Sentinel

Medical Product Safety Surveillance: Data Quality in the Sentinel Initiative

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Sentinel Program Overview

What is the Sentinel System?

One of the FDA's biggest jobs is to make sure drugs, vaccines, and medical devices are safe. FDA wants to know if patients get bad side effects from these products. To make it faster and easier to learn about problems, FDA created a special program called the Sentinel System.

How the Sentinel System Works

Sentinel System's 3 important parts

- **Information: The system looks at billing claims and patient records.**
- **Expert Team: Sentinel works with scientists, doctors and computer experts.**
- **Computer Programs: They study large groups of patients who take the same medicine, or use the same device.**

Personal privacy

- **No one at FDA or the Sentinel Operations Center has access to your name, address, or any other information that identifies you.**
- **For more information, visit sentinelinitiative.org.**

Sentinel asks questions like:

- **How many patients take the same drug?**
- **How many patients are getting bad side effects (swelling, bleeding, etc.)?**
- **Are side effects more common after taking one drug than after another drug that treats the same problem?**

How does FDA use the information?

- **FDA can choose to collect more information.**
- **FDA can provide updated safety information for patients and providers.**
- **If you have concerns about your own medical products, please contact your doctor.**

https://www.sentinelinitiative.org/sentinel-system-story

Collaborating Organizations

Lead – HPHC Institute

DEPARTMENT OF POPULATION MEDICINE
HARVARD MEDICAL SCHOOL
Harvard Pilgrim Health Care Institute

Data & Scientific Partners

Blue Cross Blue Shield Massachusetts
HealthCore Anthem
HCA Healthcare
health care systems research network
Department of Population Health Sciences
Duke University School of Medicine
VANDERBILT SCHOOL OF MEDICINE
OPTUM
HUMANA
KAISER PERMANENTE
aetna

Scientific Partners

Penn Medicine
IQVIA
Cincinnati Children's change the outcome
UNC GILLINGS SCHOOL OF GLOBAL PUBLIC HEALTH
HARVARD T.H. CHAN SCHOOL OF PUBLIC HEALTH
DEPARTMENT OF MEDICINE BRIGHAM AND WOMEN'S HOSPITAL HARVARD MEDICAL SCHOOL
AHIP America's Health Insurance Plans
UF College of Pharmacy UNIVERSITY of FLORIDA
UAB
UIC
THE UNIVERSITY OF IOWA COLLEGE OF PUBLIC HEALTH
RUTGERS

https://www.sentinelinitiative.org/collaborators

Sentinel Infrastructure: Available Data Elements

Sentinel Data Philosophy

- Includes claims, electronic health record (EHR), and registry data and flexible enough to accommodate new data domains (e.g., free text).
  - Typically, we do not include empty tables – we expand as needed when fit for purpose.
- Data are stored at most granular/raw level possible with minimal mapping.
  - Distinct data types should be kept separate (e.g., prescriptions, dispensings)
  - Construction of medical concepts (e.g., outcome algorithms) from these elemental data is a project-specific design choice.
  - Sentinel stores these algorithms in a library for future use.
- Appropriate use and interpretation of local data requires the Data Partners' local knowledge and data expertise.
  - Not all tables are populated by all Data Partners➔site-specificity is allowed.
- Designed to meet FDA needs for analytic flexibility, transparency, and control.

Available Data Elements

Administrative Data

Enrollment	Demographic	Dispensing	Encounter	Diagnosis	Procedure
Patient ID	Patient ID	Patient ID	Patient ID	Patient ID	Patient ID
Enrollment Start & End Dates	Birth Date	Dispensing Date	Service Date(s)	Service Date(s)	Service Date(s)
Drug Coverage	Sex	National Drug Code (NDC)	Encounter ID	Encounter ID	Encounter ID
Medical Coverage	Zip Code	Days Supply	Encounter Type and Provider	Encounter Type and Provider	Encounter Type and Provider
Medical Record Availability	Etc.	Amount Dispensed	Facility	Diagnosis Code & Type	Procedure Code & Type
			Etc.	Principal Discharge Diagnosis	Etc.

Clinical Data

Lab Result	Vital Signs
Patient ID	Patient ID
Result & Specimen Collection Dates	Measurement Date & Time
Test Type, Immediacy & Location	Height & Weight
Logical Observation Identifiers Names and Codes (LOINC®)	Diastolic & Systolic BP
Etc.	Tobacco Use & Type
	Etc.

Registry Data

Death	Cause of Death	State Vaccine
Patient ID	Patient ID	Patient ID
Death Date	Cause of Death	Vaccination Date
Source	Source	Admission Date
Confidence	Confidence	Vaccine Code & Type
Etc.	Etc.	Provider
		Etc.

Inpatient Data

Inpatient Pharmacy	Inpatient Transfusion
Patient ID	Patient ID
Administration Date & Time	Administration Start & End Date & Time
Encounter ID	Encounter ID
National Drug Code (NDC)	Transfusion Administration ID
Route	Transfusion Product Code
Dose	Blood Type
Etc.	Etc.

Mother-Infant Linkage Data

Mother-Infant Linkage
Mother ID
Mother Birth Date
Encounter ID & Type
Admission & Discharge Date
Child ID
Child Birth Date
Mother-Infant Match Method
Etc.

https://www.sentinelinitiative.org/sentinel/data/distributed-database-common-data-model

Single Patient Example Data in Model

DEMOGRAPHIC

PATID	BIRTH_DATE	SEX	HISPANIC	RACE	zip
PatID1	2/2/1964	F	N	5	32818

DISPENSING

PATID	RXDATE	NDC	RXSUP	RXAMT
PatID1	10/14/2005	00006074031	30	30
PatID1	10/14/2005	00185094098	30	30
PatID1	10/17/2005	00378015210	30	45
PatID1	10/17/2005	54092039101	30	30
PatID1	10/21/2005	00173073001	30	30
PatID1	10/21/2005	49884074311	30	30
PatID1	10/21/2005	58177026408	30	60
PatID1	10/22/2005	00093720656	30	30
PatID1	10/23/2005	00310027510	30	15

ENROLLMENT

PATID	ENR_START	ENR_END	MEDCOV	DRUGCOV
PatID1	7/1/2004	12/31/2004	Y	N
PatID1	1/1/2005	12/31/2005	Y	Y

DEATH

PATID	DEATHDT	DTIMPUTE	SOURCE	CONFIDENCE
PatID1	12/27/2005	N	S	E

ENCOUNTER

PATID	ENCOUNTERID	ADATE	DDATE	ENCTYPE
PatID1	EncID1	10/18/2005	10/20/2005	IP

DIAGNOSIS

PATID	ENCOUNTERID	ADATE	PROVIDER	ENCTYPE	DX	DX_CODETYPE	PDX
PatID1	EncID1	10/18/2005	Provider1	IP	296.2	9	P
PatID1	EncID1	10/18/2005	Provider1	IP	300.02	9	S
PatID1	EncID1	10/18/2005	Provider1	IP	305.6	9	S
PatID1	EncID1	10/18/2005	Provider1	IP	311	9	P
PatID1	EncID1	10/18/2005	Provider1	IP	401.9	9	S
PatID1	EncID1	10/18/2005	Provider1	IP	493.9	9	S
PatID1	EncID1	10/18/2005	Provider1	IP	715.9	9	S

