Linkage of clinical trial data to real-world data (RWD) sources: A scoping review

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BACKGROUND

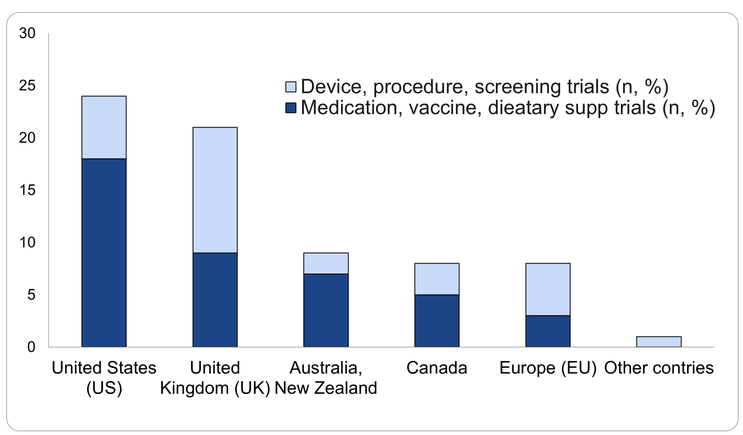
- Patients who participate in clinical trials (CTs) continue generating a wealth of real-world data (RWD) throughout their routine interaction with the healthcare system *before, during, and after a trial*.
- Routinely collected RWD including insurance claims data, electronic health records (EHR), disease 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 conducted a scoping review of clinical trials linked to RWD in various countries, identifying the use cases and designs of these linkage studies.

METHODS

- We identified research articles that reported the linkage of clinical trials to medical records, electronic health records, claims databases, disease registries, or vital statistics in their title or abstract in PubMed and MEDLINE.
- The search covered the period from January 1, 2016, through December 30, 2023.
- Opinion pieces, study protocols, or studies that involved interventions other than medications, dietary supplements, vaccines, devices, procedures, or diagnostics (eg, behavioral interventions) were excluded.
- Study eligibility and data extraction were performed independently by 2 reviewers to ensure the accuracy of findings.

Figure 1: Clinical trials linked to RWD across different countries (n=71)



In this scoping review of research articles, 71 studies linking trials to routinely collected real-world data (RWD) were identified.

Use cases included post-trial follow-up, capture of trial outcomes, validation of RWD, and measurement of resource utilization and cost.

These findings suggest that the linkage between trials and RWD is feasible and can be used to supplement evidence from trials.

Consent for linkage should be collected during the trial.

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RESULTS

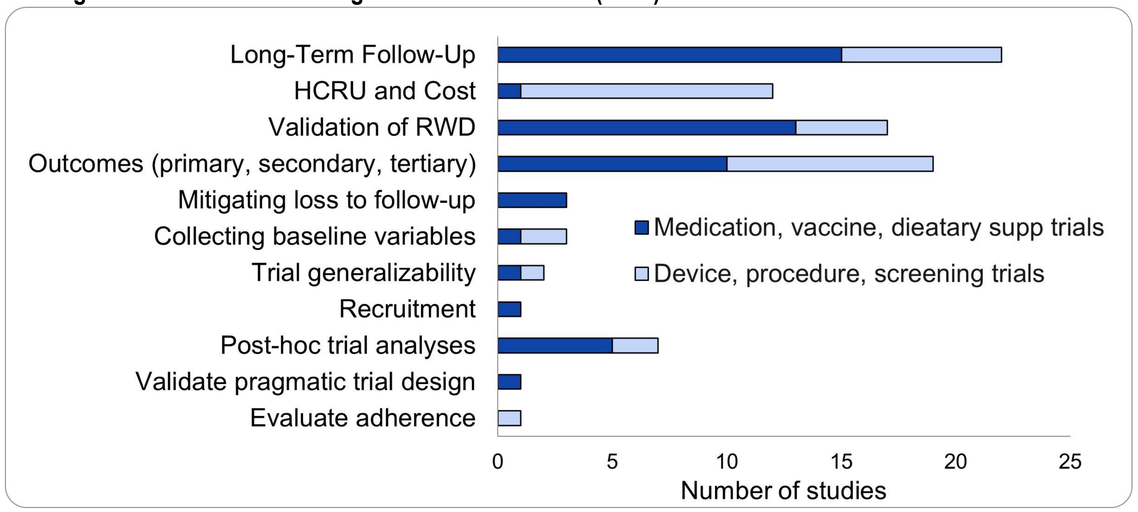
- Of the 990 abstracts initially screened, a full text review was conducted for 147 articles.
- In total, **71 studies** were included in the results:
  - 42 medication, vaccine, and dietary supplement trials (59.2%)
  - 29 device, procedure, or diagnostic trials (40.8%).

- Of these 71 studies, 24 (32.4%) were conducted in the US.

- In 32 studies (45.1%), consent for linkage was obtained prospectively as part of the main trial, while 33 studies (46.5%) received a waiver of authorization from the respective ethical review boards.

- The most frequent use cases of linkage to were posttrial long-term follow-up (22 studies [31.0%]), capturing primary or secondary outcomes of trials (19 studies [26.8%]), validation of routinely collected data outcomes (17 studies [23.9%]), and measuring health care resource utilization and cost in trials (12 studies [16.9%]).

Figure 2: Use cases of linking clinical trials to RWD (n=71)



CONCLUSION

- This study found that the linkage of patients' clinical trial data to routinely collected data has been implemented in several trials for various use cases.
- Most studies obtained consent for linkage prospectively as part of the main trial or received a waiver of authorization from ethical review boards.
- These findings demonstrate the feasibility and provide an overview of the use cases for linking trials to routinely collected data.

References:

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