
MANIC SYNDROME							تبد	
ELATION, EXPANSIV	E MOOI	<u>D</u>						
1. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
2. Last Two Weeks:	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
	on of Fi							
DECREASED NEED FO						F28-1	F763	
3. Current Episode:	(0) NI	NO NO	(2) -1	(3)	-3	(5) -4	(6) -4+	
4. Last Two Weeks:	(0) NI	(1) NO	(2) -1	(3) -2	(4) -3	(5)	(6) -4+	
UNUSUALLY ENERG	RTIC							
UNUSUALLI ENERG	<u>ाळ</u> ा	[ <del>7</del> [1]	(2)	<del>[ (3) ]</del>	(4)	[(5)]	T6)	
5. Current Episode:	NI NI	(1)	SLT	LCH	(4) MOR	(5) MM	(6) UA	
6. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	LCH	MOR	(5) MM	(6) UA	
INCREASE IN GOAL	DIDECT	ED ACT	IVITV					
INCREASE IN GOAL				[73]	[74)]	[( <u>5)</u> ]	ത്ര	
7. Current Episode:	(0)	NO NO	SLT	(3) MLD	(4) MO	(5) MKD	(6) EX	
8. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	MKD	(6) EX	
GRANDIOSITY								
GRANDIOSITI	17 <b>6</b> 0 1	100	<u>  (2)  </u>	[ <del>-(3)</del> -]	[4]	(5) SVR	(6) EX	
9. Current Episode:	(0) NI	(1) NO	SLT	(3) MLD	(4) MO			
10. Last Two Weeks:	(0) NI	(I) NO	SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
ACCELERATED, PRI	SSURED	OR INC	CREASEI	AMOU	NT OF S	PEECH		
ACCEPTAGE 120, 110					(4) MO	(5) MKD	(6) EX	
11. Current Episode:	(0) NI	(1)	(2) SLT	MLD				
12. Last Two Weeks:	(0) NI	NO NO	(2) \$LT	MLD	(4) MO	MKD	(6) EX	

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RAC	ING THOUGHTS								=	
13.	Current Episode:	(0) NI	NO NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	(6) EX		
14.	Last Two Weeks:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	(6) EX		
FLI	GHT OF IDEAS									
15.	Current Episode:	(0) NI	(I)	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX		
16.	Last Two Weeks:	(0) NI	(I)	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX		
POC	OR JUDGEMENT									
17.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) VS		
18.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) VS		
DIS	TRACTABILITY									
19.	Current Episode:	(0) IN	(1) NO	SLT	MLD	(4) MO	(5) SVR			
20.	Last Two Weeks:	(0) N1	NO (I)	(2) <u>SLT</u>	MLD	(4) MO	(5) SVR			
МС	OTOR HYPERACTI	<u>VITY</u>								
21.	Current Episode:	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX		
22.	Last Two Weeks:	(0) N1	NO NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX		
In	appropriate laughin	ig, jokin		ning						
23.	Current Episode:	(0) NI	(1) NO	DBT	MLD	(4) MOD				
24.	. Last Two Weeks:	(0) NI	NO NO	DBT	MLD	MOD				
U	ninhibited people se	eking, g	regarious							
25	. Current Episode:	(0) NI	(I)	(2) DBT	(3) MLD	(4) MOD				
26	. Last Two Weeks:	(0) NI	(I)	DBT	MLD	MOD		· · · · · ·		 

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							$\neg$
Inci	reased Productivity					<u></u>	
27.	Current Episode:	(0) NI	(1) NO	(2) DBT	PRS	(4) SVR	
28.	Last Two Weeks:	(0) NI	(I) NO	DBT	PRS	SVR	
Sha	r pened and unusual	ly creat	ive thinki	ng			
29.	Current Episode:	(0) NI	(I)	(2) DBT	(3) PRS	(4) SVR	
30.	Last Two Weeks:	(0) NI	(1) NO	(2) DBT	PRS	SVR	
Ну	persexuality						
31.	Current Episode:	(0) NI	(1) NO	DBT	PRS	SVR	
32.	Last Two Weeks:	(0)	(I) NO	DBT	PRS	SVR	
<u>INI</u>	FLUENCE OF ILL	CIT DR	UGS OR	ALCOH	<u>OL</u>		
33.	Current Episode:	(0) NA	(I) NVR	(2) SMT	(3) ONL		
34.	Last Two Weeks:	(0) NA	(1) NVR	(2) SMT	(3) ONL		
NU	MBER OF MANIC	PERIC	DS				
35.							

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### STUDY MEDICATION RECORD

Start Date lay month year	End Date day month year	Dose Level	Number of Capsules Daily	

#### STUDY MEDICATION DOSING CHANGES

		CIIDCU CII	anges in study	medication since the last visit
□ No □ Yes —	→ Indicate cha	nge(s) belo	ow .	
		-		
	Reminder:	Changes i	in dose constitut	e deviation from the protocol
	Reminder.	Onumbro .	III done companie	e authorized and passed and
	<u>Kommuor</u>			
Start Date	End Date day month year	Dose Level	Number of Capsules Daily	Reason for Dose Change
	End Date	Dose	Number of Capsules	

#### STUDY MEDICATION COMPLIANCE

Capsules Dispensed (A)	Capsules Returned (B)	Capsules Taken (A - B)	Days Since Last Visit	% Compliance			
Cor	tient been	(N★ x on the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the state of the stat	of capsules days since l  0% and \( \left( \frac{1}{2} \)	ast visit) x	100 visits?	*N =	number of capsules dail (see above)

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# STUDY MEDICATION LABEL Attach label here Attach label here Attach label here Attach label here The drug code on the study medication label must be identical to the preprinted Patient Number Important: Enter patient number (drug code as listed on clinical supplies) above.

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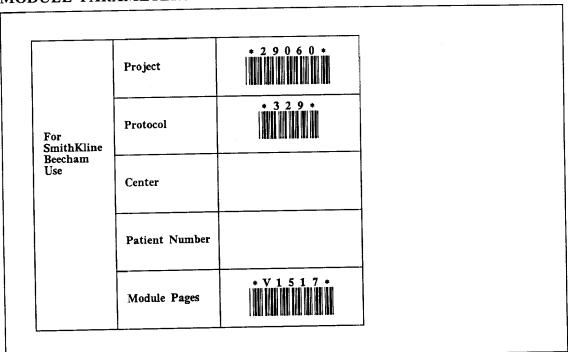
#### STUDY MEDICATION DISPENSING

Record study medication information for Weeks 17-20 in the Study Medication Record, page 291. Attach label(s) to page 292. Record number of capsules dispensed on page 291.

Reminder: The drug code on the study medication label must be identical to the preprinted Patient Number above.

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#### MODULE PARAMETERS - WEEK 20



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#### VITAL SIGNS

TT7 !-1-4		Sitting		Standing		
Weight □ lbs □ kg	Blood F (mn systolic	Pressure nHg) diastolic	Pulse (beats/ min)		Pressure nHg) diastolic	Pulse (beats/ min)
		/	11		/	11

#### ADVERSE EXPERIENCES / CONCOMITANT MEDICATION

Have a	any adverse experiences been observed or elicited by the following direct question to : "Do you feel different in any way since starting the treatment or since the last
	☐ Yes ☐ No
F	tecord in the Adverse Experience section
Has th	nere been any change in concomitant medication since the last visit?
	☐ Yes ☐ No
I	Record in the Concomitant Medication section

### CLINICAL GLOBAL IMPRESSIONS - GLOBAL IMPROVEMENT

treatm patient		Compared to his/her condition at admission to the study, how much has the
•		
	1 :	= Very much improved
	2 :	= Much improved
	3 :	= Minimally improved
		= No change
Ē	5	= Minimally worse
		= Much worse
		= Very much worse

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# HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 1 OF 3

1.	Depressed Mood (sadness, hopelessness, helpless, worthless)  0 = Absent 1 = These feeling states indicated only on questioning 2 = These feeling states spontaneously reported verbally 3 = Communicates feeling states non-verbally, i.e., through facial expression, posture, voice and tendency to weep 4 = Patient reports virtually only these feeling states in his/her spontaneous verbal and non-verbal communication
2.	Feelings of Guilt
	<ul> <li>□ 0 = Absent</li> <li>□ 1 = Self reproach, feels he/she has let people down</li> <li>□ 2 = Ideas of guilt or rumination over past errors or sinful deeds</li> <li>□ 3 = Present illness is a punishment. Delusions of guilt</li> <li>□ 4 = Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations</li> </ul>
3.	Suicide
	<ul> <li>□ 0 = Absent</li> <li>□ 1 = Feels life is not worth living</li> <li>□ 2 = Wishes he/she were dead or any thoughts of possible death to self</li> <li>□ 3 = Suicide ideas or gesture</li> <li>□ 4 = Attempts at suicide (any serious attempt rates 4)</li> </ul>
4.	Insomnia Early
	<ul> <li>□ 0 = No difficulty falling asleep</li> <li>□ 1 = Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour</li> <li>□ 2 = Complains of nightly difficulty falling asleep</li> </ul>
5.	Insomnia Middle
	<ul> <li>0 = No difficulty</li> <li>1 = Patient complains of being restless and disturbed during the night</li> <li>2 = Waking during the night - getting out of bed rates 2 (except for purposes of voiding)</li> </ul>
6.	Insomnia Late
	<ul> <li>□ 0 = No difficulty</li> <li>□ 1 = Waking in early hours of the morning but goes back to sleep</li> <li>□ 2 = Unable to fall asleep again if he/she gets out of bed</li> </ul>
7.	Work and Activities
	<ul> <li>□ 0 = No difficulty</li> <li>□ 1 = Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies</li> <li>□ 2 = Loss of interest in activity; hobbies or work - either directly reported by patient, or indirectly in listlessness, indecision and vacillation (feels he/she has to push</li> </ul>
	self to work or activities)
	<ul> <li>3 = Decrease in actual time spent in activities or decrease in productivity.</li> <li>4 = Stopped working because of present illness.</li> </ul>

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# HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 2 OF 3

8.	Retardation (slowness of thought and speech, impaired ability to concentrate; decreased motor activity)  0 = Normal speech and thought 1 = Slight retardation at interview 2 = Obvious retardation at interview 3 = Interview difficult
	4 = Complete stupor
9.	Agitation
	<ul> <li>□ 0 = None</li> <li>□ 1 = Fidgetiness</li> <li>□ 2 = "Playing with" hands, hair, etc.</li> <li>□ 3 = Moving about, can't sit still</li> <li>□ 4 = Hand wringing, nail-biting, hair-pulling, biting of lips</li> </ul>
10.	Anxiety Psychic
	<ul> <li>□ 0 = No difficulty</li> <li>□ 1 = Subjective tension and irritability</li> <li>□ 2 = Worrying about minor matters</li> <li>□ 3 = Apprehensive attitude apparent in face or speech</li> <li>□ 4 = Fears expressed without questioning</li> </ul>
11.	Anxiety Somatic (physiological concomitants of anxiety such as: Gastrointestinal (dry mouth, wind, indigestion, diarrhea, cramps, belching), Cardiovascular (palpitations, headaches), Respiratory (hyperventilation, sighing), Urinary frequency, Sweating.
	<ul> <li>□ 0 = Absent</li> <li>□ 1 = Mild</li> <li>□ 2 = Moderate</li> <li>□ 3 = Severe</li> <li>□ 4 = Incapacitating</li> </ul>
12.	Somatic Symptoms Gastrointestinal
	<ul> <li>□ 0 = None</li> <li>□ 1 = Loss of appetite but eating. Heavy feelings in abdomen</li> <li>□ 2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms</li> </ul>
13.	Somatic Symptoms General
	<ul> <li>□ 0 = None</li> <li>□ 1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability</li> <li>□ 2 = Any clear-cut symptoms rates 2</li> </ul>
14.	Genital Symptoms (such as loss of libido and menstrual disturbances)
	<ul> <li>□ 0 = Absent</li> <li>□ 1 = Mild</li> <li>□ 2 = Severe</li> </ul>

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# HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 3 OF 3

15	<ul> <li>Hypochondriasis</li> <li>□ 0 = Not present</li> <li>□ 1 = Self-absorption (bodily)</li> <li>□ 2 = Preoccupation with health</li> <li>□ 3 = Frequent complaints, requests for help, etc.</li> <li>□ 4 = Hypochondriacal delusions</li> </ul>
1	. Loss of Weight
	<ul> <li>□ 0 = No weight loss</li> <li>□ 1 = Slight or doubtful loss of weight</li> <li>□ 2 = Obvious or severe loss of weight</li> </ul>
1	'. Insight
	<ul> <li>□ 0 = Acknowledges being depressed and ill</li> <li>□ 1 = Acknowledges illness but attributes cause to bad food, climate, over-work, virus, need for rest, etc.</li> <li>□ 2 = Denies being ill at all</li> </ul>
•	HAMD Score (Items 1-17)

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	RESSED MOOD Worst Severity of Current Episode:	(0) NI	NO (1)	(2) SLT	MLD	(4) MO	(5) SVR	(6) EX	(7) VEX
	Duration of Current Episode:		# of we	æks					
2.	Worst Severity of Last Two Weeks:	(6) NI	(I)	SLT	MLD	(4) MO	(5) SVR	(6) EX	(7) VEX
	Frequency:	∐ Days	s/week						
	Average % time of the day:	L	<u> </u> %						
DEP	RESSED APPEAR	ANCE							
3.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
4.	Last Two Weeks:	NI NI	NO NO	SLT	MLD	(4) MO	(5) SVR	EX	
<u>IRR</u> 5.	Current Episode:	ANGER	(I)	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	vi
	Duration:	1	# of w	reeks					
6.	Last Two Weeks:	(0) II	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	v
	Frequency:	∐ Da	ys/week						
	Average % time of the day:		%						
SEI	PARATION-DEPE	NDENT-I	DYSPHOI	RIA					
7.	Current Episode:	(0) NI	(1) NO	(2) occ	USL	ALW			
8.	Last Two Weeks:	(0)	(1) NO	(2) OCC	USL	ALW			

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QUALITY OF DYPSHO	ORIC MO	OD					<i></i>
9. Current Episode:	(0) NI	T(I)	QUE	(3) DDF	(2) VDF		
10. Last Two Weeks:	(O) NI	(1) ND	(2) QUE	(3) DDF	(4) VDF		
It. Last Iwo woods.	[NI]	נמאַ	QOE)	<b>D</b> D1			
DEGREE OF ASSOCIA	TION OF	DEPRES	SED OR	IRRITABI	E MOOD	WITH SE	PECIFIC
EVENTS OR PREOCC	UPATION	3					
11. Current Episode:	(0) NI	(I) NAL	(2) MOT	(3) UN	(4) PN		
12. Last Two Weeks:	(0) NI	(1) NAL	(2) MOT	(3) UN	(4) PN		
	<del></del>						
				, a a a			
REACTIVITY OF DE	PRESSED	OR IRRI	TABLE M	<u>1000</u>			Ì
13. Current Enisode:	(0) NI	(1) VR	(2) FUL	(3) RES	(4) MLD	(5) SLT	(6) UNR
13. Current Episode:	_111_	_	_				
		% Usua	1 % of No	rmal			
14. Last Two Weeks:	(0) NI	(1) VR	FUL	RES	MLD	(5) SLT	(6) UNR
		% Usua	1 % of No	ormal			,
		% Max	imum % o	f Normal			
	لـــا	Number	of hours g	good feeling	g last		
DIURNAL MOOD VA	ARIATION	1					
Worse in Morning	[ <del>76)</del> ]	<del>[10]</del>	[72]	[(3)]	[(4)]	(5)	
15. Current Episode:	(0) NI	(I) NW	MIN	MLD	CW	EXT	
16. Last Two Weeks:	(0) NI	(I) NW	MIN	MLD	CW CW	EXT	
Worse in Afternoon						CT57-1	
17. Current Episode:	NI	NW	MIN	MLD	(4) CW	EXT	
18. Last Two Weeks:	(0) NI	(I) <b>NW</b>	MIN	MLD	CW	EXT	

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								·
EXCESSIVE INAPPRO	PRIATE	GUILT					÷.	
19. Current Episode:	(0) NI	(1) NO	SLT	MLD	MOD	SVR	(6) EXT	
20. Last Two Weeks:	(0)	(1) NO	SLT	(3) MLD	MOD	(5) SVR	EXT	
Frequency:	Days/We	ek [						
NEGATIVE SELF IMA	<u>AGE</u>							
21. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	MOD	(5) SVR	(6) EXT	
22. Last Two Weeks:	(0) NI	(1) NO	SLT	(3) MLD	(4) MOD	(5) SVR	EXT	
FEELING UNLOVED	FORLOF	<u>en</u>						
23. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	MOD	(5) SVR	(6) EXT	
24. Last Two Weeks:	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT	
Frequency:	Days/W	eck [						
								Ì
HOPELESSNESS, HEI	PLESSNI	ess, disc	OURAGE	MENT, PE	SSIMISM			•
25. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT	
26. Last Two Weeks:	(0) NI	NO NO	(2) SLT	(3) MLD	MOD	(5) SVR	(6) EXT	•
								ı
SELF-PITY		COT.	F757-1	1787	[T4)]			
27. Current Episode:	(0) NI	NO NO	(2) (CC)	(3) MLD	(4) COM			
28. Last Two Weeks:	(0)	(1)	occ	MLD	COM			
ACHES AND PAINS								
29. Current Episode:	(O)	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT	
30. Last Two Weeks:	ررها	(1) NO	SLT	(3) MLD	(4) MOD	SVR	(6) EXT	

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								$\neg$
HYPOCHONDRIASIS							ت.	
31. Current Episode:	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX	
32. Last Two Weeks:	(0) NI	(I) NO	SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX	
ANHEDONIA, LACK	OF INT	EREST, AP	ATHY, LO	OW MOT	IVATION,	BOREDO	<u>M</u>	
Combined Overall Ratio	ıg							Ì
33. Current Episode:	(O)	NO (1)	SLT	MLD	(4)	SVR	(6) EX	
Duration:		# of w					F777.1	
34. Last Two Weeks:	(0)	и <u>о</u>	SLT	MLD	MO	(5) SVR	(6) EX	
Frequency:	I	Days/week						
Average % time of the day:	- 1	%						
Differentiating Lack	of Inter	rest from A	Inhedonia					
Lack of Interest	(0) NI	[0]	(2) SLT	(3) MLD	(4) MO	(S) SVR	(6) EX	
35. Current Episode:	(0) NI	[(I)]	(2)	<u></u>	(4) T	(5) SVR	(6) EX	
36. Last Two Weeks:	NI	NO	SLT	MLD	МО	3VK	EA	
Anhedonia	[का	(1) NO	[2]	(3)	<b>(4)</b>	(5) SVR	(6) EX	
37. Current Episode:	NI NI		SLT (2) SLT	MLD	(4)	(3)	(6) EX	
38. Last Two Weeks:	NI	NO	SLT	MLD	мо	SVR	(EX)	
FATIGUE, LACK OF	ENERG	Y AND T	IREDNESS	į				
39. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
40. Last Two Weeks:	(0) NI	NO (1)	SLT	MLD	(4) MO	(5) SVR	(6) EX	
Frequency:		Days/Week						
L								

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DIF	FICULTY CONCENTE	RATING	, INATTE	NTION, (	OR SLOW	ED_THIN	KING	±.
41.	Current Episode:	5)	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
	_	<u></u>	(1)	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
72.	<u> </u>	<u> </u>	[NO]	(SLI)	MED	(MO)	<u> </u>	
<u>PSY</u>	CHOMOTOR AGITA	<u> </u>						
43.	Current Episode:	4I 0)	(1) NO	(2) SLT	MLD	(4) MO	(5) SVR	(6) EX
44.	Last Two Weeks:	0) VI	NO NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
	Frequency:	_ Days	/Week					
MA	NIFESTATIONS INC	LUDED:	<b>:</b>					
	Unable to sit still							
45.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR	
46.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	MOD	(5) SVR	
	Pacing							
47.	Current Episode:	(0) NI	(I) NPR	(2) DBT	(3) PR	(4) SVR	(3) SVR	
48.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) \$VR	
	Hand wringing							
49.	Current Episode:	(0) NI	(I) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR	
50.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR	
	Pulling or rubbing on	. bair a	-lotking sl	rin				
51.	-	(0)	(I) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR	
52.		rm i		(2) DBT	(3) PR	(4) SVR	(5) SVR	
34.	Last Two Wecks:	NI	NPR	[DBT]	PR	[SVR]	<u>[SVR</u>	l
	Can't stop talking, to	ilks on	and on					
53.	Current Episode	(0) NI	(I) NPR	(2) DBT	PR	(4) SVR	(5) SVR	
54.	Last Two Weeks	(0) NI	(1) NPR	DBT	PR	(4) SVR	(5) SVR	

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PSYCI	HOMOTOR RETARD	ATION					ابي	
55.	Current Episode:	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
56.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
	Frequency:	Day	s/Week					
MANI	FESTATIONS INCLU	J <b>DED</b> :						
Si	owed Speech							
57.	Current Episode:	(0) NI	(1) NPR	DBT	(3) PR	MOD	SVR	
58.	Last Two Weeks:	(O)	(1) NPR	DBT	(3) PR	MOD	SVR	
I	ncreased pauses befor				F755-1		CIEV ³	
59.	Current Episode:	(0)	(1) NPR	DBT	(3) PR	MOD	(5) SVR	
60.	Last Two Weeks:	(0) NI	(I) NPR	DBT	(3) PR	(4) MOD	(5) SVR	
L	ow or monotonous spe			1797	<b>⊤</b> 87	Lan	IT <b>S</b> T	
61.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR	
62.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR	
٨	lute or markedly dec	reased an						
63.	Current Episode:	(0) NI	(I) NPR	DBT	(3) PR	(4) MOD	(5) SVR	
64.	Last Two Weeks:	(0) NI	(I) NPR	DBT	(3) PR	MOD	(5) SVR	
s	Slowed body movement	ts.						
65.	Current Episode:	(0) NI	(I) NPR	DBT	(3) PR	MOD	(5) SVR	
66.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	PR	MOD	SVR	
	Depressive stupor					-		
67.	Current Episode:	(0) NI	(1) NPR	DET	(3) PR	MOD	(5) SVR	
68.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(3) SVR	

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SOC	IAL WITHDRAW	AL							
69.	Current Episode:	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
70.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
REJI	ECTION SENSITI								
71.	Last Year:	(0) NI	(1) NO	SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX	
72.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	MOD	(5) SVR	(6) EX	
73.	Last Year:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX	
74.	Current Episode:	(0) NI	(1) NO	SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX	
SLE	EP PROBLEMS								
75.	Hours sl	ept before	onset of o	depression					
76.	Hours sl	ept during	the curren	nt episode					
77.	Hours sl	ept during	the last t	wo weeks					
HYF	PERSOMNIA								
78.	Hours sl	lept in day	time of cu	rrent episo	de				
79.	Hours sl	lept in day	time in the	e last two	weeks				
80.	Hours ly	ying down	in current	episode					
81.	Hours ly	ying down	in last tw	o weeks					
82.	Current Episode:	(0) NI	(1) NO	(2)	(3)	(4)	(5)	(6)	
83.	Last Two Weeks:	(0) NI	(1) NO	(2)	(3)	(4)	(5)	(6)	
		استنتيا	استنتا		LI				
l									

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NSOMNIA						
4. Current Episode: (6) NI	(1) NO	(2)	(3)	(4)	(5)	(6)
5. Last Two Weeks: (0) NI	(1) NO	(2)	(3)	(4)	(5)	(6)
Frequency:	Nights/Wee	k				
TYPES OF INSOMNIA						
Initial Insomnia						
86. Current Episode:	(0) NI	(I) NPR	DBT	MLD	(4) MOD	(5) SVR
87. Last Two Weeks:	(0) NI	(I) NPR	(2) DBT	MLD	MOD	SVR
Middle Insomnia						
88. Current Episode:	(0) NI	(1) NPR	DBT	(3) MLD	(4) MOD	(5) SVR
89. Last Two Weeks:	(0) NI	(1) NPR	DBT	MLD	MOD	(5) SVR
Terminal Insomnia						
90. Current Episode:	(0) NI	(1) NPR	DBT	(3) MLD	MOD	(5) SVR
91. Last Two Weeks:	(0) NI	(I) NPR	DBT	(3) MLD	(4) MOD	(5) SVR
Circadian Reversal						
92. Current Episode:	(0) NI	(1) NPR	DBT	MLD	MOD	(5) SVR
93. Last Two Weeks:	(0) NI	(I) NPR	DBT	MLD	MOD MOD	(5) SVR
Non-restorative sleep						
94. Current Episode:	(0) NI	(1) NPR	DBT	MLD	MOD	SVR
95. Last Two Weeks:	(0) NI	(1) NPR	DBT	MLD	MOD	SVR
Daytime sleepiness						1-72V-1
96. Current Episode:	(0) N1	(I) NPR	(2) DBT	MLD	MOD	(5) SVR
97. Last Two Weeks:	(O) NI	(1) NPR	DBT	(3) MLD	MOD	(5) SVR

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98. Current Episode: 99. Last Two Weeks:	(0) NI (0) NI	(I) NO	(2) SLT	(3) MLD (3) MLD	(4) MOD (4) MOD	(5) RAR (5) RAR	(6) NVR (6) NVR	
WEIGHT LOSS								
100. Current Episode:								
Pounds lost:		lbs.						
Number of Weeks:		_						
101. Last Two Weeks:								
Pounds lost:	لـــا	lbs.						
INCREASED APPETIT	<u>TE</u>							
102. Current Episode:	(0) NI	(I) NO	(2) SLT	MLD	(4) MOD	(5) SVR	(6) EX	
103. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX	
Frequency:		Days/Weel	ζ.					
STRONG CRAVING F	OR SW	<u>EETS</u>						
104. Current Episode:	(0) NI	(1) ABS	DBT	(3) MLD	(4) MOD	(5) SVR		
105. Last Two Weeks:	(0) NI	(I) ABS	(Z) DBT	(3) MLD	(4) MOD	(5) SVR		
				<u></u>				
WEIGHT GAIN								
106. Current Episode:								
Pounds gained:		lbs.						
Number of Weeks:	لـــا							
107. Last Two Weeks:								
Pounds gained:	لـــا	lbs.						

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SUICIDAL IDEATION	Ī							
108. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	(7) VEX
109. Last Two Weeks:	(0)	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	(7) VEX
Suicidal Acts - Numbe	er.							
110. Current Episode:								
111. Last Two Weeks:								
Suicidal Acts – Seriou	sness							
112. Current Episode:	(0) NI	(1) NO	(2) MIN	(3) DEF	S	4) ER	(5) VS	(6) EXT
113. Last Two Weeks:	(0) NI	(1) NO	(2) MIN	DEF		4) ER	(5) VS	(6) EXT
Medical Lethality								
114. Current Episode	(0) NI	(I) NO	(2) MIN	(3) MLD	M	4) 10	(5) SVR	(6) EXT
115. Last Two Weeks:	(0) NI	(1) NO	MIN	(3) MLD	N	4) (O	SVR	(6) EXT
Non-Suicidal Physical	! Self-D	emaging	Acts					
116. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	, and the second	4) (O)	(5) SVR	(6) ACT
117. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD		4) 40	(5) SVR	ACT

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DDIE DIADO ELI	131111						
MANIC SYNDROME							•
ELATION, EXPANSIV	E MOO	<u>D</u>					
1. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
2. Last Two Weeks:	NI (0)	(I) NO	(2) SLT	MLD	(4) MO	(5) SVR	(6) EX
DECREASED NEED F	OR SLE	<u>EP</u>					
3. Current Episode:	(0) NI	(1) NO	(2) -1	(3) -2	(4) -3	(5) -4	(6) -4+
4. Last Two Weeks:	(0) NI	(1) NO	(2) -1	(3) -2	(4) -3	(5)	(6) -4+
UNUSUALLY ENERG	ETIC						
5. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) LCH	(4) MOR	(5) MM	(6) UA
6. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	LCH	(4) MOR	(5) MM	(6) UA
INCREASE IN GOAL	DIREC	TED ACT	IVITY				
7. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX
8. Last Two Weeks:	(0) NI	NO NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX
GRANDIOSITY							
9. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
10. Last Two Weeks:	(0)	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
ACCELERATED, PRI	SSURED	OR INC	CREASED	AMOU	NT OF S	PEECH	
11. Current Episode:	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MO	MKD	(6) EX
12. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	MLD	(4) MO	(5) MKD	(6) EX

### SMITHKline Beecham Pharmaceuticals

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RACING THOUGHTS							-
13. Current Episode:	(0) NI	(I) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	(6) EX
14. Last Two Weeks:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	(6) EX
FLIGHT OF IDEAS							
15. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
16. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
POOR JUDGEMENT							
17. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) VS
18. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) VS
DISTRACTABILITY							
19. Current Episode:	(0)	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	
20. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	MLD	(4) MO	(5) SVR	
MOTOR HYPERACTI	VITY						
21. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX
22. Last Two Weeks:	(0) NI	(I) NO	(2) SLT	MLD	(4) MO	(5) MKD	(6) EX
Inappropriate laughin							
23. Current Episode:	(0) NI	(I) NO	(2) DBT	(3) MLD	MOD		
24. Last Two Weeks:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD		
Uninhibited people sec							
25. Current Episode:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD		
26. Last Two Weeks:	NI NI	NO	(2) DBT	MLD	(4) MOD	, , <u>-</u>	

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Increased Productivity	•				
27. Current Episode:	(0) IN	(1) NO	(2) DBT	PRS	(4) SVR
28. Last Two Weeks:	(0) NI	(1) NO	(2) DBT	(3) PRS	SVR
Shar pened and unusua	lly creat	ive think	ing		
29. Current Episode:	(0) NI	(1) NO	(2) DBT	PRS	(4) SVR
30. Last Two Weeks:	NI (0)	(1) NO	(2) DBT	PRS	(4) SVR
Hypersexuality					·
31. Current Episode:	(0) NI	(1) NO	(2) DBT	PRS	SVR
32. Last Two Weeks:	(0) NI	(I) NO	DBT	PRS	SVR
INFLUENCE OF ILL	CIT DR	UGS OR	ALCOH	<u>or</u>	
33. Current Episode:	(0) NA	(1) NVR	(2) SMT	(3) ONL	
34. Last Two Weeks:	(0) NA	(I) NVR	(2) SMT	ONL	
NUMBER OF MANIC	PERIC	<u>DDS</u>			
35.					

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#### LABORATORY TESTS

Sample Date day month year	For Lab Number SB Code
Attach SBCL laboratory report behind this page.	
Are there CLINICALLY SIGNIFICANT ABNORM	MAL laboratory values?
☐ No ☐ Yes → Record the findings and/or diag	nosis in the Adverse Experiences.

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#### STUDY MEDICATION RECORD

Start Date lay month year	End Date day month year	Dose Level	Number of Capsules Daily	

#### STUDY MEDICATION DOSING CHANGES

<del></del>	icate chang	=		tute deviation from the protoco
<u> Ren</u>	ninder: Cl	hanges i	n dose consti	tute deviation from the protoco
Ken	imuer: Ci	nunges r	TI GOOG COUSE	tute actimition from the process
				-
Start Date End I day month year day mon		Dose Level	Number of Capsules Daily	Reason for Dose Change

#### STUDY MEDICATION COMPLIANCE

Capsules Dispensed (A)	Capsules Returned (B)	Capsules Taken (A - B)	Days Since Last Visit	% Compliance		
<b>ф</b> Соп	tient been	(N★ x ust be ≥ 8	of capsules days since I 0% and \( \leq \text{:} \)	ast visit) x 100	·	number of capsules dail (see above)

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# STUDY MEDICATION LABEL Attach label here Attach label here Attach label here Attach label here Important: The drug code on the study medication label must be identical to the preprinted Patient Number Enter patient number (drug code as listed on clinical supplies) above.

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#### **ELECTROCARDIOGRAM**

Was electroca for interpreta	ardiogram performed and sent to a central reader tion?	Date Performed (day month year)
☐ Yes	□ No	

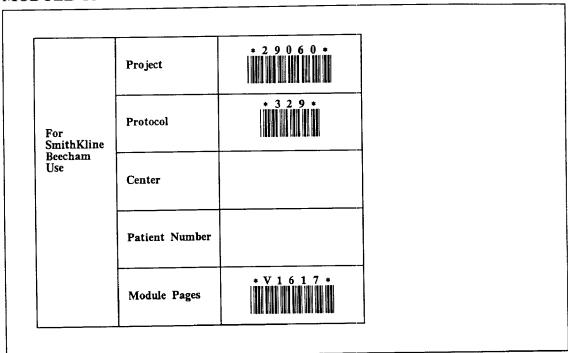
#### STUDY MEDICATION DISPENSING

Record study medication information for Weeks 21-24 in the Study Medication Record, page 311. Attach label(s) to page 312. Record number of capsules dispensed on page 311.

Reminder: The drug code on the study medication label must be identical to the preprinted Patient Number above.

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### MODULE PARAMETERS - WEEK 24



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VIT	ГΑ	T	CI	$\mathbf{C}$	NS

TT7 : 1 4	Sitting			Standing			
Weight ☐ lbs ☐ kg	Blood Pr (mmF systolic		Pulse (beats/ min)		Pressure nHg) diastolic	Pulse (beats/ min)	

#### ADVERSE EXPERIENCES / CONCOMITANT MEDICATION

Have	any adverse experiences been observed or elicited by the following direct question to the
patier	nt: "Do you feel different in any way since starting the treatment or since the last vi
	☐ Yes ☐ No
Γ	Record in the Adverse Experience section
L	
Has 1	there been any change in concomitant medication since the last visit?
	□ Yes □ No
_	
İ	Record in the Concomitant Medication section

#### CLINICAL GLOBAL IMPRESSIONS - GLOBAL IMPROVEMENT

Rate the treatmen patient c	total improvement whether or not, in your judgment, it is due entirely to drug at. Compared to his/her condition at admission to the study, how much has the changed?
-	1 = Very much improved
	2 = Much improved
	3 = Minimally improved
	4 = No change
	5 = Minimally worse
	6 = Much worse
m	7 = Very much worse

#### PLASMA SAMPLE - DRUG CONCENTRATION

Was a plasma sar	nple obtained for drug concentration?
☐ Yes	□ No

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# HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 1 OF 3

1.	Depressed Mood (sadness, hopelessness, helpless, worthless)  0 = Absent 1 = These feeling states indicated only on questioning 2 = These feeling states spontaneously reported verbally 3 = Communicates feeling states non-verbally, i.e., through facial expression, posture, voice and tendency to weep 4 = Patient reports virtually only these feeling states in his/her spontaneous
	verbal and non-verbal communication
2.	Feelings of Guilt
	<ul> <li>□ 0 = Absent</li> <li>□ 1 = Self reproach, feels he/she has let people down</li> <li>□ 2 = Ideas of guilt or rumination over past errors or sinful deeds</li> <li>□ 3 = Present illness is a punishment. Delusions of guilt</li> <li>□ 4 = Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations</li> </ul>
3.	Suicide
	<ul> <li>□ 0 = Absent</li> <li>□ 1 = Feels life is not worth living</li> <li>□ 2 = Wishes he/she were dead or any thoughts of possible death to self</li> <li>□ 3 = Suicide ideas or gesture</li> <li>□ 4 = Attempts at suicide (any serious attempt rates 4)</li> </ul>
4.	Insomnia Early
	<ul> <li>□ 0 = No difficulty falling asleep</li> <li>□ 1 = Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour</li> <li>□ 2 = Complains of nightly difficulty falling asleep</li> </ul>
5.	Insomnia Middle
	<ul> <li>0 = No difficulty</li> <li>1 = Patient complains of being restless and disturbed during the night</li> <li>2 = Waking during the night - getting out of bed rates 2 (except for purposes of voiding)</li> </ul>
6.	Insomnia Late
	<ul> <li>0 = No difficulty</li> <li>1 = Waking in early hours of the morning but goes back to sleep</li> <li>2 = Unable to fall asleep again if he/she gets out of bed</li> </ul>
7.	Work and Activities
	<ul> <li>0 = No difficulty</li> <li>1 = Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies</li> </ul>
	work or hobbies  2 = Loss of interest in activity; hobbies or work - either directly reported by patient, or indirectly in listlessness, indecision and vacillation (feels he/she has to push self to work or activities)
	<ul> <li>3 = Decrease in actual time spent in activities or decrease in productivity.</li> <li>4 = Stopped working because of present illness.</li> </ul>

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# HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 2 OF 3

8.	Retardation (slowness of thought and speech, impaired ability to concentrate; decreased motor activity)
	<ul> <li>□ 0 = Normal speech and thought</li> <li>□ 1 = Slight retardation at interview</li> <li>□ 2 = Obvious retardation at interview</li> <li>□ 3 = Interview difficult</li> <li>□ 4 = Complete stupor</li> </ul>
9.	Agitation
	<ul> <li>□ 0 = None</li> <li>□ 1 = Fidgetiness</li> <li>□ 2 = "Playing with" hands, hair, etc.</li> <li>□ 3 = Moving about, can't sit still</li> <li>□ 4 = Hand wringing, nail-biting, hair-pulling, biting of lips</li> </ul>
10.	Anxiety Psychic
	<ul> <li>□ 0 = No difficulty</li> <li>□ 1 = Subjective tension and irritability</li> <li>□ 2 = Worrying about minor matters</li> <li>□ 3 = Apprehensive attitude apparent in face or speech</li> <li>□ 4 = Fears expressed without questioning</li> </ul>
11.	Anxiety Somatic (physiological concomitants of anxiety such as: Gastrointestinal (dry mouth, wind, indigestion, diarrhea, cramps, belching), Cardiovascular (palpitations, headaches), Respiratory (hyperventilation, sighing), Urinary frequency, Sweating.
	<ul> <li>□ 0 = Absent</li> <li>□ 1 = Mild</li> <li>□ 2 = Moderate</li> <li>□ 3 = Severe</li> <li>□ 4 = Incapacitating</li> </ul>
12.	Somatic Symptoms Gastrointestinal
	<ul> <li>□ 0 = None</li> <li>□ 1 = Loss of appetite but eating. Heavy feelings in abdomen</li> <li>□ 2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms</li> </ul>
13.	Somatic Symptoms General
	<ul> <li>□ 0 = None</li> <li>□ 1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability</li> <li>□ 2 = Any clear-cut symptoms rates 2</li> </ul>
14.	Genital Symptoms (such as loss of libido and menstrual disturbances)
	<ul> <li>□ 0 = Absent</li> <li>□ 1 = Mild</li> <li>□ 2 = Severe</li> </ul>

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## HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 3 OF 3

15.	Hypochondriasis  ☐ 0 = Not present
	<ul> <li>□ 1 = Self-absorption (bodily)</li> <li>□ 2 = Preoccupation with health</li> <li>□ 3 = Frequent complaints, requests for help, etc.</li> <li>□ 4 = Hypochondriacal delusions</li> </ul>
16.	Loss of Weight
	<ul> <li>□ 0 = No weight loss</li> <li>□ 1 = Slight or doubtful loss of weight</li> <li>□ 2 = Obvious or severe loss of weight</li> </ul>
17.	Insight
	<ul> <li>□ 0 = Acknowledges being depressed and ill</li> <li>□ 1 = Acknowledges illness but attributes cause to bad food, climate, over-work, virus, need for rest, etc.</li> </ul>
	2 = Denies being ill at all
•	HAMD Score (Items 1-17)

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	RESSED MOOD  Worst Severity of Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	(7) VEX
	Duration of Current Episode:		# of we	æks					
2.	Worst Severity of Last Two Weeks:	(0)	(1)	(2) SLT	MLD	(4) MO	(5) SVR	(6) EX	(7) VEX
	Frequency:	Days	s/week						
	Average % time of the day:		%						
<u>DEP</u>	RESSED APPEAR	ANCE							
3.	Current Episode:	(0) NI	(1) NO	SLT	(3) MLD	(4) MO	SVR	(6) EX	
4.	Last Two Weeks:	(0) NI	(1) NO	SLT	MLD	(4) MO	SVR	(6) EX	
IDD	ITABILITY AND	ANCER							
<u>1KK</u>	Current Episode:	(0) NI	(I) NO	(2) SLT	MLD	(4) MO	(5) SVR	(6) EX	VE
	Duration:	<u> </u>	」# of ₩	reeks					
6.	Last Two Weeks:	(0) NI	(1) NO	SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	VE
	Frequency:	∐ Day	ys/week						
	Average % time of the day:	<u></u>	] %						
SEI	PARATION-DEPE	NDENT-I	OYSPHOI	RIA					
7.	Current Episode:	(0) NI	(1)	(2) OCC	USL	(4) ALW			
8.	Last Two Weeks:	(0) NI	(1) NO	occ	USL	(4) ALW			

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		onic MO	OD					-
QUA	LITY OF DYPSH		<u>עס</u>	(2)		T457		
9.	Current Episode:	(0) NI	ND	QUE	DDF	(4) VDF		
10.	Last Two Weeks:	(0) NI	(I) ND	QUE	DDF	VDF		
DEG	REE OF ASSOCIA	ATION OF	DEPRES	SED OR	IRRITABI	E MOOD	WITH SI	PECIFIC
<u>EVE</u>	NTS OR PREOCC	<u>UPATION</u>	<u>S</u>					
11.	Current Episode:	(0) NI	(1) NAL	(2) MOT	UN	PN		
12	Last Two Weeks:	(0) NI	(I) NAL	(2) MOT	(3) UN	(4) PN		
1. 40	Day I'm Troday	741 )	-1112	التحديق				
								1
REA	CTIVITY OF DE	PRESSED	OR IRRI	TABLE M	OOD			
		[(O)]	(1) VR	(2) FUL	(3) RES	(4) MLD	(5) SLT	(6) UNR
13.	Current Episode:	(0) NI	VR	FUL	[RES]	MLD	SLI	UNK
			% Usual	1 % of No	rmal			ļ
14.	Last Two Weeks:	(0) NI	(I) VR	FUL	(3) RES	(4) MLD	(5) SLT	UNR
			% Usua	l % of No	ormal			
			% Max	imum % o	f Normal			
		1 . 1	Number	of hours g	good feeling	g last		
				•				
DIU	JRNAL MOOD V	ARIATION	Į					
₩o	erse in Morning				[]AT	<del>- 77</del> 71	<u> </u>	
15.	Current Episode:	(0) NI	NW	MIN	MLD	(4) CW	EXT	
16.	Last Two Weeks:	(0) NI	(1) NW	(2) MIN	MLD	(4) CW	(5) EXT	
	-	<del></del>						
Wa	orse in Afternoon o		ening TOT	(2)	[(3)]	[7(4)]	(5) EXT	
17.	Current Episode:	(0) NI	NW	MIN	MLD	cw		
18.	. Last Two Weeks:	(0) NI	(1) NW	MIN	MLD.	CW	EXT	

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EXCESSIVE INAPPRO	PRIATE	GUILT						
19. Current Episode:	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT	
20. Last Two Weeks:	(0) NI	(1) NO	SLT	MLD	(4) MOD	(5) SVR	EXT	
Frequency:	Days/We	ek _	ا					
NEGATIVE SELF IMA	<u>AGE</u>							
21. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT	:
22. Last Two Weeks:	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT	
FEELING UNLOVED	FORLOF	<u>en</u>						
23. Current Episode:	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT	
24. Last Two Weeks:	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT	
Frequency:	Days/W							
			_					
HOPELESSNESS, HEL	PLESSNI	ESS, DISC	OURAGE	MENT, PE	SSIMISM			
25. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT	
26. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT	
CELE_DITY								
SELF-PITY	ത്ര	(1) NO	(2)	(3) MLD	(4)  CON			
27. Current Episode:	(0) NI		(2) OCC	MLD (3) MLD	CON (4) CON			
28. Last Two Weeks:	(0) NI	NO (1)	OCC.	MLD	COM			
ACHES AND PAINS								
29. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	MOD	(5) SVR	EXT	
30. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	MLD	MOD	(5) SVR	EXT	

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HYPOCHONDRIASIS							æ
31. Current Episode:	(0) NI	NO (I)	(2) SLT	(3) MLD	(4) ] MOD	(5) SVR	(6) EX
32. Last Two Weeks:	(0) NI	(1) NO	SLT	MLD	MOD	SVR	(6) EX
ANHEDONIA, LACK	OF INTE	REST, AF	ATHY, LO	OW MOT	IVATION,	BOREDO	<u>M</u>
Combined Overall Ratio	ng						
33. Current Episode:	(0) NI	(1) NO	SLT	MLD	(4) MO	(5) SVR	(6) EX
Duration:		_] # of ▼					
34. Last Two Weeks:	(0) NI	NO NO	(2) SLT	MLD	(4) MO	(5) SVR	(6) EX
Frequency:	Da	ys/week					
Average % time of the day:	I	_] %6					
Differentiating Lack	of Intere	st from A	Inhedonia				
Lack of Interest	(0) NI	[di]	(2)	<u>(3)</u>	(4)	(5) SVR	(6) EX
35. Current Episode:		NO.	SLT (2)	MLD (3)	<u>мо</u> ]	(5)	(6)
36. Last Two Weeks:	(0)	(1) NO	SLT	MLD	МО	SVR	EX
Anhedonia					T471	F751-1	ല
37. Current Episode:	(0) NI	NO (1)	SLT	MLD	МО	(3) SVR	(6) EX
38. Last Two Weeks:	(0) NI	(1) NO	SLT	MLD	(4) MO	SVR	(6) EX
FATIGUE, LACK OF	ENERGY	AND T	IREDNESS				
39. Current Episode:	(0)	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
40. Last Two Weeks:	(0)	(1) NO	(2) SLT	MLD	(4) MO	(5) SVR	(6) EX
Frequency:	Da	ys/Week					
							· · · · · · · · · · · · · · · · · · ·

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DIF	FICULTY CONCENTRA	TING,	INATTE	NTION, C	OR SLOW	ED THIN	KING		
41.	Current Episode: (0) NI	]	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
42.	Last Two Weeks: (0)	]	(I) NO	SLT	MLD	(4) MO	(5) SVR	(6) EX	
PSYCHOMOTOR AGITATION									
43.	Current Episode: N1	]	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
44.	Last Two Weeks: (0) NI	]	(I) NO	SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
	Frequency:	Days/	Week						
MA	NIFESTATIONS INCLU	J <b>DED</b> :							
	Unable to sit still								
45.	Current Episode:	(0) NI	(1) NPR	DBT	(3) PR	MOD	(5) SVR		
46.	Last Two Weeks:	(0) NI	(1) NPR	DBT	(3) PR	(4) MOD	(5) SVR		
	Pacing								
47.	Current Episode:	(0) NI	(1) NPR	DBT	(3) PR	SVR	(5) SVR		
48.	Last Two Weeks:	(0) NI	(1) NPR	DBT	(3) PR	(4) SVR	(5) SVR		
	Hand wringing								
49.	Current Episode:	(0) NI	(1) NPR	DBT	(3) PR	(4) SVR	(5) SVR		
50.	Last Two Weeks:	(0) NI	(I) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR		
	Pulling or rubbing on	hair. ci	lothing, sk	in					
51.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR		
52.	Last Two Weeks:	(0) NI	(I) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR		
	Can't stop talking, tali	ts on a	und on						
53.		(0) NI	(I) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR		
54.		(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR	1 .	
1									

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PSYC	HOMOTOR RETARD	ATION					ur.	
55.	Current Episode:	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MO	SVR	(6) EX
56.	Last Two Weeks:	(0) NI	(I) NO	SLT	(3) MLD	(4) MO	SVR	(6) EX
	Frequency:	Day	rs/Week					
MANI	FESTATIONS INCLU	J <b>DED</b> :						
Si	lowed Speech							
57.	Current Episode:	(O) NI	(1) NPR	DBT	PR	MOD	(5) SVR	
58.	Last Two Weeks:	(O) NI	(I) NPR	DBT	PR	(4) MOD	(5) SVR	
I.	ncreased pauses befor	e answer	ing					
59.	Current Episode:	(0) NI	(I) NPR	DBT	PR	MOD	(5) SVR	
60.	Last Two Weeks:	(0) NI	(1) NPR	DBT	PR	MOD	(5) SVR	
L	ow or monotonous spe		F-777-1	- <del> </del>	(7 <b>2</b> )"]	1720-3	17 <b>5</b> 7	
61.	Current Episode:	(0) NI	(I) NPR	DBT	(3) PR	MOD	SVR	
62.	Last Two Weeks:	(0) NI	(1) NPR	DBT	PR	(4) MOD	(5) SVR	
A	Aute or markedly dec	reased ar						
63.	Current Episode:	(0) NI	(I) NPR	DBT	(3) PR	MOD	(5) SVR	
64.	Last Two Weeks:	(0) NI	NPR	(2) D <b>B</b> T	PR	MOD	SVR	
s	Slowed body movement	ts						
65.	Current Episode:	(0) NI	NPR	DBT	(3) PR	MOD	(5) SVR	
66.	Last Two Weeks:	(0) NI	(I) NPR	DBT	PR	MOD	(5) SVR	
	Depressive stupor							
67.	Current Episode:	(0) NI	(I) NPR	DBT	PR	MOD	SVR	
68.	Last Two Weeks:	(0) NI	(1) NPR	DBT	PR	(4) MOD	(5) SVR	

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SOCIAL WITHDRAWAL										
69.	Current Episode:	(0) NI	(1) NO	SLT	(3) MLD	(4) MO	(5) SVR	(6) EX		
70.	Last Two Weeks:	(0) NI	(1) NO	SLT	MLD	(4) MO	SVR	(6) EX		
REJ	ECTION SENSITI		****	- <del></del>	( <del>-(2</del> )	(72)	শের ।	r (6) 1		
71.	Last Year:	NI NI	NO NO	SLT	(3) MLD	MOD	(5) SVR	(6) EX		
72.	Current Episode:	(0) NI	(I)	SLT	MLD	MOD	(5) SVR	(6) EX		
73.	Last Year:	(0)	(I) NO	(2) SLT	MLD	(4) MOD	(5) SVR	(6) EX		
74.	Current Episode:	(0) NI	(1) NO	SLT	(3) MLD	MOD	(5) SVR	(6) EX		
SLI	SLEEP PROBLEMS									
75.	Hours sl	ept before	onset of	depression						
76.	Hours sl	ept during	the curren	nt episode						
77.	Hours s	ept during	the last t	wo weeks						
	TOPOCOMAILA									
HY	PERSOMNIA									
78.	Hours s	lept in day	ytime of cu	ırrent episo	de					
79.	Hours s	lept in da	ytime in th	e last two	weeks					
80.	Hours 1	ying down	in current	episode						
81.	81. Li Hours lying down in last two weeks									
82	. Current Episode:	(0) NI	(I) NO	(2)	(3)	(4)	(5)	(6)		
83	-	100	(1) NO	(2)	(3)	(4)	(5)	(6)		
1										

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NSOM	NIA					,		
<b>4.</b> C	urrent Episode:	(0) NI	(I) NO	(2)	(3)	(4)	(5)	(6)
<b>5.</b> La	st Two Weeks:	(0) N <u>I</u>	NO NO	(2)	(3)	(4)	(5)	(6)
	Frequency:	Nigh	ts/Week					
TYPE	S OF INSOMNIA							
	Initial Insomnia	F 78.		<del></del> 1	LTENT	F7577	<u> </u>	[3]
86.	Current Episo		_	(1) NPR	DBT	(3) MLD	MOD	(5) SVR
87.	Last Two Wee	ks: N		(1) NPR	DBT	MLD	MOD	(5) SVR
	Middle Insomnia	[-77	77	r <del>ou</del> l	<u> </u>	[137]	[ (4) ]	(5) SVR
88.	Current Episo			(1) NPR	DBT	MLD	MOD	
89.	Last Two Wes	eks: N	) I	(1) NPR	DBT	MLD	MOD	(5) SVR
	Terminal Insomni				COV.	<del>-181</del>	<u> </u>	[(3)]
90.	Current Episo		I	(I) NPR	DBT	MLD	MOD	(5) SVR
91.	Last Two We	eks: N	<u>n</u>	(I) NPR	DBT	MLD	(4) MOD	(5) SVR
	Circadian Reverso		<del>15  </del>	[76]	<del>[ [2</del> ] ]	T(3) 1	[ ( <del>4</del> ) ]	[3]
92.	Current Epis		0) (I	(1) NPR	DBT	MLD	MOD	SVR
93.	Last Two We	eks:	0) (1)	(I) NPR	DBT	MLD	MOD	SVR
	Non-restorative s		רא	רסטו	(2)	<b>୮</b> (3) ]	[T47]	[37]
94.	Current Epis		NI NI	(1) NPR	DBT	MLD	MOD	(5) SVR
95.	Last Two We	eks:	(0) NI	(1) NPR	DBT	MLD	(4) MOD	(5) SVR
	Daytime sleepine		ron 1	гт	<del>[ (2)  </del> 1	[ <del>-(3)-1</del>	[ <del>(4)</del> ]	(5)
96.	Current Epis		NI_	(I) NPR	DBT	MLD	MOD MOD	(5) SVR
97.	Last Two W	eeks:	(0) NI	(1) NPR	(2) DBT	MLD	MOD	(5) SVR

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ANOREXIA  98. Current Episode:  99. Last Two Weeks:	(0) NI (0) NI	(1) NO	(2) SLT	(3) MLD (3) MLD	(4) MOD (4) MOD	(5) RAR (5) RAR	(6) NVR (6) NVR
WEIGHT LOSS  100. Current Episode:			(vm.)				
Pounds lost:  Number of Weeks:  101. Last Two Weeks:  Pounds lost:							
INCREASED APPETIT  102. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	MOD	(5) SVR	(6) EX
103. Last Two Weeks:  Frequency:	NI L	Days/Weel	(2) SLT	MLD	(4) MOD	(5) SVR	EX.
STRONG CRAVING F  104. Current Episode:  105. Last Two Weeks:	(0) NI	(I) ABS (II) ABS	(2) DBT (2) DBT	(3) MLD MLD	(4) MOD MOD	(5) SVR (5) SVR	
WEIGHT GAIN  106. Current Episode:  Pounds gained:  Number of Weeks:	<u></u>						
107. Last Two Weeks:		lbs.					

