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

In-Depth Interview Question Guide
Version 1.6

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 intended for medical product review into health care settings.

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: Early Decision Making

Interviewer script: I'll start by asking about the discussions had and decisions made by your company/organization when considering the conduct of interventional trials in health care settings.

2. [Rationale] What were the reasons your company/organization decided to integrate interventional trials into health care settings versus conducting a conventional clinical trial with trial sites?
    a. What did you hope to achieve by integrating your trial into health care settings?
    b. Who was involved in the decision-making process?
    c. What kind of push-back did you get, if any?
        i. From whom?

3. [Regulator correspondence] What conversations, if any, did you have with regulators as you were designing your trial?
    a. What questions did you have for them?
    b. What guidance did they give?
    c. What modifications did you make to your trial based on these discussions?

4. What conversations, if any, did you have with patient groups as you were designing your trial?
    a. How did you incorporate their input, if at all?

Section 4: Selecting Health Care Settings

Interviewer script: Now I'd like to talk about how you chose the specific health care setting to engage in your research.

5. [Care setting selection] What criteria guided your health care setting selection process?
    a. What criteria were absolutely necessary for settings to have?
        i. Why those criteria? ***[Probe for each criterion]***
    b. What criteria were preferred but not necessary?
        i. Why those criteria? ***[Probe for each criterion]***

    c. What modifications did you make to your trial to account for settings that did not have any of the preferred criteria? ***[Probe for each criterion]***

6. [Care setting identification] How did you identify which health care settings might be interested in participating in your trial?
    a. What did you find easy about identifying potential settings?
    b. What was difficult about identifying potential settings?

7. [Care setting approach and persuasive factors] How did you approach the identified health care settings to start the conversation on integrating your trial into their setting?
    a. What did you say to persuade them to partner with you?
        i. What did you offer healthcare settings as an incentive to participate in your trial, if anything?
    b. What did they ask for in order to agree to participate in your trial, if anything?

Section 5: 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]

8. 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?
    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. How did you ensure that all required ethics and clinical trial training was completed?

9. How did you manage the delegation of authority with the settings' providers?

    [Probe about FDA 1572]
    a. *Did they get a 1572 from the clinicians at the healthcare settings?*
        i. ***[If not]*** *How did they handle documenting investigators' qualifications to run the trials?*
        ii. ***[If not]*** *What was the FDA's response to not having 1572's from the clinicians?*

10. 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 collected?
        ii. How were those data being stored?
        iii. How did you access those data?

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?
    ii. How did you access those data?
c. What steps did you take to harmonize the data you needed for your trial with the data already being collected as part of routine health care?
   ***[Note to interviewer:** Harmonize = how they combined data that was already being collected by the health care setting with any additional data they were collecting from case report forms]*
d. How did you manage data collection with settings that had different electronic health systems?

11. How were data made available for monitoring?

12. What adjustments, if any, did you make in the way that you worked with the DSMB while conducting the embedded interventional trial?

13. How were the health care settings reimbursed? ***[Probe about reimbursement for the study drug and for study procedures]***.

14. 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?
    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?

15. 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?

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

17. 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]

18. 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?

19. 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 6: Benefits, Barriers, and Risks

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

20. [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?

21. [Benefits] What benefits do you feel would be most persuasive for encouraging other sponsors to do these types of trials?
    a. Why those benefits? ***[Probe for each benefit mentioned]***
    b. 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]***

22. [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.]***

23. [Risks] What did you find, if anything, to be the risks from transitioning from traditional clinical trials to integrating trials into health care settings?
    a. What were risks, if any, to the clinical settings?
    b. To you as the sponsor?
    c. To patients?
    d. How did you manage these risks? ***[Probe for each risk mentioned]***

Section 7: Lessons Learned and Conclusion

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

[Lesson Learned]

24. What are the main lessons you have learned from integrating an interventional trial within health care settings?

25. What would you do the same next time?

26. What would you do differently?

    a. What ideas do you have about variations of embedding trials that are different from your current trial?

27. What do you feel needs to happen to make these types of trials more common in the future?

28. What advice do you have for other sponsors who may want to do this?

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

29. 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.