Lack of voluntary data sharing from industry-funded clinical trials

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In a study appearing in the June 28 issue of *JAMA*, Isabelle Boutron, M.D., Ph.D., of Paris Descartes University, Paris, and colleagues investigated the proportion of randomized clinical trials (RCTs) registered at ClinicalTrials.gov that were listed at the Clinical Study Data Request website, where companies voluntarily list studies for which data can be requested.

Access to individual patient-level data from clinical trials could be an important step forward in clinical research. Some pharmaceutical companies have committed to share such data. The largest repository is the Clinical Study Data Request (CSDR) website. To evaluate the completeness of data sharing on CSDR, the researchers studied all drugs other than vaccines listed on CSDR by all sponsors actively involved in data sharing, defined as listing at least 100 studies in June 2014.

For the 61 targeted drugs from 4 sponsors (drugs: Roche, 13; Lilly, 3; Boehringer Ingelheim, 5; GlaxoSmithKline [GSK], 40), 966 RCTs (462,751 participants) registered at ClinicalTrials.gov were identified; 512 RCTs (53 percent) (342,271 participants; i.e., 74 percent of the participants involved in these studies) were listed at CSDR. Records for 385 RCTs (40 percent) reported that all documents were available. The proportion of registered trials listed on CSDR varied from 33 percent for Roche to 66 percent for GSK and trials with all information available from 24 percent for Boehringer Ingelheim to 58 percent for GSK.

"Despite a delay of 18 months since the completion of drug trials by the

company sponsor, only 53 percent of the RCTs from the 4 sponsors registered at ClinicalTrials.gov were listed at CSDR, with differences between sponsors. Data were available for a large number of participants, but an equally large amount of data was not available," the authors write.

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