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SUICIDAL IDEATION	-								
108. Current Episode:	(0) NI	NO (1)	SLT	MLD	(4) MO	SVR	(6) EX	VEX	
109. Last Two Weeks:	(0) NI	(I)	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	VEX	
Suicidal Acts – Numbe	r								
110. Current Episode:									
111. Last Two Weeks:									
Suicidal Acts – Seriou	sness								
112. Current Episode:	(0) NI	NO (I)	(2) MIN	(3) DEF	s	(4) SER	(5) VS	EXT	
113. Last Two Weeks:	(0) NI	(I)	(2) MIN	(3) DEF	s	(4) SER	(5) VS	EXT	
Medical Lethality									
114. Current Episode	(0)	(1) NO	(2) MIN	(3) MLD		(4) MO	(5) SVR	EXT	
115. Last Two Weeks:	(0) NI	(1) NO	(2) MIN	(3) MLD		(4) MO	(5) SVR	(6) EXT	
Non-Suicidal Physica	i Self-D	emaging	Acts						
116. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD		(4) MO	(5) SVR	(6) ACT	
117. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	] [	(4) MO	(5) SVR	ACT	

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DDIE-SADS-LII								
MANIC SYNDROME								±*
ELATION, EXPANSIV	E MOO	<u>D</u>						
1. Current Episode:	(0) NI	(1) NO	SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
2. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
DECREASED NEED F	OR SLEI	EΡ						
3. Current Episode:	(0) NI	(I)	(2) -1	(3)	(4) -3	(5)	(6) -4+	
4. Last Two Weeks:	(0) NI	(I) NO	(2)	(3)	(4) -3	(5) -4	(6) -4+	
		_ <del>_</del>						
UNUSUALLY ENERG		LACT.	[79V]	<u> [737 ]</u>	T4T1	T3D1	[767]	
5. Current Episode:	(0) NI	NO (1)	SLT	(3) LCH	(4) MOR	(5) MM	(6) UA	
6. Last Two Weeks:	(0)	(1) NO	(2) SLT	LCH	MOR	(5) MM	(6) UA	
INCREASE IN GOAL	DIREC	TED ACT	IVITY					
7. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX	
8. Last Two Weeks:	(0) NI	(I)	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX	
GRANDIOSITY								
	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	•
9. Current Episode:					(4) MO	(5) SVR	(6) EX	
10. Last Two Weeks:	(0) NI	(I) NO	(2) SLT	MLD	мо	SVR	[EX]	
ACCELERATED, PRE	SSURED	OR INC	REASEL	AMOU	NT OF S	PEECH		
11. Current Episode:	(0) NI	(I)	(2) <b>S</b> LT	(3) MLD	(4) MO	(5) MKD	(6) EX	
12. Last Two Weeks:	(0) NI	NO (I)	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX	
						····		

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ADDIE-SAD									 
RACING THO	UGHTS								
13. Current E	pisode:	(0) NI	(I)	(2) DBT	(3) MLD	(4) MO	(5) SVR	(6) EX	
14. Last Two	Weeks:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	(6) EX	
FLIGHT OF I	DE <u>AS</u>								
15. Current E	pisode:	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
16. Last Two	Weeks:	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
POOR JUDGE	MENT								
17. Current F	-	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) VS	
18. Last Two		(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) VS	
DISTRACTAB	ILITY								
19. Current l		(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR		
20. Last Two		(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR		
MOTOR HYP	ERACTI	VITY							
21. Current		(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKI	(6) EX	
22. Last Two	-	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX	
I na p pro priate	e laughin;	g, jokinį	g or puni						
23. Current	Episode:	(0) NI	NO NO	DBT	MLD	MOD			
24. Last Two	Weeks:	(0) NI	(1) NO	(2) DBT	MLD	MOD			
Uninhibited j	people sec								
25. Current	Episode:	(0) NI	(I)	(2) (DBT)	MLD	(4) MOD			
26. Last Two	Weeks:	(0) NI	(I)	(2) DBT	(3) MLD	(4) MOD			 

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Inc	reased Productivity					J.	
27.	Current Episode:	(0) NI	NO (I)	DBT	PRS	SVR	
28.	Last Two Weeks:	(0) NI	NO NO	(2) DBT	PRS	SVR	
Ç.	rpened and unusua	liv creat	ivo thinki	Rσ			
Snu	грепец или влазац	isy creas	.,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,	***			
29.	Current Episode:	(0) NI	(I) NO	(Z) DBT	PRS	SVR	
30.	Last Two Weeks:	(0) NI	(1) NO	(2) DBT	(3) PRS	(4) SVR	
Ну	persexuality						
31.	Current Episode:	(0) NI	(1) NO	(2) DBT	(3) PRS	(4) SVR	
32.	Last Two Weeks:	(0)	NO NO	(2) DBT	PRS	SVR	
IN	LUENCE OF ILLI	CIT DR	UGS OR	ALCOH	<u>OL</u>		
33.	Current Episode:	(0) NA	(1) NVR	(2) SMT	(3) ONL		
34.		(0) NA	(1) NVR	(2) SMT	(3) ONL		
			<del></del>				
NU	MBER OF MANIC	PERIC	<u>DDS</u>				
35.							

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#### STUDY MEDICATION RECORD

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily	
<u>,                                    </u>				

#### STUDY MEDICATION DOSING CHANGES

☐ Yes ——	N Y 32 4 16			
	→ Indicate char	nge(s) belo	OW .	
	Reminder:	Changes i	in dose constitu	e deviation from the protoco
	Reminder.	CHame		
Start Date	End Date day month year	Dose Level	Number of Capsules Daily	Reason for Dose Change

#### STUDY MEDICATION COMPLIANCE

Capsules Dispensed (A)	Capsules Returned (B)	Capsules Taken (A - B)	Days Since Last Visit	% Compliance			
•	npliance m	(N [★] x oust be ≥ 8	of capsules days since 1 0% and $\leq$ 1 lant for two	ast visit) x	100 100 visits?	* _N =	number of capsules dail (see above)

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# STUDY MEDICATION LABEL Attach label here Attach label here Attach label here Attach label here The drug code on the study medication label must be identical to the preprinted Patient Number above. Important: Enter patient number (drug code as listed on clinical supplies)

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#### STUDY MEDICATION DISPENSING

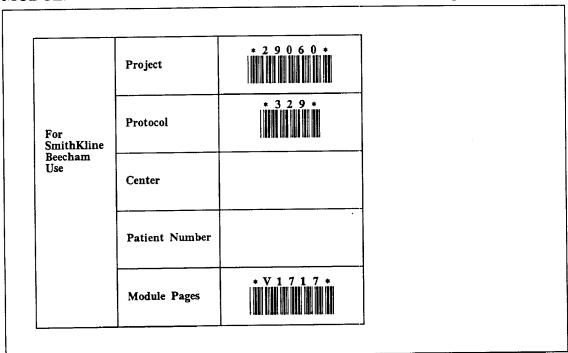
Record study medication information for Weeks 25-28 in the Study Medication Record, page 331. Attach label(s) to page 332. Record number of capsules dispensed on page 331.

The drug code on the study medication label must be identical to the preprinted Patient Number above.

### SMITHKline Beecham Pharmaceuticals

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### MODULE PARAMETERS - WEEK 28



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#### **VITAL SIGNS**

*** · 1 4	s	itting		Standing	
Weight □ lbs □ kg	Blood Pro (mmH systolic		Pulse (beats/ min)	Pressure nHg) diastolic	Pulse (beats/ min)
	1 1/		, , ,	/	

### ADVERSE EXPERIENCES / CONCOMITANT MEDICATION

	any adverse experiences seem any way since starting the treatment or since the last
	Yes No
ſ	Record in the Adverse Experience section
las 1	there been any change in concomitant medication since the last visit?

### CLINICAL GLOBAL IMPRESSIONS - GLOBAL IMPROVEMENT

treatm patient		Compared to his/her condition at admission to the study, how much has the
•		
	1 =	Very much improved
	2 =	Much improved
	3 =	Minimally improved
	4 =	No change
	5 =	Minimally worse
	6 =	Much worse
	7 -	Very much worse

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# HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 1 OF 3

1.	Depressed Mood (sadness, hopelessness, helpless, worthless)  0 = Absent 1 = These feeling states indicated only on questioning 2 = These feeling states spontaneously reported verbally 3 = Communicates feeling states non-verbally, i.e., through facial expression, posture, voice and tendency to weep 4 = Patient reports virtually only these feeling states in his/her spontaneous verbal and non-verbal communication
2.	Feelings of Guilt
	<ul> <li>0 = Absent</li> <li>1 = Self reproach, feels he/she has let people down</li> <li>2 = Ideas of guilt or rumination over past errors or sinful deeds</li> <li>3 = Present illness is a punishment. Delusions of guilt</li> <li>4 = Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations</li> </ul>
3.	Suicide
	□ 0 = Absent □ 1 = Feels life is not worth living □ 2 = Wishes he/she were dead or any thoughts of possible death to self □ 3 = Suicide ideas or gesture □ 4 = Attempts at suicide (any serious attempt rates 4)
4.	Insomnia Early
	Insumme rand
	□ 0 = No difficulty falling asleep □ 1 = Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour □ 2 = Complains of nightly difficulty falling asleep
5.	<ul> <li>□ 0 = No difficulty falling asleep</li> <li>□ 1 = Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour</li> </ul>
	<ul> <li>□ 0 = No difficulty falling asleep</li> <li>□ 1 = Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour</li> <li>□ 2 = Complains of nightly difficulty falling asleep</li> </ul>
5.	<ul> <li>□ 0 = No difficulty falling asleep</li> <li>□ 1 = Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour</li> <li>□ 2 = Complains of nightly difficulty falling asleep</li> <li>Insomnia Middle</li> <li>□ 0 = No difficulty</li> <li>□ 1 = Patient complains of being restless and disturbed during the night</li> <li>□ 2 = Waking during the night - getting out of bed rates 2 (except for</li> </ul>
5.	<ul> <li>□ 0 = No difficulty falling asleep</li> <li>□ 1 = Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour</li> <li>□ 2 = Complains of nightly difficulty falling asleep</li> <li>Insomnia Middle</li> <li>□ 0 = No difficulty</li> <li>□ 1 = Patient complains of being restless and disturbed during the night</li> <li>□ 2 = Waking during the night - getting out of bed rates 2 (except for purposes of voiding)</li> </ul>
5.	<ul> <li>□ 0 = No difficulty falling asleep</li> <li>□ 1 = Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour</li> <li>□ 2 = Complains of nightly difficulty falling asleep</li> <li>Insomnia Middle</li> <li>□ 0 = No difficulty</li> <li>□ 1 = Patient complains of being restless and disturbed during the night</li> <li>□ 2 = Waking during the night - getting out of bed rates 2 (except for purposes of voiding)</li> <li>Insomnia Late</li> <li>□ 0 = No difficulty</li> <li>□ 1 = Waking in early hours of the morning but goes back to sleep</li> <li>□ 2 = Unable to fall asleep again if he/she gets out of bed</li> </ul>
5.	<ul> <li>□ 0 = No difficulty falling asleep</li> <li>□ 1 = Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour</li> <li>□ 2 = Complains of nightly difficulty falling asleep</li> <li>Insomnia Middle</li> <li>□ 0 = No difficulty</li> <li>□ 1 = Patient complains of being restless and disturbed during the night</li> <li>□ 2 = Waking during the night - getting out of bed rates 2 (except for purposes of voiding)</li> <li>Insomnia Late</li> <li>□ 0 = No difficulty</li> <li>□ 1 = Waking in early hours of the morning but goes back to sleep</li> <li>□ 2 = Unable to fall asleep again if he/she gets out of bed</li> </ul>

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## HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 2 OF 3

8. Retardation (slowness of thought and speech, impaired ability to concentrate; decreased motor activity)    0 = Normal speech and thought   1 = Slight retardation at interview   2 = Obvious retardation at interview   3 = Interview difficult   4 + Complete stupor  9. Agitation   0 = None   1 = Fidgetiness   2 = "Playing with" hands, hair, etc.   3 = Moving about, can't sit still   4 + Hand wringing, nail-biting, hair-pulling, biting of lips  10. Anxiety Psychic   0 = No difficulty   1 = Subjective tension and irritability   2 = Worrying about minor matters   3 = Apprehensive attitude apparent in face or speech   4 + Fears expressed without questioning  11. Anxiety Somatic (physiological concomitants of anxiety such as: Gastrointestinal (dry mouth, wind, indigestion, diarrhea, cramps, belching), Cardiovascular (palpitations, headaches), Respiratory (hyperventilation, sighing), Urinary frequency, Sweating.   0 = Absent   1 = Mild   2 = Moderate   3 = Severe   4 = Incapacitating  12. Somatic Symptoms Gastrointestinal   0 = None   1 = Loss of appetite but eating, Heavy feelings in abdomen   2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms  13. Somatic Symptoms General   0 = None   1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability   2 = Any clear-cut symptoms rates 2  14. Genital Symptoms (such as loss of libido and menstrual disturbances)   0 = Absent   1 = Mild   2 = Severe			
4 = Complete stupor  9. Agitation		8.	(slowness of thought and speech, impaired ability to concentrate; decreased motor activity)  ☐ 0 = Normal speech and thought ☐ 1 = Slight retardation at interview ☐ 2 = Obvious retardation at interview
0 = None   1 = Fidgetiness   2 = "Playing with" hands, hair, etc.   3 = Moving about, can't sit still   4 = Hand wringing, nail-biting, hair-pulling, biting of lips			
1 = Fidgetiness   2 = "Playing with" hands, hair, etc.   3 = Moving about, can't sit still   4 = Hand wringing, nail-biting, hair-pulling, biting of lips		9.	Agitation
0 = No difficulty   1 = Subjective tension and irritability   2 = Worrying about minor matters   3 = Apprehensive attitude apparent in face or speech   4 = Fears expressed without questioning    11. Anxiety Somatic (physiological concomitants of anxiety such as: Gastrointestinal (dry mouth, wind, indigestion, diarrhea, cramps, belching), Cardiovascular (palpitations, headaches), Respiratory (hyperventilation, sighing), Urinary frequency, Sweating.   0 = Absent   1 = Mild   2 = Moderate   3 = Severe   4 = Incapacitating    12. Somatic Symptoms Gastrointestinal   0 = None   1 = Loss of appetite but eating. Heavy feelings in abdomen   2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms   13. Somatic Symptoms General   0 = None   1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability   2 = Any clear-cut symptoms rates 2   14. Genital Symptoms (such as loss of libido and menstrual disturbances)   0 = Absent   1 = Mild			<ul> <li>□ 1 = Fidgetiness</li> <li>□ 2 = "Playing with" hands, hair, etc.</li> <li>□ 3 = Moving about, can't sit still</li> </ul>
1 = Subjective tension and irritability   2 = Worrying about minor matters   3 = Apprehensive attitude apparent in face or speech   4 = Fears expressed without questioning    11. Anxiety Somatic (physiological concomitants of anxiety such as: Gastrointestinal (dry mouth, wind, indigestion, diarrhea, cramps, belching), Cardiovascular (palpitations, headaches), Respiratory (hyperventilation, sighing), Urinary frequency, Sweating.   0 = Absent   1 = Mild   2 = Moderate   3 = Severe   4 = Incapacitating    12. Somatic Symptoms Gastrointestinal   0 = None   1 = Loss of appetite but eating. Heavy feelings in abdomen   2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms   13. Somatic Symptoms General   0 = None   1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability   2 = Any clear-cut symptoms rates 2   14. Genital Symptoms (such as loss of libido and menstrual disturbances)   0 = Absent   1 = Mild		10.	Anxiety Psychic
(physiological concomitants of anxiety such as: Gastrointestinal (dry mouth, wind, indigestion, diarrhea, cramps, belching), Cardiovascular (palpitations, headaches), Respiratory (hyperventilation, sighing), Urinary frequency, Sweating.    0 = Absent			<ul> <li>□ 1 = Subjective tension and irritability</li> <li>□ 2 = Worrying about minor matters</li> <li>□ 3 = Apprehensive attitude apparent in face or speech</li> </ul>
1 = Mild   2 = Moderate   3 = Severe   4 = Incapacitating     12. Somatic Symptoms Gastrointestinal   0 = None   1 = Loss of appetite but eating. Heavy feelings in abdomen   2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms     13. Somatic Symptoms General   0 = None   1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability   2 = Any clear-cut symptoms rates 2     14. Genital Symptoms (such as loss of libido and menstrual disturbances)   0 = Absent   1 = Mild		11.	(physiological concomitants of anxiety such as: Gastrointestinal (dry mouth, wind, indirection, diarrhea, cramps, belching), Cardiovascular (palpitations, headaches),
<ul> <li>□ 0 = None</li> <li>□ 1 = Loss of appetite but eating. Heavy feelings in abdomen</li> <li>□ 2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms</li> <li>13. Somatic Symptoms General</li> <li>□ 0 = None</li> <li>□ 1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability</li> <li>□ 2 = Any clear-cut symptoms rates 2</li> <li>14. Genital Symptoms (such as loss of libido and menstrual disturbances)</li> <li>□ 0 = Absent</li> <li>□ 1 = Mild</li> </ul>			☐ 1 = Mild ☐ 2 = Moderate ☐ 3 = Severe
<ul> <li>□ 1 = Loss of appetite but eating. Heavy feelings in abdomen</li> <li>□ 2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms</li> <li>13. Somatic Symptoms General</li> <li>□ 0 = None</li> <li>□ 1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability</li> <li>□ 2 = Any clear-cut symptoms rates 2</li> <li>14. Genital Symptoms (such as loss of libido and menstrual disturbances)</li> <li>□ 0 = Absent</li> <li>□ 1 = Mild</li> </ul>		12.	Somatic Symptoms Gastrointestinal
<ul> <li>□ 0 = None</li> <li>□ 1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability</li> <li>□ 2 = Any clear-cut symptoms rates 2</li> <li>14. Genital Symptoms (such as loss of libido and menstrual disturbances)</li> <li>□ 0 = Absent</li> <li>□ 1 = Mild</li> </ul>			☐ 1 = Loss of appetite but eating. Heavy feelings in abdomen ☐ 2 = Difficulty eating without urging. Requests or requires laxatives or medication for
☐ 1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability ☐ 2 = Any clear-cut symptoms rates 2  14. Genital Symptoms (such as loss of libido and menstrual disturbances) ☐ 0 = Absent ☐ 1 = Mild		13.	Somatic Symptoms General
□ 0 = Absent □ 1 = Mild			1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability
$\square$ 1 = Mild	ļ	14.	Genital Symptoms (such as loss of libido and menstrual disturbances)
			$\square$ 1 = Mild

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## HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 3 OF 3

	15.	Hypochondriasis
		<ul> <li>□ 0 = Not present</li> <li>□ 1 = Self-absorption (bodily)</li> <li>□ 2 = Preoccupation with health</li> <li>□ 3 = Frequent complaints, requests for help, etc.</li> <li>□ 4 = Hypochondriacal delusions</li> </ul>
	16.	Loss of Weight
		<ul> <li>□ 0 = No weight loss</li> <li>□ 1 = Slight or doubtful loss of weight</li> <li>□ 2 = Obvious or severe loss of weight</li> </ul>
	17.	Insight
		<ul> <li>□ 0 = Acknowledges being depressed and ill</li> <li>□ 1 = Acknowledges illness but attributes cause to bad food, climate, over-work, virus, need for rest, etc.</li> </ul>
i		2 = Denies being ill at all
	•	HAMD Score (Items 1-17)

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DEF	PRESSED MOOD		-					-	
1.	Worst Severity of Current Episode:	(0) NI	(I)	(2) SLT	(3) MLD	(4) MO	SVR	(6) EX	(7) VEX
	Duration of Current Episode:		# of we	eeks					
2.	Worst Severity of Last Two Weeks:	(0) NI	(1) NO	SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	(7) VEX
	Frequency:	∐ Days	s/week						
	Average % time of the day:	<u></u>	96						
DEF	PRESSED APPEAR	ANCE							
3.	Current Episode:	(0) NI	NO NO	SLT	MLD	(4) MO	SVR	(6) EX	
4.	Last Two Weeks:	(0) NI	NO NO	SLT	MLD	(4) MO	(5) SVR	EX	
IRR	RITABILITY AND	ANGER							
5.	Current Episode:	(0) NI	(I) NO	SLT	MLD	(4) MO	(5) SVR	(6) EX	(7) VEX
	Duration:	<u> </u>	# of w	eeks					
6.	Last Two Weeks:	(0) NI	(1) NO	SLT	MLD	(4) MO	(5) SVR	(6) EX	(7) VEX
	Frequency:	∐ Day	s/week						
	Average % time of the day:	L	J %						
SEF	PARATION-DEPE	NDENT-D	YSPHOR	<u>IA</u>					
7.	Current Episode:	(0) NI	(I) NO	(2) OCC	USL	(4) ALW			
8.	Last Two Weeks:	(0) NI	NO (I)	OCC	USL	(4) ALW			

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QUALITY OF DYPSH	ORIC MO	ЮD										
9. Current Episode:	(0) NI	(I) ND	QUE	(3) DDF	VDF							
10. Last Two Weeks:	(0) NI	(1) ND	QUE	(3) DDF	(4) VDF							
DEGREE OF ASSOCIATION OF DEPRESSED OR IRRITABLE MOOD WITH SPECIFIC EVENTS OR PREOCCUPATIONS												
11. Current Episode:	(0) N1	(I) NAL	(2) MOT	(3) UN	(4) PN							
12. Last Two Weeks:	(0) NI	(1) NAL	(2) MOT	(3) UN	(4) PN							
DE CONTRACTO OF DE	DDECCED	יוסמו מח	TADIE M	(OOD								
REACTIVITY OF DE	PKESSED	OK IKKI	IADLE IV	ЮОВ								
13. Current Episode:	(0) NI	(1) VR	(Ž) FUL	(3) RES	(4) MLD	(5) SLT	(6) UNR					
		% Usua	1 % of No	ormal								
14. Last Two Weeks:	(0) N <u>I</u>	(1) VR	(2) FUL	(3) RES	(4) MLD	(5) SLT	UNR					
		% Usua	1 % of No	ormal								
	لـــــا	% Maxi	imum % o	f Normal								
		Number	of hours g	good feeling	g l <b>a</b> st							
DIURNAL MOOD V	<u>ARIATION</u>	Ĭ										
Worse in Morning												
15. Current Episode:	(0) NI	NW	MIN	MLD	(4) CW	EXT						
16. Last Two Weeks:	(0) NI	(1) N <b>W</b>	(2) MIN	MLD	CW	EXT						
Worse in Afternoon	and/or Eve	ning										
17. Current Episode:	(0) NI	NW	(2) MIN	MLD	CW	EXT						
18. Last Two Weeks:	(0) NI	(I) NW	MIN	(3) MLD	CW CW	EXT						

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EXCESSIVE INAPPRO	PRIATE	GUILT						
19. Current Episode:	(0) NI	NO NO	(2) SLT	(3) MLD	(4) MOI	(5) SVR	(6) EXT	
20. Last Two Weeks:	(0) NI	(I) NO	SLT	MLD	MOD	(5) SVR	(6) EXT	
Frequency:	Days/We	æk [						
NEGATIVE SELF IM	<u>AGE</u>							
21. Current Episode:	(0) IN	(1) NO	SLT	(3) MLD	(4) MOD	(5) SVR	EXT	
22. Last Two Weeks:	NI (0)	(I) NO	SLT	(3) MLD	MOD	SVR	(6) EXT	
					-			
FEELING UNLOVED	/FORLO	<u>en</u>						
23. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT	
24. Last Two Weeks:	(0) NI	NO NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT	
Frequency:	Days/W	eek [						
HOPELESSNESS, HEL	PLESSNI	ESS, DISC	<u>OURAGEN</u>	MENT, PE	SSIMISM			
25. Current Episode:	(0)	(I)	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT	
26. Last Two Weeks:	(0) NI	(I) NO	SLT	(3) MLD	(4) MOD	SVR	(6) EXT	
SELF-PITY								
37 G A Princip	(0) NI	(1) NO	(2) OCC	(3) MLD	(4) CON			
27. Current Episode: 28. Last Two Weeks:	(0) NI	(I) NO	(2) OCC	(3) MLD	(4) CON			
Zo. Last Iwo Weeks.	[NI]	[NO]	[OCC]	111.2.2.				
ACHES AND PAINS					<b></b>		r-76-1	
29. Current Episode:	(0) NI	NO NO	(2) SLT	MLD	(4) MOD	(5) SVR	(6) EXT	
30. Last Two Weeks:	(0) NI	(I)	SLT	MLD	MOD	(5) SVR	EXT	_

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HYPOCHONDRIASIS													
31. Current Episode:	(0) NI	(1) NO	(2) SLT	MLD	MOD	(5) SVR	(6) EX						
32. Last Two Weeks:	(0) NI	(I) NO	SLT	MLD	MOD	(5) SVR	(6) EX						
ANHEDONIA, LACK OF INTEREST, APATHY, LOW MOTIVATION, BOREDOM													
Combined Overall Rating													
33. Current Episode:	(0) NI	(1) NO	SLT	MLD	MO	SVR	(6) EX						
Duration:		# of			F-773	<del></del>	[72V]						
34. Last Two Weeks:	NI	NO NO	SLT	MLD	(4) MO	(5) SVR	(6) EX						
Frequency:		Days/week											
Average % time of the day:	ـــــا	96											
Differentiating Lack	of Inte	erest from .	Anhedonia										
Lack of Interest	رها	רשן	(2)	(3)	(4) MO	(5) SVR	(6) EX						
35. Current Episode:	[N]	(I)	SLT (2)	MLD (3)		(5) SVR	(6) EX						
36. Last Two Weeks:	NI	NO	SLT	MLD	МО	SVR	[EX]						
Anhedonia	ெ	[0]	(2) SLT	(3)	(4)	(5)	(6)						
37. Current Episode:	и	NO (1)	SLT (2)	MLD	<u>MO</u>	SVR (5) SVR	EX (6) EX						
38. Last Two Weeks:	NI NI	NO	SLT	MLD	<u>MO</u>	SVR	EX						
FATIGUE, LACK OF	ENER	GY AND T	IREDNESS	į									
39. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4)	SVR	(6) EX						
40. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX						
Frequency	Ц	Days/Week				· <u></u>	-						

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	DIFFICULTY CONCENTRATING, INATTENTION, OR SLOWED THINKING												
DIF	FICULTY CONCENTR	ATING,	INATTE	NTION, C	K SLUW	ED IHIN							
41.	Current Episode: NI		NO NO	(2) SLT	(3) MLD	(4) MO	SVR	(6) EX					
42.	Last Two Weeks: (0)	] [	(1) NO	SLT	MLD	(4) MO	(5) SVR	(6) EX					
PSY	CHOMOTOR AGITAT	<u>ION</u>											
43.	Current Episode: N		(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX					
44.	Last Two Weeks:		(I) NO	SLT	(3) MLD	(4) MO	(5) SVR	(6) EX					
	Frequency:	Days/V	Veck										
MA	NIFESTATIONS INCL	UDED:											
	Unable to sit still						_	·					
45.	Current Episode:	(0) NI	(I) NPR	DBT	(3) PR	(4) MOD	S.	5) /R					
46.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	sy	5) VR					
	Pacing												
47.	Current Episode:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	s'	5) VR					
48.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	<u>s</u>	(3) VR					
	Hand wringing												
49.	Current Episode:	(0) NI	(I) NPR	(2) DBT	(3) PR	(4) SVR	] <u>[</u>	(5) VR					
50.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	] [s	(5) VR					
	Pulling or rubbing on	hair, cl	othing, sk	in									
51.		(0) NI	(I) NPR	(2) DBT	(3) PR	(4) SVI		(5) SVR					
52.		1.101	(I) NPR	(2) DBT	_	_		(5) SVR					
32	Last Iwo weeks:	NI_	NPR	ក្រធរ	LPK	_ [ <del>31</del> ]	يا د						
	Can't stop talking, ta				, ,			- ( <del>5)</del> 1					
53	. Current Episode:	(0) NI	(I) NPR		<u>  PR</u>			SVR					
54	. Last Two Weeks:	(0) NI	(I) NPR	DBT	PR	(4 SV	R [	SVR					
i													

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SYCI	HOMOTOR RETARE	ATION						
5.	Current Episode:	(0) NI	(I)	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
56.	Last Two Weeks:	(6) NI	NO NO	SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
	Frequency:	Day	/s/Week					
MANI	FESTATIONS INCL	U <b>DED</b> :						
Si	lowed Speech				<del></del>	- <del> </del>	C757-1	
57.	Current Episode:	(0) NI	NPR	DBT	(3) PR	(4) MOD	(5) SVR	
58.	Last Two Weeks:	(0) NI	(I) NPR	(2) DBT	(3) PR	MOD	SVR	
I	ncreased pauses befor				(75 <u>)</u>	F25	F75-1	
59.	Current Episode:	(0) NI	(1) NPR	DBT	PR	MOD	SVR	
60.	Last Two Weeks:	(0) NI	(I) NPR	DBT	(3) PR	MOD	SVR	
L	ow or monotonous sp			<del>- 741 - 1</del>	[Tex.]	( <del>187</del> 1	<u>िका</u>	
61.	Current Episode:	NI	(I) NPR	DBT	PR	(4) MOD	(5) SVR	
62.	Last Two Weeks:	(0) NI	NPR	(2) DBT	(3) PR	(4) MOD	(S) SVR	
A	Mute or markedly dec	reased a						
63.	Current Episode:	(0) NI	NPR	DBT	(3) PR	MOD	(5) SVR	
64.	Last Two Weeks:	(0)	(1) NPR	(2) DBT	(3) PR	MOD	(5) SVR	
	Slowed body movemen				<del>( 741 - 1</del>		C47	
65.	Current Episode:	(0) NI	(1) NPR	DBT	(3) PR	MOD	(5) SVR	
66.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR	
	Depressive stupor						1785	
67.	Current Episode:	(0) NI	NPR	DBT	(3) PR	MOD	(5) SVR	
68.	Last Two Weeks:	(0) NI	(I) NPR	(2) DBT	(3) PR	(4) MOD	(5) SVR	

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ZIDI	IE-SADS-LI	E. E. H. H. H. HAT.	L AIT		DVILL	CILITO			1 0101
soc	IAL WITHDRAW	/AL						±*	
69.	Current Episode:	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
70.	Last Two Weeks:	(0) NI	NO	SLT	MLD	(4) MO	(5) SVR	(6) EX	
REJ	ECTION SENSITI	VITY							:
71.	Last Year:	(0) NI	(1) NO	SLT	MLD	MOD	SVR	(6) EX	
72.	Current Episode:	(0) NI	(I) NO	SLT	(3) MLD	MOD	(5) SVR	(6) EX	j
73.	Last Year:	(0)	NO NO	SLT	MLD	MOD	(5) SVR	(6) EX	
74.	Current Episode:	(0)	NO (I)	SLT	MLD	MOD	(5) SVR	(6) EX	
SLE	EP PROBLEMS								
75.	Hours s	lept before	onset of	depression					
76.	Hours s	lept during	the curren	nt episode					
77.	Hours s	lept during	the last t	wo weeks					
<u>HY</u>	PERSOMNIA								
78.	Hours s	slept in day	ytime of cu	irrent episo	de				
79.	Hours s	slept in day	ytime in th	e last two	weeks				
80.	Hours 1	ying down	in current	episode					
81.	Hours 1	lying down	in last tw	o weeks			-		
82.	Current Episode:		NO (1)	(2)	(3)	(4)	(5)	(6)	
83.	Last Two Weeks:	(0) NI	(1) NO	(2)	(3)	(4)	(5)	(6)	

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INSC	<u>DMNIA</u>						
84.	Current Episode: (0) NI	(1) NO	(2)	(3)	(4)	(5)	(6)
85.	Last Two Weeks: (0) NI	(1) NO	(2)	(3)	(4)	(5)	(6)
	Frequency:	Nights/Wee	k				:
TY	PES OF INSOMNIA						
	Initial Insomnia						
86.	Current Episode:	(0)	(1) NPR	DBT	MLD	MOD	SVR
87.	Last Two Weeks:	(0) NI	(1) NPR	DBT	MLD	MOD	SVR
	Middle Insomnia						
88.	Current Episode:	NI	(I) NPR	DBT	MLD	MOD MOD	SVR
89.	Last Two Weeks:	(0) NI	(I) NPR	(2) DBT	MLD	MOD	(5) SVR
	Terminal Insomnia						
90.	Current Episode:	(0) NI	(1) NPR	DBT	MLD	MOD	SVR
91.	Last Two Weeks:	(0) NI	NPR	DBT	MLD	MOD	(5) SVR
	Circadian Reversal						
92	. Current Episode:	(6) NI	(I) NPR	(2) DBT	MLD	MOD	SVR
93	-	(0) NI	(1) NPR	DBT	MLD	MOD	SVR
	Non-restorative sleep						
94	. Current Episode:	(0) NI	(I) NPR	(2) (DBT	MLD	MOD	SVR
95	Last Two Weeks:	(0)	(I) NPR	DBT	(3) MLD	(4) MOD	(5) SVR
	Daytime sleepiness						
96	. Current Episode:	(0) NI	NPR	DBT	MLD	MOD	SVR
97	_	(0) NI	NPR	DBT	MLD	MOD	SVR

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								$\neg \neg$
ANOREXIA  98. Current Episode:  99. Last Two Weeks:	(0) NI (0) NI	(I) NO	(2) SLT (2) SLT	(3) MLD (3) MLD	(4) MOD (4) MOD	(5) RAR (5) RAR	(6) NVR (6) NVR	
WEIGHT LOSS  100. Current Episode:  Pounds lost:	1.1	1hs						
Number of Weeks:  101. Last Two Weeks:								
Pounds lost:  INCREASED APPETIT  102. Current Episode:		lbs.	(2) SLT	(3) MLD	(4) MOD	(5)  SVR	(6) EX	
103. Last Two Weeks:  Frequency:	(0) NI	(1) NO Days/Wee	(2) SLT	MLD	MOD	(5) SVR	(6) EX	
STRONG CRAVING I	OR SW	EETS						
104. Current Episode: 105. Last Two Weeks:	(0) NI	(1) ABS	(2) DBT	(3) MLD MLD	(4) MOD (4) MOD	(5) SVR (5) SVR		
WEIGHT GAIN  106. Current Episode:								
Pounds gained:	: [							
107. Last Two Weeks  Pounds gained		lbs.		,, ,, ,, ,, ,, ,, ,, ,, ,, ,, ,, ,, ,,				

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SUICIDAL IDEATION	[							2	
108. Current Episode:	(0) NI	(I)	SLT	MLD	(4) MO	(5) SVR	(6) EX	(7) VEX	
109. Last Two Weeks:	(0) NI	NO (1)	(2) SLT	MLD	(4) MO	SVR	(6) EX	(7) VEX	
Suicidal Acts - Numbe	T								
110. Current Episode:									
111. Last Two Weeks:									
Suicidal Acts – Seriou	sness								
112. Current Episode:	(0) NI	(I) NO	(2) MIN	(3) DEF		(4) SER	(5) VS	EXT	
113. Last Two Weeks:	(0) NI	NO NO	(2) MIN	(3) DEF		SER	(5) VS	(6) EXT	
Medical Lethality									
114. Current Episode	(0) NI	(1) NO	(2) MIN	MLD		(4) MO	(5) SVR	EXT	
115. Last Two Weeks:	(0) NI	(I) NO	(2) MIN	(3) MLD		(4) MO	SVR	EXT	
Non-Suicidal Physical	i Self-D	emaging .	Acts						
116. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	]	(4) MO	(5) SVR	ACT	
117. Last Two Weeks:	(0) NI	(I) NO	(2) SLT	(3) MLE	]	(4) MO	(5) SVR	(6) ACT	

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MA	NIC SYNDROME								÷	
	TION, EXPANSIV	E MOOI	D							
1.	Current Episode:	(O) NI	(1) NO	SLT	(3) MLD	(4) MO	SVR	(6) EX		
2.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX		
nec	REASED NEED FO	OR SLEI	ē <b>P</b>							
DEC		(0) NI	NO NO	(2)	(3)	(4) -3	(5)	(6) -4+		
3.	Current Episode:									
4.	Last Two Weeks:	(0) NI	(1) NO	(2) -1	(3)	(4) -3	(5)	(6) -4+		
UN	USUALLY ENERGE	ETIC								
5.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) LCH	(4) MOR	(5) MM	(6) UA		
6.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	LCH	(4) MOR	(5) MM	(6) UA		
TNI	CREASE IN GOAL	DIREC	CED ACT	TIVITY						
1174	KEASE IN GOAL				[(3)]	[74)]	[(S)]	(6) EX		
7.	Current Episode:	(0) NI	(I) NO	SLT	MLD	(4) MO	MKD			
8.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	MLD	(4) MO	(5) MKD	(6) EX		
GR	ANDIOSITY									
9.		(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX		
	_	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX		
10.	. Last Two Weeks:	NI	NO	SLT	MLD	MO	[ <u>3 v k</u> ]	لمعا		
<u>A(</u>	CELERATED, PRE	SSUREI	OR IN	CREASEI	AMOU	NT OF S				
11	. Current Episode:	(0) NI	(I) NO	SLT	MLD	(4) MO	(5) MKD	(6) EX		
12	. Last Two Weeks:	(O) NI	(1) NO	SLT	MLD	(4) MO	(5) MKD	(6) EX		

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RACING THOUGHTS  13. Current Episode: NI NO DBT (27)	(3) (4) MLD MO	[(5)]	J.
13. Current Episode: (0) NI NO (2) DB1	(3) (4) MLD MO	(5)	1
		SVR	(6) EX
_	(3) (4) MLD MO	(5) SVR	(6) EX
, <del></del>			
FLIGHT OF IDEAS		<u> </u>	[6]
<u> </u>	(3) (4) MLD MO	(5) SVR	(6) EX
16. Last Two Weeks: (0) (1) (2) (2) (1) (1) (1) (2) (2) (1)	(3) (4) MLD MO	SVR	(6) EX
POOR JUDGEMENT			
17. Current Episode: (0) NI NO SLT	(3) (4) MO	(5) SVR	(6) Vs
18. Last Two Weeks: (0) (1) (2) (2) (SLT	(3) (4) MLD MO	(5) SVR	(6) VS
DISTRACTABILITY			
19. Current Episode: (0) (1) (2) (2) NO (SLT)	(3) (4) MLD MO	(5) SVR	
20. Last Two Weeks: (0) (1) (2) (2) (1) NO (2)	(3) MLD MO	SVR	
MOTOR HYPERACTIVITY			
21. Current Episode: (0) (1) (2) SLT	(3) (4) MLD MO	(5) MKD	(6) EX
22. Last Two Weeks: (0) (1) (2) (2) SLT	(3) (4) MLD MO	(5) MKD	(6) EX
Inappropriate laughing, joking or punning			
23. Current Episode: (0) (1) (2) (DBT)	(3) (4) MLD MOD		
24. Last Two Weeks: (0) (1) NO DBT	(4) MLD MOD		
Uninhibited people seeking, gregarious			
25. Current Episode: (1) NO DB1	(3) (4) MLD MOD		
26. Last Two Weeks: (1) NO DBT	(3) (4) MLD MOD		

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			_				 _	
Inci	reased Productivity						ے ۔	
27.	Current Episode:	(0) NI	NO	(2) DBT	PRS	(4) SVR		
28.	Last Two Weeks:	(0) NI	NO NO	(2) DBT	PRS	SVR		
Sha	r pened and unusual	ly creat	ive thinki	ng				
29.	Current Episode:	(0) NI	(I) NO	(2) DBT	(3) PRS	(4) SVR		
30.	Last Two Weeks:	(0) NI	(1) NO	DBT	PRS	SVR		
Ну	persexuality							
31.	Current Episode:	(0) NI	(1) NO	(2) DBT	(3) PRS	(4) SVR		
32.	Last Two Weeks:	(0) NI	NO NO	DBT	PRS	SVR		
INI	FLUENCE OF ILLI	CIT DR	ugs or	ALCOH	<b>OL</b>			
33.	Current Episode:	(0) NA	(1) NVR	(2) SMT	(3) ONL			
	Last Two Weeks:	(0) NA	(I) NVR	(2) SMT	(3) ONL			
NIT!	MBER OF MANIO	י סקסור	nns					
NU	WIDER OF WIANK	LEKIC						
35.								

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#### STUDY MEDICATION RECORD

Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily		
, 1 <u>, , 1 , </u>					

#### STUDY MEDICATION DOSING CHANGES

□ No				
☐ Yes ——	→ Indicate cha	nge(s) belo	)W	
	Reminder:	Changes	in dose constitu	te deviation from the protocol
Start Date day month year	End Date day month year	Dose Level	Number of Capsules Daily	Reason for Dose Change

### STUDY MEDICATION COMPLIANCE

Capsules Dispensed (A)	Capsules Returned (B)	Capsules Taken (A - B)	Days Since Last Visit	% Compliance		
<b>♦</b> Cor	npliance m	$(N \times x)$ ust be $\geq 8$	of capsules days since 1 0% and \( \left( \); iant for two	ast visit) x 10	<b>★</b> _N =	number of capsules dail (see above)

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# STUDY MEDICATION LABEL Attach label here Attach label here Attach label here Attach label here Important: The drug code on the study medication label must be identical to the preprinted Patient Number Enter patient number (drug code as listed on clinical supplies) above.

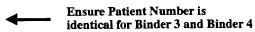
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#### STUDY MEDICATION DISPENSING

Record study medication information for Weeks 29-32 in the Study Medication Record, page 397. Attach label(s) to page 398. Record number of capsules dispensed on page 397.

Reminder: The drug code on the study medication label must be identical to the preprinted Patient Number above.

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### **CONFIDENTIAL**

#### CASE REPORT FORM

PROTOCOL 29060/329

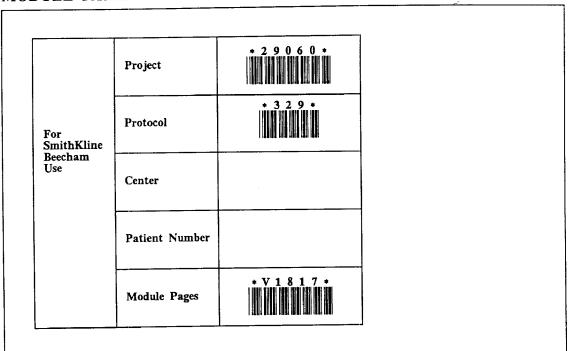
### **CONTINUATION PHASE - BINDER 4**

A Multi-Center, Double-Blind, Placebo Controlled Study of Paroxetine and Imipramine in Adolescents with Unipolar Major Depression

Patient Initials	Country	

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### MODULE PARAMETERS - WEEK 32



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VIT	A	ľ	CI	C	NC

*** * 1 *	Sitting		Standing		
Weight	Blood Pressure	Pulse	Blood Pressure	Pulse	
□ lbs	(mmHg)	(beats/	(mmHg)	(beats/	
□ kg	systolic diastolic	min)	systolic diastolic	min)	

### ADVERSE EXPERIENCES / CONCOMITANT MEDICATION

lave ar stient:	y adverse experie "Do vou feel dif	ences been observed or Eferent in any way sin	elicited by the for sce starting the tr	llowing direct question t eatment or since the las
motor M	⊋ Yes □		-	
Re	ord in the Adver	rse Experience section		
Ias the	re been any chan	nge in concomitant med	dication since the	last visit?
	□ Yes □			

### CLINICAL GLOBAL IMPRESSIONS - GLOBAL IMPROVEMENT

Rate the total improvement whether or not, in your judgment, it is due entirely to drug treatment. Compared to his/her condition at admission to the study, how much has the patient changed?
patient changes.
☐ 1 = Very much improved
$\square$ 2 = Much improved
3 = Minimally improved
4 = No change
5 = Minimally worse
6 = Much worse
7 = Very much worse

### PLASMA SAMPLE - DRUG CONCENTRATION

Was a plasma san	nple obtained for drug concentration?	•
☐ Yes	□ No	

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# HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 1 OF 3

1.	•	Depressed Mood (sadness, hopelessness, helpless, worthless)  □ 0 = Absent
		1 = These feeling states indicated only on questioning
		☐ 2 = These feeling states spontaneously reported verbally ☐ 3 = Communicates feeling states non-verbally, i.e., through facial
		expression posture voice and tendency to weep
		4 = Patient reports virtually only these feeling states in his/her spontaneous verbal and non-verbal communication
2		Feelings of Guilt
		<ul> <li>□ 0 = Absent</li> <li>□ 1 = Self reproach, feels he/she has let people down</li> <li>□ 2 = Ideas of guilt or rumination over past errors or sinful deeds</li> <li>□ 3 = Present illness is a punishment. Delusions of guilt</li> <li>□ 4 = Hears accusatory or denunciatory voices and/or experiences threatening visual hallucinations</li> </ul>
3	3.	Suicide
		<ul> <li>□ 0 = Absent</li> <li>□ 1 = Feels life is not worth living</li> <li>□ 2 = Wishes he/she were dead or any thoughts of possible death to self</li> <li>□ 3 = Suicide ideas or gesture</li> </ul>
		4 = Attempts at suicide (any serious attempt rates 4)
•	4.	Insomnia Early
		<ul> <li>□ 0 = No difficulty falling asleep</li> <li>□ 1 = Complains of occasional difficulty falling asleep - i.e., more than 1/2 hour</li> <li>□ 2 = Complains of nightly difficulty falling asleep</li> </ul>
	5.	Insomnia Middle
		<ul> <li>0 = No difficulty</li> <li>1 = Patient complains of being restless and disturbed during the night</li> <li>2 = Waking during the night - getting out of bed rates 2 (except for purposes of voiding)</li> </ul>
	6.	Insomnia Late
		<ul> <li>0 = No difficulty</li> <li>1 = Waking in early hours of the morning but goes back to sleep</li> <li>2 = Unable to fall asleep again if he/she gets out of bed</li> </ul>
	7.	Work and Activities
		<ul> <li>0 = No difficulty</li> <li>1 = Thoughts and feelings of incapacity, fatigue or weakness related to activities; work or hobbies</li> </ul>
		2 = Loss of interest in activity; hobbies or work - either directly reported by patient, or indirectly in listlessness, indecision and vacillation (feels he/she has to push self to work or activities)
		<ul> <li>3 = Decrease in actual time spent in activities or decrease in productivity.</li> <li>4 = Stopped working because of present illness.</li> </ul>

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# HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 2 OF 3

	8.	Retardation (slowness of thought and speech, impaired ability to concentrate; decreased motor activity)  0 = Normal speech and thought 1 = Slight retardation at interview 2 = Obvious retardation at interview 3 = Interview difficult 4 = Complete stupor
	9.	Agitation
		<ul> <li>□ 0 = None</li> <li>□ 1 = Fidgetiness</li> <li>□ 2 = "Playing with" hands, hair, etc.</li> <li>□ 3 = Moving about, can't sit still</li> <li>□ 4 = Hand wringing, nail-biting, hair-pulling, biting of lips</li> </ul>
	10.	Anxiety Psychic
		<ul> <li>□ 0 = No difficulty</li> <li>□ 1 = Subjective tension and irritability</li> <li>□ 2 = Worrying about minor matters</li> <li>□ 3 = Apprehensive attitude apparent in face or speech</li> <li>□ 4 = Fears expressed without questioning</li> </ul>
	11.	Anxiety Somatic (physiological concomitants of anxiety such as: Gastrointestinal (dry mouth, wind, indigestion, diarrhea, cramps, belching), Cardiovascular (palpitations, headaches), Respiratory (hyperventilation, sighing), Urinary frequency, Sweating.
		<ul> <li>□ 0 = Absent</li> <li>□ 1 = Mild</li> <li>□ 2 = Moderate</li> <li>□ 3 = Severe</li> <li>□ 4 = Incapacitating</li> </ul>
	12.	Somatic Symptoms Gastrointestinal
		<ul> <li>□ 0 = None</li> <li>□ 1 = Loss of appetite but eating. Heavy feelings in abdomen</li> <li>□ 2 = Difficulty eating without urging. Requests or requires laxatives or medication for bowels or medication for G.I. symptoms</li> </ul>
	13.	Somatic Symptoms General
		<ul> <li>□ 0 = None</li> <li>□ 1 = Heaviness in limbs, back of head. Backaches, headache, muscle aches. Loss of energy and fatigability</li> <li>□ 2 = Any clear-cut symptoms rates 2</li> </ul>
	14.	Genital Symptoms (such as loss of libido and menstrual disturbances)
		<ul> <li>□ 0 = Absent</li> <li>□ 1 = Mild</li> <li>□ 2 = Severe</li> </ul>
1		

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# HAMILTON PSYCHIATRIC RATING SCALE FOR DEPRESSION (HAMD) PAGE 3 OF 3

15.	Hypochondriasis
	<ul> <li>□ 0 = Not present</li> <li>□ 1 = Self-absorption (bodily)</li> <li>□ 2 = Preoccupation with health</li> <li>□ 3 = Frequent complaints, requests for help, etc.</li> <li>□ 4 = Hypochondriacal delusions</li> </ul>
16.	Loss of Weight
	<ul> <li>□ 0 = No weight loss</li> <li>□ 1 = Slight or doubtful loss of weight</li> <li>□ 2 = Obvious or severe loss of weight</li> </ul>
17.	Insight
	<ul> <li>□ 0 = Acknowledges being depressed and ill</li> <li>□ 1 = Acknowledges illness but attributes cause to bad food, climate, over-work, virus, need for rest, etc.</li> </ul>
	2 = Denies being ill at all
•	HAMD Score (Items 1-17)

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### AUTONOMOUS FUNCTIONING CHECKLIST

Grade in School	Informant (mother, father, guardian, other)
	guardian, other)

#### Instructions

The purpose of this checklist is to learn about what your teenager does every day. There are no "right" or "wrong" things for your teenager to do, since teenagers of different ages do many different things. These questions are simply for the purpose of getting an idea of your teenager's daily activity.

