ICAREdata: Integrating Clinical Trials & Real-World Endpoints

The Challenge

Less than 6% of cancer patients in the U.S. enroll in clinical trials in which high quality data are collected to improve cancer care. Electronic health record (EHR) data are generated during routine clinical practice outside of clinical trials and can support the understanding of the efficacy and safety of approved therapeutic agents in broad populations. However, the use of EHR data in research is limited due to variable quality and lack of data standardization. The near-universal adoption of EHRs by health care providers provides a tool for collecting data for use in both clinical trials and clinical practice.

CodeX Use Case

The ICAREdata (Integrating Clinical Trials and Real-World Endpoints) project aims to demonstrate that EHR data can be structured and contribute to efficient clinical research by including a broad population of patients while maintaining the same data quality as traditional clinical trials. This collaboration between MITRE and the Alliance for Clinical Trials in Oncology is conducted in association with the National Cancer Institute’s National Clinical Trials Network institutions and EHR vendors.

ICAREdata will evaluate outcome elements of mCODE and demonstrate a strategy for clinical trials based on EHR data and mCODE. An open-source infrastructure and automated standards-based interface for data capture and exchange are being developed and piloted.

CodeX (Common Oncology Data Elements eXtensions) is a member-driven HL7® FHIR® Accelerator, building communities to create interoperable data models and applications leading to step-change improvements in cancer patient care and research.

CodeX projects center on use cases that address cancer care and research. CodeX members are achieving interoperability by implementing the FHIR standard mCODE (minimal Common Oncology Data Elements), which defines key cancer characteristics in an interoperable framework.

To learn more about CodeX, visit www.hl7.org/codex.

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