Data and Infrastructure for Medical Product Surveillance

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Progress in Medical Product Safety Surveillance

- Use of existing electronic health data for new purpose
- Multiple examples ongoing
  - Vaccine safety datalink (CDC)
  - PRISM (HHS/FDA)
  - OMOP (FNIH)
  - Sentinel (FDA)

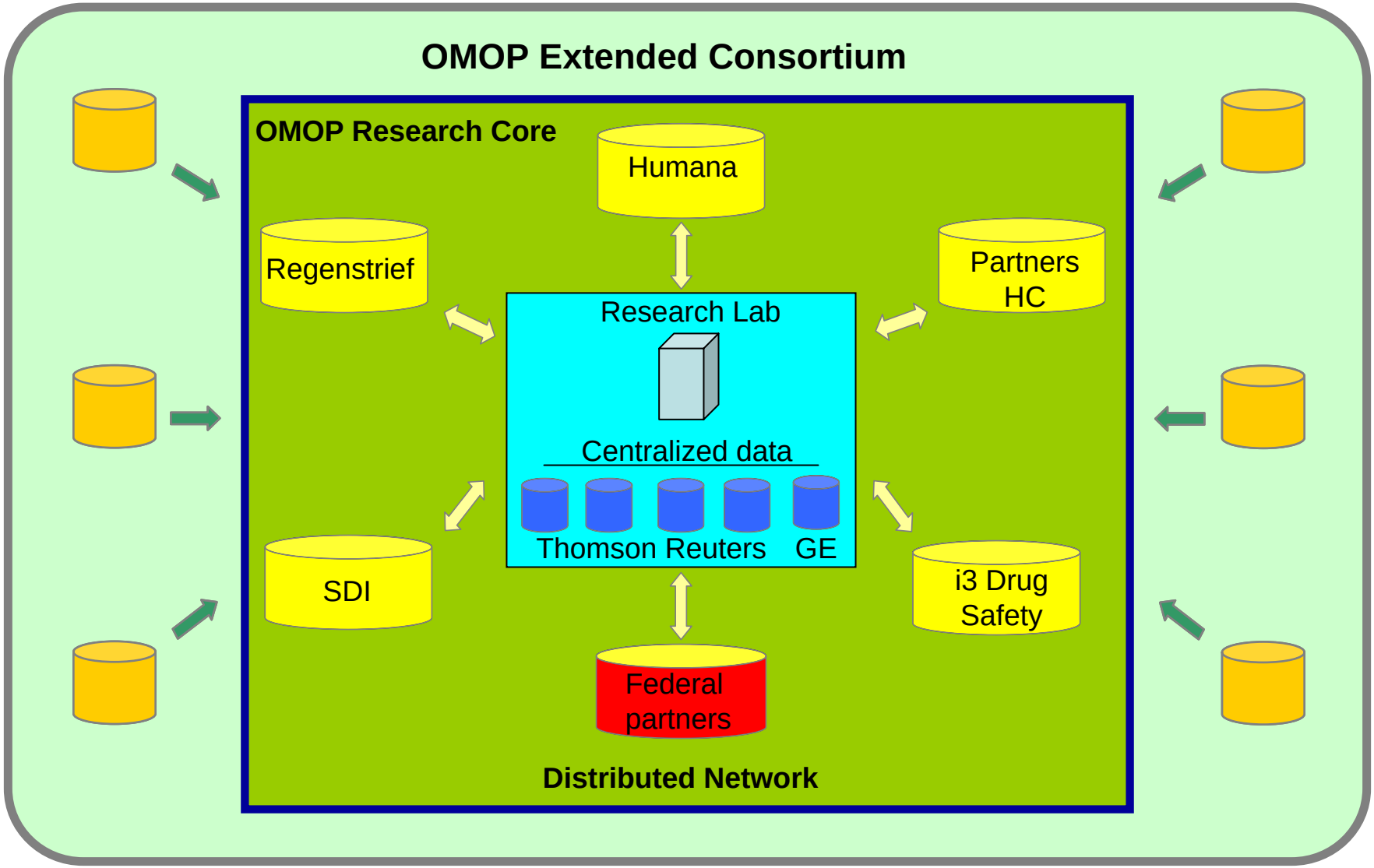
PRISM

- Post-licensure rapid immunization safety monitoring system
- Health plans and state immunization registries
- 25M persons in health plans and 14M in state programs
- Compare selected events during post immunization windows to historical and personal controls