When you answer these questions, first, read the question and think about whether or not it describes what you see or have seen your teenager do. You should answer the questions according to what you know your teenager does or does not do rather than what you believe or think he or she could do or could not do.

**Second**, tell us how the question describes what you teenager does by choosing one of the alternatives "0", "1", "2", "3", or "4" from the scale and circling that number in the space to the right of the item. Here is how to use the rating scale with a sample question.

0	1	2	3	4	
Does Not Do	Does Only Rarely	Does About Half the Time There is an Opportunity	Does Most of the Time There is an Opportunity	Does Every Time There is an Opportunity	

#### Sample Item. Pick up trash in the yard.

0 1 2 3 4

- 0 Circle "0" if you have never seen your teenager do this, even if he or she may never have had an opportunity. (For example mark "0" if your teenager has never done it, even if you live in an apartment and do not have a yard.)
- 1 Circle "1" if you have seen your teenager do this when there has been a chance, but if there have been many more times that he or she has not done it.
- 2 Circle "2" if your teenager does this about half the time there is a chance, but if he or she does not do it readily or comfortably.
- 3 Circle "3" if there are more times that your teenager does this than does not do it, given the chance, and if he or she does it readily.
- 4 Circle "4" if your teenager does this whenever there is a chance and if he or she does it readily.

Your teenager will not have had the chance to participate in some of the activities the questions described. These items should be answered as "does not do," even though you may feel that your teenager would do it if given the chance. Please circle "0" for questions that describe activities your teenager has never had the chance to do.

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#### **AUTONOMOUS FUNCTIONING CHECKLIST**

Some questions describe things that your teenager may do with help from others. Answer-these questions after you think about who has the most responsibility for completing the activity. For example, your teenager may cook the family meals and may be helped by other family members who set the table or chop vegetables. If your teenager is the family member with the most responsibility for cooking every meal that the family eats together, your answer would be "4", which stands for "does every time there is an opporunity." On the other hand, if your teenager helps other family members by doing jobs that they tell him or her to do, and never has the most responsibility for fixing dinner, your answer would be "0", for "does not do."

	0	1	2 Does About Half Doe		Most of	Does Every			
Does Not Do		Does Only Rarely	the Time There is an Opportunity	the Tim	es Most of Time There is Opportunity		Time There is an Opportunity		ere is
Му	teenager:								
1.	Keeps own p makes bed,	ersonal items and be puts away own cloth	clongings in order (for exing and belongings).	xample	0	1	2	3	4
2.		d that does not requi	ire cooking for himself/dwich).		0	1	2	3	4
3.	Care for his, repair, shoe		or example, laundry, sim	ple	0	1	2	3	4
4.	4. Travels to and from daily activities (for example, rides bike or walks, takes bus, arranges for transportation, drives car).					1	2	3	4
5.		d that requires cooki e, hamburger, soup).	ng for himself/herself		0	1	2	3	4
6.			tical care for himself/takes own temperature).		0	1	2	3	4
7.		Purchases his/her own clothing and personal items that are used on a daily basis (for example, underwear, toiletries).				1	2	3	4
8.		Performs minor repair and maintance in his/her owm environment (for example, changes light bulbs, hangs pitcure).				1	2	3	4
9.	Shops for an	nd purchases his/her	own groceries.		0	1	2	3	4
10.	Responds to	his/her own medical	emergency by calling p	arent.	0	1	2	3	4
11.	Responds to hospital.	Responds to his/her own medical emergency by calling doctor or nospital.				1	2	3	4
12.	Does designativing areas	(for example, cleans	enance chores involving s, takes out trash, does	family simple	0	1	2	3	4

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	0	1	2	3	3			4	_
Do	oes Not Do	Does Only Rarely	Does About Half the Time There is an Opportunity	the Tin	Most of ne There portunit		Time	s Eve e The pport	re is
13.	Performs rout	tine daily personal, dresses, feeds).	care for another family n	nember.	0	1	2	3	4
14.	Keens nersons	al items and belong	gings of another family m puts away clothing and l	ember in belongings	0).	1	2	3	4
15.	Prepares mea	ls for other family	member(s).		0	1	2	3	4
16.		r arranges for tran	asport of) another family	member	0	1	2	3	4
17.	Purchases clobasis) for ot	othing and personal her family member	items (that are used on a	a daily	0	1	2	3	4
18.	Shops for an	d purchases family	groceries.		0	1	2	3	4
19.	Performs min	nor repairs and man	intenance in family living lbs, hangs picture).	areas	0	1	2	3	4
20.	and mainten	maintains (or make ance of) major hou electrical wiring).	es arrangement for repair usehold needs (for example	e, plumbir	0 ng,	1	2	3	4
21.	Responds to problem) by	household emergen calling parent or	cy (for example, stove fir neighbor.	e, plumbi	ng 0	1	2	3	4
22.	problem) by	nousehold emergenc calling fire depar ir service or shutin	ey (for example, stove fire tment, using fire extinguising off water.	e, plumbin ther, or	g 0	1	2	3	4
Му	teenager:								
23.	Uses the tel	phone and telephon	e directories.		0	1	2	3	4
24.	Carries out listens to in change).	transactions with s nformation, asks qu	ales people (for example, lestions, gives payment, re	ceives	0	1	2	3	4
25.	Uses postal packages).	services (for exam	iple, uses postage, mails l	etters.	0	1	2	3	4
26.	Uses bank uses passbo		out deposit or withdrawal	slips,	0	1	2	3	4

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	0	1	2	3			تب	4	
D	oes Not Do	Does Only Rarely	Does About Half the Time There is an Opportunity	Does Mo the Time an Oppo	There	is	Tim	es Eve e The Opport	re is
27.	Uses travel-resubway).	elated services for s	hort trips (for example,	taxi, bus	0	1	2	3	4
28.	Uses travel-re train, bus).	elated services for l	ong trips (for example,	airline,	0	1	2	3	4
29.	Uses library machine).	services (for example	le, checks out books or	uses Xerox	0	1	2	3	4
30.	Maintains and	d uses his/her own	savings account.		0	1	2	3	4
31.	Maintains and	d uses his/her own	checking or charge acco	unt.	0	1	2	3	4
32.		equate personal care nails and toenails wh	and grooming (for examen needed)	nple, bathes,	0	1	2	3	4
33.	Maintains his	s/her routine general eating, sleeping and	health and fitness (for dexercise habits).	example,	0	1	2	3	4
34.		ing that is suited to raining, warm clothe	weather (for example, s in winter).		0	1	2	3	4
35.	unscheduled	itiates activity for h free time (for exam a hobby if bored).	nimself/herself in everday	elevision	0	1	2	3	4
36.	Plans activity makes plans	y for his/her long-te for summer vacation	erm free time (for examon, mid-semester vacation	ple, n).	0	1	2	3	4
37.		ndships with peers ( ngs, games, club me	for example, plans or atectings).	ttends	0	1	2	3	4
38.	example, ke	ademic social obliga eps appointments for s arranged by self o	ations or commitments (for family and peer related or others).	or I	0	1	2	3	4
39.		omework assignment	commitments (for exams on time, brings necess		0	1	2	3	4
40.	arranges for	rtation to and from rides with friends nd schedule).	special activities (for exor family or plans care	xample or	0	1	2	3	4

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	0	1	2	3				4	_
Do	oes Not Do	Does Only Rarely	Does About Half the Time There is an Opportunity	Does Mosthe Time Tan Oppor	here	is	Time	s Eve e The pport	rė is
41.	example, say	es money for large	n allowance or income (for purchases, pays for routing ut running out of money).	ie	0	1	2	3	4
42.	Make long-to selects cours	erm educational and ses, investigates coll	or career plans (for exam eges or technical schools).	ple,	0	1	2	3	4
	n my teenager ne chooses to		how he/she will spend his	her unschedu	ıled	free t	ime.		
43.	Listen to mu	isic (for example, r	adio or stereo).		0	1	2	3	4
44.	Read for rel	axation (for exampl	e, books, newspapers)		0	1	2	3	4
45.	Play games jigsaw puzz	or puzzles (for exameles, computer games	mple, cards, crossword puz	zzles,	0	1	2	3	4
46.	Write letters	to friends, relative	s, aquaintances.		0	1	2	3	4
47.	Work on or cooking, cocar repair).	llections, pet care, s	fts or hobbies (for exampl sewing, model building,	e	0	1	2	3	4
48.	skill (for e	take lessons that invample, piano or ot ative writing, foreig	volve a trained artistic or her musical instrument, ba in languages).	academic llet,	0	1	2	3	4
49.	Go to the n	novies, rock concert	s, dances.						
50.	Go to plays	, theater, lectures.			0	1	2	3	4
51.	(for examp)	rities that are related le, runs a business, professional preparati	d to his or her career inte works on a computer, pra ion).	erest(s) actices	0	1	2	3	4
52.	Go for wal	ks.			0	1	2	3	4
53.	Go shopping	g, or spend time at	shopping centers or in sho	opping areas.	0	1	2	3	4
54.	Attend club	meetings or other	organized social group me	etings.	0	1	2	3	4
55.	Work for p	ay (for example, balk dogs, work at pa	abysit, play in a band, do art-time job, deliver papers	yard	0	1	2	3	4

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	0	1	2	3		4	
De	oes Not Do	Does Only Rarely	Does About Half the Time There is an Opportunity	Does Most of the Time There is an Opportunity	Time		re is
56.		ean house, wash or	ironment or belongings (frepair clothes, wash car,		2	3	4
57.			ole, spend extra time on lass projects, spend time		2	3	4
58.	have discuss	with family (for exa sions or casual conv uch as picnics or pa	ample, work on family pressured family arties).	rojects, 0 1	2	3	4
On t	hese final ite e description	ems, please check "Y fits your teenager.	Yes" or "No" in response Check "No" if it does t	to each description. not.	Check "Y	Yes''	
Му	teenager:				3	/es	No
59.	Has casual	friendships with teer	nagers of opposite sex.		[		
60.	Has close fi	riendships with teens	igers of opposite sex.		{		
61.	Has casual neighbors,	friendships with adu	lts outside the family (fors)	r example, teachers,	I		
62.		riendships with adult coaches, scout leader	ts outside the family (for	example, teachers,	1		
63.	Has casual	friendships with you	inger children.				
64.	Has close f	riendships with your	nger children.				
65.			groups of teenage friends	<b>.</b>			
66.	Has many f						
67.	Is active in	•	ized extracurricular group	o (for example,			
68.	Has leaders	hip position in one	or more organized extracted council, captain of the	urricular group (for e sports team).			
69.		friendship with adult aunt, grandparent).	member of the extended	family (for example,			
70.	Works or b		r pay or volunteer in an	area of particular			

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71. Works or has worked to earn money by providing a service on a regular scheduled basis (for example, contracts for yard work, dog walking, baby sitting)  72. Works or has worked to earn money by using a special skill (for example, musical performance, typing, tutoring).  73. Works or has worked to earn money in a self-or-peer-run organization or business.  74. Works or has worked to earn money fundraising for an organization or charity (for example, scouts, church groups, political organizations).  75. Does or has done volunteer work without pay for a service, a school or political organization, a social agency, a club, a church, or a hospital.  76. Participates or has participated in prevocational (career) classes or training (for example, any technical training or career development class).  77. Has explored career interest by visiting work sites or interviewing people in that job or career.  78. Has spent time reading, researching, or "finding out" about a career that particularly interests him/her.  Comments:  If you have any additional information about your teenager's everyday independent or self-sufficient behavior, use the space below to write your comments. Thank you.		-	Yes	No
musical performance, typing, tutoring).  73. Works or has worked to earn money in a self-or-peer-run organization or business.   74. Works or has worked to earn money fundraising for an organization or charity (for example, scouts, church groups, political organizations).  75. Does or has done volunteer work without pay for a service, a school or political organization, a social agency, a club, a church, or a hospital.  76. Participates or has participated in prevocational (career) or vocational (career) classes or training (for example, any technical training or career development class).  77. Has explored career interest by visiting work sites or interviewing people in that job or career.  78. Has spent time reading, researching, or "finding out" about a career that particularly interests him/her.  Comments:  If you have any additional information about your teenager's everyday independent or self-sufficient	71.	Works or has worked to earn money by providing a service on a regular scheduled basis (for example, contracts for yard work, dog walking, baby sitting)		
74. Works or has worked to earn money fundraising for an organization or charity (for example, scouts, church groups, political organizations).  75. Does or has done volunteer work without pay for a service, a school or political organization, a social agency, a club, a church, or a hospital.  76. Participates or has participated in prevocational (career) or vocational (career) classes or training (for example, any technical training or career development class).  77. Has explored career interest by visiting work sites or interviewing people in that job or career.  78. Has spent time reading, researching, or "finding out" about a career that particularly interests him/her.  Comments:  If you have any additional information about your teenager's everyday independent or self-sufficient	72.			
(for example, scouts, church groups, political organizations).  75. Does or has done volunteer work without pay for a service, a school or political organization, a social agency, a club, a church, or a hospital.  76. Participates or has participated in prevocational (career) or vocational (career) classes or training (for example, any technical training or career development class).  77. Has explored career interest by visiting work sites or interviewing people in that job or career.  78. Has spent time reading, researching, or "finding out" about a career that particularly interests him/her.  Comments:  If you have any additional information about your teenager's everyday independent or self-sufficient	73.	Works or has worked to earn money in a self-or-peer-run organization or business.		
organization, a social agency, a club, a church, or a hospital.  76. Participates or has participated in prevocational (career) or vocational (career) classes or training (for example, any technical training or career development class).  77. Has explored career interest by visiting work sites or interviewing people in that job or career.  78. Has spent time reading, researching, or "finding out" about a career that particularly interests him/her.  Comments:  If you have any additional information about your teenager's everyday independent or self-sufficient	74.	Works or has worked to earn money fundraising for an organization or charity (for example, scouts, church groups, political organizations).		
classes or training (for example, any technical training or career development class).  77. Has explored career interest by visiting work sites or interviewing people in that	75.			
job or career.  78. Has spent time reading, researching, or "finding out" about a career that particularly interests him/her.  Comments:  If you have any additional information about your teenager's everyday independent or self-sufficient	76.	Participates or has participated in prevocational (career) or vocational (career) classes or training (for example, any technical training or career development class).		
particularly interests him/her.  Comments:  If you have any additional information about your teenager's everyday independent or self-sufficient	77.			
If you have any additional information about your teenager's everyday independent or self-sufficient	78.	Has spent time reading, researching, or "finding out" about a career that particularly interests him/her.		
	If y	ou have any additional information about your teenager's everyday independent or self-	suffici	ent

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			WHAT	AM I L	IKE	"	
Т	eally rue Me	Sort of True for Me	Samp	le Sentence	ė	Sort of True for Me	Really True for Me
a. [			Some teenagers like to go to movies in their spare time	BUT	Other teenagers would rather go to sport events.		
1.			Some teenagers feel that they are just as smart as others their age	BUT	Other teenagers aren't so sure and wonder if they are as smart.		
2. [			Some teenagers find it hard to make friends	BUT	For other teenagers it's pretty easy.		
3. [			Some teenagers do very well at all kinds of sports	BUT	Other teenagers don't feel that they are very good when it comes to sports.		
4. [			Some teenagers are not happy with the way they look	BUT	Other teenagers are happy with the way they look.		
5. [			Some teenagers feel that they are ready to do well at a part-time job	BUT	Other teenagers feel that they are not quite ready to handle a part-time job.		
6. [			Some teenagers feel that if they are romantically interested in someone, that person will like them back	BUT	Other teenagers worry that when they like someone romantically that person won't like them back.		
7. [			Some teenagers usually do the right thing	BUT	Other teenagers often don't do what they know is right		
8. [			Some teenagers are able to make really close friends.	BUT	Other teenagers find it hard to make really close friends.		
9. [			Some teenagers are often disappointed with them-selves	BUT	Other teenagers are pretty pleased with themselves.		
10. [			Some teenagers are pretty slow in finishing their school work	BUT	Other teenagers can do their school work more quickly		

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Really True for Me	Sort of True for Me		A 6.00. A 60.00		Sort of True for Me	Really True for Me
11.		Some teenagers have a lot of friends	BUT	Other teenagers don't have very many friends.		
12.		Some teenagers think they could do well at just about any new athletic activity	BUT	Other teenagers are afraid they might not do well at a new athletic activity.		
13.		Some teenagers wish their body was different	BUT	Other teenagers like their body the way it is.		
14.		Some teenagers feel that they don't have enough skills to do well at a job	BUT	Other teenagers feel that they do have enough skills to do a job well.		
15.		Some teenagers are not dating the people they are really attracted to	BUT	Other teenagers are dating those people they are attracted to		
16.		Some teenagers often feel guilty about certain things they do	BUT	Other teenagers hardly ever feel guilty about what they do.		
17.		Some teenagers can be trusted to keep secrets that their friends tell them	BUT	Other teenagers have a har- time keeping secrets that their friends tell them.	đ	
18.		Some teenagers don't like the way they are leading their life	BUT	Other teenagers do like the way they are leading their life.		
19.		Some teenagers do very well at their classwork	BUT	Other teenagers don't do very well at their classwork.		
20.		Some teenagers are very hard to like	BUT	Other teenagers are really easy to like.		
21.		Some teenagers feel that they are better than others their age at sports	BUT	Other teenagers don't feel they can play as well.		
22.		Some teenagers wish their physical appearance was different	BUT	Other teenagers like their physical appearance the way it is.		
1						

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Really True for Me	Sort of True for Me				Sort of True for Me	Really True for Me
23.		Some teenagers are proud of the work they do on jobs they get paid for	BUT	For other teenagers, getting paid is more important than feeling proud of what they	ı 🗍	
24.		Some teenagers feel that people their age will be romantically attracted to them	BUT	Other teenagers worry about whether people their age with be attacted to them.	f 1	
25.		Some teenagers are usually pleased with the way they act	BUT	Other teenagers are often ashamed of the way they act.		
26.		Some teenagers don't really have a close friend to share things with.	BUT	Other teenagers do have a close friend to share things with.		
27.		Some teenagers are happy with themselves most of the time	BUT	Other teenagers are often not happy with themselves.		
28.		Some teenagers have trouble figuring out the answers in school	BUT	Other teenagers almost always can figure out the answers.		
29.		Some teenagers are popular with others their age	BUT	Other teenagers are not very popular.	,	
30.		Some teenagers don't do well at new outdoor games	BUT	Other teenagers are good at new outdoor games righ away.	t $\square$	
31.		Some teenagers think that they are good looking	BUT	Other teenagers think that they are not very good looking.		
32.		Some teenagers feel like they could do better at work they do pay for	BUT	Other teenagers feel that they are doing really well at work they do pay for.		
33.		Some teenagers feel that they are fun and interesting on a date	BUT	Other teenagers wonder about fun and interesting they are on a date.	out	
34.		Some teenagers do things they know they shouldn't do	BUT	Other teenagers hardly ever do things they know they shouldn't do.		

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Really True	Sort of True				Sort of True	Really True
for Me	for Me	Some teenagers find it hard to make friends they can really trust	BUT	Other teenagers are able to make close friends they can really trust.	for Me	for Me
36.		Some teenagers like the kind of person they are	BUT	Other teenagers often wish they were someone else.		
37.		Some teenagers feel that they are pretty intelligent	BUT	Other teenagers question whether they are intelligent	. 🗌	
38.		Some teenagers feel that they are socially acceptable	BUT	Other teenagers wished that more people their age accepted them.		
39.		Some teenagers do not feel that they are very athletic	BUT	Other teenagers feel that they are very athletic.		
40.		Some teenagers really like their looks	BUT	Other teenagers wished they looked different.		
41.		Some teenagers feel that it's really important to do the best you can on paying jobs	BUT	Other teenagers feel that getting the job done is what really counts.		
42.		Some teenagers usually don't get asked out by people they would like to date	BUT	Other teenagers do get ask out by people they really want to date.	ted	
43.		Some teenagers usually act the way they know the are supposed to	BUT	Other teenagers often don't act the way they are supposed to.		
44.		Some teenagers don't have a friend that is close enough to share really personal thoughts with	BUT	Other teenagers do have a close friend that they can share personal thoughts ar feelings with.		
45.		Some teenagers are very happy being the way they are	BUT	Other teenagers wish they were different.		

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Introduction									
On the next few pages are statements which describe things people often do when they are not well.									
As you read them, think of yourself today:									
- If a statement describes you TODAY, mark the box under "Yes" (Yes, this statement describes me today).									
- However, if a statement does not describe you TODAY, or does not apply you, mark the box under "No". (No, this statement does not describe me today or does not apply to me).									
For Example:									
"I am not doing any of the shopping that I would usually do."									
- If you have not been doing any shopping for some time, and still are not doing any shopping today, check "YES". (Yes, this statement describes me today).									
- If you are doing your shopping as usual, check "NO" (No this statement does not describe me today or does not apply to me).									
Read and respond to the statements in the order listed. Some of the statements will differ only in a few words, so please read each one carefully. While you may wish to go back to change a response, your first answer is usually best. Please do not read ahead in the questionnaire.									
Please do not discuss the statements with anyone, including family members, while doing the questionnaire.									
Please mark your answers by placing an "X" in the appropriate box like this.									
Thank you for your time and help.									
How would you describe your present health  very good good fair poor very poor									
How would you describe you present quality of life (how things are going for you generally)?  very good good pair poor very poor									
L very good L good L									

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### PATIENT LOG - CONTINUATION PHASE

Directions:	Enter <u>ALL</u> patients who h interviewed. For patients exclusion in the designated	ave been considered for the study and who have been not entering the Continuation Phase, note the reason for column.
Patient Initials	Initial Interview (day month year)	Reason for Exclusion
*		
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### PATIENT ASSIGNMENT SHEET - CONTINUATION PHASE

Iı	nvestigator									Fo SI	or E	ate 🗀		ı ı
D	irections:	conti	not enter the inuation phas l Dose Status	se med s: C	licat	ion. Co	mnle	eted a	ll treat	ment	visi	ts		starts nt visits
	Patient Initials		Patient Open Continuation Phase Date of I Number (day month year)						ast ith	Dose Status year) (C/W)	Status (C/W)			
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		-	
A.	These statements describe your sleep and rest this week.	Yes	No
	1. I spend much of the day lying down in order to rest.		
	2. I sit for much of the day.		
	3. I am sleeping or dozing much of the time - day and night.		
	4. I lie down more often than my friends during the day in order to rest.		
	5. I sit around half asleep.		
	<ol> <li>I sleep less at night, for example, I wake up easily, I do not fall asleep for a long time, I keep waking up.</li> </ol>		
	7. I sleep or doze more during the day.		
В.	These statements describe your daily work around the house.	Yes	No
	<ol> <li>I only do work that I need to do around the house for short periods of time or I rest often.</li> </ol>		
	2. I am doing less of the daily household chores that I would usually do.		
	3. I am not doing any of the daily household chores that I would usually do.		
	4. I am not doing any of the shopping that I would usually do.		
	5. I am not doing any of the cleaning that I would usually do.		
	6. I am not doing any of the clothes washing that I would usually do.		
c.	These statements describe your contact with your family and friends today.	Yes	No
	1. I am going out less to visit people.		
	2. I am not going out to visit people at all.		
	<ol> <li>I show less interest in other people's problems, for example, I do not listen when they tell me about their problems. I do not offer to help.</li> </ol>		
	<ol> <li>I am often irritable with those around me, for example, I snap at people or criticize easily.</li> </ol>		
	5. I show less affection.		
	<ol> <li>I take part in fewer social activities than I used to, for example, I go to fewer parties or social events.</li> </ol>		

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		<b>T</b> 7	TAT .
	7. I am cutting down the length of visits to friends.	Yes	No
	8. I avoid having visitors.		
	9. My sexual activity is decreased.		
	10. I talk less with those around me.		
	11. I make demands on other people that they find irritating, for example, I in that they do things for me, or tell them how to do things.	nsist 🗌	
	12. I stay alone much of the time.		
	13. I am disagreeable with my family, for example, I act spitefully or stubbor	nly.	
	14. I frequently get angry with my family, for example, I hit them, scream of throw things at them.		
	15. I isolate myself as much as I can from the rest of my family.		
	16. I refuse contact with my family, for example, I turn away from them.		
	17. I am not joking with my family members as I usually do.		
Į.			
D.	These statements describe your feelings.	Yes	No
D.	These statements describe your feelings.  1. I am confused and start to do more than one thing at a time.	Yes	No
D.			No
D.	<ol> <li>I am confused and start to do more than one thing at a time.</li> <li>I have more minor accidents, for example, I drop things, I trip and fall</li> </ol>		No
D.	<ol> <li>I am confused and start to do more than one thing at a time.</li> <li>I have more minor accidents, for example, I drop things, I trip and fall bump into things.</li> </ol>		No
D.	<ol> <li>I am confused and start to do more than one thing at a time.</li> <li>I have more minor accidents, for example, I drop things, I trip and fall bump into things.</li> <li>I react slowly to things that are said or done.</li> </ol>	or	No
D.	<ol> <li>I am confused and start to do more than one thing at a time.</li> <li>I have more minor accidents, for example, I drop things, I trip and fall bump into things.</li> <li>I react slowly to things that are said or done.</li> <li>I do not finish things I start.</li> <li>I have difficulty reasoning and solving problems, for example, making pla</li> </ol>	or	No
D.	<ol> <li>I am confused and start to do more than one thing at a time.</li> <li>I have more minor accidents, for example, I drop things, I trip and fall bump into things.</li> <li>I react slowly to things that are said or done.</li> <li>I do not finish things I start.</li> <li>I have difficulty reasoning and solving problems, for example, making pla making decisions, learning new things.</li> <li>I sometimes get confused, for example, I do not know where I am, who</li> </ol>	or   or   ns,   is	No
D.	<ol> <li>I am confused and start to do more than one thing at a time.</li> <li>I have more minor accidents, for example, I drop things, I trip and fall bump into things.</li> <li>I react slowly to things that are said or done.</li> <li>I do not finish things I start.</li> <li>I have difficulty reasoning and solving problems, for example, making pla making decisions, learning new things.</li> <li>I sometimes get confused, for example, I do not know where I am, who around, or what day it is.</li> <li>I forget a lot, for example, things that happened recently, where I put the</li> </ol>	or   or   ns,   is	xº
D.	<ol> <li>I am confused and start to do more than one thing at a time.</li> <li>I have more minor accidents, for example, I drop things, I trip and fall bump into things.</li> <li>I react slowly to things that are said or done.</li> <li>I do not finish things I start.</li> <li>I have difficulty reasoning and solving problems, for example, making pla making decisions, learning new things.</li> <li>I sometimes get confused, for example, I do not know where I am, who around, or what day it is.</li> <li>I forget a lot, for example, things that happened recently, where I put the or to keep appointments.</li> </ol>	or   or   ns,   is	xº

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	CRITEDS INTROL TROTILE		
E.	These statements are about how you talk to other people and write.	Yes	No
	1. I am having trouble writing or typing.		
	2. I am having trouble talking to people.		
	3. I am not comfortable in most social situations like parties.		
	<ol> <li>I speak with difficulty, for example, I get stuck for words, I stutter, I stammer, I slur my words.</li> </ol>		
	5. I do not speak clearly when I am under stress.		
F.	The following statements decribe the activities you usually do in your spare time for relaxation, entertainment or just to pass the time.	Yes	No
	1. I spend shorter periods of time on my hobbies and recreation.		
	2. I am going out and enjoying myself less often.		
	<ol> <li>I am cutting down on some of my usual inactive pastimes, for example,</li> <li>I watch less TV, play cards less, or read less.</li> </ol>	. 🗀	
	<ol> <li>I am not doing any of my usual inactive pastimes, for example, I watch less TV, play cards less, or read less.</li> </ol>		
	5. I am doing more inactive pastimes in place of my other usual activities.		
	6. I am taking part in fewer activities with my friends.		
	<ol> <li>I am cutting down on some of my usual physical recreation or more active pastimes.</li> </ol>		
	8. I am not doing any of my usual physical recreation or more active pastimes.		
ļ	Now please look through this questionnaire and make sure that you have read every qu	estion.	

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	RESSED MOOD Worst Severity of Current Episode:	(0) NI	NO NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	(7) VEX
	Duration of Current Episode:		# of we	æks					
	Worst Severity of Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	(7) VE
	Frequency:	∐ Days	s/week						
	Average % time of the day:	<u> </u>	j %						
<u>DEP</u>	RESSED APPEAR	ANCE							
3.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
4.	Last Two Weeks:	(0) NI	NO NO	SLT	MLD	(4) MO	(5) SVR	(6) EX	
<u>IRR</u>	ITABILITY AND		(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	[T
5.	Current Episode:	(0) NI	_		MLD	[WO]	[ <u>SV</u> K]	(EA.)	<u>( )</u>
	Duration:		_] # of w		[ (ST )	C72/C1	[3]	ா	П
6.	Last Two Weeks:	(0) NI	(1) NO	(2) SLT	MLD	(4) MO	(5) SVR	EX	v
	Frequency:	∐ Day	ys/week						
	Average % time of the day:	<u> </u>	_] %						
SEP	ARATION-DEPE	NDENT-1	DYSPHOI	RIA					
7.	Current Episode:	(0) NI	(1) NO	(2) OCC	(3) USL	(4) ALW			
8.	Last Two Weeks:	(0) NI	(I) NO	occ	USL	ALW			

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								<del></del>				
QUALITY OF DYPSHORIC MOOD												
9.	Current Episode:	(0) NI	(1) ND	QUE	DDF	VDF						
10.	Last Two Weeks:	(0) NI	(I)	QUE	DDF	VDF						
DEC	REE OF ASSOCIA	ATION O	DEPRE	SSED OR	IRRITAB	LE MOOD	WITH S	PECIFIC				
EVE	NTS OR PREOCC	UPATION	S	022								
11.	Current Episode:	(0) NI	(1) NAL	(2) MOT	UN	PN						
12.	Last Two Weeks:	(0) NI	(I) NAL	(2) MOT	(3) UN	(4) PN						
DEA	CTIVITY OF DE	PRESSED	OR IRRI	ITABLE N	MOOD							
<u>KEA</u>	CIIVIII OF DE						1	F-75-1				
13.	Current Episode:	(0) NI	(1) VR	FUL	RES	MLD	SLT	(6) UNR				
		<u></u>	% Usu	al % of N	ormal							
14.	Last Two Weeks:	(0) NI	(1) VR	FUL	(3) RES	(4) MLD	(5) SLT	(6) UNR				
			j % Usu	al % of N	formal							
			96 Max	cimum %	of Normal							
			Number	of hours	good feelin	ig last						
DIU	JRNAL MOOD V	ARIATIO!	Ā									
Wo	orse in Morning				£1	F-7-47-1	(787					
15.	Current Episode:	(0)	NW.	MIN	MLD	(4) CW	EXT					
16.	Last Two Weeks:	(0)	NW	(2) MIN	(3) MLD	CW	EXT					
W	orse in Afternoon	and/or Ev				<del></del>	<del>- 121 -</del>					
17.	Current Episode:	(0) NI	NW.	MIN	MLD	CW	EXT					
18.	. Last Two Weeks:	(0) NI	(I) NW	(2) MIN	MLD	CW	EXT					

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								1				
EXCESSIVE INAPPRO	PRIATE	GUILT										
19. Current Episode:	(0) NI	NO NO	SLT	MLD	MOD	(5) SVR	EXT					
20. Last Two Weeks:	NI NI	NO NO	SLT	MLD	MOD	(5) SVR	EXT					
Frequency:	Days/We	æk _	ا									
NEGATIVE SELF IMAGE												
21. Current Episode:	(0) NI	(I)	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT					
	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT					
22. Last Two Weeks:	[NI]	[NO]	(3L1)	MEL	<u> </u>	(EXXX)	(					
FEELING UNLOVED	/FORLO	<u>en</u>										
23. Current Episode:	(0) NI	NO NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT					
	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT					
24. Last Two Weeks:			SLT	WILD	МОП	SVK	LAI					
Frequency:	Days/W	eek [										
			orm . CE3	CENTE DE	CCIMICM							
HOPELESSNESS, HEI	LPLESSNI	ESS, DISC	OURAGEN	MENT, PE	221W12W							
25. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT					
1	(O) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT					
26. Last Two Weeks:	LNL	[NO]	(22.)			<u> </u>						
SELF-PITY												
37 Comment British	(0) NI	NO NO	(2) OCC	(3) MLD	CON							
27. Current Episode:		(I) NO	(2) OCC	(3) MLD	(4) CON							
28. Last Two Weeks:	(0) NI	NO.	OCCI	MLD	COM							
ACTIFIC AND PAINC	ı											
ACHES AND PAINS		اِسَا	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EXT					
29. Current Episode:		(I) NO										
30. Last Two Weeks	(0) NI	NO NO	SLT	MLD	MOD	SVR	EXT					

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HYPOCHONDRIASIS							ي.
31. Current Episode:	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MOD	SVR	(6) EX
32. Last Two Weeks:	(0) NI	NO (I)	SLT	MLD	MOD	SVR	(6) EX
ANHEDONIA, LACK	OF INTE	REST, AP	ATHY, L	OW MOT	IVATION,	BOREDO	M
Combined Overall Ratin	ıg						
33. Current Episode:	(0) NI	NO NO	SLT	MLD	(4) MO	(5) SVR	EX
Duration:		# of w			F-77-1	[75]	1761
34. Last Two Weeks:	(0) NI	NO (1)	(2) SLT	MLD	(4) MO	SVR	EX
Frequency:	Da	ys/week					
Average % time of the day:		%					
Differentiating Lack	of Intere	st from A	nhedonia				
Lack of Interest	<u>∟∞</u> ⊐	(I) NO	(2) SLT	(3)	(4) MO	(5) SVR	(6) EX
35. Current Episode:	(0)	NO	(2)	MLD	(4) ]	<u></u>	
36. Last Two Weeks:	(0) NI	МО	SLT	MLD	МО	SVR	(6) EX
<u>A</u> nhedonia		<del>                                    </del>	<u> </u>	(3)	[ <del>(4</del> )]	[(3)]	[167]
37. Current Episode:	(O) NI	NO NO	SLT	MLD	МО	SVR	EX
38. Last Two Weeks:	(0) NI	(1) NO	SLT	MLD	(4) MO	SVR	(6) EX
FATIGUE, LACK OF	ENERGY	AND TI	REDNESS	}			
39. Current Episode:	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
40. Last Two Weeks:	(0) NI	(1) NO	SLT	MLD	(4) MO	(5) SVR	(6) EX
Frequency:	D:	ays/Week					
1							

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DIF	FICULTY CONCENT	RATINO	, INATTE	NTION, C	OR SLOW	ED THINE	KING	ب
41.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
		(O) NI	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
42.	Last 1 wo weeks.	NI I	[NO]	[301]	MED	[ WO]	اجتعا	
PSY	CHOMOTOR AGITA	TION						
43.	Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
44.	Last Two Weeks:	(0) NI	(I)	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
44.	Frequency:		:/Week					
MA	NIFESTATIONS INC	LUDED	•					
	Unable to sit still		רטו	(2)	[73) T	[74]	r <del>(s</del> )1	
45.	Current Episode:	(0) NI	NPR	DBT	(3) PR	MOD	(5) SVR	
46.	Last Two Weeks	(0) NI	(I) NPR	(2) DBT	(3) PR	MOD	(5) SVR	
	Barden							
	Pacing	(0) NI	[m]	(2) DBT	(3) PR	(4) SVR	(5) SVR	
47.	Current Episode	-	NPR.					
48.	Last Two Weeks	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR	
	Hand wringing							
49.	Current Episode	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR	
50.	Last Two Weeks	(0) NI	(I) NPR	(2) DBT	(3) PR	(4) \$VR	(5) SVR	
	Pulling or rubbing o				(77.7)	1787	F785	•
51.	Current Episode	(0) NI	(I) NPR	DBT	(3) PR		(5) SVR	
52.	Last Two Weeks	(0) NI	(1) NPR	(2) DBT	(3) PR	(4) SVR	(5) SVR	]
	Can't stop talking, t	alks o=	and on					
		1 (0)		(2) DBT	(3) PR	(4)	(5)	1
53.	. Current Episod	· ·		[DBT			(5)	_
54	. Last Two Week	s: (0)	NPR	DBT	(3) PR	(4) SVR	(5) SVF	

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PSYCI	HOMOTOR RETARL	ATION					جي.	
55.	Current Episode:	(0) NI	(I)	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX
56.	Last Two Weeks:	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MO	SVR	(6) EX
	Frequency:	Day	rs/Week					
MANI	FESTATIONS INCL	U <b>DED</b> :						
SI	owed Speech							
57.	Current Episode:	(0) NI	(I) NPR	DBT	(3) PR	MOD	(3) SVR	
58.	Last Two Weeks:	NI	(1) NPR	DBT	PR	MOD	(5) SVR	
Į,	acreased pauses befol	re answei						
59.	Current Episode:	(0) NI	(I) NPR	DBT	PR	MOD	(5) SVR	
60.	Last Two Weeks:	(0) NI	NPR	DBT	PR	MOD	(5) SVR	
L	ow or monotonous spe			F-145-1	1777	CW.	ारा ।	
61.	Current Episode:	(0) NI	(I) NPR	DBT	(3) PR	MOD	SVR	
62.	Last Two Weeks:	(0) NI	(I) NPR	DBT	(3) PR	(4) MOD	(5) SVR	
A	(ute or markedly dec	reased ar						
63.	Current Episode:	(0) NI	(1) NPR	DBT	(3) PR	(4) MOD	(5) SVR	
64.	Last Two Weeks:	(0) NI	(1) NPR	(2) DBT	(3) PR	MOD	(5) SVR	
s	lowed body movemen	ts						
65.	Current Episode:	(0) NI	(1) NPR	DBT	(3) PR	MOD	(5) SVR	
66.	Last Two Weeks:	(0)	NPR	DBT	PR	MOD	(5) SVR	
	Depressive stupor							
67.	Current Episode:	(0) NI	(I) NPR	DBT	PR	(4) MOD	(5) SVR	
68.	Last Two Weeks:	(0) NI	NPR	DBT	(3) PR	MOD	(5) SVR	

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		12 1 1141							
SOCIAL WIT	THDRAW	AL						ت	
	Episode:	(0) NI	(I)	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
70. Last Two	Weeks:	(0) N1	(1) NO	SLT	MLD	(4) MO	SVR	(6) EX	
REJECTION	SENSITI	VITY							
71. Las	st Year:	(0)	(1) NO	SLT	MLD	MOD	(5) SVR	(6) EX	
72. Current l	Episode:	(0)	(I)	SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX	
73. La:	st Year:	(0) NI	(1) NO	(2) SLT	MLD	(4) MOD	SVR	(6) EX	
74. Current	Episode:	(0) NI	NO NO	SLT	MLD	(4) MOD	SVR	(6) EX	
SLEEP PROI	BLEMS								
75.	Hours sl	ept before	onset of	depression					
76.	Hours sl	ept during	the curren	nt episode					
77.	Hours sl	ept during	the last t	wo weeks					
HYPERSOM	NIA								
78.	Hours sl	lept in da	ytime of cu	irrent episo	de				
79.	Hours s	lept in da	ytime in th	e last two	weeks				
80.			in current						
81.	Hours 1	ying down	in last tw	o weeks					
82. Curren	t Episode:	(0) NI	NO NO	(2)	(3)	(4)	(5)	(6)	
83. Last Tw	vo Weeks:	(0) NI	(1) NO	(2)	(3)	(4)	(5)	(6)	

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INSOM	INIA							
84.	Current Episode: (0) NI	(1) NO	(2)	(3)	(4)	(5)	(6)	
<b>85.</b> La	ast Two Weeks: (0)	(1) NO	(2)	(3)	(4)	(5)	(6)	
	Frequency:	Nights/Wee	:k					
TVPF.	S OF INSOMNIA							
	Initial Insomnia							
86.	Current Episode:	(0) NI	(I) NPR	(2) DBT	(3) MLD	(4) MOD	(5) SVR	
87.	Last Two Weeks:	(0) NI	(I) NPR	DBT	MLD	MOD MOD	(5) SVR	
	Middle Insomnia						DSC1	
88.	Current Episode:	(0)	NPR	DBT	MLD	MOD	(5) SVR	
89.	Last Two Weeks:	(0)	(1) NPR	DBT	MLD	MOD	(5) SVR	
	Terminal Insomnia						[78 <u>]</u>	
90.	Current Episode:	(0) NI	(1) NPR	DBT	MLD	MOD	(5) SVR	
91.	Last Two Weeks:	(0) NI	(I) NPR	DBT	MLD	MOD	(5) SVR	
	Circadian Reversal					<del>- zar</del>	<b>ार</b> ा	
92.	Current Episode:	(0)	NPR	DBT	MLD	MOD	(5) SVR	
93.	Last Two Weeks:	NI	(I) NPR	DBT	MLD	MOD	SVR	
	Non-restorative sleep			<del>[ 751 ]</del>	<u> </u>	[T(4)]	[3]	
94.	Current Episode:		(I) NPR	DBT	MLD	(4) MOD	SVR	
95.	Last Two Weeks	(0) NI	NPR	DBT	MLD	(4) MOD	SVR	
	Daytime sleepiness	<del>- 700 - 1</del>	רשו	<del>[ [2] ]</del>	[(3)]	<del>[ (4)</del> ]	[757]	
96.	Current Episode		NPR	(2) DBT	MLD	мор	(5) (SVR	
97.	Last Two Wæks	(0)	NPR	DBT	MLD	MOD	SVR	

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							-	
ANOREXIA	רמכו	r <del>m 1</del>	F (2) 1	(3)	(4) MOD	(5) RAR	(6) NVR	
98. Current Episode:	(0) NI	(1) NO	SLT	MLD				
99. Last Two Weeks:	(0) NI	NO I	SLT	MLD	MOD	(5) RAR	NVR	
WEIGHT LOSS								
WEIGHT LOSS								
100. Current Episode:								į
Pounds lost:		lbs.						
Number of Weeks:								
101. Last Two Weeks:								
Pounds lost:		lbs.						
INCREASED APPETI	TE							
	(0) NI	(1)	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX	
102. Current Episode:	(0) NI	(I)	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX	
103. Last Two Weeks:				MILL	<u> </u>	سيت		
Frequency:		Days/W∞	K					
STRONG CRAVING	FOR SW	EETS						
SIRONG CRAVITO		(1) ABS	(2) DBT	(3) MLD	(4) MOD	(5) SVR		
104. Current Episode:	(0) NI							
105. Last Two Weeks:	(0) NI	(1) ABS	DBT	(3) MLD	MOD	SVR		
WEIGHT GAIN								
106. Current Episode	e:							
Pounds gained	i:	lbs.						
Number of Week	s:	J						
107. Last Two Week	s:							
Pounds gaine	d:	lbs.						
1								

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SUICIDAL IDEATION											
108. Current Episode:	(0) NI	NO (I)	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	(7) VEX			
109. Last Two Weeks:	(O) NI	(1) NO	(2) SLT	MLD	(4) MO	(5) SVR	(6) EX	(7) VEX			
Suicidal Acts – Numbe	r										
110. Current Episode:											
111. Last Two Weeks:											
Suicidal Acts - Serious	rness										
112. Current Episode:	(0) NI	(I)	(2) MIN	(3) DEF		(4) SER	(5) VS	(6) EXT			
113. Last Two Weeks:	(0) NI	(1) NO	(2) MIN	(3) DEF	[	(4) SER	(5) VS	(6) EXT			
Medical Lethality											
114. Current Episode	(0) NI	(1) NO	(2) MIN	(3) MLD		(4) MO	(5) SVR	(6) EXT			
115. Last Two Weeks:	(O)	(1) NO	(2) MIN	(3) MLD		(4) MO	SVR	EXT			
Non-Suicidal Physical Self-Demaging Acts											
116. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	] [	(4) MO	(5) SVR	(6) ACT			
117. Last Two Weeks:	(0) NI	(I)	(2) SLT	(3) MLD	] [	(4) MO	(5) SVR	ACT			
		<del></del>									

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DIAG	NOSTIC CRITERIA	- MAJ	OR DEPRESSIVE EPISODE	ے
Ģ	Onset and Course			
118. 1	Number of Episodes		L	
	Ages of onset and o	ffset of	each episode	
119.	Onset	120.	Onset	
	Offset		Offset	
	Weeks		Weeks	
121.	Onset	122.	Onset	
	Offset		Offset	
	Weeks		Weeks	

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MANIC SYNDROME ELATION, EXPANSIVE MOOD										
1. Current Episode:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX			
2. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	MLD	(4) MO	(5) SVR	(6) EX			
DECREASED NEED 1	OR SLEI	E <b>P</b>								
3. Current Episode:	(0)	(I) NO	(2) -1	(3) -2	(4) -3	(5)	(6) -4+			
4. Last Two Weeks:	(0) NI	NO NO	(2) -1	(3) -2	(4) -3	(5)	(6) -4+			
UNUSUALLY ENERG	GETIC									
5. Current Episode:	(0) N1	NO NO	SLT	(3) LCH	(4) MOR	(5) MM	(6) UA			
6. Last Two Weeks:	(0) NI	(1) NO	SLT	LCH (3)	MOR	(5) MM	UA			
INCREASE IN GOAL	L DIREC	TED ACT	IVITY							
7. Current Episode:	(0) NI	(1) NO	SLT	(3) MLD	(4) MO	(5) MKD	(6) EX			
8. Last Two Weeks:	(0) NI	NO (I)	(2) SLT	MLD	(4) MO	MKD	(6) EX			
GRANDIOSITY										
9. Current Episode:	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX			
10. Last Two Weeks:	(0) NI	(1) NO	SLT	MLD	(4) MO	(5) SVR	(6) EX			
ACCELERATED, PR	ESSURED	OR INC	REASEI	AMOU	NT OF S	PEECH				
11. Current Episode	(0) NI	(1) NO	SLT	MLD	(4) MO	(3) MKD	(6) EX			
12. Last Two Weeks	(0) NI	NO (1)	SLT	MLD	(4) MO	(5) MKD	(6) EX			

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									_
RACING THOUGHTS								<u></u> -	
13. Current Episode:	(0) NI	(1) NO	(2) DBT	MLD	(4) MO	(5) SVR	(6) EX		
14. Last Two Weeks:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR	(6) EX		
FLIGHT OF IDEAS									
15. Current Episode:	(0) 1N	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX		
16. Last Two Weeks:	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX		
POOR JUDGEMENT									
17. Current Episode:	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) VS		
18. Last Two Weeks:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) VS		
DISTRACTABILITY									
19. Current Episode:	(0) N1	(I) NO	SLT	MLD	(4) MO	(5) SVR			
20. Last Two Weeks:	(0) NI	NO (1)	(2) SLT	MLD	(4) MO	(5) SVR			
MOTOR HYPERACTI	VITY								
21. Current Episode:	(0) NI	(I)	(2) SLT	(3) MLD	(4) MO	(5) MKD	(6) EX		
22. Last Two Weeks:	(0) NI	NO	SLT	(3) MLD	(4) MO	MKD	(6) EX		
Inappropriate laughin	g, jokin								
23. Current Episode:	NI NI	NO NO	(2) DBT	MLD	MOD				
24. Last Two Weeks:	(0) NI	NO NO	(2) DBT	MLD	MOD				
Uninhibited people se	eking, gi								
25. Current Episode:	(0) IN	NO NO	(2) DBT	(3) MLD	(4) MOD			-	
26. Last Two Weeks:	(0) NI	NO NO	(2) DBT	MLD	(4) MOD				

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reased Productivity	<del></del>							<i>=</i>	
Current Episode:	(0) NI	(1) NO	DBT	PRS	SVR				
	(0) N1	(1) NO	(2) DBT	PRS	(4) SVR				
rnened and unusua	llv creat	ive thinki	ng						
penes and anatom				F(3) 1	<u>(4)</u> 1				
Current Episode:	NI	NO	DBT						
Last Two Weeks:	(0) NI	NO (I)	DBT	PRS	SVR				
persexuality									
Current Episode:	(0) NI	(1) NO	(2) DBT	(3) PRS	(4) SVR				
Last Two Weeks:	(0) NI	(I) NO	(2) DBT	PRS	SVR				
LUENCE OF ILL	CIT DR	ugs o <u>r</u>	ALCOH	<u>OL</u>					
Current Episode:	NA	NVR	SMT	ONL					
Last Two Weeks:	(0) NA	(I) NVR	SMT	ONL					
MRER OF MANIO	C PERIO	DDS							
	Current Episode:  Last Two Weeks:  persexuality  Current Episode:  Last Two Weeks:  FLUENCE OF ILL!  Current Episode:  Last Two Weeks:	Current Episode:  Last Two Weeks:  Current Episode:  Current Episode:  Last Two Weeks:  Current Episode:  Last Two Weeks:  Current Episode:  NI  Persexuality  Current Episode:  Last Two Weeks:  Current Episode:  Last Two Weeks:  Current Episode:  Last Two Weeks:  Current Episode:  Current Episode:  Current Episode:  Current Episode:  Current Episode:  Current Episode:  Current Episode:  Current Episode:  Current Episode:  Current Episode:  Current Episode:  Current Episode:  Current Episode:  Current Episode:  Current Episode:  Current Episode:  Current Episode:  Current Episode:  Current Episode:  Current Episode:  Current Episode:  Current Episode:  Current Episode:  Current Episode:  Current Episode:  Current Episode:  Current Episode:  Current Episode:  Current Episode:  Current Episode:  Current Episode:  Current Episode:  Current Episode:  Current Episode:  Current Episode:  Current Episode:  Current Episode:  Current Episode:  Current Episode:  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Episode:  Current Episode:  Current Episode:  Current Episode:  Current Episode:	Current Episode: [0] [1] [1] [1] [1] [1] [1] [1] [1] [1] [1	Current Episode: NI NO DBT  Last Two Weeks: NI NO DBT  Typened and unusually creative thinking  Current Episode: NI NO DBT  Last Two Weeks: NI NO DBT  Persexuality  Current Episode: NI NO DBT  Last Two Weeks: NI NO DBT  Current Episode: NI NO DBT  Current Episode: NI NO DBT  Current Episode: NI NO DBT  Current Episode: NI NO DBT  Current Episode: NI NO DBT  Current Episode: NI NO DBT  Current Episode: NI NO DBT  Current Episode: NI NO DBT  Current Episode: NI NO DBT  Current Episode: NI NO DBT  Current Episode: NI NVE SMT  Current Episode: NI NVE SMT	Current Episode:    Column	Current Episode:    Column	Current Episode:  (O) NI NO DBT PRS SVR  Last Two Weeks:  (O) NI NO DBT PRS SVR  (A) SVR  (A) SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT PRS SVR  (A) DBT P	Current Episode:  Current Episode:  Current Episode:  Current Episode:  Current Episode:  Current Episode:  Current Episode:  Current Episode:  Current Episode:  Current Episode:  Current Episode:  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Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   Total   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DIA	GNOSTIC CRITERIA - HYPOMANIC EPISODE	ĺ									
	Onset and Course	ĺ									
36.	Number of Episodes										
Ages of onset and offset of each episode											
37.	Onset 38. Onset	l									
	Offset Offset										
	Weeks										
DI	AGNOSTIC CRITERIA - MANIC EPISODE										
39.	Onset and Course										
	Number of Episodes										
	Ages of onset and offset of each episode										
40.	Onset 41. Onset										
	Offset Offset										
	Weeks										
1		_									

