

# Research

Research and development (R&D) of new medicines and vaccines is at the core of our business and makes a significant contribution to society.

**Our product pipeline**  
GSK's R&D pipeline includes potential new treatments and vaccines for many serious and debilitating conditions including:

- Alzheimer's disease
- Asthma
- Atherosclerosis
- Cancer
- Depression
- Diabetes
- Heart disease
- HIV/AIDS
- Influenza
- Malaria
- Rheumatoid arthritis
- TB

New medicines and vaccines have brought huge benefits to the health and quality of life of millions of people over the last 100 years. But continued R&D remains as important as ever. There are still many serious, debilitating and life-threatening illnesses for which there are no effective treatments or where treatments could be significantly improved.

Our goal is to build the best product pipeline in the industry. In 2006 we invested £3.5 billion (\$6.4 billion) and employed over 15,000 people in R&D.

Our research aims to address unmet medical needs. Our pipeline includes compounds with the potential to make a major contribution to healthcare in developing countries, see [Access to medicines](#). Throughout the R&D process we seek the views of patients to inform our research. Focusing on patient needs drives innovation which brings commercial success.

We recognise that biomedical and pharmaceutical research raises ethical concerns – from the use of new technologies to the objective reporting of clinical trial results. We are committed to attaining high ethical and scientific standards in all our R&D work. This section explains our approach to:

- Animal research, and our efforts to reduce, refine and replace animal testing
- The conduct of clinical trials. How we ensure GSK sponsored clinical trials are carried out to the same high ethical standards irrespective of where they are conducted
- Training and auditing for clinical trials. How we train GSK employees involved in clinical trials and how we check that trials are carried out to Good Clinical Practice (GCP) standards
- Clinical trial information and results. How we publicly disclose trial information and results through journal articles, the GSK Clinical Trial Register and other public databases
- Patient safety. How we monitor the safety of our medicines

Background information on our approach to new technologies, including [pharmacogenetic research](#) and the use of [transgenic animals](#), is available on our website.

## ANIMAL RESEARCH

Animal research and testing is an essential component of understanding disease and evaluating safety and effectiveness of new vaccines and prescription and over-the-counter medicines.

Safety regulations require us to test all new medicines on animals before they are tested in clinical trials using humans. Most vaccines have to be tested on animals each time a new batch is produced.

GSK has 17 animal research laboratories in Europe, Asia and the US. Some animal research is conducted by external contractors on our behalf. This represents an additional 9 percent of animals<sup>1</sup>. We estimate that animal research accounts for around 5 percent of all GSK research expenditure.

Around 99 percent of the animals used by GSK are rodents (such as rats, mice, guinea pigs) and rabbits. The remaining 1 percent includes fish, ferrets, pigs, dogs, cats and primates.