OMOP

- Observational Medical Outcomes Pilot
- Operated through Foundation for NIH
- Assembling commercial data (centralized), health plan and billing data (behind firewalls) and extended partners (run parallel analyses in own systems)
- Focus on data model, methods and definition/detection of known drug/health outcome of interest pairs

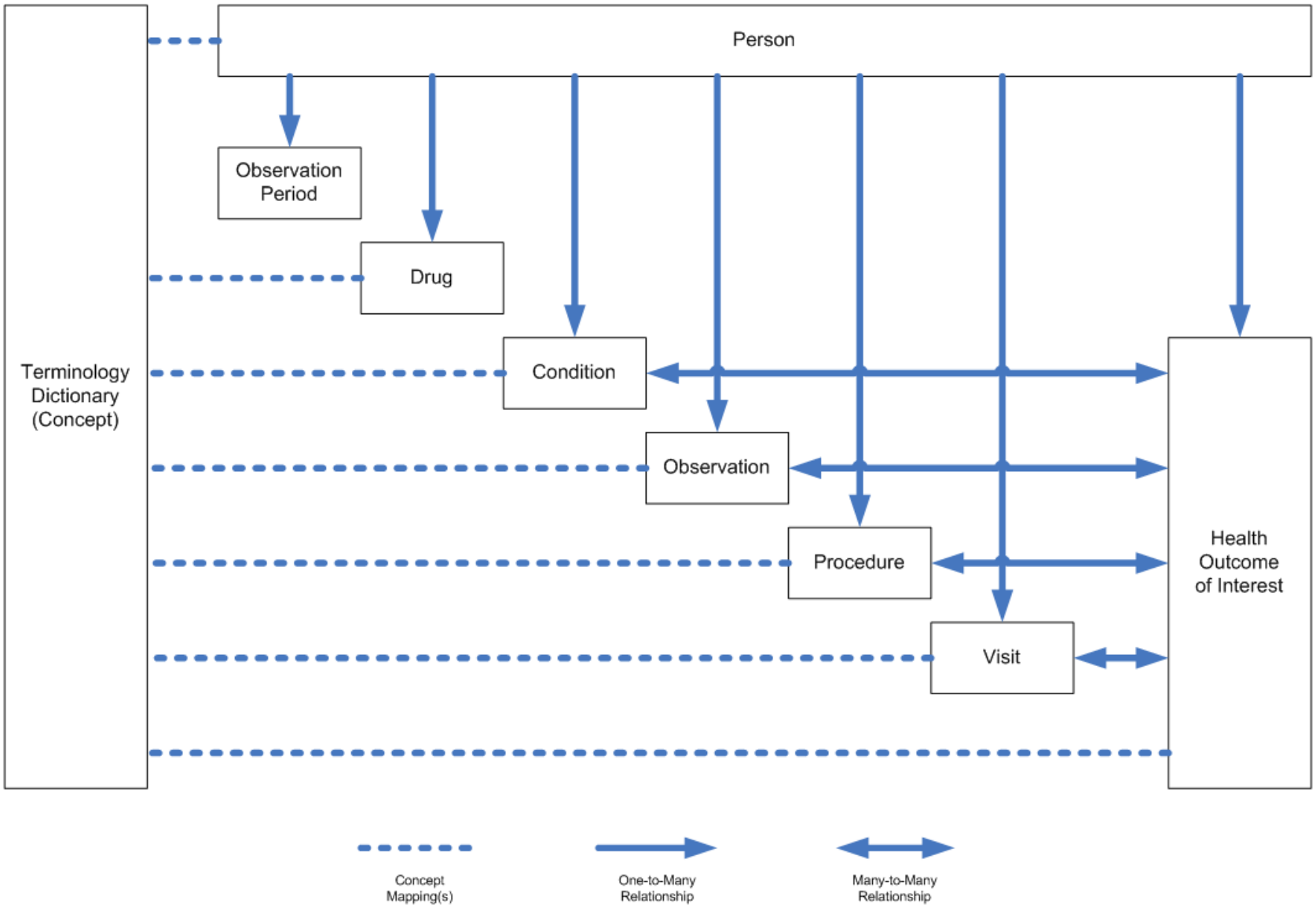
OMOP Data Community



- The common data model includes:
  - A single data schema that can be applied to disparate data types
  - Standardized terminologies
  - Consistent transformation for key data elements
- A common data model can:
  - Enable consistent and systematic application of analysis methods to produce comparable results across sources
  - Create a community to facilitate the sharing of tools and practices
  - Impose data quality standards
  - Create implementation efficiencies

