Experience in Implementing Clinical Trial to Real-World Data (RWD) Linkage

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BACKGROUND

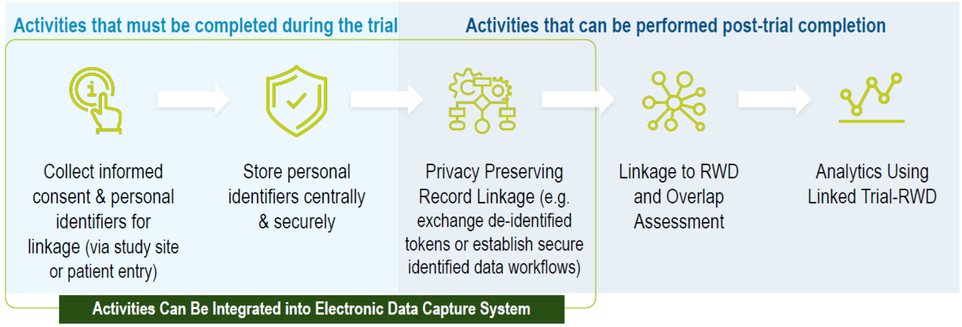
- Patients who participate in clinical trials (CTs) continue generating a wealth of real-world data (RWD) throughout their routine interaction with the healthcare system before, during, and after a trial.
- Routinely collected RWD including insurance claims data, electronic health records (EHR), disease registries contain valuable information about trial patients' clinical events, diagnosis, procedures, and health resources utilization, beyond data captured through case report forms in the trial.
- Trial patients' RWD can supplement active collection of clinical trial data and provide a deeper insight on benefits, risks, and cost of treatments. However, the disconnect between trial data and RWD delays access to critical data.

- **Objectives:** We report the effort needed for implementing linkage of multiple clinical trials to RWD in collaboration with several trial sponsors.

METHODS

- Patients who are enrolled in several clinical trials, were offered to participate in linkage sub- studies. Those who signed informed consent forms provided personal identifiers to enable investigators linking their trial data to their RWD.
- The process for collecting consent, personal identifiers, and the linkage were integrated into the trial standard electronic data capture (EDC) system to ensure minimizing burden on study site investigators/staff.
- All linkage sub-studies were approved by respective Institutional Review Boards.

Figure 1: Overview of the data linkage process From collection of patient identifiers to analytics



By connecting clinical trial data and real-world data, we can gain a fuller view of the patient journey and enhance
The process for evidence generation.

We observed an acceptable level of effort required across different trials/sponsors for implementing trial linkage sub-studies and efficiency gains from scaling data linkage across trials.

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RESULTS

- We reviewed implementation efforts needed for linking a subsample of 11 trials for 5 sponsors.
- These trials enrolled >103,300 participants and spanned multiple indications in oncology, cardiovascular, metabolic disorders, antivirals, and diagnostics. Linkage was implemented in the United States study sites of these trials.
- Median duration from contract execution to start of PII collection for linkage sub-studies was 19 weeks (IQR:15-30.5).
- This duration is reduced from initial deployments (27.5weeks [IQR:20.5-35.3]) at each sponsor to subsequent deployments (15 weeks [IQR: 15-19]).
- Number of meeting hours (Median, IQR) different organizational roles spent for implementation were: Director 6h(IQR:3.5-11), Trial Lead/Manager 6h (IQR:3-12), Data Manager 2h (IQR:0-10), Real-World Evidence Lead 2h(IQR:1-9), and Technical/IT Lead 0h (IQR:0-2).
- Capturing outcomes for patients' loss to follow-up and healthcare resources utilization data during the clinical trial and capturing long-term effectiveness and safety after trial completion were common use cases for trial linkage.

Figure 2: Use Cases of Linking CTD to RWD. The linkage can offer Long & short-term benefits for Clinical Ops/Development, Market Access, and HEOR

Validate RWD-based outcomes and variables against adjudicated trial outcomes

Enrich patient baselining at trial entry using passively- collected RWD

Understand and mitigate patients lost to follow-up in trial by monitoring their linked RWD

Extend longitudinal follow-up after trial completion to establish long-term benefits, risks, and treatment patterns

Reuse your trial data to study new outcomes, subgroups, or indications not included in the original trial protocol

CONCLUSION

- We observed an acceptable level of effort required across different trials/sponsors for implementing trial linkage sub-studies and efficiency gains from scaling data linkage across trials.
- The process of integration into standard EDC systems was seamless and easily adopted by clinical site investigators/staff.
- Early planning and inclusion of informed consent language for linkage are key to facilitate trial linkage.