

CANADIAN NETWORK FOR OBSERVATIONAL  
DRUG EFFECT STUDIES (CNODES)

# ***CNODES CDM Pilot Project: Challenges and Opportunities***

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Robert Platt

EMA Workshop

“A Common Data Model for Europe: Why? Which? How?”

December 12, 2017

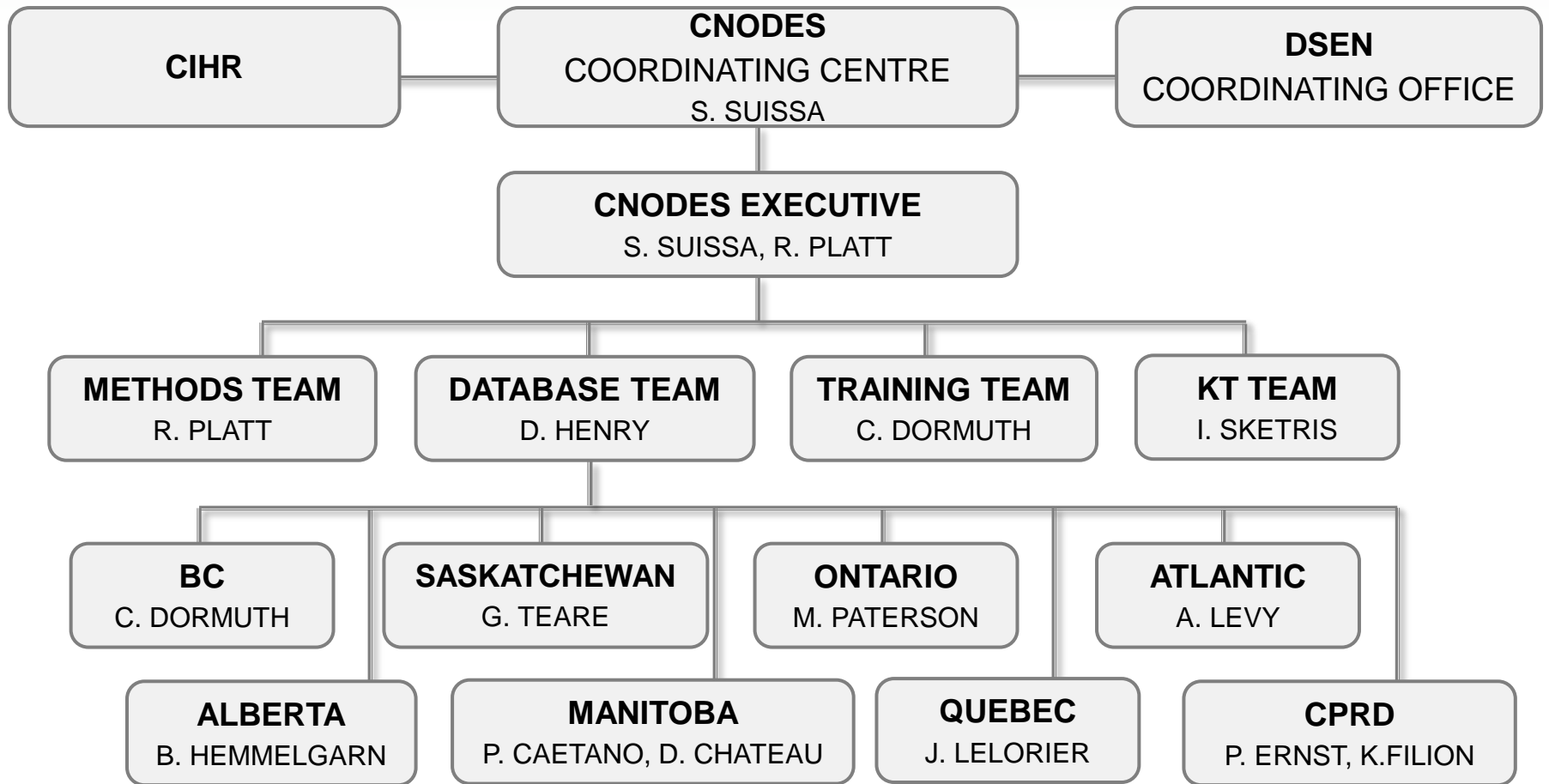
# ***CNODES funding and investigators***