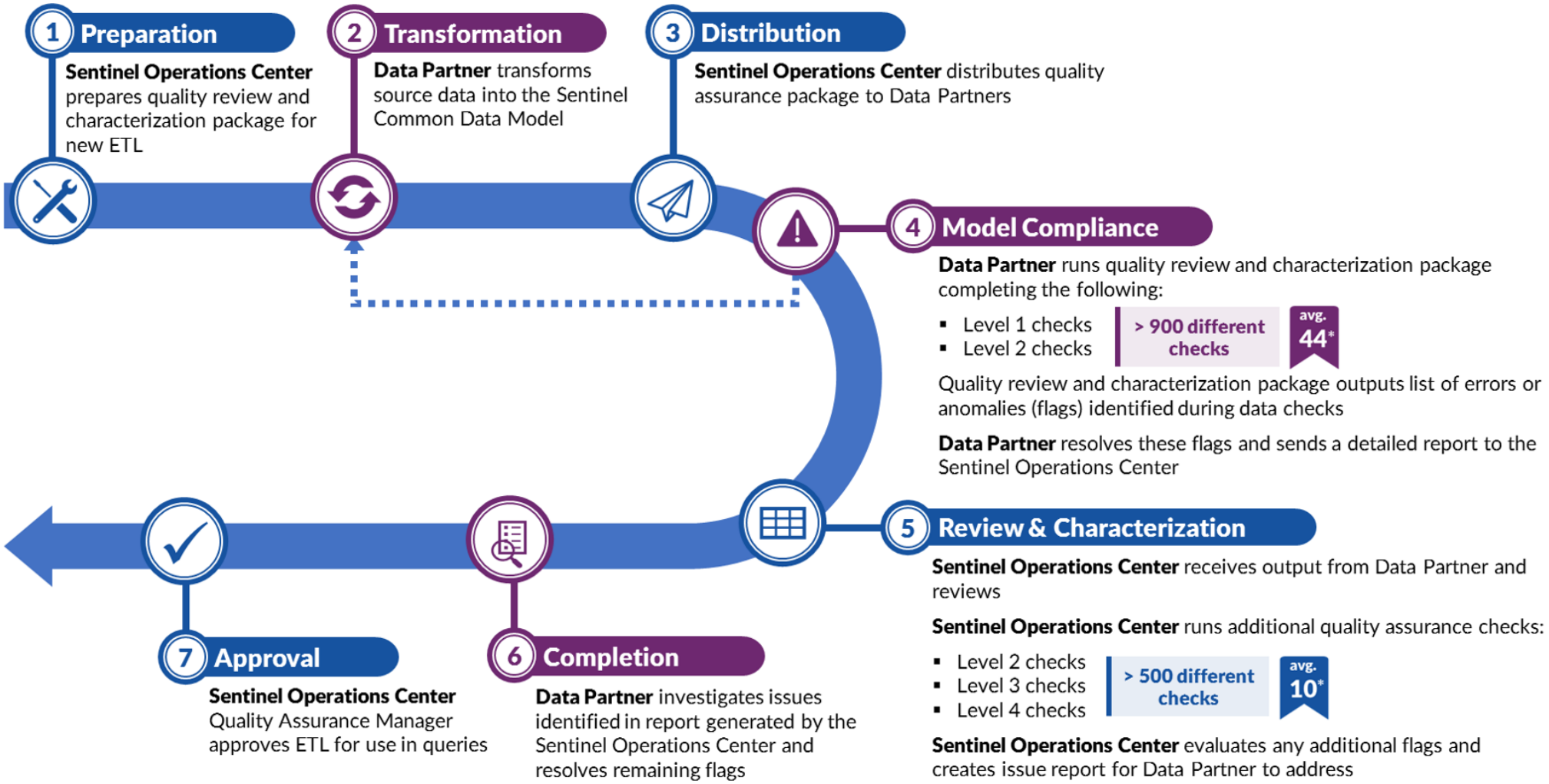
PROCEDURE

PATID	ENCOUNTERID	ADATE	PROVIDER	ENCTYPE	PX	PX_CODETYPE
PatID1	EncID1	10/18/2005	Provider1	IP	84443	C4
PatID1	EncID1	10/18/2005	Provider1	IP	99222	C4
PatID1	EncID1	10/18/2005	Provider1	IP	99238	C4
PatID1	EncID1	10/18/2005	Provider2	IP	27445	C4

CAUSE OF DEATH

PATID	COD	CODETYPE	CAUSETYPE	SOURCE	CONFIDENCE
PatID1	J18.0	10	U	S	E

Data Quality Review and Characterization Process



* On average, there are 44 flags identified by the program and 10 additional flags identified by the Sentinel Operations Center per ETL

https://www.sentinelinitiative.org/sentinel/data-quality-review-and-characterization

Data Quality Checks and Examples

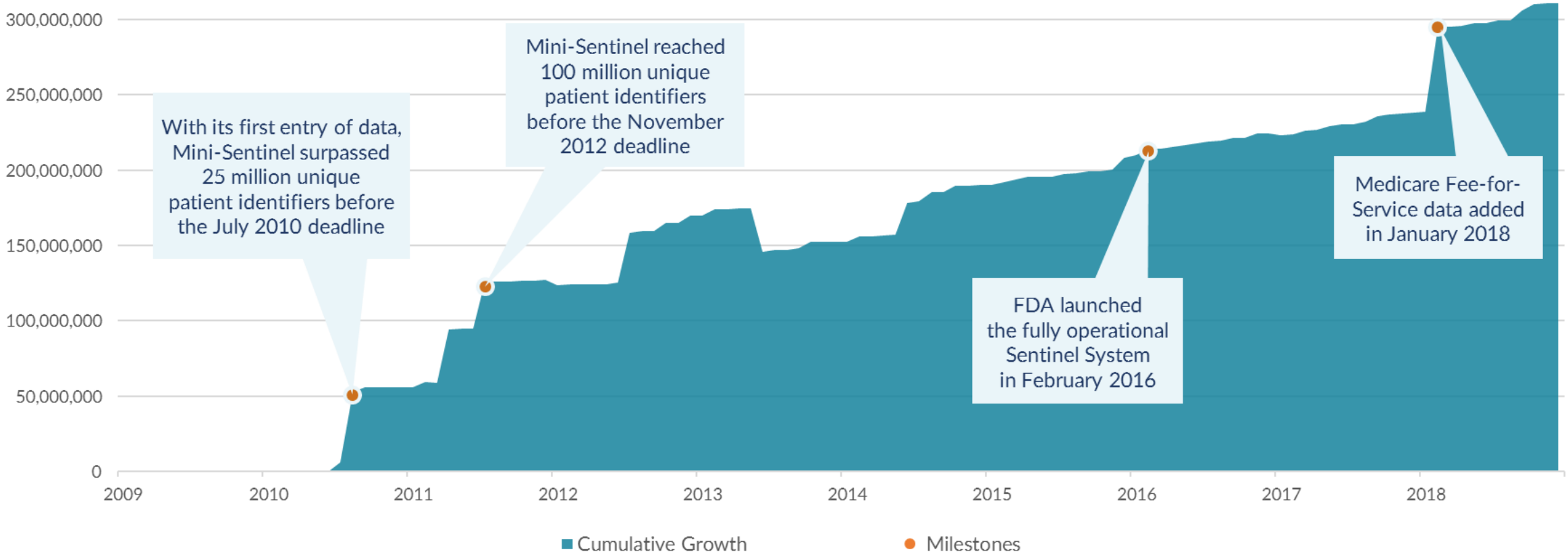
Level 1 Checks	**Completeness** ✓ Admission date is not missing value **Validity** ✓ Admission date is in date format	Sentinel Common Data Model Compliance
Level 2 Checks	**Accuracy** ✓ Admission date occurs before the patient's discharge date **Integrity** ✓ Admission date occurs within the patient's active enrollment period	Cross-Variable and Cross-Tabular
Level 3 Checks	**Consistency of Trends** ✓ There is no sizable percent change in admission date record counts by month-year	Cross-ETLs
Level 4 Checks	**Plausibility** ✓ There is no sizable percent change in the number of prostate cancer encounters by sex*	Cross-ETLs