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EAT	ING DISORD	<u>ERS</u>							ت	
REI	FUSAL TO M.	AINTAI	N BODY	WEIGH	Ţ					
1.	Lifetime:	(0) NI	(I) NP	(2)	(3)	(4)	(5)	(6)		
ME	THODS OF W	EIGHT	LOSS							
2.	Restriction Lifetime:	(0) NI	(I) NVR	SMT	OFT	(4) ROU				
3.	Only Liquids Lifetime:	(0) NI	(I) NVR	SMT	(3) OFT	(4) ROU				
4.	Vomiting Lifetime:	(0) NI	(I) NVR	(2) SMT	(3) OFT	(4) ROU				
5.	Supressants Lifetime:	(0) NI	NVR	(2) SMT	OFT	(4) ROU				
6.	Laxatives Lifetime:	(0) NI	(I) NVR	SMT	OFT	(4) ROU				
7.	Diurectics Lifetime:	(0)	(1) NVR	(2) SMT	(3) OFT	(4) ROU				
BO	DY IMAGE E	ISTURI	BANCE							
8.	Lifetime:	(0) NI	NO NO	SLT	(3) MLD	(4) MO	(5) SYR	(6) EX		
IN	TENSE AND I	PERSIST	ENT FEA	AR OF G	AINING	WEIGH	<u>T</u>			
9.	Lifetime:	(0) NI	NO	(2)	(3)	(4)	(5)	(6)		
IN	TENSE PREO	CUPAT	TION WI	гн гоо	D AND	EATING				
10.	Lifetime:	(0) NI	(1) NO	(2)	(3)	(4)	(5)	(6)		
AM	MENORRHEA									
11.	Age of Me	narche:								
12.	(0) NI N	<u>o</u> [	(2) YES							
13.	(0) NI N	0	(2) YES						-	
11. 12.	Age of Me	0 [0	(2) YES							

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14. Weeks:								÷	
15. Weeks:	لــا								
16. NI (1) NO	YES								
BULIMIA									
17. Lifetime:	(0) NI	(1) NO	(2)	(3)	(4)	(5)	(6)		
18. Eats faster Lifetime:	(0) NI	(I) NVR	(2) SMT	(3) OFT	(4) AS				
19. Uncontrollable Lifetime:	(0) NI	(I) NVR	(2) SMT	OFT	(4) AS				
20. Eats alone Lifetime:	(0) NI	(I) NVR	(2) SMT	(3) OFT	(4) AS				
21. Abdominal Pain Lifetime:	(0) NI	(I) NVR	(2) SMT	(3) OFT	(4) AS				
22. Vomiting Lifetime:	(0) IN	(1) NVR	(2) SMT	(3) OFT	(4) AS				
23. Sleep Lifetime:	(0) NI	(1) NVR	(2) SMT	(3) OFT	(4) AS				
24. Interruption Lifetime:	(0) NI	(1) NVR	(2) SMT	(3) OFT	(4) AS				
25. <b>Depression</b> Lifetime:	(0) NI	(1) NVR	(2) SMT	(3) OFT	(4) AS				
<b>26.</b> Binges:	ho	urs							
			<u></u>						

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<u>DI</u> .	AGNOSTIC CRITERIA - AN	OREXIA NERVOSA
	Onset and Course	
27.	Number of Episodes	
	Ages of onset and offset of ea	ach episode
28.	Onset 29.	Onset
	Offset	Offset
	Weeks	Weeks
<u>DI</u>	AGNOSTIC CRITERIA - BU	LIMIA NERVOSA
	Onset and Course	
30.	Number of Episodes	
	Ages of onset and offset of ea	ach episode
31.	Onset 32.	Onset
	Offset	Offset
	Weeks	Weeks

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AN	XIETY DISORDER	<u>s</u>							٠٠.	
SPI	ECIFIC PHOBIAS									
1.	Overall Lifetime:	(0) NI	(I) NO	SLT	(3) MLD	MO	(5) SVR	(6) EX		
2.	Flying Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR			
3.	Elevators Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR			
4.	Small Spaces Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR			
5.	Heights Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR			
6.	Dark Lifetime:	(0) NI	(I) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR			
7.	Swimming Lifetime:	(0) NI	(I) NO	DBT	(3) MLD	(4) MO	(5) SVR			
8.	Dogs/animals Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR			
9.	Insects Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR			
10.	Thunderstorms Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR			
11.	Cars/Buses/Train Lifetime:	(0) NI	(I) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR			
12.	Dentist/Doctors Lifetime:	(0) NI	NO NO	(2) DBT	(3) MLD	(4) MO	(5) SVR			
13.	Other Lifetime:	(0) NI	(I) NO	(2) DBT	(3) MLD	(4) MO	(5) SVR			
DI	AGNOSTIC CRITE	RIA - S	SPECIFIC	PHOBI	<u>A</u>					
	Onset and Course									
14.	Number of Episod	les	لـــا							
	Ages of onset and	offset o	f each ep	isode						
15.	Onset	1	6. Ons	set	ا					
	Offset		Off	set	J					
	Weeks		We	eks	لـــا					

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SEP	ARATION AND	CIETY							æ	
PRE	OCCUPATION	WITH TH	OUGHTS	OF HA	RM TO	PARENT	<u>s</u>			
1.	Lifetime:	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX		
PRE	OCCUPATION	WITH HA	RM BEI	FALLING	SELF					
2.	Lifetime:	(0) NI	(1) NO	SLT	(3) MLD	(4) MO	(5) SVR	(6) EX		
FEA	R OF BEING	HOME ALC	<u>ONE</u>							
3.	Lifetime:	(O)	NO (I)	(2) SLT	MLD	(4) MO	(5) SVR	(6) EX		
EXC	ESSIVE REAC							~~~		
4.	Lifetime:	(0) NI	(I)	SLT	(3) MLD	(4) MO	(5) SVR	(6) EX		
DIF	FICULTY BEIN						CORT.			
5.	Lifetime:	(0) NI	(1) NO	SLT	MLD	(4) MO	(5) SVR	(6) EX		
HO	MESICKNESS									
6.	Lifetime:	(0) NI	NO NO	(2) \$LT	MLD	MO	(3) SVR	(6) EX		
FEA	AR OF SLEEPI	NG AWAY	FROM							
7.	Lifetime:	(0) NI	NO NO	(2) SLT	MLD	(4) MO	SVR	(6) EX		
NIC	<b>HTMARES</b>						C785-1	<del> </del>		
8.	Lifetime:	(0) NI	(I)	SLT	MLD	(4) MO	(5) SVR	(6) EX		
SCI	HOOL REFUSA					<del>- a</del>	1.05	I776171		
9.	Lifetime:	NI NI	(I)	SLT	MLD	(4) MO	SVR	(6) EX		
PH	YSICAL SYMP	TOMS DUI	RING SE							
10.	Lifetime:	(0) NI	(1) NO	(2) SLT	MLD	(4) MO	(5) SVR	(6) EX		
DIA	AGNOSTIC CRI	TERIA - S	EPARA	TION AN	XIETY	DISORDI	<u>er</u>			
	Onset and Cour	rse								
11.	Number of Epi	sodes		1	. <b>2.</b> c	nset		13.	Onset	
	Ages of onset	and offset o	f each e	oisode	C	offset			Offset	
					V	Veeks			Weeks	<u> </u>

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PA	NIC DISORDER A	ND AG	ORAPHO	<u>BIA</u>					,	
1.	Lifetime:	(0) NI	(1) NP	(2) DBT	DPR	6	(5) 3X	DLY		
SP	ONTANEOUS ATTA	CKS								
2.	Lifetime:	(0) NI	(1) NO	(2)	2-3	4	(5) 4+			
DU	RATION OF SPON	TANE	OUS ATTA	ACKS						
3.	Lifetime:	(0) NI	(1)	(2) 10	SOM	(4) MST	(5) ALL			
SI	TUATIONALLY PR	EDISPO	OSED AT	<u>racks</u>						
4.	Lifetime:	(0) IN	(1) NO	(2) -4	(3)	(4)	(5) 4+			
PH	OBIA RELATED A	TTACE	<u>cs</u>							
5.	Lifetime:	(O) NI	NO NO	(2)	(3)					
6.	Shortness of Breate Lifetime:	(0) NI	NO NO	(2) DBT	(3) MLD	(4) MOD				
7.	Pal pitations Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD				
8.	Chest Pains Lifetime:	(0) NI	(I) NO	(2) DBT	(3) MLD	(4) MOD				
9.	Choking Lifetime:	(0) NI	NO NO	(2) DBT	MLD	(4) MOD				
10.	Dizziness Lifetime:	(0) NI	(I) NO	(2) DBT	(3) MLD	(4) MOD				
11.	<b>Numbness</b> Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD				
12.	Sweating Lifetime:	(0) NI	NO (1)	(2) DBT	(3) MLD	MOD				
13.	Trembling Lifetime:	(0) NI	NO (I)	DBT	MLD	MOD				
14.	Dying Lifetime:	(0) NI	(1)	DBT	(3) MLD	MOD				
15.	Losing Control Lifetime:	(0) NI	(1) NO	DBT	(3) MLD	MOD				
16.	Nausea Lifetime:	(0) NI	(1) NO	DBT	MLD	MOD				
17.	<b>De personalization</b> Lifetime:	(0) NI	(I) NO	(2) DBT	(3) MLD	MOD				
18.	Flashes/Chills Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD				
19.	Most Number of A	tacks:	i i	ıa 4 we	ek period					
20.	Lifetime:	(0) NI	(1) NP	(2) VM	(3) MLD	(4) MO	(5) SVR	(6) EX		

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AG	ORAPHOBIA	WITH PAN	C DISO	RDER				<u></u>				
21.	Lifetime:	(0) NI	NO NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX				
<u>AG</u>	ORAPHOBIA	WITHOUT	PANIC I	DISORD	<u>ER</u>							
22.	Lifetime:	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MO	SVR	(6) EX				
D.T.	CNOCETO CE	ranni - P	ANIIO P	TC() PP	D Milana	<b>ነ</b> መሞ ልድረ	ייזים ג מר	DIA				
DIA	<u>DIAGNOSTIC CRITERIA - PANIC DISORDER WITHOUT AGORAPHOBIA</u> Onset and Course Ages of onset and offset of each episode											
23.			. 1	24.	Onset		25.	Onset				
<b>4</b> .J.	Number of E	pisodes		24.	Onset [		20.	Onzer []				
					Offset [			Offset				
					Weeks [			Weeks				
DIA	GNOSTIC CR	RITERIA - P	ANIC D	ISORDE	R WITH	<b>AGORA</b>	PHOBIA					
26.	Onset and Co	urse		A	ges of onse	et and off	set of eac	ch episode				
	Number of E	pisodes		27.	Onset L		28.	Onset				
					Offset _	لــا		Offset				
					Weeks _	لــــا		Weeks				
DIA	GNOSTIC CE	RITERIA - A	GORAP	HOBIA	WITHOU	т ністо	RY OF	PANIC DISORDER				
29.	Onset and Co				ages of ons							
	Number of E	pisodes		30.	Onset L		31.	Onset				
					Offset _			Offset				
					Weeks [	لــــــ		Weeks				

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<u>soc</u> 1.	CIAL PHOBIA  Lifetime:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	-9				
DIA	GNOSTIC CRITE	CRIA - S	OCIAL 1	PHOBIA									
2.	Onset and Course												
	Number of Episod	ies 🗀											
	Ages of onset and offset of each episode												
3.	Onset	4	l. Ons	et	J								
	Offset		Off	set	J								
	Weeks	_	Wee	ks	لـــ								

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OBS	SESSIONS OR CO	OMPULSIO	ONS						÷	
<u>OB</u>	SESSIONS									
1.	Lifetime:	(0) NI	(1) NO	SLT	MLD	(4) MO	(5) SVR	(6) EX		
<u>co</u>	MPULSIONS									
2.	Lifetime:	(0) NI	NO (1)	SLT	MLD	(4) MO	SVR	(6) EX		
3.	Touching Lifetime:	NI (0)	(I) NO	(2) DBT	MLD	(4) MOD				
4.	Counting Lifetime:	(0) NI	(I) NO	DBT	MLD	(4) MOD				
5.	Washing Lifetime:	(0) NI	(I) NO	DBT	MLD	(4) MOD				
6.	Checking Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	MOD				
7.	Collecting Lifetime:	(0) NI	(1) NO	DBT	MLD	MOD				
8.	Arranging Lifetime:	(0) NI	(I) NO	DBT	(3) MLD	(4) MOD				
9.	Other Lifetime:	(0) NI	(I) NO	DBT	MLD	(4) MOD				
DE	PERSONALIZAT	ION OR	DEREAL	IZATION	1					
10.	Lifetime:	(0) NI	(1) NO	FLT	(3) OCC	(4) SVL	(5) MRK	(6) FQT		
DIA	AGNOSTIC CRIT	ERIA - (	DBSESSIV	Æ-COM	PULSIVI	E DISOR	<u>DER</u>			
11.	Onset and Cours	•								
11.	Number of Epis									
	Ages of onset a	nd offset o	f each ep	isode						
	-									
12.	Onset	] 1:	3. Ons	ict	J					
	Offset	J	Off	set	J					
	Weeks		We	eks	لــا					
l										

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GENERALIZED ANXIETY DISORDER											
wo	RRY										
1.	Lifetime:	(0) NI	(1) NO	SLT	(3) MLD	(4) MO	(5) SVR	(6) EX			
2.	Lifetime:	(0) NI	(1) NO	(2) DBT	(3) MLD	(4) MOD					
DIF	FICULTY CONT	ROLLING	work	IES							
3.	Lifetime:	(0) NI	(1) NO	(2) SLT	MLD	(4) MO	(5) SVR	(6) EX			
SYN	APTOMS ASSOC	IATED V	VITH W	ORRY							
4.	Lifetime:	(0) NI	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX			
DIA	DIAGNOSTIC CRITERIA - GENERALIZED ANXIETY DISORDER										
5.	Onset and Course										
	Number of Episo	des L									
	Ages of onset an	d offset o	f each ep	isode							
6.	Onset	•	7. Ons	et L	J						
	Offset		Off	set	L						
	Weeks	_]	We	eks							

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POST-TRAUMATIC STRESS DISORDER												
TRA	TRAUMA TO OTHERS											
1.	Lifetime:	(0) NI	NO NO	(2)	(3)	(4)	(5)	(6)				
TRA	UMATIC TO SE	ELF										
2.	Lifetime:	(0) NI	(I) NO	SLT	(3) MLD	MOD	(5) SVR					
INT	RUSIVE RECOL											
3.	Lifetime:	(6) NI	(1) NO	SLT	MLD	(4) MOD	(5) SVR	EXT				
REC	URRENT DISTR											
4.	Lifetime:	(0) NI	(1) NO	SLT	MLD	MOD	SVR	EXT				
SEN	SE OF RELIVIN				-							
5.	Lifetime:	(0) NI	NO NO	SLT	MLD	MOD	SVR	EXT				
PHY	SIOLOGICAL R											
6.	Lifetime:	(O) NI	NO NO	SLT	MLD	(4) MOD	SVR	EXT				
THO	OUGHTS, FEELI	NGS, CO	NVERSA'	rions, A	CTIVIT	IES, PLA	CES OF	PEOPLE				
7.	Lifetime:	(0) NI	NO	YES								
NO	RECALL OF IM	1PORTAN	T ASPE	CTS OF	TRAUM	A						
8.	Lifetime:	(0) NI	(1) NO	(2) YES								
MA	RKEDLY REDU	CED ACT	IVITIES	/INTERI	EST							
9.	Lifetime:	(0) NI	(1)	(2) YES								
DET	rachment, en	STRANGI	EMENT.	RESTRIC	TED AF	FECT						
10.	Lifetime:	(0) NI	(I)	(2) YES		-						
SEN	SE OF FORESH											
11.	Lifetime:	(0) NI	(I) NO	(2) YES								
	EP PROBLEMS											
12.	Lifetime:	(0) NI	(I) NO	YES								
		•	لحبب									

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IRI	RITABILITY							-2	
13.	Lifetime:	(0) NI	(1) NO	YES					
DII	FICULTY CONC		ING						
14.	Lifetime:	(0) NI	(I) NO	(2) YES					
HY	PERVIGILENCE								
15.	Lifetime:	(0) NI	NO NO	YES					
EX	AGGERATED ST.		RESPON	SE					
16.	Lifetime:	(0) NI	NO (I)	YES					
ov	ERALL SEVERIT	TY OF PO	ST-TRA	UMATI	C STRES	S DISOR	DER		
17.	Lifetime:	(0) NI	NO (1)	SLT	(3) MLD	(4) MOD	(5) SVR	EXT	
DIA	GNOSTIC CRITE	ERIA - P	OST-TR	AUMAT	IC STRE	SS DISOF	RDER		
18.	Onset and Course	}							
	Number of Episo	des							
	Ages of onset and	d offset of	each epi	sode					
40									
19.	Onset	20	· Onse	et	j				
	Offset		Offs	et	J				
	Weeks	_]	Wee	ks	لــا				

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ATTENTION-DEFICIT/HYPERACTIVITY DISORDER											
INA	TTENTION				["TAT"]						
1.	Lifetime:	(0) NI	(1) NO	SLT	(3) MLD	(4) MO	(5) SVR	(6) EX			
HYI	PERACTIVITY										
2.	Lifetime:	(0)	(I) NO	SLT	MLD	(4) MO	(5) SVR	(6) EX			
<u>IMI</u>	PULSIVITY										
3.	Lifetime:	(0) NI	NO (1)	SLT	(3) MLD	(4) MO	(5) SVR	(6) EX			
DIA	GNOSTIC CRIT	ERIA - A	TTENTI	ON-DEF	ICIT/HY	PERACT	IVITY I	DISORDER			
4.	Onset and Course	e									
	Number of Episo	_									
	Ages of onset an	nd offset of	each epi	sode							
5.	5. Onset 6. Onset										
	Offset		Offs	set L							
	Weeks		Wee	ks							

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CONDUCT DISORDER/ANTISOCIAL PERSONALITY									
СНЕ	RONIC VIOL	ATION OF E	RULES A	т номі	E AND/C	OR SCHOOL			
1.	Lifetime:	(O)	NO NO	(2)	(3)	(4)			
SCH	OOL SUSPEN	····							
2.	Lifetime:	NI (0)	NO	(2)	(3)	EXP			
TRU	J <u>ANC</u> Y								
3.	Lifetime:	(O) NI	(I)	(2) OCC	PQT	50%			
PAT	THOLOGICAL								
4.	Lifetime:	(0)	NO (I)	(2)	(3)	(4)			
STA	YING OUT								
5.	Lifetime:	(0) NI	(1) NO	(2)	(3)	(4)			
RUN	NAWAY OVE								
6.	Lifetime:	(0) NI	(1) NO	(2)	(3)	PQT			
NO	NAGGRESIVE								
7.	Lifetime:	NI (0)	NO NO	(2)	\$10	\$50			
BUI	LLYING								
8.	Lifetime:	(O)	NO NO	(2)	FQT	DLY			
PER	RSISTENT PH								
9.	Lifetime:	NI NI	(I) NO	(2)	PQT	(4)			
USE	OF A WEA								
10.	Lifetime:	NI (0)	(I) NVR	CON	1	(4) 1+			
<u>VA</u>	NDALISM		- CSC		p	<b></b>			
11.	Lifetime:	(0) NI	NO NO	(2)	(3)	(4)			
FIR	ESETTING		[75 <del>]</del>						
12.	Lifetime:	(0)	(1) NO	(2)	(3)	(4)			

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BRI	EAKING AND EN	TERING						÷	
13.	Lifetime:	(0) 11	(I) NO	(2) -1	(3)	(4) 2+			
AG	GRESSIVE STEAL	ING							
14.	Lifetime:	(O)	(1) NO	(2) -1	(3)	(4) 2+			
CRI	JELTY TO ANIM								
15.	Lifetime:	(0) NI	NO	OCC	(3)	(4)			
PH	YSICAL CRUELT	Y TO PE	RSONS						
16.	Lifetime:	(0) NI	NO NO	(2) -1	(3)	2+			
НО	MICIDAL ACTS								
17.	Lifetime:	(0) NI	NO (1)	GTR	ATT	(4) COM			
FO	RCED SEX								
18.	Lifetime:	(0) NI	(1) NO	(2)	(3)	(4)	(5) RAP		
<u>GA</u>	NG ACTIVITIES								
19.	Lifetime:	(0) NI	NO.	PER	MEM	(4) LDR			
DE	LINQUENCY								
20.	Lifetime:	(0) NI	(1) NO	(2) ARR	CHA	CON			
INC	CARCERATION								
21.	Lifetime:	(0) NI	(1) NO	(2) HLD	(3) REF	(4) JAL			
SU	MMARY RATING	<u>}</u>							
22.	Lifetime:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX	
DIA	GNOSTIC CRITE	RIA - C	ONDUC	T DISOR	DER				
23.	Onset and Course			Ages	of onset	and offse	t of each	episode	
	Number of Episod	ies		24.	Onse	t L	2:	5. Onset	
			Offse	et		Offset _	ٔ ا		
					Weel	ks I , ,	ļ	Weeks _	
					50.	<u> </u>			

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ANTISOCIAL PERSONALITY DISORDER										
wo	<u>rk</u>									
1.	Lifetime:	(0) NI	(1) NO	(2) MLD	(3) MOD	(4) SVR	(5) EX			
FIN	ANCIAL RESPO	ONSIBILIT	<u>ry</u>							
2.	Lifetime:	(0) NI	NO NO	(2) MLD	(3) MOD	(4) SVR	(5) EX			
CO	NNING									
3.	Lifetime:	(0) NI	(I) MLD	(2) MOD	(3) SVR	(4) EX				
DIS	REGARD FOR	SAFETY (	OF SELF	OTHER:	<u>s</u>					
4.	Lifetime:	(0) NI	(I) MLD	(2) MOD	(3) EX					
LAC	CK OF REMOR	<u>SE</u>								
5.	Lifetime:	(0) NI	(1) MLD	MOD	(3) EX					
DIA	GNOSTIC CRIT	ERIA - A	NTISOC	IAL PER	SONALI	TY DISC	ORDER			
6.	Onset and Cours	<u>e</u>								
	Number of Epis	odes								
	Ages of onset as	ad offset of	f each epi	sode						
7.	Onset	_	3. Ons		j					
	Offset   ,		Offe	set   ,	1					
	Weeks		Wee	ks						
							,			

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<u>OP</u> F	OPPOSITIONAL DEFIANT DISORDER												
1.	Lifetime:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX					
				_									
DIA	GNOSTIC CRITE	<u>eria - C</u>	PPOSIT	<u>IONAL 1</u>	DEFIANT	<u> Disori</u>	<u>DER</u>						
2.	Onset and Course	!											
	Number of Episo	des											
	Ages of onset and	d offset of	each ep	isode									
3.	Onset	4	Ons	et 🖳	]								
	Offset		Off	set	J								
	Weeks		Wee	ks	لــا								

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AL	COHOL								<u>-</u> -				
AL	ALCOHOL ABUSE												
1.	Lifetime:	(0) NI	(I)	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX					
AL	COHOL DEPEND	ENCE											
2.	Lifetime:	(0) IN	(I) NO	(2) SLT	(3) MLD	(4) MO	(5) SVR	(6) EX					
DIA	GNOSTIC CRITE	RIA - A	LCOHOL	DEPEN	DENCE								
3.	DIAGNOSTIC CRITERIA - ALCOHOL DEPENDENCE  3. Onset and Course												
	Number of Episod	es											
	Ages of onset and	offset of	each epi	sode									
4.	Ages of onset and offset of each episode  4. Onset   5. Onset												
	Offset		Offs	et [									
	Weeks		Wee	ks									
DI A	CNOCEIC CDIES	<b>D.</b>											
DIA	GNOSTIC CRITE	RIA - A	LCOHOL	ABUSE									
6.	Onset and Course												
	Number of Episod	es 💷											
	Ages of onset and	offset of	each epi	sode									
7.	Onset	8	· Onse	et									
	Offset		Offs	et									
	Weeks		Wee	ks									
			C										

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DRI	<u>UGS</u>								£	
DR	UG ABUSE									
1.	Lifetime:	(0)	(1) NO	SLT	MLD	MO	SVR	(6) EX		
DR	UG DEPENDENC	-								
2.	Lifetime:	(0) NI	NO NO	(2) MLD	MOD	SVR	(5) EX			
DIA	AGNOSTIC CRIT	ERIA - S	UBSTAN	CE DEP	ENDENC	<u>E</u>				
3.	Onset and Cours	<u>e</u>								
	Number of Episo	odes								
	Ages of onset an									
4.	Onset	;	5. Ons	et	]					
	Offset		Off	set	_					
	Weeks		We	eks						
<u>DI</u>	AGNOSTIC CRIT	ERIA - S	UBSTAN	ICE ABU	<u>SE</u>					
6.	Onset and Cours	<u>ie</u>								
	Number of Epis	odes	لب							
	Ages of onset a	nd offset o	of each ep	oisode						
7.	Onset	J	8. On	set						
	Offset	J	Of	fset	ا					
	Weeks		We	eks	لـــا					
	<u> </u>									

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TIC	MOTOR TICS  1. Lifetime:									
MC		(6) NI NO SLT MLD MO SVR EX  (7) NO SLT MLD MO SVR EX  (8) NO SLT MLD MO SVR EX  (6) EX  (6) EX  (7) NO SLT MLD MO SVR EX  (8) EX  (8) CRITERIA - TIC DISORDERS  (9) CRITERIA - TIC DISORDERS  (9) CRITERIA - TIC DISORDERS  (9) CRITERIA - TIC DISORDERS  (1) CRITERIA - TIC DISORDERS  (1) CRITERIA - TIC DISORDERS  (1) CRITERIA - TIC DISORDERS  (1) CRITERIA - TIC DISORDERS  (1) CRITERIA - TIC DISORDERS  (1) CRITERIA - TIC DISORDERS  (2) CRITERIA - TIC DISORDERS  (3) MLD MO SVR EX  (4) CRITERIA - TIC DISORDERS  (4) CRITERIA - TIC DISORDERS  (5) CRITERIA - TIC DISORDERS  (6) CRITERIA - TIC DISORDERS  (6) CRITERIA - TIC DISORDERS  (6) CRITERIA - TIC DISORDERS  (6) CRITERIA - TIC DISORDERS  (6) CRITERIA - TIC DISORDERS  (6) CRITERIA - TIC DISORDERS  (6) CRITERIA - TIC DISORDERS  (6) CRITERIA - TIC DISORDERS  (6) CRITERIA - TIC DISORDERS  (6) CRITERIA - TIC DISORDERS  (6) CRITERIA - TIC DISORDERS  (6) CRITERIA - TIC DISORDERS  (6) CRITERIA - TIC DISORDERS  (6) CRITERIA - TIC DISORDERS  (6) CRITERIA - TIC DISORDERS  (6) CRITERIA - TIC DISORDERS  (6) CRITERIA - TIC DISORDERS  (6) CRITERIA - TIC DISORDERS  (6) CRITERIA - TIC DISORDERS  (6) CRITERIA - TIC DISORDERS  (6) CRITERIA - TIC DISORDERS  (6) CRITERIA - TIC DISORDERS  (6) CRITERIA - TIC DISORDERS  (6) CRITERIA - TIC DISORDERS  (6) CRITERIA - TIC DISORDERS  (6) CRITERIA - TIC DISORDERS  (6) CRITERIA - TIC DISORDERS  (6) CRITERIA - TIC DISORDERS  (6) CRITERIA - TIC DISORDERS  (6) CRITERIA - TIC DISORDERS  (6) CRITERIA - TIC DISORDERS  (6) CRITERIA - TIC DISORDERS  (6) CRITERIA - TIC DISORDERS  (6) CRITERIA - TIC DISORDERS  (6) CRITERIA - TIC DISORDERS  (6) CRITERIA - TIC DISORDERS  (6) CRITERIA - TIC DISORDERS  (7) CRITERIA - TIC DISORDERS  (8) CRITERIA - TIC DISORDERS  (8) CRITERIA - TIC DISORDERS  (8) CRITERIA - TIC DISORDERS  (8) CRITERIA - TIC DISORDERS  (8) CRITERIA - TIC DISORDERS  (8) CRITERIA - TIC DISORDERS  (8) CRITERIA - TIC DISORDERS  (8) CRITERIA - TIC DISORDERS  (8) CRITERIA - TIC DISORDERS  (8) CRITERIA - TIC DISORDERS  (8) CRITERIA - TIC DISORDERS  (8) CR								
1.	Lifetime:	NI	NO	SLT	MLD	МО	SVR	[EX]		
<u>vo</u>	CAL TICS			F78-1	- <del>77</del> 0	F780-1	m <del>a</del> n	LIKT.		
2.	Lifetime:	(0) NI	NO NO	SLT	MLD	MO	SVR	EX		
3.	Onset and Cou  Number of Ep.  Ages of onset  Onset	isodes and offset o	f each ep  5. Ons	isode set Set	١					

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PSYC	HOTIC SYM	PTOMOLOGY	<u> </u>		
COM	IMAND HAL	LUCINATION			
1.	Lifetime:	(0) NI	(1) ABS	SUS	DEF
CON	VERSING V	OICES			
2.	Lifetime:	(0) NI	(1) ABS	(2) SUS	DEF
PER	SECUTORY 1	HALLUCINAT	IONS		
3.	Lifetime:	(0) NI	(1) ABS	(2) SUS	DEF
COM	MENTING Y	VOICE			
4.	Lifetime:	(O)	(1) ABS	(2) SUS	(3) DEF
REL	IGIOUS HAI	LUCINATIO	NS_		
5.	Lifetime:	(0) NI	(I) ABS	(2)   SUS	(3) DEF
-	OUGHTS ALC				
6.	Lifetime:	(0) NI	(1) ABS	(2) SUS	(3) DEF
		HALLUCIN	_		
7.	Lifetime:	(0) NI	(I) ABS	(2) SUS	(3) DEF
		AUDITORY I			NS
8.	Lifetime:	(0) NI	(1) ABS	(2) SUS	(3) DEF
		(0) NI	ത	(2) SUS	(3) DEF
9.	Lifetime:		[ABS]		DEF 3
10.	Lifetime:	(O)	(I) ABS	(2) SUS	DEF
VIS	SUAL HALLU	JCINATIONS			
11.	Lifetime:	(0) NI	(1) ABS	(2) SUS	DEF
Tr.4	CTITE HAIT	UCINATIONS	2		
_		(0)	(I) ABS	(2) SUS	(3)
12.	Lifetime:			[ <u>sus</u> ]	DEF
<u>OL</u>	FACTORY H	ALLUCINATI		<del></del>	<del>  741  </del>
13.	Lifetime:	(0) NI	(I) ABS	(2) SUS	(3) DEF
14.	Lifetime:	(0) NI	(1) ABS	SUS	(3) DEF

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	ER PERCEPTI					5		<b>∵</b>	
HYP	NAGOGIC OF	R HYPNAPO	MPIC F			<u>s</u>			
1.	Lifetime:	(0) NI	(I) ABS	SUS	DEF				
2.	Lifetime:	(0) NI	(I) ABS	(2) SUS	DEF				
3.	Lifetime:	(0) NI	(1) ABS	SUS	DEF				
ILL	<u>USIONS</u>								
4.	Lifetime:	(0) NI	(I) ABS	(2) SUS	DEF				
EID	ETIC IMAGE	RY							
5.	Lifetime:	(0)	ABS	(2) SUS	DEF				
ELA	BORATED FA	ANTASIES							
6.	Lifetime:	(0) NI	(1) ABS	(2) SUS	DEF				
IMA	AGINARY CO	MPANIONS							
7.	Lifetime:	(0) NI	(1) ABS	(2) SUS	DEF				
CH.	RACTERISTI	CS OF PSYC	HOPAT	HOLOGI	CALLY N	MEANING	FUL HA	LLUCINAT	IONS
FRI	EQUENCY								
8.	Lifetime:	(0) NI	(1) NO	(2) SUS	(3) -5	(4) SOM	(5) LOT	DLY	
SEV	VERITY								
9.	Lifetime:	(0) NI	NO (I)	(2) SUS	(3) DEF	(4) GEN	(5) CNV	(6) ACT	
TH	EMATIC CON	SISTENCY	WITH M	100D DI	SORDER				
DE	PRESSION	[-M-1	[17]	(2)	(3)				
10.	Lifetime:	(0) NI	(I)	(2) POS	сом				
MA 11.	ANIA Lifetime:	(0) NI	(1) NO	(2) POS	(3) COM				
TE	MPORAL CO	NSISTENCY	WITH I	MOOD D	ISORDER	<u>L</u>			
	PRESSION								
12.	Lifetime:	(0) NI	NO	(2) SUS	POS				
M. 13.	ANIA Lifetime:	(0) NI	(I)	(2)   SUS	(3) POS				
13.	Directine.								

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DEL	USIONS					
DE	LUSIONS OF	REFERENCE				
1.	Lifetime:	(0) NI	(I) ABS	(2) NON	SUS	(4) DEF
<u>DE</u> l	LUSIONS OF	BEING CONT	ROLLE	D OR IN	FLUENC	ED
2.	Lifetime:	(0) NI	(1) ABS	(2) NON	SUS	(4) DEF
DE	LUSIONS TH	AT PEOPLE (	CAN RE	AD HIS	MIND	
3.	Lifetime:	(0) NI	(I) ABS	(2) NON	(3) SUS	(4) DEF
TH	OUGHT BRO	ADCASTING				
4.	Lifetime:	(0) NI	(1) ABS	(2) NON	(3) sus	(4) DEF
тн	OUGHT INSE	ERTION				
5.	Lifetime:	(0) NI	(I) ABS	(2) NON	(3) SUS	(4) DEF
			الاسما	<u> 11011</u>	[230]	
<u>TH</u>	OUGHT WIT		[10]	[75]	(3)	[क]
6.	Lifetime:	(0) NI	ABS	(2) NON	sus	DEF
DE	LUSIONS OF	GUILT OR S	SIN			
7.	Lifetime:	(0) NI	(1) ABS	(2) NON	SUS	(4) DEF
DE	LUSIONS OF	INFLUENCE	•			
8.	Lifetime:	(0) NI	(I) ABS	(2) NON	SUS	(4) DEF
PE	RSECUTORY	DELUSIONS				
9.	Lifetime:	(0) NI	(I) ABS	(2) NON	SUS	(4) DEF
GU	JILT RELATI	ED PERSECUT	ORY D	ELUSION	is	
10.	Lifetime:	(0) NI	(1) ABS	(2) NON	(3) SUS	(4) DEF
SC	MATIC DEL	USIONS				
11.	Lifetime:	(0) NI	(I) ABS	(2) NON	(3) SUS	(4) DEF
GI	UILT RELAT	ED SOMATIC	DELUS	IONS		
12.	Lifetime:	(0) NI	(1) ABS	(2) NON	(3) SUS	(4) DEF
			<del></del>			

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NIHI	LISTIC DEL							حي	
13.	Lifetime:	(0) NI	(I) ABS	(2) NON	SUS	DEF			
GUII	T RELATED	NIHILISTIC	DELUS	SIONS					
14.	Lifetime:	(0) NI	(1) ABS	(2) NON	SUS	DEF			
GRA	NDIOSE DEI					[74]			
15.	Lifetime:	(0) NI	(1) ABS	NON	SUS	DEF			
SUBO	CULTURAL (	OR FAMILY	DELUS	IONS					
16.	Lifetime:	(0) NI	(I) DEF	(2) LIK	(3) ALL				
SEV	ERITY OF D	ELUSIONS C	F ANY	TYPE					
17.	Lifetime:	(0) NI	NO NO	(2) SUS	PST	(4) GEN	(5) sig	ACT	
SEN:	SORIUM WI								
18.	Lifetime:	(0) NI	(I)	PLX	(3) ALW				
THE	MATIC CON	SISTENCY V	VITH M	OOD DI	SORDER				
DEP	RESSION								
19.	Lifetime:	(0) NI	NO (I)	POSS	(3) COM				
	NIA	<u></u>   ™	[क	(2)	(3)				
20.	Lifetime:	(0) NI	(I) NO	POSS	сом				
TEN	MPORAL CO	NSISTENCY	WITH I	MOOD D	ISORDER				
DEF	PRESSION	CINC)	ш	[ <del>72\ ]</del>	(3)				
21.	Lifetime:	NI NI	NO_	SUS	POS				
	NIA	(0)	(I)	(2) SUS	POS				
22.	Lifetime:	NI	[NO]	[ <u>SUS_I</u>	POS				
BIZ	ARRENESS (	OF DELUSIO	NAL CO						
23.	Lifetime:	(0) NI	NO	(2) SLT	MLD	(4) MOD	(5) SVR	(6) EX	
<u>M</u> U	LTIPLE DEI	LUSIONS							
24.	Lifetime:	(0) NI	(I) ABS	SUS	DEF			-	

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									·
FOR	MAL THOUGI	HT DISORD	ER					æ.	
SEN	TENCE INCOL	IERENCE							
1.	Lifetime:	(0) NI	(1) NO	SLT	MLD	(4) MOD	(5) SVR	(6) EX	
2.	Observed:	(0) NI	NO NO	SLT	MLD	(4) MOD	(5) SVR	(6) EX	
DER	AILMENT								
3.	Lifetime:	(0)	(1) NO	(2) SLT	(3) MLD	MOD	(5) SVR	(6) EX	
4.	Observed:	NI NI	NO NO	(2) SLT	MLD	(4) MOD	SVR	(6) EX	
ILLA	OGICAL THIN	KING							
5.	Lifetime:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX	
6.	Observed:	(0) NI	NO NO	(2) SLT	(3) MLD	MOD	(5) SVR	(6) EX	
POV	ERTY OF CO	NTENT OF	SPEECI	<u>H</u>					
7.	Lifetime:	(O) NI	(1) NO	(2) SLT	MLD	(4) MOD	SVR	(6) EX	
8.	Observed:	(0) NI	NO	SLT	MLD	MOD	SVR	(6) EX	
NEC	OLOGISMS								
9.	Lifetime:	(0) NI	(I) ABS	(2) SLT	MLD	(4) MOD	(5) 20%	JAR	
10.	Observed:	(0) NI	(I) ABS	(2) SLT	MLD	MOD	(5)	JAR	
PRI	ESSURE OF SI	PEECH							
11.	Lifetime:	(0) NI	(1) NO	(2) SLT	(3) MLD	(4) MOD	(5) SVR	(6) EX	
12.	Observed:	(0) NI	(I) NO	(2) SLT	(3)	(4) MOD	(5) SVR	(6) EX	

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OBSI	ERVATIONAL	ITEMS						<u></u>	
INA	PPROPRIATE	AFFECT							
1.	Observed:	(0) NI	(1) NO	(2) SLT	MLD	(4) MOD	(5) SVR	(6) EX	
BLU	NTED AFFECT	]							
2.	Observed:	(0) NI	NO NO	(2) SLT	MLD	(4) MOD	SVR	(6) EX	
CAT	ATONIC MOT	OR BEHA	VIOR_						
3.	Observed:	(0) NI	(1) ABS	DBT	(3) MM	SVR			
4.	Observed:	(0) NI	(1) ABS	(2) DBT	(3) MM	SVR			
5.	Observed:	(0) NI	(1) ABS	(2) DBT	(3) MM	(4) SVR			
6.	Observed:	(0) NI	(I)	(2) DBT	(3) MM	(4) SVR			
7.	Observed:	(0) NI	(I) ABS	(2) DBT	(3) MM	(4) SVR			
BIZ	ARRENESS								
8.	Observed:	(0) NI	(I) NO	(2) SLT	MLD	MOD	SVR	(6) EX	
9.	Observed:	(0) NI	(1) ABS	(2) DBT	PST	SVR			
10.	Observed:	(0) NI	(1) ABS	(2) DBT	PST	(4) SVR			
11.	Observed:	(0) NI	(1) ABS	(2) DBT	(3) PST	(4) SVR			
12.	Observed:	(0) VG	(I)	(2) OF	(3) P	(4) VP			

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DIAGNOSTIC CRITERIA - SCHIZOPHRENIA	عد ا
1. Onset and Course	
Number of Episodes	
Ages of onset and offset of each episode	
2. Onset 3. Onset	
Offset Offset	
Weeks	
DIAGNOSTIC CRITERIA - SCHIZOAFFECTIVE DISORDER	
4. Onset and Course	
Number of Episodes	
Ages of onset and offset of each episode	
5. Onset 6. Onset	
Offset	
Weeks	
DIAGNOSTIC CRITERIA - BRIEF PSYCHOTIC DISORDER	
7. Onset and Course	
Number of Episodes	
Ages of onset and offset of each episode	
8. Onset 9. Onset	
Offset	
Weeks	

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### KIDDIE-SADS-LIFETIME - SCORING FORM

DIA	GNOSTIC CRITERIA - DEL	USIONAL DISORDER								
10.	10. Onset and Course									
	Number of Episodes									
	Ages of onset and offset of ea	ach episode								
11.	Onset 12.	Onset								
	Offset	Offset								
	Weeks	Weeks								

#### KIDDY-GAS (C-GAS)

1. Current Episode:	100- 91	90- 81	80- 71	70 <b>-</b> 61	60- 51	50- 41	40 <b>-</b> 31	30- 21	20 <b>-</b> 11	10-1
2. Last Two Weeks:	100- 91	90- 81	80- 71	70- 61	60- 51	50- 41	40- 31	30- 21	20- 11	10-1

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### LABORATORY TESTS

Sample Date day month year	For Lab Number SB Code
Attach SBCL laboratory report behind this page.	
Are there CLINICALLY SIGNIFICANT ABNORM	IAL laboratory values?
☐ No ☐ Yes — Record the findings and/or diagn	nosis in the Adverse Experiences.

ſ	Project	Protocol	Center	Patient Number		Page
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#### STUDY MEDICATION RECORD

Start Date lay month year	End Date day month year	Dose Level	Number of Capsules Daily	
. 1 1 .				

## STUDY MEDICATION DOSING CHANGES

□ No				
☐ Yes —	→ Indicate cha	nge(s) belo	ow .	
	Reminder:	Changes	in dose constitu	te deviation from the protocol.
	Reminder.	Changes	in dose constitu	The same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the same process of the sa
Start Date	End Date	Dose Level	Number of Capsules Daily	Reason for Dose Change
day month year	day month year			

#### STUDY MEDICATION COMPLIANCE

Capsules Dispensed (A)	Capsules Returned (B)	Capsules Taken (A - B)	Days Since Last Visit	% Compliance		
Compli		(N [★] x	of capsules lays since l 0% and \( \lambda \)	ast visit) X	100	★ N = number of capsules dail (see above)

Project	Protocol	Center	Patient Number	Visit	Page
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#### STUDY MEDICATION LABEL

1001	MEDICATION 1	ADEL		
				ب
	Ţ.	Attach label here		
	г		コ	
	L	Attach label here		
	[	Attach label here		
		Attach label here		
•	Enter patient number (drug code as listed on clinical supplies)		Important:	The drug code on the study medication label must be identic to the preprinted Patient Numb above.

Project	Protocol	Center	Patient Number	Visit		Page
29060	329	0 0		Continuation Week 3	Phase 2	399

#### **ELECTROCARDIOGRAM**

or interpreta	rdiogram performed and sent to a central reader tion?	Date Performed (day month year)
☐ Yes	□ No	tudy monen your

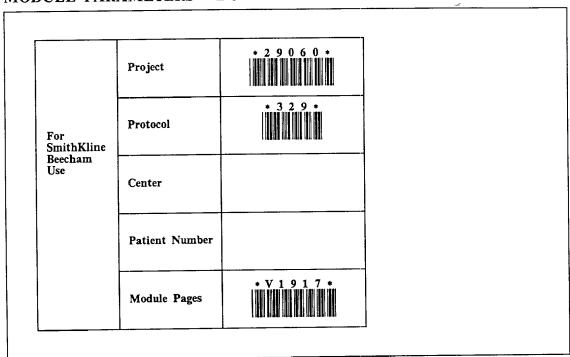
#### STUDY MEDICATION DISPENSING

Record study medication information for Down Titration in the Study Medication Record, page 401. Attach label to page 400. Record number of capsules dispensed on page 401.

Reminder: The drug code on the study medication label must be identical to the preprinted Patient Number above.

Project	Protocol	Center	Patient Number	Visit	
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### MODULE PARAMETERS - DOWN TITRATION



	Project	Protocol	Center	Patient Number	Visit	motor ®	Visit Date	Page	
-	29060	329	0 0		Down Titration		day month year	400	

## ADVERSE EXPERIENCES / CONCOMITANT MEDICATION

Have any adverse experiences been observed or elicited by the following direct question to the patient: "Do you feel different in any way since starting the treatment or since the last visit"?
☐ Yes ☐ No
Record in the Adverse Experience section
Has there been any change in concomitant medication since the last visit?
☐ Yes ☐ No
Record in the Concomitant Medication section
STUDY MEDICATION LABEL
Attach label here
Enter patient number (drug code as listed on clinical supplies)  Important: The drug code on the study medication label must be identical to the preprinted Patient Number above.

