



Our position on Disclosure of Clinical Research



What is the issue?

Transparency is an integral part of conducting research to the highest standards. Sharing information is a crucial part of showing respect to the trial participants and maximising the benefit of their contribution to research and knowledge. It also contributes to ensuring that future patients, trial participants and healthcare professionals can make informed choices about treatments and future research.

In this policy position, we set out our commitments to transparency; and registering and disclosing the results of all human subject research of GSK products.

What is GSK's view?

- We are committed to providing access to information about our research and their results to study participants, patients, healthcare providers and the wider public. Our approach goes beyond what is required by laws and regulations and is built on the following principles:
 - To be transparent about ongoing research, before it begins.
 - To consider how information can be made accessible and shared appropriately with patients and the public.
 - To disclose the results, irrespective of whether they might be perceived as positive or negative.
 - To share information in a way that protects privacy and intellectual property.
 - To promote new research, through the appropriate sharing of trial data.

Our commitments

Our policy commitments are in addition to providing information to regulatory authorities (as part of the product development and approval process) and as part of our ongoing scientific engagement with healthcare professionals through the lifecycle of our products.

For clinical trials and non-interventional research of our products, we post the following on public registers:

- Protocol summaries on public internet registers, before the first subject is enrolled or initiating the study. Registration of ongoing clinical research can help to increase participation and provides an important reference point to track the public disclosure of the results.
- Result summaries, the full protocol, statistical analysis plans and clinical study report synopsis.
- The names of the investigators who participate in our clinical studies.
- For our phase 2-4 clinical trials, we post plain language summaries. We encourage trial investigators to share these with participants and we translate these summaries into the languages of the consent form to ensure they can be read by as many of the trial participants as possible.



As part of maximising the benefit and encouraging new research, we also take several steps aimed at healthcare professionals and the research community:

- Provide access to full Clinical Study Reports on request.
- Enable researchers to request access to anonymised patient level data to conduct further research. These requests are submitted through data sharing portals, with steps in place to protect data privacy and ensure that further research is legitimate and done by qualified researchers.
- Submit manuscripts for publication in peer-reviewed journals. Authorship and acknowledgements for publications follow best practices, including International Committee of Medical Journal Editors criteria. When developing our publications, we consider patients and the public. We aim for clear communication of content, include lay summaries where possible and have an increased focus on open access journals.

We reinforce our commitments by continually assessing our performance. A monthly dashboard of metrics on our transparency activities is maintained as part of our internal business monitoring.

Further information and the posting described above can be found on public registers including: the GSK Study Register, ClinicalTrials.gov and www.trialssummaries.com.