Using Clinical Research Informatics to Continually Improve Processes

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Abstract

Randomized clinical trials are the gold standard for evaluating healthcare interventions and, more broadly, contribute to medical knowledge in the areas of illness treatment, diagnosis, and prevention. Health informatics strategies that can help increase study efficiency throughout the life cycle of a clinical trial have been identified in recent literature. Data from electronic medical records (EMRs) can be used to aid clinical trial research during the planning and execution phases of a study, as well as to improve recruitment. This data is used to measure internal and environmental capability, as well as the alignment of a clinical trial with its environment in terms of study design, dose of investigational product, comparator, and patient type. By addressing these issues early on, you may be able to save money and overcome recruitment roadblocks. Additionally, feasibility data is used as a source of data to improve trial recruitment. The timely identification of eligible subjects is a major challenge for researchers.

Keywords

EMRs, Clinical Research, Health Informatics

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1. Introduction

Clinical Research Informatics (CRI), a newly defined topic of biomedical informatics that focuses on informatics assistance for medical evidence creation, has grown in breadth and importance in support of clinical and translational science agendas. Biomedical research has moved into the era of massive-scale data digitalization and computationally-intensive quantitative analytics, spanning molecular, clinical, and population-level data and including measuring events from picoseconds to decades-long time scales, at a breakneck pace over the last decade [1]. New digital devices, like as high-throughput next-generation deep sequencing machines and continuous real-time bio-sensing tattoos, continue to push the CRI community to build new infrastructure capabilities, as well as data and knowledge discovery tools that can manage petabyte-scale data repositories. The "Information Commons," as mentioned in the IOM report on Precision Medicine, is designed to integrate massive volumes of data with continually changing biological knowledge. The informatics underpinning that permits and speeds the transition to large-scale integrated data and knowledge systems must respond with CRI-related advancements. Simultaneously, research and discovery at the scale that is technically possible poses new problems, not only for CRI, but also for data sharing and privacy rules, as well as regulatory organisations that must adapt to this quickly changing data-driven agenda [2]. Unlike „traditional" prospective clinical trials, which rely on trained data collection personnel and detailed data collection tools and procedures, EHR and PHR databases contain data collected during routine clinical care by practitioners focused on patient care or by patients interested in capturing their health care experiences rather than research. What data is gathered and how it is documented is influenced by differences in clinical workflows, practise standards, patient groups, available technologies, and referral resources. Numerous researches have raised serious issues about the data quality in EHRs. CER studies aim to take advantage of real-world diversity in order to identify and understand the factors that influence outcome variation. However, data quality and completeness issues may compromise the validity of CER conclusions [3]. The value of high-quality data in clinical research is well acknowledged. Although significant efforts are being made to build robust analytic methods for deriving accurate knowledge from observational data, no official data quality evaluation guidelines, analytic methods, or reporting requirements exist. How will these data be used to expedite translational research and new discoveries as CRI investigators adopt these expansive data resources and build new methods for linking, examining, visualising, and analysing complicated data sets? Retrospective clinical research, study feasibility, cohort selection, and patient recruiting are all examples of „traditional" usage. New data sources also provide new possibilities, such as the creation of „deep clinical phenotypes," which combine biomarkers, imaging results, and natural language processing (NLP) to extract clinical traits not seen in traditional databases focused on „coded" data items [4]. Clinical and billing data links allow for longitudinal research, while environmental exposures give new aspects to

estimating disease risks across large patient populations. The inclusion of a wide range of clinical practises allows researchers to examine the impact of health-care system characteristics on disease diagnosis, treatment patterns, and outcomes.

2. Conclusion

Expect more patient-centered research decision support and novel consent programmes in clinical informatics research to increase patient participation and participation, including stating how and by whom an individual‘s research data will be utilised. Expect more CRI research that is informed by and responsive to patient or population needs, and encourage investigators to continue to contribute to the explosive growth in the peer-reviewed literature in clinical research informatics by developing new methods and tools that accelerate clinical and translational research.

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