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Challenges and Enablers in the Collection of Health Data for use in Phase II-III Clinical Trials

Sheila Kelly

Abstract

The purpose of this study is to evaluate the Challenges and Enablers in the Collection of Health Data for use in Phase II-III Clinical Trials. The focus is on the current processes for the collection of health data, the gaps in these processes and how new technologies and other factors are creating new ways to harness healthcare data for phase II-III clinical trials.

Clinical research is facing many challenges in the collection of health data for use in phase II-III clinical trials. The key elements that will shape health data collection in clinical research are the collection of data securely for secondary use; the development of consistent standards; adherence to applicable regulatory and ethical guidelines and legislation; collaboration across teams and networks; improved end user experience; and the convergence of patient care and clinical research practices (Embi & Payne, 2014).

The shifting clinical research landscape means that researchers are forced to review current practices and look for new ways to collect data. Reviewing current literature and qualitative research through interviews with key informants, the challenges and enablers in collection of health data for use in phase II-III clinical trials have been explored. Several key themes emerged, and despite the desire to use data collected in health records as the primary source of clinical research data, obstacles such as regulation and data privacy remain, and no clear path has yet emerged for how the data collection process for phase II-III clinical trials will evolve.

Further studies will be required to establish if initiatives to harness health records for use in clinical research will be effective in streamlining the collection of health data for use in phase II-III trials in the intermediate to longer term.