* [LOGIN](https://www.scienceboard.net/login?return_url=https://www.scienceboard.net/content//)

Top of Form



Bottom of Form

[SciPulse Insights: The Science Advisory Board blog](http://www.scienceboard.net/content)

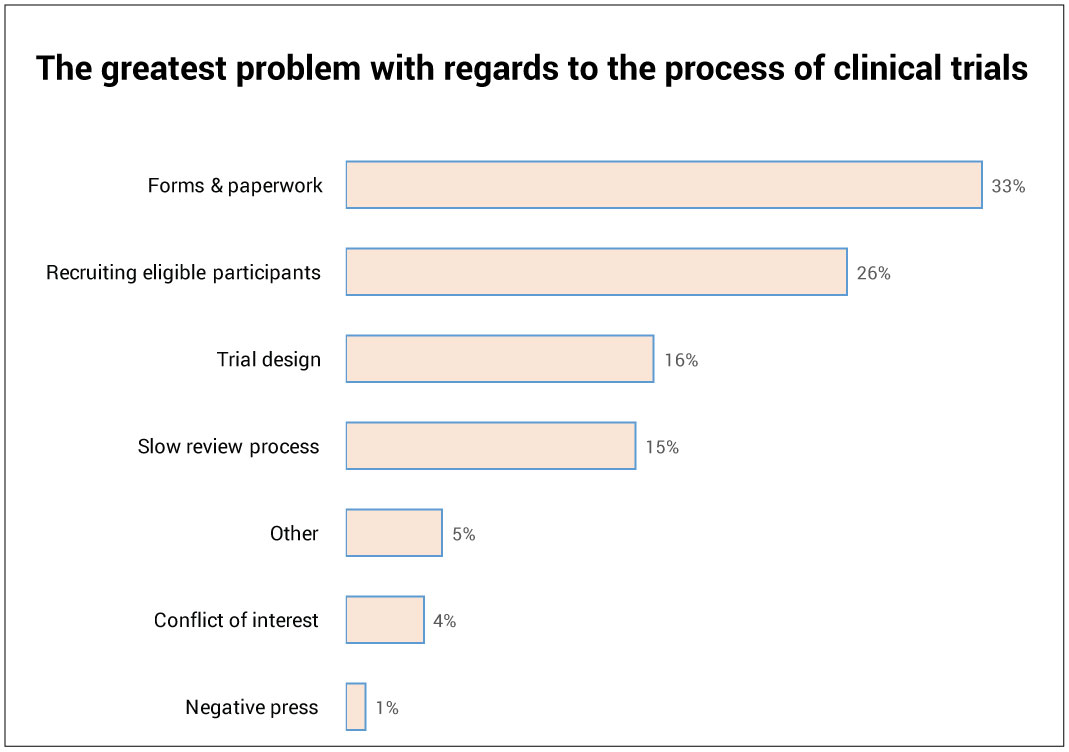
Scientists highlight the flaws of clinical trials

posted by [The Science Advisory Board](javascript:void(0);), May 24, 2016

New data from the 2016 Clinical Trial Overview (CTO), an opinion study of 1,000 published clinical trial scientists conducted by The Science Advisory Board, highlights flaws in the process of clinical trials from an insider’s perspective. To provide additional context, study participants were offered an opportunity to view and provide commentary on the survey results.

The CTO study shows that a majority of scientists working in clinical trials (77%) are generally satisfied with the overall process, although many bring up important issues that affect the clinical trial process — and possibly the results.

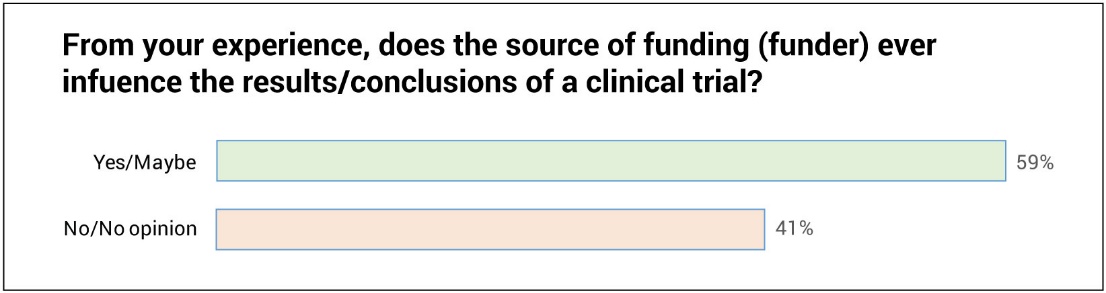
The problem most often cited by clinical trial scientists face (selected by 34% of participants) is the inefficiency, redundancy, and inter-agency incompatibility of the paperwork required to initiate, conduct, file, and submit trial results. *“Not a surprise,”*says Radwa Aly, M.Sc. (PhD Candidate Clinical Research, George Washington University Medical Center). *“The regulatory process of clinical trials could be much more efficient if the forms that are standard across all trials were kept in a centralized location.”*Over one third of CTO participants reported having to create multiple submissions to agencies for the same trial. Requirements for approval of new medicines vary between agencies causing redundancy in paperwork.

