CTTI Project: Practical Approaches for Embedding Interventional Trials into Health Care Settings

In-Depth Interview Question Guide: Implementers of Embedded Trials (Groups 3 & 4)
Version 1.1

1. Interviewer name	
2. Participant ID#	
3. Interview date (mm/dd/yyyy)	|___|___|/|___|___|/|___|___|___|___|
4. Participant agrees to digitally record interview	☐ Yes ☐ No
5. Time interview began (hh:mm)	|___|___ | : |___|___| am/pm
6. Time interview ended (hh:mm)	|___|___| : |___|___| am/pm

Step 1: Complete Q1—3 above before starting the interview.
Step 2: Introduce yourself at the beginning of the interview.
Step 3: Thank participant for taking part in the interview.
Step 4: Read *Section 1: Information about the study* to the participant.
Step 5: Ask for the participant's permission to record the interview. Tick appropriate box in Q4 above.
Step 6: Turn on audio recorder if permitted. Document time interview begins in Q5 above.
Step 7: Conduct interview.
Step 8: Thank the participant at the end of the interview. Ask if has any questions.
Step 9: Document time interview ended in Q6 above.
Step 10: Ask participants if they want a summary of the interview findings and if CTTI can contact them in the future with additional questions/requests. Document response.

Section 1: Information about the study

The Clinical Trials Transformation Initiative—otherwise known as CTTI—is interested in identifying practical approaches for embedding interventional trials into health care settings. We're ultimately interested in trials for medical product review; however, we're speaking with implementers of trials intended for medical product review and those that are not.

Before we continue, I'll provide clarity on two terms we're using as they can have multiple interpretations. We'll share with you our working definition.

By "embedding" we mean trials that are integrated within health care settings. These trials are conducted with patients where they get their medical care. They are streamlined with clinical work flows and use available data to design and execute the study.

By "interventional trials" we mean trials evaluating a drug or device. The goal of these trials is to gather data for regulatory review of medical products.

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: Trial overview

Interviewer script: Let's start by learning a bit more about your trial.

1. Please describe your trial that was integrated into a health care system. I'm specifically interested in knowing:

    a. the types of participants
    b. the type of health care systems that were involved
    c. the intervention
    d. the trial's objectives

*[**Note to the interviewer:** please make sure that all these probes are answered at the end of this question.]*

Section 3: Clinical Trial Elements

Interviewer script: Now I'd like to talk about how you integrated elements of clinical trials into health care settings and the modifications that were necessary.

[Elements of clinical trial integration—critical components]

2. Let's start by talking about the composition of staff who conducted the research and their training. I'm interested in learning more about the balance of non-research health care staff and research staff. How, if at all, were staff from the healthcare setting involved in your study? (Make sure clear about roles of each staff—health care and research—and how work together/remote)

    [PIs and ClinOps ONLY]

    a. Did you hire anyone to join the health care setting to focus exclusively on your research?
        i. ***[If yes]*** What role did they play?
    b. What ethics training was required of health care staff?
    c. How does the team trouble shoot problems that arise with the research at the healthcare center?

3. Now let's talk about data capture. How did you gather data for your study? For example, I'm interested in hearing about if data were collected from electronic health records, case report forms, both, or in another way.
    a. What type of data were already being collected as part of routine health care?
        i. How were those data being stored?

[PIs and ClinOps ONLY]

ii. How did you access those data once they were in the patient's record?

b. What data did you need to collect that were not already being collected as part of routine health care?

i. How did you end up collecting those data?

[PIs and ClinOps ONLY]

ii. How did you access those data once they were in the patient's record?

c. Who was responsible for collecting and entering data?

[PIs and ClinOps ONLY]

d. How did you manage data collection with settings that had different electronic health systems?

4. How were data made available for monitoring?

[PIs and ClinOps ONLY]

5. How were the health care settings reimbursed? ***[Probe about reimbursement for the study drug and for study procedures and time and effort of the physician—how is that recognized—even beyond compensation]***.

