



The Clinical Trials Transformation Initiative
CTTI Project: ClinicalTrials.gov

In-Depth Interview QUESTION BANK
FINAL: August 14, 2021

Introduction

Thank you for speaking with me today. Before we begin the interview, I'd like to tell you more about the project.

The Clinical Trials Transformation Initiative, otherwise known as CTTI, is interested in describing challenges facing responsible parties—or their delegates—in registering applicable clinical trials and submitting results information and efforts at your institution/organization to ensure the quality of submissions. We also want to learn about potential solutions or existing practices that have helped or could help to address those challenges. The goal of this study is to provide information to support and strengthen more complete reporting of clinical trial information to ClinicalTrials.gov.

Section 1: Information about the study

In this interview I'll ask you questions about your experiences with registering clinical trials and reporting results information into ClinicalTrials.gov.

Please know that there are no right or wrong answers to the questions I'll ask, only opinions. Please feel free to share your candid thoughts. You are the expert here, and there is no one else we can ask to get the unique information that you can tell me about your experience. We will not share your name or company's name when we describe the result of this study.

Do you have any questions for me so far about the interview?

If you agree, I would like to audio record the interview because I want to make sure I don't miss any of your comments. If you prefer for the interview to not be audio recorded, I will take detailed notes during the interview instead. The recording will be stored securely and eventually destroyed after we publish the study's findings.

Is it acceptable that I audio-record our conversation?

IF YES—TURN ON AUDIO-RECORDER—IF NO, TAKE DETAILED NOTES

OK -- Let's get started!

Section 2: **Job responsibilities, organizational approaches, and resources related to ClinicalTrials.gov**

Interviewer script: I'd like to start by learning about your job responsibilities and approaches and resources related to registering clinical trials conducted at your institution/organization and reporting of results information into ClinicalTrials.gov.

1. **[Job responsibilities—Tasks/Organizational approaches]** Walk me through the process of registering clinical trials and reporting results information into ClinicalTrials.gov at your institution/organization, focusing on the tasks that are your responsibility. Let's first start with registering clinical trials.

[Probe for each task mentioned: Tell me about what [name of task] involves. Also probe about administrative tasks: applying for a PRS account | entering responses to required and optional questions | previewing, inspecting, and submitting the record.]

If not mentioned in description of job responsibilities:

- a. How do you become aware of trials that may need to be registered and results reported into ClinicalTrials.gov?
 - b. How do you determine if a trial needs to be registered in ClinicalTrials.gov? (Probe about the need and with whom to seek input from others to make determination)
 - c. Now let's talk about submitting clinical trials results information. ***[Probe for each task mentioned: Tell me about what [name of task] involves. Also probe about administrative tasks: entering responses to required and optional questions | previewing, inspecting, and submitting the record.]***
2. **[Job responsibilities—Percent effort]** What percent of your time is spent on your ClinicalTrials.gov job responsibilities?
- a. Among your ClinicalTrials.gov job responsibilities, what roles or tasks take up most of your time?
 - i. Why do these tasks take up most of your time?
 - ii. Overall, do you feel that the time it takes to accomplish all these tasks is too much, too little, or just right?
 1. What makes you feel that way?
 - b. **[Job responsibilities—Tasks and percent of others]** Beyond you, who is involved in ensuring that ClinicalTrials.gov requirements are met?
 - i. **[If Yes]:** What tasks do they do? ***[Probe about tasks specific to registering and tasks specific to reporting results information]***
 1. What percent of their time is spent on ClinicalTrials.gov job responsibilities?
 2. Do you feel that the time it takes for others to complete these tasks is too much, too little, or just right?
 - a. What makes you feel that way?
3. **[Organizational approaches—dedicated office vs. distributed approach vs. something else]** Does your institution/organization use a dedicated office, a distributed approach, or another approach to submitting information into ClinicalTrials.gov?