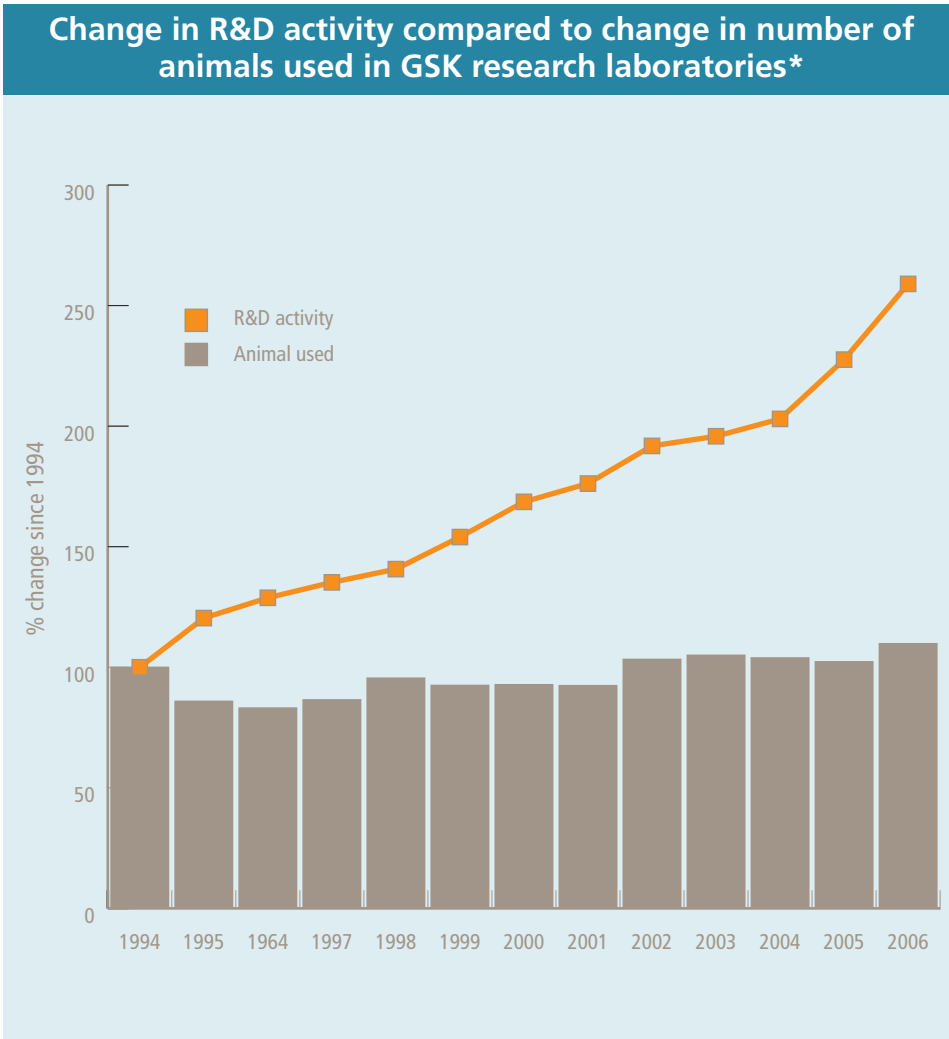
Animals used by GSK in 2006	%
mouse	67.7
rat	25.0
guinea pig	5.2
other rodent	0.1
rabbit	0.8
other	1.2

Ultimately GSK would like to see the important benefits of research being achieved without the use of experimentation which has the potential to cause pain or distress to animals. We do not believe this can be achieved in the foreseeable future, therefore GSK is committed to the 3Rs – reduction, refinement and replacement of animals in research – and to achieving high standards of animal welfare. Our goal is to use animals only when scientifically necessary, use as few as scientifically feasible and to minimise pain and distress.

This approach continues to have an impact. In 2006 there was a small increase in the absolute numbers of animals used from a baseline in 1994<sup>2</sup>, however the growth in R&D activity continues to greatly exceed any increase in animal use.

<sup>1</sup> We started estimating our external animal use in 2002, and to 2006 have recorded external animal use as representing 3.3%, 4.5%, 7.1%, 6.7%, 8.9% of the total animal use in our own laboratories. This change may both represent a rise but also improvement in reporting of data from our diverse external collaborations.

<sup>2</sup> We use 1994 as a baseline for comparison as this was the first year we were able to collect reliable data. The increased use in 2006 was due to more mice being used, especially for vaccines testing.



\*These data do not include animal research conducted by external contractors on our behalf. R&D activity combines our R&D budget and our vaccine sales, the two main drivers of animal use. Vaccine sales are included since most vaccines have to be tested on animals each time a new batch is produced.

### Change in R&D activity compared to change in number of animals used in GSK research laboratories\*

Year	Animals used	R&D activity
1994	100.0%	100.0%
1995	85.9%	120.4%
1996	83.1%	128.8%
1997	86.5%	135.2%
1998	95.5%	140.7%
1999	92.5%	154.0%
2000	92.8%	168.6%
2001	92.4%	176.2%
2002	103.3%	191.8%
2003	105.0%	195.8%
2004	103.9%	203.0%
2005	102.3%	227.6%
2006	109.8%	259.0%

## Recent GSK advances in the 3Rs:

- We replaced all wild-caught primates used for safety testing of oral polio vaccines with primates bred in captivity. In 2006 we also reduced the number of primates used for this purpose by 58 percent compared to 2005. We are progressing the replacement of all primates used for safety testing of oral polio vaccines with genetically modified mice; the date to achieve this remains subject to regulatory approval.
- We replaced rats used to supply brain tissue with a rat stem cell culture. This continuously produces more cells without the need to use animals, avoiding the use of 2,000 rats each year.
- We have increased the number of macaque monkeys housed in pairs allowing more social interaction which improves animal wellbeing.
- We introduced use of catheters and automated blood collection systems to significantly reduce the number of rats used in pharmacokinetic studies (studies into the absorption, distribution, metabolism and excretion of medicines). The new approach significantly reduces animal use by 60 percent in this commonly used type of study.