Canadian Network for Observational Drug Effect Studies (CNODES), a collaborating center of the Drug Safety and Effectiveness Network (DSEN), is funded by the Canadian Institutes of Health Research (CIHR, Grant #DSE – 146021).

| <b>CNODES INVESTIGATORS</b>       |                                  |
|-----------------------------------|----------------------------------|
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| <b>Alberta</b>                    | Brenda Hemmelgarn                |
| <b>Saskatchewan</b>               | Gary Teare                       |
| <b>Manitoba</b>                   | Patricia Caetano, Dan Chateau    |
| <b>Ontario</b>                    | David Henry, Michael Paterson    |
| <b>Québec</b>                     | Jacques LeLorier                 |
| <b>Atlantic (NB, NL, NS, PEI)</b> | Adrian Levy, Ingrid Sketris      |
| <b>UK CPRD</b>                    | Pierre Ernst, Kristian Filion    |

\*Nominated Principal Investigator

# CNODES Network



Data on over 100 million people

# Data Sources

- Linked provincial administrative health data

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## CORE

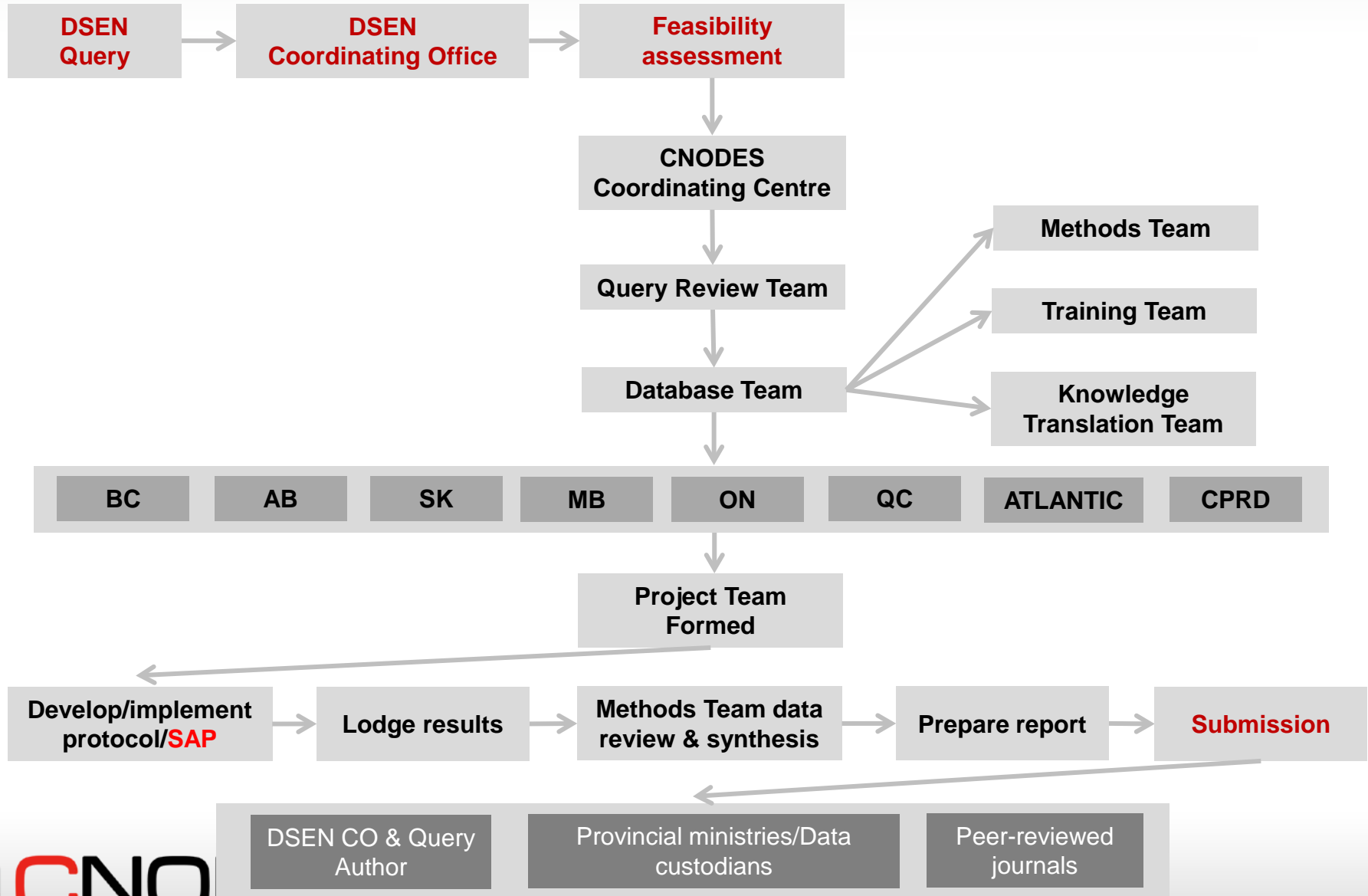
- health insurance registries
- prescription drug claims
- physician service claims
- hospital discharge abstracts
- emergency department records
- vital statistics

