German scientists develop a dashboard to ensure transparency for clinical trials

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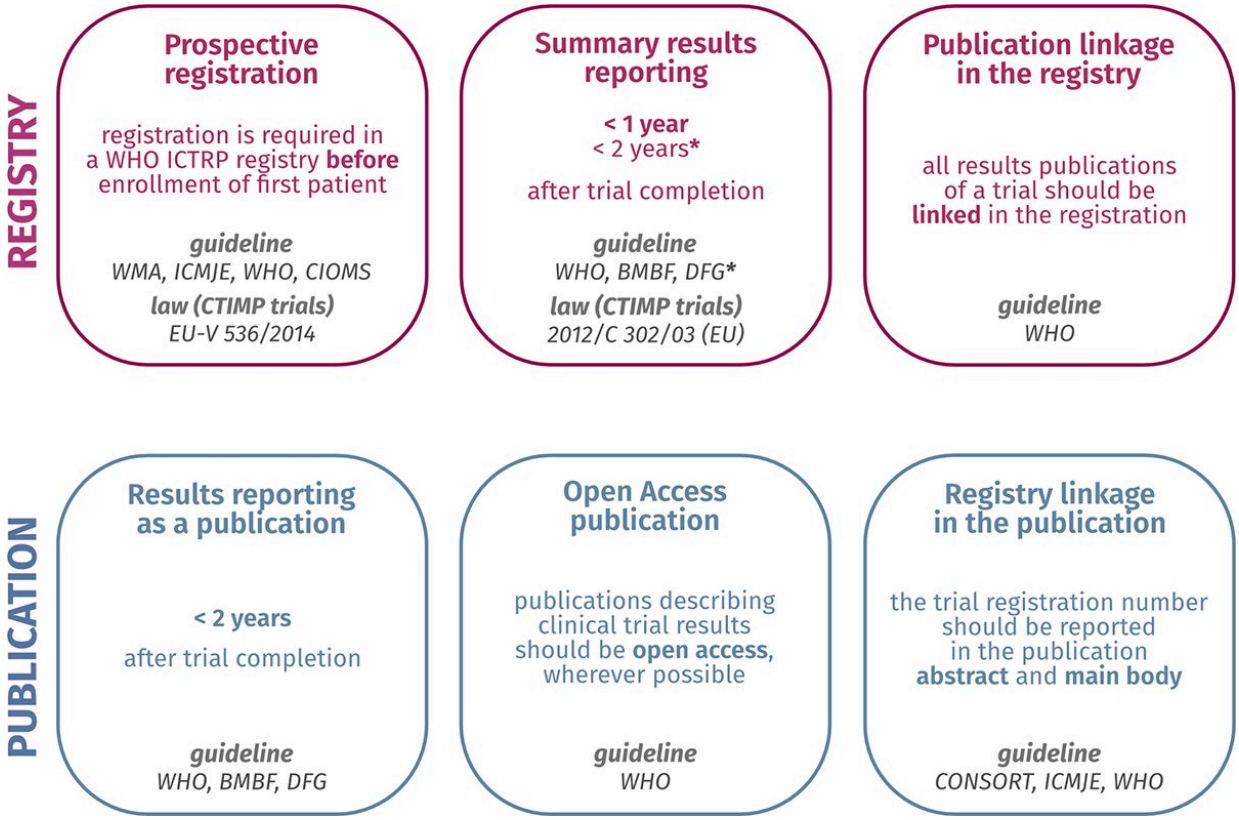

Overview of the clinical trial transparency practices included in the dashboard. Relevant guidelines and/or laws are provided for each practice (as of November 2022). A list of references can be found in S4 Supplement. An adaptation of this overview is included in the “Why these practices?” page of the dashboard. *DFG: According to the DFG guidelines at the time of writing, summary results should be posted in the registry at the latest 2 years after trial completion, or earlier if required by applicable legal regulations. BMBF, Bundesministerium für Bildung und Forschung; CIOMS, Council for International Organizations of

