DSEN ABSTRACT

CNODES Common Data Model (CDM) Pilot Project (Q17-02 and 19-04)

A study conducted by the Canadian Network for Observational Drug Effect Studies (CNODES)

Summary

- The Sentinel CDM was adapted for use in Canada at all six CNODES sites and successfully demonstrated with three pilot projects.
- CDM queries have reduced the timelines by an estimated 60%.
- Further work to be done to improve timelines, expand the data sources and analytical tools.

Key messages

- The Sentinel CDM was successfully transformed and piloted-tested in six CNODES provincial sites.

Project Lead & Team

- Michael Paterson and Robert Platt
- Team members available here

What is the issue?

- CNODES has addressed many important questions regarding the use and safety of prescription drugs in Canada but these were necessarily time consuming.
- While such studies are essential to evaluate the real-world impact of medications, decision-makers also often have less complex, pressing questions about how drugs are used in practice. Specifically, about use in combination with other drugs, their indications and the co-morbidities of patients who use them, and the extent of variation in these characteristics and practices across Canada.
- Such descriptive studies could be done more efficiently by leveraging the tools and experience of the FDA Sentinel Initiative.

What was the aim of the study?

- The purpose of this project was for CNODES to create and pilot-test a Canadian version of the Sentinel Common Data Model (SCDM) at multiple CNODES sites (Alberta, British Columbia, Manitoba, Nova Scotia, Ontario, and Sasktachewan).

How was the study conducted?

- The CNODES CDM team established a multi-stakeholder advisory committee and an internal working group. Following this, they developed the Canadian common data model tables at multiple CNODES sites.
- The CDM tables and Sentinel analytical packages were tested through multiple demonstration projects.
- Outcome measures of feasibility and timeliness included successful adaptation of the Sentinel CDM; successful construction and quality assurance of the core CDM tables at each site; successful completion and pooling of the demonstration study results; and the timelines associated with study approval and conduct.

What did the study find?

- We successfully adapted the Sentinel CDM for use in Canada and transformed the source data files at all six CNODES sites included in the pilot.
- We developed the policies and procedures needed to successfully complete and pool the results of all three pilot studies.
- The average time to study approval was 22 days overall (range 5 to 50 days).
- Overall study timeline of approximately 80 days.
- We estimated that our efforts have reduced the timeline for CDM-suitable queries by at least 60% to a maximum of 140 days, shorter for studies involving fewer sites.

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CIHR IRSC Canadian Institutes of Health Research / Instituts de recherche en santé du Canada

CNODES CANADIAN NETWORK FOR OBSERVATIONAL DRUG EFFECT STUDIES

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