[More information on how we implement the 3Rs is available on our website.](#)

## Regulation and internal controls

Our animal research laboratories comply with national laws on animal welfare. Regulators carry out regular unannounced inspections of our sites.

All proposed research and testing using animals is considered by GSK ethical review committees. GSK laboratories, and any external laboratories conducting research on our behalf, must follow our [code of practice on animal research](#) which includes best practice standards for animal care and use.

Independent accreditation by the Association for the Accreditation and Assessment of Laboratory Animal Care (AAALAC) International is one way laboratories can demonstrate that they meet best practice standards. Ten of our animal laboratories are accredited by AAALAC. These are located in Belgium, Italy, Spain, the UK and the US and this accreditation now covers more than 91 percent of the animals used in GSK-owned laboratories. Our aim is to achieve AAALAC accreditation for all our laboratories<sup>1</sup>.

As we expand our business into new markets, increase vaccine production and work with more external partners to develop new medicines, we will also conduct animal research and testing in more countries worldwide. We are assessing the impact of these changes on our programme of animal research and in 2006 we updated our policy on the review of studies we sponsor externally.

### The three Rs

Implementing the 3Rs commits us to:

- **replacing** animal studies with alternative methods wherever possible
- **reducing** the number of animals used in each study
- **refining** studies to minimise pain and maximise the information obtained from each animal

For example, we are currently replacing the use of primates with mice in vaccine batch testing. Beyond this we are looking at ways to use the advances in quality control processes for vaccine production to change testing requirements so that eventually it will not be necessary to test each batch of vaccines on animals.

### Training and awareness

We provide training on the 3Rs to all staff who are involved in the care and use of animals and publish quarterly news bulletins on the 3Rs to raise awareness.

Our ethical review committees of GSK scientists, statisticians, senior managers, animal technicians and veterinarians encourages a 3Rs culture at GSK through seminars and 'Recommended Practice' guidelines for scientific procedures and animal welfare.

Our Animal Welfare Awards recognise employees who have made outstanding advances in implementing the 3Rs. In 2006 a research team looking at smoking cessation products, received the award for reducing by 40 percent the number of rats used in studies into the addictive properties of smoking products.

### Sharing best practice

We fund the [UK National Centre for the 3Rs](#) (NC3Rs) prize which recognises the best new techniques for implementing the 3Rs. In 2006, the £10,000 prize money was won for a technique that reduced the number of mice subjected to an invasive procedure used in bacterial disease research.

Together with industry partners in the Association of the British Pharmaceutical Industry, we are funding a three-year job post at the NC3Rs to encourage sharing of best practice.

In 2006, we donated our internal guide to refining the collection of blood samples from laboratory animals. This is now available for free on the NC3Rs website.

We are involved in many other initiatives to encourage research into the 3Rs and to stimulate the sharing of best practice on animal research. In 2006, GSK:

- Took part in working groups run by the NC3Rs on replacing and reducing the use of primates in research
- Supported the Universities Federation for Animal Welfare's projects to improve housing and husbandry for laboratory animals
- Participated in the European RSPCA, FRAME and industry initiative to reduce the use of dogs in safety testing
- Supported the National Academy's Institute of Laboratory Animal Research and the Johns Hopkins Center for Alternatives to Animal Testing in the US

### Advocacy

We work with stakeholders to encourage reduction, refinement and replacement of animal research and testing. In 2006 we:

- Joined the European Partnership for Alternatives to Animal Testing, which is a collaboration between the European Commission and major companies from seven industry sectors
- Worked with a range of stakeholders to ensure the impact on animals of the REACH chemicals initiative were addressed. We believe that existing data records, long-term human exposure records, and modern techniques that do not use animals can provide most of, if not all, the data required for product testing of many of the established products that have been in use for some time

<sup>1</sup> In 2006 we closed a laboratory in Japan, acquired laboratories in Croatia and Canada, and established GSK-managed laboratories in Singapore and the US, giving a current total of 17 GSK laboratories where we use animals.

