An Overview of Sentinel's Publicly Available Analytics Tools

Sentinel Community Building and Outreach Center (CBOC)

Agenda and Learning Objectives

The purpose of this webinar is to provide an understanding of the Sentinel Common Data Model (SCDM), Sentinel's publicly available analytics tools, and how to access these resources from the Sentinel website.

Agenda

Welcome and Introductions

Key Components of SCDM

Routine Querying Tools

Accessing Sentinel's Routine Querying Tools and Common Data Model

Conclusion

Q&A

Objectives

Learn about the key components in the SCDM

Learn about the different types of Sentinel's Routine Querying Tools

Learn how to access Routine Querying Tools and SCDM on the Sentinel Website

Welcome and Introductions

Work with the FDA to assess the risks and benefits of marketed medical products.

Sentinel Operations Center (SOC)

Sentinel Innovation Center (IC)

Identify, develop, and evaluate innovative methods to study drug safety and effectiveness using real-world data.

Sentinel Community Building and Outreach Center (CBOC)

Develop and engage the Sentinel community, expand the Sentinel System's user base and strengthen Sentinel's capability to distribute knowledge based on real world data.

The Sentinel Common Data Model

Key Components of the SCDM
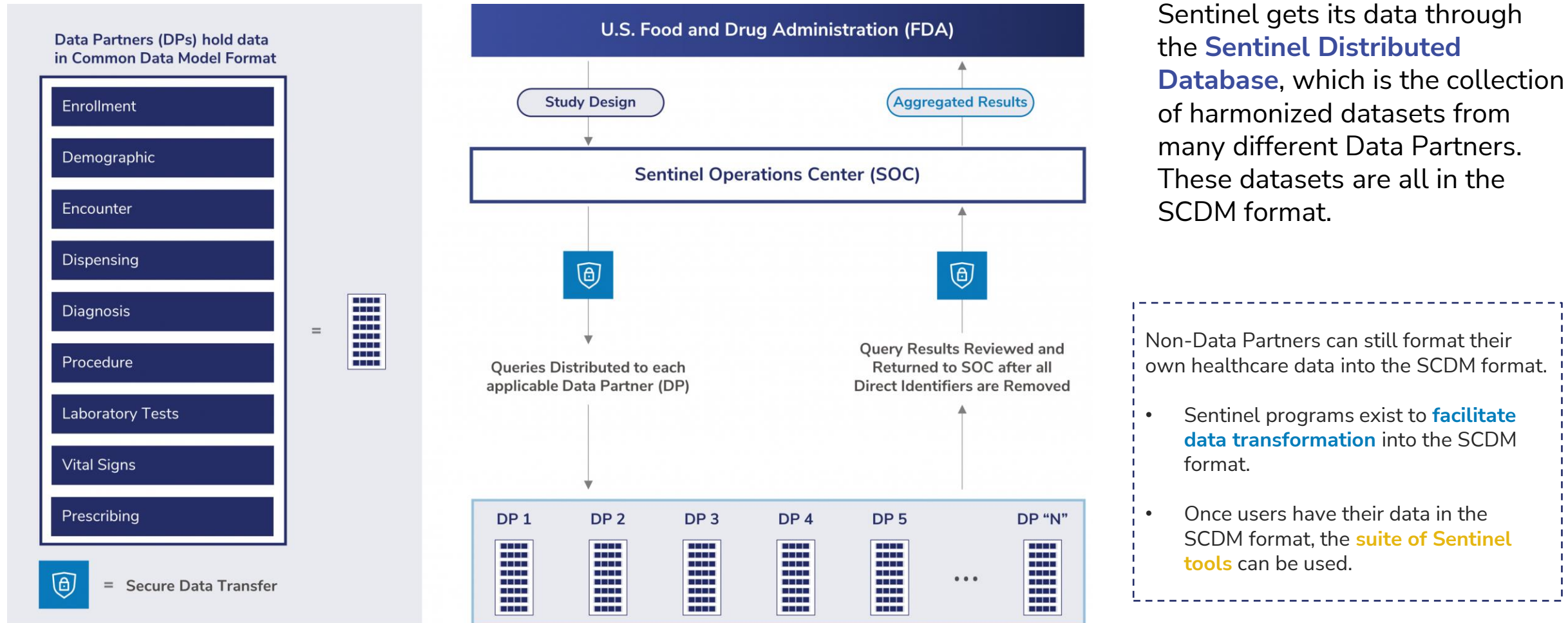
Sentinel's Distributed Data Process

Data Partners (DPs) hold data in Common Data Model Format

- Enrollment
- Demographic
- Encounter
- Dispensing
- Diagnosis
- Procedure
- Laboratory Tests
- Vital Signs
- Prescribing

= Secure Data Transfer

U.S. Food and Drug Administration (FDA)

Study Design

Aggregated Results

Sentinel Operations Center (SOC)

Queries Distributed to each applicable Data Partner (DP)

Query Results Reviewed and Returned to SOC after all Direct Identifiers are Removed

DP 1 DP 2 DP 3 DP 4 DP 5 DP "N"

Sentinel gets its data through the **Sentinel Distributed Database**, which is the collection of harmonized datasets from many different Data Partners. These datasets are all in the SCDM format.

Non-Data Partners can still format their own healthcare data into the SCDM format.

- Sentinel programs exist to **facilitate data transformation** into the SCDM format.

- Once users have their data in the SCDM format, the **suite of Sentinel tools** can be used.

https://www.sentinelinitiative.org/methods-data-tools
https://www.fda.gov/media/120333/download
https://www.sentinelinitiative.org/about/how-sentinel-gets-its-data

