

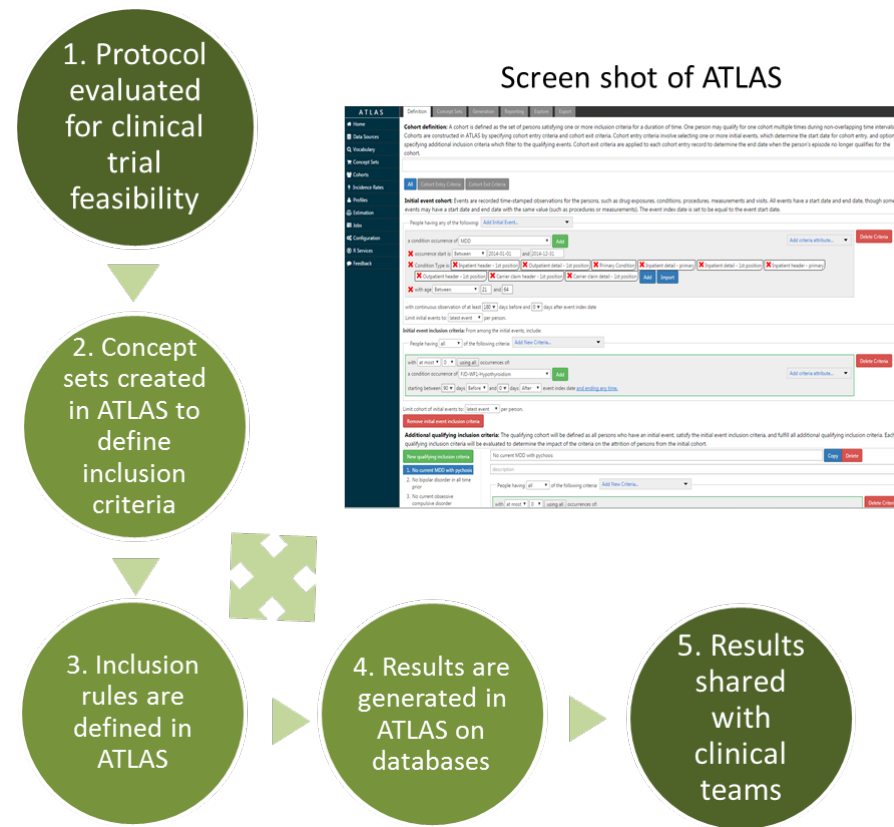
OHDSI-enabled distributed network analysis for clinical trial feasibility: a collaborative case study to inform a pediatrics randomized trial.

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Clinical trial feasibility, what is it and why is this important?

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.



Case study: Pediatric patients with Type II diabetes

This study presents a two-site (U.S. claims networks and hospital network) analysis using the OHDSI toolset (OMOP common data model (CDM) and ATLAS) to conduct clinical trial feasibility based on the protocol for an ongoing phase III randomized study to investigate the efficacy and safety of canagliflozin in a type II diabetic pediatric population.

Conducting feasibility with de-identified claims data in ATLAS

1. Find appropriate databases

Databases: 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)

2. Set index criteria

Patients aged 10-17 with a Type II diabetes diagnosis; with at least 365 days of enrollment time; an additional Type II diabetes diagnosis prior to index and limited evidence of Type I diabetes.

Conducting feasibility with de-identified claims data

3. Define inclusion and exclusion criteria

Protocol specified 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

4. Analyze results

709 patients satisfy the index criteria with 487 patients (68.69%) matching all criteria implemented in CCAE

Collaboration with PEDSnet

PEDSnet contains electronic health records from 7 of the nation's largest pediatric health systems, covering outpatient and inpatient care. Data has been transformed to the CDM, and can be addressed using ATLAS.