- Gave evidence to the UK Academy of Medical Sciences study on the use of non-human primates in research. This confirmed that a strong justification is essential for any such use. However it concluded that where there are no other means to address clearly defined questions of particular biological or medical importance, there is a strong scientific and moral case for the carefully regulated use of non-human primates
- Participated in a study on animal pain and distress in research. The study conducted by the Laboratory Animal Science Association and the Animal Procedures Committee assessed whether the severity of pain and distress could be retrospectively reported. The study found that most research institutions already keep a record of pain or distress experienced by individual animals. It concluded that making this information public would be useful and would increase transparency. The study is now looking at ways this could be done without introducing excessive bureaucracy

#### Communicating our approach

Some people hold strong views on animal research and testing. We believe it is important to explain the need for animal research and testing and to be open about what we do.

Our laboratories host visits from schools, colleges, animal welfare organisations and others. In 2006, we made over 28 visits to UK schools and hosted 4 site visits. In the US we host regular Science Literacy teacher workshops on animal research with the Pennsylvania and North Carolina Associations for Biomedical Research. Over 1,000 teachers have taken part since 1994.

We engage regularly with animal welfare organisations and our investors, as well as contributing to the debate in the media. An article on animal research in the UK Times (29<sup>th</sup> April 2006) followed a visit to a GSK UK animal laboratory.

In 2006, SustainAbility, the corporate responsibility consultancy and think-tank, benchmarked our reporting on animal research. They concluded it was "Overall, the most comprehensive discussion of animals in research in the industry's reporting" and that "animal welfare concerns are integrated into GSK's operations and contracting".

#### Protest

We accept the right of lawful protest against animal research as a part of a free society, but condemn the use of violence and intimidation by some who are opposed to animal use. Our public stance against extremism has been complimented in the media (UK Guardian 9<sup>th</sup> May 2006), and by the UK Prime Minister (UK Sunday Telegraph 14<sup>th</sup> May 2006) for its robustness and openness. We welcome the apparent shift in the UK away from extremism to debate, and the passage of new legislation against animal extremism in the United States.

## CONDUCT OF CLINICAL TRIALS

The safety and effectiveness of new medicines and vaccines must be evaluated in human clinical trials before they can be approved for marketing. Regulators will only give approval if trials demonstrate that a product is safe and effective and that its benefits outweigh any risks from potential side effects.

A new product will typically be tested through three stages of clinical trials. These involve both healthy individuals and patients with the relevant disease.

In 2006 there were 159 projects in [clinical development](#).

#### Standards for clinical trials

All GSK clinical trials, wherever they are carried out, are conducted according to the [Good Clinical Practice](#) (GCP) guidelines developed by the International Conference on Harmonisation (ICH) and the principles contained in the World Medical Association Declaration of Helsinki on the '[Ethical Principles for Medical Research Involving Human Subjects \(2004\)](#)'.

The ICH guidelines provide an internationally accepted ethical and scientific quality standard for designing, conducting, recording and reporting trials. They cover issues such as the selection and training of trial investigators, gaining informed consent from trial participants, monitoring and quality assurance.

Trial protocols (the plan for how a clinical trial will be conducted) are reviewed by external regulatory agencies in the relevant countries when required, and all protocols are considered by the relevant ethical review committees which cover the sites where studies will take place.

An ethics review committee is composed of lay people, medical professionals and scientists. They assess whether a trial is justified and whether it is designed and will be conducted according to appropriate ethical standards. Ethics committees have the power to reject or stop a clinical trial.

Safety data are routinely collected throughout development programmes and are reported to regulators in line with applicable regulations. Data are also reviewed by GSK on an ongoing basis for any safety signals (events not necessarily caused by the treatment that require further exploration). GSK has a Global Safety Board (GSB) led by the Chief Medical Officer and composed of senior physicians and scientists. The GSB oversees the safety of all investigational and marketed compounds, approving the administration of investigational compounds to humans and defining the doses and duration of treatment that are considered safe. The GSK Global Safety Board is responsible both for approval of pivotal protocols (pivotal trials are those which provide the primary data on which regulatory approval is based) and internal assessment of any issues related to patient safety that arise during the product development programme or when it is marketed.