Common Data Model	
What We Are Doing	**What We Are Not Doing**
• Creating one model that could accommodate any relevant type of observational data • Facilitating comparison of analysis results across sources • Providing a conceptual model to allow researchers to develop analysis methods that are be portable across data sources	• Combining multiple datasets into one centralized database • Trying to force claims data into a EHR model or vice versa • Developing a graphical user interface to automatically create structured queries

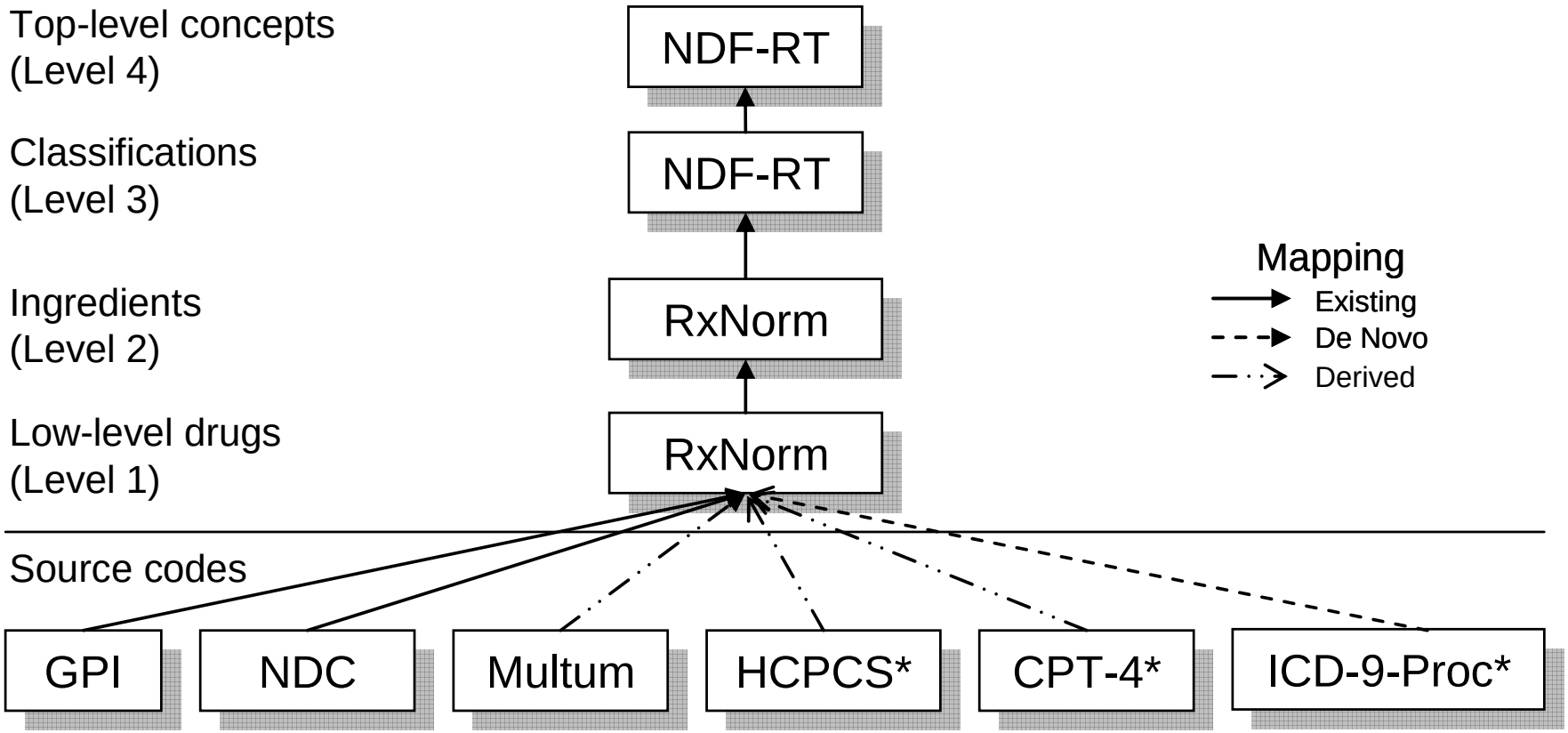
Conceptual Schematic of OMOP