SCDM Data Tables Overview

The SCDM incorporates healthcare data that are organized across **multiple domains**.
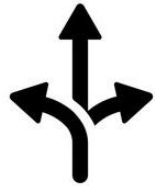
The SCDM is **flexible** enough to accommodate new data domains, expanding as needed for specific purposes.
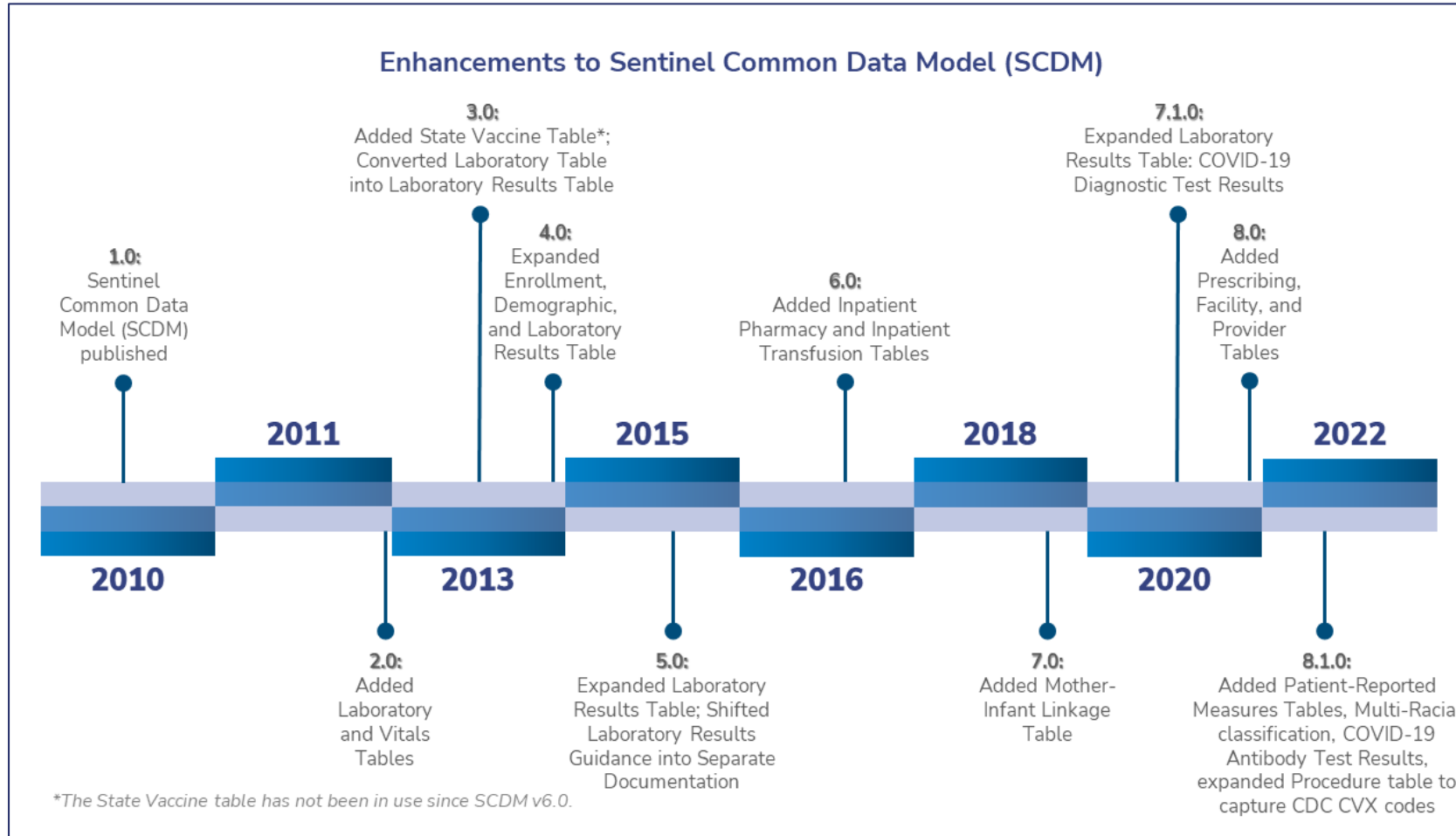
Sentinel Common Data Model

Administrative Data

Enrollment	Demographic	Dispensing	Encounter	Diagnosis	Procedure	Prescribing
Patient ID	Patient ID	Patient ID	Patient ID	Patient ID	Patient ID	Patient ID
Enrollment Start & End Dates	Birth Date	Provider ID	Encounter ID & Type	Encounter ID & Type	Encounter ID & Type	Encounter ID
Medical Coverage	Sex	Dispensing Date	Service Date(s)	Provider ID	Provider ID	Provider ID
Drug Coverage	Postal Code	Rx	Facility ID	Service Date(s)	Service Date(s)	Order Date
Medical Record Availability	Race	Rx Code Type	Etc.	Diagnosis Code & Type	Procedure Code & Type	Rx
	Etc.	Days Supply		Principal Discharge Diagnosis	Etc.	Days Supply
		Amount Dispensed				Rx Route of Delivery
						Etc.

Mother-Infant Linkage Data

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

Auxiliary Data

Facility	Provider
Facility ID	Provider ID
Facility Location	Provider Specialty & Specialty Code Type

Registry Data

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

Inpatient Data

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

Patient-Reported Measures (PRM) Data

PRM Survey	PRM Survey Response
Measure ID	Patient ID
Survey ID	Encounter ID
Question ID	Measure ID
Etc.	Survey ID
	Question ID
	Response Text
	Etc.

The State Vaccine table has not been in use since SCDM v6.0.

Enhancements to the SCDM

Enhancements to Sentinel Common Data Model (SCDM)

1.0:
Sentinel Common Data Model (SCDM) published

2.0:
Added Laboratory and Vitals Tables

3.0:
Added State Vaccine Table*; Converted Laboratory Table into Laboratory Results Table

4.0:
Expanded Enrollment, Demographic, and Laboratory Results Table

5.0:
Expanded Laboratory Results Table; Shifted Laboratory Results Guidance into Separate Documentation

6.0:
Added Inpatient Pharmacy and Inpatient Transfusion Tables

7.0:
Added Mother-Infant Linkage Table

7.1.0:
Expanded Laboratory Results Table: COVID-19 Diagnostic Test Results

8.0:
Added Prescribing, Facility, and Provider Tables

8.1.0:
Added Patient-Reported Measures Tables, Multi-Racial classification, COVID-19 Antibody Test Results, expanded Procedure table to capture CDC CVX codes

*The State Vaccine table has not been in use since SCDM v6.0.

2010   2011   2013   2015   2016   2018   2020   2022

The SCDM was first published in 2010. Since then, updates have been implemented on a roughly annual basis.

The SCDM is **continuously evolving** to respond to changes in regulatory science and public health surveillance.

Sentinel's Routine Querying Tools

Routine Querying Tool Categories

The Sentinel System's routine querying tools fall into four categories:

SI Signal Identification Analyses

L1 Level 1 Analyses

L2 Level 2 Analyses

L3 Level 3 Analyses

Signal Identification	Level 1	Level 2	Level 3
Detection of New and Unsuspected Potential Safety Concerns	Descriptive Analyses, Unadjusted Rates	Adjusted Analyses with Sophisticated Confounding Control	Sequential Adjusted Analyses with Sophisticated Confounding Control
	Sentinel Query Builder		

Routine Querying Tool Types

Which Sentinel routine querying tool to use depends on the topic being investigated. These programs serve as templates that get populated based on the particular question(s) being posed.

What are you investigating?

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

Medical Products Only

How is the drug being utilized?

- Utilization of Individual Drugs → **Type 5** (L1) Medical Product Utilization
- Utilization Patterns Between Multiple Drugs →
  - **Type 6** (L1) Medical Product Switching
  - **Type 2** (L1) Medical Product Use Overlap
- Utilization in Pregnancy → **Type 4** (L1) Medical Product Use in Pregnancy

Outcomes Only → **Type 1** (L1) Background Rates

Medical Products & Outcomes

| Type 2 (L1) Incidence Rates | Type 2 or 4 (SI) (L2) (L3) Propensity Score Analysis | Type 2 or 4 (L2) (L3) Covariate Stratification | Type 3 (SI) (L2) (L3) Self-Controlled Risk Interval Design | Type 2 (L2) Interrupted Time Series | Type 2 (L1) Multiple Events Tool |

Routine Querying Tool Types

Which Sentinel routine querying tool to use depends on the topic being investigated. These programs serve as templates that get populated based on the particular question(s) being posed.

What are you investigating?

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

Medical Products Only

How is the drug being utilized?

