Applications of the OMOP Common Data Model for Clinical Trial Feasibility Assessment

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BACKGROUND

The Problem:

- Randomized clinical trials are resource-intensive.
- Patient recruitment is often the most significant challenge.
  - Difficult to define and identify the target population eligible for screening.
  - Among patients identified for screening, many may fail to satisfy study inclusion criteria.
- Study protocols often based on expert perspectives or clinical intuition.
- Protocol amendments are frequently required to modify the inclusion criteria and improve recruitment performance.

The Solution:

Implement a web based application (PSYCHIC):

- Define cohorts using rules
- Query the Common Data Model (CDM) data source and build a cohort for each rule
- Visualize the intersection between cohorts
- Provide reports on cohorts in order to refine rules
- Generate results across a distributed network that include only aggregated information without person identifiers.

METHODS

1. Define the initial population based on an index event. This is the **Index Rule**. (Figure 1)
2. Define additional rules based on criteria relative to the **Index Date**. These are **Inclusion Rules**. (Figure 2)
3. Create the Index Cohort and Inclusion Cohorts by executing the rules against the CDMv4 data source and populate the COHORT CDM table. (Figure 3,4)
4. Generate population Visualization (Figure 5) and tabular reports for analysis. (Figure 6)
5. Refine rules if match rate is not satisfactory.

CRITERIA DEVELOPMENT

Figure 1: Index Rule Editor

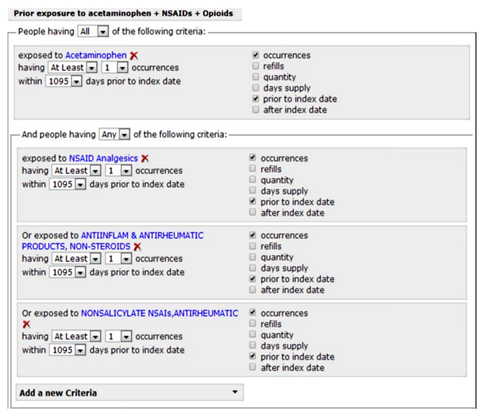

Figure 2: Inclusion Rule Editor

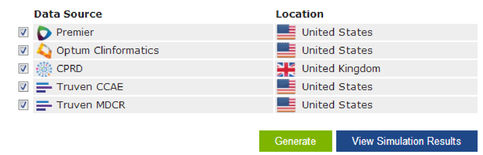

Figure 3: Data Source Selection

PROTOCOL SIMULATION

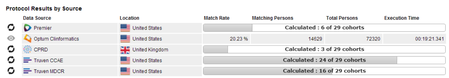

Figure 4: Protocol Progress

Each data source is processed independently and the user can review the results without waiting for all simulations to finish.

POPULATION VISUALIZATION

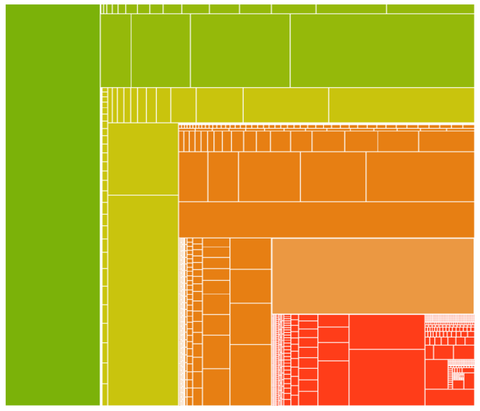

Figure 5: Treemap Visualization

The treemap displays each cohort intersection.

- One box per unique criteria combination
- Size is relative to the overall population
- Color represents number of missed criteria
  - Green: 0 miss
  - Lt. Green: 1 Miss
  - Yellow: 2 Miss
  - Orange: 3-4 Miss
  - Red: 5+ Miss

The researcher would focus on the largest boxes that have the least missed criteria.

COHORT ANALYSIS

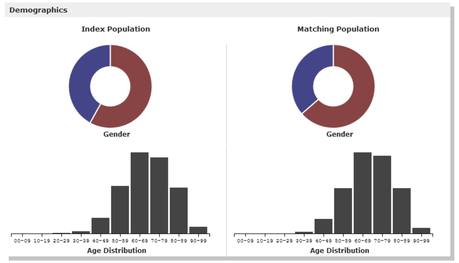

Figure 6A: Demographics

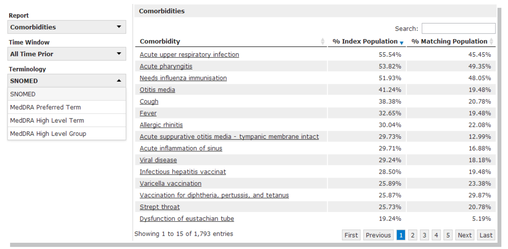

Figure 6B: Comorbidities

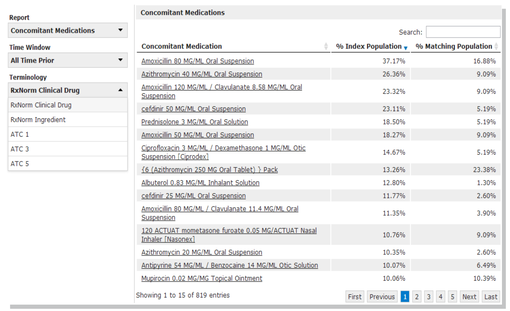

Figure 6C: Concomitant Medications

The Comorbidities and Concomitant Medications reports leverage the CDM Vocabulary to allow users to analyze cohorts using different ontologies (e.g.: SNOMED, MedDRA, RxNorm, WHO ATC)

RESULTS

- Successfully applied to multiple clinical trials
- Leveraged 5 CDM v4 networked sources:
  - Optum ClinFormatics,
  - Truven MarketScan CCAE & MDCR
  - Premier
  - Clinical Practice Research Datalink
- Rapid results for complex protocols:
  - Contained up to 30 different criteria
  - Input into system in under an hour
  - Generated results in under an hour

DISCUSSION

- Clinical trial feasibility assessment is an important use case for observational health data.
- The OMOP Common Data Model v4 supports many of the key data elements necessary for feasibility assessment.
- Applications, such as PSYCHIC, can be developed to enable observational data to be efficiently analyzed in a more standardized manner, facilitating immediate and direct access for interested stakeholders.

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If you have an interest in becoming an external data provider, please contact us:

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