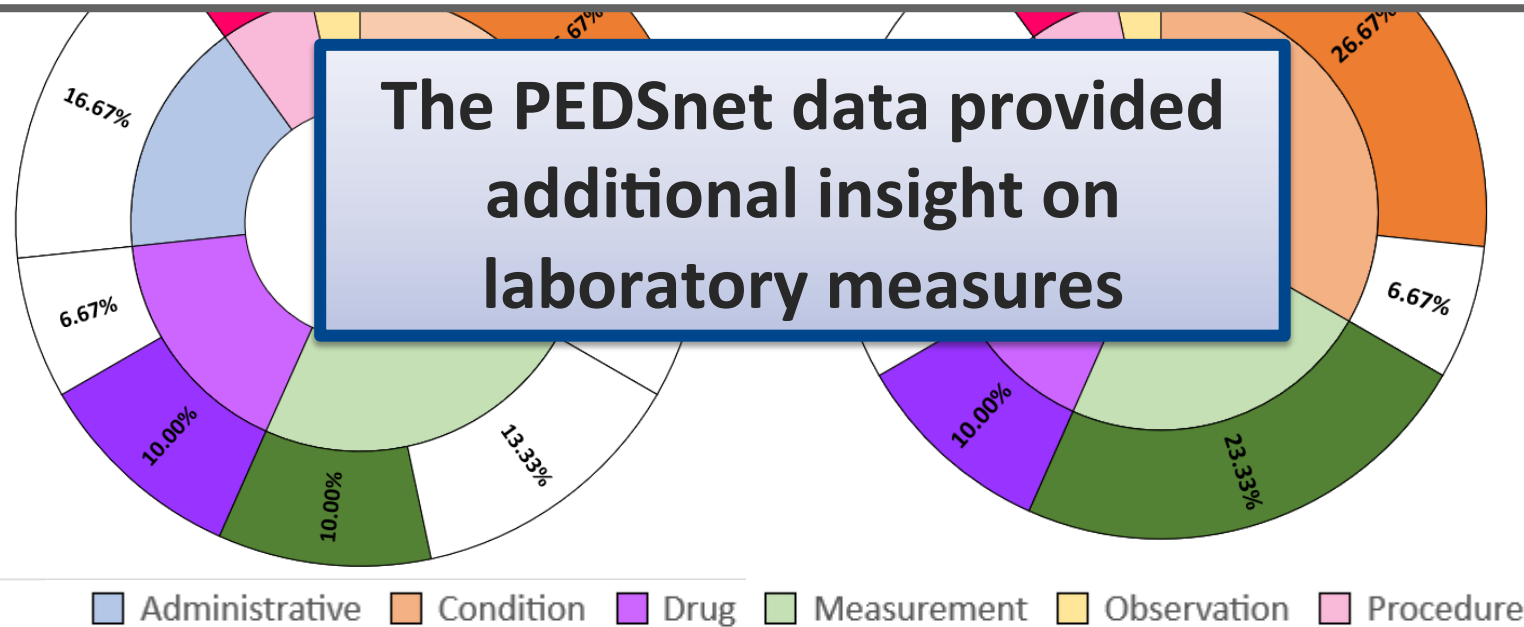
We spent a day together and were able to solely use ATLAS and share JSON to start the process of conducting similar feasibility—without sharing patient level data, or re-entering code sets!

What did we find?

Measurable criteria

Conditions, procedures, observations are measured similarly from both the claims dataset and PEDSnet