- Utilization of Individual Drugs → **Type 5** (L1) — Medical Product Utilization
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  - **Type 2** (L1) — Medical Product Use Overlap
- Utilization in Pregnancy → **Type 4** (L1) — Medical Product Use in Pregnancy

Outcomes Only → **Type 1** (L1) — Background Rates

Medical Products & Outcomes

Type 2 (L1)	Type 2 or 4 (SI)(L2)(L3)	Type 2 or 4 (L2)(L3)	Type 3 (SI)(L2)(L3)	Type 2 (L2)	Type 2 (L1)
Incidence Rates	Propensity Score Analysis	Covariate Stratification	Self-Controlled Risk Interval Design	Interrupted Time Series	Multiple Events Tool

https://www.sentinelinitiative.org/methods-data-tools/routine-querying-tools
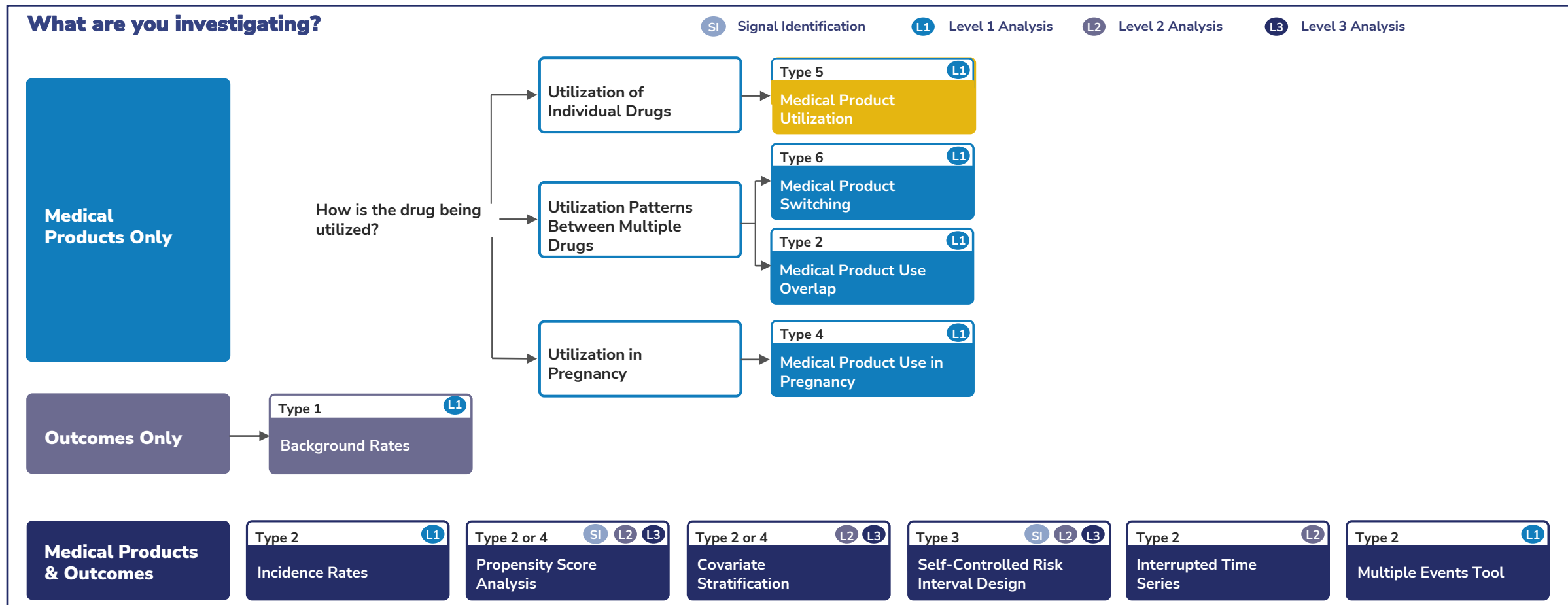
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What are you investigating?

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

Medical Products Only

How is the drug being utilized?

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  - **Type 2** L1 — Medical Product Use Overlap
- Utilization in Pregnancy → **Type 4** L1 — Medical Product Use in Pregnancy

Outcomes Only → **Type 1** L1 — Background Rates

Medical Products & Outcomes

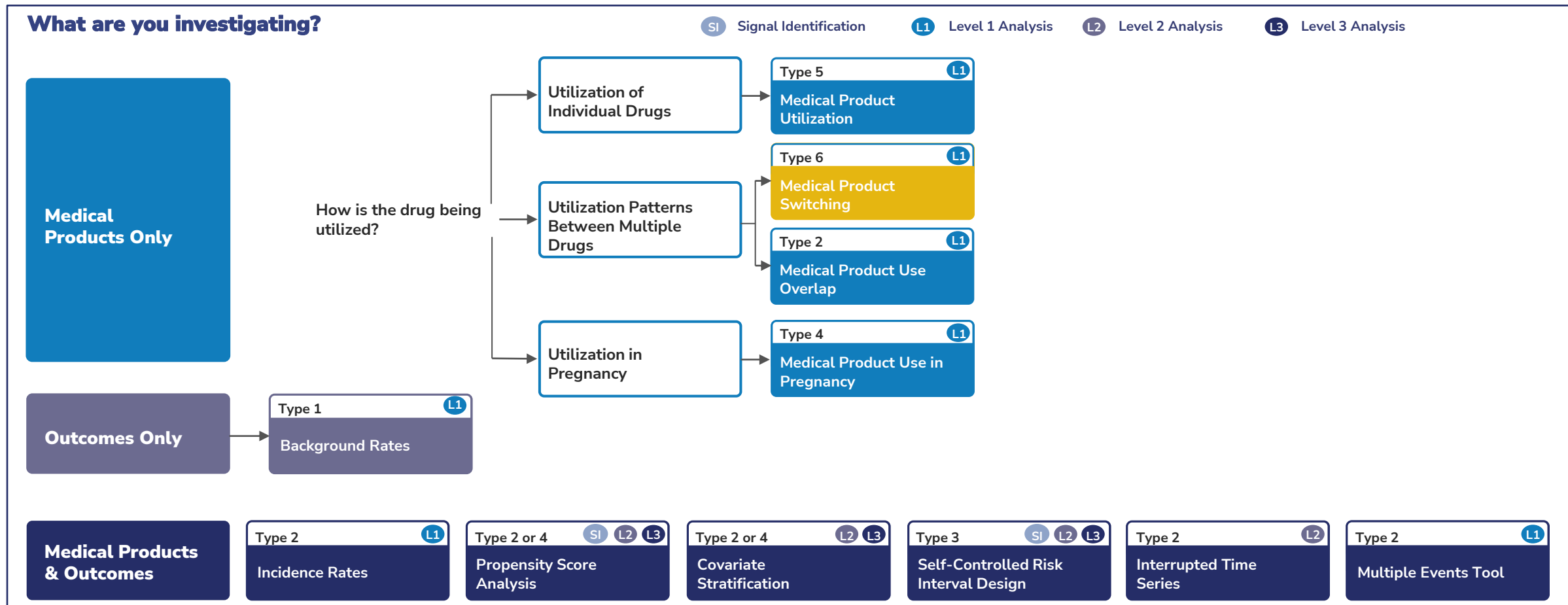| Type 2 | L1 | Incidence Rates |
Type 2 or 4	SI L2 L3	Propensity Score Analysis
Type 2 or 4	L2 L3	Covariate Stratification
Type 3	SI L2 L3	Self-Controlled Risk Interval Design
Type 2	L2	Interrupted Time Series
Type 2	L1	Multiple Events Tool

Routine Querying Tool Types

Which Sentinel routine querying tool to use depends on the topic being investigated. These programs serve as templates that get populated based on the particular question(s) being posed.