Medical Sciences; CONSORT, Consolidated Standards of Reporting Trials; CTIMP, Clinical Trial of an Investigational Medicinal Product; DFG, Deutsche Forschungsgemeinschaft; ICMJE, International Committee of Medical Journal Editors; ICTRP, International Clinical Trials Registry Platform; WHO, World Health Organization; WMA, World Medical Association. Credit: *PLOS Medicine* (2023). DOI: 10.1371/journal.pmed.1004175

Clinical trials are the backbone of evidence-based medicine. This is where new drugs and treatments are tested on humans for the first time. The results of such trials are therefore highly relevant. But unfortunately many clinical trial results from German universities are not published at all or are registered too late—and if they are published, the results are often not openly accessible.

To change this, scientists at the BIH QUEST Center have developed a publicly accessible dashboard that displays how 35 German universities fare in terms of transparency of the clinical trials they have conducted. A total of some 3,000 clinical trials were evaluated for this purpose.

The scientists have now published their methodology and results in *PLOS Medicine*.

Clinical trials test whether a new procedure or drug is safe, effective, and better than previous therapies. The results of the trials are therefore highly relevant: If a new substance or procedure proves to be better than the standard treatment, it will then usually go through an extensive approval process before entering the market. If this is not the case, the new alternative treatment is often forgotten.

A good quarter of the clinical trials conducted at universities and hospitals in Germany don't publish any results even many years after the

study is completed—despite existing transparency rules such as those in the Declaration of Helsinki, which are morally binding on physicians. As a result, all other scientists and physicians fail to learn whether a particular medical intervention has already been tested or whether a further analysis of the trial results might be worthwhile because it would have revealed benefits for a subgroup of patients.

Daniel Strech, BIH Professor for Translational Bioethics and Deputy Director of the BIH QUEST Center, found this situation unsatisfactory. "Patients have agreed to participate in clinical trials in order to advance science and medicine. We are obligated to them to publish the trial results," he argues. "But also from an ethical perspective, it is at least problematic not to disclose results of trials that were paid for with taxpayer money."

Transparency of study results in a public dashboard

Together with his team at the Berlin Institute of Health at Charité (BIH), he decided to address this issue. "We collected information on about 3,000 clinical trials that were listed in one of two established registries and conducted at one of the 35 university medical centers in Germany," reports Delwen Franzen, a research fellow in Strech's group and first author of the paper.

"We were above all interested in data related to transparency: Did the principal investigator publish the trial results? Was the trial registered before it started? Did the registry indicate that the trial results had been published? Were the results made publicly available?"

A dashboard now presents the results on the various transparency indicators for Germany as a whole as well as for individual universities. "The last few years have shown that public information on clinical trial transparency can have a major impact," reports Strech.

"Another publicly accessible website, created by colleagues at Oxford University, has for three years been providing information on the transparency of drug trials listed in the relevant EU registry. Here Charité fared poorly, landing toward the bottom of the pack. After we discussed this with the Charité Clinical Study Center, and an improvement process was launched there, a marked increase in transparency could be observed: Charité has now risen to the top of the pack, publishing the results of 97 percent of its clinical trials. We were very pleased to see that."

Transparency as a pillar of evidence-based medicine

This is because, surprisingly, university medical centers themselves often don't know exactly how many of their clinical trials are transparently registered and published. Nor do the funding agencies know the publication rate of the trials they fund. "We are confident that the information provided by our dashboard will make a difference for the better at all university medical centers," explains Franzen.

That has also caught the attention of colleagues abroad. A number of European and American colleagues now want to introduce similar dashboards, explains Strech. "During my sabbatical last year at Stanford University, I was able to convince my colleagues there to implement our concept in the U.S. as well," he says. Strech is convinced that publishing clinical trial results is worthwhile: "Clinical studies are the backbone of evidence-based medicine. And transparency keeps this backbone healthy."

More information: Delwen L. Franzen et al, Institutional dashboards on clinical trial transparency for University Medical Centers: A case study, *PLOS Medicine* (2023). DOI: 10.1371/journal.pmed.1004175

Provided by Berlin Institute of Health in der Charité (BIH)