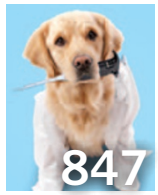

841

Home schooled:
Over-the-counter test offers in-home HIV diagnosis


843

Weight watchers:
A timeline of antiobesity drugs in the US


847

A zoo out there:
A new species-spanning approach to biomedical research

Clinical trial website struggles to serve as research data hub

It's been 15 years since the US government mandated the creation of ClinicalTrials.gov, and the registry website has hit some growing pains in its teens. The web portal—a crucial resource for physicians wanting to place a patient in a trial or researchers doing meta-analyses on drug effectiveness—struggles to get researchers to report results and is being outshone by more dynamic trial-recruitment sites run by patient advocacy groups. Now, new legislation has been proposed to institute harsher penalties for failing to upload the outcomes of certain types of trials in the registry.

A report published earlier this year found that only 22% of the 738 registered trials on the website that wrapped up in 2009 and were required to report results within a year actually did so (*BMJ* **344**, 7373–7379, 2012). The US Food and Drug Administration (FDA) maintains that the study overestimated noncompliance, based on data only the agency has access to, but criticisms continue. In May, an editorial published in the *Journal of the American Medical Association* deemed the registry to be "coming up short" on the requirements for data collection, as stipulated in the FDA Amendments Act of 2007 (*JAMA*, **307**, 1861–1864, 2012).

In the same issue of *JAMA,* an analysis by a group that includes Deborah Zarin, director of ClinicalTrials.gov and assistant director for clinical research projects at the US National Library of Medicine in Bethesda, Maryland, paints a rosier picture of progress. For instance, the percentage of trials not reporting either enrollment number or type decreased from 34% between October 2004 and late 2007 to less than 2% between late 2007 and September 2010. However, the same paper also found that the proportion of studies that lacked information about their primary objectives inched up from around 5% to nearly 7% over the same time period (*JAMA*, **307**, 1838–1847, 2012).

Individuals concerned about missing data in ClinicalTrials.gov say better enforcement of the current regulations, as well as harsher penalties for failing to follow regulations, could make a difference. Currently, "penalties are tiny and not enforced," says Kay Dickersin, director of the Center for Clinical Trials at Johns Hopkins University Bloomberg School of Public Health in Baltimore and coauthor of the *JAMA* editorial.

Roxanne Khamsi

Tangled web: Proposed legislation would harshen penalties for failing to update ClinicalTrials.gov.

Last month, Congressman Tom Reed, a Republican from New York, introduced legislation in the US House of Representatives that would oblige all clinical trials to register and report results regardless of whether the outcome of the trial was positive or negative—not just those related to drugs approved by the FDA, as currently required. The proposed bill would also revoke federal funds from applicants that failed to comply and deem them ineligible from receiving future federal grants until they complied with the regulations.

Zarin, for her part, told *Nature Medicine* that the US Department of Human Health and Services is currently in the process of developing proposed additional regulations that it plans to make available for public comment this month.

Impatient patients

To ensure their members have the most up-to-date information, some patient advocacy groups and nonprofit organizations have already taken matters into their own hands, creating disease-specific registries that help people with specific disorders find trials to enroll in. For example, the Alzheimer's Association runs a portal called TrialMatch, and the Michael J. Fox Foundation for Parkinson's Research recently launched its Fox Trial Finder to match patients with Parkinson's to trials.

"We didn't feel that ClinicalTrials.gov was meeting our needs of wanting to increase the number of people in trials," says William Thies, chief medical and scientific officer of the Alzheimer's Association, based in Chicago. The disease advocacy group uses ClinicalTrials.gov to populate its own registry, he explains, but follows up with the trials to make sure the data are accurate and up to date. TrialMatch also includes smaller trials that aren't listed in ClinicalTrials.gov.

Thies doesn't see TrialMatch or other trial registries as taking over from ClinicalTrials.gov, but rather as being supplementary, providing information that is beyond the scope of the government-run site. "The size of ClinicalTrials.gov would make it difficult for patients to navigate," he says, "so we've tried to add a user-friendly front end."

Ultimately, improving ClinicalTrials.gov is in everyone's best interest, says Andrew Prayle, the lead author of the *BMJ* study and a clinical research fellow at the University of Nottingham in the UK. Clinical trial registries prevent the duplication of clinical research, enable meta-analyses and prevent suppression of trial results, he argues.

"Registries are improving," he notes, "but if progress is halted, the goal of a fully transparent and open medical literature and the resulting benefits for evidence-based medicine will not be achieved."

Monica Heger