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  - **Type 2** L1 — Medical Product Use Overlap
- Utilization in Pregnancy → **Type 4** L1 — Medical Product Use in Pregnancy

Outcomes Only → **Type 1** L1 — Background Rates

Medical Products & Outcomes

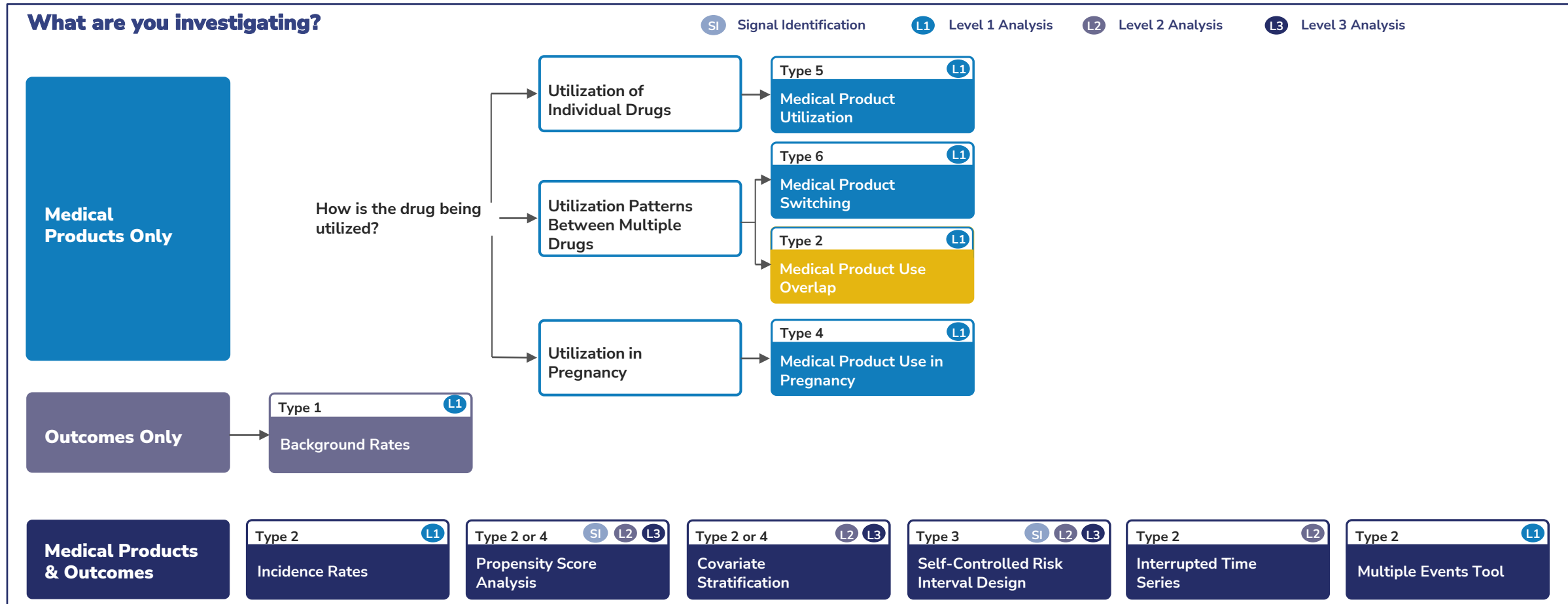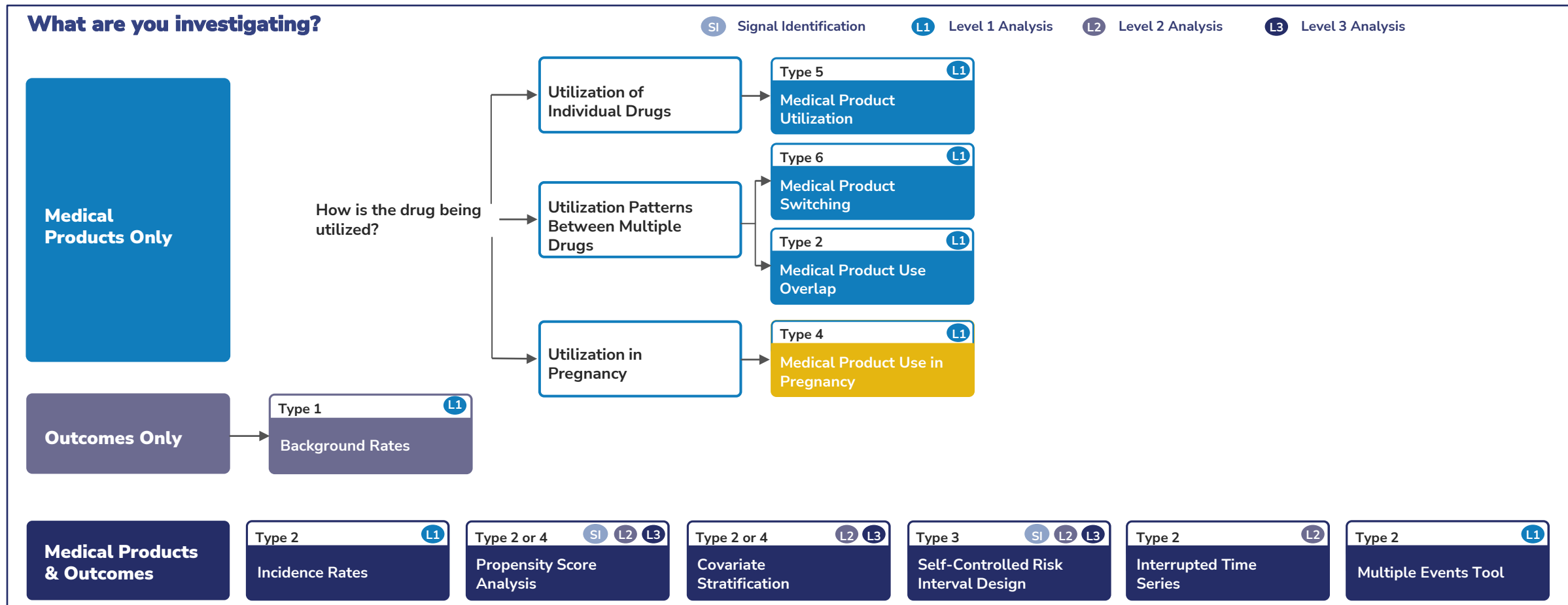| Type 2 | L1 | Incidence Rates |
Type 2 or 4	SI L2 L3	Propensity Score Analysis
Type 2 or 4	L2 L3	Covariate Stratification
Type 3	SI L2 L3	Self-Controlled Risk Interval Design
Type 2	L2	Interrupted Time Series
Type 2	L1	Multiple Events Tool

Routine Querying Tool Types

Which Sentinel routine querying tool to use depends on the topic being investigated. These programs serve as templates that get populated based on the particular question(s) being posed.

What are you investigating?

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

Medical Products Only

How is the drug being utilized?

- Utilization of Individual Drugs
  - **Type 5** **L1** — Medical Product Utilization
- Utilization Patterns Between Multiple Drugs
  - **Type 6** **L1** — Medical Product Switching
  - **Type 2** **L1** — Medical Product Use Overlap
- Utilization in Pregnancy
  - **Type 4** **L1** — Medical Product Use in Pregnancy

