Optimizing Clinical Trials for Patients with Chronic Disease

OMB 0925-0648
Exp.: 06/2024

The *Optimizing Clinical Trials for Patients with Chronic Disease* workshop workshop will identify areas of improvement in planning better clinical trials and will consider the key factors that are critical to a successful trial, including patient and stakeholder engagement, pre-trial analysis of the study population and landscape, with a focus on better planning and achieving optimal recruitment.

We are contacting you as a registrant for the purpose of gaining useful insight for framing content and areas for workshop discussion. The following questions should take approximately 20 minutes of your time. Thank you in advance for any and all feedback.

Responses to this survey are optional and you may exit it at any time.

Attendee Organization and Role Information

1. Please choose the category that best describes your organization:

- ○ University
- ○ Industry
- ○ Federal Agency
- ○ Community Organization (Foundation, Service Organization, Advocacy Group)
- ○ Other - Write In

2. Please choose one or more categories that best describes your relevant role in context of this workshop:

- ○ Trial Investigator
- ○ Trial Coordinator
- ○ Trial Methodologist (including operations)
- ○ Trial Funder (including program officer)
- ○ Community Engagement Expert
- ○ Community Leader or Key Informant
- ○ Funder
- ○ Other - Write In

3. For projects in which you have personally participated (lead or collaborator), please indicate the number of:

Grants successfully funded to support a clinical trial? (to understand how many people design their own trials) (0-N)

Industry sponsored trials as a participating site? (to understand how many people run protocols designed by industry) (0-N)

Investigator-initiated, grant funded trials as a participating site? (to understand # people who participate in NIH funded trials as a participating site) (0-N)

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Attendee Perspective on Trial Barriers Related to Participant Engagement, Recruitment, and Retention

4. Based on your experience, please indicate the level of difficulty you've encountered around these common barriers to conducting successful NIH/NIDDK clinical trials (Please indicate 0-10 for each item for its difficulty, 0 easy, 10 most difficult):

0	1	2	3	4	5	6	7	8	9	10
○	○	○	○	○	○	○	○	○	○	○

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Attendee Perspective on NIH (specifically NIDDK) Program Interaction

5. How difficult Is it to contact someone at NIH (specifically NIDDK) to discuss a clinical trial idea while you are in the planning stage? (scale 1-10, 1 easiest, 10 most difficult)

0	1	2	3	4	5	6	7	8	9	10
○	○	○	○	○	○	○	○	○	○	○

6. What would you suggest to optimize NIH (specifically NIDDK) early phase trial ideation and planning discussions? (Indicate all that apply)

- ☐ Improved staff directory with targeted areas of interest
- ☐ More robust FAQs
- ☐ Grants management assistance
- ☐ Other - Write In

7. Have you found the NIDDK points of contacts listed in the clinical trial program announcements helpful? (Y/N)

- ○ Yes
- ○ No

8. Are you aware of NIH tools and resources for assistance in planning clinical trials? Y/N

- ○ Yes
- ○ No

9. Do you have suggestions for improvement of current tools?

10. Were there barriers to use that you can share?

11. Are there tools you think NIH could supply that would be helpful?

Attendee Conference Motivation

12. What do you hope to learn OR contribute by attending this workshop?

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Trial Metrics

13. Are you aware of current NIH policy requiring the reporting of "final results" of a clinical trial in ClinicalTrials.gov within 365 days of "primary results reporting"? https://grants.nih.gov/policy/clinical-trials/reporting/understanding/nih-policy.htm Summary results of NIH-supported clinical trials be submitted to ClinicalTrials.gov within 365 days of the actual primary completion date.

- ○ Yes
- ○ No

14. As above, current NIH and ClinicalTrials.gov policy include studies that were terminated early as well as studies that completed their original goals as "primary results reporting." Do you think it is important to the research community to include a separate metric for assessing how many clinical trials definitively met their goals (sufficiently to answer the primary research question

- ○ Yes
- ○ No

15. Which of the following best describes your attitude about clinical trials that did NOT provide a definitive answer to the primary study question (ie, "failed trials", as opposed either yes the intervention made a difference "positive trial", or no the intervention did not make a difference "negative trial"). Choose all that apply.

- ☐ Such trials effectively wasted taxpayer money, participant time and effort, and should be avoided/minimized as aggressively as possible.
- ☐ Such trials are an unavoidable part of the nature of clinical trials, and efforts to address them would be misguided.
- ☐ "Failed trials" are a significant disincentive to enrolling patients.
- ☐ Other - Write In

16. How important do you think it is to indicate whether clinical trials provided a definitive answer (yes or no) to the primary study question (ie the primary powered outcomes)? 1-10, 1 least, 10 most important.

1	2	3	4	5	6	7	8	9	10
○	○	○	○	○	○	○	○	○	○

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