**Under development*

https://www.sentinelinitiative.org/sentinel/data-quality-review-and-characterization

Growth of the Sentinel Distributed Database

- 70 million members currently accruing new data



The area above depicts the cumulative number of unique patient identifiers in the Sentinel Distributed Database from 2010 to present. If patients move health plans, they may have more than one patient identifier.

http://www.sentinelinitiative.org/sentinel/data/snapshot-database-statistics

Publicly Available Formatted Data

Submit Comment

Medicare Claims Synthetic Public Use Files in Sentinel Common Data Model Format

Project Title	Medicare Claims Synthetic Public Use Files in Sentinel Common Data Model Format
Date Posted	*Wednesday, March 27, 2019*
Status	Complete
Deliverables	Sentinel's SynPUFs Software Toolkit SynPUFs Example Sentinel Modular Program Report
Related Links	Centers for Medicare and Medicaid Services Synthetic Public Use Files (SynPUFs)
Description	Sentinel has made available the CMS 2008-2010 Data Entrepreneurs' Synthetic Public Use Files (SynPUFs) in the Sentinel Common Data Model (SCDM) format. This transformation of data allows for the running of Sentinel's Routine Querying System tools, including the Cohort Identification and Descriptive Analysis (CIDA) tool, on the SynPUFs data. The CMS SynPUFs are available in the form of 20 mutually exclusive datasets, which together make up a 5% sample of the entire CMS database from 2008-2010. Each of the 20 datasets contains about 110,000 members. The intended use of these data in SCDM format is to generate familiarity with the CIDA tool and its capabilities and to allow for methodological expansion.

- 2.2M synthetic beneficiaries
- 20 mutually exclusive data samples

http://www.sentinelinitiative.org/sentinel/surveillance-tools/software-toolkits/Medicare-SynPUFs-in-SCDM

Mechanism to Transform Commercial Data

Submit Comment

SAS Code for Transforming the IBM MarketScan® Research Databases (MarketScan) into the Sentinel Common Data Model

Project Title	**SAS Code for Transforming the IBM MarketScan® Research Databases (MarketScan) into the Sentinel Common Data Model**
Date Posted	*Tuesday, January 29, 2019*
Status	Complete
Description	The Sentinel Operations Center and IBM Watson Health have partnered to make SAS® code available for transforming the IBM MarketScan® Commercial and Medicare Supplemental Databases into the Sentinel Common Data Model. If your organization currently licenses either of these databases and wishes to leverage the analytic infrastructure developed by Sentinel by transforming these data into the Sentinel Common Data Model, please click the 'Submit Comment' button on this page to request access. The Sentinel Operations Center will send you a MarketScan License Verification form. Contingent on license validation by IBM Watson Health, Sentinel will share the SAS code and documentation with your organization.

https://www.sentinelinitiative.org/sentinel/data/distributed-database-common-data-model/sas-code-transforming-ibm-marketscan-research

Sentinel Data Queries: Routine Querying Tools

Sentinel Infrastructure Supports Multiple Aims

Sentinel Infrastructure

Sentinel System

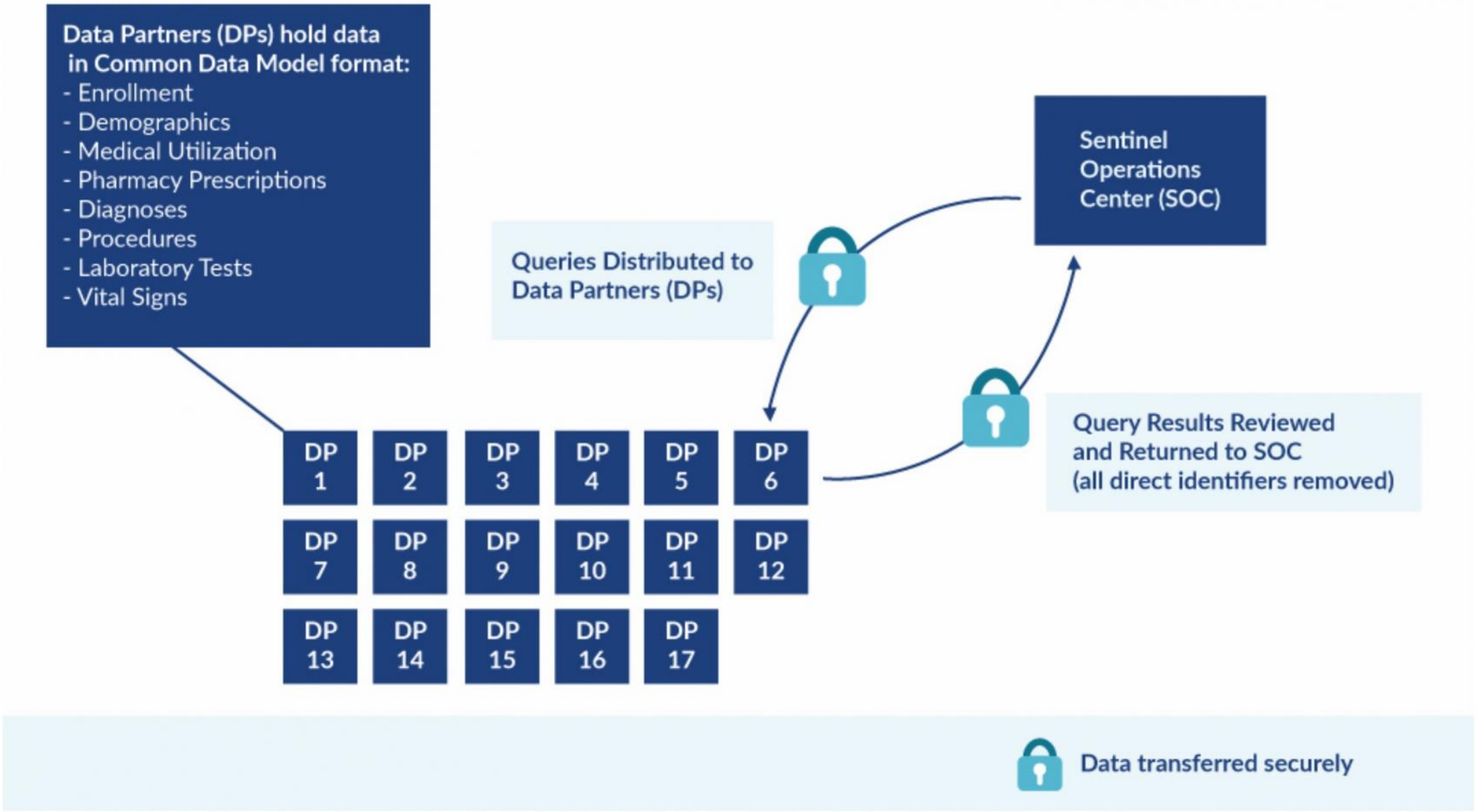
Routine queries and other activities that use pre-existing data