The PEDSnet data provided additional insight on laboratory measures



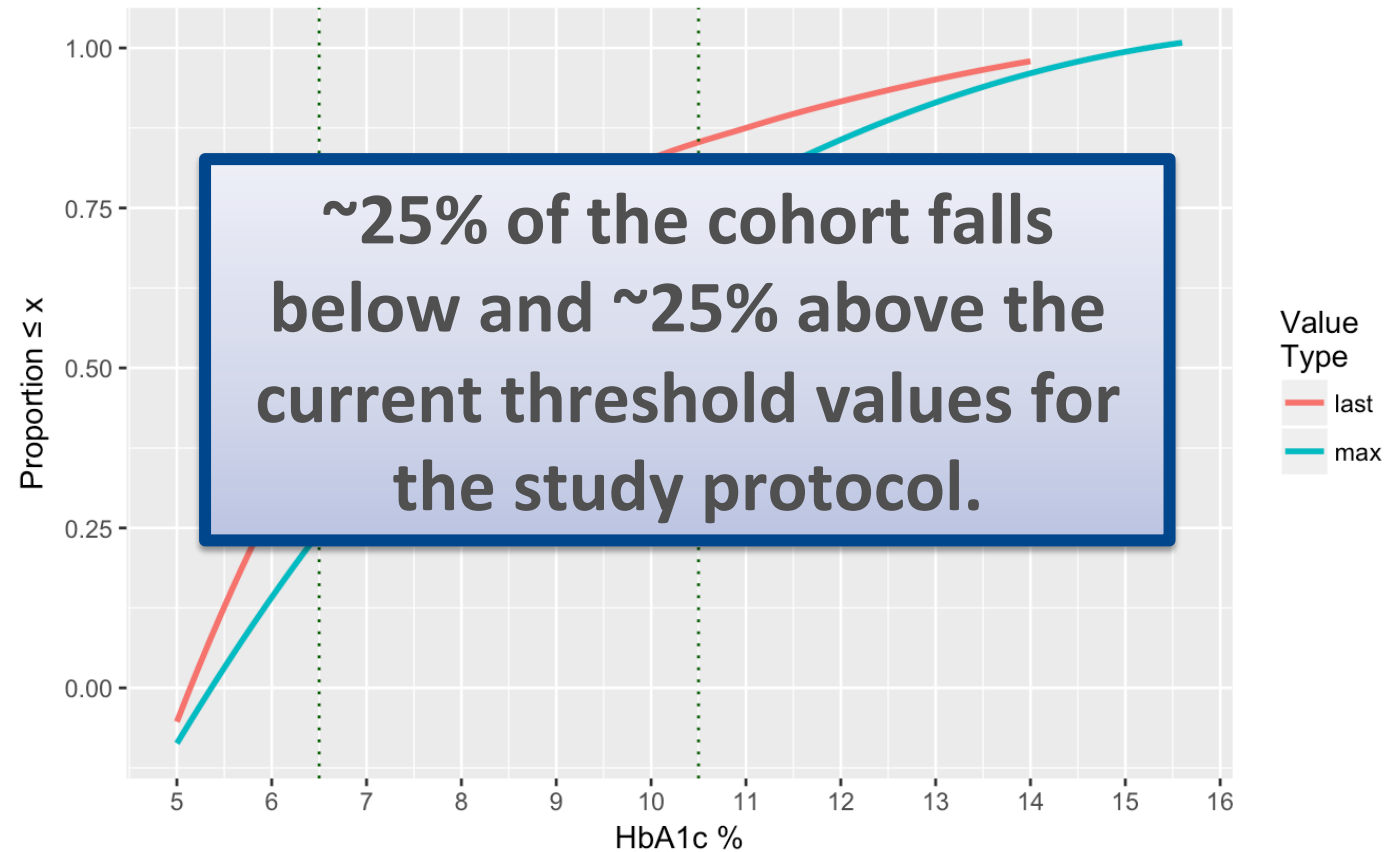
What did we find?

Measurable criteria

- No single criteria affected the protocol more than 10% of the population in either dataset (IBM CCAE & PEDSnet).
- The biggest drop-off in patients was with criteria in regarding anti-convulsant medications, prior history of type I diabetes, severe hypoglycemia or seizure or loss of consciousness 6 months prior to and including index and prior diagnosis of diabetic ketoacidosis.