Project	Protocol	Center	Patient Number		Page
29060	329	0,0		Down Titration	401

#### STUDY MEDICATION RECORD

Start Date day month year				
	1.1.1.1.1			

## STUDY MEDICATION DOSING CHANGES

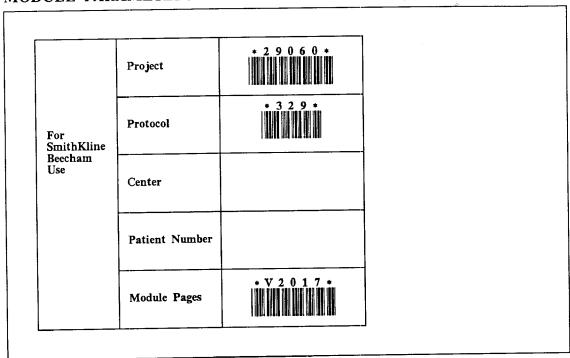
□ No				
☐ Yes ——	→ Indicate cha	nge(s) belo	ow.	
	Reminder:	Changes	in dose constitu	te deviation from the protocol
	Reminder.	CHANGO	in dose compare	· · · · · · · · · · · · · · · · · · ·
<u>.                                    </u>		Dose	Number of Capsules	
Start Date day month year	End Date day month year	Level	Daily	Reason for Dose Change

### STUDY MEDICATION COMPLIANCE

Capsules Dispensed (A)	Capsules Returned (B)	Capsules Taken (A - B)	Days Since Last Visit	% Compliance			
_	ance = m	(N <b>★</b> x	of capsules days since l	last visit)	100	* _N =	number of capsules daily (see above)

Project	Protocol	Center	Patient Number	Visit	
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## MODULE PARAMETERS - CONCOMITANT MEDICATION



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#### CONCOMITANT MEDICATION

Where appropriate, medical conditions should be recorded on the Adverse Experiences form utilizing the same terminology.										
Drug Name (Trade name preferred)	Total Daily Dose (e.g., 500 mg)	Route	Medical Condition	Start Date	End Date * or Continuation (mark box)					
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Project	Protocol	Center	Patient Number	Page
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Drug Name (Trade name preferred)	Total Daily Dose (e.g., 500 mg)	Route	Medical Condition	Start Date★	End Date ★ or Continuation (mark box)		
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Drug Name (Trade name preferred)	Total Daily Dose (e.g., 500 mg)	Route	Medical Condition	Start Date ★	End Date * or Continuation (mark box)		
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Drug Name (Trade name preferred)	Total Daily	Route	e Medical Condition		Start Date*			End Date * or Continuation (mark box) day month year		
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(e.g., 500 mg)			day month year	day month year
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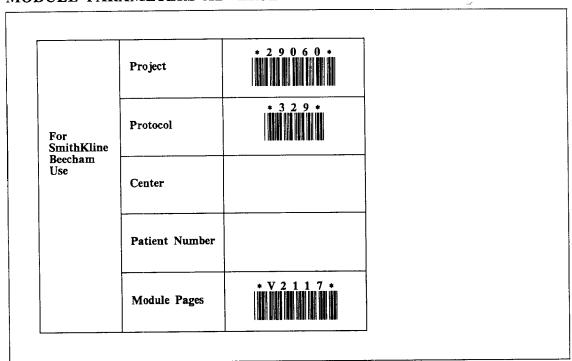
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Drug Name (Trade name preferred)	Total Daily Dose (e.g., 500 mg)	Route		Start Date	End Date * or Continuation (mark box)	
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### Signature SmithKline Beecham Pharmaceuticals

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### MODULE PARAMETERS-ADVERSE EXPERIENCE



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Record follow treatm	in standard medicing direct question lent or since the la	cal terminology any a to patient: "Do you ast visit?" Mark app	dverse experience observe feel different in any wa copriate boxes (one exper	ed or elicited by the y since starting the ience per column).
Experience				
For Smith	(line Beecham			
Date Starte	ed _	day month year	day month year	day month year
Date Stopp		day month year	day month year	day month year
than	tion if less 24 hours rience continuing	hours minutes	hours minutes	hours minutes
Expe	rience continuing d of study			
Course	Continuous? - if no, number of episodes	☐ Yes ☐ No - ☐	☐ Yes ☐ No -	☐ Yes ☐ No -
Intensity	1 Mild 2 Moderate 3 Severe			
Action Taken on Study Medication	1 None 2 Dose decreased 3 Dose increased	0000		000
Suspected Relationship To Study	3 Probably			
Medication	unrelated 4 Unrelated			☐ Yes
Corrective Therapy	on Concomitant Medication form	☐ Yes ☐ No	☐ Yes ☐ No	□ No
adverse exp	sider this a serious erience by the on previous page?	□ No	☐ Yes ☐ No	☐ Yes ☐ No
to SB within	, report experience by telephone 24 hours	AE Number	AE Number	AE Number
Investigator	's Signature			complete Form D

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Record follow treatm	l in standard mediing direct question tent or since the l	ical terminolog to patient: "l ast visit?" Ma	any ad Do you f rk appro	verse exp eel differe priate box	erience ent in a xes (one	observe ny way experi	d or elic y since s ence per	cited by starting column	the the ).
Experience									
For Smithl	Kline Beecham								
Date Starte	ed	day month	year	day n	ionth	year	day	month	year
Date Stopp		day month	year	day n	nonth	year	day	month	year
than	tion if less 24 hours rience continuing	hours minut	es	hours	∟⊥⊥ minutes □		hours	minute	s s
Expe	rience continuing nd of study								****
Course	Continuous? - if no, number of episodes	☐ Yes ☐ No - ☐		☐ Ye	- 1		_	res lo -	
Intensity	1 Mild 2 Moderate 3 Severe								
Action Taken on Study Medication	1 None 2 Dose decreased 3 Dose increased 4 Drug stopped								
Suspected Relationship To Study Medication	3 Probably unrelated								
Corrective Therapy	4 Unrelated  If yes, record on Concomitant Medication form		Yes No		☐ Ye	_		□ Y □ N	0
adverse exp definitions	sider this a serious erience by the on previous page? , report experience		Yes No		□ Ye	-		□ Y □ N	es o
to SB within	by telephone 1 24 hours	AE Number		AE Nun	nber		AE Nu	mber atient d	ied.
Investigator's Signature							com	plete Fo	rm D

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7 follow	ing direct question	to natient: "Do you f	verse experience observe eel different in any wa priate boxes (one experi	y since starting the
Experience				
For Smithl	Kline Beecham			
Date Starte	ed	day month year	day month year	day month year
Date Stopp		day month year	day month year	day month year
than	tion if less 24 hours	hours minutes	hours minutes	hours minutes
Expe	rience continuing rience continuing id of study			Ö
Course	Continuous? - if no, number of episodes	☐ Yes ☐ No -	☐ Yes ☐ No - ☐	☐ Yes ☐ No -
Intensity	1 Mild 2 Moderate 3 Severe			
Action Taken on Study Medication	<ol> <li>None</li> <li>Dose decreased</li> <li>Dose increased</li> <li>Drug stopped</li> </ol>			
Suspected Relationship To Study Medication	1 Related 2 Possibly related 3 Probably unrelated			
Corrective Therapy	4 Unrelated  If yes, record on Concomitant Medication form	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
adverse exp	sider this a serious erience by the on previous page?	□ No	☐ Yes ☐ No	☐ Yes ☐ No
to SB within	, report experience by telephone 24 hours	AE Number	AE Number	AE Number
Investigator	's Signature			If patient died, complete Form D

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Record follow treatm	d in standard meding direct question nent or since the l	ical terminology any act to patient: "Do you fast visit?" Mark appro	lverse experience observe eel different in any wa opriate boxes (one experi	ed or elicited by the y since starting the ence per column).
Experience				
For Smithl	Kline Beecham			
Date Starte	ed	day month year	day month year	day month year
Date Stopp	i	day month year	day month year	day month year
Dura than	tion if less 24 hours	hours minutes	hours minutes	hours minutes
Experience continuing Experience continuing at end of study				
Course	Continuous? - if no, number of episodes	☐ Yes ☐ No -	☐ Yes ☐ No -	☐ Yes ☐ No - ☐
Intensity	1 Mild 2 Moderate 3 Severe			
Action Taken on Study Medication	<ol> <li>None</li> <li>Dose decreased</li> <li>Dose increased</li> <li>Drug stopped</li> </ol>			
Suspected Relationship To Study Medication	1 Related 2 Possibly related 3 Probably unrelated	0		
Corrective Therapy 4 Unrelated  If yes, record on Concomitant Medication form		☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
adverse exp definitions	sider this a serious erience by the on previous page? report experience	□ No	☐ Yes ☐ No	☐ Yes ☐ No
to SB within	, report experience by telephone 24 hours	AE Number	AE Number	AE Number
	's Signature			If patient died, complete Form D

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Record follow treatm	Record in standard medical terminology any adverse experience observed or elicited by the following direct question to patient: "Do you feel different in any way since starting the treatment or since the last visit?" Mark appropriate boxes (one experience per column).							
Experience								
For Smith	Kline Beecham							
Date Starte	ed	day month year	day month year	day month year				
Date Stopp	ed	day month year	day month year	day month year				
than	tion if less 24 hours	hours minutes	hours minutes	hours minutes				
Expe	rience continuing rience continuing nd of study							
Course	Continuous? - if no, number of episodes	☐ Yes ☐ No - ☐	☐ Yes ☐ No - ☐	☐ Yes ☐ No - ☐				
Intensity	<ul><li>1 Mild</li><li>2 Moderate</li><li>3 Severe</li></ul>							
Action Taken on Study Medication	1 None 2 Dose decreased 3 Dose increased 4 Drug stopped							
Suspected Relationship To Study Medication	3 Probably unrelated		0 0 0					
Corrective Therapy	If yes, record on Concomitant Medication form	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No				
adverse expe definitions (	sider this a serious erience by the on previous page?	□ No	☐ Yes ☐ No	☐ Yes ☐ No				
to SB within	, report experience by telephone 24 hours	AE Number	AE Number	AE Number				
Investigator	's Signature			If patient died, complete Form D				

Project	Protocol	Center	Patient Number	Page
29060	329	0.0		413

Recorfollow	d in <u>standard med</u> ving direct question nent or since the l	ical terminology any act to patient: "Do you fast visit?" Mark appro	lverse experience observe feel different in any wa opriate boxes (one exper	ed or elicited by the y since starting the ience per column).
Experience				
For Smith	Kline Beecham			
Date Start	ed	day month year	day month year	day month year
Date Stopp	ed .	day month year	day month year	day month year
than	tion if less 24 hours rience continuing	hours minutes	hours minutes	hours minutes
Expe	rience continuing id of study	ā		
Course	Continuous? - if no, number of episodes	☐ Yes ☐ No - ☐	☐ Yes ☐ No - ☐	☐ Yes ☐ No - ☐ ☐
Intensity	1 Mild 2 Moderate 3 Severe			
Action Taken on Study Medication	1 None 2 Dose decreased 3 Dose increased			
Suspected Relationship	4 Drug stopped 1 Related 2 Possibly related 3 Probably			
To Study Medication	unrelated 4 Unrelated			
Corrective Therapy	If yes, record on Concomitant Medication form	☐ Yes	☐ Yes ☐ No	☐ Yes ☐ No
adverse exp definitions	sider this a serious erience by the on previous page? , report experience	☐ Yes ☐ No	☐ Yes	☐ Yes ☐ No
to SB within	by telephone 24 hours	AE Number	AE Number	AE Number
Investigator	's Signature			complete Form D

Project	Protocol	Center	Patient Number	Page
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Recorfollow treatm	d in standard medi ring direct question nent or since the l	ical terminology any ad to patient: "Do you f ast visit?" Mark appro	lverse experience observe eel different in any wa priate boxes (one exper	ed or elicited by the y since starting the ience per column).
Experience				
For Smith	Kline Beecham			
Date Start	ed	day month year	day month year	day month year
Date Stopp		day month year	day month year	day month year
than	tion if less 24 hours rience continuing	hours minutes	hours minutes	hours minutes
Expe at er	rience continuing id of study			
Course	Continuous? - if no, number of episodes	☐ Yes ☐ No - ☐	☐ Yes ☐ No -	☐ Yes ☐ No - ☐
Intensity	<ul><li>1 Mild</li><li>2 Moderate</li><li>3 Severe</li></ul>			
Action Taken on Study Medication	1 None 2 Dose decreased 3 Dose increased 4 Drug stopped			
Suspected Relationship To Study Medication	3 Probably unrelated			
Corrective Therapy	If yes, record on Concomitant Medication form	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
adverse exp	sider this a serious erience by the on previous page?	□ No	☐ Yes ☐ No	☐ Yes ☐ No
to SB within	, report experience by telephone 24 hours	AE Number	AE Number	AE Number
Investigator	's Signature			If patient died,

Project	Protocol	Center	Patient Number	Page
29060	329	0.0		415

Recor follow treats	d in standard med ring direct question nent or since the l	ical terminology any a to patient: "Do you i ast visit?" Mark appro	dverse experience observe feel different in any wa opriate boxes (one exper	ed or elicited by the sy since starting the ience per column).
Experience				
For Smith	Kline Beecham			
Date Start	ed	day month year	day month year	day month year
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Expe	rience continuing id of study		Ö	
Course	Continuous? - if no, number of episodes	☐ Yes ☐ No - ☐	☐ Yes ☐ No - ☐	☐ Yes ☐ No - ☐
Intensity	<ul><li>1 Mild</li><li>2 Moderate</li><li>3 Severe</li></ul>			
Action Taken on Study Medication	1 None 2 Dose decreased 3 Dose increased 4 Drug stopped			
Suspected Relationship To Study Medication	1 Related			
Corrective Therapy	4 Unrelated  If yes, record on Concomitant Medication form	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
adverse exp	sider this a serious erience by the on previous page?	□ No	☐ Yes ☐ No	☐ Yes ☐ No
to SB within	, report experience by telephone . 24 hours	AE Number	AE Number	AE Number
Investigator	's Signature			If patient died,

Project	Protocol	Center	Patient Number	Page
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Record follow treatm	l in standard med ing direct question nent or since the l	ical terminology any ad to patient: "Do you f ast visit?" Mark appro	verse experience observe eel different in any wa priate boxes (one experi	ed or elicited by the y since starting the ence per column).
Experience				
For Smith	Kline Beecham			
Date Starte	ed	day month year	day month year	day month year
Date Stopp	ed	day month year	day month year	day month year
than	tion if less 24 hours	hours minutes	hours minutes	hours minutes
Expe	rience continuing rience continuing id of study			
Course	Continuous? - if no, number of episodes	☐ Yes ☐ No - ☐	☐ Yes ☐ No -	☐ Yes ☐ No - ☐
Intensity	1 Mild 2 Moderate 3 Severe			
Action Taken on Study Medication	<ol> <li>None</li> <li>Dose decreased</li> <li>Dose increased</li> <li>Drug stopped</li> </ol>			
Suspected Relationship To Study Medication	<ol> <li>Related</li> <li>Possibly related</li> <li>Probably unrelated</li> </ol>			
Corrective Therapy	4 Unrelated  If yes, record on Concomitant Medication form	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
adverse exp	sider this a serious erience by the on previous page?	□ No	☐ Yes ☐ No	☐ Yes ☐ No
to SB within	report experience by telephone 24 hours	AE Number	AE Number	AE Number
Investigator	's Signature			If patient died, complete Form D

Project	Protocol	Center	Patient Number	Page
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Record follow treatm	l in standard medicing direct question tent or since the la	cal terminology any ad to patient: "Do you f ast visit?" Mark appro	verse experience observe eel different in any wa priate boxes (one experi	d or elicited by the y since starting the ence per column).
Experience				
For Smithl	Kline Beecham			
Date Starte	ed	day month year	day month year	day month year
Date Stopp	ed	day month year	day month year	day month year
than	tion if less 24 hours rience continuing	hours minutes	hours minutes	hours minutes
Expe	rience continuing nd of study	<u> </u>		
Course	Continuous? - if no, number of episodes	☐ Yes ☐ No - ☐	☐ Yes ☐ No - ☐	☐ Yes ☐ No - ☐
Intensity	1 Mild 2 Moderate 3 Severe			
Action Taken on Study Medication	1 None 2 Dose decreased 3 Dose increased 4 Drug stopped			
Suspected Relationship To Study Medication	1 Related			
Corrective Therapy	4 Unrelated  If yes, record on Concomitant Medication form	☐ Yes ☐ No	☐ Yes ☐ No	☐ Yes ☐ No
adverse exp definitions	sider this a serious erience by the on previous page? report experience	☐ No	☐ Yes ☐ No	☐ Yes ☐ No
to SB within	, report experience by telephone 1 24 hours	AE Number	AE Number	AE Number
Investigator	r's Signature			complete Form D

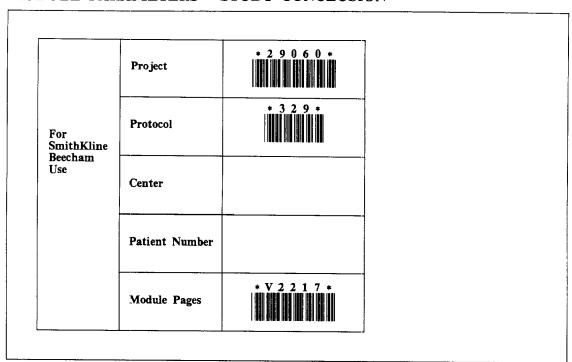
[	Project	Protocol	Center	Patient Number	Page	
	29060	329	0,0		418	

#### STUDY CONCLUSION

☐ Yes ☐ No	
•	If 'No', mark the ONE most appropriate category
	Adverse experience (complete Adverse Experience section)  Lack of efficacy  Deviation from protocol (including non-compliance)  Lost to follow-up  Termination by sponsor  Other
Comments  Date of La	
	ast Visit  day month year
Date of La	ast Visit  day month year  ast Dose

Project	Protocol	Center	Patient Number	Visit	
29060	329	0 0		Continuation Phase	

#### MODULE PARAMETERS - STUDY CONCLUSION



	Project	Protocol	Center		7
	29060	329	,00	Page	ļ
i		L		D	

### PATIENT LOG - CONTINUATION PHASE

Directions:	Ent inte excl	Enter ALL patients who have been considered for the study and who have been interviewed. For patients not entering the Continuation Phase, note the reason exclusion in the designated column.						
Patient Initials	Ini (day	tial Inter month	view year)	Reason for Exclusion				
			1 ,					
		<del></del>	<del></del>					
			4					
			ı . T					
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#### PATIENT ASSIGNMENT SHEET - CONTINUATION PHASE

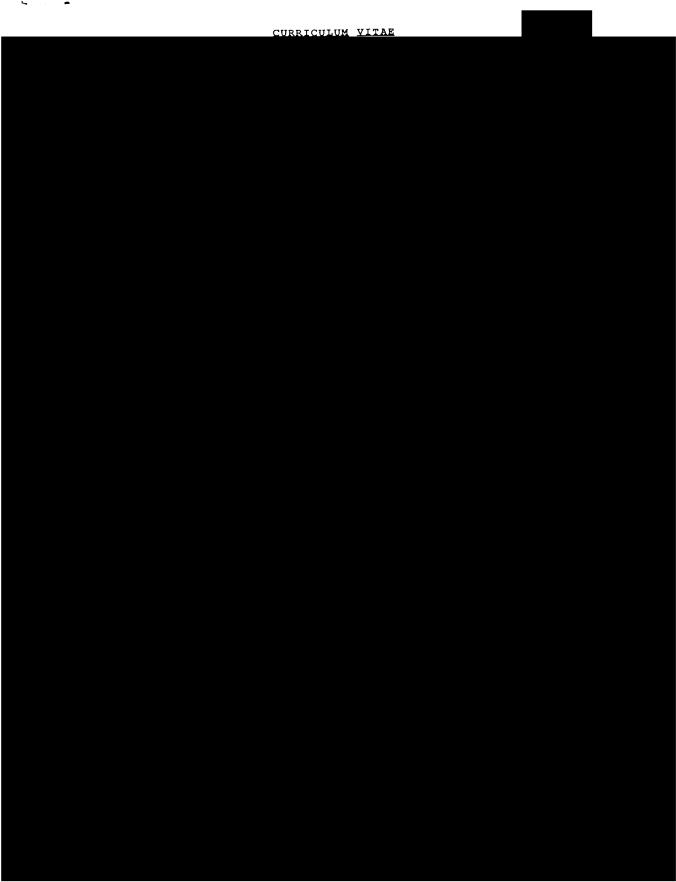
Investigator						For 3	Date _	day n	ıonth yea
D	irections:	Do not enter the patient on the patient assignment sheet until he/she starts continuation phase medication.							
		Final Dose Stat	tus: $C = Co$ W = W	mpleted al	ll treati prior to	nent visi complet	ts ing all	treatme	nt visits
	Patient Initials	Patient Number	Date of Find of Continuate (day mont	ion Phase	Date (day	of Last month	Dose year)	Status (C/W)	
1				1 1 1	1				
2					1		<u></u>		
3	······································								
4				1 1	1				
5				1 1 1	1 1				
6									
7									
8				<u>. 1</u>	, 1		1		
9			1 1 1 1 1 1 1 1 1	<u>.                                    </u>			11		
10						1 1			
11				1   1			1 ,		
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13					, 1	. I			
14			1 1 1	1 1 1	, 1	1 1	1 1		
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### **Investigator CVs**

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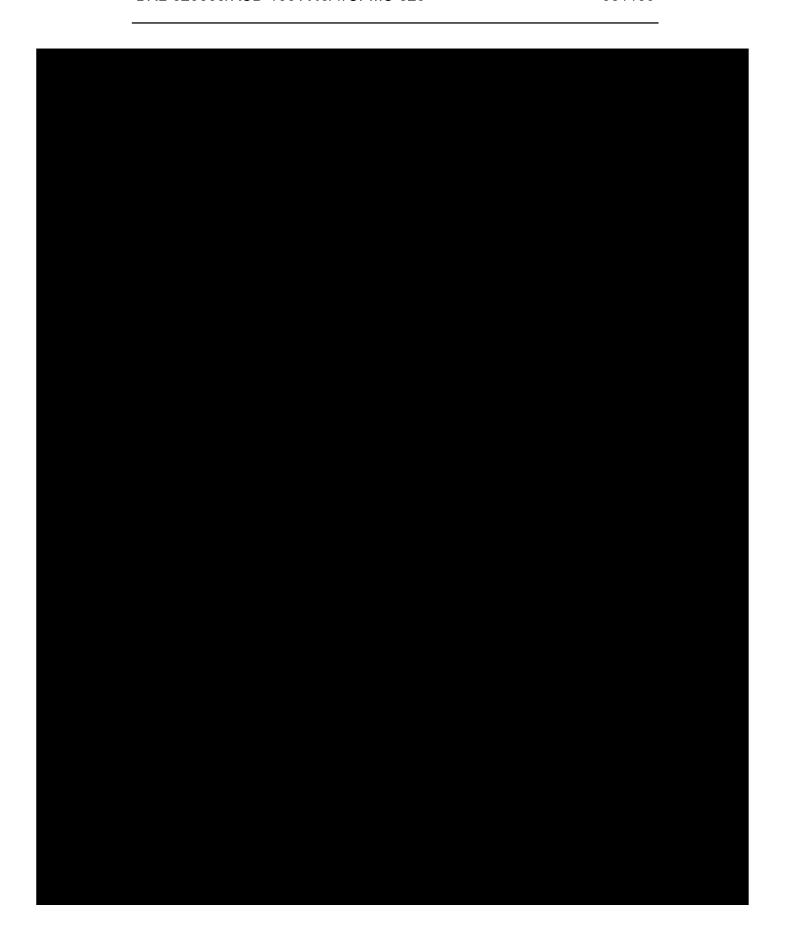


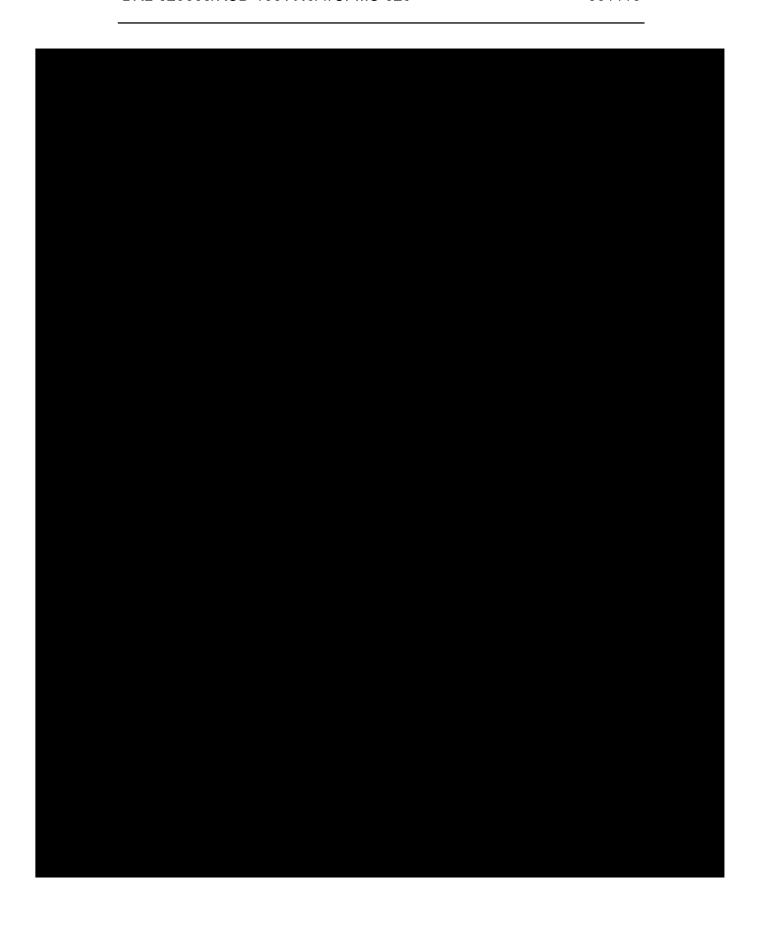








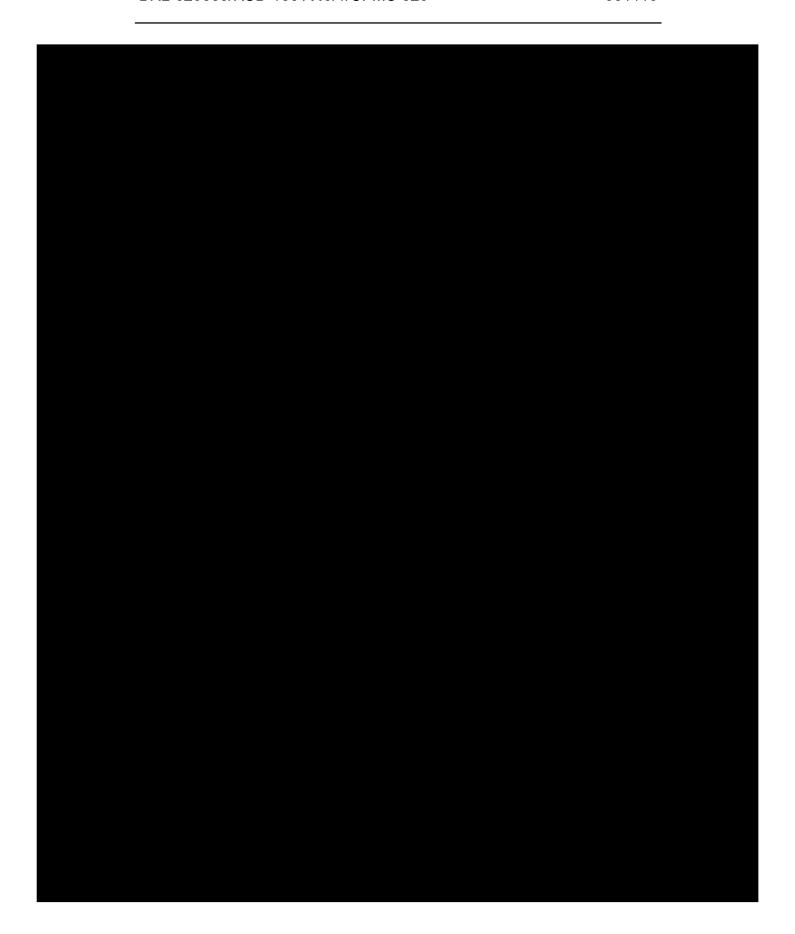












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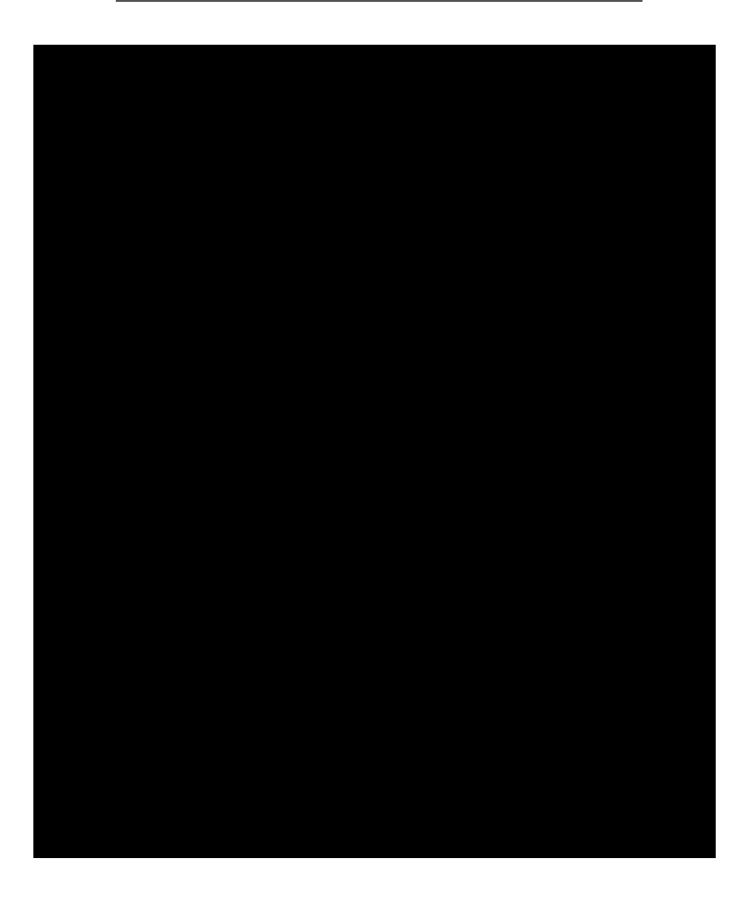










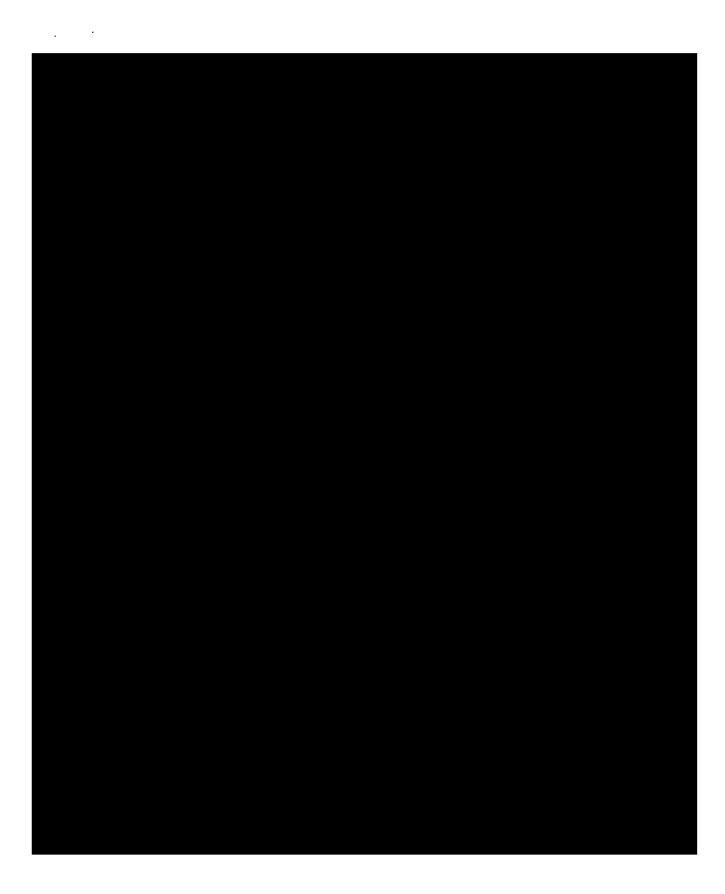






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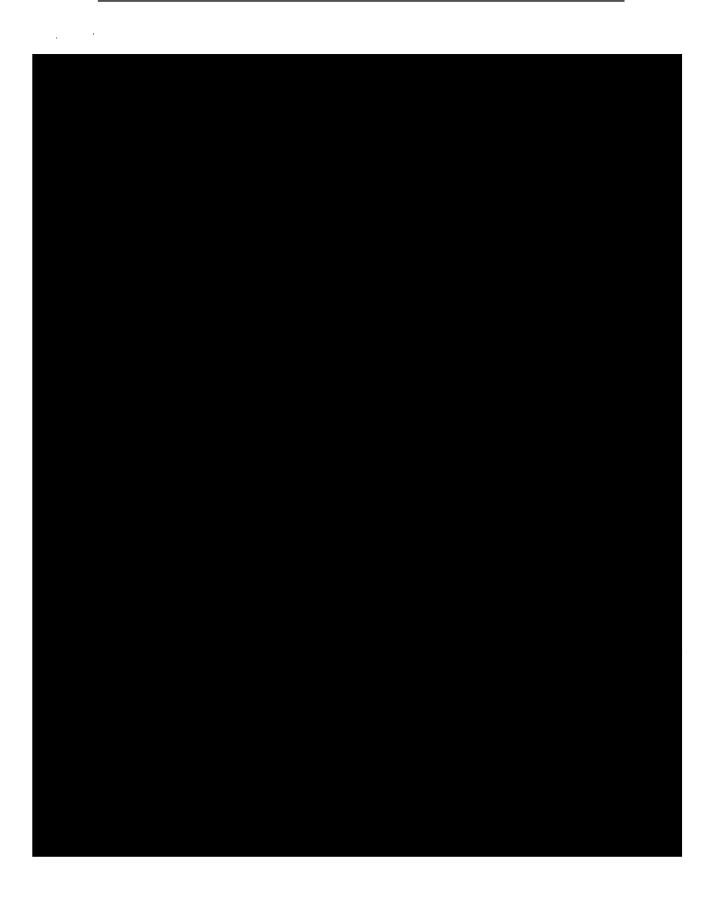










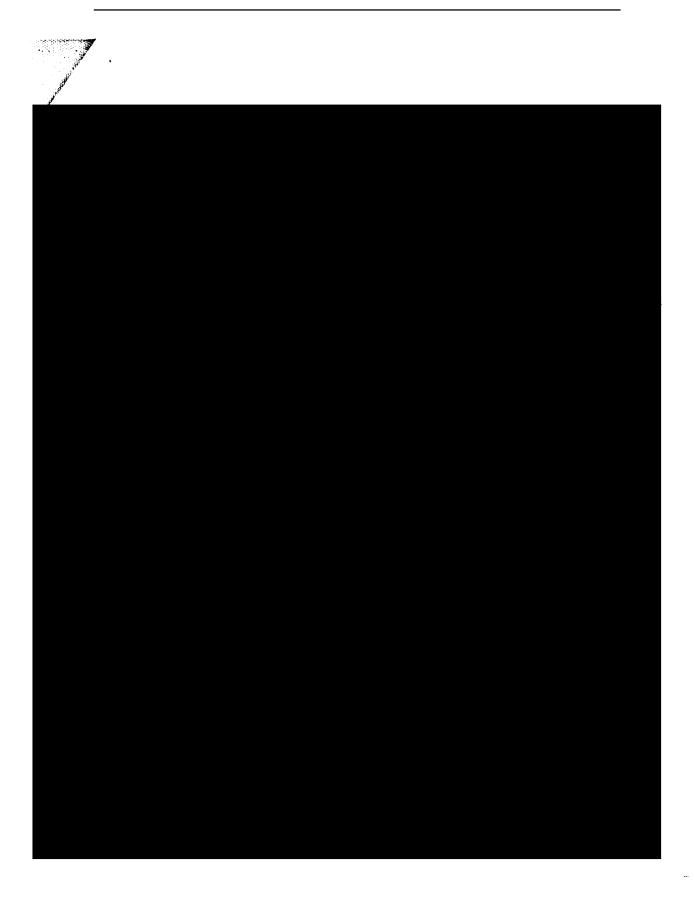


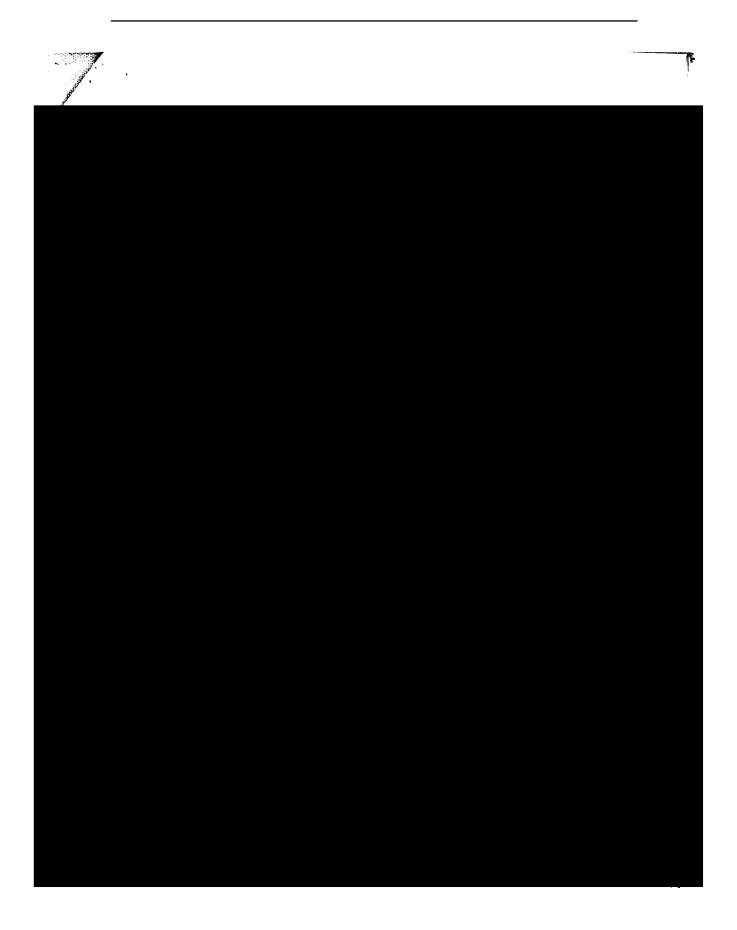


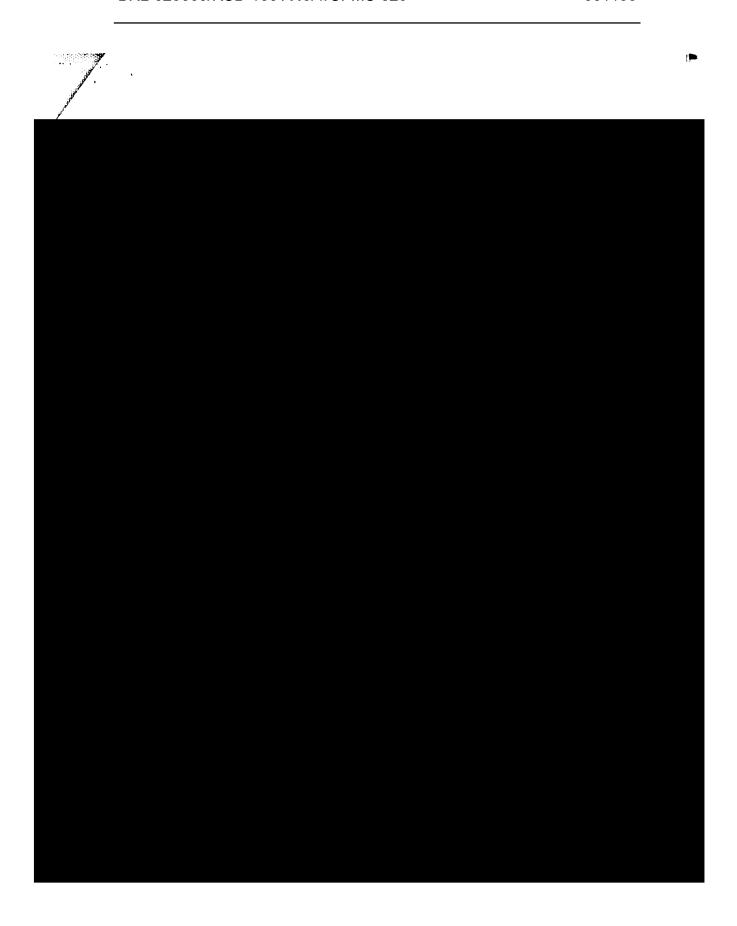


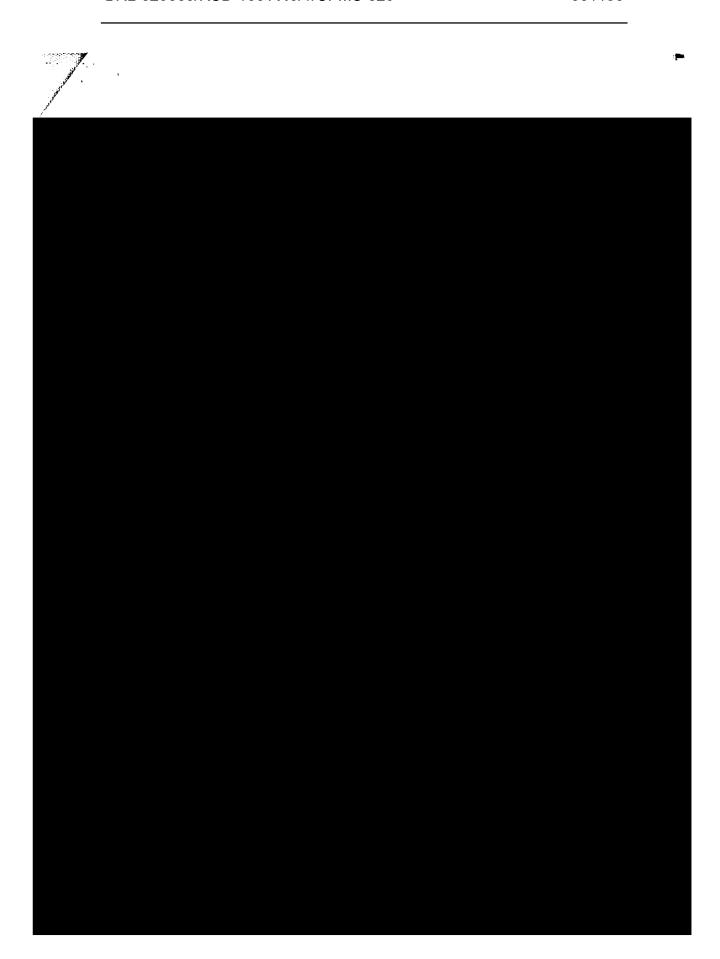


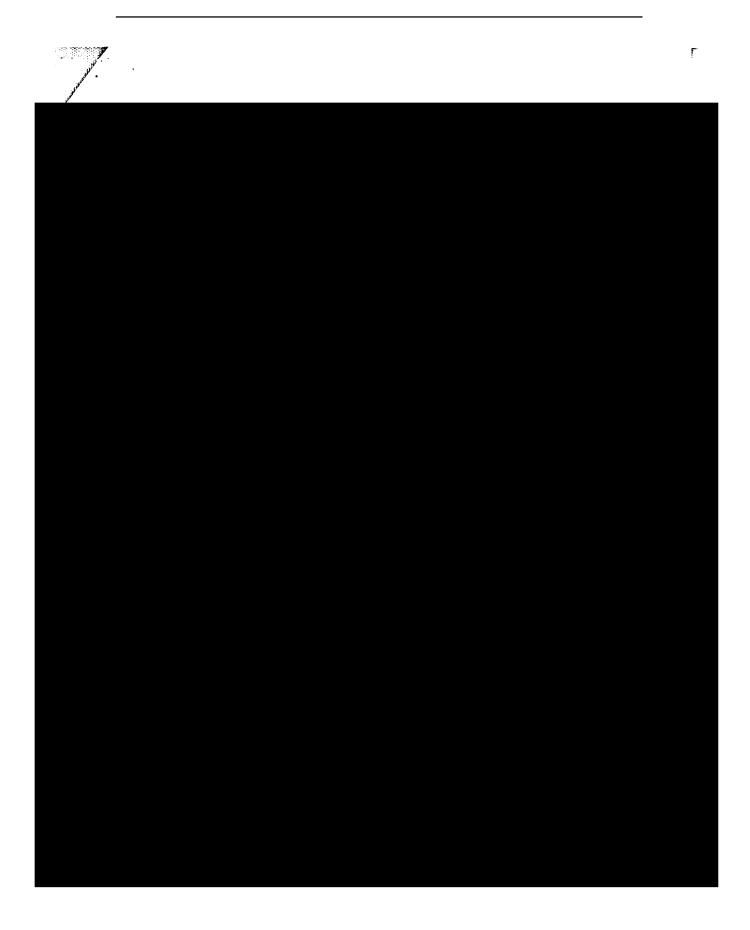
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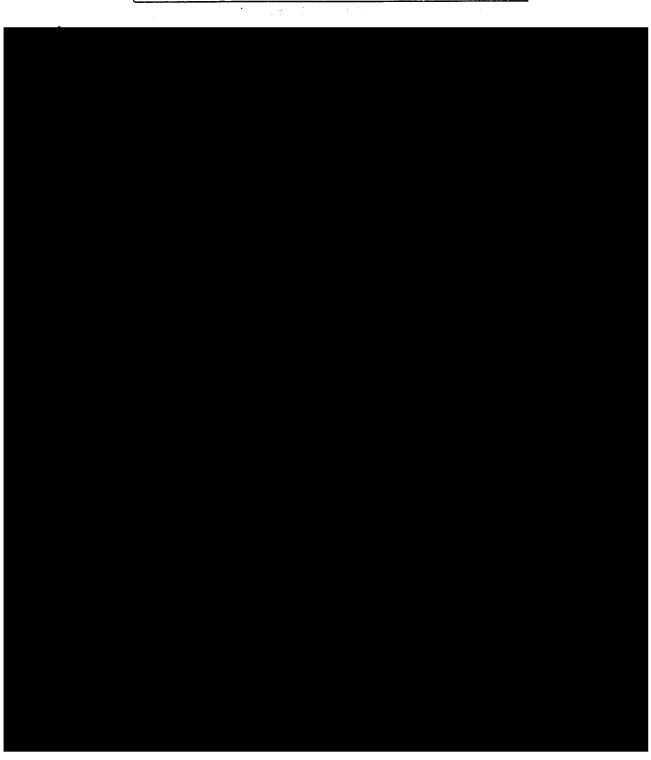


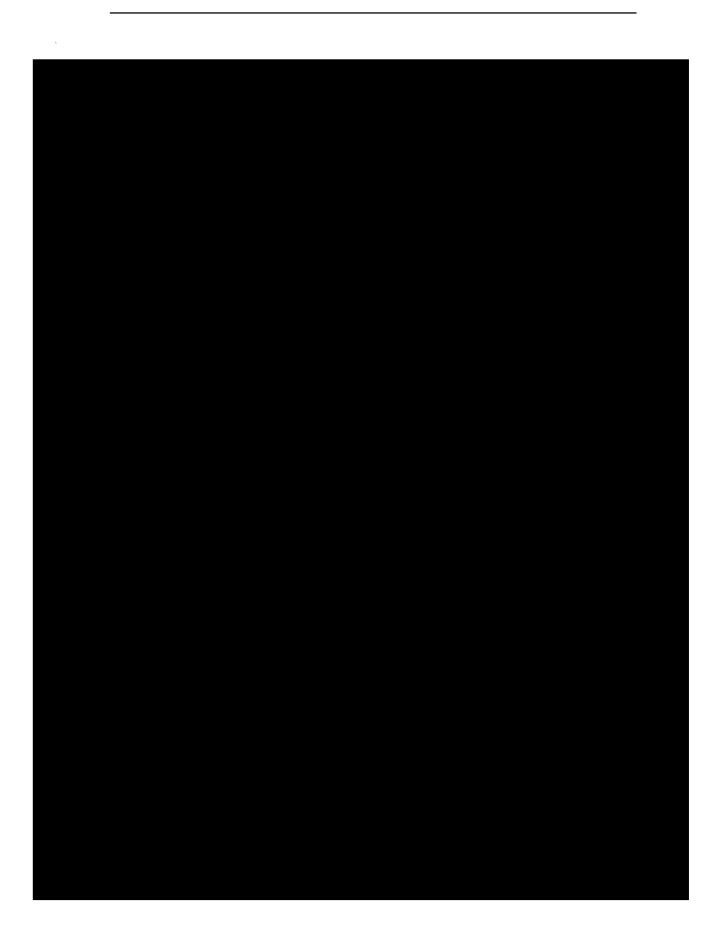






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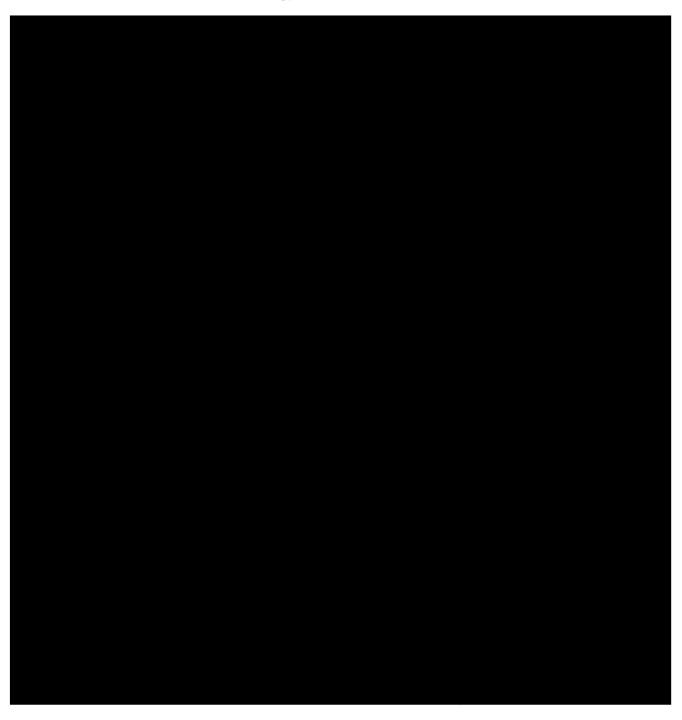




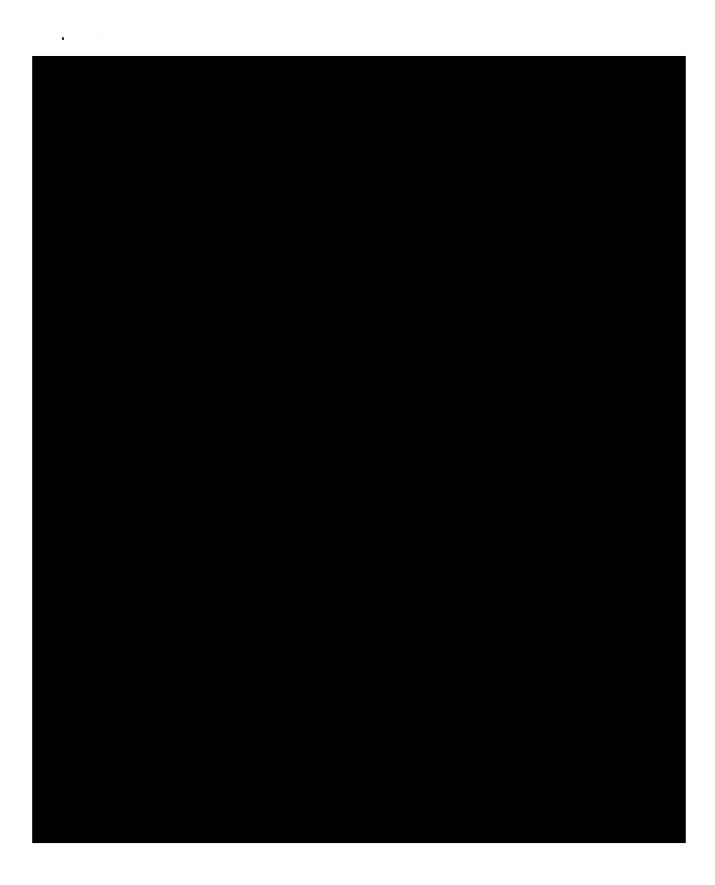




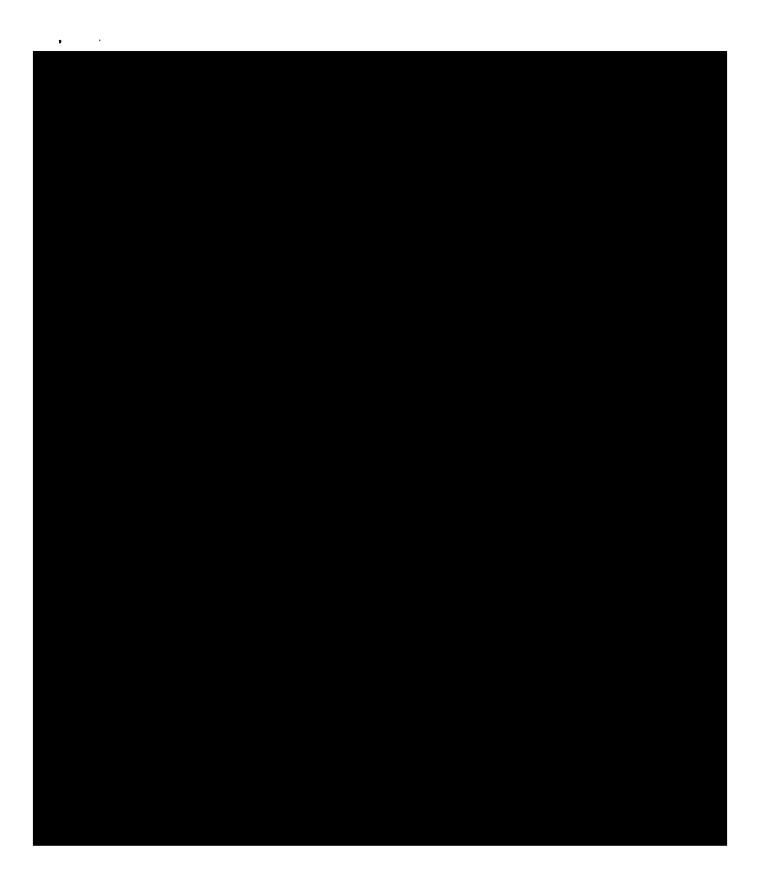
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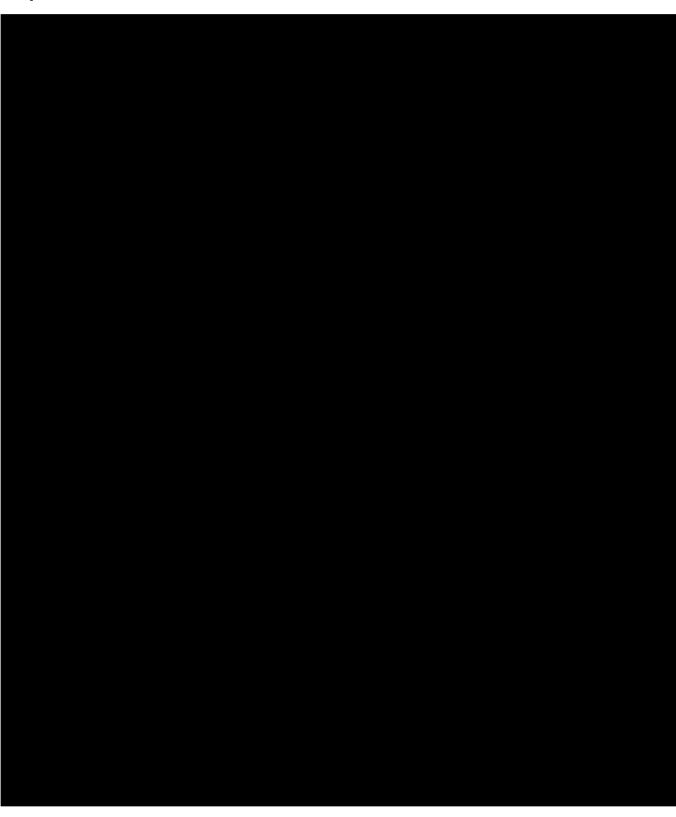