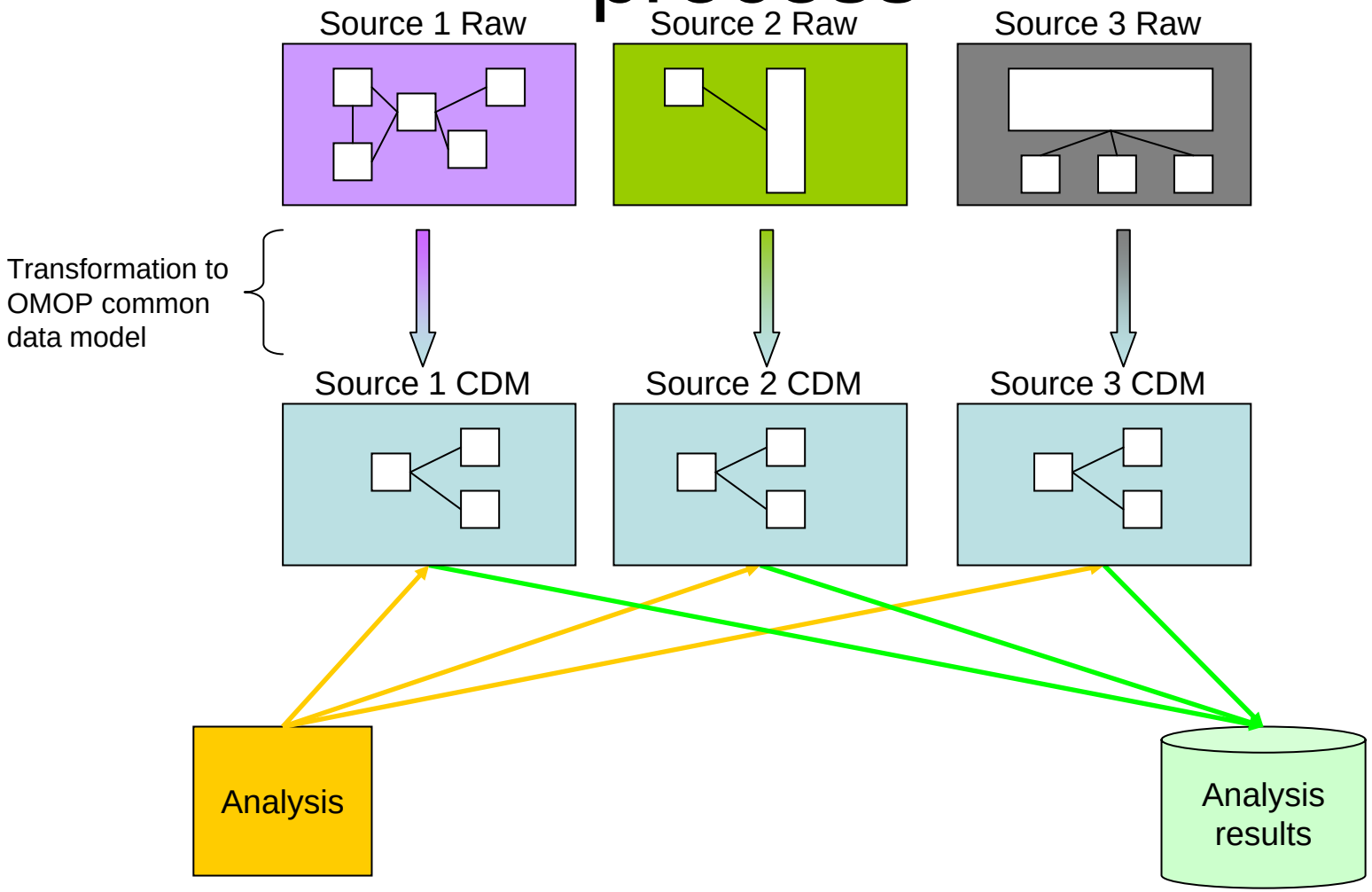
Drug-HOI Pairs

Drug/class	Health Outcome of Interest
ACE inhibitors	Angioedema
ACE inhibitors	Hospitalization (including readmission and mortality)
Amphotericin B	Renal failure
Antibiotics: erythromycins, sulfonamides, and tetracyclines	Acute liver injury (symptomatic hepatitis)
Antiepileptics: carbamazepine, valproic acid, and phenytoin	Aplastic anemia
Benzodiazepines	Hip fracture
Beta blockers	Mortality after MI
Bisphosphonates: alendronate	GI ulcer hospitalizations
Tricyclic antidepressants	Myocardial infarction
Typical antipsychotics	Myocardial infarction
Warfarin	Bleeding

