

A Common Data Model for Europe: Why? Which? How?

The FDA Sentinel Common Data Model

European Medicines Agency

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HARVARD
MEDICAL SCHOOL



Harvard Pilgrim
Health Care Institute

Conflicts and Disclosures

I have no conflicts of interest related to this presentation.

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In summary

- The Sentinel common data model includes claims, EHR and registry data
- The Sentinel common data model can incorporate other data domains (eg, free text), and is extensible to any data source
- The Sentinel data model supports any type of analysis because the data are stored at the most granular level available
- The Sentinel data model was designed to meet FDA needs for analytic flexibility, transparency, and control
- The Sentinel distributed querying approach allows automated query execution and response
- The Sentinel approach gives FDA maximum control of the network, data, and tools

Electronic data types

- Insurance claims data*
- Electronic health records (inpatient* and outpatient*)
- Registries
 - Birth*
 - Death*
 - Immunization*
 - Disease*
- Patient-generated data†

* Sentinel uses / has used these

† Sentinel is developing capability to use these

Data networks have different goals and needs

- Provide information about individuals, e.g., Health information exchanges
 - Exchange patient data for patient care at the point of care
 - *Need: real-time access, patient identity, minimal need for completeness or standardization (sending notes to read)*
- Provide information about groups, e.g., Sentinel
 - Public health surveillance
 - Health services research
 - Clinical trial planning and enrollment
 - Patient level prediction modeling
 - *Need: size, standardization, and consistency across sources*

How do you query multiple data sources?

- Translate the data to a common data model or translate every query
- Sentinel and most other networks translate the data

Some distributed data networks I've worked on

- CDC Vaccine Safety Datalink
- Health Care Systems Research Network
- NIH Cancer Research Network
- Meningococcal Vaccine Safety Study
- Massachusetts Department of Public Health (MDPHnet)
- FDA Sentinel
- Asthma Cohort Study
- NIH Health Care Systems Research Collaboratory
- Reagan-Udall Foundation Innovation in Medical Evidence Development and Surveillance (IMEDS)
- PCORI PCORnet
- Biologics and Biosimilars Collective Intelligence Consortium

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- **PCORI PCORnet**
- **Biologics and Biosimilars Collective Intelligence Consortium**
- **Multiple sponsored studies**

**Projects that leverage
FDA Sentinel**

Sentinel Overview



ABOUT

- Background
- Coordinating Center
- Privacy and Security
- The Sentinel System Story
- Reagan-Udall Foundation and IMEDS

MEDICAL PRODUCT ASSESSMENTS

- Active Risk Identification and Analysis System
- Ongoing ARIA Assessments
- Assessments of Drugs
- Assessments of Vaccines, Blood, & Biologics
- FDA-Catalyst

DATA & SURVEILLANCE TOOLS

COMMUNICATIONS

Latest Postings

▼ SPOTLIGHT

- [CDER Conversation: The FDA's Sentinel Initiative](#)
Mon, 11/27/2017

☰ PUBLICATIONS AND PRESENTATIONS

- [Development of Metrics to Assess Appropriate Prescribing of Opioids in the Mini-Sentinel Distributed Database \(MSDD\)](#)
Mon, 11/20/2017
- [Prospective Postmarketing Surveillance of Acute Myocardial Infarction in New Users of Saxagliptin: A Population-Based Study](#)
Fri, 11/10/2017
- [Safety Assessment of Niacin in the U.S. Food and](#)

<https://www.sentinelinitiative.org/>

Sentinel Partner Organizations

Lead – HPHC Institute

DEPARTMENT OF POPULATION MEDICINE



Data and scientific partners



Scientific partners



Sentinel distributed database

- Populations with well-defined person-time for which most medically-attended events are known
 - 425 million person-years of observation time
 - 43 million people currently accruing new data
 - 5.9 billion pharmacy dispensings
 - 7.2 billion unique medical encounters
 - 42 million people with at least one laboratory test result

<https://www.sentinelinitiative.org/sentinel/snapshot-database-statistics>

Sentinel common data model: How it came to be

All data models have same basic concepts, constrained by data availability

- **Information about people**
 - Demographics (eg, age, sex, race, ethnicity, residence)
 - Other characteristics (eg, disease and family history)
- **Information about care provided and documented during medical encounters**
 - Standardized vocabularies document care during health care encounters with clinicians
 - Vital signs and other measurements
- **Patient reported information**

Sentinel CDM Development

- Requirements gathering with FDA
- Data model development with data partners
- Draft data model for review and comment
 - Informed by prior work
- Final data model documenting availability and issues for every data element by every data partner
- Implementation
- Data quality review
- Iterate...now on version 6.01

FDA anticipated uses of the Sentinel System

■ **Primary functions include**

- Adverse event signal detection and strengthening for drug, vaccine, biologics, and devices
 - Acute and chronic
 - Routine surveillance and ad hoc requests
- Confirmatory safety studies (hypothesis evaluation)
- Data mining (hypothesis generation)
- Monitor adoption, diffusion, and use of medical products
- Augment registry information (e.g., medical devices)

■ **Additional uses and needs identified**

- Assess background incidence rates for outcomes of interest
- Assess sensitivity and predictive value of selected outcome definitions

From: FDA Sentinel Data Model Report, 2009.