- PRISM
- BloodSCAN
- ARIA

FDA-Catalyst

Routine queries + interventions and interactions with members and/or providers

Sentinel is a Distributed Data Network

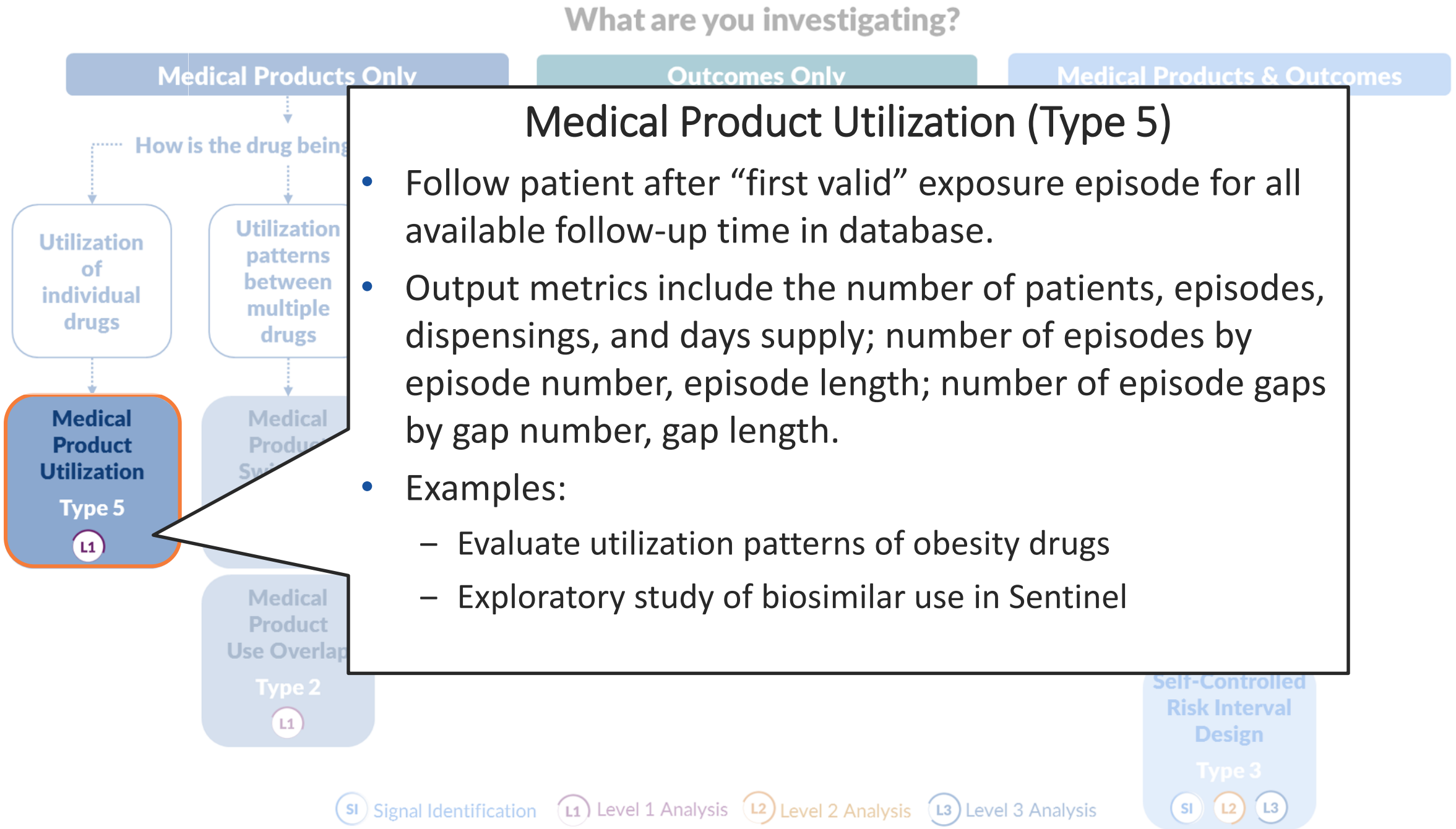


https://www.sentinelinitiative.org/sentinel/sentinels-distributed-database

Active Risk Identification and Analysis (ARIA)

- Template computer programs with standardized questions
- Parameterized at program execution
- Pre-tested and quality-checked
- Standard output

https://www.sentinelinitiative.org/active-risk-identification-and-analysis-aria



Medical Product Utilization (Type 5)

- Follow patient after "first valid" exposure episode for all available follow-up time in database.
- Output metrics include the number of patients, episodes, dispensings, and days supply; number of episodes by episode number, episode length; number of episode gaps by gap number, gap length.
- Examples:
  - Evaluate utilization patterns of obesity drugs
  - Exploratory study of biosimilar use in Sentinel

https://www.sentinelinitiative.org/sentinel/surveillance-tools/routine-querying-tools

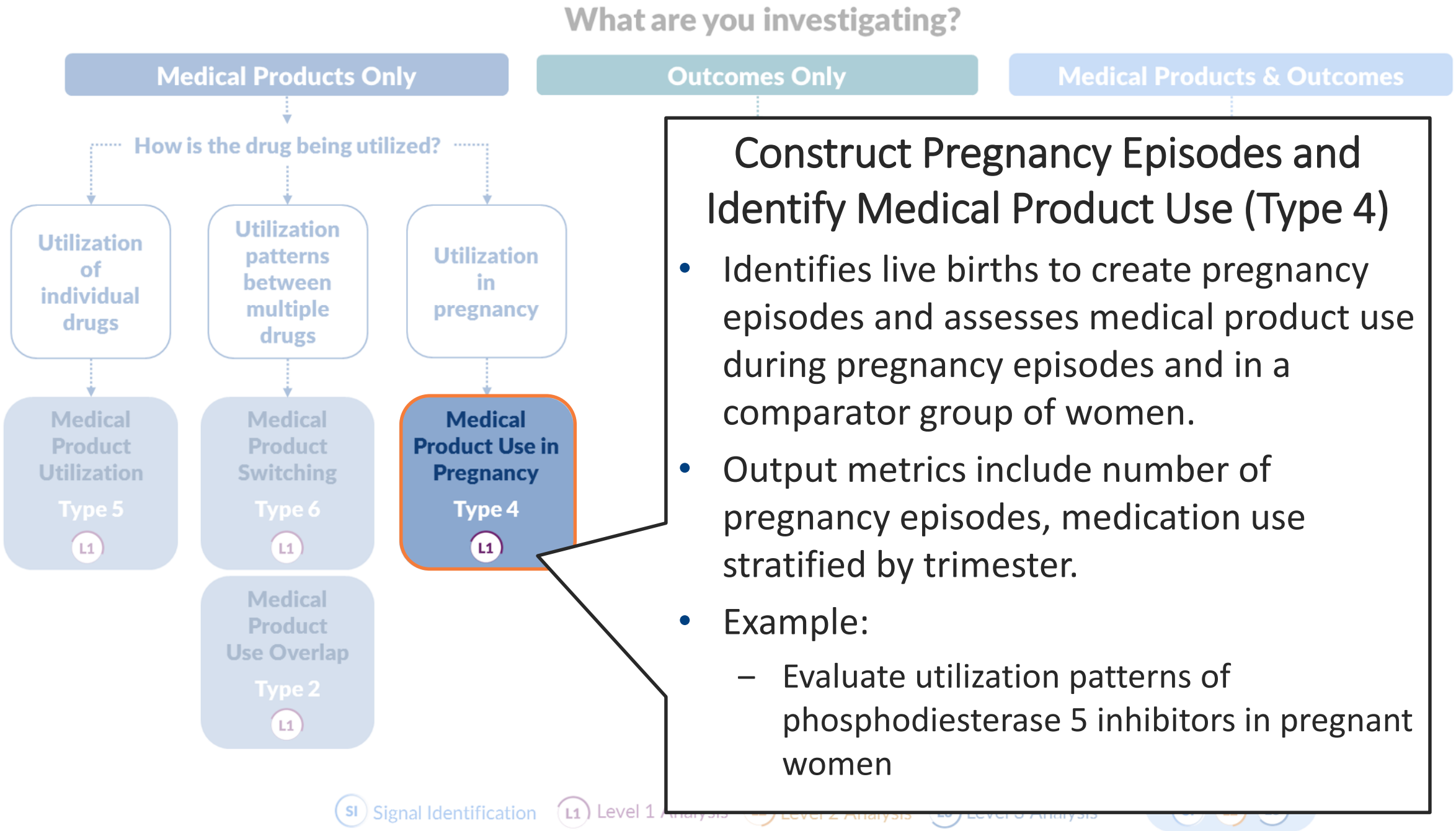
Submit Comment

Utilization Patterns of Obesity Drugs

Project Title	Utilization Patterns of Obesity Drugs
Date Posted	*Tuesday, March 19, 2019*
Project ID	cder_mpl1r_wp129
Status	Complete
Deliverables	Sentinel Modular Program Report: Utilization Patterns of Obesity Drugs, Report 1 Sentinel Modular Program Report: Utilization Patterns of Obesity Drugs, Report 2
Description	This request examines utilization patterns of nine obesity drugs in the Sentinel Distributed Database (SDD) between January 1, 2008 and December 31, 2017. This request was distributed to 17 Data Partners on December 21, 2018.
Medical Product	benzphetamine bupropion/naltrexone diethylpropion liraglutide lorcaserin HCL orlistat phendimetrazine phentermine HCL phentermine/topiramate

