I would like to clarify a few points made in a recent news article about clinical trial registration (1).

First, the article states that the National Cancer Institute’s Physician Data Query (PDQ) clinical trials registry and NIH’s ClinicalTrials.gov registry “share all data from cancer trials submitted to either database.” However, readers should be aware that both registries receive clinical trial information that is not made available to the public, and such information is not shared between the registries. In addition, PDQ and ClinicalTrials.gov each generate internal administrative data related to submitted trials, and this information is also not shared.

Second, although it is true, as the article suggests, that registration of clinical trials—including NCI-sponsored trials—in PDQ is strictly voluntary, NCI is not exempt from the registration requirements specified under the FDA Modernization Act (FDAMA) of 1997. NCI-sponsored clinical trials of drugs to treat serious or life-threatening conditions (i.e., cancer-related conditions) that are conducted under an FDA Investigational New Drug (IND) Application must be registered in ClinicalTrials.gov. PDQ serves as the principal conduit through which NCI-sponsored trials are submitted to ClinicalTrials.gov. The current FDA guidance related to FDAMA permits intermediaries (e.g., PDQ) to submit clinical trial data to ClinicalTrials.gov on behalf of a sponsor (e.g., NCI’s Divisions and Cancer Centers).

Finally, the article states that “four pharmaceutical industry organizations—the European Federation of Pharmaceutical Industries and Associations, the International Federation of Pharmaceutical Manufacturers and Associations, the Japanese Pharmaceutical Manufacturers Association, and the Pharmaceutical Research and Manufacturers of America … promised that all clinical trials, except for exploratory trials, would be registered in a database such as ClinicalTrials.gov within 21 days of the start of patient accrual.” It is important to note that pharmaceutical companies that are testing treatments for serious or life-threatening diseases in phase II or higher trials under an FDA IND do not have a choice of which clinical trial database in which to register their trials: Under FDAMA, these trials must be registered in ClinicalTrials.gov. Furthermore, the 21-day time frame was established not by the pharmaceutical industry organizations but by Congress in section 113 of FDAMA [42 USC 282(j) (3)].

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Reference


Notes

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