

Interview Guide for Discussions of Trials Transparency at UK Public Research Institutions

Research Question: What are the barriers and best practices that impact the complete and timely registration and reporting of clinical trials at UK public research institutions?

Format: Semi-structured

Timeframe: 30-90 minutes

The questions in **RED** are core questions and can be prioritised in a time-limited situation.

Pre-Interview Reminders

1. Give short introduction to the interview (scripted, separate document)
2. Obtain oral consent if have not returned signed consent form
3. Make clear when recording starts.

Introduction

We'll be talking today about trial transparency at your organisation. We will generally focus on the registration and reporting of clinical trials but if you have other areas of trials transparency you would like to touch on, please feel free to include them in your responses. Ultimately, the aim of this research is to identify barriers and best practices to research that can be shared with the larger community to inform discussion and plans for improvement.

Part 1: Individual and Organisational Background (5-15 minutes)

In this section we will collect some basic information on research at the participant's organisation, the research support infrastructure in place, and their role within the organisation. This will allow for essential context for the rest of the interview and allow for establishment of rapport through these background questions.

Question 1: Can you tell me about your role?

- Potential follow-ups:
 - How are you involved with the registration and reporting of clinical trials?
 - How long have you worked in this area?
 - Can you talk about the responsibilities of anyone else in your organisation who works specifically in these areas?

Question 2: Tell me a bit about your organisation and the type of clinical research it undertakes?

- Potential follow-ups:
 - Probe on CTIMPS vs. non-CTIMPS as necessary based on response

Part 2: Investigating Participant's Reflections on Trials Transparency (5-10 minutes)

In this section the participants are asked to explain their understanding of trials transparency topics and reflect on their personal role in trials transparency at their organisation. This allows an overall sense of their understanding of the topic and hopefully their own underlying opinions on the value of these activities. These questions will most easily move around in the actual interview context.

Question 1: Can you explain to me, in your own words, why requirements for the registration and reporting of clinical trials are in place?

- Potential follow-ups:
 - Could there be any potential disagreements that arise from this expectation?

For senior participants:

Question S1: What has helped to inform the policies and procedures you have been involved in creating and implementing?

For junior participants:

Question J1: How do you feedback information about the registration and reporting process to those above you?

Part 3: How registration and reporting works at your organisation (20-45 minutes)

Here we get into the specifics of the policies and procedures at the institution as well as the specific role of the participant at the institution.

Question 1: Can you talk me through the process of how trials are registered at your organisation?

- Potential follow-ups:
 - How is that registration maintained throughout the trial process?
 - How is this process monitored?
 - What registries do you use?
 - Potentially ask to expand on specific examples or anecdotes from the response.

Question 2: When a trial is completed, what is the process for reporting the results of that trial?

- Potential follow-ups:
 - Are there different processes for different forms of dissemination, for example journal articles vs. putting results on a registry?
 - How is this process monitored?
 - Are you working to ensure older trials are reported? How?
 - Potentially ask to expand on specific examples or anecdotes from the response.

Question 3: How are you involved in these processes?

- Potential follow-ups:
 - Can you talk about any changes you've seen in these processes over time?

- What was the impetus for these changes?

Question 4: What, in your opinion, has worked well about the way your organisation manages these processes?

- Potential follow-ups:
 - What could be the key aspects that allow these processes to work well?

Question 5: What has not worked well or could be improved in your experience?

- Potential follow-ups:
 - What could be biggest barriers to full compliance?
 - What could be the key aspects that allow these processes to not work well?

Question 6: Do you have any examples in which changes led to a barrier being removed or a process running more smoothly?

Question 7: Can you compare how the registration and reporting of clinical trials works at your current organisation compared to others you've worked at?

Question 8: Are you planning/aware of any impending changes to the way your organisation manages the registration and reporting of clinical trials?

Question 9: How would you describe top-level support for this work at your institution?

Question 10: Are you aware of how your organisation performs on ensuring trials are registered and reported according to legal or ethical standards? How?

Question 11: Have there been notable moments of external change or pressure in the trials transparency space that your organisation had to adapt or respond to?

- Potential follow-ups:
 - Consider prompting on external events if they have not been covered for example:
 - Brexit
 - House of Commons Letters
 - AllTrials
 - HRA Strategy

Part 4: Individual Support & Learning (10-20 minutes)

Here we will get to how knowledge, support, and best practice is shared and disseminated to the participant both by their organisation and from other entities.

Question 1: Can you talk about the level of practical support and training provided by your institution in these areas?

- Potential follow-ups:

- What resources could support you in order to do your job successfully?
- When does this training/support typically occur?

Question 2: When there are changes related to the processes for registering and reporting of clinical trials, how do you hear about them?

Question 3: What groups outside your organisation, if any, have been useful for you to learn about working on the registration and reporting of clinical trials?

- Potential follow-ups:
 - How could these groups external to your organisation better support you?
 - What about informal support and self-teaching?

Conclusion (5 minutes)

That is all my questions. Do you have any final thoughts or would you like to expand on anything else we talked about today? Is there anything you think I should have asked about but did not?

Thank you again for participating in this study. Do not hesitate to let me know if you have any questions related to your participation or if you would like to note any additional information related to what we talked about today. I'm also happy to share the transcript, my final analysis, or both with you for your review. Please let me know and we can arrange that.

One-Page Guide Index:

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Topic Overview

1. Individual and Organisational Background
 - 1.1. Individual position
 - 1.2. Org structure
2. Participant Reflection Questions
 - 2.1. Why requirements are in place
 - 2.2. [Senior] Inform policies + proc
 - 2.3. [Junior] How do you feedback info
3. How does Reg and Reporting work?
 - 3.1. How are trials registered?
 - 3.2. How are trials reported?
 - 3.3. How are you involved in these processes?
 - 3.4. What works well?
 - 3.5. What doesn't work well?
 - 3.6. Examples of changes
 - 3.7. Comparison to past orgs
 - 3.8. Changes coming in future
 - 3.9. Top-level support and buy-in
 - 3.10. Organisational performance
 - 3.11. External change and/or pressure
4. Individual support and learning
 - 4.1. Practical support from institution
 - 4.2. How do you hear about changes?
 - 4.3. External groups and self-learning