By dedicated office, I mean that the institution/organization has an office or group that vets and supports all submissions of clinical trial information to ClinicalTrials.gov and monitors compliance with requirements. By distributed, I mean that the principal investigator or another institution/organization employee is responsible for meeting clinical trial information reporting requirements.

- a. Please describe the approach that your institution/organization uses.
 - i. What do you see as the advantages? Tell me more.

- ii. What do you see as the disadvantages? Tell me more.
 - iii. Which approach do you believe better supports the timely, accurate, and complete submission of information into ClinicalTrials.gov? Tell me more [**Probe about the circumstances in which one approach may be better than the other**]
- 4. [**Organizational approaches—Submitting data to ClinicalTrials.gov**] Data can be submitted to ClinicalTrials.gov in one of two ways—either directly into their Protocol Registration and Results System, referred to as **PRS**, or indirectly through an internal system that transmits data to ClinicalTrials.gov via an Application Programming Interface, called **API**, which allows apps to talk to each other. How do you submit data to ClinicalTrials.gov?
 - a. What do you find easy, if anything, about the process your organization follows?
 - b. What is difficult, if anything, about the process your organization follows?
- 5. [**Organizational approaches—Monitoring**] Tell me about the processes, if any, that your institution/organization has in place to monitor the submission of information into ClinicalTrials.gov.
 - a. [**If monitoring system is in place**] From your perspective, how effective or not effective is the monitoring system?
 - i. What makes you feel that way?
 - ii. [**Probe if mentions that it could be improved**]: What would need to be done to improve the monitoring system?
 - b. [**If no monitoring system is in place**] From your perspective, would a monitoring system be helpful or not helpful?
 - i. What makes you feel that way?
 - ii. What could a monitoring system look like at your organization?
- 6. [**Organizational approaches—Quality assurance**] What kind of processes or systems, if any, are in place at your institution/organization to conduct quality assurance and quality control checks of submissions to ClinicalTrials.gov?
 - a. How, if at all, are you involved in checking the quality of submissions to ClinicalTrials.gov? [**Probe for specific details of how they are involved in the QA/QC process**]
- 7. [**Resources—Training on ClinicalTrials.gov role**] What kind of training if any, did you receive for your ClinicalTrials.gov role? [**Probe about the specifics of the training, if not mentioned, ask whether they took the NIH's Train the Trainer course**]
 - a. How useful or not useful did you find the training?
 - i. What makes you feel that way?
 - b. What type of training, if any, do you feel would be helpful for your role?
 - i. What makes you feel that way?
- 8. [**Resources—Questions**] What questions have you had in the past when registering a new clinical trial?
 - a. What about reporting information on clinical trial results?

- b. What resources, if any, have you found helpful when registering clinical trials and reporting results information? This can include resources provided by your institution/organization or guidance documents that are publically available from the FDA and NIH.
 - i. **[If not mentioned]** Have you ever used resources available on the ClinicalTrials.gov website?
 - 1. **[If yes]** How helpful or unhelpful were those resources?
 - ii. How would you prefer to get the information that you need when you have questions about the registration and reporting requirements? (e.g., website, webinar, training)
 - iii. What types of additional guidance, if any, would be helpful to you in regard to your ClinicalTrials.gov related job responsibilities?

Section 3: Awareness/understanding/existence of ClinicalTrials.gov organizational policies and support for ClinicalTrials.gov registration and reporting requirements

Interviewer script: Now let's talk about the requirements for clinical trial registration and results information reporting into ClinicalTrials.gov and your institution/organization's policies for meeting those requirements.