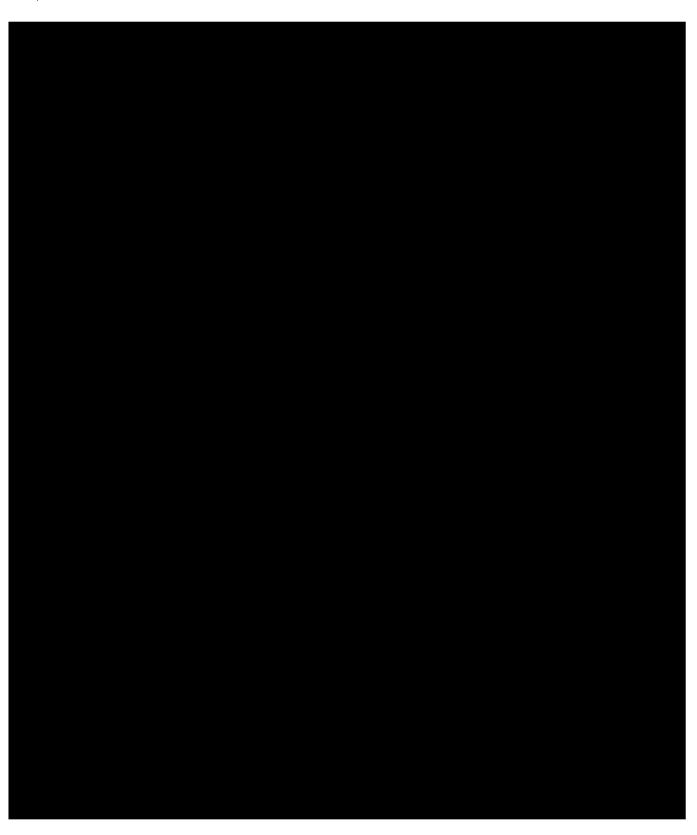


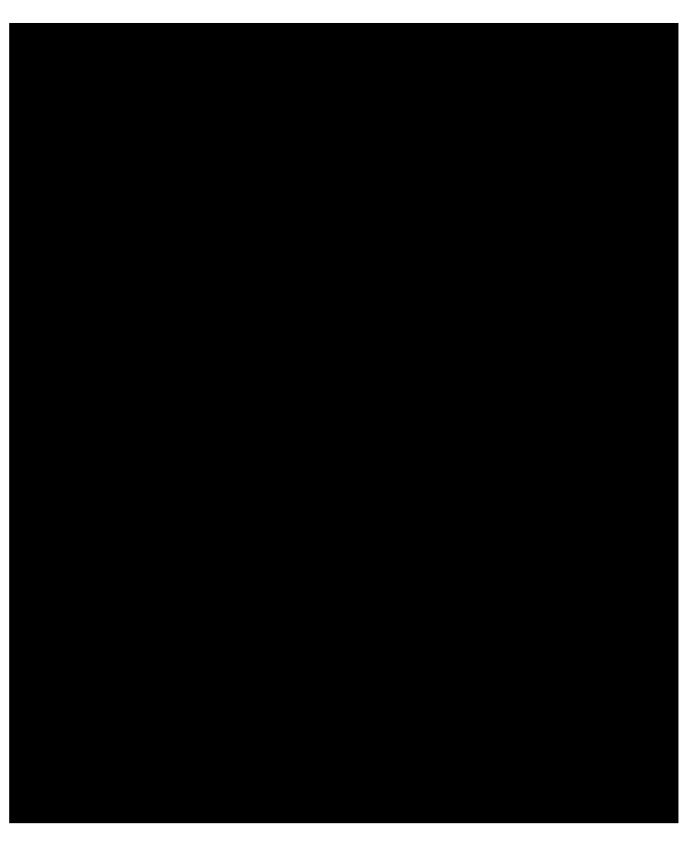
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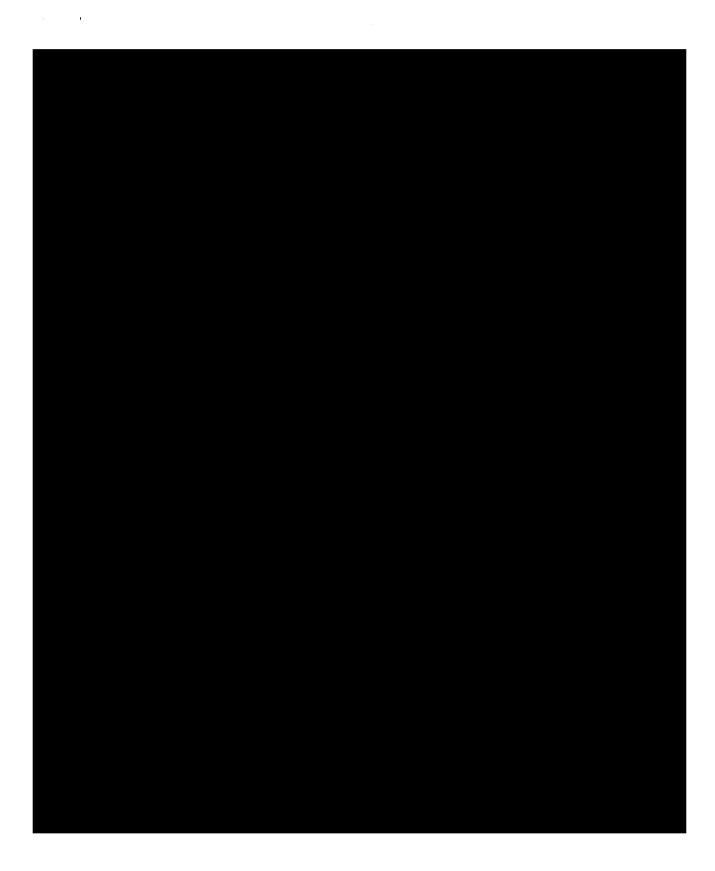


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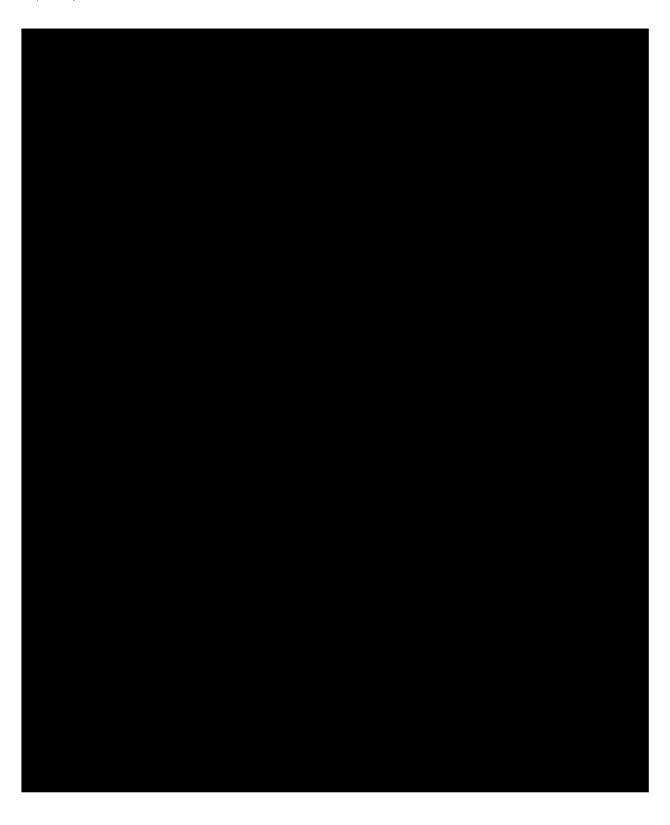


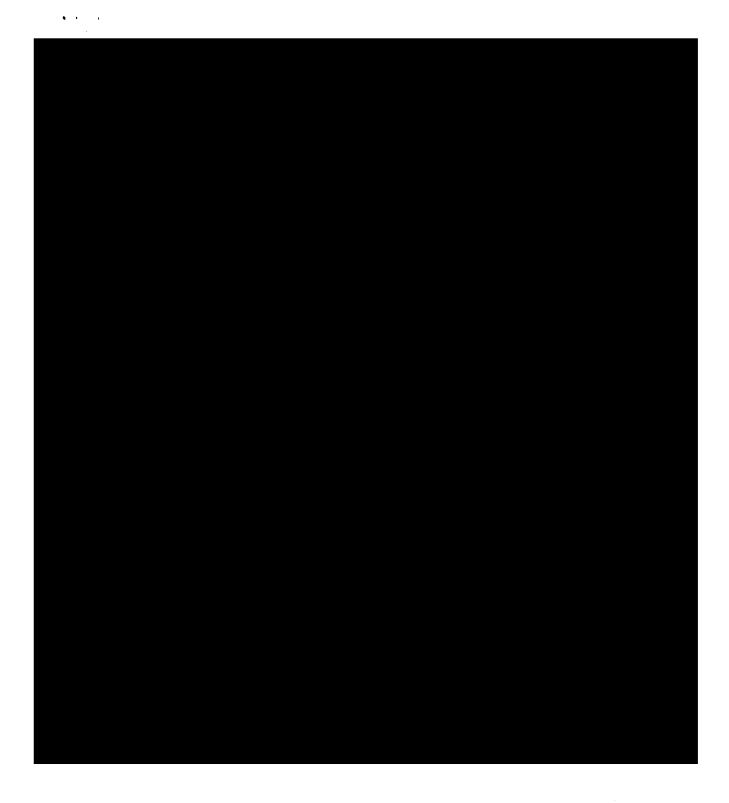


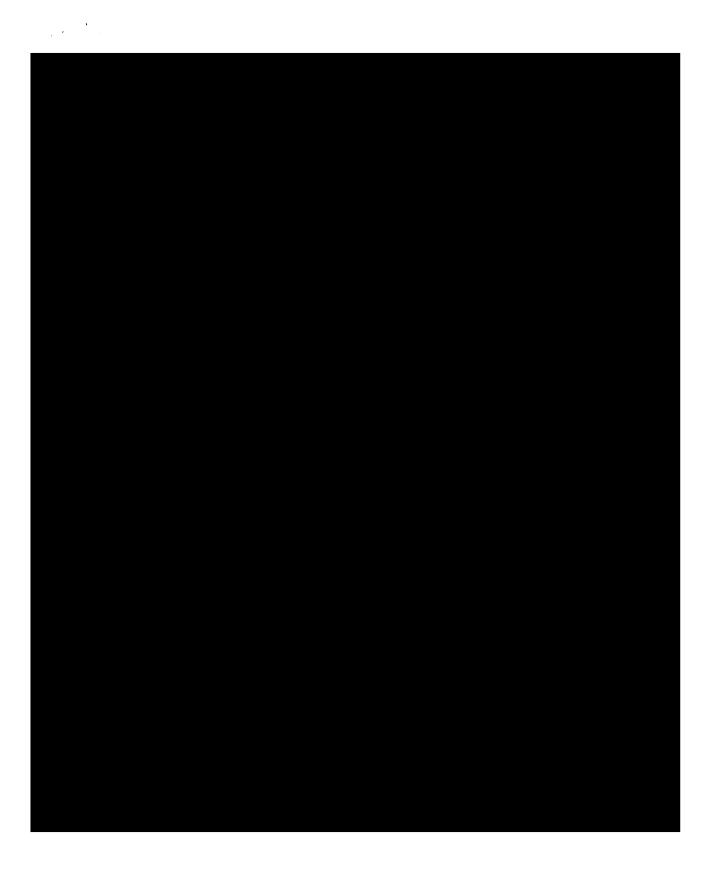




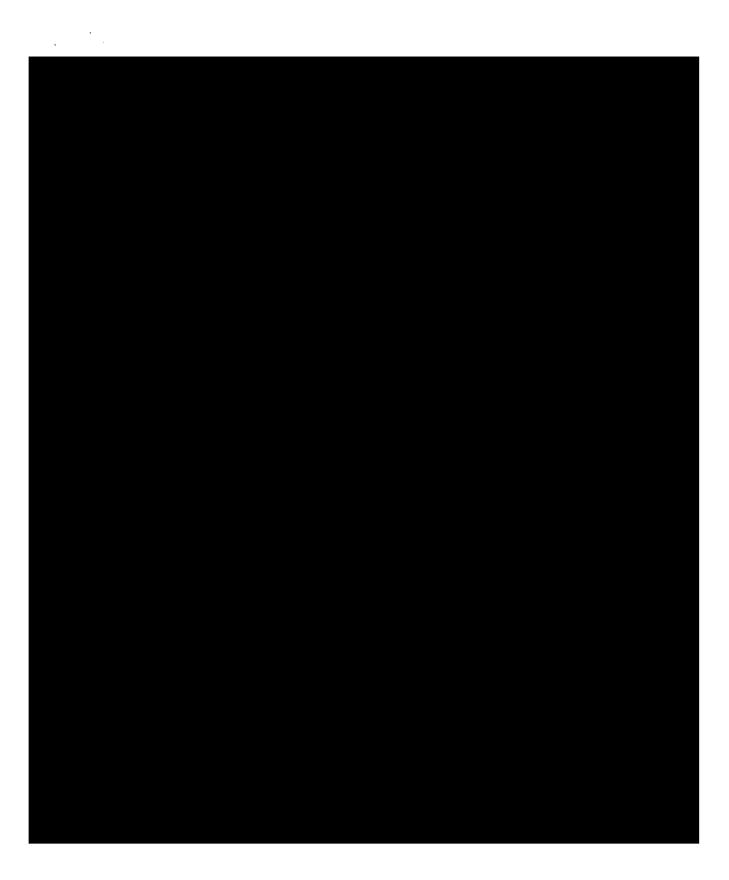
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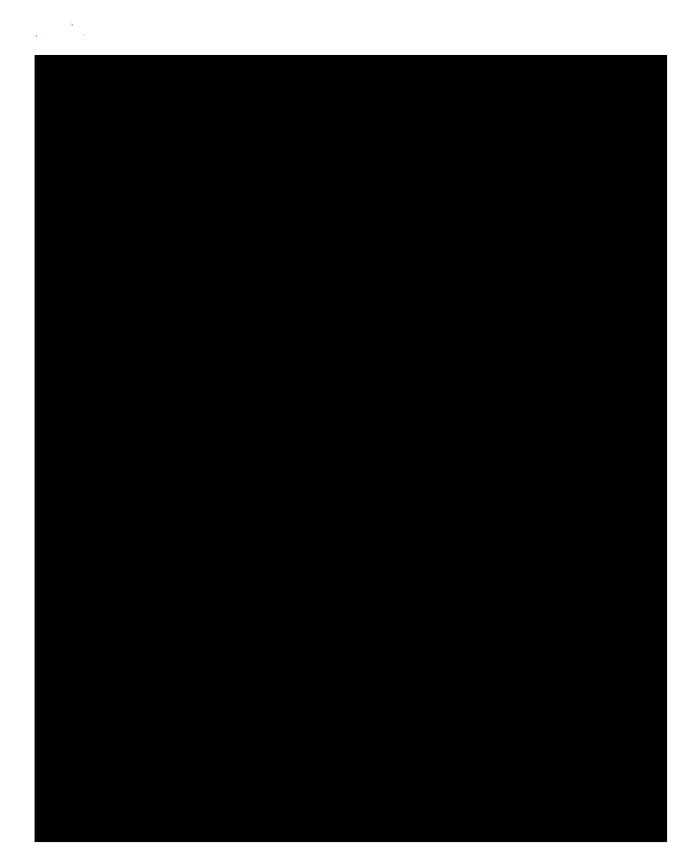


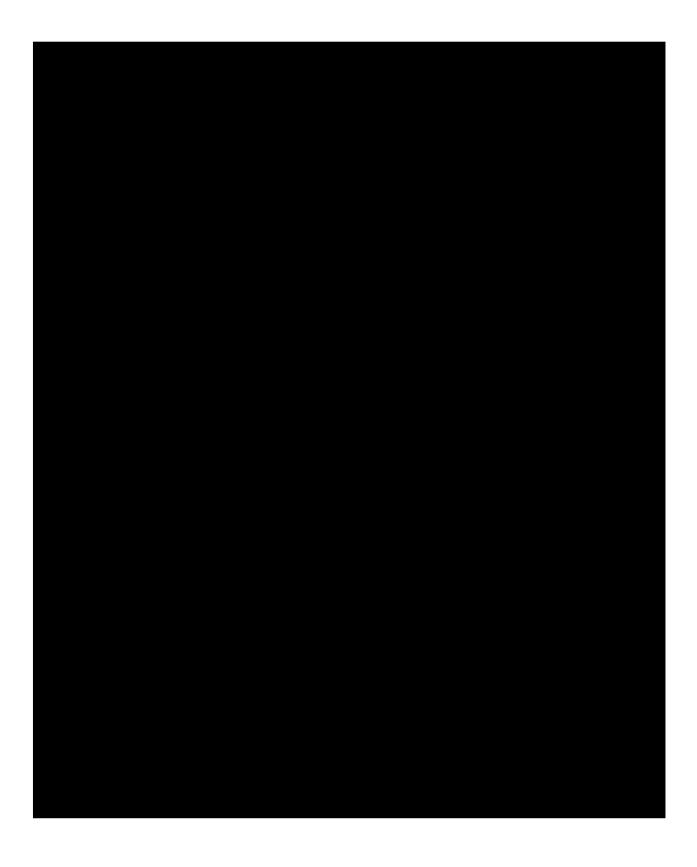


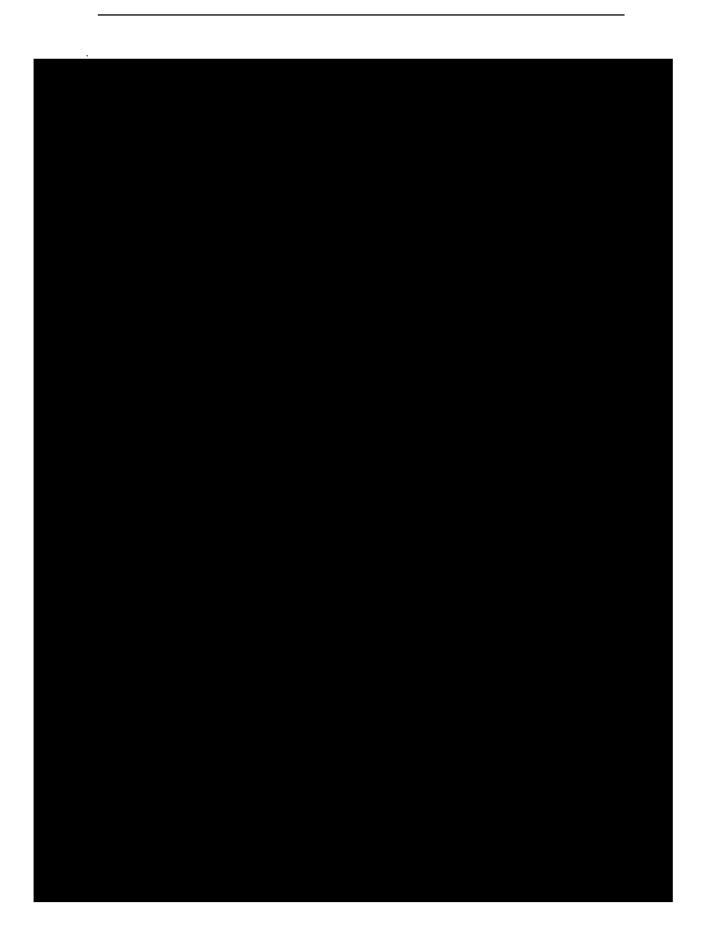






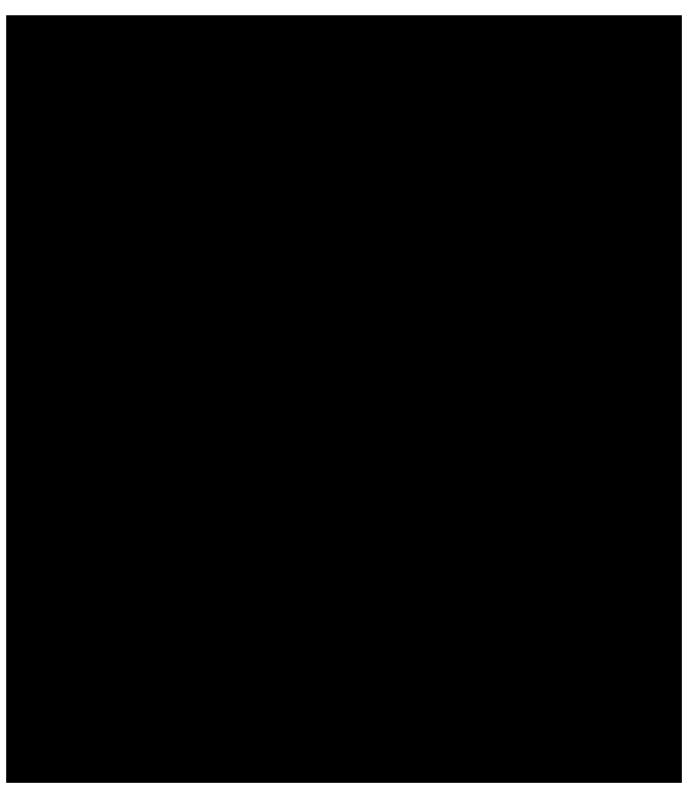








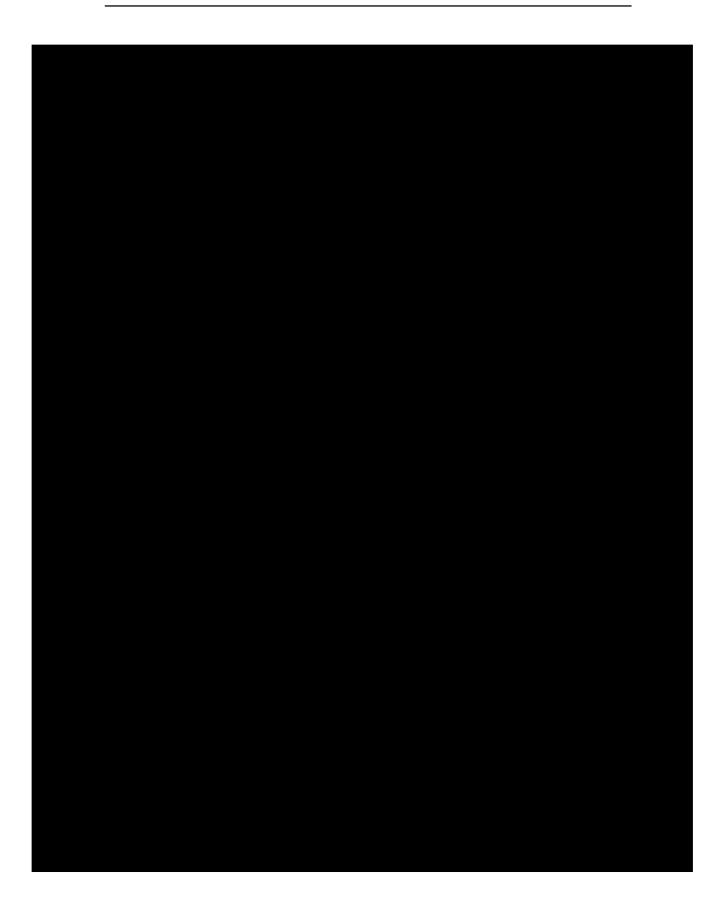




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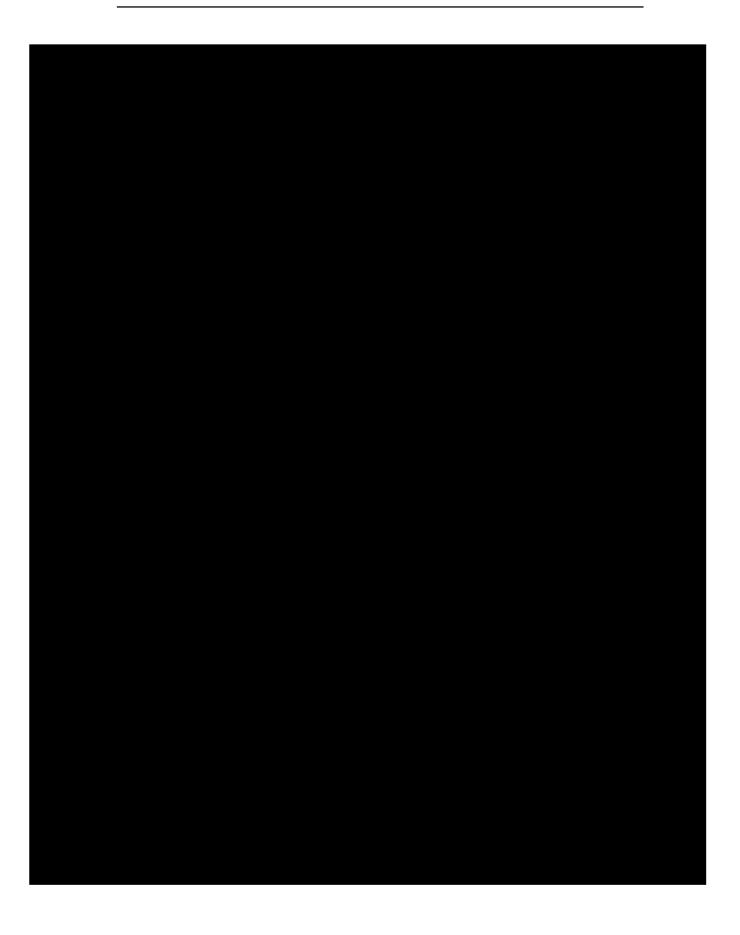


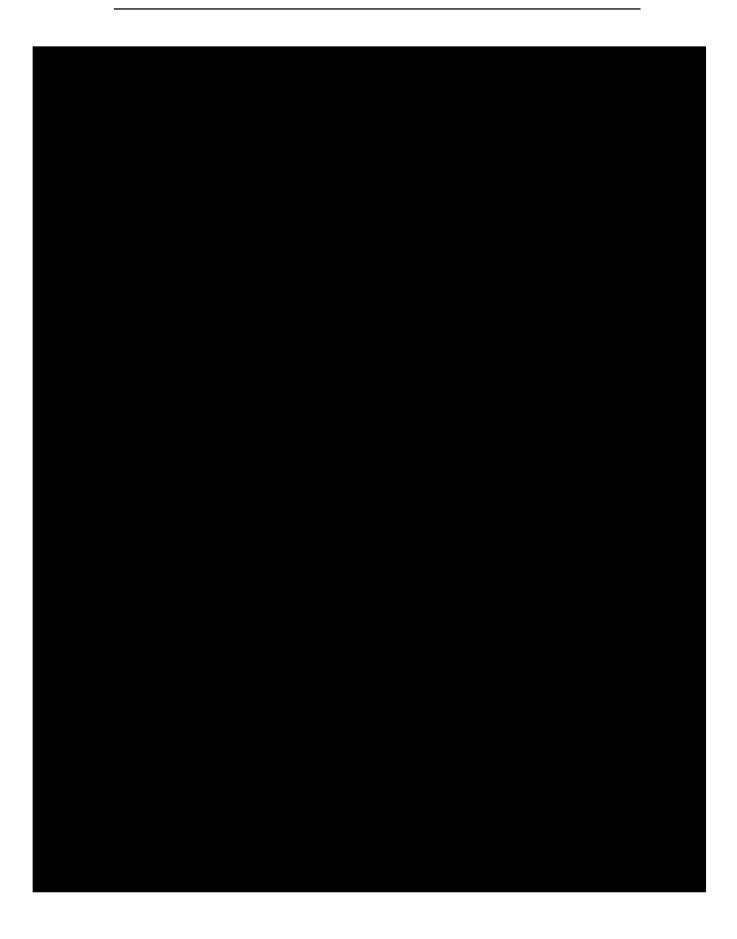










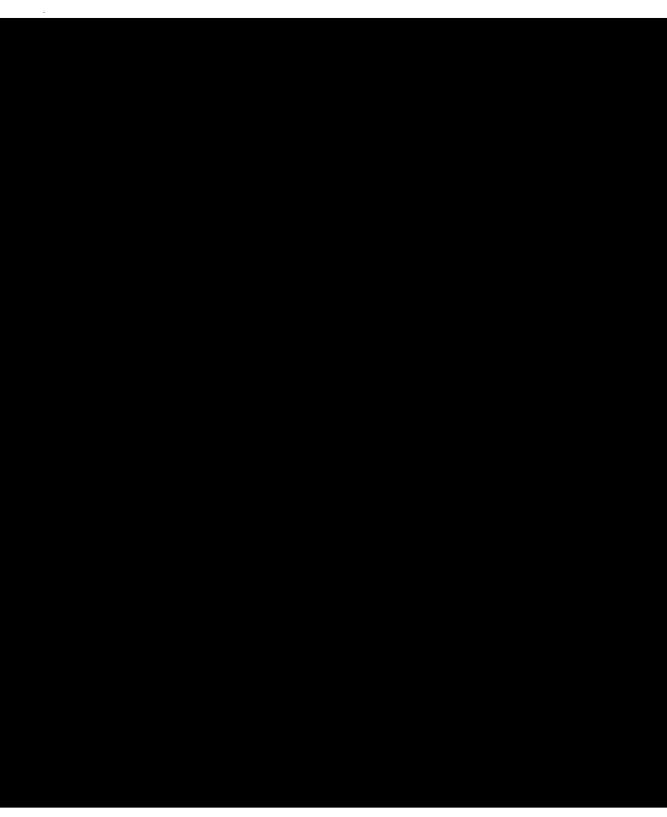


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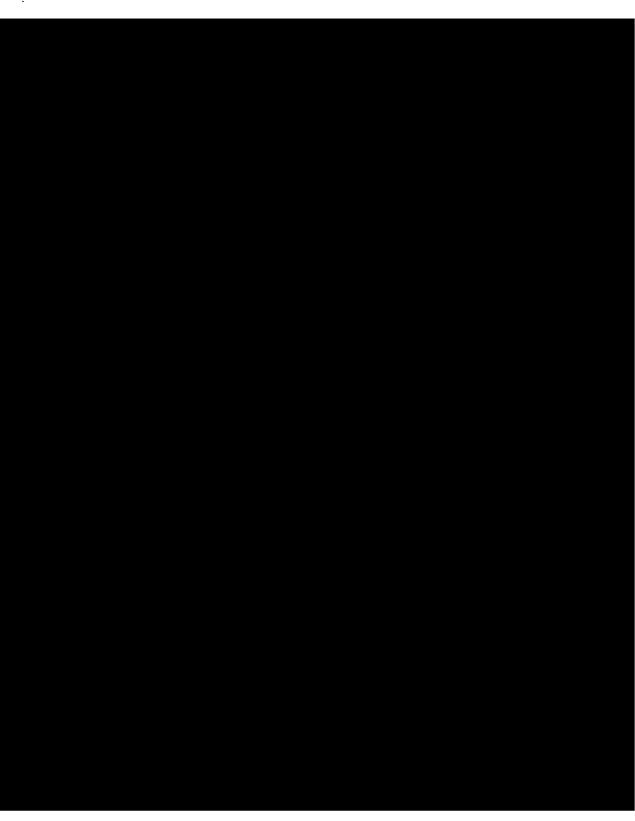
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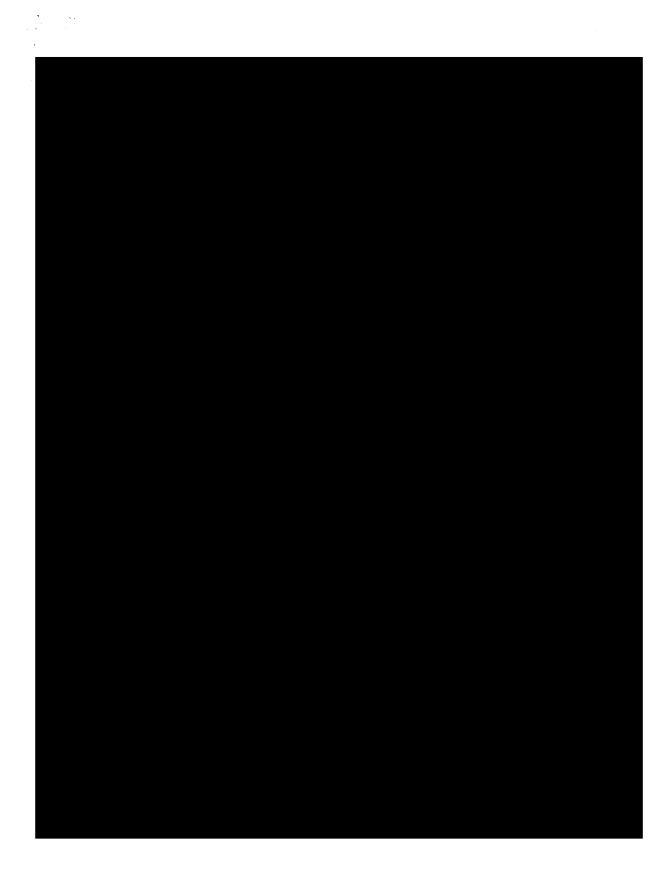


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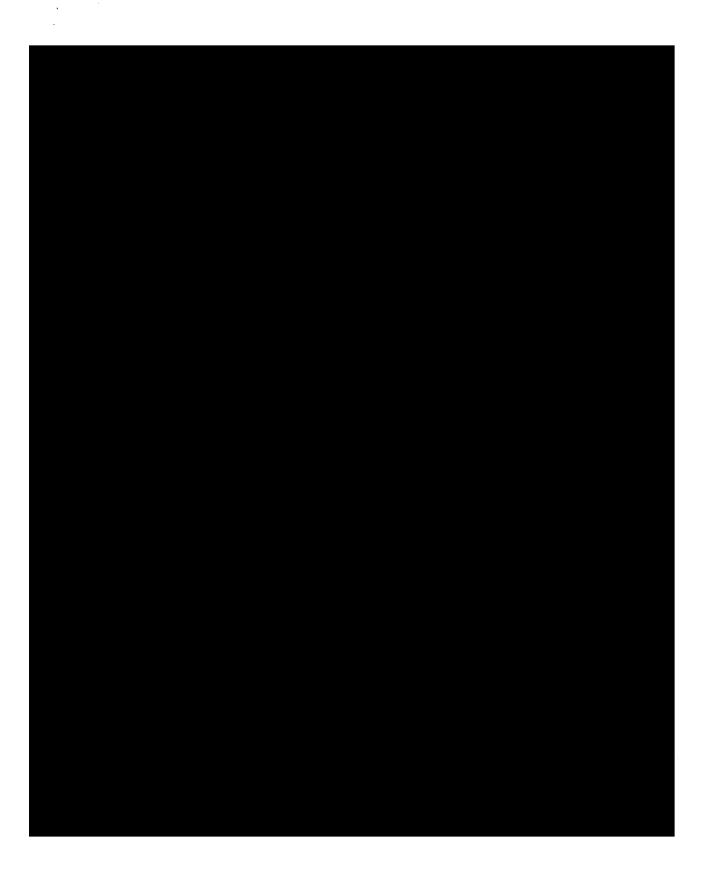
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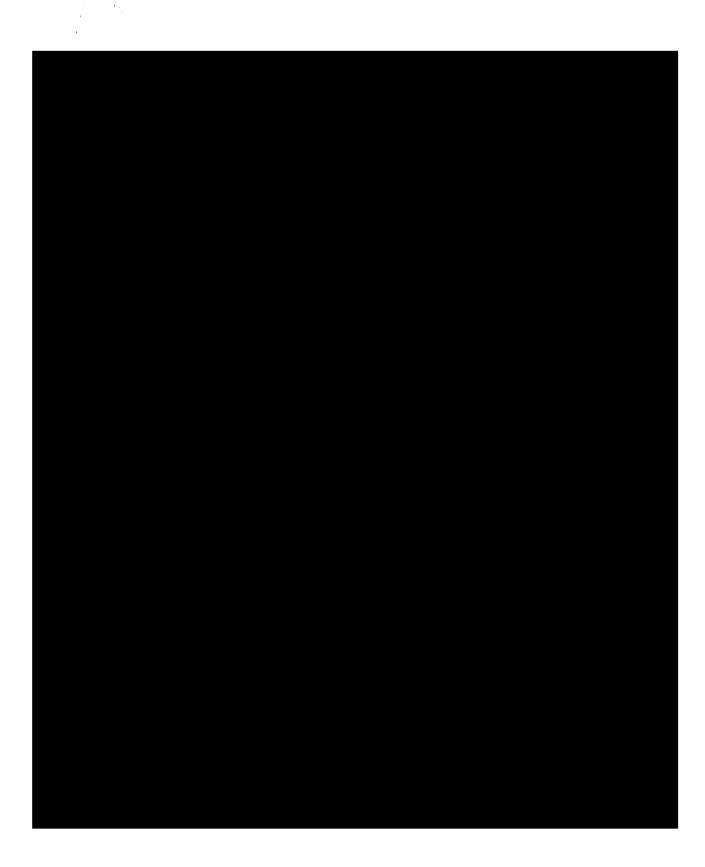
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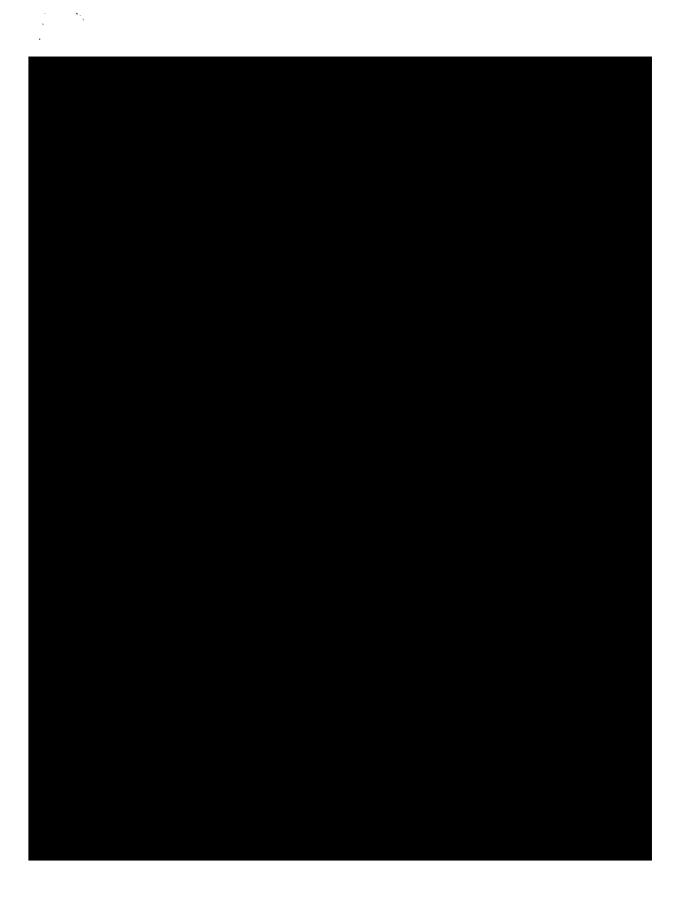






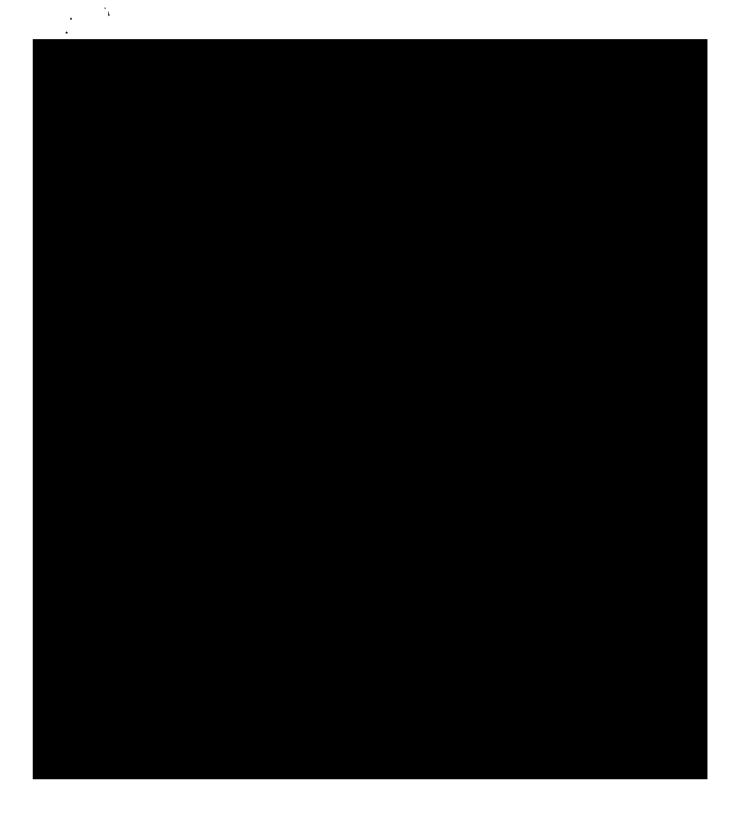












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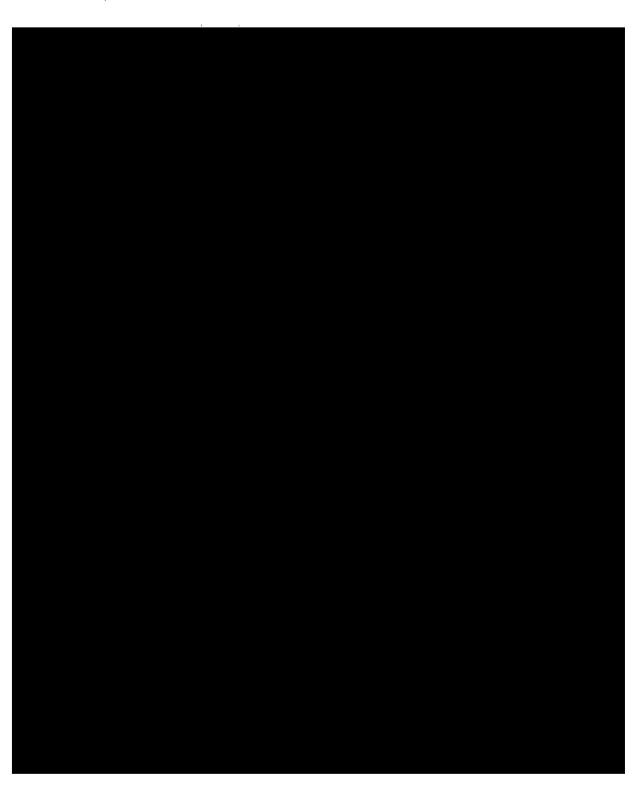


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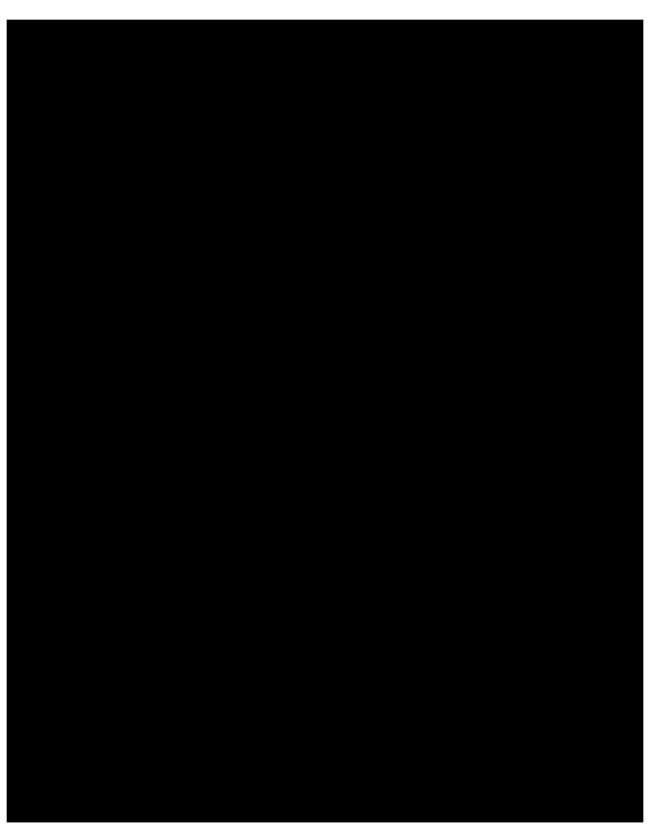
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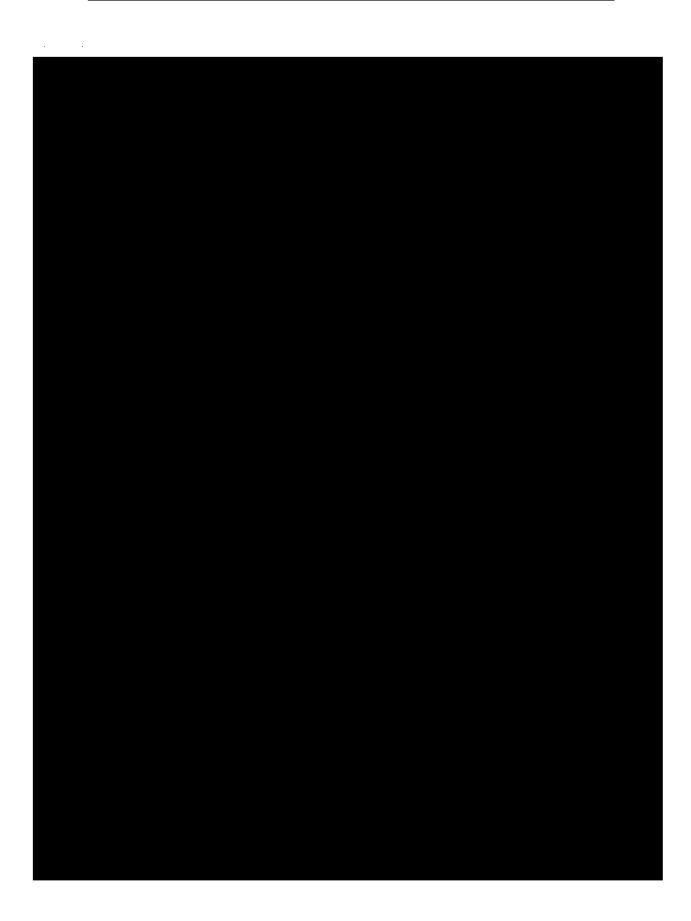
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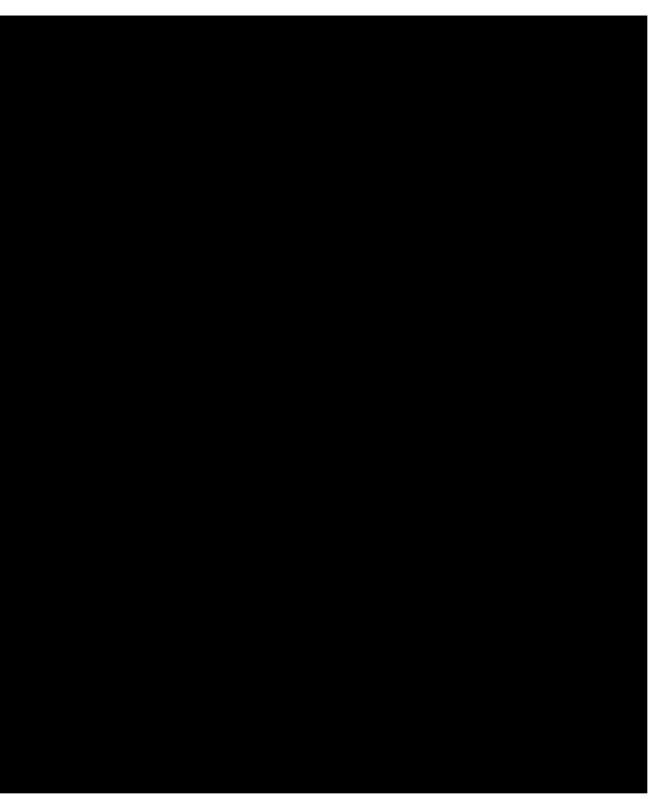