Sentinel CDM prioritizes uniform meaning and data readiness

- Data comparable in **format and definition** are stored at all sites
- This requires extensive curation before use

Sentinel Common Data Model Guiding Principles (abbreviated)

1. Accommodates current Sentinel requirements
2. Able to incorporate new data types and data elements as future needs dictate
3. Appropriate use and interpretation of local data requires the data partners' local knowledge and data expertise
4. Documentation of site-specific issues and qualifiers is crucial for the effective operation

Sentinel Common Data Model Guiding Principles (abbreviated)

5. The design is transparent, intuitive, well documented and easily understood
6. Interoperable with evolving healthcare coding standards
7. Captures values found in the source data; any mapping to standard vocabularies is transparent
8. Derived variables or tables should not be included

Sentinel Common Data Model Guiding Principles (abbreviated)

9. Distinct data types should be kept separate (e.g., prescriptions, dispensings, and drug administrations)
10. Distributed programs should be executed without site-specific modification
11. Only the minimum necessary information is shared
12. Can include “site-specific” information

Sentinel Common Data

Medical Encounters					
Enrollment	Demographic	Dispensing	Encounter	Diagnosis	Procedure
Person ID	Person ID	Person ID	Person ID	Person ID	Person 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 & provider	Encounter type & provider	Encounter type & provider
Medical record availability	Etc.	Amount dispensed	Facility	Diagnosis code & type	Procedure code & type
			Etc.	Principal discharge diagnosis	Etc.

Clinical		Registry			Inpatient	
Lab Result	Vital Signs	Death	Cause of Death	State Vaccine	Inpatient Pharmacy	Inpatient Transfusion
Person ID	Person ID	Person ID	Person ID	Person ID	Person ID	Person ID
Result and specimen collection dates	Measurement date and time	Death date	Cause of death	Vaccination date	Administration date and time	Administration start and end date and time
Test type, immediacy & location	Height and weight	Source	Source	Admission Type	Encounter ID	Encounter ID
Logical Observation Identifiers Names and Codes (LOINC ®)	Diastolic & systolic BP	Confidence	Confidence	Vaccine code & type	National Drug Code (NDC)	Transfusion administration ID
Test result & unit	Tobacco use & type	Etc.	Etc.	Provider	Route	Transfusion product code
Etc.	Etc.			Etc.	Dose	Blood Type
					Etc.	Etc.

Sentinel Common Data Model:

One patient

DEMOGRAPHIC

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

ENCOUNTER

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

ENROLLMENT

PATID	ENR_START	ENR_END	MEDCOV	DRUGCOV
PatID1	7/1/2004	12/31/2006	Y	Y
PatID1	9/1/2007	6/30/2009	Y	Y

DIAGNOSIS

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

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

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

Sentinel Common Data Model: Transparency and extensibility

DEMOGRAPHIC

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

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PatID1	EncID1	10/18/2005	Provider2	IP	27445	C4

Sentinel Comr Transparency

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Sex

- A = Ambiguous (e.g., transgender/hermaphrodite)
- F = Female
- M = Male
- U = Unknown

Hispanic

- N = No
- U = Unknown
- Y = Yes

Race

- 0 = Unknown
- 1 = American Indian or Alaska Native
- 2 = Asian
- 3 = Black or African American
- 4 = Native Hawaiian or Other Pacific Islander
- 5 = White

STP Model:

EncType	AV = Ambulatory Visit
	ED = Emergency Department
	IP = Inpatient Hospital Stay
	IS = Non-Acute Institutional Stay
	OA = Other Ambulatory Visit
DX	Diagnosis code
Dx_Codetype	09 = ICD-9-CM
	10 = ICD-10-CM
	11 = ICD-11-CM
	SM = SNOMED CT
	OT = Other
PDX	P = Principal
	S = Secondary
	X = Unable to Classify