#### Our policy on Payments to Healthcare Practitioners and Institutions Conducting GSK-Sponsored or GSK-Supported Clinical Studies

- All clinical trial investigators are selected solely on their qualifications to conduct clinical research. Their history of using GSK products is not taken into account.
- Payments to practitioners reflect fair market value for the work performed.
- No payments are offered or made that could influence their judgement on whether to enrol or maintain a participant in a clinical study.

We audit clinical trials to ensure they are conducted to the appropriate standards. See Training and Auditing for Clinical Trials.

### Clinical trials outside Western Europe and North America

Most clinical trials take place in Western Europe and North America but GSK is starting to perform more trials in regions such as Central and Eastern Europe, South Africa, Latin America and parts of Asia.

We seek to conduct clinical trials where:

- The population is relevant to the scientific question and where the results can be generalised to broader populations
- There are qualified investigators capable of carrying out the research
- There are people who qualify for participation in the research
- The research can be carried out as quickly and efficiently as possible

All GSK-sponsored clinical trials are conducted to the same ethical standards irrespective of the location. All studies meet international and national regulatory and legislative requirements and are conducted in accordance with the principles of Good Clinical Practice (GCP) standards, the principles contained in the World Medical Association Declaration of Helsinki on the 'Ethical Principles for Medical Research Involving Human Subjects' (2004) and GSK's own policies.

GSK is committed to investing in R&D for diseases disproportionately affecting developing countries, see [Access to Medicines](#). These compounds must usually be tested through clinical trials in developing countries where the disease is prevalent and the medicine is relevant for the local population.

In some of the least-developed countries additional safeguards may be needed. For example, in some cultures, while still complying with normal ethical and legal requirements, additional steps are taken to match the objectives of informed consent to local culture. So for example local leaders and/or family members may need to be involved in the consent process.

You can read our [position on clinical trials in the developing world](#) in the background section of our website.

## TRAINING AND AUDITING FOR CLINICAL TRIALS

We provide training to ensure that clinical trials are performed to high ethical and quality standards. We audit the conduct of clinical trials to ensure they are carried out according to the study protocol, GSK Standard Operating Procedures (SOPs), Good Clinical Practice (GCP), current regulatory directives, laws, guidelines and the ethical considerations of the Declaration of Helsinki.

All employees involved in designing, conducting and monitoring GSK-sponsored trials are trained in GCP. Training is mandatory and employees must have completed the required training before starting or changing jobs.

In 2006 there were 14,988 training activities related to GCP. Each 'training activity' represents a successful completion of an e-learning module or instructor-led course related to GCP by one of our employees or contractors.

We keep detailed training records which are routinely requested by regulatory authorities when undertaking an inspection to assess the competence of employees undertaking clinical trials.

GSK's internal audit department audits GSK systems and processes involved in the conduct of trials, as well as auditing external clinical research organisations and investigators performing clinical research on our behalf. A risk management approach is used to determine which trials are audited. Risk factors evaluated include the complexity of the study, the patient population, the location of the study, previous audit history and any unusual findings during the conduct of the study.

In 2006, 213 audits were conducted:

- 132 audits of investigator sites conducting GSK-sponsored trials. This represents approximately 5 percent of investigator sites participating in pivotal clinical trials
- 22 audits of internal GSK systems and processes used in managing clinical trials and data
- 29 audits of clinical research organisations carrying out clinical trials on GSK's behalf
- 13 audits of GSK local operating companies, including the medical departments managing the clinical research in those countries
- 17 "For Cause" audits were conducted in response to suspected irregularities and six investigators were reported to regulatory agencies

Audit results are reported quarterly to the R&D Risk Management & Compliance Board, and annually to the GSK Audit Committee. Any concerns or issues identified during audits are fully investigated and appropriate action taken. This may include retraining or, in severe cases, dismissal for the individuals concerned as well as development of new training programmes or procedures to prevent a reoccurrence. Trial data may also be re-analysed.

Inspections of investigators, clinical research organisations, Independent Ethics Committees /Institutional Review Boards and sponsors of clinical trials are also carried out by regulatory authorities to ensure the safety of trial participants, the quality of data, and that trials are conducted according to GCP. During 2006 there were more than 30 such inspections of GSK and investigators used by GSK to conduct clinical studies.

## CLINICAL TRIAL INFORMATION AND RESULTS

We make the results of our clinical trials widely available to healthcare practitioners and others who use or evaluate the use of our medicines. We also publicly disclose information about ongoing trials.