- 9. **[Awareness/understanding—HHS registration requirements]** What is your understanding of the requirements for **registering** clinical trials into ClinicalTrials.gov?
 - a. What types of studies are subject to those requirements?
 - i. Which types of studies are not required to be registered?
- 10. **[Awareness/understanding—HHS reporting requirements]** What is your understanding of the requirements for **reporting** clinical trial results information into ClinicalTrials.gov?
 - a. What types of studies are subject to those requirements?
 - i. Which types of studies are not required to be registered?
- 11. **[Awareness/involvement—PIs/Job responsibilities]** Overall, in thinking of the PIs at your organization who are responsible for the trials that you register into ClinicalTrials.gov, how would you characterize their awareness of the requirements for **registering** clinical trials into ClinicalTrials.gov?
 - a. **[If not mentioned above]** How involved are these PIs in ensuring that those requirements are met? **[Probe for examples of delegated PIs' involvement]**
- 12. **[Awareness/involvement—PIs/Job responsibilities]** What about these PI's awareness about **reporting** clinical trial results information into ClinicalTrials.gov?
 - a. **[If not mentioned above]** How involved are these PIs in ensuring that those requirements are met? **[Probe for examples of PIs' involvement]**
- 13. **[Organizational policies—existence of]** Does your institution/organization have written policies on registering clinical trials and reporting results information into ClinicalTrials.gov?

If yes:

- a. What does your institution/organization’s policy state about registering clinical trials?
 - b. What about for results information reporting?
 - c. Which types of trials are covered by these policies?
 - d. What are the processes, if any, for notifying PIs when results are due?
 - i. **[If has a process]** Tell me about how that process works.
14. **[Organizational policies—penalties]** What penalties, if any, does your institution/organization impose when there is a failure to register required clinical trials or report results information into ClinicalTrials.gov?
- a. Who are these penalties imposed upon?
 - b. If your institution/organization designates PIs as the Responsible Party, are any penalties imposed on a PI who does not register a required clinical trial or report results information into ClinicalTrials.gov?
 - i. What steps, if any, has your institution/organization taken to ensure that PIs meet ClinicalTrials.gov registration and reporting requirements? **[Probe for details about any programmatic or educational efforts]**
15. **[Organizational support]** How would you characterize your institution/organization’s level of institutional support and leadership buy-in for registering clinical trials and reporting results information to ClinicalTrials.gov?
- a. How about their level of support for quality control of clinical trial registration and results information submissions into ClinicalTrials.gov?

Section 4: Challenges

Interviewer script: Thanks for all of the helpful information you’ve shared. Now I want to move on to discussing any challenges that you may have experienced in registering and reporting the results of clinical trials.

16. **[Challenges experienced—Registering trials]** What kinds of challenges, if any, have you experienced in *registering* clinical trials into ClinicalTrials.gov?

[Probes if needed: burden for data submitters ♦ unfamiliar format and terminology ♦ availability of required information for registering trials and reporting results ♦ confusion over who is legally responsible to register and report results ♦ confusing and onerous reporting requirements; clinical trial types]

17. **[Challenges experienced—Reporting trial results]** What kinds of challenges or concerns, if any, have you experienced or heard about at your institution regarding *reporting* results information into ClinicalTrials.gov?

[**Probes if needed:** reporting burden for data submitters ♦ unfamiliar format and terminology ♦ availability of required information for registering trials and reporting results ♦ confusion over who is legally responsible to register and report results ♦ confusing and onerous reporting requirements; clinical trial types ♦ numerous and competing reporting requirements ♦ hesitancy about reporting unsuccessful results ♦ confusion over need to submit results information if the results have been published in a journal ♦ concern about reporting competitive data ♦ concern with reporting adequate information ♦ concern with reporting in ClinicalTrials.gov and ability to report elsewhere]

18. [Challenges experienced—QC'ing submissions] **Ask participants involved in QC'ing submissions:** What kinds of challenges, if any, have you experienced in conducting quality control checks of clinical trial registration and results information prior to submitting it to ClinicalTrials.gov?