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## SUPPLEMENTARY

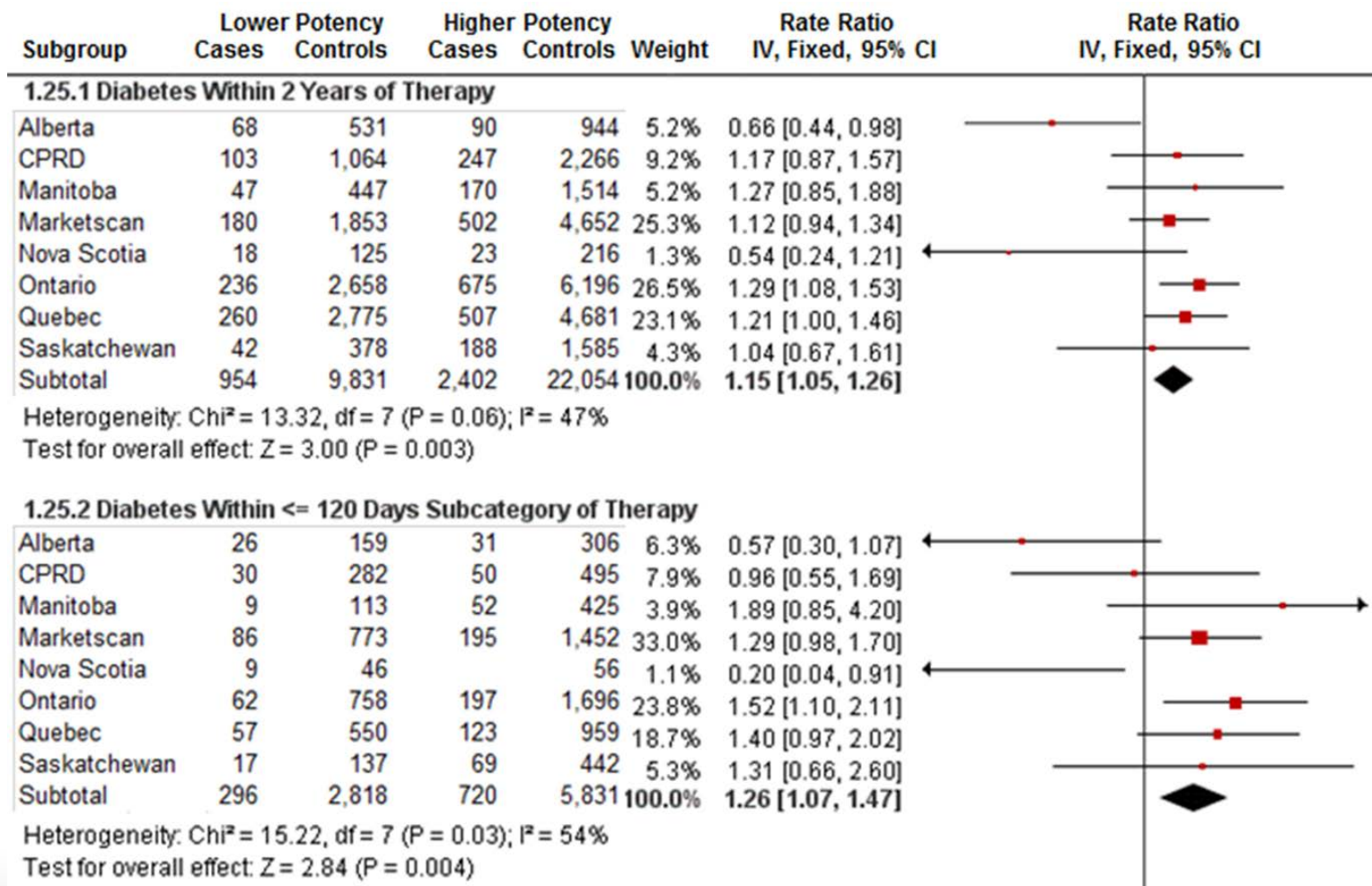
- cancer registries
- pregnancy registries
- laboratory test results
- health surveys
- CPRD: EMR-based risk factor data (e.g., smoking status, alcohol use, BMI, blood pressure, lipids, etc.)

