OHDSI-enabled distributed network analysis for clinical trial feasibility: a collaborative case study to inform a pediatrics randomized trial.

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INTRO

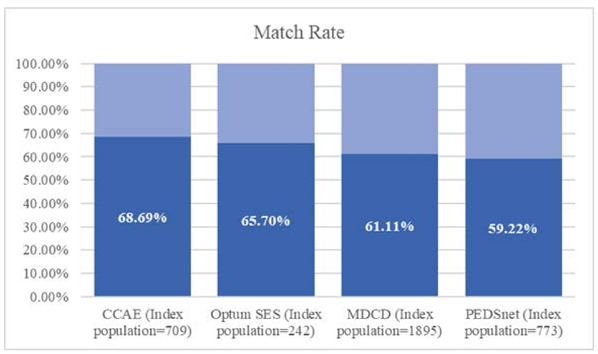
Successful clinical trial design requires matching experimentally desirable cohort characteristics with the actual population of potential participants. Clinical trial feasibility analyses address operational questions, provide insight in overall population eligibility, impact protocol design, and can potentially avoid protocol amendments for a clinical trial. The work supports a pediatric phase III trial in type 2 diabetes with slow accrual to date.

METHODS

1. Protocol specifications in the form of inclusion/exclusion criteria are identified
2. Concept sets, and index cohorts are implemented as inclusion rules in ATLAS[3] which are run against claims databases using the OMOP common data model (OMOP CDM)[1,2]
3. Results are shared with the clinical team. In this study,
4. ATLAS was used at both sites across the PEDSnet network, IBM MarketScan® Commercial Database (CCAE), IBM MarketScan® Multi-State Medicaid Database (MDCD) and Optum© De-Identified Clinformatics® Data Mart Database – Socio-Economic Status (SES) (Optum SES) datasets.
5. The impact of various inclusion/exclusion criteria, database denominators, match rates and sensitivity analyses around definitions applied were compared

RESULTS

Figure 1. Match rate by database and index population size



Assessing the **impact of a clinical trial protocol implementation** with the OHDSI framework provides an avenue to understand feasibility of a population as well as a **path to recruit patients from data networks**

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The study protocol document consisted of 31 eligibility criteria from various data domains (10 conditions, 7 measurements, 5 drug, 5 administrative, 2 procedures, 1 observation, 1 demographic). Of the 31 criteria, 18 could be evaluated in the US claims databases and 22 in PEDSnet. The additional 4 criteria evaluated were specific to laboratory measurements captured in the PEDSnet database that were not adequately captured in U.S. claims datasets. The database denominators or patient population (the pool of patients available that meet age and recent time criteria, exclusive of specific diagnoses) from the 3 US claims datasets (CCAE, Optum SES and MDCD) and PEDSnet are presented in Table 1.

Table 1. Database denominators from U.S. claims dataset and PEDSnet.

Database	Total population in database with observation time in 2016 and at least 1 visit	Aged 10 to 17 with observation time 2016 and at least 1 visit	%
CCAE	16,478,892	1,985,478	12.05
Optum	10,402,217	781,280	7.51
MDCD	5,263,861	1,360,050	25.84
PEDSnet	1,852,980*	687,647*	37.11

*PEDSnet used 2017 data.

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