Outcomes Only
- **Type 1** **L1** — Background Rates

Medical Products & Outcomes

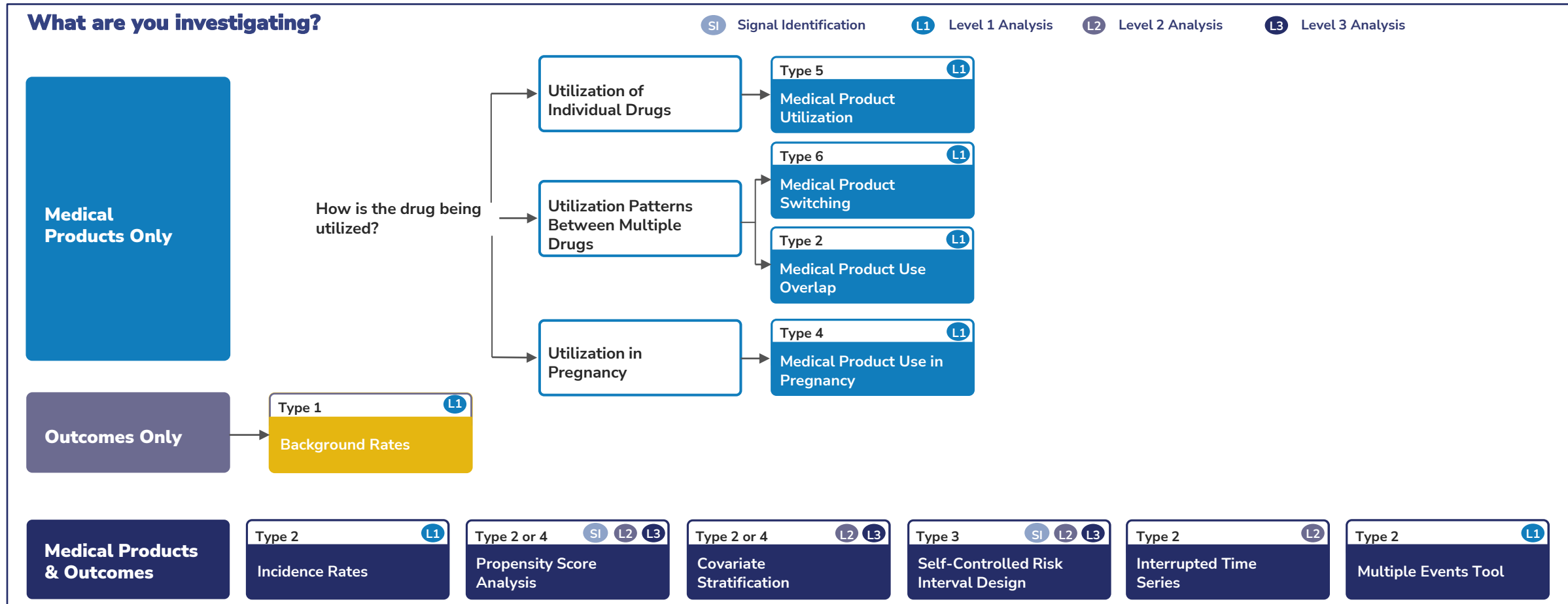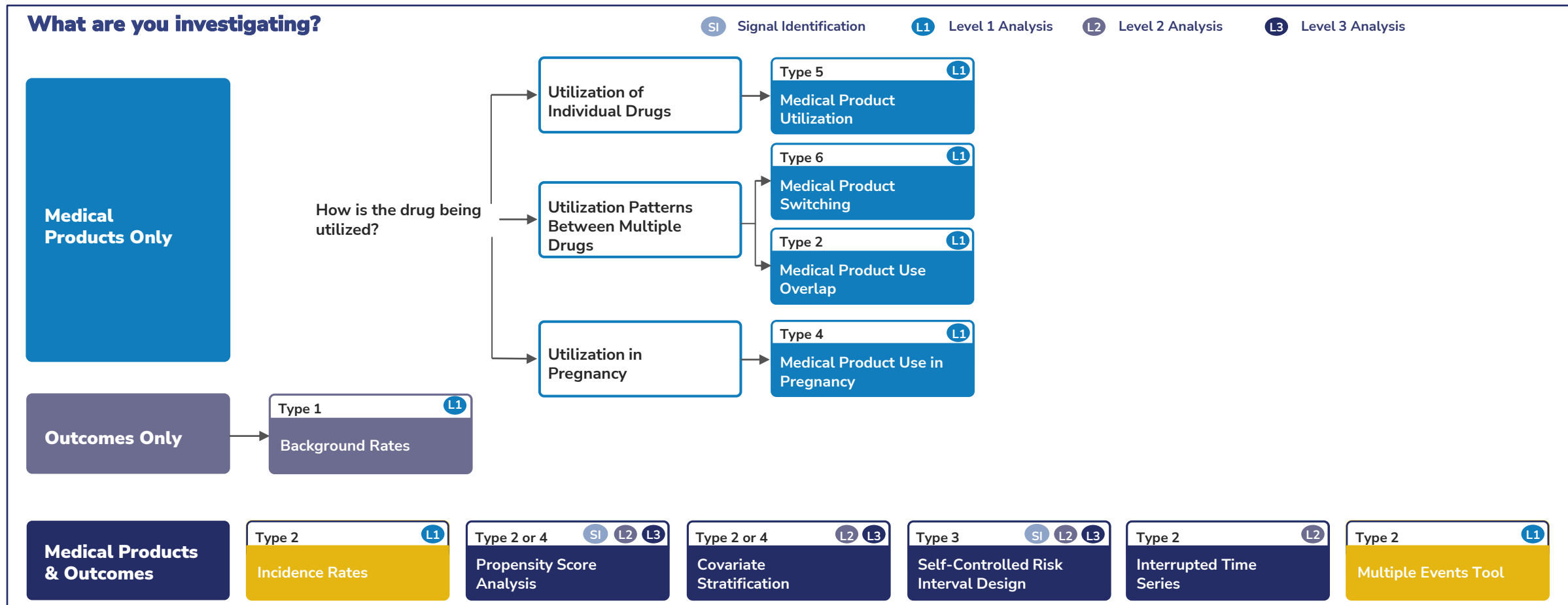| Type 2 **L1**	Type 2 or 4 **SI** **L2** **L3**	Type 2 or 4 **L2** **L3**	Type 3 **SI** **L2** **L3**	Type 2 **L2**	Type 2 **L1**
Incidence Rates	Propensity Score Analysis	Covariate Stratification	Self-Controlled Risk Interval Design	Interrupted Time Series	Multiple Events Tool

Routine Querying Tool Types

Which Sentinel routine querying tool to use depends on the topic being investigated. These programs serve as templates that get populated based on the particular question(s) being posed.

What are you investigating?

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

Medical Products Only

How is the drug being utilized?

Utilization of Individual Drugs → **Type 5** L1 — Medical Product Utilization

Utilization Patterns Between Multiple Drugs → **Type 6** L1 — Medical Product Switching

