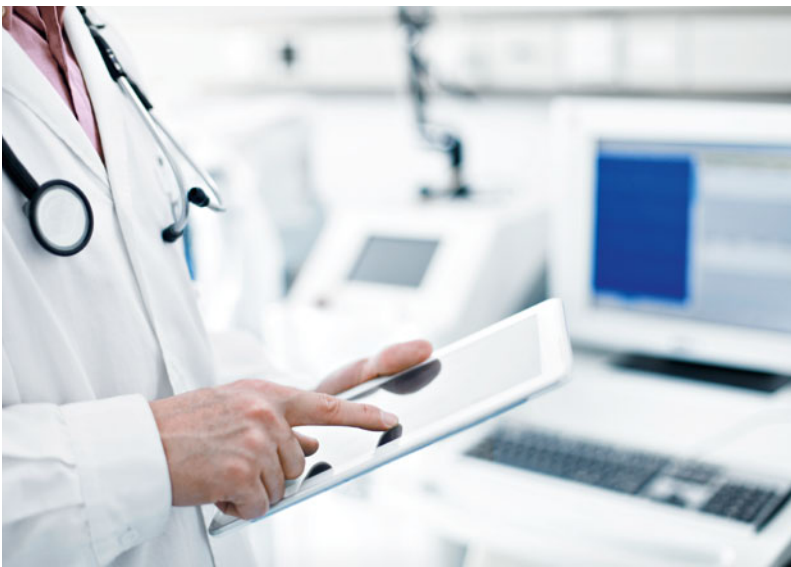


TRANSPARENCY INITIATIVE: BAYER DISCLOSES DATA FROM CLINICAL TRIALS

Transferring knowledge

Science depends on networks: to be able to efficiently develop new drug products, researchers rely on information from their colleagues working in related therapeutic areas. Bayer HealthCare is therefore now providing access to anonymized patient data from its clinical trials on an online platform in support of a new transparency initiative.



Valuable findings: the data that doctors derive from clinical trials have to be carefully evaluated. The new online platform now allows scientists access to anonymized source data of clinical trials.

Clinical trials are an important stage on the road to a new drug product: they can provide scientific evidence that the new treatment is effective and safe for patients to use in a specific indication. But the massive pile of data collected during a clinical study may also contain valuable information for other scientists working in related therapeutic areas. Bayer HealthCare is now supporting an exchange of such information by providing access to anonymized patient data on the online platform www.clinicalstudydatarequest.com, in compliance with the terms of an agreement of the European Federation of Pharmaceutical Industries and Associations EFPIA and its counterpart in

the United States PhRMA. "We hope that this transparency initiative will generate knowledge that will facilitate innovative therapeutic approaches or allow reevaluation of existing treatments," explains Dr. Johann Brüning, Head of Clinical Trial Transparency at Bayer HealthCare.

Expert committee decides which data are released

Following the completion of every clinical study, physicians and scientists evaluate the compiled data thoroughly to determine the efficacy and safety of the drug product for future patients. Summaries of these findings are available in public

databases on Bayer's homepage and on the website of the U.S. health authorities. Both websites also contain information about ongoing and planned clinical trials.

The database now launched is the product of an initiative by several pharmaceutical companies in 2014. For the first time, Bayer scientists are sharing more than just their clinical trial results: "We will also make the anonymized source data of our assessments available, for our drug products that have been granted regulatory approval in Europe and the United States from 2014 onwards," explains Brüning. The trial protocols and detailed result reports will also be provided.

Anybody interested in the data can register on the website to view a list of available studies and propose research projects for specific studies. An independent expert committee of international scientists decides which data may be made accessible to third parties and which research projects will be supported with these data. "We have to make sure that the patient data are handled responsibly," explains Brüning. It's an effort that is extremely worthwhile from the perspective of the companies that are involved to date - and one that will help to make new treatments available to patients worldwide more efficiently and quickly.

 www.research.bayer.com/clinicaltrials
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