[](https://www.scienceboard.net/content/wp-content/uploads/2016/05/Greatest-problem1.jpg)

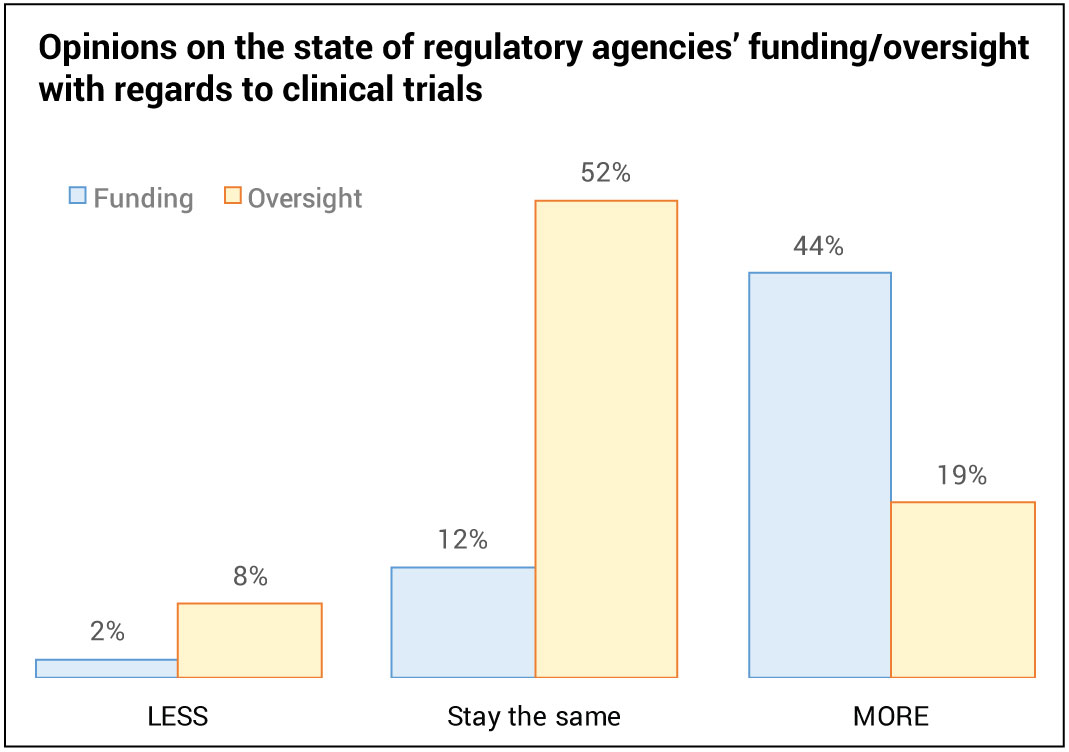
Recruiting eligible participants is the second most cited problem for scientists working in clinical trials (selected by 26% of participants). *“Finding subjects meeting inclusion and exclusion criteria as stated in protocols and abiding by FDA guidelines could delay the results of clinical research programs by years,”*noted Richard A. Guarino, M.D. (Vice President Medical & Regulatory Affairs, Validus Pharmaceuticals, LLC.).

A majority of participants (57%) think that the diversity of participants in clinical trials does not adequately represent the target patient population. Although a significant proportion of respondents reported this concern, Jed Gorlin, M.D. (Pathologist, Innovative Blood Resources), shares that, *“while it is unlikely that trial participants completely reflect the public in general, there is very little objective data to demonstrate that this disconnect has great clinical impact.”*

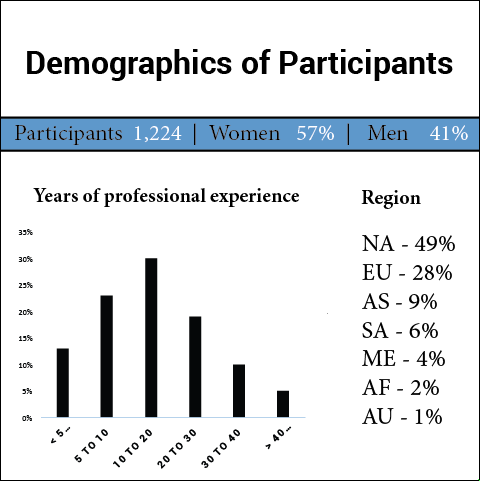
A majority of participants (59%) also reported that the source of funding has, or might have, influenced the results of a clinical trial they worked on. Richard A. Guarino, M.D. suggests that, *“those that answered “maybe” might be mis-informed. That is why they gave an unconditional answer*.” Sameh Emile, M.D. (Staff Member, General Surgery, Mansoura Faculty of Medicine) has a contrasting view and thinks that, *“we can count their answer of ‘maybe’ as a shy yes.”*

[](https://www.scienceboard.net/content/wp-content/uploads/2016/05/Funder-clinical-trials2.jpg)