Type 2 L1 — Medical Product Use Overlap

Utilization in Pregnancy → **Type 4** L1 — Medical Product Use in Pregnancy

Outcomes Only → **Type 1** L1 — Background Rates

Medical Products & Outcomes

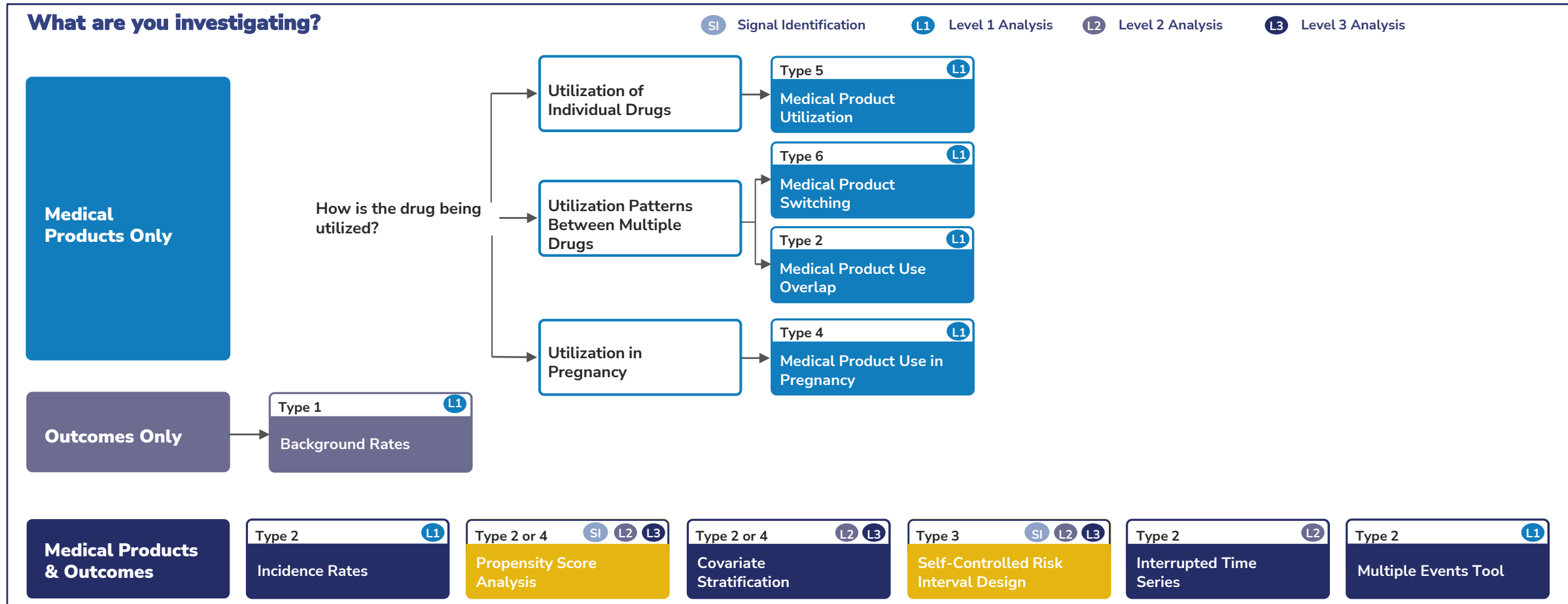| Type 2 L1	Type 2 or 4 SI L2 L3	Type 2 or 4 L2 L3	Type 3 SI L2 L3	Type 2 L2	Type 2 L1
Incidence Rates	Propensity Score Analysis	Covariate Stratification	Self-Controlled Risk Interval Design	Interrupted Time Series	Multiple Events Tool

Routine Querying Tool Types

Which Sentinel routine querying tool to use depends on the topic being investigated. These programs serve as templates that get populated based on the particular question(s) being posed.

What are you investigating?

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

Medical Products Only

How is the drug being utilized?
- Utilization of Individual Drugs → Type 5 (L1) Medical Product Utilization
- Utilization Patterns Between Multiple Drugs → Type 6 (L1) Medical Product Switching; Type 2 (L1) Medical Product Use Overlap
- Utilization in Pregnancy → Type 4 (L1) Medical Product Use in Pregnancy

Outcomes Only
- Type 1 (L1) Background Rates

Medical Products & Outcomes
- Type 2 (L1) Incidence Rates
- Type 2 or 4 (SI L2 L3) Propensity Score Analysis
- Type 2 or 4 (L2 L3) Covariate Stratification
- Type 3 (SI L2 L3) Self-Controlled Risk Interval Design
- Type 2 (L2) Interrupted Time Series
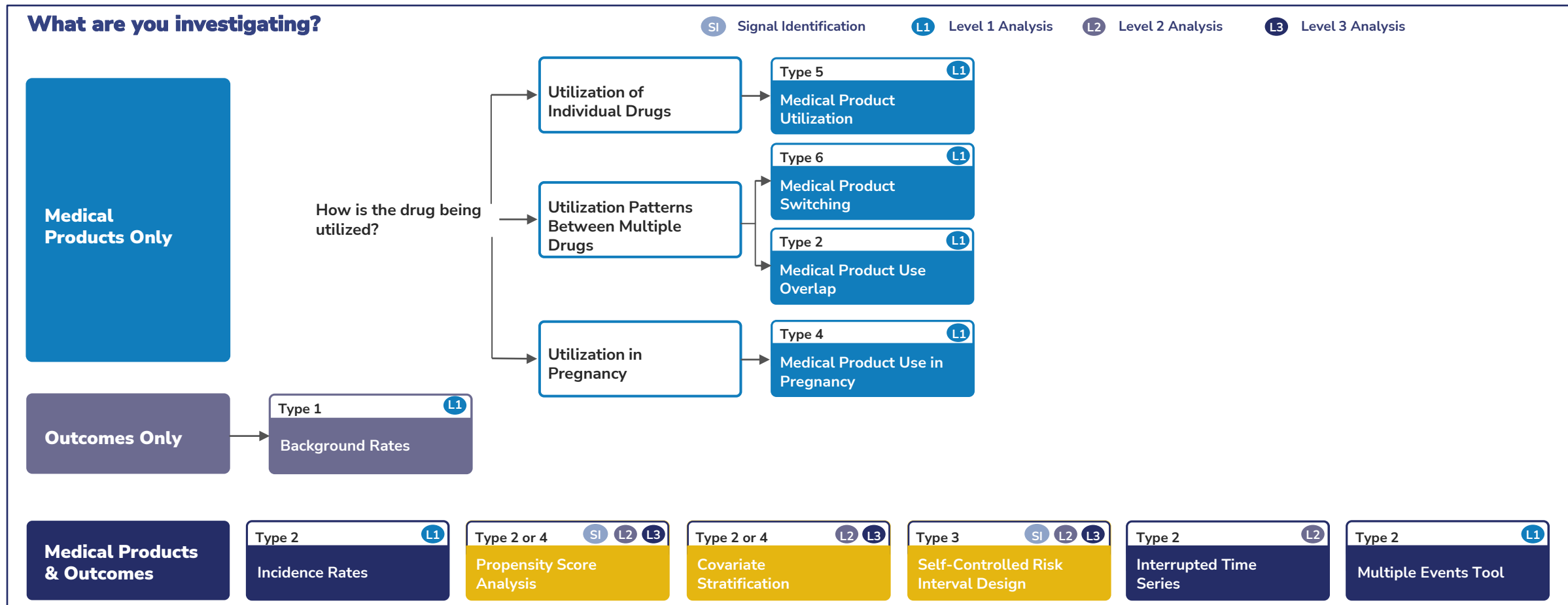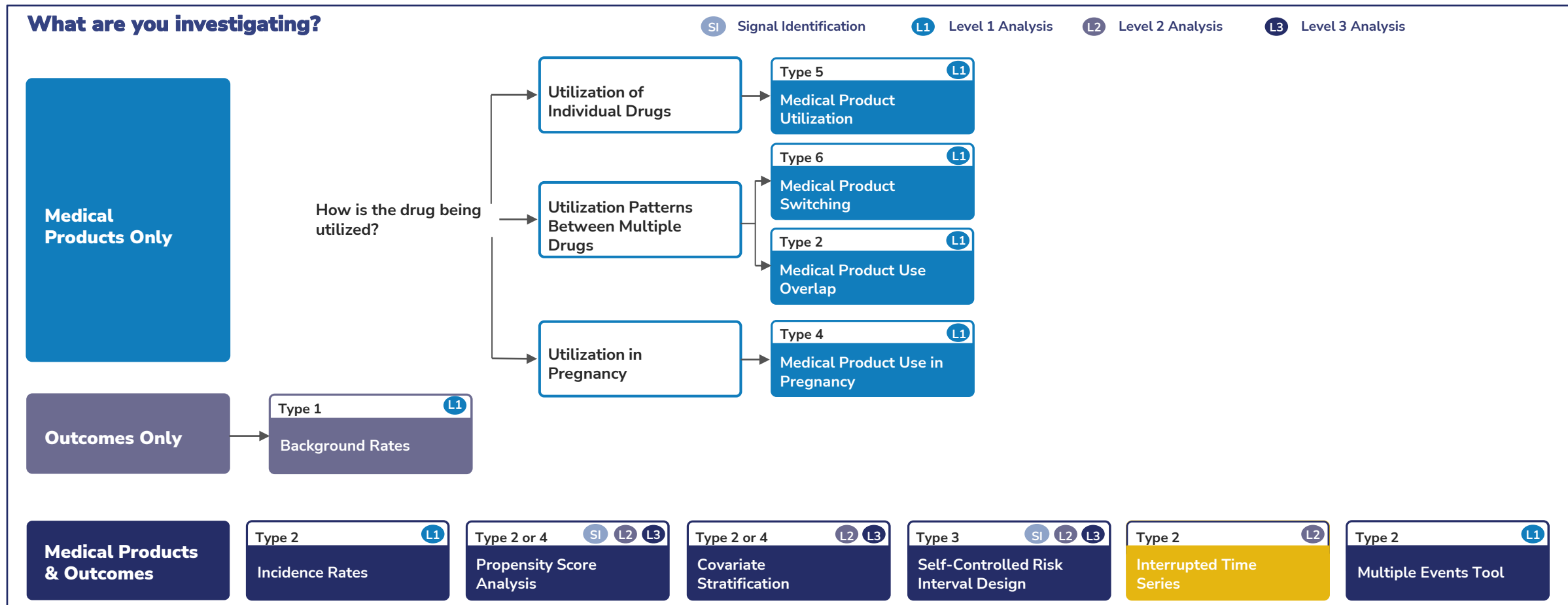- Type 2 (L1) Multiple Events Tool

