Case Study

GSK's road to clinical trial transparency

GSK launched its Clinical Study Register website back in 2004 – before clinical trial data transparency was in fashion. The site, which serves as a public register for GSK-sponsored clinical studies, started small but has grown substantially since. Today, it lists 6,835 GSK trials in 185 countries, including over 5,600 result summaries and approximately 230 clinical study reports (CSRs).

The move was a major commitment and took GSK on a path to greater openness. The result summaries include aggregate information and are posted regardless of the outcome of the study.

Yet, for GSK it was not enough and so in 2013, the company launched two important initiatives signalling its commitment to provide even greater access to information from its clinical trials – announcing its support for the AllTrials campaign, committing to publish CSRs for all new studies and existing medicines going back to 2000; and launching a new platform that would allow researchers to request access to the underlying data to conduct further research that can benefit medical science or improve patient care.

This platform expanded to become Clinical Study Data Request which now enables researchers to request data from clinical trials sponsored by GSK as well as Astellas, Bayer, Boehringer Ingelheim, Eisai, Lilly, Novartis, Roche, Sanofi, Takeda, UCB and ViiV Healthcare**.**

Researchers can submit proposals and request anonymised data from clinical studies listed on the site. The research proposals are reviewed by an Independent Review Panel that decides whether to grant access. Since March 2015, the Wellcome Trust has taken responsibility for managing the review of research proposals and operation of the panel.

For all of the sponsors using the site, a total of 119 requests for access to patient level data were made between May 2013 and March 2015. The majority were approved and six were rejected or advised by the Independent Review Panel to re-submit.

Some sponsors allow researchers to submit enquiries to ask about the availability of data from studies not listed on this site**.** For example, GSK received 127 enquiries for access to data from studies not available on the platform. Some 102 of these were approved and these studies can then be included as part of a research proposal submitted to the Panel. The reasons some enquiries for non-listed studies have been declined include prohibitive costs for studies before 2000 or because GSK does not have the legal authority to provide the data.

"Increasing transparency is a critical area we've been pursuing at GSK for a decade," Robert Frost, Policy Director, Medical Policy at the office of GSK's Chief Medical Officer. "The system we launched enabling researchers to request access to data was intended as a first step toward a broad, independent system that brings together data from across the research community."

GSK's commitment to disclosure is here to stay, with more data shared every month. The journey may have started over a decade ago but this is just the beginning.

"We believe this strengthens trust in clinical research through enhanced openness and transparency," says Frost.