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'No More Boutique Studies': NIH Mulls 'Stopping Rules,' Other Changes to Improve Clinical Trials

By Theresa Defino

At some point in the future, NIH may halt funding for clinical trials deemed too underpowered to produce meaningful findings or that fail to meet enrollment goals. To do this, the agency would have to adopt so-called “stopping rules,” which is among the recommendations of a task force that spent two years studying NIH’s “stewardship” of clinical trials.

The recommendations were presented to the NIH Advisory Committee to the Director (ACD) during its most recent meeting; members did not vote on them. However, acting NIH Director Larry Tabak signaled his support for the concept.

NIH officials will need “the discipline to stop supporting underpowered boutique studies, which, quite frankly, many investigators around the country have built and sustained their careers on,” Tabak said. “We’re going to have to strike a better balance because the resources have to come from somewhere.”^[1]

Before offering the recommendations, Debara Tucci, M.D., co-chair of the task force, presented data on NIH trials, some of which was gathered from ClinicalTrials.gov.^[2] The committee also discussed the problem of timely filing of trial results on the website,^[3] and the confirmation process for the new NIH director nominee.^[4]

Tucci, also director of the National Institute on Deafness and Other Communication Disorders, noted that “about 40% of NIH’s annual budget supports clinical research.” More than \$6 billion of NIH’s \$18 billion annual expenditures for “clinical research goes to clinical trials.” NIH is funding fewer clinical trials testing treatments and drugs, with increased support being devoted to “prevention” and “behavioral” studies, according to Tucci’s presentation.

Treatment Trials See Big Drop

Looking just at NIH data for those trials on ClinicalTrials.gov, in 2005, the purpose of more than 70% of NIH-funded trials was “treatment,” according to bar graphs Tucci presented. Although treatment trials remain the largest type that NIH funds, by March of this year, the percentage had tumbled to approximately 46%.

Meanwhile, the percentage of basic science trials has increased from about 3% in 2005 to about 9% this year. Prevention studies increased slightly during this period, from about 12% to 15%. Health service research saw a jump from about 1% to approximately 8%.

The decline in treatment trials was concerning to ACD member Wafaa El-Sadr, M.D.

“I’m a little bit worried that [we] may be drifting away or shift[ing] away from that very fundamental role for NIH and really answering the big questions,” she said. “NIH is the only real entity that supports these types of trials.” El-Sadr is the founder and director of the International Center for AIDS Care and Treatment Program and a professor at Columbia University Mailman School of Public Health.

Tucci acknowledged she found the shifts “surprising,” saying, “That’s the reason I presented those data.”

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