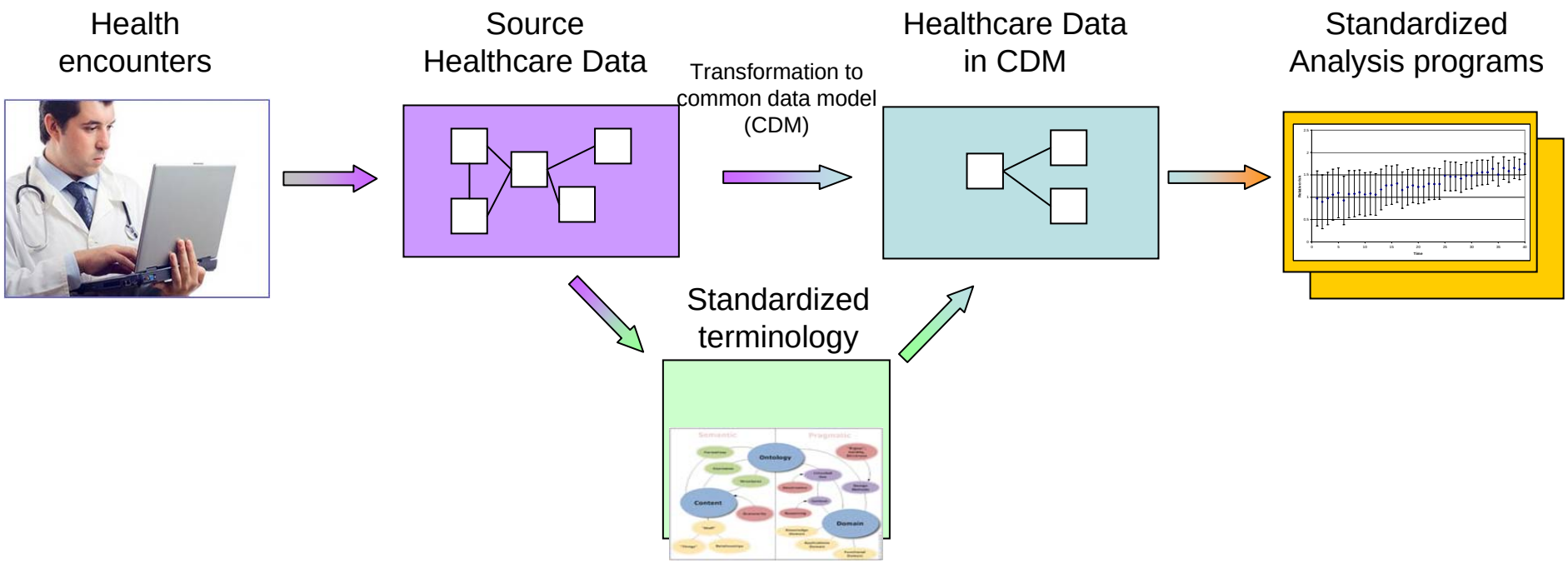
Standardizing terminologies for drugs



Role of CDM in OMOP Analysis process



Systematic Learning



- This process is being studied across the OMOP Data Community today to study the effects of medicines
- Provides a vehicle to systematically compare results of analysis across disparate data sources
- The process is enabled by standardized terminology mappings, a common data model, and standardized statistical analysis programs

Sentinel System

- Develop an active electronic safety monitoring system to
  - Strengthen FDA's ability to monitor postmarket performance of medical products
  - Augment, not replace, existing safety monitoring systems
  - Enable FDA to access existing automated healthcare data by partnering with data holders (e.g., insurance companies with large claims databases, owners of electronic health records, others)

Sentinel Prototype

- Develop a coordinating center for a distributed system
  - Access three or more health data environments with varied attributes to conduct analyses
  - Convene a Planning Board to develop governing documents and establish a Safety Science Committee charged with the day-to-day operations
  - Develop a means for secure communication with contracted data holders
- Evaluate emerging methods in safety science
  - Develop epidemiological and statistical methodologies for signal detection, signal strengthening, and signal validation
  - Test such methodologies in the evaluation of FDA-identified medical product-adverse event pairs of concern

Federal Partners Collaboration

- An active surveillance initiative via intra-agency agreements with CMS, VA, DoD
- Identify medical product – AE pairs to evaluate
- Evolve active surveillance methodologies
- Evaluate interpretability of query findings resulting from a decentralized analytic approach

Capturing Reliable Information

- Pharmacoepidemiology: “health outcome”
- Classical epidemiology: “case definition”
- Pharmacovigilance: “adverse event”
- Genomics: “phenotype”
- Meta-analyses: “standardized data”

- Challenges very similar for effectiveness outcomes, quality of care, etc.

Common Themes with New Infrastructure

- Perform analyses at site of data owner: do not create centralized data set
- Build analytic and data standardization at sites
- How to integrate standardized data capture with medical workflow: CMS experience
- Capacity building at sites will be needed