



# Our commitment to clinical data transparency

Being transparent with our clinical trial data helps to advance global scientific understanding and improve patient care. It also helps ensure the important contribution made by people who take part in clinical trials is used to maximum effect in the creation of knowledge and understanding. Recent steps build on our long standing commitment to share the results of our research.

## 2004 **Online Clinical Study Register launches**

Summary information about our clinical trials is available to everyone, in the form of:

-  **Protocol summaries** that describe the research at the start of clinical trials.
-  **Results summaries** describing the outcome of the research whether positive or negative.
- All postings on the Register are additional to efforts to publish the results in peer reviewed scientific journals.

## 2009 **The scope of the Register expands**

In addition to posting all Phase 1–4 clinical trial results, the scope of the Register now includes:

- Results from certain research done outside of the clinic (i.e. observational studies and meta-analyses).
- Information from terminated research programmes. This informs future research and reduces the likelihood of others undertaking unnecessary trials in the future.

## 2011 **GSK introduces specific timelines for disclosing clinical research results**

- Historically our timings for posting research results have been linked with the time of medicine approval, or the decision to stop developing it.
- We now commit to publishing all clinical research results, via the Register and peer reviewed journals, within specific timelines from the completion of clinical studies.

## 2012 **5,000 results summaries**

December

Nearly 5,000 results summaries have been posted onto the Clinical Study Register.

## **11,000 visitors each month**

An average of almost 11,000 visitors to the Register each month.

## 2013 **GSK endorses the AllTrials campaign and commits to publishing clinical study reports (CSRs)**

February

As part of our support for AllTrials, we became the first pharmaceutical company to commit to publishing CSRs. This commitment extends back to the formation of GSK in 2000. CSRs will be published for clinical trials of approved or discontinued GSK medicines<sup>1</sup>. They will be posted onto our Clinical Study Register, with personal information removed to maintain the privacy of research participants.

## May **GSK provides access to anonymised patient-level data**

We are the first pharmaceutical company to launch an online system enabling researchers to request access to the detailed anonymised patient-level data from our clinical trials<sup>1</sup>. Scientists will use this information to conduct further research that could advance medical science and improve patient care.

<sup>1</sup> Studies will be listed on this system once a medicine has been approved by regulators or terminated from development, and after the study has been accepted for publication. Studies that do not progress to publication will also be included.

Find out more about the drug development process, including the different phases of a clinical trial.  
<http://www.gsk.com/research/how-we-discover-new-medicines.html>

### What is a clinical study?

A potential new medicine discovered by R&D scientists will undergo rigorous laboratory tests to prove the case for it to be developed further. If it passes those tests a clinical study programme will then be launched. This is a series of scientific studies in people, designed to measure the safety, efficacy and appropriate dosage of a new drug or vaccine. Clinical studies pass through a number of stages (known as Phases 1–4) which typically progress from initially testing the medicine's safety in a small number of healthy human volunteers, through to trialling the medicine in hundreds and frequently thousands of patients.



### Protocol summaries

Summaries of how clinical studies are planned and organised. They outline the type of study, its objective(s), methodology, time lines and who can participate in it.



### Results summaries

Scientific summaries of clinical study results written in a consistent format. They contain data from the study population but do not include the patient-level data from each research participant.



### Clinical study reports (CSR)

Written study reports that provide more details than our summaries on the design, methods and results of clinical trials. They form the basis of submissions to the US Food and Drug Administration (FDA), European Medicines Agency (EMA) and other regulatory bodies.



### Patient-level data

Detailed data about each individual patient taking part in a clinical trial. Requests for access are reviewed by an independent panel and where approved, access is granted via a secure web site. The data are anonymised to maintain the privacy and confidentiality of research participants.