[**Probes if needed:** challenges communicating with data submitters ♦ addressing issues of quality of protocols and absence of well-specified outcome measures ♦ limited knowledge of RPs and support staff about requirements ♦ reporting burden for data submitters ♦ unfamiliar format and terminology ♦ availability of required information for registering trials and reporting results ♦ confusion over who is legally responsible to register and report results ♦ confusing and onerous reporting requirements; clinical trial types ♦ numerous and competing reporting requirements ♦ hesitancy about reporting unsuccessful results ♦ concern about reporting competitive data ♦ concern with reporting in ClinicalTrials.gov and ability to report elsewhere ♦ concern with reporting results information that conflicts with known or published information on the same trial]

Section 5: Potential solutions to challenges

Interviewer script: Moving on, I'd like to learn about your suggestions for overcoming the challenges related to registering clinical trials and reporting results information to ClinicalTrials.gov.

19. [Recommendations—Overcoming challenges--general] What are your recommendations for overcoming [**Recap challenges previously mentioned one-by-one**]
- What steps need to be taken to improve trial registration and results information reporting at your institution/organization?

[**Probe if needed:** Address issues with quality of protocols and absence of well-specified outcome measures ♦ Train/educate RPs and support staff about requirements ♦ Implement policies and procedures to support registration and results reporting ♦ Establish institutional/organizational consequences for failure to meet registration and reporting requirements]

20. [Recommendations—Overcoming challenges of quality of submissions] **Ask participants involved in QC'ing submissions:** How about your recommendations for overcoming challenges you discussed related to conducting quality control checks of submissions to ClinicalTrials.gov? [**Recap QCing challenges one-by-one**]

[**Probe, if needed:** Address issues with quality of protocols and absence of well-specified outcome measures ♦ Train/educate RPs and support staff about requirements ♦ Implement policies and procedures to support registration and results information reporting ♦ Establish institutional/organizational consequences for failure to meet registration and results information reporting requirements ♦ Reconcile discrepancies with published trial information and clinicaltrials.gov information found on ClinicalTrials.gov database]

Section 7: Existing helpful practices

Interviewer script: Now I'd like to learn about your view on the helpfulness of practices that your institution/organization has implemented to ensure that requirements are met in registering clinical trials and reporting results information into ClinicalTrials.gov.

21. [Existing helpful practices] In thinking about the practices that have been implemented at your institution/organization, which practices have worked best to improve the submission of clinical trial information into ClinicalTrials.gov? [**Probe for explanation of why each practice mentioned is helpful**]

[**Probes, if needed:** Daily monitoring/reviews of problem records ♦ Zero tolerance policy for late results ♦ Voluntary in-person training sessions to help investigators maintain compliance and avoid penalties ♦ Voluntary in-person training sessions ♦ Incentivize submissions that meet the requirements ♦ Establish multiple workflows for various aspect of entering data into ClinicalTrials.gov ♦ Centralized vs. decentralized approach, CT.gov coordinator/administrator approach]

22. [Existing unhelpful practices] What practices, if any, has your institution/organization implemented that have not worked well/been as helpful for improving the submission of clinical trial information into ClinicalTrials.gov? [**Probe for explanation of each unhelpful practice**]

Section 7: Conclusion

Interviewer script: To wrap up, I'd like to learn your views on the benefits and main lessons that you've learned from registering clinical trials and reporting results information into ClinicalTrials.gov.

23. [Benefits] What do you see as the benefits of registering and reporting clinical trial results into ClinicalTrials.gov?
- a. How, if at all, does the public benefit from clinical trials **being registered** into ClinicalTrials.gov?
 - i. What are other benefits of registering trials information into ClinicalTrials.gov?
 - b. How, if at all, does the public benefit from the **reporting of clinical trial results information** into ClinicalTrials.gov?
 - i. What are other benefits of reporting clinical trial results information into ClinicalTrials.gov?
24. Based on your experience, what are the main lessons you have learned from **registering clinical trials** into ClinicalTrials.gov?
- a. What about **reporting clinical trials results information** into ClinicalTrials.gov?

Interviewer script: That's the end of my questions that I have for you today.

25. Is there anything else that you would like to add?

I want to sincerely thank you for your time and for the helpful information that you provided.

Thank you very much.