Routine Querying Tool Types

Which Sentinel routine querying tool to use depends on the topic being investigated. These programs serve as templates that get populated based on the particular question(s) being posed.

What are you investigating?

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

Medical Products Only

How is the drug being utilized?

- **Utilization of Individual Drugs** → **Type 5** L1 — Medical Product Utilization

- **Utilization Patterns Between Multiple Drugs** →
  - **Type 6** L1 — Medical Product Switching
  - **Type 2** L1 — Medical Product Use Overlap

- **Utilization in Pregnancy** → **Type 4** L1 — Medical Product Use in Pregnancy

Outcomes Only → **Type 1** L1 — Background Rates

Medical Products & Outcomes

| Type 2 | L1 | Incidence Rates |
Type 2 or 4	SI L2 L3	Propensity Score Analysis
Type 2 or 4	L2 L3	Covariate Stratification
Type 3	SI L2 L3	Self-Controlled Risk Interval Design
Type 2	L2	Interrupted Time Series
Type 2	L1	Multiple Events Tool

Routine Querying Tool Types

Which Sentinel routine querying tool to use depends on the topic being investigated. These programs serve as templates that get populated based on the particular question(s) being posed.

What are you investigating?

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

Medical Products Only

How is the drug being utilized?

- Utilization of Individual Drugs → **Type 5** L1 — Medical Product Utilization
- Utilization Patterns Between Multiple Drugs →
  - **Type 6** L1 — Medical Product Switching
  - **Type 2** L1 — Medical Product Use Overlap
- Utilization in Pregnancy → **Type 4** L1 — Medical Product Use in Pregnancy

Outcomes Only → **Type 1** L1 — Background Rates

Medical Products & Outcomes

| Type 2 L1 — Incidence Rates | Type 2 or 4 SI L2 L3 — Propensity Score Analysis | Type 2 or 4 L2 L3 — Covariate Stratification | Type 3 SI L2 L3 — Self-Controlled Risk Interval Design | Type 2 L2 — Interrupted Time Series | Type 2 L1 — Multiple Events Tool |

Routine Querying Tool Types

Which Sentinel routine querying tool to use depends on the topic being investigated. These programs serve as templates that get populated based on the particular question(s) being posed.
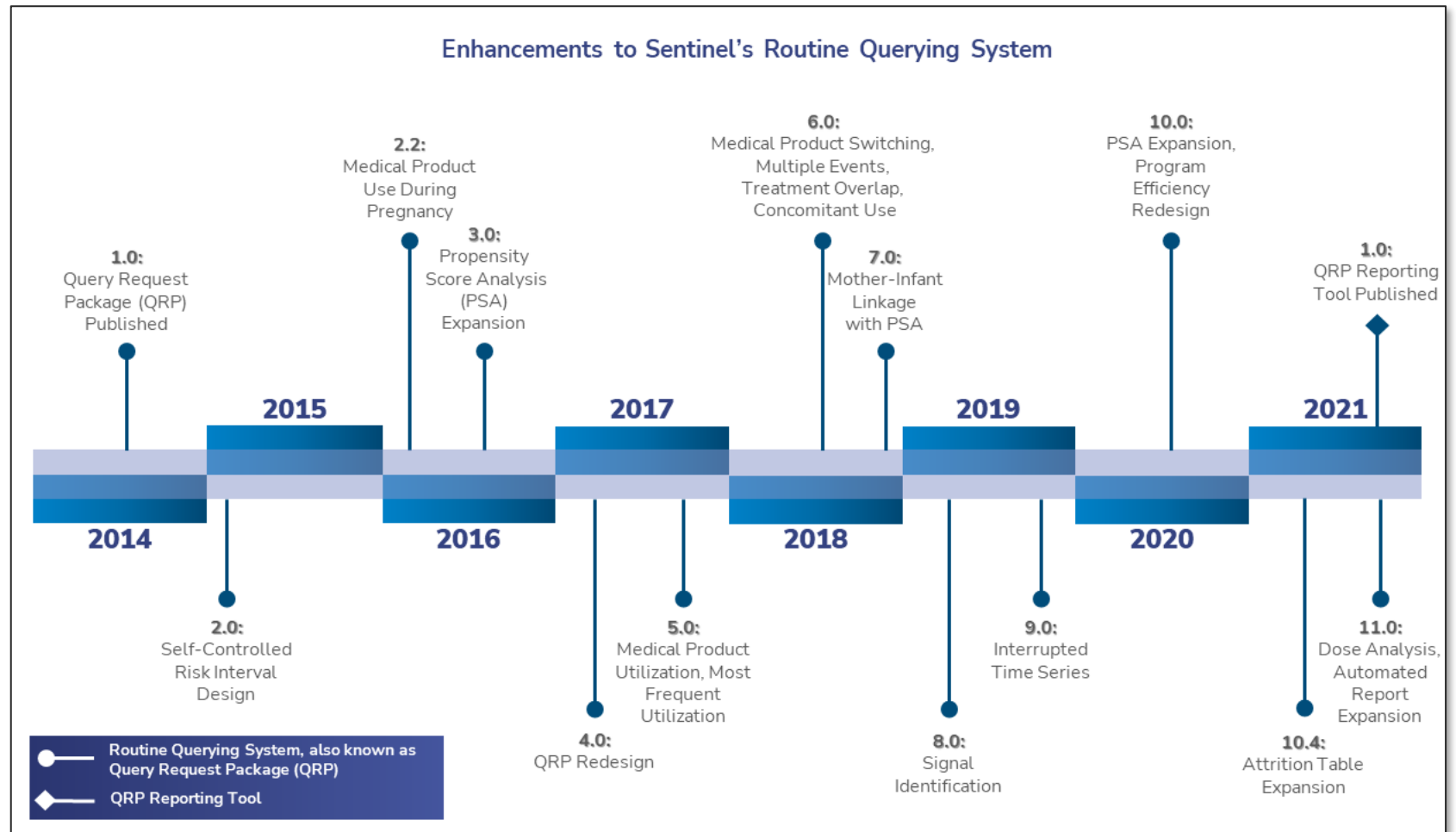

What are you investigating?

