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International Comparison of Approaches to Common Data Models for Comparative Effectiveness Research

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Over the past decade, characterizing the safety and effectiveness of drugs has advanced through distributed networks of data repositories where investigators implement the same procedures to address the same topic using a common data model. Distributed networks for pharmacoepidemiology have now been established in the United States (US), Globally/Europe Canada, and Asian countries. Sentinel in the US was developed in response to legislation and is funded by the US Food and Drug Administration to address their safety queries. The Observational Medical Outcomes Partnership (OMOP) is an international collaborative with a growing European data network that developed a common data model through a public-private partnership. The Canadian Network of Observational Drug Effect Studies (CNODES) receives funding and study queries from Health Canada and dissemination is directly back to the regulator as well as through the peer-reviewed literature. The Asian Pharmacoepidemiology Network (AsPEN) is an investigator-initiated multi-national research network formed to support the safety and effectiveness assessment of medications and other therapeutics and to facilitate the prompt identification and validation of emerging safety issues among the countries in Asia and Pacific regions. While these networks have implemented two different common data models (CNODES with Sentinel, ASPEN with OMOP), each network differs from the others in the aims, stage and implementation, operational approach, data quality assurance mechanisms, funding, and dissemination.

The objectives of this session are to compare and contrast the role and goals, design principles, implementation approaches, and analytic conventions and procedures between common data models implemented by SENTINEL, OMOP, CNODES, ands AsPEN.

Divided into seven 15-minute segments the session begins with an overview of distributed networks of common data models for pharmacoepidemiology. In four slides, each presenter then characterizes their network by describing the following:

- number of data holders, lives covered, and records, data holdings, data access model, network governance.
- process for transforming a repository's data into the common data model
- target audience(s), process of identifying queries and knowledge dissemination plan
- two key challenges faced by the network and the lessons learned

In identifying similarities and meaningful differences between the networks, in the next segment the discussant will articulate the relative strengths of the different approaches taken. This will lead into the last segment in which the floor will be opened for questions and comments from the audience. The session would be of benefit to researchers seeking to better understand or join an existing distributed network as well as researchers interested in broadening their understanding of global comparative effectiveness research.

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