While it can be tempting to criticize the U.S. Food & Drug Administration (FDA) or other regulatory agencies for concerns raised by this study, interestingly, only 2% of respondents believe that regulatory agencies should receive less funding.Loren Gorgol, M.Sc. (Research Project Manager, Geisinger Medical Center) agrees with the results and reminds us that, *“the FDA’s role in research throughout the years has come a long way and has gone through some rough patches. I think where it is now is a good place.”*

[](https://www.scienceboard.net/content/wp-content/uploads/2016/05/regulatory-agency1.jpg)

Commenting on the study results, Larry Miller, Ph.D. (Executive Director of The Science Advisory Board) found it interesting that a majority of participants feel that the clinical trial process is generally satisfactory. He adds that,*“given high regulatory hurdles and inherent complexity, one might have expected more calls for reforms.”*

[](https://www.scienceboard.net/content/wp-content/uploads/2016/05/Screen-Shot-2016-05-24-at-11.38.11-AM.png)

To collect opinions for the Clinical Trial Overview survey, The Science Advisory Board invited scientists who have published work on ClinicalTrials.gov to complete an online questionnaire. This research yielded over 1,000 responses during the first quarter of 2016. The survey does not include the opinion of scientists who have not been published on[ClinicalTrials.gov](https://clinicaltrials.gov/ct2/resources/trends) . Opinions expressed in the CTO study, or reported within this release, were those solely of the participants. The Science Advisory Board, or its sponsor, BioInformatics, LLC, do not endorse or refute the findings from the CTO. For additional information regarding this study, contact Quentin Kreilmann ([q.kreilmann@scienceboard.net](mailto:q.kreilmann@scienceboard.net)) or Sunny Piya ([s.piya@scienceboard.net](mailto:s.piya@scienceboard.net)).

* **[https://www.scienceboard.net/content/wp-includes/images/widget_images/twitter.png](https://twitter.com/scienceboard)**
* **[https://www.scienceboard.net/content/wp-includes/images/widget_images/facebook.png](https://www.facebook.com/ScienceAdvisoryBoard)**
* **[https://www.scienceboard.net/content/wp-includes/images/widget_images/linkedin.png](https://www.linkedin.com/groups/Science-Advisory-Board-700687)**
* **[https://www.scienceboard.net/content/wp-includes/images/widget_images/pinfeed.png](https://www.pinterest.com/scienceadvboard/)**
* **[https://www.scienceboard.net/content/wp-includes/images/widget_images/rss.png](https://www.scienceboard.net/content/feed/)**

Top of Form

* 
* 
* 
* 

Bottom of Form

**Recent Posts**

* [**Scientists highlight the flaws of clinical trials**](https://www.scienceboard.net/content/scipulse-perspectives/scientists-highlight-flaws-in-the-process-clinical-trials/)
* [**Vitamin D**](https://www.scienceboard.net/content/article/vitamin-d/)
* [**Zika Virus**](https://www.scienceboard.net/content/article/zika-virus/)
* [**Iceman: the Wim Hof method**](https://www.scienceboard.net/content/article/iceman-the-wim-hof-method/)
* [**Mind over health, the placebo effect**](https://www.scienceboard.net/content/article/mind-over-health-the-placebo-effect/)

**Archives**

* [**May 2016**](https://www.scienceboard.net/content/2016/05/)
* [**March 2016**](https://www.scienceboard.net/content/2016/03/)
* [**February 2016**](https://www.scienceboard.net/content/2016/02/)
* [**January 2016**](https://www.scienceboard.net/content/2016/01/)
* [**December 2015**](https://www.scienceboard.net/content/2015/12/)
* [**November 2015**](https://www.scienceboard.net/content/2015/11/)
* [**October 2015**](https://www.scienceboard.net/content/2015/10/)
* [**September 2015**](https://www.scienceboard.net/content/2015/09/)
* [**August 2015**](https://www.scienceboard.net/content/2015/08/)
* [**July 2015**](https://www.scienceboard.net/content/2015/07/)
* [**June 2015**](https://www.scienceboard.net/content/2015/06/)
* [**May 2015**](https://www.scienceboard.net/content/2015/05/)
* [**April 2015**](https://www.scienceboard.net/content/2015/04/)
* [**March 2015**](https://www.scienceboard.net/content/2015/03/)
* [**February 2015**](https://www.scienceboard.net/content/2015/02/)
* [**January 2015**](https://www.scienceboard.net/content/2015/01/)
* [**December 2014**](https://www.scienceboard.net/content/2014/12/)
* [**November 2014**](https://www.scienceboard.net/content/2014/11/)
* [**May 2014**](https://www.scienceboard.net/content/2014/05/)

Copyright 2014 - [Privacy](http://support.scienceboard.net/hc/en-us/articles/201836495-Privacy-Policy) - [Terms of Service](http://support.scienceboard.net/hc/en-us/articles/201836465-Terms-of-Service) - [Contact Us](http://support.scienceboard.net/hc/en-us/requests/new)