### Ongoing clinical trials

Publicly available internet-based registration of ongoing clinical trials can provide a stimulus for increased participation in clinical research. It also provides an important reference point so interested parties can track the subsequent disclosure of clinical trial results.

GSK is legally required to post summary protocol information for ongoing studies of treatments for serious or life-threatening diseases conducted under a US Investigational New Drug Application on the National Institutes of Health website [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov).

In addition, GSK is posting protocol summaries of all clinical trials, irrespective of the countries involved, to ClinicalTrials.gov.

At the end of 2006 there were 223 protocol summaries of actively recruiting clinical trials on ClinicalTrials.gov. These meet the requirements of such postings as set out by the International Committee of Medical Journal editors. For non-phase III trials, our policy is to delay the posting on the website of certain data elements on an exceptional basis when they are competitively sensitive.

### Clinical trial results

Pharmaceutical companies are legally required to disclose all relevant data from clinical trials to the appropriate regulatory authorities when seeking approval for a new product.

After approval, sponsors have a continuing obligation to provide regulatory authorities with updated safety information from clinical trials, see patient safety. Safety and efficacy information is provided to doctors through prescribing information which is approved by regulators.

In addition there is a need to use other ways to communicate the results of our clinical trials to healthcare practitioners and others who use or evaluate the use of our medicines.

GSK follows the [PhRMA Principles on the Conduct of Clinical Trials and the Communication of Clinical Trial Results](#) and is committed to timely communication of results for all products approved for marketing. Wherever possible we publish our trial results in peer-reviewed scientific and medical journals, or in conference abstracts and proceedings. These are used by research and healthcare communities to obtain the latest information on treatments.

GSK cannot guarantee publication by these methods since this is at the discretion of journal editors and conference organisers. For this reason, we launched the GSK online [Clinical Trial Register](#) in 2004, to supplement prescribing information and publications in the scientific literature.

The Register contains results and protocol information from GSK-sponsored trials of marketed medicines. It also provides references to publications that have appeared in medical journals. Anyone can use the internet to access the register.

### Activity in 2006

At the end of 2006 there were 2,760 clinical trial summaries on the GSK Clinical Trial Register (<http://ctr.gsk.co.uk/welcome.asp>). This includes all clinical trials of our major marketed products which have been completed since the formation of GSK in 2000, or that were completed before this and are likely to inform medical judgement.

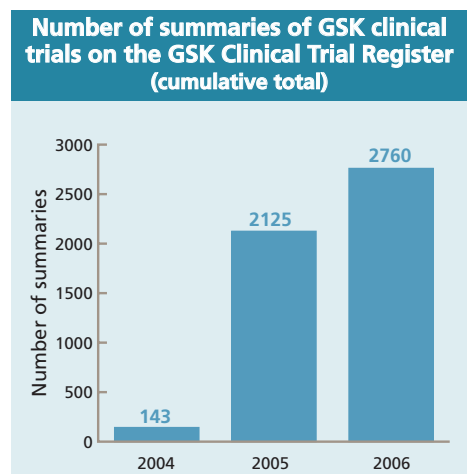
We have continued to populate the register with clinical trials that relate to our other marketed medicines and this was largely completed in 2006.

### Our approach to authorship of journal articles

There have been concerns about “ghost writing” of journal articles, where doctors put their names to articles written by pharmaceutical companies. GSK’s policy is that:

- Authorship and acknowledgements for articles must be consistent with journal guidelines and be determined on the level of contribution to study design, data acquisition, analysis and interpretation and writing or revising the manuscript.
- The named senior author for a paper must actively participate in the drafting process, lead the content development, and retain final approval authority for the manuscript.
- Any GSK staff or contractors who contribute to the development of manuscripts for external authors must be named in the article.

Read our [Public Policy on Disclosure of Clinical Trial Information Authorship of Journal Articles](#).



Year	Summaries
2004	143
2005	2,125
2006	2,760

## Genetic research and patient safety

Pharmacogenetic research is the study of genetic variations that predispose individuals to respond differently to medicines. It is a research area with the potential to improve the effectiveness of medicines and patient safety, by identifying which patients are more likely to benefit from a medicine and which may be susceptible to side-effects.

Pharmacogenetics relies on analysing the DNA of participants in clinical trials against the results from their treatment. We collect blood samples for potential DNA analysis in the majority of our phase I, II and III drug development trials. This includes with ethics committee reviews and approval and informed patient consent.

