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Using OHDSI tools to conduct clinical trial feasibility

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Abstract

Observational data has been used in support of various epidemiological studies including safety surveillance, cohort characterization and outcomes research. A novel use of observational data that has recently been enabled through the use of OHDSI tools is assessing clinical trial feasibility. Using the tools from the OHDSI network we are able to apply standard methods to effectively assess inclusion criteria to a potential clinical trial population. The result of using observational data has provided efficiencies in protocol design, the ability to address operational questions and possibly avoid protocol amendments. By using the common data model, standard vocabularies and OHDSI tools we are able to deliver results in a standard, concise, timely and reproducible manner.

Introduction

The use of observational data in retrospective analyses have been thoroughly explored and studied. Applying this data in the use of clinical trial feasibility has been a new application of the data(1). By utilizing the OMOP common data model (OMOP CDM) and the current OHDSI tools, the ability to utilize the data in clinical trial feasibility is possible and can address operational questions, provide insight in overall population eligibility, impact protocol design, and possibly avoid protocol amendments for a clinical trial.. At Janssen this utility is provided to clinical teams by identifying appropriate protocols that could be studied using observational data.

Methods

A typical protocol will go through the following steps:

1.) Eligible protocols are identified in therapeutic areas that are of interest to the organization throughout the clinical trial lifecycle from as early as trial design through active trials facing recruitment challenges.

2.) Review of inclusion/exclusion criteria that can be addressed through the data elements available in the CDM data available.

3.) Creation of concept sets and/or utilization of concept sets from standard vocabularies in ATLAS to describe inclusion criteria. Each criteria of interest is applied to the index population (or inclusion criteria) in CALYPSO.

4.) The individual match percentages for each criteria and overall match criteria are evaluated for each protocol (Figure 1)
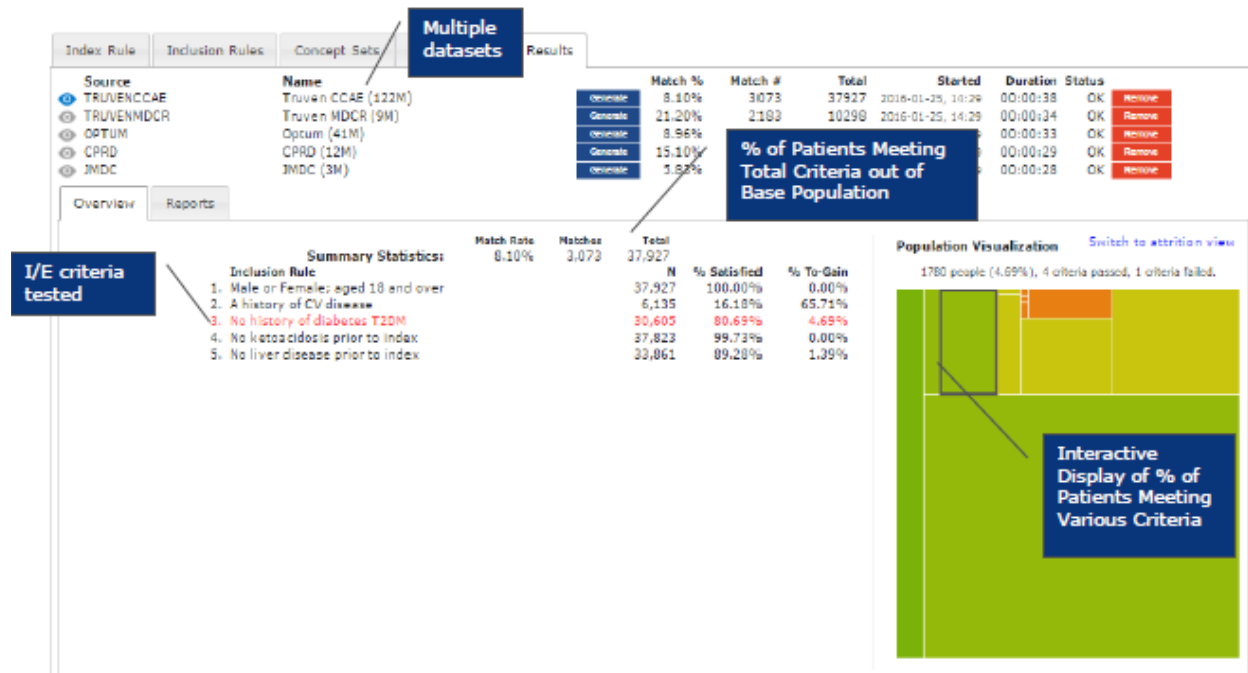
Figure 1. Screen shot of CALYPSO tool used for clinical trial feasibility

Results

Protocols have been analyzed in the following therapeutic areas: cardiovascular and metabolic, CNS (central nervous system), oncology, and infectious disease. For these protocols we were able to apply all diagnostic, procedural, laboratory criteria from various protocols. After completing the analysis for various teams, the analysis provided actionable insights about their population that were otherwise unknown. A protocol in CNS provided actionable insights around inclusion age ranges. Other insights gained were: confirmation of the inclusion population, assessing restrictive criteria in a protocol, checking for adequate match rates. All of these insights provided more realistic recruitment assumptions and overall trial viability. The ability to execute the analyses in a timely manner and on various database by utilizing the common data model provided teams with a variety of recruitment populations based on enrollment regions.

Conclusion

The ability to analyze clinical trial feasibility thorough observational data can provide substantial insights in avoiding amendments, recruitment challenges and protocol design. The ability to utilize the common data model across various databases allows for the analysis to be simulated in different populations and geographies which can be representable of recruitment regions. The tool can facilitate many assumptions in a protocol for clinical trial feasibility a priori which is a valuable proposition. The OHDSI tools provide a strong framework to conduct the analysis in a standardized and reproducible manner.

References

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