SI Signal Identification L1 Level 1 Analysis L2 Level 2 Analysis L3 Level 3 Analysis

https://www.sentinelinitiative.org/drugs/assessments/utilization-patterns-obesity-drugs



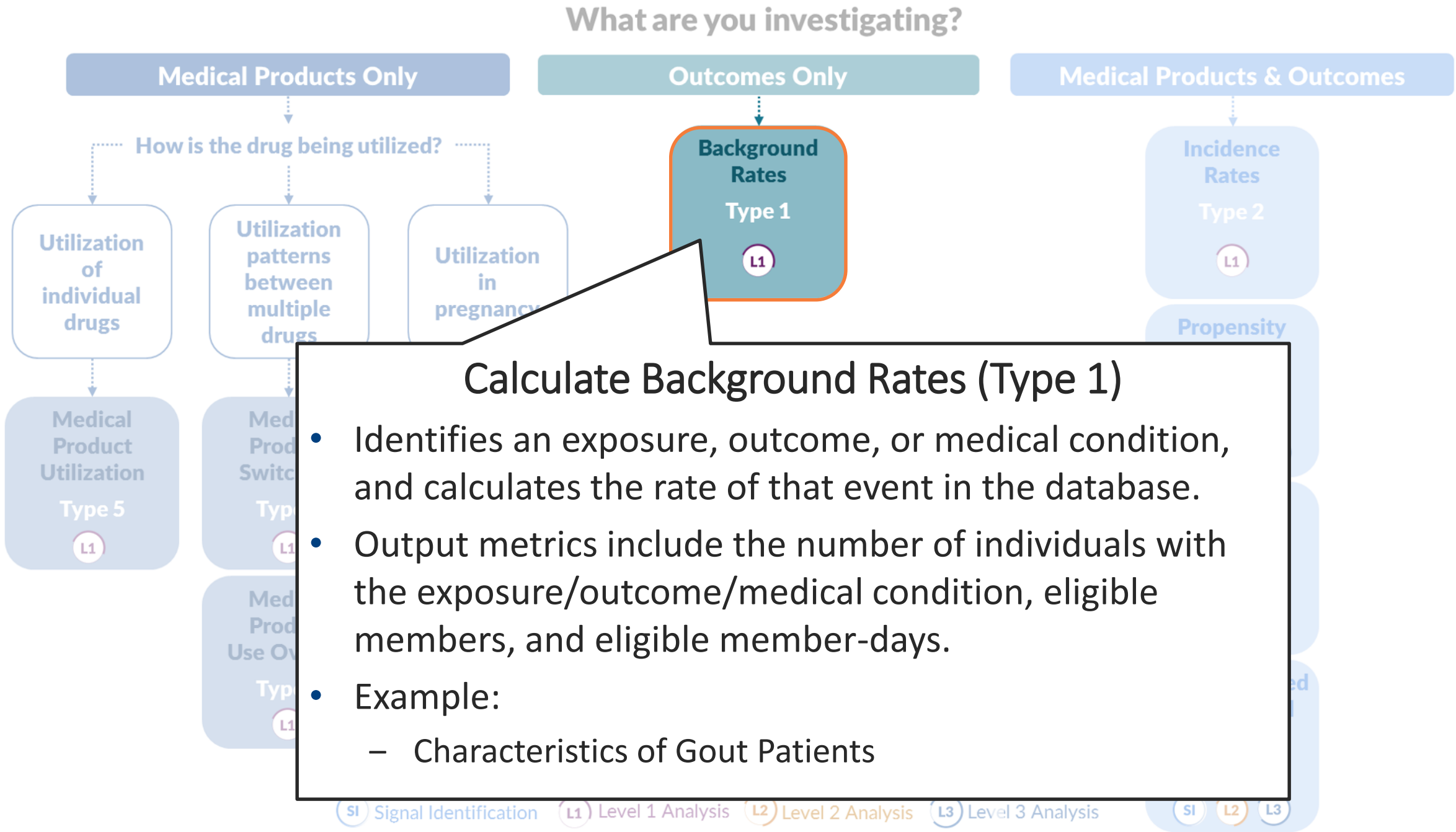
Construct Pregnancy Episodes and Identify Medical Product Use (Type 4)

- Identifies live births to create pregnancy episodes and assesses medical product use during pregnancy episodes and in a comparator group of women.
- Output metrics include number of pregnancy episodes, medication use stratified by trimester.
- Example:
  - Evaluate utilization patterns of phosphodiesterase 5 inhibitors in pregnant women

Submit Comment

Phosphodiesterase Type 5 (PDE5) Inhibitor Utilization Among Women

Project Title	**Phosphodiesterase Type 5 (PDE5) Inhibitor Utilization Among Women**
Date Posted	*Friday, October 12, 2018*
Project ID	cder_mpl1r_wp111-112
Status	Complete
Deliverables	Sentinel Modular Program Report: Phosphodiesterase Type 5 (PDE5) Inhibitor Utilization Among Reproductive-Aged Women, Report 1 Sentinel Modular Program Report: Phosphodiesterase Type 5 (PDE5) Inhibitor Utilization Among Pregnant Women, Report 2
Description	The goal of this query was to estimate phosphodiesterase type 5 (PDE5) inhibitor utilization among women in the Sentinel Distributed Database (SDD). Report 1 contains estimates of phosphodiesterase type 5 (PDE5) inhibitor use among reproductive-aged women. Report 2 contains estimates of PDE5 inhibitor use that occurred during a pregnancy ending in a live-born delivery or within 90 days prior to pregnancy start, among women. Data from January 1, 2001 to March 31, 2018 from 16 Data Partners contributing to the SDD were included in this report. This request was distributed to Data Partners on August 27, 2018.
Medical Product	phosphodiesterase type 5 (PDE5) inhibitor



Calculate Background Rates (Type 1)