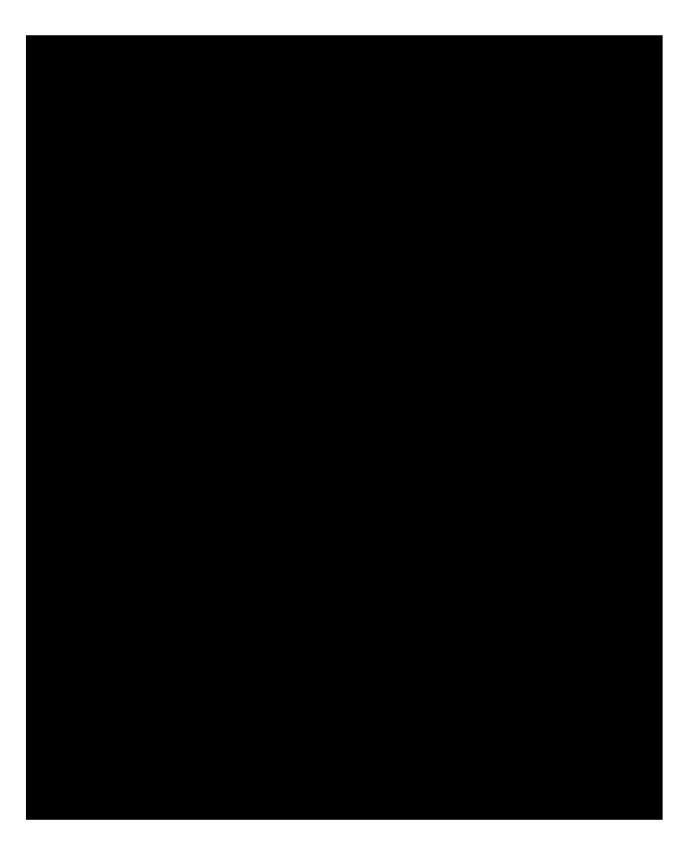




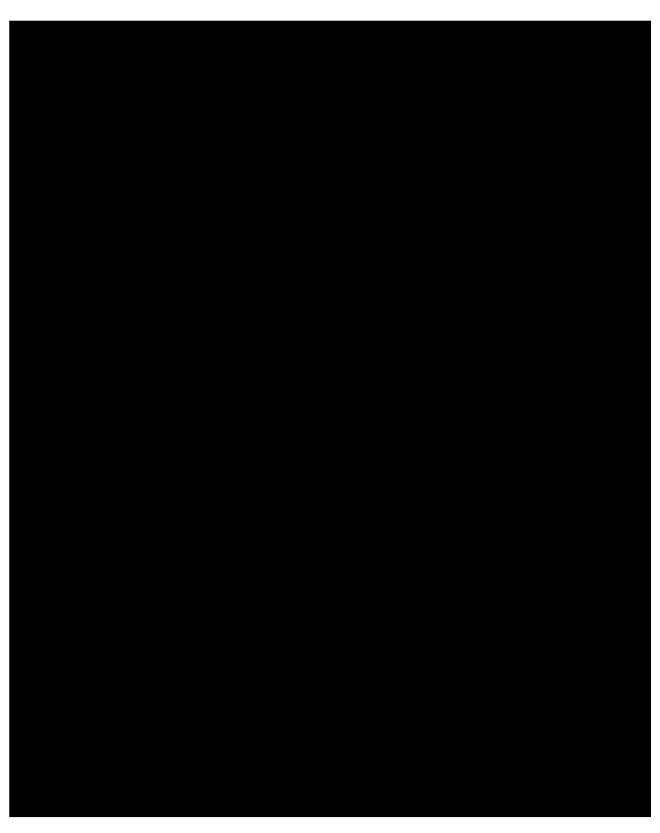


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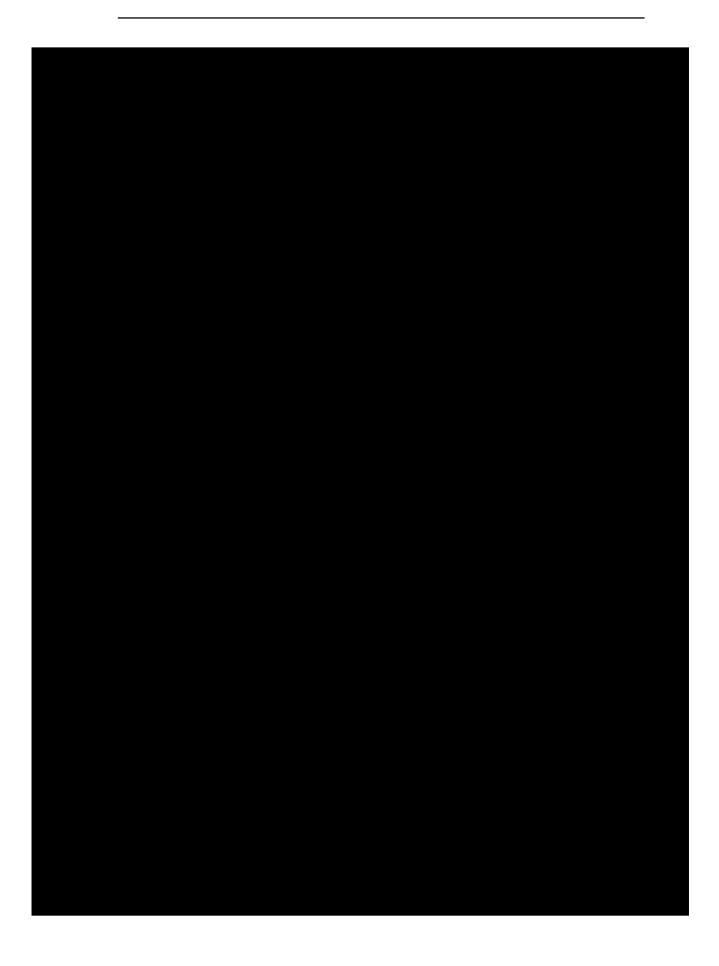


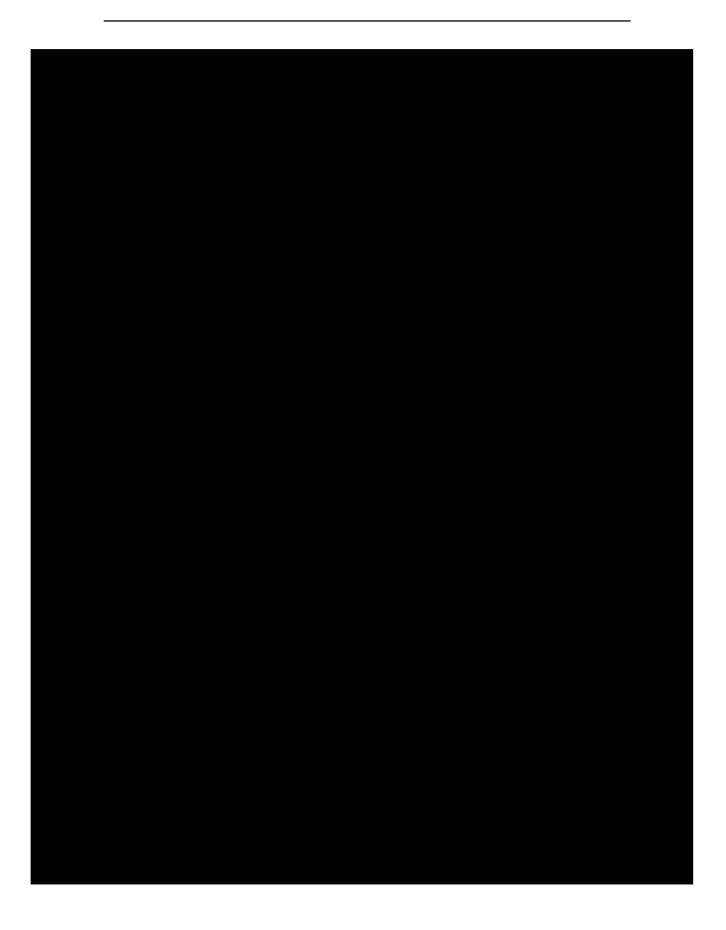




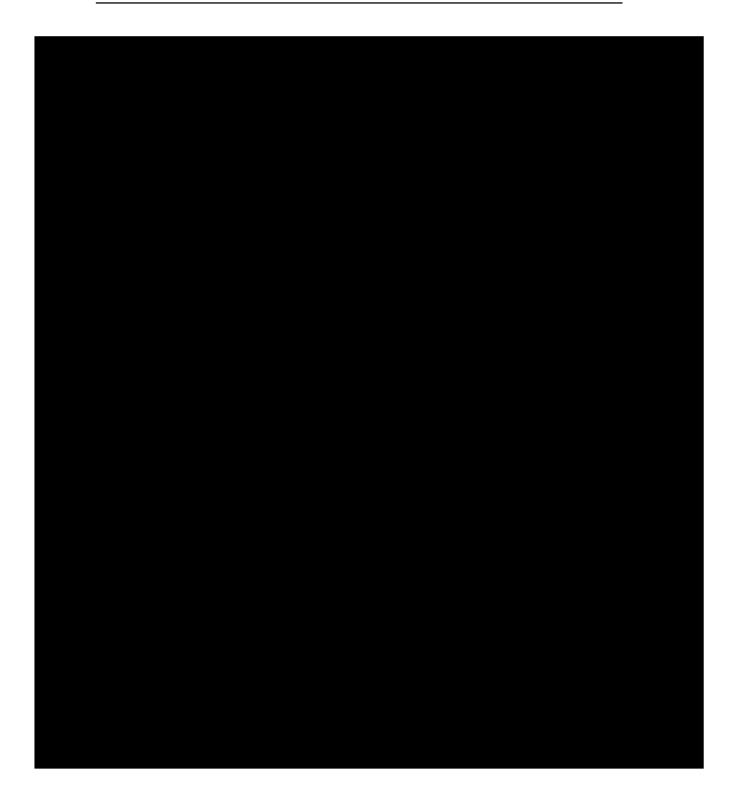












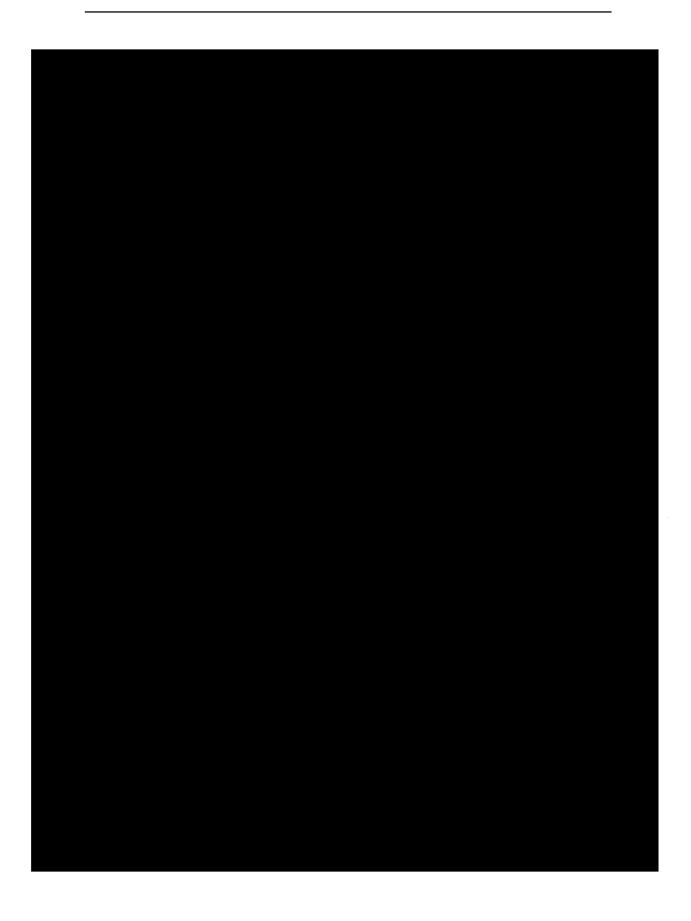


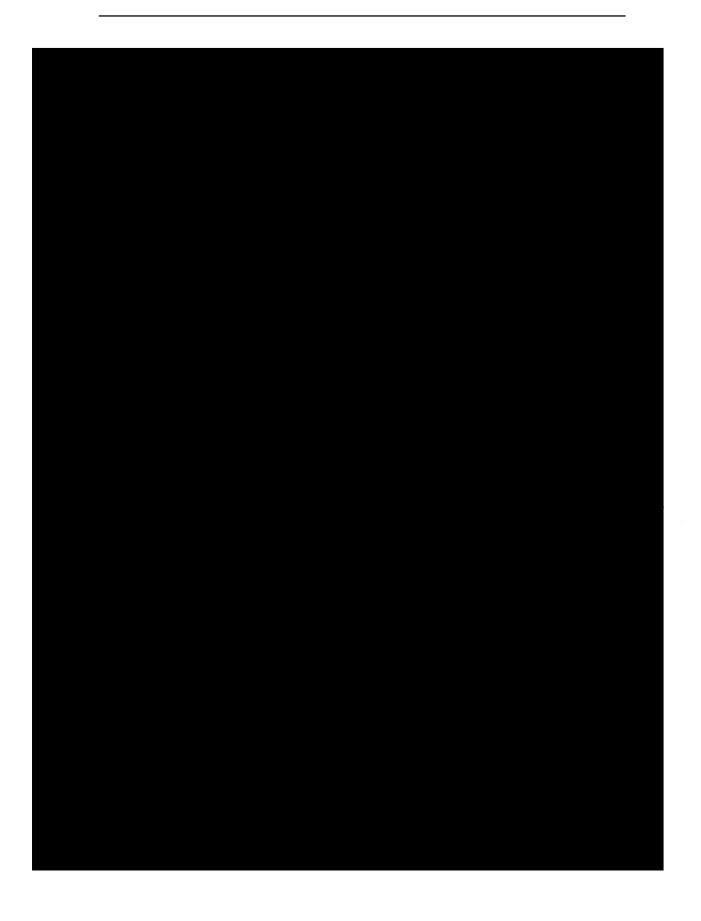




















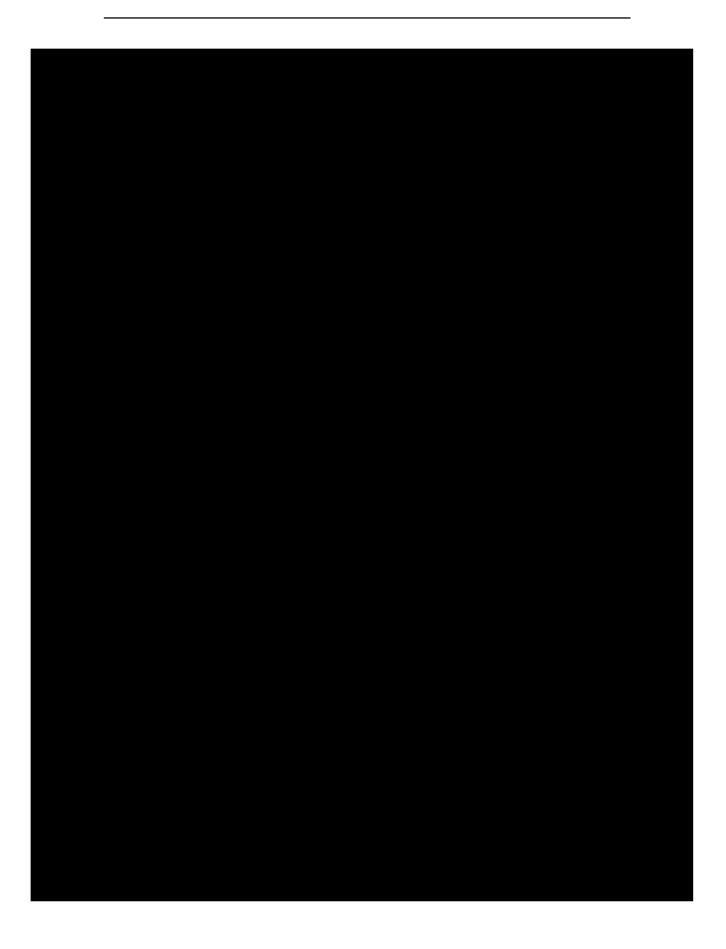




















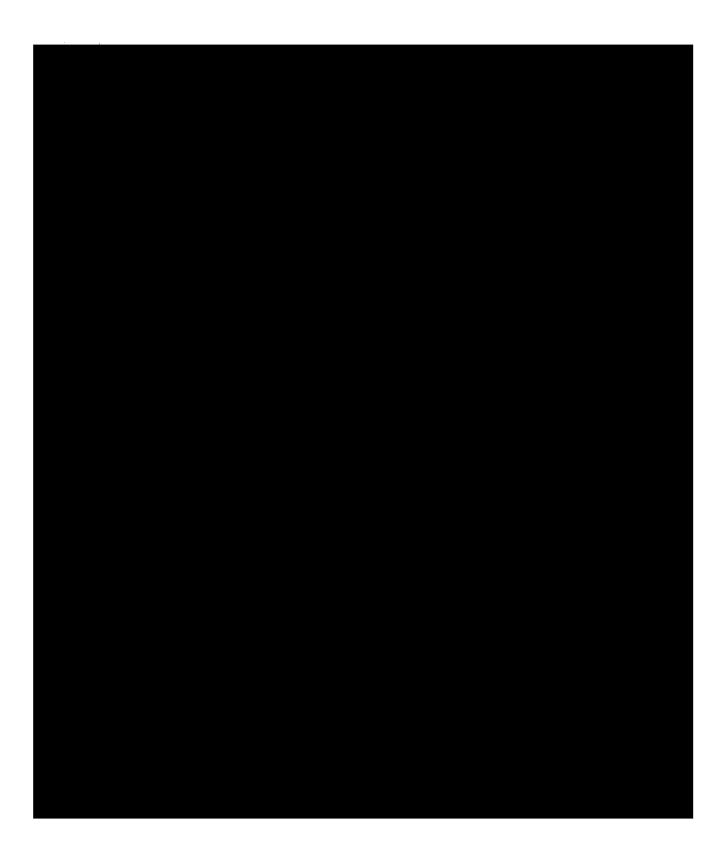


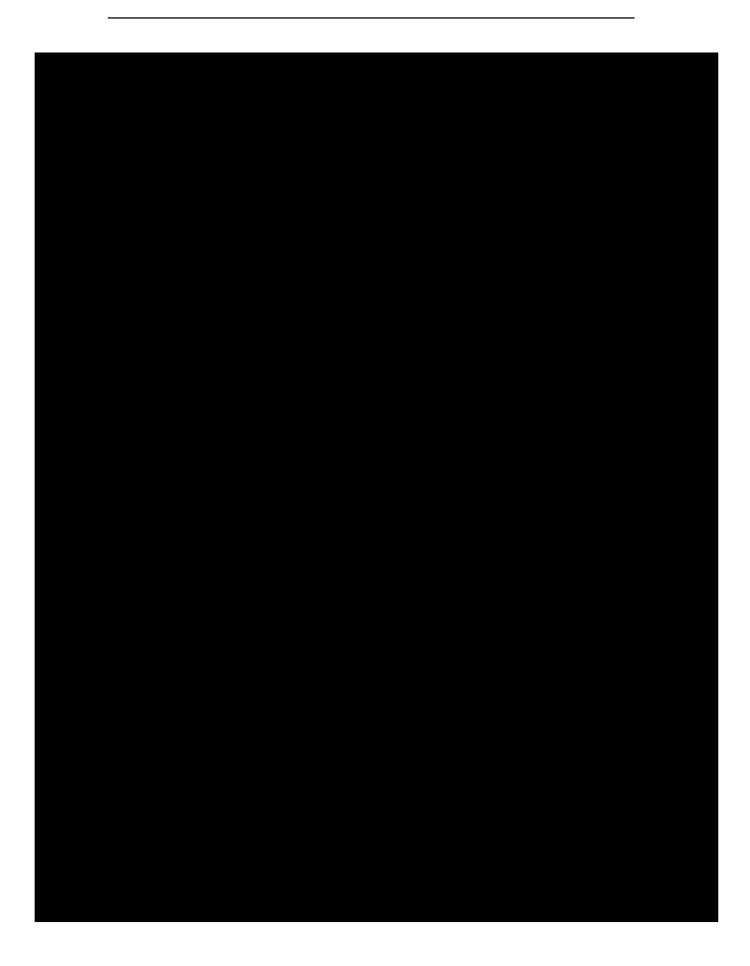












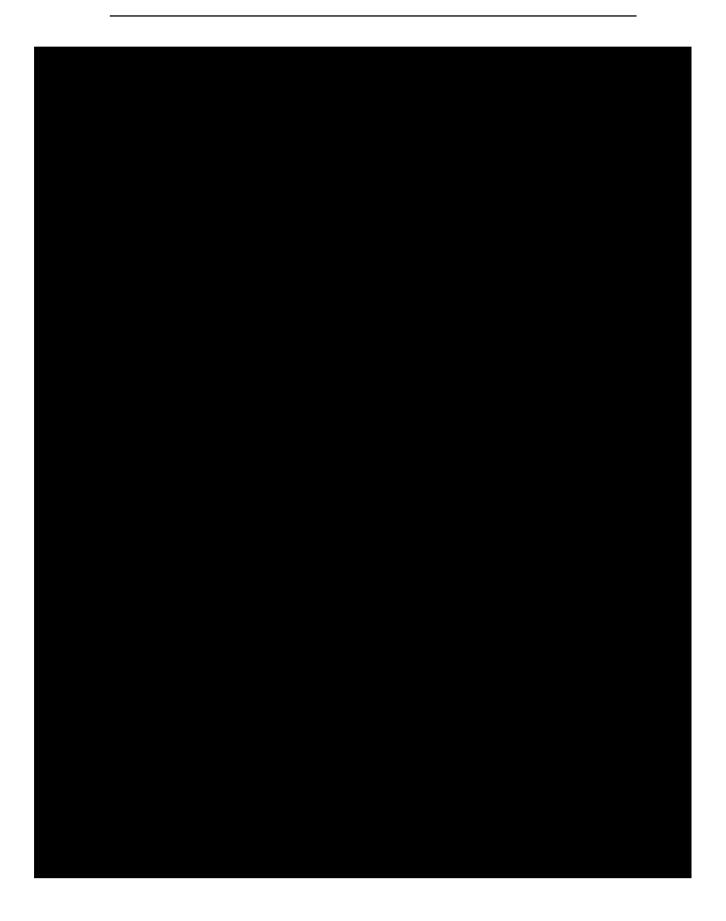


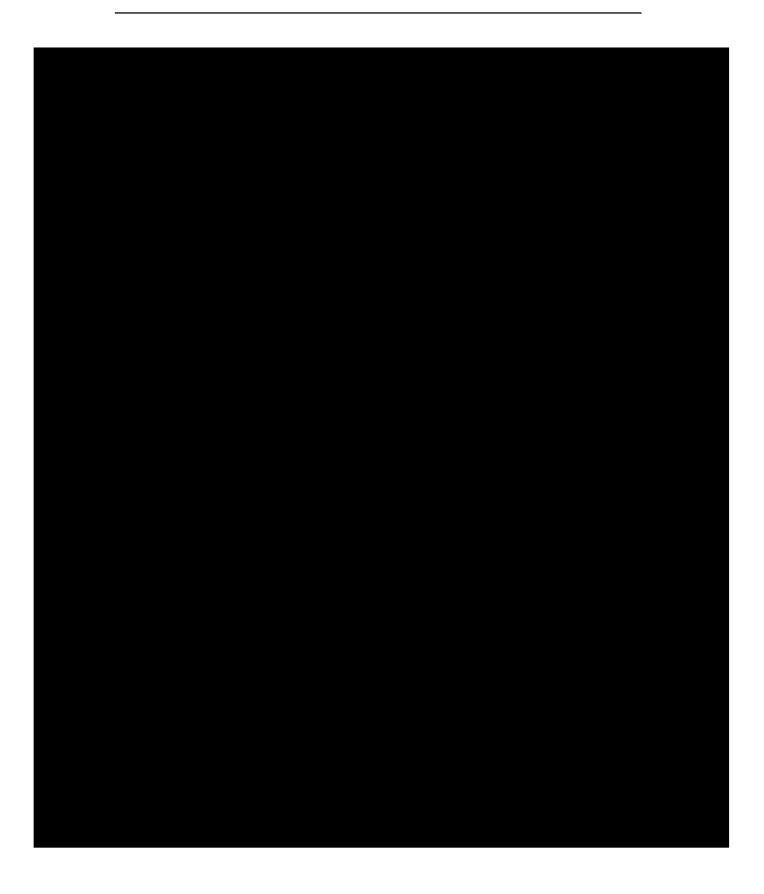












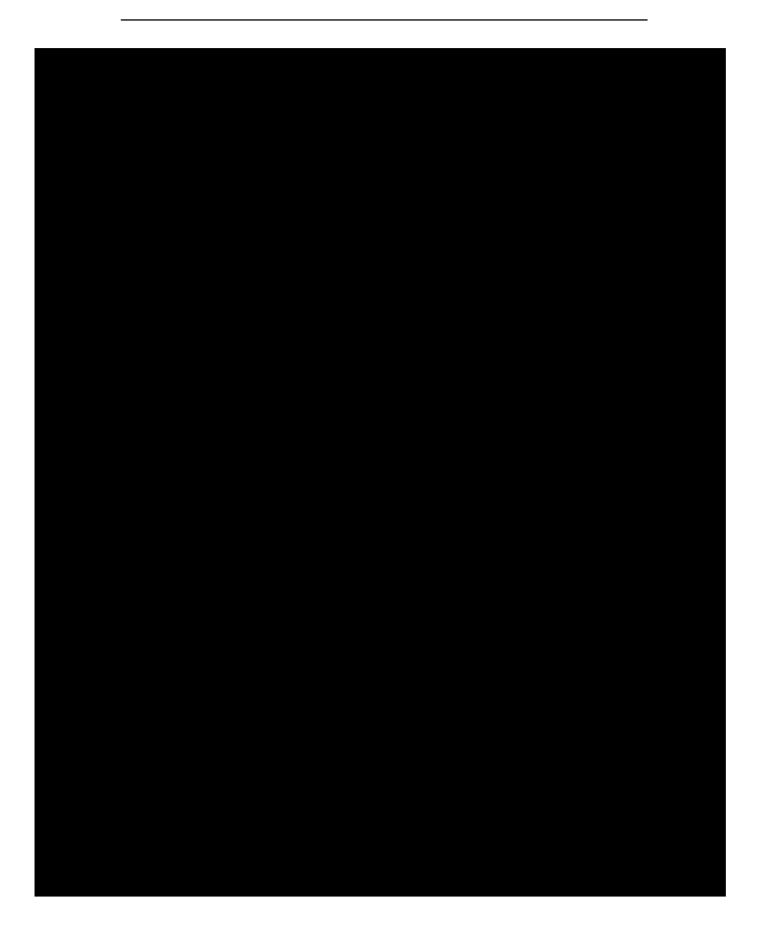






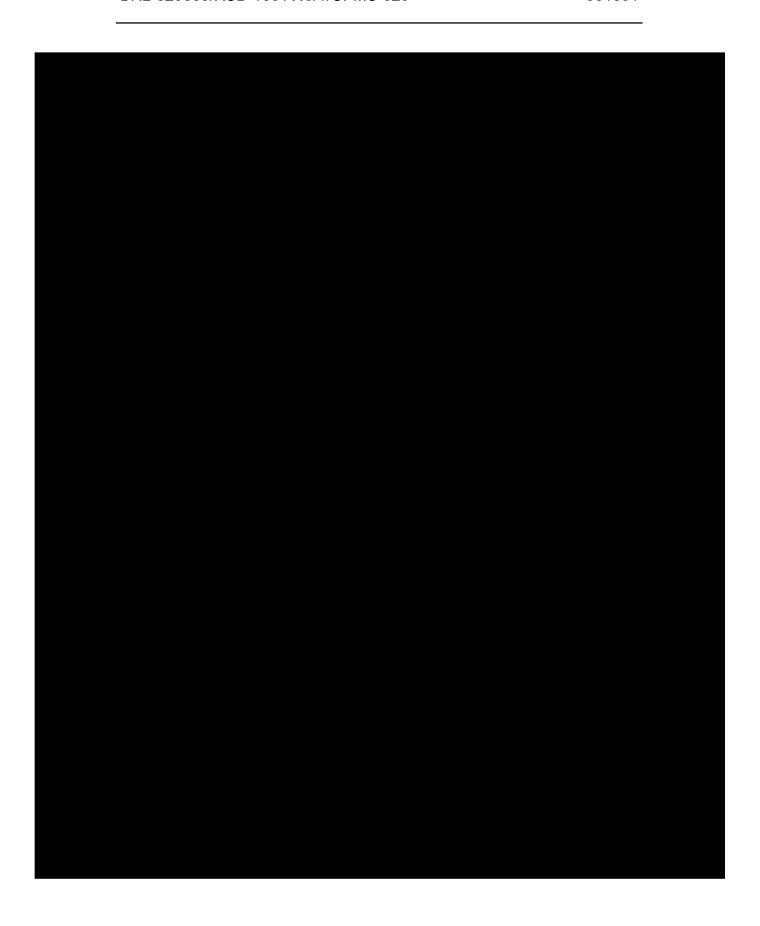




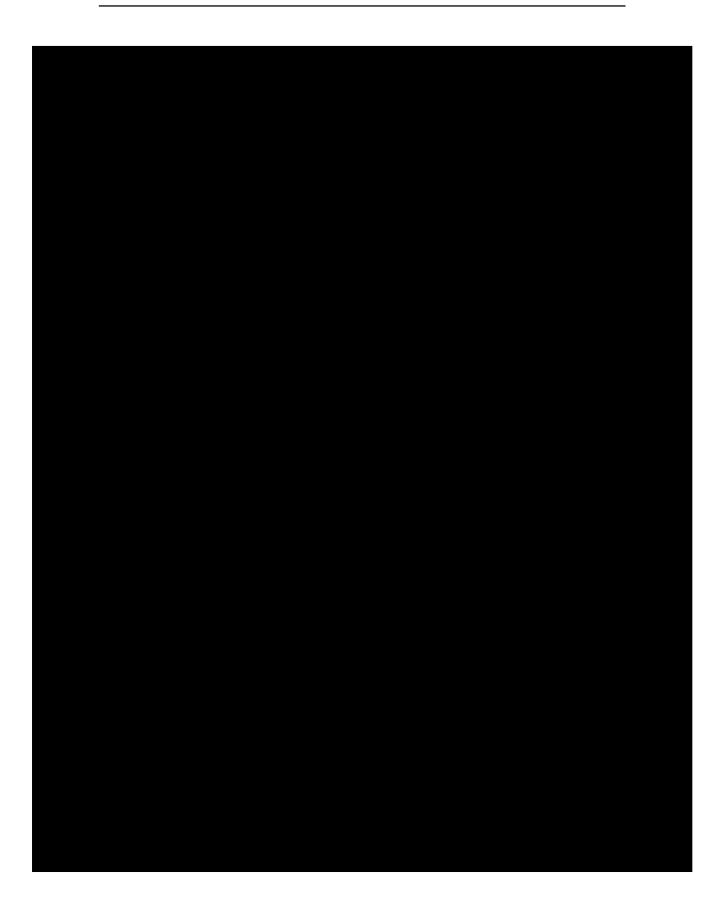


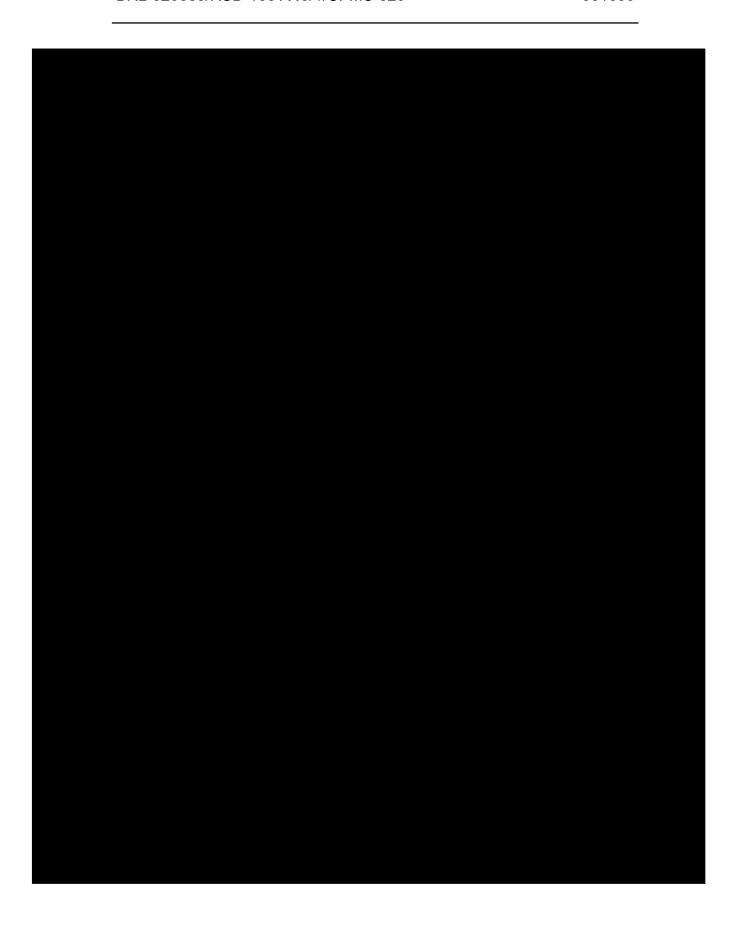








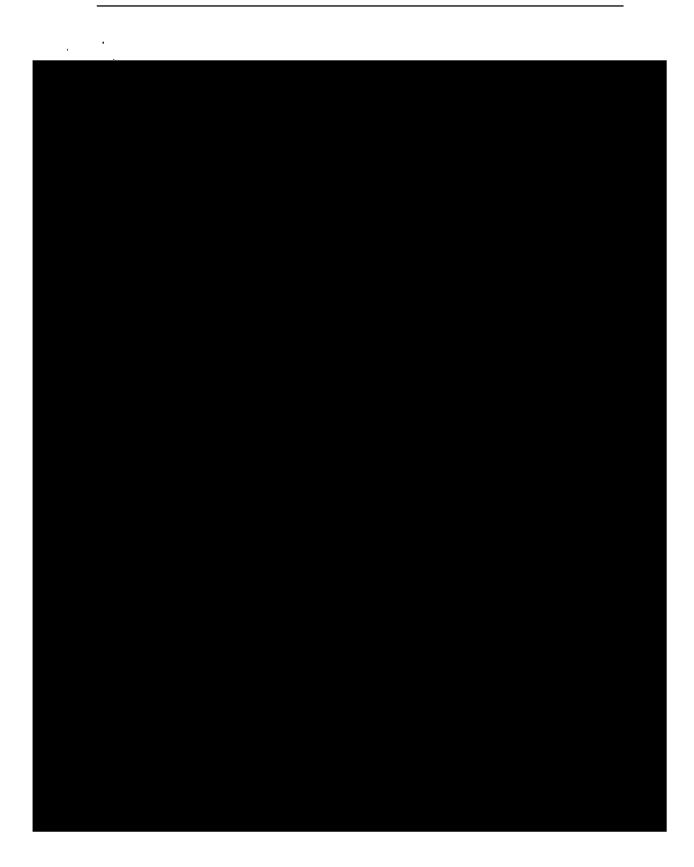






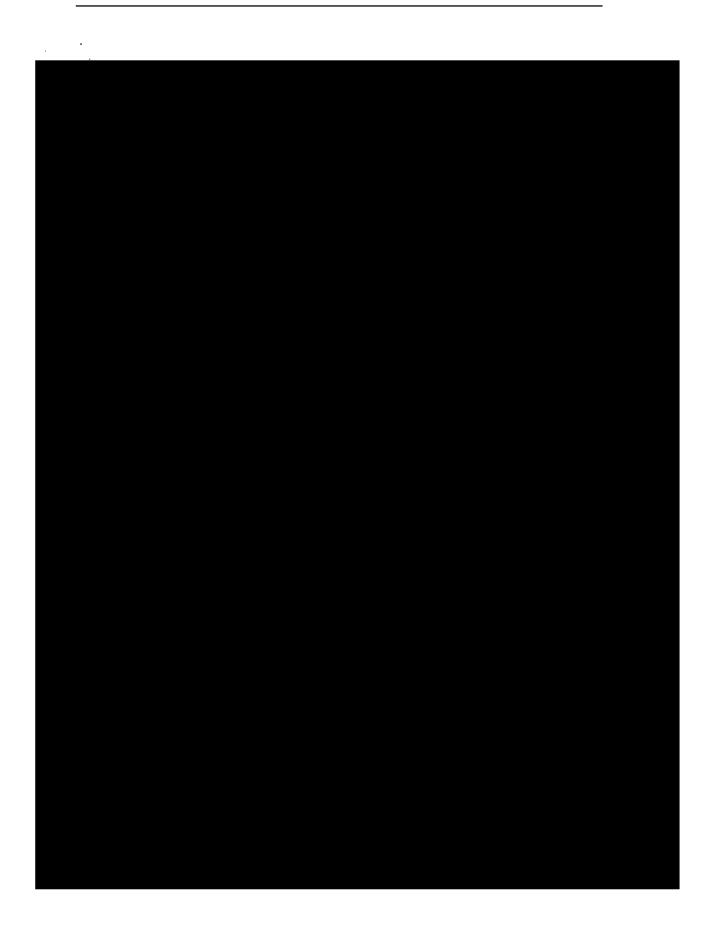
## **CURRICULUM VITAE**

OSIGNOCESIN VITAL

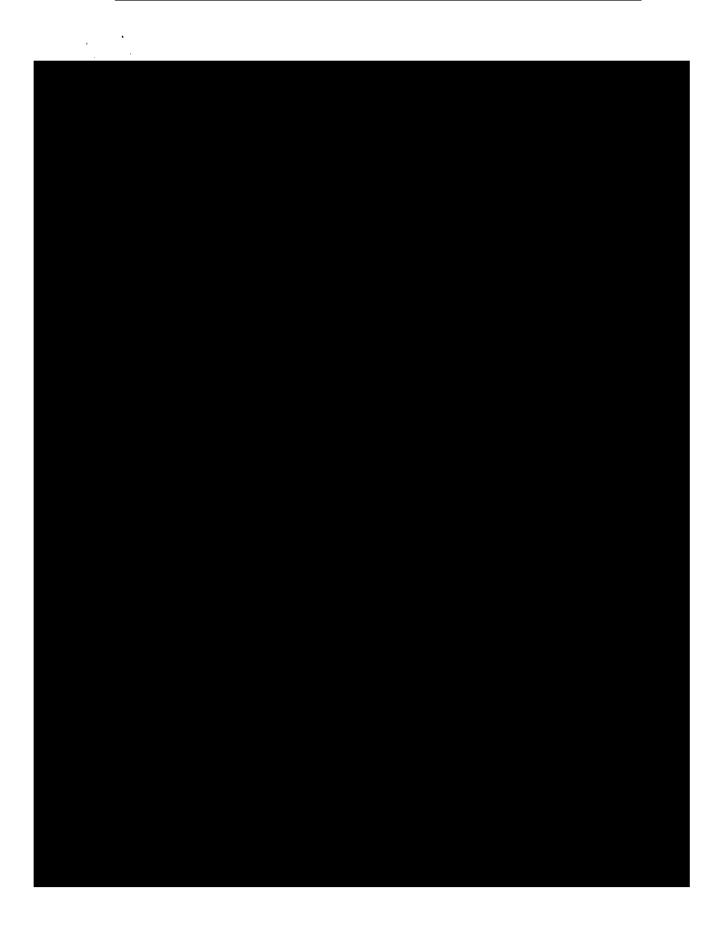








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CURRICULUM VITAE





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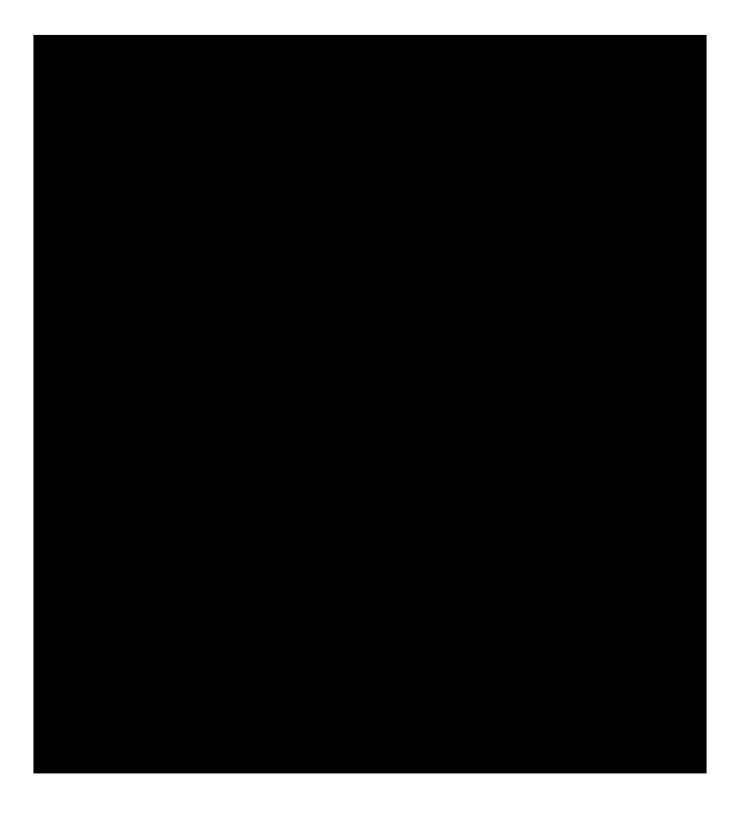














## **Randomisation Code**

Page - 1 CODING MEMO

PROJECT - 29060 PROTOCOL - 329I Coding Memo Creator - OAKESR8

Date Printed: August 12, 1993 Date Created: August 12, 1993 Seed: 8570387 Block Size: 6

		TREATMENT	CDOTTO - DT	ACEBO	
	Inte	rval Numbe		PHASE 1	
	111.00	Drug:	PLACEBO		
		_			
00001	00005	00010	00012	00016	00018
00020	00024	00027	00028	00031	00033
00037	00042	00047	00048	00049	00053
00059	00060	00062	00064	00069	00071
00074	00078	00080	00084	00085	00086
00094	00095	00097	00101	00107	00108
00111	00114	00115	00120	00123	00125
00128	00129	00135	00136	00141	00144
00148	00150	00155	00156	00158	00162
00164	00168	00169	00174	00176	00177
00183	00184	00189	00191	00197	00198
00200	00202	00207	00210	00213	00216
00217	00218	00224	00225	00229	00232
00237	00238	00241	00246	00251	00252
00253	00254	00259	00263	00266	00267
00274	00276	00277	00282	00285	00287
00291	00293	00296	00298	00302	00306
00311	00312	00315	00316	00320	00323
00327	00330	00331	00334	00337	00342 00359
00343	00345	00349	00353	00357	00339
	TRI	EATMENT GRO	OUP - IMIPE	RAMINE PO	
		EATMENT GRO	r 1 Name	PHASE 1	
		erval Numbe		PHASE 1	
00003		erval Numbe	r 1 Named	PHASE 1	00014
00003 00022	Inte	erval Numbe Drug: F	r 1 Named	1 PHASE 1	00014 00036
	Inte	erval Numbe Drug: P	r 1 Named O IMIPRAM 00009	PHASE 1 INE 00013	
00022	Inte	erval Numbe Drug: F 00007 00026	O IMIPRAM 00009 00030	1 PHASE 1 INE 00013 00035	00036
00022 00040	00006 00023 00041	Drug: P 00007 00026 00044	00009 00030 00045	O0013 00035 00050	00036 00054 00070 00090
00022 00040 00056	Inte 00006 00023 00041 00057	Drug: P 00007 00026 00044 00061	00009 00030 00045 00066	1 PHASE 1 INE 00013 00035 00050 00067 00088 00103	00036 00054 00070 00090 00104
00022 00040 00056 00073	00006 00023 00041 00057 00076	Drug: P 00007 00026 00044 00061 00079	00009 00030 00045 00082 00100 00118	00013 00035 00050 00067 00068 00103 00122	00036 00054 00070 00090 00104 00126
00022 00040 00056 00073 00092	00006 00023 00041 00057 00076 00093	Drug: F 00007 00026 00044 00061 00079 00098	00009 00030 00045 00066 00082 00100 00118 00137	00013 00035 00050 00067 00068 00103 00122 00139	00036 00054 00070 00090 00104 00126 00143
00022 00040 00056 00073 00092 00110	00006 00023 00041 00057 00076 00093 00113	ON THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERT	00009 00030 00045 00082 00118 00137 00154	00013 00035 00035 00050 00067 00088 00103 00122 00139 00159	00036 00054 00070 00090 00104 00126 00143 00161
00022 00040 00056 00073 00092 00110 00127	00006 00023 00041 00057 00076 00093 00113	ON THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERT	00009 00009 00030 00045 00066 00082 00100 00118 00137 00154 00172	00013 00035 00035 00050 00067 00088 00103 00122 00139 00159 00175	00036 00054 00070 00090 00104 00126 00143 00161 00180
00022 00040 00056 00073 00092 00110 00127 00146 00163 00185	00006 00023 00041 00057 00076 00093 00113 00132 00149 00166 00186	Drug: F 00007 00026 00044 00061 00079 00098 00117 00134 00153 00171 00187	00009 00009 00030 00045 00066 00082 00100 00118 00137 00154 00172 00192	00013 00035 00050 00067 00088 00103 00122 00139 00159 00175 00194	00036 00054 00070 00090 00104 00126 00143 00161 00180 00195
00022 00040 00056 00073 00092 00110 00127 00146 00163 00185 00199	00006 00023 00041 00057 00076 00093 00113 00132 00149 00166 00186 00203	Drug: P  00007 00026 00044 00061 00079 00098 00117 00134 00153 00171 00187 00208	00009 00009 00030 00045 00066 00082 00100 00118 00137 00154 00172 00192	00013 00035 00050 00067 00088 00103 00122 00139 00159 00175 00194 00211	00036 00054 00070 00090 00104 00126 00143 00161 00180 00195
00022 00040 00056 00073 00092 00110 00127 00146 00163 00185 00199 00219	00006 00023 00041 00057 00076 00093 00113 00132 00149 00166 00186 00203	Drug: P  00007 00026 00044 00061 00079 00098 00117 00134 00153 00171 00187 00208 00223	00009 00009 00030 00045 00066 00082 00100 00118 00137 00154 00172 00192 00209	00013 00035 00050 00067 00088 00103 00122 00139 00159 00175 00194 00211	00036 00054 00070 00090 00104 00126 00143 00161 00180 00195 00215
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00022 00040 00056 00073 00092 00110 00127 00146 00163 00185 00199 00219 00236 00255	00006 00023 00041 00057 00076 00093 00113 00132 00149 00166 00186 00203 00221 00239 00256	One of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of the control of	00009 00030 00045 00066 00082 00100 00118 00137 00154 00172 00192 00209 00227 00244 00264	00013 00035 00035 00050 00067 00088 00103 00122 00139 00159 00175 00194 00211 00230 00247 00269	00036 00054 00070 00090 00104 00126 00143 00161 00180 00195 00215 00233 00249 00270
00022 00040 00056 00073 00092 00110 00127 00146 00163 00185 00199 00219 00236 00255 00272	00006 00023 00041 00057 00076 00093 00113 00132 00149 00166 00186 00203 00221 00239 00256 00273	ON THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERT	00009 00030 00045 00066 00082 00100 00118 00137 00154 00172 00192 00209 00227 00244 00264	00013 00035 00035 00050 00067 00088 00103 00122 00139 00159 00175 00194 00211 00230 00247 00269 00284	00036 00054 00070 00090 00104 00126 00143 00161 00180 00195 00215 00233 00249 00270
00022 00040 00056 00073 00092 00110 00127 00146 00163 00185 00199 00219 00219 00236 00255 00272 00289	00006 00023 00041 00057 00076 00093 00113 00132 00149 00166 00203 00221 00239 00256 00273 00290	ON THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERT	00009 00030 00045 00066 00082 00100 00118 00137 00154 00172 00192 00209 00227 00264 00281 00297	00013 00035 00050 00050 00067 00088 00103 00122 00139 00159 00175 00194 00211 00230 00247 00269 00284 00301	00036 00054 00070 00090 00104 00126 00143 00161 00180 00195 00215 00233 00249 00270 00286 00305
00022 00040 00056 00073 00092 00110 00127 00146 00163 00185 00199 00219 00219 00255 00272 00289 00307	00006 00023 00041 00057 00076 00093 00113 00132 00149 00166 00203 00221 00239 00256 00273 00290 00308	ON CONTROL OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF	00009 00030 00045 00066 00082 00100 00118 00137 00154 00172 00192 00209 00227 00244 00264 00281 00297	00013 00035 00050 00050 00067 00088 00103 00122 00139 00159 00175 00194 00211 00230 00247 00269 00284 00301	00036 00054 00070 00090 00104 00126 00143 00161 00180 00195 00215 00233 00249 00270 00286 00305 00322
00022 00040 00056 00073 00092 00110 00127 00146 00163 00185 00199 00219 00219 00236 00255 00272 00289	00006 00023 00041 00057 00076 00093 00113 00132 00149 00166 00203 00221 00239 00256 00273 00290	ON THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERTY OF THE PROPERT	00009 00030 00045 00066 00082 00100 00118 00137 00154 00172 00192 00209 00227 00264 00281 00297	00013 00035 00050 00050 00067 00088 00103 00122 00139 00159 00175 00194 00211 00230 00247 00269 00284 00301	00036 00054 00070 00090 00104 00126 00143 00161 00180 00195 00215 00233 00249 00270 00286 00305

 $\begin{array}{cccc} \underline{\text{TREATMENT GROUP}} & - & \underline{\text{PAROXETINE}} & \underline{\text{PO}} \\ \underline{\text{Interval Number}} & 1 & \underline{\text{Named PHASE 1}} \end{array}$ Drug: PO PAROXETINE

Page - 1 CODING MEMO

PROJECT - 29060 PROTOCOL - 329II

Coding Memo Creator - OAKESR8

Date Printed: August 12, 1993 Date Created: August 12, 1993

Seed: 4108925 Block Size: 8

TREAT	PMENT G	ROUP	- PL	CEBO	
Interval	Number	1	Named	PHASE	2
	Drug:	DT.A	CEBO		

00003	00007	00009	00016	00018	00020
00026	00029	00038	00039	00043	00046
00050	00055	00058	00063	00065	00066
00077	00080	00083	00087	00090	00096
00098	00101	00107	00111	00115	00117
00122	00126	00129	00135	00139	00141
00145	00146	00156	00160	00161	00165
00175	00176	00177	00182	00185	00186

## $\frac{\texttt{TREATMENT} \ \texttt{GROUP}}{\texttt{Interval Number}} \ \frac{-}{1} \ \frac{\texttt{IMIPRAMINE}}{\texttt{Named PHASE}} \ \frac{\texttt{PO}}{2}$ Drug: PO IMIPRAMINE

00001	00006	00008	00013	00014	00015
00017	00019	00022	00027	00028	00032
00035	00036	00037	00045	00047	00048
00049	00052	00053	00059	00061	00062
00067	00069	00072	00074	00076	00078
00082	00084	00085	00089	00092	00094
00097	00099	00103	00105	00106	00112
00114	00116	00120	00121	00125	00128
00131	00133	00134	00138	00140	00142
00147	00150	00151	00153	00154	00158
00166	00167	00168	00171	00173	00174
00178	00183	00184	00188	00189	00191

## TREATMENT GROUP - PAROXETINE PO | Interval Number | 1 Named PHASE 2 | Drug: PO PAROXETINE

00002	00004	00005	00010	00011	00012
00021	00023	00024	00025	00030	00031
00033	00034	00040	00041	00042	00044
00051	00054	00056	00057	00060	00064
00068	00070	00071	00073	00075	00079
00081	00086	88000	00091	00093	00095
00100	00102	00104	00108	00109	00110
00113	00118	00119	00123	00124	00127
00130	00132	00136	00137	00143	00144
00148	00149	00152	00155	00157	00159
00162	00163	00164	00169	00170	00172
00179	00180	00181	00187	00190	00192

CODING MEMO

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PROJECT - 29060 PROTOCOL - 3291

Coding Memo Creator - OAKESR8

Date Printed: August 12, 1993 Date Created: August 12, 1993

Seed: 8570387 Block Size: 6

TREATMENT	GROUP -	PAROXETINE E	20			(CONT.)
00002	00004	00008	00011	00015	00017	
00019	00021	00025	00029	00032	00034	
00038	00039	00043	00046	00051	00052	
00055	00058	00063	00065	00068	00072	
00075	00077	00081	00083	00087	00089	
00091	00096	00099	00102	00105	00106	
00109	00112	00116	00119	00121	00124	
00130	00131	00133	00138	00140	00142	
00145	00147	00151	00152	00157	00160	
00165	00167	00170	00173	00178	00179	
00181	00182	00188	00190	00193	00196	
00201	00204	00205	00206	00212	00214	
00220	00222	00226	00228	00231	00234	
00235	00240	00242	00245	00248	00250	
00257	00258	00260	00261	00265	00268	
00271	00275	00278	00280	00283	00288	
00292	00294	00299	00300	00303	00304	
00309	00310	00313	00318	00319	00324	
00328	00329	00333	00336	00338	00340	
00344	00348	00350	00354	00355	00358	

## **Certificates of Analysis**



## **Drug Product Certificate of Analysis**

**Product:** 

Overencapsulated Paxil Tablets

**Batch Number:** 

U95085

Formula Code: AM

Date of Manufacture:

08-May-1995

Strength:

10 mg

Sample Log Number:

9500258

Use-by Date:

31-Jul-1999

**Test** 

Result

General Appearance

Passes

Bluish green opaque Supro B capsules containing a yellow capsule shaped,

film coated tablet.