# Process



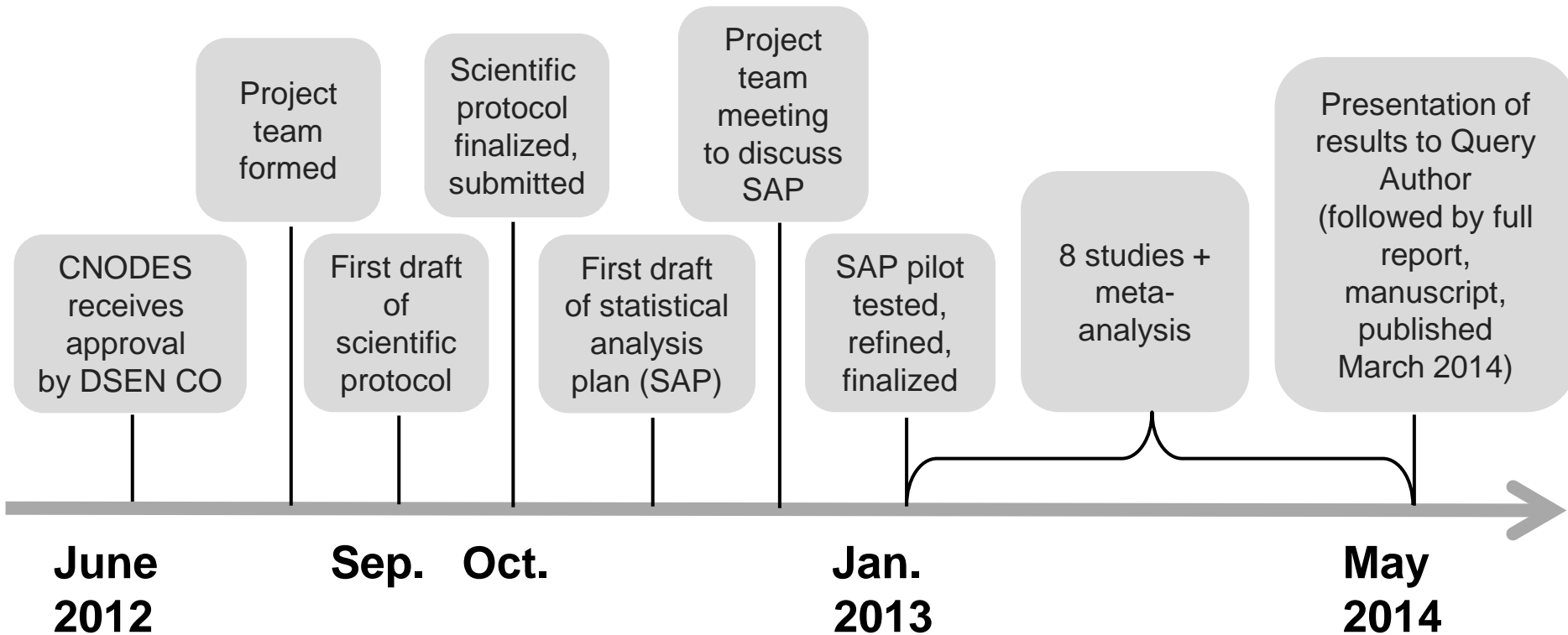
# Product

## High-Potency Statins and Diabetes



# Timeline

## High-Potency Statins and Diabetes



# ***Advantages of CNODES' Current Approach to Distributed Analytics***

- **Analytical flexibility**
  - Study design, data sources, statistical methods