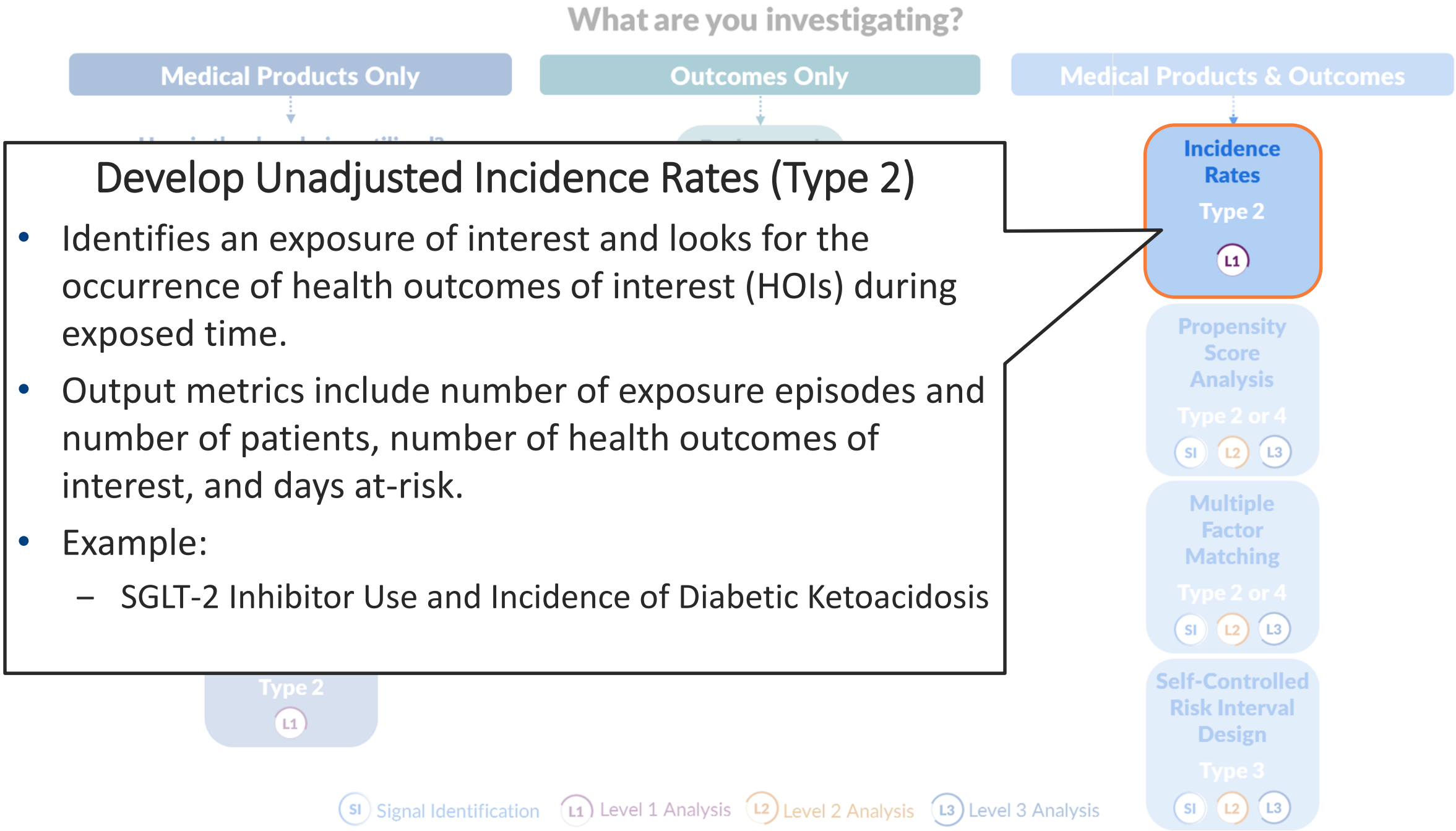
- Identifies an exposure, outcome, or medical condition, and calculates the rate of that event in the database.
- Output metrics include the number of individuals with the exposure/outcome/medical condition, eligible members, and eligible member-days.
- Example:
  - Characteristics of Gout Patients

Submit Comment

Characteristics of Gout Patients and Use of Urate-Lowering Therapies

Project Title	**Characteristics of Gout Patients and Use of Urate-Lowering Therapies**
Date Posted	*Friday, March 22, 2019*
Project ID	cder_mpl1r_wp123, cder_mpl1r_wp126
Status	Complete
Deliverables	Sentinel Modular Program Report: Characteristics of Gout Patients and Use of Urate-Lowering Therapies, Report 1 Sentinel Modular Program Report: Characteristics of Gout Patients and Use of Urate-Lowering Therapies, Report 2 Sentinel Modular Program Report: Characteristics of Gout Patients and Use of Urate-Lowering Therapies, Report 3
Description	The goal of this request was to assess characteristics of gout patients and use of urate lowering therapies (ULT) among individuals in the Sentinel Distributed Database (SDD). This request contains three reports: • Report 1 examines counts of individuals with gout diagnoses, and cardiovascular morbidities and gout severity among those individuals. • Report 2 contains counts of individuals using the ULTs febuxostat and allopurinol, and captures switching between ULT drug products and doses. • Report 3 contains cumulative exposure duration of febuxostat and allopurinol prior to dose or drug switching.

https://www.sentinelinitiative.org/drugs/assessments/characteristics-gout-patients-and-use-urate-lowering-therapies