Identification (HPLC)

Passes

Assay - Paroxetine (HPLC)

100.8% LC

(n=2)

Dissolution (HPLC)

Avg = 99% dissolved

(n=6)

L = 93%H = 102%RSD% = 3.2

This product conforms with Product Specification CPSC/PDSU 0203/01.

This product was manufactured and tested in accordance with current Good Manufacturing Practice.

Approved by

**Ouality Assurance** 





## SmithKline Beecham Pharmaceuticals

Pharmaceutical Technologies

### **Drug Product Certificate of Analysis**

Certificate of Analysis: PDRU 0500

Product: Overencapsulated Paxil Tablets

Strength: 10 mg
Formula: N/A
Lot Number: U-93127

Date of Overencapsulation: 27-Jul-93

Test

Request Log Number: 9300697

Specification Results

General Appearance Bluish green opaque Supro B capsules Passes

containing a yellow capsule shaped, film

coated tablet.

Identification (HPLC) The retention time of the major peak in Passes

the sample preparation corresponds with

that of the standard preparation as

obtained in the assay.

Assay - Paroxetine (HPLC) 90.0 - 110.0% of claim 99.0%

(n=2)

Dissolution (UV) Not less than 80% (Q) in 60 minutes 95%

or

(n=6)

Low=91% High=99%

RSD%=3.2

Overencapsulated tablet average must not be less than 90% of the tablet average and

the commercial tablet must comply with

TICD - C - - 4 1 - - - 900/ (O) :-

USP of not less than 80% (Q) in

60 minutes

This product conforms with Product Specification CPSC/PDSU 0203/01

Approved by:

Date: 09 Dec 93

Prepared by: page 1 of 1





#### **Drug Product Certificate of Analysis**

**Product:** 

Overencapsulated Paxil Tablets

**Batch Number:** 

U95086

Formula Code: AN

Date of Manufacture: Sample Log Number:

08-May-1995 9500257

Strength: **Use-by Date:** 

20 mg 31-Jul-1999

Test

Result

General Appearance

Passes

Bluish green opaque Supro B capsules containing a pink capsule shaped, film

coated tablet.

Identification (HPLC)

Passes

Assay - Paroxetine (HPLC)

101.7% LC

(n=2)

Dissolution (HPLC)

Avg = 102% dissolved

(n=6)L = 96%H = 108%

RSD% = 4.5

This product conforms with Product Specification CPSC/PDSU 0204/01.

This product was manufactured and tested in accordance with current Good Manufacturing Practice.

Approved by



## SmithKline Beecham Pharmaceuticals Pharmaceutical Technologies

### **Drug Product Certificate of Analysis**

Certificate of Analysis: PDRU 0501

Product:

Overencapsulated Paxil Tablets

Strength: 20 mg Formula: N/A

Lot Number: U-93128

Date of Overencapsulation:

03-Aug-93

Request Log Number:

9300696

Test	Specification	Results
General Appearance	Bluish green opaque Supro B capsules containing a pink capsule shaped, bisected film coated tablet.	Passes
Identification (HPLC)	The retention time of the major peak in the sample preparation corresponds with that of the standard preparation as obtained in the assay.	Passes
Assay - Paroxetine (HPLC)	90.0 - 110.0% of claim	100.4% (n=2)
Dissolution (UV)	Not less than 80% (Q) in 60 minutes or  Overencapsulated tablet average must not be less than 90% of the tablet average and	96% (n=6) Low=89% High=102% RSD%=4.7

This product conforms with Product Specification CPSC/PDSU 0204/01

the commercial tablet must comply with

USP of not less than 80% (Q) in

Approved by:

60 minutes

Date: 09 DEC 93

RSD%=4.7

Prepared by:

page 1 of 1





## **Pharmaceuticals**

## **Drug Product Certificate of Analysis**

**Product:** 

Overencapsulated Placebo for Paxil Tablets, 20 mg

**Batch Number:** 

U95084

Formula Code: ER

placebo

Date of Manufacture: Sample Log Number: 02-May-1995 9500256

Strength: **Use-by Date:** 

31-Jul-1999

Test

Specification

General Appearance

Passes

Bluish green opaque Supro B capsules containing a pink capsule shaped, bisected film coated tablet.

Paroxetine Content

Passes

(HPLC)

Absence of Active

This product conforms with Product Specification CPSC/PDSU 0207/01.

This product was manufactured and tested in accordance with current Good Manufacturing Practice.

Approved by

Quality Assurance

_ on <u>01) M199</u>7 Date



# SmithKline Beecham Pharmaceuticals Pharmaceutical Technologies

### **Drug Product Certificate of Analysis**

Certificate of Analysis: PDRU 0497

Product: Overencapsulated Placebo for Paxil Tablets, 20 mg

Strength: Placebo

Formula: N/A

Lot Number: U-93126

Date of Overencapsulation: 21-Jul-93

Request Log Number: 9300634

Test Specification Results

General Appearance Bluish green opaque Supro B capsules Passes

containing a pink capsule shaped, bisected

film coated tablet.

Paroxetine Content (HPLC) Absence of Active Passes

This product conforms with Product Specification CPSC/PDSU 0207/01

Approved by:

Prepared by:

Date: 09 DEC 93

page 1 of 1





Pharmaceutical Technologies

### **Drug Product Analytical Report**

Analytical Report: PDRU 0915

Product: Overencapsulated Imipramine HCl Tablets

Strength: 50 mg Formula: AA

Lot Number: U 9 5 1 2 1

Date of Overencapsulation: 07-Jun-95

Commercial Lot Number: 22763 (Biocraft Laboratories)

Use by Date: 01-Feb-98
Request Log Number: 9500298

Test	Specification	Results
General Appearance	Bluish green opaque Supro B capsules containing a round green film coated tablet debossed with BL on one side and 21 on the other side.	Passes
Identification (UV)	The ultraviolet spectrum for the sample closely matches that of the standard similarly prepared in the Assay or dissolution procedure for Imipramine HCl tablets.	Passes
Assay - Imipramine HCl (UV)	93.0 - 107.0% of claim	101.9% (n=2)
Dissolution (UV)	Not less than 75% (Q) in 45 minutes or Overencapsulated tablet average must not be less than 90% of the tablet average and the commercial tablet must comply with USP of not less than 75% (Q) in 45 minutes	Avg = 100% (n=6) L = 83% H = 106% RSD% = 8.5

This product conforms with Product Specification CPSC/PDSU 0209/01.

Approved by:

Prepared by: CAG

LNB Reference: SLM-24857 pp. 22-27.

Date: 37:





## SmithKline Beecham Pharmaceuticals

Pharmaceutical Technologies

### **Drug Product Certificate of Analysis**

Certificate of Analysis: PDRU 0499

Overencapsulated Imipramine Hydrochloride USP Tablets Product:

Strength: 50 mg

commercial Formula: Lot Number: U-93135

30-Jun-1993 Date of Overencapsulation:

0300506

Request Log Number:	9300596	
Test	Specification	Results
General Appearance	Bluish green opaque Supro B capsules containing a round green film coated tablet debossed with BL on one side and 21 on the other side.	Passes
Identification (UV)	The ultraviolet spectrum for the sample closely matches that of the standard similarly prepared in the Assay or dissolution procedure for Imipramine HCl tablets.	Passes
Assay - Imipramine HCl (UV)	93.0 - 107.0% of claim	100.5% (n=2)
Dissolution (UV)	Not less than 75% (Q) in 45 minutes	102%

(n=6)or Low=100%

Overencapsulated tablet average must not be less than 90% of the commercial tablet

average and the commercial tablet must comply with USP of not less than 75%

(Q) in 45 minutes

This product conforms with Product Specification CPSC/PDSU 0209/01

Approved by:

Prepared by:

Date: C9DEC 93

High=104%

page 1 of 1



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## SmithKline Beecham Pharmaceuticals

Pharmaceutical Technologies

## **Drug Product Certificate of Analysis**

Certificate of Analysis: PDRU 0498

Product: Overencapsulated Imipramine Hydrochloride USP Tablets

Strength: 50 mg
Formula: commercial

Lot Number: U-93139

Date of Overencapsulation: 16-Aug-93
Request Log Number: 9300695

Test Specification Results

General Appearance Bluish green opaque Supro B capsules Passes containing a round green film coated

tablet debossed with BL on one side and

21 on the other side.

Identification (UV) The ultraviolet spectrum for the sample Passes

closely matches that of the standard similarly prepared in the Assay or

dissolution procedure for Imipramine HCl

tablets.

Assay - Imipramine HCl 93.0 - 107.0% of claim 100.3%

(UV) (n=2)

Dissolution (UV) Not less than 75% (Q) in 45 minutes 102%

or (n=6) Low=101%

Overencapsulated tablet average must not be less than 90% of the commercial tablet

average and the commercial tablet must comply with USP of not less than 75%

(Q) in 45 minutes

This product conforms with Product Specification CPSC/PDSU 0209/01

Approved by:

Date: 09 DEC 93

High=103%

Prepared by:

page 1 of 1





## Drug Product Certificate of Analysis

Product:

Overencapsulated Placebo for Imipramine Tablets

Batch Number:
Date of Manufacture:

U 9 5 0 8 7 Formula Code: BF

placebo

Sample Log Number:

11-May-1995 9 5 0 0 2 6 8 Strength: Use-by Date:

30-Apr-1998

Test

Specification

General Appearance

Passes

Bluish green opaque Supro B capsules containing a round green film coated tablet debossed with RL on one side and 71 on the

other side.

Imipramine Content (UV)

Passes

Absence of Active

This product conforms with Product Specification CPSC/PDSU 0210/01.

This product was manufactured and tested in accordance with current Good Manufacturing Practice.

Approved by Quality Assurance on Olivery Date



# SMITHKline Beecham Pharmaceuticals Pharmaceutical Technologies

#### **Drug Product Certificate of Analysis**

Certificate of Analysis: PDRU 0493

Product: Overencapsulated Placebo for Imipramine HCl

Tablets, 50 mg

Strength: Placebo Formula: N/A

Lot Number: U-93178

Date of Overencapsulation: 07-Sep-93
Request Log Number: 9300771

Test Specification Results

General Appearance Bluish green opaque Supro B capsules

containing a round green film coated tablet debossed with RL on one side and

71 on the other side.

Imipramine Content (UV) Absence of Active as per dissolution Passes

procedure for Imipraimine HCl tablets.

This product conforms with Product Specification CPSC/PDSU 0210/01

Approved by:

Prepared by:

Date: 06 DEC 9 3

Passes

page 1 of 1



## **Statistical Report**

Confidential



**Paroxetine** 

BRL-029060

**Statistical Report** 

329

SB Document Number: BRL-029060/RSD-100V2V/1

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Population	1468

## 1 Introduction

The purpose of this appendix is to describe the statistical methodology used to analyze results presented in the clinical report. Summaries for the clinical report were provided for the double-blind acute and continuation phases. The focus of this appendix will be on methodology for the acute phase. Analysis for the continuation phase was performed similarly as the acute phase. All model testing was performed on acute phase data.

The primary efficacy parameters of consideration were HAMD Total (17 item) mean change from baseline at endpoint, K-SADS-L Depression subscale mean change from baseline at endpoint and percentage of responders at endpoint, where response was defined as a HAMD total score less than or equal to 8 or a decrease from baseline in HAMD total score of 50% or greater. Endpoint of the acute phase was defined as the last observation carried forward to week 8.

The following results from the acute phase endpoint (last observation carried forward) statistical analyses are presented for the primary efficacy parameters: parametric ANOVA tables from analysis of variance of mean change from baseline for full and reduced models, and p-values for responders at endpoint, patients in remission at endpoint, patients with sustained response, and patients withdrawing due to lack of efficacy.

Covariate analyses which were performed to determine the importance of prognostic variables in predicting a patients' response at endpoint and to determine the effect of various covariates on the HAMD Total and K-SADS-L Depression subscale at endpoint are also presented.

## 1.1 Patient Populations

The primary population of interest was the Intent-to-Treat (ITT) population. The acute phase was of primary interest in this study. Two hundred seventy-five (275) patients were included in acute phase of the ITT population. Only 271 randomized patients having at least one post-dose assessment during the acute phase were included in the efficacy analyses and only this subset of patients was included in calculations of baseline scores presented in acute phase efficacy tables. One hundred ninety (190) patients completed the acute phase of the study. Of these 190 patients, 125 patients entered the continuation phase. One hundred eighteen (118) patients had at least one efficacy assessment during the

continuation phase and only this subset of patients was included in continuation phase tables.

Also of interest was the Per Protocol population for the acute phase. This population does not include patients having significant protocol violations during the acute phase as specified by the inclusion/exclusion criteria of the protocol. There were 30 patients determined to be protocol violators during the acute phase. Since more than 5% of the ITT patients were protocol violators, the primary efficacy variables were analyzed for the per protocol population, as well as for the intent-to-treat population. Protocol violators were identified prior to the breaking of the blind. No patients were identified with significant protocol violations during the continuation phase. The acute phase protocol violators and reason for violation are provided in Table 1.

Table 1 Summary of Patients Identified as Acute Phase Protocol Violators and Reason for Violation

Has C-GAS scor	e 🗆 60 at screening:		
329.002.00099	329.002.00241	329.002.00323	329.005.00006
329.002.00099	329.002.00241	329.002.00323	329.005.00006
329.005.00012	329.005.00336	329.005.00112	329.006.00038
329.006.00041	329.006.00042	329.008.00273	329.012.00227
		323.008.00273	323.012.00227
Is non-compliant	Ţ.		
329.003.00075	329.003.00092	329.003.00093	329.003.00248
329.003.00292	329.003.00314	329.008.00157	329.009.00131
329.009.00199			
Received prohibit	ited concomitant med	lication(s):	
329.005.00002			
Does not meet ag	ge requirement:		
329.007.00140			
Has severe or un	controlled medical co	ondition(s):	
329.009.00203			
Has received pro	phibited medication(s)	prior to screening ar	nd/or baseline:
329.007.00311			
Has no previous	episodes of major de	pression as specified	in the protocol:
329.009.00237			

## 2 Statistical Methodology

## 2.1 Efficacy Variables at Baseline

The general linear model procedure, PROC GLM, in SAS version 6.08 was used to analyze data at baseline to demonstrate comparability. A model with effects for treatment and investigator was used. If the treatment effect was found to be significant (p  $\square$  0.05), then the baseline score was included in the model. SAS type III sums of squares were used.

## 2.2 Change from Baseline

The calculation of change from baseline (change = score - baseline score) required a baseline value. Therefore, if a patient was missing a baseline evaluation for a variable, the screening visit evaluation was used, if available. If no screening or baseline data were available for a patient, then treatment period data for that patient were not included in the analysis of change from baseline. Means presented in the study report summary tables are least squares (adjusted) means.

The change from baseline of efficacy variables, was analyzed by the general linear models procedure, PROC GLM, in SAS version 6.08 for each of the treatment groups. SAS type III sums of squares were used.

Comparisons between paroxetine and placebo and between imipramine and placebo were made using the CONTRAST statement. Treatment comparisons were made at a significance level of 0.05.

The statistical model was determined by analyzing data at endpoint. A full model was tested using effects for treatment, investigator, and treatment by investigator interaction. If the interaction was not found to be significant (p > 0.10), then a reduced model was used in the analyses including effects for treatment and investigator.

Data were analyzed at each week of the acute phase using the statistical model determined from the endpoint analysis (last observation carried forward to week 8).

The primary efficacy parameters analyzed were HAMD Total (17 item) and K-SADS-L Depression subscale. The K-SADS-L Depression subscale was

computed by summing the scores from the following 9 items: 2, 20, 34, 42, 44, 56, 83, 85, and 109

The mean change from baseline for the following secondary efficacy parameters was analyzed: HAMD depressed mood item (item 1), HAMD anxiety/somatization subfactor (items 10, 11, 12, 13, 15, 17), HAMD sleep subfactor (items 4, 5, 6), HAMD cognitive disturbance subfactor (items 2, 3, 9), HAMD retardation subfactor (items 1, 7, 8, 14), self perception profile (SPP) score, autonomous functioning checklist total (AFC) score, AFC self/family care subscore (items 1-22), AFC management subscore (items 23-42), AFC recreational activity subscore (items 43-58), AFC social/vocational activities subscore (items 59-78), sickness impact profile (SIP) score, SIP present health subscore, SIP present quality of life subscore, SIP sleep/rest subscore (section A), SIP home maintenance subscore (section B), SIP social interaction subscore (section C), SIP alertness behavior subscore (section D), SIP communication subscore (section E) and SIP recreational pastimes subscore (section F) were analyzed in the same manner as the primary change from baseline variables. Variables were analyzed at weekly intervals and at endpoint.

The mean CGI Global Improvement score was analyzed at weekly intervals and at endpoint using the same methodology as that used for mean change from baseline.

## 2.3 Percent Responders

The percent of responders was analyzed using the categorical modeling procedure, PROC CATMOD, in SAS version 6.08. Response was defined as a HAMD total score less than or equal to 8 or a decrease from baseline in HAMD total score of 50% or greater. Patients were classified as being a responder or non-responder. The proportion of responders was then compared among the treatments. A generalized logit model with maximum likelihood parameter estimations was used.

Comparisons between paroxetine and placebo and between imipramine and placebo were made using the CONTRAST statement with a significance level of 0.05

The statistical model was determined by analyzing data at endpoint. A full model was tested using effects for treatment, investigator, and treatment by investigator interaction. If the interaction was not found to be significant ( $p \Box 0.10$ ), then a

reduced model was used in the analyses only including effects for treatment and investigator.

The following secondary variables were analyzed similarly as percent of patients responding: percent of patients withdrawing due to lack of efficacy and percent of patients in remission at weekly intervals and at endpoint. Remission was defined as HAMD total score less than or equal to 8.

## 2.4 Survival Analysis

Survival analysis was performed for the time to sustained response, defined as response lasting until endpoint of the acute phase. The Cox proportional hazards modeling procedure, PROC PHREG, of SAS version 6.08 was used. Patients who did not achieve sustained respond were censored.

A test of the validity of the proportional hazards model was first considered using a time-dependent variable in the model. If the time-dependent variable was significant ( $p\square 0.05$ ), then the hazard ratio changes with time and the proportional hazards model assumption is invalid. If the assumptions were met, the survival analysis was performed comparing treatment groups.

The failure time was considered to be on a continuous scale, thus the default option (*Breslow*) for the handling of ties was used.

## 2.5 Covariate Analyses

Exploratory analyses were done to determine the effect of various covariates on percentage of responders at endpoint of the acute phase and the mean HAMD Total and K-SADS-L Depression subscale at endpoint of the acute phase. Response was defined as HAMD Total score less than or equal to 8 or a 50% or greater decrease from baseline in HAMD Total. The ten covariates of interest included the following: AFC at endpoint, SPP at endpoint, SIP at endpoint, atypical depression (yes, no), melancholic/endogenous subtype of depression (yes, no), current anxiety disorder (yes, no), current comorbid disorder other than major depressive disorder (yes, no), age at first onset of depression, number of episodes of major depressive disorder, and family history of major depressive disorder (yes, no).

For responders at endpoint of the acute phase, an analysis via logistic regression was performed for each variable of interest using a model with an effect for the variable. PROC LOGISTIC of the SAS system was used.

For mean HAMD and K-SADS-L at endpoint of the acute phase, an analysis of variance was performed for each covariate via the General Linear Models procedure, PROC GLM of SAS, using type III sums of squares. Each analysis used a model including effects for treatment, covariate, and treatment by covariate interaction.

## 3 Summary of Statistical Results

All patients randomized with data from at least one post dose assessment were included in the intent-to-treat efficacy analyses. Endpoint was used to determine the statistical model.

## 3.1 Efficacy Variables at Baseline

No significant differences at baseline were observed.

## 3.2 Change from Baseline Model Verification

The full model at endpoint was tested. The treatment-by-investigator interaction was found to be nonsignificant for all variables except the HAMD Retardation subscale. All nonsignificant interactions were removed from the model for analysis at all timepoints. For these analyses, a reduced model with effects for treatment and investigator was used.

ANOVA tables are included below which show the results of the full model with interaction and the reduced model without interaction at endpoint for mean change from baseline for the primary efficacy variables.

The treatment-by-investigator interaction p-values at endpoint from the analysis of variance (ANOVA) are provided in Table 2 for each efficacy parameter.

Table 2 Treatment-by-Investigator ANOVA P-values for Efficacy Parameters

Variable	Treatment-by-Investigator P-value			
HAMD Total	0.811			
K-SADS-L Depression	0.965			
HAMD Depressed Mood				
HAMD Anxiety/Somatization	0.706			
HAMD Sleep Disturbance	0.796			
HAMD Cognitive Disturbance	0.990			
HAMD Retardation	0.042			
SPP Total	0.962			
AFC Total	0.499			
AFC Self/Family Care	0.646			
AFC Management	0.324			
AFC Recreational Activity	0.831			
AFC Social/Vocational Activities	0.435			
SIP Total	0.939			
SIP Present Health	0.180			
SIP Present Quality of Life	0.505			
SIP Sleep/Rest	0.807			
SIP Home Maintenance	0.902			
SIP Social Interaction	0.763			
SIP Alertness Behavior	0.980			
SIP Communication	0.899			
SIP Recreational Pastimes	0.765			

### 3.2.1 HAMD Total (17 items)

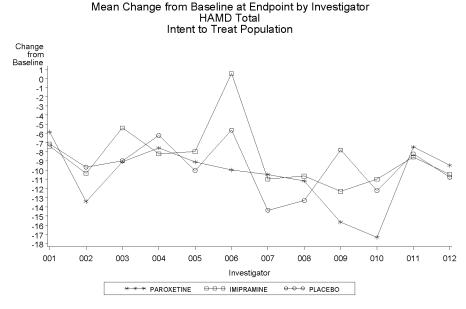
Analysis of the mean change from baseline of the HAMD total yielded no statistically significant treatment by investigator interaction (p=0.811). The baseline treatment effect was also not significant (p=0.220). A reduced model without interaction was used for this analysis. For the calculation of the HAMD score, individual missing results were not replaced. The missing items were allowed for by calculating the total as (S/n)x N, where S was the score recorded for n items and N was the number of items which should have been present.

Table 3 ANOVA Table for HAMD Total Mean Change from Baseline at Endpoint

Analysis of Varia	nce of Improvemen	nt from Baseline	at Endpoint			
HAMD Total (17	items)					
Intent-to-Treat Po	pulation					
		Degrees of	Sum of			Root
	Source	Freedom	Squares	F Value	P-value	MSE
Full Model	Treatment	2	120.82	1.12	0.329	
	Investigator	11	1145.48	1.93	0.037	
	Treat. by Inv.	22	863.59	0.73	0.811	
	Error	235	12712.23			7.35
Reduced Model	Treatment	2	181.44	1.72	0.182	
	Investigator	11	1090.83	1.88	0.043	
	Error	257	13575.82			7.27
Type III Sum of Squa	res are presented for tre	eatment, investigato	r, and treatment	by investigato	r effects.	•

Figure 1 Plot of Treatment-by-Investigator HAMD Total Mean Change from Baseline at Endpoint

Paroxetine - Protocol 329



## 3.2.2 K-SADS-L Depression Subscale

Analysis of the mean change from baseline of the K-SADS-L total yielded no statistically significant treatment by investigator interaction (p=0.965). The baseline treatment effect was also not significant (p=0.164). A reduced model without interaction was used for this analysis. For the calculation of the

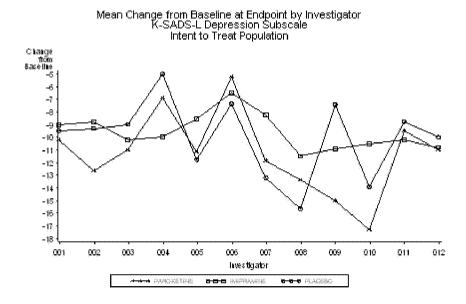
K-SADS-L depression subscale, individual missing results were not replaced. The missing items were allowed for by calculating the total as (S/n)x N, where S was the score recorded for n items and N was the number of items which should have been present.

Table 4 ANOVA Table for K-SADS-L Depression Subscale Mean Change from Baseline at Endpoint

*	nce of Improveme	nt from Baseline	at Endpoint			
K-SADS-L Depre	ession Subscale					
Intent-to-Treat Po	opulation					
		Degrees of	Sum of			Root
	Source	Freedom	Squares	F Value	P-value	MSE
Full Model	Treatment	2	87.53	0.79	0.455	
	Investigator	11	542.13	0.89	0.551	
	Treat. by Inv.	22	630.97	0.52	0.965	
	Error	220	12183.12			7.44
Reduced Model	Treatment	2	245.82	2.32	0.100	
	Investigator	11	583.23	1.00	0.446	
	Error	242	12814.09	·		7.28

Figure 2 Plot of Treatment-by-Investigator K-SADS-L Depression Subscale Mean Change from Baseline at Endpoint

Paroxetine - Protocol 329



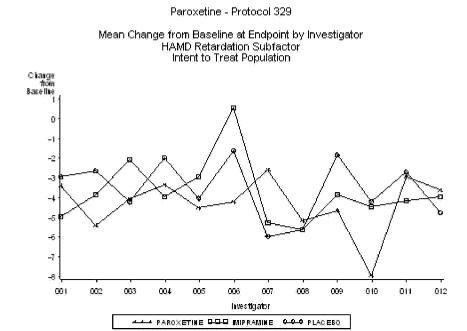
### 3.2.3 HAMD Retardation Subfactor

The HAMD retardation subfactor was found to have a significant treatment-by-investigator interaction (p=0.042) at endpoint. Treatment by investigator means were plotted. Centers 006, 010, and 007 were investigated for their effect on the interaction. When center 007 was removed, the interaction effect was nonsignificant (p=0.205). There was no reason to believe that the results observed at any center were not accurate. Therefore, the retardation subscale was analyzed with a full model including effects for treatment, investigator, and treatment-by-investigator interaction.

Table 5 ANOVA Table for HAMD Retardation Subfactor Mean Change from Baseline at Endpoint

Analysis of Va	ariance of Improven	nent from Baselin	e at Endpoint						
HAMD Retard	lation Subfactor								
Intent-to-Treat	t Population								
		Degrees of Sum of Root							
	Source	Freedom	Squares	F Value	P-value	MSE			
Full Model	Treatment	2	20.89	1.46	0.234				
	Investigator	11	129.34	1.65	0.087				
	Treat. by Inv.	22	255.09	1.62	0.042				
	Error	235	1677.65			2.67			
Type III Sum of S	Squares are presented for	treatment, investigat	or, and treatment by	v investigator et	ffects.				

Figure 3 Plot of Treatment-by-Investigator HAMD Retardation Subfactor Mean Change from Baseline at Endpoint



## 3.3 Percent Response Model Verification

The percent of patients responding, as defined by HAMD total score less than or equal to 8 or a decrease from baseline in HAMD total score of 50% or greater was analyzed using categorical modeling methods on a model including treatment and investigator effects.

Due to the small treatment-by-investigator cells by response for some sites, no test of the interaction effect could be made.

## 3.4 Survival Analysis

Survival analysis was performed for the time to sustained response, defined as response lasting until endpoint of the acute phase. Response was defined as a HAMD total score less than or equal to 8 or a decrease from baseline in HAMD total score of 50% or greater. Patients were classified as being a responder or non-responder. Nonresponders were considered as censored values.

Survival analysis was performed for time to sustained response during the acute phase. The test for the model assumptions included effects for treatment and a

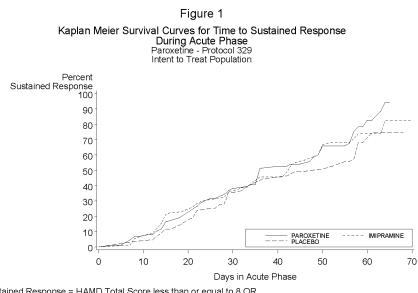
time-dependent variable, *treatment*  $x \log(\# of days)$ . Two treatment effects were included: paroxetine relative to placebo and imipramine relative to placebo. Two time-dependent variables were included similarly. This tests were not significant (p=0.180 and 0.066), thus we conclude that there is no evidence of an increasing or decreasing trend over time in the hazard ratio. Since the model assumptions were met, the analysis was done using a model with the treatment effect.

The results are presented in Table 6. When comparing each active drug to placebo, no significant treatment effect was observed. A plot of the Kaplan Meier curves is also provided below.

Table 6 Survival Analysis of Sustained Response During the Acute Phase

	Par vs Pla	Imp vs Pla
P-value	0.095	0.222
Risk Ratio	1.383	1.273
95% C. I.	(0.946, 2.022)	(0.864, 1.877)

Figure 4 Kaplan Meier Survival Curves for Time to Sustained Response During
Acute Phase



Sustained Response = HAMD Total Score less than or equal to 8 OR decrease from baseline of 50% or greater (lasting until endpoint).

## 3.5 Per Protocol Analyses

An analysis of mean change from baseline in HAMD Total and K-SADS-L Depression subscale at endpoint of the acute phase was performed for the per protocol population.

Similarly to the ITT analyses, the full model at endpoint was tested. The treatment-by-investigator interaction was found to be nonsignificant for both variable. Therefore, for these analyses, a reduced model with effects for treatment and investigator was used.

ANOVA tables are included below which show the results of the full model with interaction and the reduced model without interaction for each variable.

#### 3.5.1 HAMD Total (17 items)

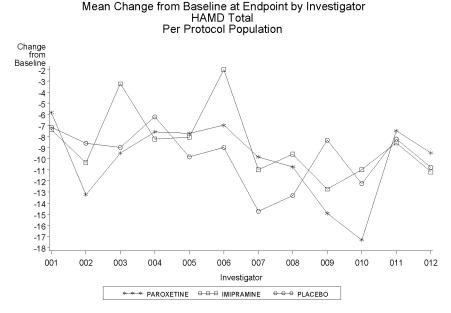
Analysis of the mean change from baseline of the HAMD total yielded no statistically significant treatment by investigator interaction (p=0.850). The baseline treatment effect was also not significant (p=0.290). A reduced model without interaction was used for this analysis.

Table 7 ANOVA Table for HAMD Total Mean Change from Baseline at Endpoint Per Protocol Population

	nce of Improvem	circ iroin Bu	senne at Ena	Politi		
HAMD Total (17	items)					
Per Protocol Popu	ılation					
		Root				
	Source	Freedom	Squares	F Value	P-value	MSE
Full Model	Treatment	2	58.73	0.52	0.593	
	Investigator	11	1014.54	1.65	0.088	
	Treat. by Inv.	22	845.99	0.69	0.850	
	Error	205	11479.00			7.48
Reduced Model	Treatment	2	77.29	0.71	0.492	
	Investigator	11	1041.82	1.74	0.065	
	Error	227	12324.98			7.36

Figure 5 Plot of Treatment-by-Investigator HAMD Total Mean Change from Baseline at Endpoint Per Protocol Population

Paroxetine - Protocol 329



## 3.5.2 K-SADS-L Depression Subscale

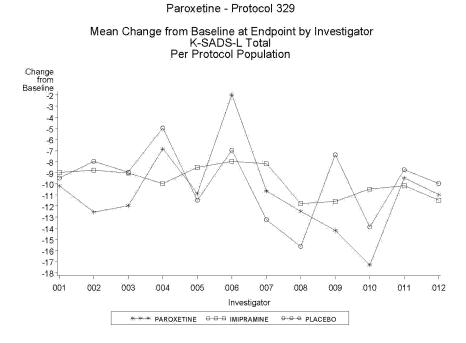
Analysis of the mean change from baseline of the K-SADS-L total yielded no statistically significant treatment by investigator interaction (p=0.975). The

baseline treatment effect was also not significant (p=0.247). A reduced model without interaction was used for this analysis.

Table 8 ANOVA Table for K-SADS-L Depression Subscale Mean Change from Baseline at Endpoint Per Protocol Population

Analysis of Varia	nce of Improvem	ent from Basel	ine at Endpoir	nt					
K-SADS-L Depre	ession Subscale								
Per Protocol Popu	ılation								
Degrees of Sum of Root									
	Source	Freedom	Squares	F Value	P-value	MSE			
Full Model	Treatment	2	32.77	0.28	0.754				
	Investigator	11	468.09	0.73	0.705				
	Treat. by Inv.	22	622.15	0.49	0.975				
	Error	192	11137.08			7.62			
Reduced Model	Treatment	2	185.68	1.69	0.187				
	Investigator	11	619.86	1.03	0.425				
	Error	214	11759.23			4.41			
Type III Sum of Squa	res are presented for	treatment, investig	gator, and treatme	nt by investiga	ntor effects.				

Figure 6 Plot of Treatment-by-Investigator K-SADS-L Depression Subscale Mean Change from Baseline at Endpoint Per Protocol Population



### 3.6 Covariate Analyses

#### 3.6.1 Percentage of Responders

The effect of covariates was evaluated using response as defined by the HAMD Total. Logistic analyses were performed for each covariate with a model including effects for treatment, covariate, and treatment-by-covariate interaction. For categorical covariates, analyses were done via the Categorical Modeling (CATMOD) procedure of the SAS system. For continuous covariates (AFC, SPP, SIP, age at first onset, and number of episodes), analyses were done via the Logistic (LOGISTIC) procedure of the SAS system. Given below are the p-values at endpoint for treatment, covariate, and treatment-by-covariate interaction effects (Table 13.28.1). The number and percentage of responders are also presented for each covariate (Table 13.28.2). Tests of interactions were made at the 0.10 level of significance and tests of overall treatment effects were made at the 0.05 level of significance. Due to the small number of patients without a family history of depression (5-paroxetine, 4-imipramine, 3-placebo), categorical analyses were not performed for this covariate.

To determine the overall treatment effect for logistic analysis of continuous covariates, an indicator variable denoting paroxetine versus placebo and imipramine versus placebo were included as effects. For the interaction effect, each of the treatment comparison indicators was multiplied by the covariate to obtained two interaction effects. The overall interaction p-value was obtained by taking the difference in the log likelihood and degrees of freedom from models with and without the interactions terms and obtaining the p-value from the Chi-Square distribution. The overall treatment effect was obtained in a similar manner by comparing the model without the interaction terms to a model containing only the covariate.

A significant treatment-by-covariate interaction was found for AFC, SIP, age at first onset, and number of episodes. The overall treatment effect was not significant except for the SIP covariate. The overall treatment p-value for each covariate was consistent with the model with no covariate (Table 13.28.1) with the exception of SIP. The significant atypical depression effect should be interpreted as the patients with atypical depression showed more response. The significant melancholic/endogenous subtype effect should be interpreted as the patients not classified as this subtype showed more response.

Table 13.28.1 Summary of Covariate Analysis for Percentage of Responders at Endpoint

#### Protocol 329

Covariate	Treatment P-value	Covariate P-value	Treatment-by- Covariate P-value
None	0.275	-	-
AFC ²	0.257	0.101	0.001
SPP ²	0.129	0.003	0.717
excluding interaction	0.129	□0.001	
SIP ²	0.050	□0.001	0.082
Atypical Depression ¹	0.356	0.023	0.503
excluding interaction	0.564	0.017	
Melancholic/Endogenous Subtype 1	0.413	0.025	0.797
excluding interaction	0.339	0.027	
Current Anxiety Disorder ¹	0.116	0.208	0.114
excluding interaction	0.442	0.068	
Current Comorbid Disorder ¹	0.227	0.440	0.436
excluding interaction	0.352	0.387	
Age at First Onset of Depression ²	0.337	0.932	0.034
Number of Major Depressive	0.352	0.028	0.010
Episodes ²			

 $^{^1}$  Categorical analysis via logistic analysis (CATMOD) with a model including effects for treatment, covariate, treatment-by-covariate interaction, and study.

 $^{^2}$  Analysis via logistic regression (LOGISTIC) with a model including effects for treatment, covariate, treatment-by-covariate interaction, and study

Table 13.28.2 Summary of Response at Endpoint by Covariate

		Paroxetine		Imipramine			Placebo			
Covariate		n	N	%	n	N	%	n	N	<b>%</b>
None		60	90	66.7	55	94	58.5	48	87	55.2
AFC		48	60	80.0	41	57	71.9	41	62	66.1
SIP		51	63	81.0	42	60	70.0	41	66	62.1
SPP		50	62	80.7	42	60	70.0	41	66	62.1
Atypical Depression	Yes	19	22	86.4	10	15	66.7	6	8	75.0
	No	40	67	59.7	44	77	57.1	42	78	53.9
Melancholic/Endogenous Subtype of Depression	Yes	18	33	54.6	17	33	51.5	17	35	48.6
	No	41	56	73.2	37	60	61.7	31	51	60.8
Current Anxiety Disorder	Yes	9	12	75.0	7	21	33.3	10	21	47.6
	No	50	77	64.9	47	72	65.3	38	65	58.5
Current Comorbid Disorder	Yes	21	30	70.0	20	37	54.1	16	34	47.1
	No	38	59	64.4	34	56	60.7	32	52	61.5
Age at Onset of Depression		59	89	66.3	54	93	58.1	48	86	55.8
Number of Episodes of Major Depressive Disorder		59	89	66.3	54	93	58.1	48	86	55.8
Family History of Major Depressive Disorder	Yes	51	77	66.2	51	84	60.7	44	83	53.0
•	No	3	5	60.0	2	4	50.0	3	3	100.
										0

#### 3.6.2 HAMD Total

An analysis of variance was performed for each covariate with a model including effects for treatment, covariate, and treatment-by-covariate interaction. Analyses were done via the General Linear Models (GLM) procedure of the SAS system. Provided below are the p-values at endpoint for each effect from the type III sums of squares for treatment, covariate, and treatment-by-covariate interaction effects (Table 13.29.1). The sample size, least square means, and standard errors from the analysis of variance are also presented for each covariate (Table 13.29.2). Tests of interactions were made at the 0.10 level of significance and tests of overall treatment effects were made at the 0.05 level of significance.

As shown in Table 13.29.1, there were two treatment-by-covariate interaction with a p-value  $\square$  0.10. A significant interaction was observed in analyses with the covariate of AFC at endpoint and number of episodes. The significant AFC at endpoint and number of depressive episodes covariates can be interpreted as a significant linear relationship with magnitude of the covariate and magnitude of the HAMD Total at endpoint. The significant atypical depression effect should be interpreted as the patients without atypical depression showed greater improvement. The significant melancholic/endogenous subtype effect should be interpreted as the patients classified as this subtype showed greater improvement. The significant current anxiety disorder effect should be interpreted as the patients having current anxiety disorder in general showed greater improvement.

Table 13.29.1 Summary of Covariate Analysis for HAMD Total at Endpoint

#### Protocol 329

Covariate	Treatment	Covariate	Treatment-by-
	P-value	P-value	Covariate P-value
None	0.290	-	-
AFC	0.019	0.017	0.013
SPP	0.860	□0.001	0.627
excluding interaction	0.327	□0.001	
SIP	0.114	□0.001	0.272
excluding interaction	0.088	□0.001	
Atypical Depression	0.266	0.010	0.458
excluding interaction	0.497	0.036	
Melancholic/Endogenous Subtype	0.427	0.014	0.761
excluding interaction	0.325	0.014	
Current Anxiety Disorder	0.094	0.104	0.103
excluding interaction	0.420	0.040	
Current Comorbid Disorder	0.134	0.200	0.107
excluding interaction	0.333	0.191	
Age at First Onset of Depression	0.797	0.229	0.810
excluding interaction	0.306	0.255	
Number of Major Depressive	0.063	□0.001	0.018
Episodes			
Family History of Major Depressive	0.897	0.120	0.590
Disorder			
excluding interaction	0.255	0.160	

Analysis of variance (GLM) with a model including effect for treatment, covariate, treatment-by-covariate interaction, and study.

Table 13.29.2 Summary of HAMD Total at Endpoint by Covariate

		Parc	exetine		Imij	pramine		Plac	ebo	
Covariate		n	mean	s.e.	n	mean	s.e.	n	mean	s.e.
None		90	8.47	0.76	94	9.34	0.75	87	10.18	0.78
AFC		60	6.41	0.82	57	7.46	0.84	62	8.10	0.80
SIP		63	6.42	0.63	60	8.24	0.66	66	7.44	0.63
SPP		62	6.70	0.74	60	7.59	0.75	66	8.26	0.72
Atypical Depression	Yes	22	5.32	1.54	15	8.13	1.86	8	9.50	2.56
	No	67	9.46	0.88	77	9.58	0.82	78	10.21	0.82
Melancholic/Endogenous Subtype of Depression	Yes	33	10.45	1.26	33	10.48	1.26	35	11.26	1.22
	No	56	7.25	0.96	60	8.80	0.93	51	9.37	1.01
Current Anxiety Disorder	Yes	12	7.17	2.08	21	13.00	1.57	21	11.90	1.57
	No	77	8.64	0.82	72	8.35	0.85	65	9.57	0.89
Current Comorbid Disorder	Yes	30	7.60	1.32	37	10.13	1.19	34	12.29	1.24
	No	59	8.86	0.94	56	8.91	0.97	52	8.73	1.00
Age at Onset of Depression		88	8.48	0.78	93	9.39	0.76	86	10.21	0.79
Number of Episodes of Major Depressive Disorder		89	8.62	0.75	93	9.38	0.73	86	10.08	0.76
Family History of Major Depressive Disorder	Yes	77	8.40	0.82	84	9.13	0.79	83	10.43	0.79
• • •	No	5	6.60	3.22	4	7.50	3.61	3	3.67	4.16

#### 3.6.3 KSADS Total

An analysis of variance was also performed for each covariate with a model including effects for treatment, covariate, and treatment-by-covariate interaction. Analyses were done via the General Linear Models (GLM) procedure of the SAS system. Provided below are the p-values at endpoint for each effect from the type III sums of squares for treatment, covariate, and treatment-by-covariate interaction effects (Table 13.30.1). The sample size, least square means, and standard errors from the analysis of variance are also presented for each covariate (Table 13.30.2). Tests of interactions were made at the 0.10 level of significance and tests of overall treatment effects were made at the 0.05 level of significance.

As shown in Table 13.30.1, there were two treatment-by-covariate interaction with a p-value  $\square$  0.10. A significant interaction was observed in analyses with the covariate of current comorbidity and number of episodes. The significant AFC at endpoint, SPP at endpoint, SIP at endpoint, and number of depressive episodes covariates can be interpreted as a significant linear relationship with magnitude of the covariate and magnitude of the K-SADS-L depressive subscale at endpoint. The significant atypical depression effect should be interpreted as the patients without atypical depression showed greater improvement. The significant melancholic/ endogenous subtype effect should be interpreted as the patients classified as this subtype showed greater improvement.

Table 13.30.1 Summary of Covariate Analysis for KSAD Total at Endpoint

#### Protocol 329

Covariate	Treatment P-value	Covariate	Treatment-by-
		P-value	Covariate P-value
None	0.058	-	-
AFC	0.212	0.004	0.261
excluding interaction	0.168	0.006	
SPP	0.670	□0.001	0.359
excluding interaction	0.227	□0.001	
SIP	0.382	□0.001	0.825
excluding interaction	0.097	□0.001	
Atypical Depression	0.096	0.107	0.452
excluding interaction	0.182	0.026	
Melancholic/Endogenous Subtype	0.112	0.002	0.833
excluding interaction	0.092	0.002	
Current Anxiety Disorder	0.019	0.540	0.183
excluding interaction	0.098	0.264	
Current Comorbid Disorder	0.014	0.725	0.050
Age at First Onset of Depression	0.580	0.143	0.810
excluding interaction	0.073	0.153	
Number of Major Depressive	0.055	0.001	0.010
Episodes			
Family History of Major	0.949	0.104	0.640
Depressive Disorder			
excluding interaction	0.054	0.143	

Analysis of variance (GLM) with a model including effect for treatment, covariate, treatment-by-covariate interaction, and study.

Table 13.30.2 Summary of KSAD Total at Endpoint by Covariate

		Paro	xetine		Imip	ramine		Place	ebo	
Covariate		n	mean	s.e.	n	mean	s.e.	n	mean	s.e.
None		83	16.75	0.85	89	18.00	0.82	85	19.59	0.84
AFC		60	15.39	0.92	57	16.74	0.94	62	17.74	0.91
SIP		63	15.56	0.71	60	17.58	0.75	66	17.08	0.71
SPP		62	15.90	0.84	60	16.72	0.85	66	17.94	0.82
Atypical Depression	Yes	22	13.68	1.64	14	15.43	2.06	7	19.86	2.91
	No	60	17.83	0.99	73	18.51	0.90	77	19.48	0.88
Melancholic/Endogenous Subtype of Depression	Yes	29	18.62	1.42	32	20.50	1.35	35	20.94	1.29
	No	53	15.68	1.05	56	16.63	1.02	49	18.49	1.09
Current Anxiety Disorder	Yes	10	14.3	2.44	19	19.58	1.77	21	21.86	1.68
•	No	72	17.06	0.91	69	17.61	0.93	63	18.73	0.97
Current Comorbid Disorder	Yes	25	14.68	1.54	35	17.74	1.06	33	21.48	1.34
	No	57	17.61	1.02	53	18.49	1.30	51	18.24	1.08
Age at Onset of Depression		81	16.80	0.86	88	17.98	0.83	84	19.60	0.85
Number of Episodes of Major Depressive Disorder		82	16.89	0.84	88	18.04	0.81	84	19.45	0.82
Family History of Major Depressive Disorder	Yes	71	16.67	0.93	81	18.16	0.87	81	19.90	0.87
	No	5	15.60	3.49	3	13.33	4.50	3	13.67	4.50

# 3.7 Confidence Intervals for Efficacy Results at Week 8

The following table provides results for the mean change from baseline in depression related scales and in % responders including the 95% confidence intervals for the treatment difference between active drug and placebo at Week 8 of the observed cases (OC) and last observation carried forward (LOCF) datasets.

# Mean Change from Baseline in HAM-D Total Score, Depression Item, K-SADS-L Depression Subgroup, K-SADS-L Depression Item, Mean CGI Score, and Percent of Patients Meeting Definition of Responder or Remission

Week 8, ITT Population

				95% Confidence Intervals	
	Paroxetine	Imipramine	Placebo	Paroxetine vs Placebo	Imipramine vs Placebo
Mean Change in HAM-D	Total (SEM)				
Wk 8 LOCF	-10.7 □ 0.81	-8.9 🗆 0.81	-9.1 🗆 0.83	(-3.92, 0.62)	(-2.09, 2.45)
Wk 8 OC	-12.2 □ 0.88	-10.6 □ 0.97	-10.5 □ 0.88	(-4.11, 0.77)	(-2.65, 2.49)
Mean Change HAM-D D	epression Item (SEM)				
Wk 8 LOCF	-2.00 🗆 0.14	-1.62 □ 0.14	-1.33 □ 0.14	(-1.06, -0.28)	(-0.68, 0.10)
Wk 8 OC	-2.21 🗆 0.17	-1.76 □ 0.18	-1.54 □ 0.17	(-1.14, -0.20)	(-0.71, 0.27)
Mean Change in K-SADS	S-L 9-Item Depression Subs	core (SEM)			
Wk 8 LOCF	-11.7 □ 0.84	-9.6 🗆 0.83	-9.6 🗆 0.83	(-4.40, 0.22)	(-2.28, 2.32)
Wk 8 OC	-12.0 □ 0.93	-10.7 □ 1.02	-10.8 □ 0.93	(-3.74, 1.42)	(-2.52, 2.90)
Mean Change in K-SADS	S-L Depression Item (SEM)				
Wk 8 LOCF	-2.20 🗆 0.18	-1.77 □ 0.18	-1.73 □ 0.19	(-0.97, 0.03)	(-0.54, 0.46)
Wk 8 OC	-2.35 🗆 0.20	-2.05 □ 0.22	-1.93 □ 0.20	(-0.97, 0.13)	(-0.70, 0.46)
Mean Clinical Global Im	provement Score (SEM)				
Wk 8 LOCF	$2.4 \square 0.16$	2.7 □ 0.15	$2.7 \square 0.16$	(-0.80, 0.08)	(-0.46, 0.40)
Wk 8 OC	$1.9 \square 0.15$	$2.2 \square 0.17$	$2.4 \Box 0.16$	(-0.88, -0.02)	(-0.66, 0.26)
% Responders (50% 🗆 H	AM-D Total or a Score □8)				
Wk 8 LOCF	67% (60/90)	59% (55/94)	55% (48/87)	(-2.8, 25.7)	(-11.1, 17.7)
Wk 8 OC	81% (54/67)	73% (41/56)	65% (43/66)	(0.5, 30.3)	(-8.3, 24.3)
% Responders (CGI Rati	ing of "Very Much Improve	d" or "Much Improved")			
Wk 8 LOCF	66% (59/90)	52% (49/94)	48% (42/87)	(2.9, 31.7)	(-10.6, 18.4)
Wk 8 OC	79% (53/67)	68% (38/56)	61% (40/66)	(3.2, 33.8)	(-9.7, 24.3)
% Remission (HAM-D Se	core 🗆 8)				
Wk 8 LOCF	63% (57/90)	50% (47/94)	46% (40/87)	(2.8, 31.8)	(-10.6, 18.6)
Wk 8 OC	76% (51/67)	64% (36/56)	58% (38/66)	(2.8, 34.2)	(-10.6, 24.0)

# **Audited Investigator Sites**

Confidential



# **Paroxetine**

BRL-029060

**List of Audited Investigator Sites** 

329

SB Document Number: BRL-029060/RSD-100V2W/1

# **Audited Investigator Sites**

Worldwide Regulatory Compliance-GCP is an independent function within SmithKline Beecham with responsibility for assuring Company management that clinical trials are organised, performed and reported in compliance with Company protocols and working practices and the requirements of national and international GCP (Good Clinical Practice) guidelines. This is achieved through a combination of study specific audits of investigator sites and audits, at regular intervals, of SmithKline Beecham systems for data handling, reporting and archiving.

Details of the selection of investigators for audit, and the methods of performing and reporting the audits are documented in WRC SOPs.

List of Audited Investigators											
Study Nu	Study Number:										
Centre No	Investigator	Site Address	Country	Audit Date							
005		University of Pittsburgh, Pittsburgh, PA.	USA	16-Sep-97 - 17-Sep-97							
009		UT Southwestern at Dallas, TX.	USA	30-July-97 - 1-Aug-97							