- **Capacity building**
  - Local data repository development
  - Analytical and methods expertise
- **Policy relevance**
  - Query author actively involved in question refinement and protocol development



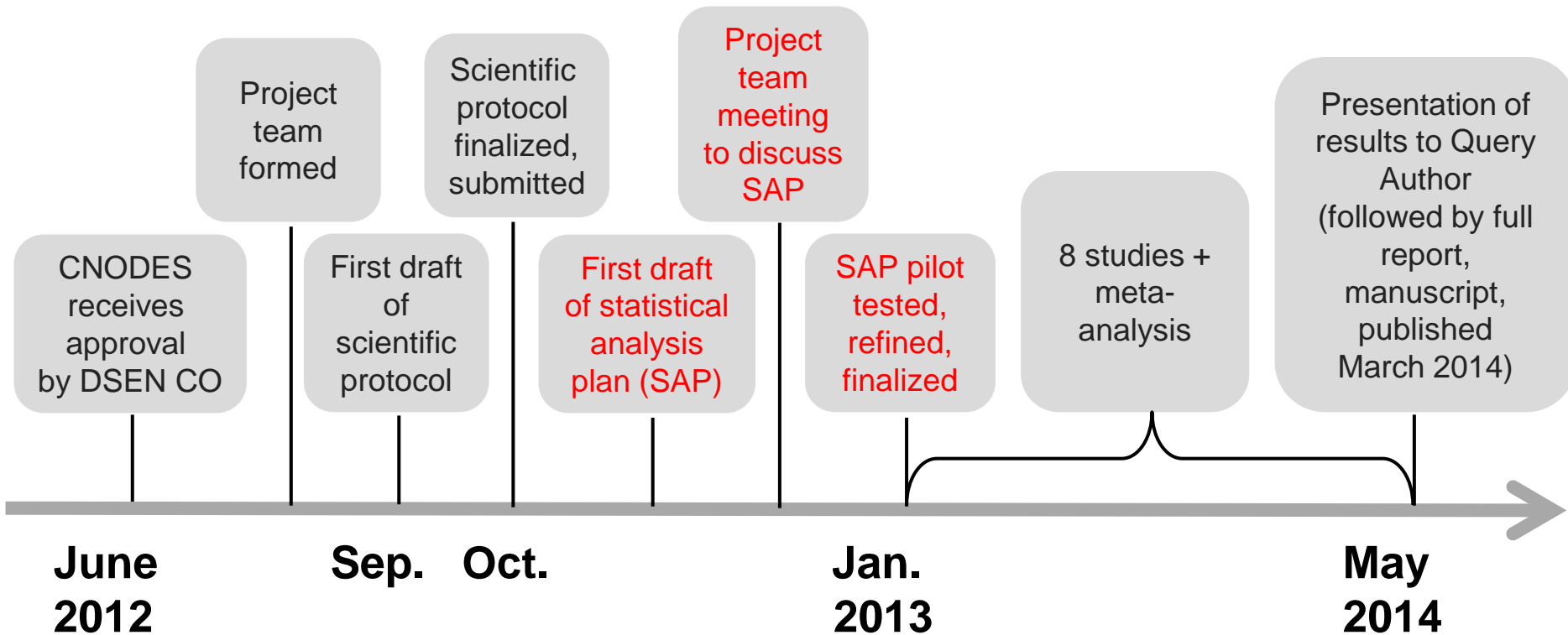
# ***Main Challenge of CNODES Approach***