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

Medical Products Only

How is the drug being utilized?

- Utilization of Individual Drugs → **Type 5** (L1) Medical Product Utilization
- Utilization Patterns Between Multiple Drugs → **Type 6** (L1) Medical Product Switching / **Type 2** (L1) Medical Product Use Overlap
- Utilization in Pregnancy → **Type 4** (L1) Medical Product Use in Pregnancy

Outcomes Only → **Type 1** (L1) Background Rates

Medical Products & Outcomes
- **Type 2** (L1) Incidence Rates
- **Type 2 or 4** (SI L2 L3) Propensity Score Analysis
- **Type 2 or 4** (L2 L3) Covariate Stratification
- **Type 3** (SI L2 L3) Self-Controlled Risk Interval Design
- **Type 2** (L2) Interrupted Time Series
- **Type 2** (L1) Multiple Events Tool

Enhancements to the Sentinel's Routine Querying System

Sentinel regularly releases enhancements to its routine querying system.
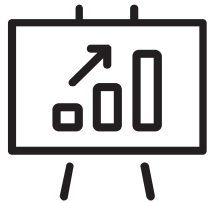
These enhancements **expand**, **improve**, and **refine** analytics and methodological capabilities. Sentinel hosts annual Training Days which highlight these new capabilities to the public.

Enhancements to Sentinel's Routine Querying System

1.0: Query Request Package (QRP) Published

2.0: Self-Controlled Risk Interval Design

2.2: Medical Product Use During Pregnancy

3.0: Propensity Score Analysis (PSA) Expansion

4.0: QRP Redesign

5.0: Medical Product Utilization, Most Frequent Utilization

6.0: Medical Product Switching, Multiple Events, Treatment Overlap, Concomitant Use

7.0: Mother-Infant Linkage with PSA

8.0: Signal Identification

9.0: Interrupted Time Series

10.0: PSA Expansion, Program Efficiency Redesign

10.4: Attrition Table Expansion

11.0: Dose Analysis, Automated Report Expansion

1.0: QRP Reporting Tool Published

2014 — 2015 — 2016 — 2017 — 2018 — 2019 — 2020 — 2021

● Routine Querying System, also known as Query Request Package (QRP)
◆ QRP Reporting Tool

Accessing Sentinel's Routine Querying Tools and Common Data Model

Accessing Sentinel's Routine Querying Tools and the SCDM

We will now demonstrate how to use the Sentinel website to access Sentinel's Routine Querying tools and Common Data Model.
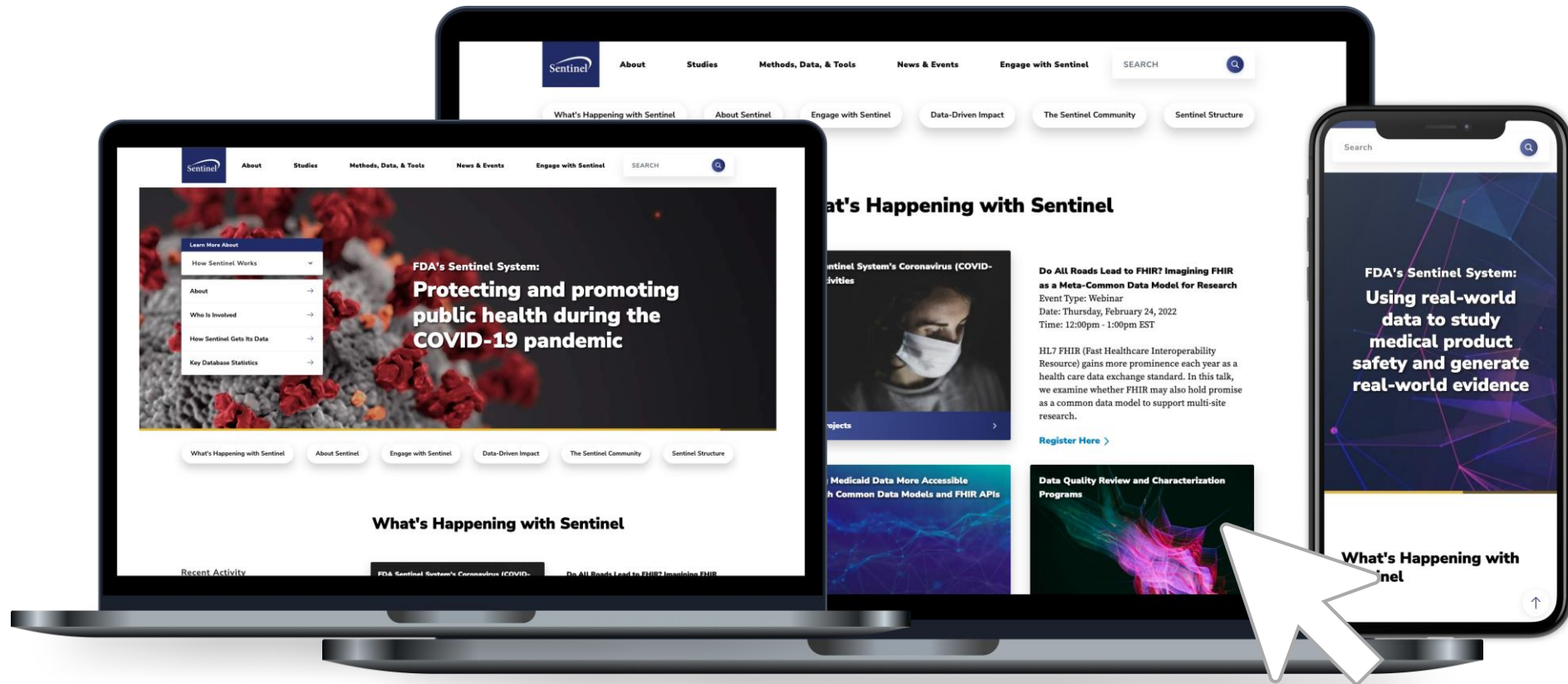
Conclusion

Today's Webinar covered three learning objectives:

1	2	3
Key Components of the SCDM	**Available Analytics Tools**	**Accessing Routine Querying Tools**

Users can understand the basics of the Sentinel Common Data Model on the Sentinel Website, including the foundations of the SCDM, the specific data tables within the SCDM, and the timeline of enhancements that have occurred since the SCDM was first established.

Analytics tools are publicly available to users on the Sentinel Website. Once users have their own data in the SCDM format, they can perform descriptive and inferential analyses using Sentinel's analytics tools. Level 1 analyses, Level 2 analyses, Level 3 analyses, and signal identification analyses were covered.

Users can access Sentinel's Routine Querying Tools and the data tables of the Sentinel Common Data Model on the Sentinel Website, under the Methods, Data, & Tools page. Any user with their own health data in the SCDM format may utilize these publicly available tools.
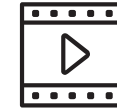
Q&A

Get Engaged with Sentinel

https://www.sentinelinitiative.org/engage-sentinel

Newsletter

Receive information about the latest Sentinel updates, assessment results, event information and changes to the Sentinel System.

Public Training

View trainings on Sentinel data, tools, or other areas of interest.

RSS Feed

Stay informed about the latest updates to the Sentinel website by subscribing to our RSS feed.