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GSK to publish clinical study reports of drugs

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Singapore: Demonstrating its commitment to clinical trial transparency, multinational pharmaceutical company GlaxoSmithKline has announced its support for the AllTrials campaign.

The campaign is calling for registration of clinical trials and the disclosure of clinical trial results and clinical study reports (CSRs) to help drive further scientific understanding. A press release issued by the company states that GSK is committing to make CSRs publicly available through its clinical trials register. CSRs are formal study reports that provide more details on the design, methods and results of clinical trials and form the basis of submissions to the US Food and Drug Administration (FDA), European Medicines Agency (EMA) and other regulatory agencies.

From now, GSK will publish CSRs for all of its medicines once they have been approved or discontinued from development and the results have been published. This is to allow for the data to be first reviewed by regulators and the scientific community.

The company will ensure patient confidentiality by removing all patient data in the CSRs and their appendices. In addition, the company also intends to publish CSRs for clinical outcomes trials for all approved medicines dating back to the formation of GSK. This will require retrieval and examination of each historic CSR to remove confidential patient information. Given the significant volume of studies involved, the company will put in place a dedicated team to conduct this work which it expects to complete over a number of years. Posting will take place in a step-wise manner, with priority given to CSRs for its most commonly prescribed medicines.

"We are committed to being transparent with our clinical trial data to help advance scientific understanding and inform medical judgment. Our commitment also acknowledges the very great contribution made by the individuals who participate in clinical research. All those involved in the conduct and publication of clinical research, whether healthcare companies like GSK, academia or research organizations, have a role to play in ensuring that the data they generate are made publicly available to help bring patient benefit,"said Mr Patrick Vallance, president, Pharmaceuticals R&D, GlaxoSmithKline.

In October 2012, GSK had announced that it would develop a system where researchers will be able request access to detailed anonymised patient level data that sit behind the results of clinical trials to enable additional scientific inquiry and analyses to help further scientific knowledge.