

**INTERVIEW GUIDE**  
*Use of Real-world Data in Clinical Trials*  
 INTERVIEW GUIDE – FIELD VERSION

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1. Interviewer Name	
2. Participant ID#	
3. Interview Date (dd/mm/yyyy)	_ _ _ / _ _ _ / _ _ _ _ _
4. Participant agrees for interview to be audio-recorded	Yes..... <input type="checkbox"/> No..... <input type="checkbox"/>
5. Time Interview Began (hhmm-24hr clock)	_ _ _ _ _
6. Time Interview Ended (hhmm-24hr clock)	_ _ _ _ _

**Step 1:** Complete Q1-3 above before calling the participant.

**Step 2:** Once you connect with the participant(s), introduce yourself; thank participant for taking part in the interview.

**Step 3:** Read Section A below to the participant(s).

**Step 4:** Ask permission to record interview; tick the appropriate boxes in Q4 above.

**Step 5:** For one-on-one interviews only: Turn on recorder if acceptable, document time interview begins in Q5 above, and conduct interview. Skip if group interview.

**Step 6:** At the end of the interview, thank the participant(s) and ask if she/he has any further questions; document time interview ended in Q6 above.

**Step 7:** Ask if the participant(s) is interested in being re-contacted to receive a summary of the study results and if willing to be contact for future CTTI studies and activities; if yes, document appropriate contact information for follow-up.

**SECTION A: Information about the study**

- Hello, thank you for taking time out of your busy schedule to speak with me today. My name is [Name], and I am an interviewer with the Clinical Trials Transformation Initiative. Is now still a good time to talk?

As you are aware, researchers are increasingly interested in using patient information from existing sources, such electronic health records, registries, and medical claims, for research purposes.

- CTTI is interested in exploring the potential to use such real-world data to support evaluation of new medical products, new indications, and labeling changes that potentially lower participant burden than is possible with traditional RCTs. CTTI defines real-world data as data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources.
- During today’s interview, I would like to hear about your experience with using real-world data for research purposes and your opinions and suggestions on its use in future regulatory trials.
- There are no right or wrong answers to the questions I will ask, only opinions. Please feel free to share your candid thoughts to the questions that I ask you. It’s very helpful to hear your point of view.
- As described in the informational sheet provided to you earlier, participating in this interview is voluntary. You can choose not to answer a question or you can stop participating at any time. We do not think there will be any personal risks or benefits from the interview today. However, there is a risk of loss of confidentiality. This means that people outside the study team could learn what you said in the interview. But we think this is unlikely because we do many things to protect the information you tell us such as storing your data on secure servers and removing any information that would link the data directly to you from the study records. Your responses will not be associated with any information that could identify you.
- 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. For one-on-one interviews only: If you agree to be audio recorded, please do not use your name or the names of others in your conversation. If you don’t want the interview recorded, I will take detailed notes during the interview instead.
- The interview will take roughly 1 to 1 ½ hours. Information about who to contact if you have questions about the study, including the Duke IRB, can be found in the informational sheet.
- Do you have any questions for me so far about the interview?

***[If yes, answer the participant’s questions then proceed with the interview.]***

***[If no, proceed with the interview.]***

Is it okay if I turn on the recorder now?

***[If yes, begin recording now.]***

***[If no]*** That’s okay, I’ll take detailed notes as we talk.

Ok, let’s get started!

## **SECTION B: Experience with real-world data**

*[Objective of Section Questioning: Identify lessons learned from using data from electronic health records, payment claims, registries and other real-world data sources. In addition, we will identify*

concerns with real-world data/evidence, how they can be addressed, and when using real-world data/evidence is impractical or unwise.]

To begin, I'd like to get a sense of how you have used real-world data in the past.

**[Note to interviewer: Prior to the interview, use the screening data to identify the specific uses of real-world data that you will explore with the participant. Focus discussion on the use of RWD in prospective research – ideally research conducted to inform regulatory decisions and/or in the conduct of Phase II or Phase III trials.]**

1. From your responses to the screening questions, I see that you have used real-world data from EHRs/Claims Database/Registries [see screening document]. Is that correct?

- a. Were any of these studies used to support regulatory decisions?
  - i. **[If yes]** Tell me more about those studies in particular. **[Note to interviewer: Focus only on those studies that were used to support regulatory decisions, unless participant(s) was purposely recruited without such experience.]**

**[For each source, probe]**

- b. What permissions did you need to get in order to access the data?
    - i. Who provided the approval to use the data (e.g., patients, hospitals, private registry owners, your IRB)?
    - ii. Were payments associated with accessing and using the data?
    - iii. Were restrictions placed on your use of the data (e.g., publication rules)? If so, what were they?
      - 1. **[Follow-up with each type of challenge]** How did you manage this restriction?
  - c. What challenges did you face with retrieving data from this/these source(s) (e.g., privacy/confidentiality, data ownership issues, regional variations/difference in data availability, cost, and technical issues)?
    - i. **[Follow-up with each type of challenge]** How did you manage this challenge?
2. You indicated that you have used this/these source(s) of real-world data in pre-study planning/study setup/recruitment/study conduct [see screening document]. Is that correct?

