

CTTI REGISTRY TRIALS PROJECT
BACKGROUND INFORMATION FOR EXPERT INTERVIEW

The Clinical Trials Transformation Initiative's (CTTI) Registry Trials Project (RTP) focuses on the opportunity to increase efficiencies and decrease costs of research by embedding clinical trials within registries, for both pre and post-marketing clinical trials.

Current barriers and gaps include:

- 1) Identifying appropriate registries;
- 2) Ensuring data quality/comparability;
- 3) Meeting variable regulatory/legal requirements;
- 4) Protecting privacy/security; and
- 5) Clarifying the processes needed to implement a registry-based clinical trial.

For this project, we are using an adapted version of the EMA's (European Medicines Agency) definition of registries:

An organized system that uses observational methods to collect uniform data on specified outcomes in a population defined by a particular disease, condition or exposure. A registry can be used as a data source within which studies can be performed. Entry in a registry is generally defined either by diagnosis of a disease -- such as a disease registry -- or prescription of a drug, device, or other treatment -- such as an exposure registry.

Some examples of published embedded registry trials are TASTE: Thrombus Aspiration in ST-Elevation Myocardial Infarction and SAFE-PCI for Women: Study of Access Site for Enhancement of PCI for Women Trial.

PLEASE REVIEW THE FOLLOWING QUESTIONS BEFORE YOUR INTERVIEW

1. Is the above EMA definition similar or different to your own thoughts about a registry? If different, how is it different?
2. Do you feel registries can be more widely used to facilitate embedded clinical trials? Why or why not?
3. What do you feel are the major strengths or weaknesses of registries that make them suitable for facilitating randomized clinical trials?
4. Please describe what you believe are the top three barriers to embedding a randomized clinical trial within an existing registry. What do you think are potential solutions to address those barriers?
5. Aside from your top three barriers, I will read you a list of other barriers identified by our Project Team. Which three of these barriers do you also believe are major barriers and what potential solutions do you think could overcome them? (Only choose barriers that were not used in your response to the previous question)
 - a. Regulatory requirements
 - b. Up-front costs
 - c. Interoperability (the ability for multiple systems to exchange and interpret information).
 - d. Identification of appropriate registries
 - e. Ensuring data quality
 - f. Lack of staff training
 - g. Informed consent
 - h. Data governance
 - i. Data ownership
6. Do you think the data collected in a patient registry is sufficient or insufficient to support a clinical trial? Why?
7. Now, I would like to hear your thoughts on the use of registries, specifically within the device sector.
IF NOT ALREADY KNOWN, Do you have experience in the device sector?

YES → GO TO Q8
NO → GO TO Q10
8. In the device sector, there are several examples where registries have been utilized effectively for clinical trials. How do you think the device landscape is different from the drug landscape with respect to utilizing registries?

9. Do you think it is feasible or not feasible to adapt the tools, experiences, and/or regulations, used in registries, for device trials or randomized drug trials?
10. What operational adjustments do you think need to be made to registries, so they could be used for randomized clinical trials?
11. Please identify which three issues you feel are the most pressing and what potential solutions there may be to those issues. Of the remaining issues which you didn't identify as 'most pressing', are there any others to which you can offer potential solutions?
 - a. Harmonization and standardization
 - b. Reliability of data
 - c. Regulatory flexibility
 - d. Regulatory guidance
 - e. Lack of will among relevant leaders
 - f. Data integration
 - g. Data use agreements
 - h. Electronic transfer of data from registry to a case report form and/or pharmaceutical company databases
 - i. Communication between registry personnel and site coordinators
 - j. Regulatory and/or company-specific (e.g., SOPs) compliance
12. If you could make ONE *near-term* ACTIONABLE change for increasing the use of registries in randomized clinical trials, what would it be? Why?
13. If you could make ONE *longer-term* ACTIONABLE change for facilitating the use of registries in randomized clinical trials, what would it be? Why?
14. Is there any topic that you would like to expand on or anything that we haven't covered that you believe is important?