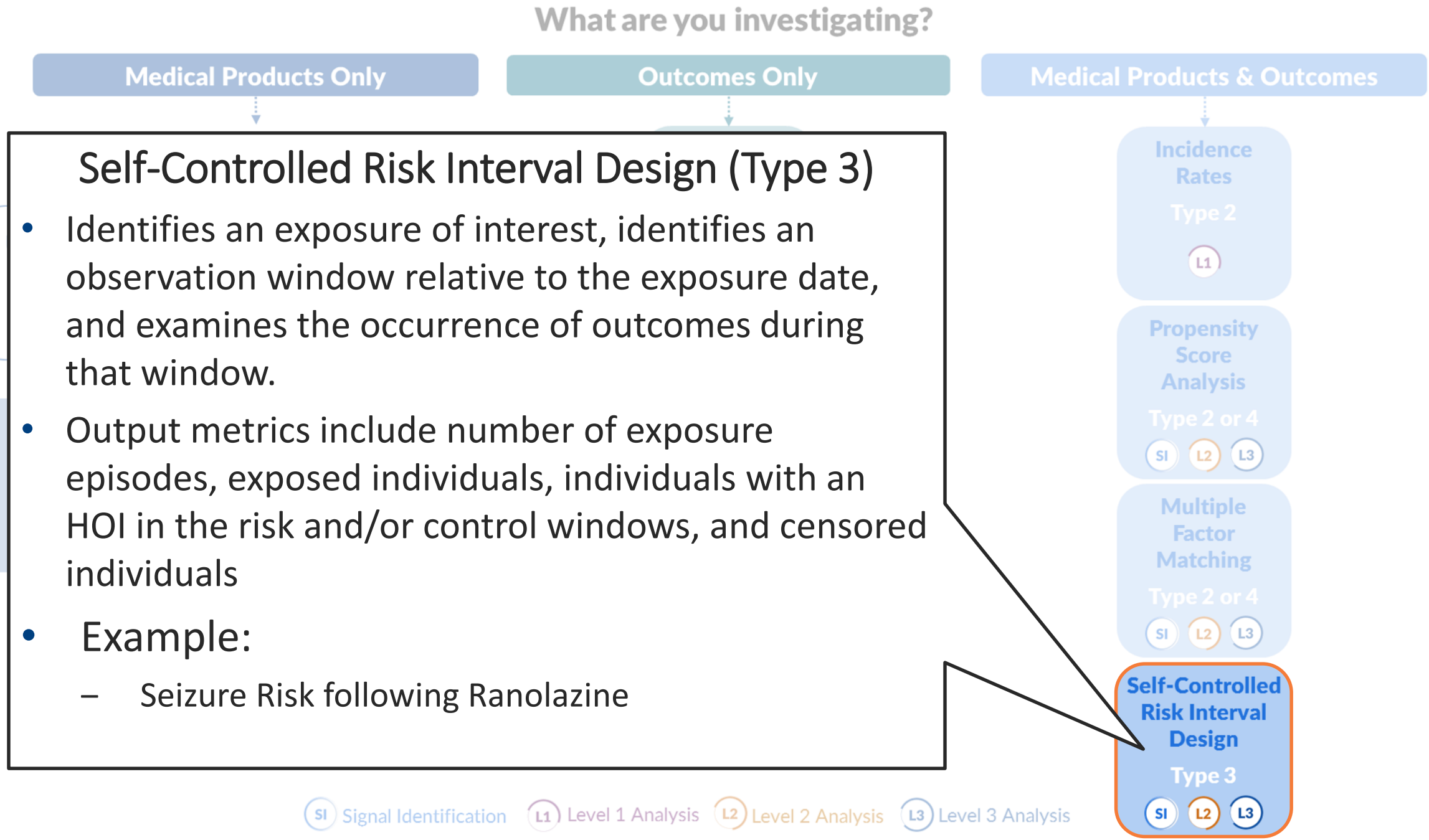

What are you investigating?
Medical Products Only
Outcomes Only
Medical Products & Outcomes
Develop Unadjusted Incidence Rates (Type 2)
• Identifies an exposure of interest and looks for the occurrence of health outcomes of interest (HOIs) during exposed time.
• Output metrics include number of exposure episodes and number of patients, number of health outcomes of interest, and days at-risk.
• Example:
– SGLT-2 Inhibitor Use and Incidence of Diabetic Ketoacidosis
Incidence Rates
Type 2
L1
Propensity Score Analysis
Type 2 or 4
SI L2 L3
Multiple Factor Matching
Type 2 or 4
SI L2 L3
Self-Controlled Risk Interval Design
Type 3
SI L2 L3
Type 2
L1
SI Signal Identification
L1 Level 1 Analysis
L2 Level 2 Analysis
L3 Level 3 Analysis

Submit Comment

SGLT-2 Inhibitor Use and Incidence of Diabetic Ketoacidosis in Patients with Diabetes Mellitus

Project Title	**SGLT-2 Inhibitor Use and Incidence of Diabetic Ketoacidosis in Patients with Diabetes Mellitus**
Date Posted	*Tuesday, March 19, 2019*
Project ID	cder_mpl1p_wp026
Status	Complete
Deliverables	Sentinel Modular Program Report: SGLT-2 Inhibitor Use and Incidence of Diabetic Ketoacidosis in Patients with Diabetes Mellitus
Description	The goal of this request was to estimate rates of diabetic ketoacidosis (DKA) among new users of sodium-glucose cotransporter-2 (SGLT-2) inhibitors canagliflozin, dapagliflozin, empagliflozin, or sitagliptin in the Sentinel Distributed Database (SDD). Data from March 1, 2013 through June 30, 2018 from 17 Data Partners contributing to the SDD were included in this report. This request was distributed to Data Partners on November 28, 2018.
Medical Product	canagliflozin dapagliflozin empagliflozin sitagliptin sodium-glucose cotransporter-2 (SGLT-2) inhibitor
Health Outcome	diabetic ketoacidosis

https://www.sentinelinitiative.org/drugs/assessments/sglt-2-inhibitor-use-and-incidence-diabetic-ketoacidosis-patients-diabetes

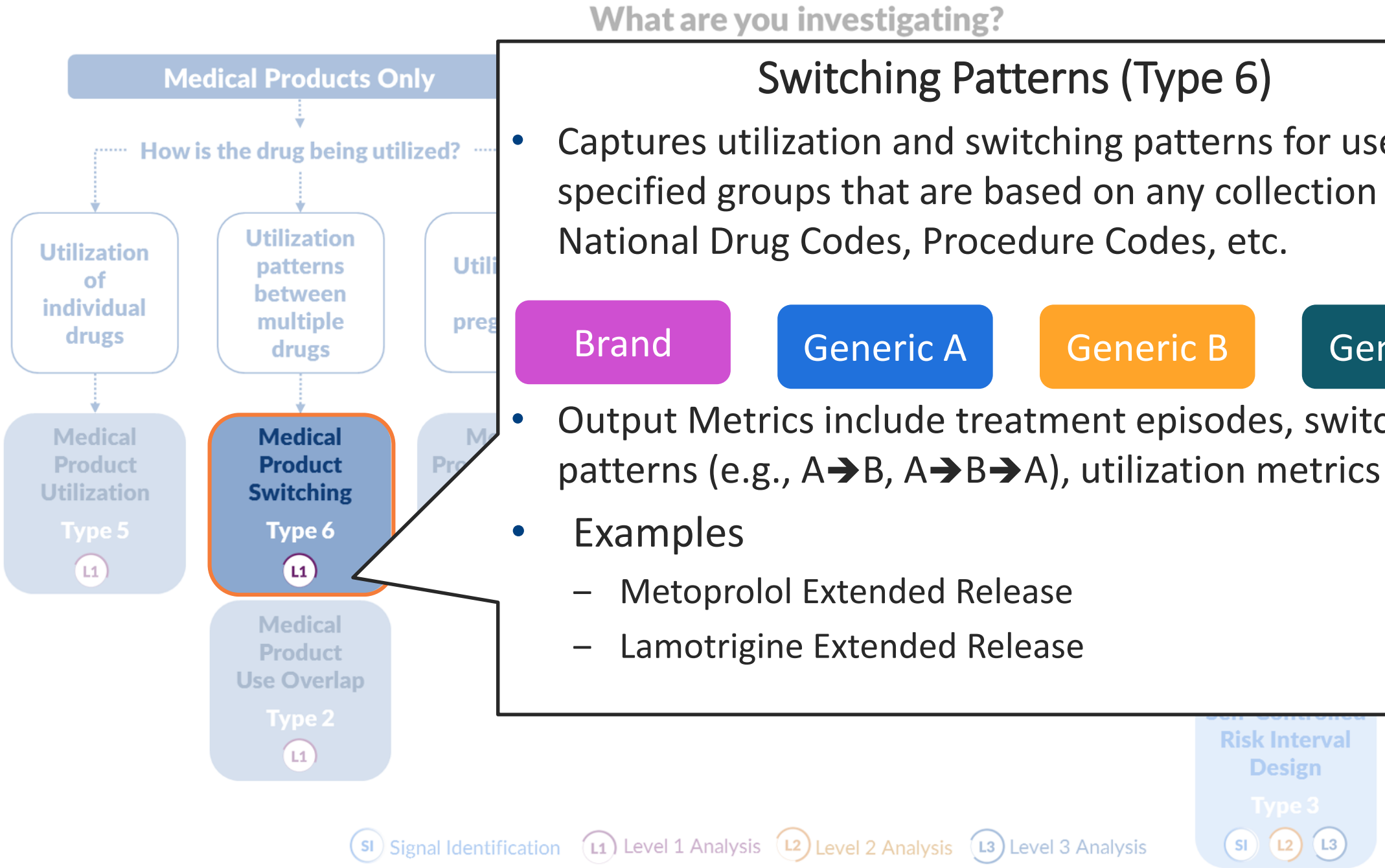

What are you investigating?
Medical Products Only
Outcomes Only
Medical Products & Outcomes
Incidence Rates
Type 2
L1
Propensity Score Analysis
Type 2 or 4
SI L2 L3
Multiple Factor Matching
Type 2 or 4
SI L2 L3
Self-Controlled Risk Interval Design
Type 3
SI L2 L3
Self-Controlled Risk Interval Design (Type 3)
• Identifies an exposure of interest, identifies an observation window relative to the exposure date, and examines the occurrence of outcomes during that window.
• Output metrics include number of exposure episodes, exposed individuals, individuals with an HOI in the risk and/or control windows, and censored individuals
• Example:
– Seizure Risk following Ranolazine
SI Signal Identification
L1 Level 1 Analysis
L2 Level 2 Analysis
L3 Level 3 Analysis

Submit Comment

Seizure following Ranolazine Use

Project Title	Seizure following Ranolazine Use
Date Posted	*Thursday, January 3, 2019*
Status	Complete
Deliverables	Sentinel Modular Program Report: Seizure following Ranolazine Use, Report 1 Sentinel Modular Program Report: Seizure following Ranolazine Use: a Self-Controlled Risk Interval Analysis, Report 2 Sentinel Modular Program Report: Seizure following Ranolazine Use: a Self-Controlled Risk Interval Analysis (an update to cder_mpl2p_wp002), Report 3 Sentinel Analytic Packages: Seizure following Ranolazine Use: a Self-Controlled Risk Interval Analysis
Related Links	Prevalent and Incident Dispensings of Ranolazine 2017 ICPE Symposium: Integrating Sentinel into Routine Regulatory Drug Review: A Snapshot of the First Year Seizure Algorithm Defined in "Seizure following Ranolazine Use: a Self-Controlled Risk Interval Analysis" Use of FDA's Sentinel System to Quantify Seizure Risk Immediately Following New Ranolazine Exposure

http://www.sentinelinitiative.org/drugs/assessments/ranexa-ranolazine-and-seizures



Switching Patterns (Type 6)

- Captures utilization and switching patterns for user-specified groups that are based on any collection of National Drug Codes, Procedure Codes, etc.