Our objective is to disclose on the Clinical Trial Register the trial results for all new products within 10 months of the product reaching the market and to disclose the results of trials completed after a product is approved for marketing within one year of trial completion. In 2006 a small number of postings were delayed for various reasons, including so that publication in scientific journals was not jeopardised.

An independent assessment of documentation processes and procedures used by GSK in populating the Clinical Trial Register has been conducted by an external organisation. We will continue to engage the services of this organisation to ensure that GSK complies with the policies and procedures that we have established to fulfil our commitment to make information from our clinical research activities available to the public.

## PATIENT SAFETY

Ensuring patient safety is extremely important and we take the safety of all our medicines, vaccines and medical devices very seriously.

### Safety of medicines

Medicines are a part of modern life. In an ideal world, a medicine would target only the disease or disorder it's meant to and never do anything else. Unfortunately, despite the best efforts of scientists, such a medicine does not yet exist.

All medicines have potential risks as well as benefits although not everyone who takes a medicine will experience side effects. It is important that we identify, evaluate and minimise safety concerns to ensure that the overall benefits of a medicine outweigh any risks. This is known as pharmacovigilance.

### Monitoring the safety of medicines

The pharmaceutical industry has two major roles in managing the safety of medicines:

1. To collect, investigate and proactively evaluate information relating to side effects of medicines for the purpose of protecting patients and advising on drug safety
2. To fulfil its legal obligations to the regulatory authorities by reporting individual adverse events (AEs) on an expedited basis and/or periodically, according to the drug safety regulations of each country

We strive to ensure patient interest is served through the prompt detection of a potential safety issue with one of our drugs so that appropriate communication with regulators occurs. Following evaluation, decisions can then be made and action taken. See collecting and reporting [safety data](#).

## How do we monitor safety?

An efficient, fully operational, worldwide system for pharmacovigilance is maintained within our company. We have dedicated teams of scientists and healthcare professionals across the world who monitor, review, evaluate and communicate safety issues with our medicines.

The safety of our products is assessed in clinical trials before a product can be approved for marketing. Sometimes adverse events occur after approval when a product is being used by large numbers of patients. We have policies and a governance framework in place to help us detect and act on any adverse events reasonably associated with our products. See drug safety [governance framework](#).

Adverse events are recorded on our global safety database and clinical trial database and investigated by our clinical and pharmacovigilance teams. This helps us to monitor the balance between benefits and risks. See [benefit-risk management](#).

When appropriate, we respond to safety issues by changing product labelling and communicating with doctors. In most cases these actions are sufficient; in a small number of cases we conduct risk minimisation activities, such as further clinical trials. In certain cases it may also be appropriate to stop clinical trials or to withdraw the medicine from the market. See [collecting and reporting safety data](#).

GSK is investing in a number of areas of emerging science that have the potential to improve patient safety, for example, pharmacogenetic research, see sidebar.

### Enhancing the pharmacovigilance system

The science of pharmacovigilance is continually evolving, providing new ways of enhancing the pharmacovigilance framework to the benefit of industry, regulators, healthcare professionals and most importantly patients. To enhance pharmacovigilance GSK recommends that:

- Initiatives are undertaken to increase the quantity and quality of the reporting of possible side effects of medicines by healthcare professionals and patients
- There is a focus on the development of electronic patient records which would permit "real time" access to anonymised data for the detection and evaluation of possible side effects
- Pregnancy registries are established by health care systems to enable the rapid collection and evaluation of data related to possible adverse events, including birth defects
- Research is undertaken to establish the most effective ways to minimise the risks of medicines including effective ways of communicating the benefits and risks of medicines to healthcare professionals and patients

- There is increased harmonisation of pharmacovigilance rules through the rapid and consistent implementation of ICH guidelines by the EU, US and Japan
- An EU Pharmacovigilance Regulation is introduced to streamline and simplify pharmacovigilance reporting requirements in Europe

In order to achieve this it is necessary for the industry and regulators to work together. Safety monitoring is not considered to be a competitive area, since it benefits all parties if carried out to the highest standards. GSK makes new ideas and technology available to other pharmaceutical companies and regulators by presenting at scientific conferences and also by working with third party software suppliers to make new advances accessible to all.