PATID	ADATE	ENCOUNTERID	DDATE	ENCTYPE
PatID1	10/21/2005	49884074311	30	30
PatID1	10/21/2005	58177026408	30	60
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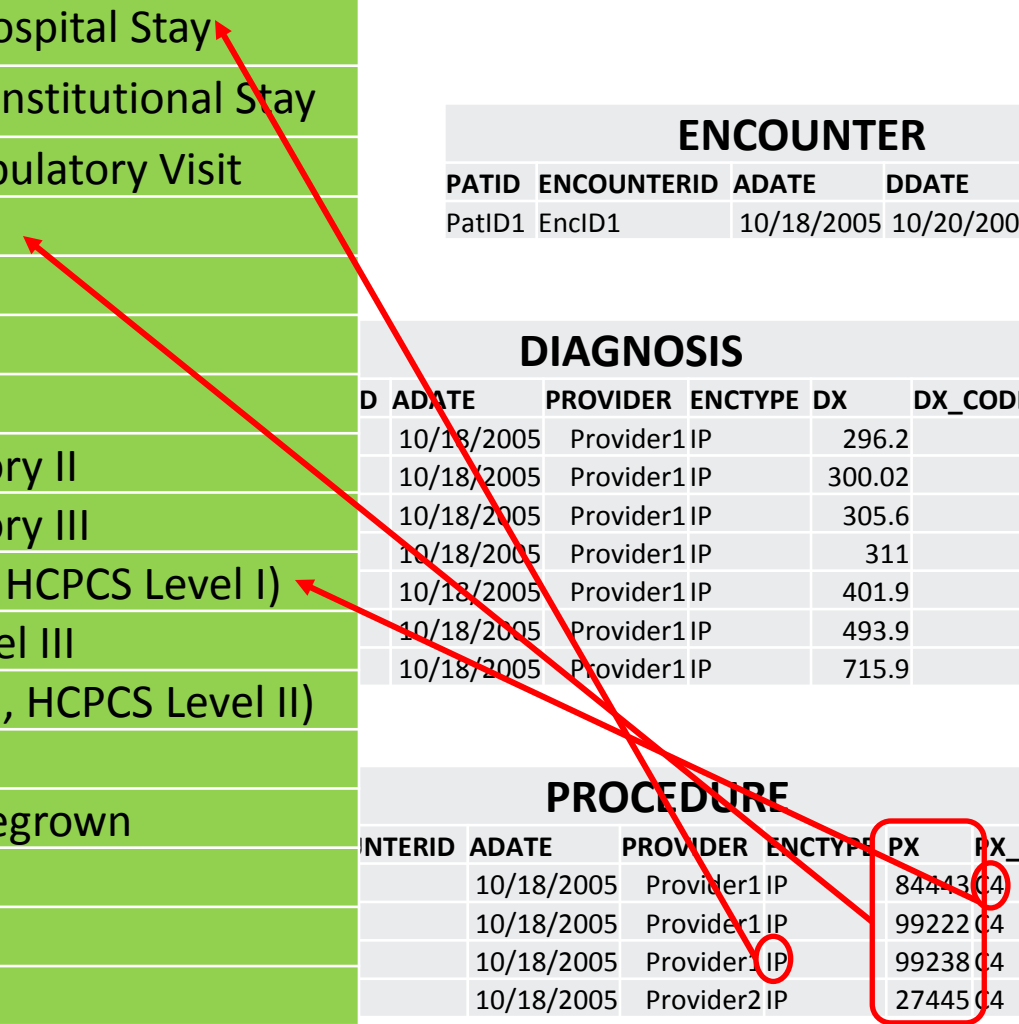
Standard Data Model:

PATID	EncType	AV = Ambulatory Visit
PatID		ED = Emergency Department
		IP = Inpatient Hospital Stay
		IS = Non-Acute Institutional Stay
		OA = Other Ambulatory Visit
PATID	PX	Procedure code
PatID	PX_CodeType	09 = ICD-9-CM
		10 = ICD-10-CM
		11 = ICD-11-CM
PATID		C2 = CPT Category II
PatID		C3 = CPT Category III
PatID		C4 = CPT-4 (i.e., HCPCS Level I)
		H3 = HCPCS Level III
PATID		HC = HCPCS (i.e., HCPCS Level II)
PatID		LC = LOINC
PatID		LO = Local homegrown
PatID		ND = NDC
PatID		OT = Other
PatID		RE = Revenue
PatID1	10/23/200500310027510	30 15

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

DIAGNOSIS						
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	10/18/2005	Provider1	IP	99238	C4
	10/18/2005	Provider2	IP	27445	C4



Capturing time-varying information

- Some important concepts are time-dependent
 - Person residence, primary care provider, and primary care location
 - Insurance benefit coverage (medical/ drug)
- These concepts need an anchor date or period
- Without an anchor date some data elements are difficult to interpret
 - Location of residence as of when?
 - Someone with drug benefit but no medical benefit won't have outcomes

Defining observation time

- Claims data: Person time defined using enrollment period
- EHR data: Person time definition is complex but must be defined
 - No standard definition
 - Has to be applied in the model (hard-coded) or at analysis

