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The Impact of Digitalization and Data Sciences

How Real-World Data is Shaping the Clinical Landscape

The evolution of digitalization and data sciences has resulted in a tremendous impact and disruption within healthcare. This impact has been embraced throughout clinical research, accelerating availability of new therapies to patients and placing these therapies into the hands of treating physicians. The application of real-world data today connects research sponsors, healthcare organizations, physicians and patients in ways previously impossible.

A key example of the way real-world data is shaping the clinical landscape today is the use of cloud-based electronic health record management systems to connect data from patients across healthcare systems globally, such as the TriNetX health research network. Research sponsors are now able to systematically assess protocol feasibility at an early stage with confidence through the use of objective data provided from sites. Furthermore, these platforms provide increased visibility of sites, and their patients, to the global research environment as research sponsors access these platforms. The functionality of these tools extends to different stages of clinical trial execution, such as allowing research sponsors to directly support identification of candidate patients. This creates an environment that facilitates rapid trial recruitment by enabling investigator teams to reach out to patients who have practically been prescreened for participation. This in turn reduces frustration on the part of investigators and patients by decreasing the number of patients who get subjected to rigorous clinical trial screening procedures only to screen fail.

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Regulators have acknowledged the impact of real-world data and electronic health records on shaping clinical research. In the United States, the Prescription Drug User Fee Act (PDUFA) IV and the 21st Century Cures Act provided the foundation for the full engagement from the Food and Drug Administration (FDA), which has since issued multiple guidance documents including a framework for how to use real-world evidence (December 2018) and for the use of electronic health records (July 2018). These guidance documents have been supported by multiple subsequent workshops and FDA-run forums which provide insight to the high priority given to this topic both by the pharmaceutical industry and the agency. Similar activity can be found with regulators throughout the globe, with examples including recent guidance from Health Canada (April 2019) and international updates to the General Data Protection Regulation (GDPR).

The horizon of clinical research continues to accelerate at a rapid pace and embracing capabilities of technologies today is a critical step towards shaping the future landscape. Extending into the future it is clear clinical trials will continue to increasingly leverage real-world data in various modalities. Areas of current exploration include capabilities to load trial data directly from hospital systems to electronic data capture platforms, the use of real-world data to support placebo analysis and connecting electronic health records with data directly from the patient, such as the FDA MyStudies application. The full capabilities of real-world data remain to be unlocked as data warehouses grow alongside the ability to utilize and connect the data in new ways.

Clinical research continues to only be possible through the close collaboration and combined efforts of sponsors, healthcare organizations, physicians and patients. It is important to recognize that the way clinical trials are being performed has changed, with digital and data sciences now acting as partners in this journey to deliver better patient care.

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Leading the Journey

Every member of the research community can serve as an agent of change that embraces the adoption of real-world data.

- Advocate for greater utilization of real-world data within your organization for clinical trials and research collaboration
- Support data enrichment efforts that improve the longitudinality of real-world data available for research, such as:
    - Integrating genomic, tumor registry and unstructured data from clinician notes and pathology reports
    - Increasing how frequently data is refreshed
    - Linking third-party data sets such as claims to your patient population
- Collaborate with urgency. We must help one another to fully realize the power of real-world data to accelerate research discoveries