Brand | Generic A | Generic B | Generic C

- Output Metrics include treatment episodes, switching patterns (e.g., A➔B, A➔B➔A), utilization metrics
- Examples
  - Metoprolol Extended Release
  - Lamotrigine Extended Release

What are you investigating?

Submit Comment

Evaluation of Switching Patterns in FDA's Sentinel System: A New Tool to Assess Generic Drugs

Project Title	**Evaluation of Switching Patterns in FDA's Sentinel System: A New Tool to Assess Generic Drugs**
Date	*Friday, August 17, 2018*
Location	Drug Saf. 2018 Aug 17. doi: 10.1007/s40264-018-0709-4
Description	The aim of this study was to develop and implement a tool for analyzing manufacturer-level drug utilization and switching patterns within the U.S. Food and Drug Administration's Sentinel System. A descriptive tool was designed to analyze data in the Sentinel Common Data Model and was tested with two case studies, metoprolol extended release (ER) and lamotrigine ER, using claims data from four Sentinel Data Partners. This developed tool was able to elucidate novel utilization and switching patterns in two case studies. Such information can be used to support surveillance of generic drugs and biosimilars.

Type 2

L1

Self-Controlled Risk Interval Design

Type 3

SI L2 L3

SI Signal Identification L1 Level 1 Analysis L2 Level 2 Analysis L3 Level 3 Analysis

https://www.sentinelinitiative.org/communications/publications/evaluation-switching-patterns-fdas-sentinel-system-new-tool-assess

Sentinel's Public Documentation and SAS Program Depot (Public GIT) dev.sentinelsystem.org

Data Quality Review and Characterization Programs

Quality Assurance (QA) Package

Overview

This document describes the program package used to perform quality assurance (QA) review and characterization of data in the Sentinel Common Data Model (SCDM) format. This program package helps to ensure the data meets the necessary standards for data transformation consistency and quality.

Analytic programs that are executed against data that is not in SCDM format will likely yield errors. Successful execution of the QA package indicates that the source data adheres to SCDM rules. Note that data must be in the form of SAS® datasets in order to use these analytic programs.

Folder Structure

- **docs:** is where specifications are saved; specifications provide details about the request parameters and functionality of the QA package
- **dplocal:** is where datasets with patient identifiers are saved. For more information about Sentinel's privacy standards, please refer to **The Sentinel System Principles and Policies.**
- **inputfiles:** is the subfolder containing all input files and lookup tables needed to execute a request. Input files contain information on what tables should be output and the type of analyses conducted on the variables in each table
- **msoc:** is where aggregated program results are saved
- **sasprograms:** contains the file(s) to be executed

Requirements

- UNIX/Linux or Windows environment
- SAS version 9.3 or higher
- SCDM formatted data (Medicare Claims Synthetic Public Use Files are available in the Sentinel Common Data Model Format **here**)

https://dev.sentinelsystem.org/projects/QA/repos/qa_package/browse

Cohort Identification and Descriptive Analysis (CIDA)

SENTINEL ROUTINE QUERYING SYSTEM OVERVIEW

The purpose of this repository is to document version 8.0.3 of the Sentinel Routine Querying System, also known as the Query Request Package (QRP). This system is comprised of cohort identification and analytic modules.

This documentation describes QRP capabilities and provides the information required to build query packages (i.e., input and output specifications) to address questions of interest.

COHORT IDENTIFICATION AND DESCRIPTIVE ANALYSIS (CIDA) MODULE

QRP's Cohort Identification and Descriptive Analysis Module (CIDA) identifies and extracts cohorts of interest from the Sentinel Distributed Database based on requester-defined options (e.g., exposures, outcomes, continuous enrollment requirements, incidence criteria, inclusion/exclusion criteria, relevant age groups, demographics).

CIDA calculates descriptive statistics for the cohort(s) of interest and outputs datasets that may be useful for additional analyses.

CIDA Cohort Identification Strategies

- Type 1: **Extract information to calculate background rates**
- Type 2: **Extract information on exposures and follow-up time**
- Type 3: **Extract information for a self-controlled risk interval design**
- Type 4: **Extract information for medical product use during pregnancy**
- Type 5: **Extract information for medical product utilization**
- Type 6: **Extract information on manufacturer-level product utilization and switching patterns**

https://dev.sentinelsystem.org/projects/SENTINEL/repos/sentinel-routine-querying-tool-documentation/browse

Downloading Sentinel Analytic Packages

Sentinel Analytic Packages

Overview

A Sentinel analytic package is a standard folder structure containing detailed user-defined specifications, input files, SAS® macros, and SAS programs used to conduct Sentinel's routine querying analyses. A package allows the user to select the cohort(s) of interest in order to examine their health profile and outcomes.

Sentinel's analytic request packages are intended to run on data formatted in accordance with the Sentinel Common Data Model (SCDM). Note that data must be in SAS datasets to use these analytic programs.

Analytic Request Packages Available for Download

Request ID	Summary
cder_mpl2p_wp011	Osteoporotic Fractures following Lupron Depot-PED Use: A Multiple Factor Matched Analysis
cder_mpl2p_wp016	Non-Melanoma Skin Cancer following Hydrochlorothiazide Use: A Propensity Score Matched Analysis
cder_mpl2p_wp007	Severe Uterine Bleed following Novel Oral Anticoagulants Use: A Propensity Score Matched Analysis
cder_mpl2r_wp008	Acute Myocardial Infarction and Hospitalized Heart Failure following Saxagliptin or Sitagliptin Use: A Propensity Score Matched Analysis
cder_mpl2p_wp009	Stroke, Gastrointestinal Bleeding, and Intracranial Hemorrhage following Apixaban or Warfarin Use in Patients with Non-Valvular Atrial Fibrillation: A Propensity Score Matched Analysis
cder_mpl2p_wp006	Seizure following Ranolazine Use: A Self-Controlled Risk Interval Analysis (an update to cder_mpl2p_wp002)
cder_mpl2p_wp005	Stroke following Atypical Antipsychotic or Z-Hypnotic Use in Patients with Prior Use of Selective Serotonin Reuptake Inhibitors (SSRIs): A Propensity Score Matched Analysis
cder_mpl2p_wp001	Venous Thromboembolism following Continuous or Extended Cycle Contraceptive Use: A Propensity Score Matched Analysis
cder_mpl2p_wp004	Stroke following Typical or Atypical Antipsychotic Use in non-Elderly Patients: A Propensity Score Matched Analysis
cder_mpl2p_wp002	Seizure following Ranolazine Use: A Self-Controlled Risk Interval Analysis

https://dev.sentinelsystem.org/projects/AP/repos/sentinel-analytic-packages/browse

Questions?

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