6. Describe the steps that were taken to assess patients' eligibility. ***[Probe about who assessed and who made the final determination]***

7. How were participants recruited?
   a. Who was responsible for recruiting?

8. How was the scheduling of participants' visits handled?
   a. How did you ensure that participants' visits occurred in-window?

9. How did you obtain informed consent?
   a. Who was responsible at the health care setting for obtaining informed consent?
   b. How was the process woven into standard care processes?

10. How were participants randomized?
    a. How did you limit potential bias that could emerge during the randomization process?
    [Note to interviewer: this refers to, for example, health care setting staff deciding to break randomization for a patient because they would prefer for that particular patient to receive study drug]

11. How did you track participants?

[PIs and ClinOps ONLY – question 12 AND all probes]

12. In addition to standard clinical trial elements that we've already spoken about, what other trial elements did you find were not part of routine health care? (e.g., tests, questionnaires, and procedures that are not part of standard care).
    a. How did you address these missing elements?
    b. What standard clinical trial elements, if any, did you ultimately find not necessary?
       i. Why were they no longer necessary?

[PIs and ClinOps ONLY]

13. Overall, what would you say are the main changes that you made to the way you traditionally conduct clinical trials so you could integrate your trial into health care settings?

14. Overall, what were the main changes necessary for *the health care settings to do* in order to integrate clinical trials into health care settings?

[PIs and ClinOps ONLY – question 15 AND probe]

15. Based on all these factors, what modifications, if any, were necessary to make to the trial's outcomes?
    a. What modifications were necessary to make to how you were measuring the outcome?
    [Note to interviewer:** the modifications of interest are intended to be made during the planning phase, not after the trial is underway**]

[Clinical trial standards]

[PIs and ClinOps ONLY]

16. What steps did you take to ensure that your trial's data collection and other study procedures were conducted per the standards expected of clinical trials?

17. Based on all your experience, what could be done to transform this kind of clinical research and increase the number of interventional clinical trials that are embedded within health care settings?

Section 4: Benefits, Barriers, and Risks

Interviewer script: Now I'd like to talk about the benefits, barriers, and risks to conducting interventional trials this way.

18. [Benefits] Based on your experience, what are the benefits, if any, of integrating interventional clinical trials into health care settings?
    a. What characteristics of your trial, if any, made it particularly suited to be integrated into health care settings?

19. [Benefits] What benefits do you feel should be most emphasized to persuade leadership at health care settings to consider integrating interventional trials into their settings?
        i. Why those benefits? ***[Probe for each benefit mentioned]***

20. [Barriers] What did you find, if anything, to be the most significant barriers to integrating trials into healthcare settings? For example, these can be related to administration, finance, staffing, and/or patients.
    a. What do you think could be done to overcome these barriers to make it possible for more trials to be integrated into routine health care? ***[Probe for each barrier mentioned.]***

21. [Risks] What did you find, if anything, to be the drawbacks of integrating clinical trials into health care settings?
    a. What were drawbacks, if any, to the clinical settings?
    [PIs and ClinOps ONLY]
    b. To the sponsor organization?
    c. To patients?
    d. How did you manage these issues? ***[Probe for each drawback mentioned]***

Section 5: Lessons Learned and Conclusion

Interviewer script: The final topic I'd like to talk about is lessons learned.

[Lesson Learned]

22. What are the main lessons you have learned from conducting clinical research within a health care setting?

23. What would you do the same next time?

24. What would you do differently?
    [PIs and ClinOps ONLY]
    a. What ideas do you have about variations of embedding trials that are different from your current trial?

25. What do you feel needs to happen to make these types of trials more common in the future?
    a. What types of tools or resources would be helpful?

26. What advice do you have for other PIs/research staff who may want to get involved with embedded trials?

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

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

Interviewer: Ask and document—

A. Would you like a summary of the study findings? ☐ Yes ☐ No

   Notes for interviews with more than 1 person:

B. Can CTTI contact you in the future with any additional questions or requests about this project? ☐ Yes ☐ No

   Notes for interviews with more than 1 person:

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