**[Focus probing on use of RWD in research conduct if applicable]**

- a. Please describe how you used the data from \_\_\_\_\_ [source] in the conduct of clinical research?

**[Probe if necessary]**

- i. Where these data used exclusively for this purpose or were they used in addition to other data?
- ii. When did you initially consider using real-world data for this purpose?
- iii. Why did you choose to use real-world data in your study?

3. What challenges did you face using that data in this way? ***[Probe until list of challenges are exhausted; then for each one, ask about how they were managed].***
  - a. ***[If multiple sources used in a study, probe]*** What challenges did you face with combining data from various sources (e.g., variations in formatting, quality, definitions, subject identification issues, contradictory data and equivalency)?
    - i. ***[Follow-up with each type of challenge]*** How did you manage this challenge?
  - b. ***[If appropriate]*** What challenges did you face with analyzing the data (e.g., data quality issues, data gaps, conflicting timing or endpoints, availability of analytical expertise)?
    - i. ***[Follow-up with each type of challenge]*** How did you manage this challenge?
    - ii. ***[If appropriate]*** Please describe any steps that you took, if any, to assess the validity and reliability of the data.
  - c. ***[If appropriate]*** What challenges did you face with obtaining IRB approval to either collect or use the data?
    - i. ***[Follow-up with each type of challenge]*** How did you manage this challenge?
  - d. What other challenges did you face when using real-world data in this way?
    - i. ***[Follow-up with each type of challenge]*** How did you manage this challenge?
4. Of all the topics we just discussed, what would you do differently next time?
  - a. What recommendations would you give to other researchers interested in using real-world data in similar ways?

### **SECTION C: Opportunities for using Real-World Data in RCTs**

*[Objective of Section Questioning: Describe opportunities to adopt use of real-world data more broadly for use in RCTs, and identify what barriers might need to be addressed for successful adoption of real-world evidence generation]*

I would now like us to talk more generally about the use of real-world data in (other) clinical research intended to support regulatory decisions, including your opinion regarding the opportunities and barriers to using real-world data now and in the future.

5. ***[If not already discussed in relation to their past studies]*** How could data from the sources you used be leveraged now to generate evidence for regulatory decisions?
6. How can *other* real-world data be appropriately leveraged now for use in clinical research intended to support regulatory decisions? ***[Clarify the source of real-world data referenced.]***
  - a. When might the use of real-world data be inappropriate or unwise?
    - i. Why?
7. How can future clinical trials be designed to better leverage data from real-world sources to produce the evidence needed to support regulatory claims and decision-making?  
***[Clarify the source of real-world data.]***  
***[Probe specifically about use of RWD in Phase II and Phase III trials for an NDA.]***

- a. If any, what limitations to using real-world data for regulatory decisions currently exist that are likely surmountable sometime in the *near* future? **[Clarify the source of real-world data.]**
    - i. How can they be overcome?
  - b. What limitations currently exist to using real-world data for regulatory decisions that would require more time to address? **[Clarify the source of real-world data.]**
    - i. How can they be overcome?
  - c. What limitations to using real-world data for regulatory decisions are likely *never* going to be surmountable?
    - i. Why are they not surmountable?
8. In your opinion, what is the future of traditional RCTs as the gold standard for assessing drug/device efficacy in a world with increasing availability of real-world datasets?

#### **SECTION D: Strategies for applying Real-World Data to Clinical Trial Activities**

*[Objective of Section Questioning: Identify practical models and operational guidance for the use of real-world data in RCTs to generate real-world evidence in one or more specific clinical trial operations activities]*

Some have mentioned that further regulatory guidelines should be drafted that help guide the use of real-world data in clinical trials.

9. In your opinion, what considerations should a regulatory framework address?
- a. What information should it provide to trial sponsors and investigators?
10. What questions do you have for regulators regarding the use of real-world data to generate evidence to support regulatory decisions? **[Ask the participant to specify the regulatory authority, e.g., FDA, EMA].**
11. What other tools would be useful?

#### **SECTION E: Closing**

I only have one final question for you today...

12. What are your top three recommendations or suggestions for other stakeholders who are considering using real-world data to generate evidence to support regulatory decisions? **[Clarify to whom the recommendations/suggestions are targeted.]**

That's the end of the questions that I have for you today. Do you have any final thoughts or questions that you'd like to ask about this study?

Would you be interested in being re-contacted for a summary of the interview results once we have completed the study? ***[Record their contact information on the Re-Contact Information Form]***

Yes

No

Would you be interested in having your name and/or your company's name acknowledged in publications stating that your experience contributed to our research? ***[Record their contact information on the Re-Contact Information Form]***

Yes

No

Would you be interested in being re-contacted for any future CTTI research studies or activities? ***[Record their contact information on the Re-Contact Information Form]***

Yes

No

I want to sincerely thank you for your time and for the helpful information that you provided. Thank you very much and I hope that you have a great day!