## ➤ **Timeliness**

- Data access
  - Improved at some sites, but continues to be a challenge at others (BC, QC)
- Efficiency in protocol development
  - Reference documents and tools
  - Standardization
    - Study cohort and covariate definitions, exposures (predefined ATC and DIN extract protocols), outcomes (ICD code library)
    - Maximum use of standardized, tested SAS code, macros

# Timeline

## High-Potency Statins and Diabetes



# ***CNODES Common Data Model Pilot Project***

- Launch April 2017
- Initially, 3 sites with prompt data access: SK, MB, ON
  - Anticipated query response times: 2-3 weeks
  - NS coming on line
  - Other provinces in planning stage
- CNODES CDM tables
  - Enrollment, Demographic, Dispensing, Encounter, Diagnosis, Procedure, Death (+ Location)
- Using Sentinel CDM structure
- Demonstration queries and operational structure, process
  - Determined with input from Advisory Committee chaired by DSEN Coordinating Office and members, including Health Canada and Canadian Institute for Health Information (CIHI)

# ***Progress to Date***

- Table conversions almost complete
  - Generally straightforward process
  - Minor tweaks/decisions to be made
    - Fields we don't use but are necessary for query tools
    - Field digit lengths (e.g., ICD codes) need standardizing
- Advisory committee met to prioritize first queries
  - One each of: simple drug utilization, utilization within defined cohort, compute outcome rates among users

# ***Why Sentinel CDM?***

- Pragmatic
  - Close relationship with Sentinel team
  - Demonstrated process working with regulator
  - Close mapping of their core data tables/elements to our core admin data sources
  - Sentinel staff, experience and tools to support data partner data extraction and QA process
    - Well-established data QA processes and procedures

# ***Why Sentinel CDM?***

- Technical
  - Alignment and ready availability of well tested query tools (SAS programs) of proven value to a regulator
  - Data granularity: no recoding/collapsing of data (“minimal mapping”)
    - Allows different definitions of key exposures and events across projects
    - Data relatively homogeneous, so no need for common vocabulary a la OMOP
  - Scalability with other data sources, e.g. in Manitoba where other data may be easily brought on board

# ***Validation***

- Work in progress
- Informal:
  - Collaboration with Sentinel
  - Replicate early CNODES study using same (MarketScan) data and CDM
- Formal:
  - Initial CDM queries will be run 3 ways
    - CDM
    - CNODES “standard” tools
    - CIHI for utilization

# ***Future Directions***

- CNODES CDM should facilitate rapid responses to simple queries from HC
- Should enable cross-jurisdiction collaborations
  - FDA, HC can specify common studies and get rapid results
  - Complementary studies:
    - US larger population
    - Canada longer average follow-up



# ***Synthetic Data***

- Wanted synthetic/simulated data for
  - Training
  - Methods development
- Modified OSIM tool to generate OMOP CDM-like data
- Working to generate Sentinel CDM-like data
  - More granular data -> challenge to simulate

# ***Concluding Thoughts***

- Canadian CDM a work in progress
- Sentinel data structures and analytic tools are easy to implement
  - Other options (eg OMOP) probably would have worked too
  - Possibility for Sentinel/CNODES (FDA/HC) collaborations seen as a strength

# ***Concluding Thoughts***

- CDM will advance response times for some queries
  - Utilization/combinations/event rates
  - Will not eliminate need for CNODES standard tools (full epidemiologic studies for signal evaluation)
    - Careful design required for complex questions
- Lots of common governance/privacy/academic-regulatory challenges
  - Data access in some sites
  - Academic “credit”
  - Funding/development costs

# *Thank you*

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