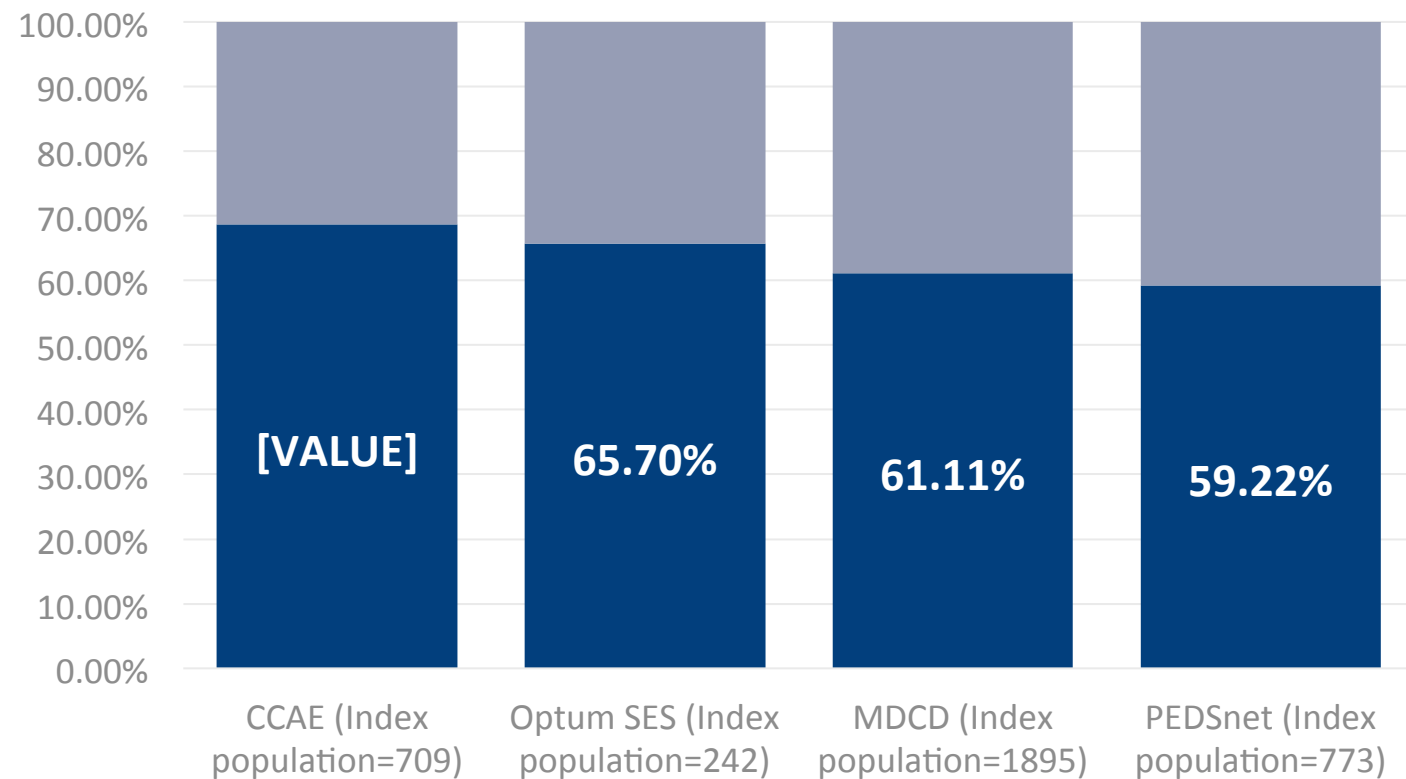
What did we find?

Criteria thresholds



What did we find?

Matching population



Feasibility to patient recruitment

- By utilizing the OHDSI framework and ATLAS we are able to conduct multi-site feasibility in real- time with real world evidence that can meaningfully inform clinical trial design and aid in recruitment and enrollment of eligible populations.
- Clinical trial inclusion criteria can often, but not always, be evaluated in observational data and by the extension of including a pediatric network that contain possible sites for enrollment we can further validate the exercise of feasibility and its role in clinical development and patient recruitment.
- **By assessing the impact of protocol implementation on the proportion of patients from a clinical trial 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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