Medication exposure considerations

- Dispensing table captures dispensing from outpatient pharmacies
 - NDC, days supplied, amount dispensed, date of dispensing
- Medications distributed in other settings (e.g., infusions in medical practices) are captured in the utilization tables
 - *Avoid comingling different concepts in the same table, especially with different data latency periods*
- Rollback transactions and other adjustments indicating a dispensing was canceled or not picked up are processed before table creation

Procedure and diagnosis table considerations

- Design is extensible to any data source (eg, EHR, international, etc)
 - Add new encounter types by expanding value set
 - Add new code types by expanding value set or vocabulary
 - No change to tools required

Encounter Type
AV = Ambulatory Visit
ED = Emergency Department
IP = Inpatient Hospital Stay
IS = Non-Acute Institutional Stay
OA = Other Ambulatory Visit

Diagnosis Type
09 = ICD-9-CM
10 = ICD-10-CM
11 = ICD-11-CM
SM = SNOMED CT
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Procedure Type
09 = ICD-9-CM
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C2 = CPT Category II
C3 = CPT Category III
C4 = CPT-4 (HCPCS Level I)
H3 = HCPCS Level III
HC = HCPCS (HCPCS Level II)
LC = LOINC
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OT = Other
RE = Revenue

Procedure and diagnosis table considerations

- Design is extensible to any data source (eg, EHR, international, etc)
 - Add new encounter types by expanding value set
 - Add new code types by expanding value set or vocabulary**
 - No change to tools required

Encounter Type

AV = Ambulatory Visit

ED = Emergency Department

IP = Inpatient Hospital Stay

IS = Non-Acute Institutional Stay

OA = Other Ambulatory Visit

TM = Telemedicine/ Telehealth

Diagnosis Type

09 = ICD-9-CM

10 = ICD-10-CM

11 = ICD-11-CM

SM = SNOMED CT

OT = Other

RD = READ

Procedure Type

09 = ICD-9-CM

10 = ICD-10-CM

11 = ICD-11-CM

C2 = CPT Category II

C3 = CPT Category III

C4 = CPT-4 (HCPCS Level I)

H3 = HCPCS Level III

HC = HCPCS (HCPCS Level II)

LC = LOINC

LO = Local homegrown

ND = NDC

OT = Other

RE = Revenue

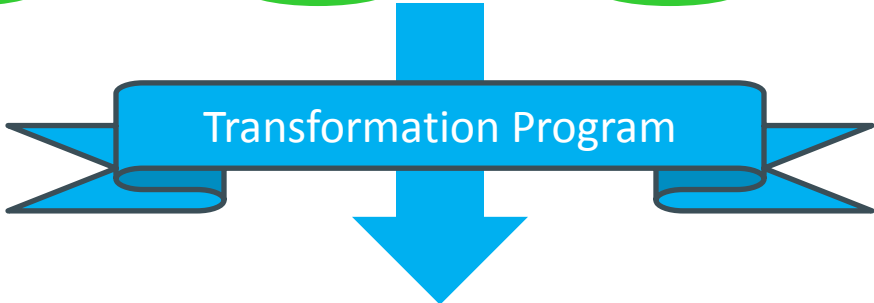
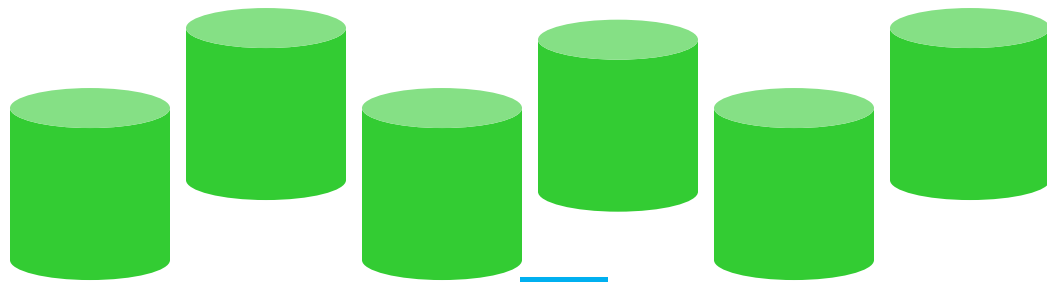
Sentinel CDM key considerations

- Inclusion of a variable does not imply completeness
- Completeness may vary by source and over time
- Availability of data in the source system does not mean it is usable for FDA's purposes
- Maintaining standardization is an ongoing process
- FDA determines the direction of the data model and the timing of data model changes
 - Change management is critical in a complex network due to the multiple dependencies and costs
 - System change must be directed by FDA for FDA needs

Rapid Response Requires Robust Data Quality Assurance – In Advance of Its Use

Every Data Partner transforms their data into the Sentinel Common Data Model

Unique Data Partner's Source Database Structure

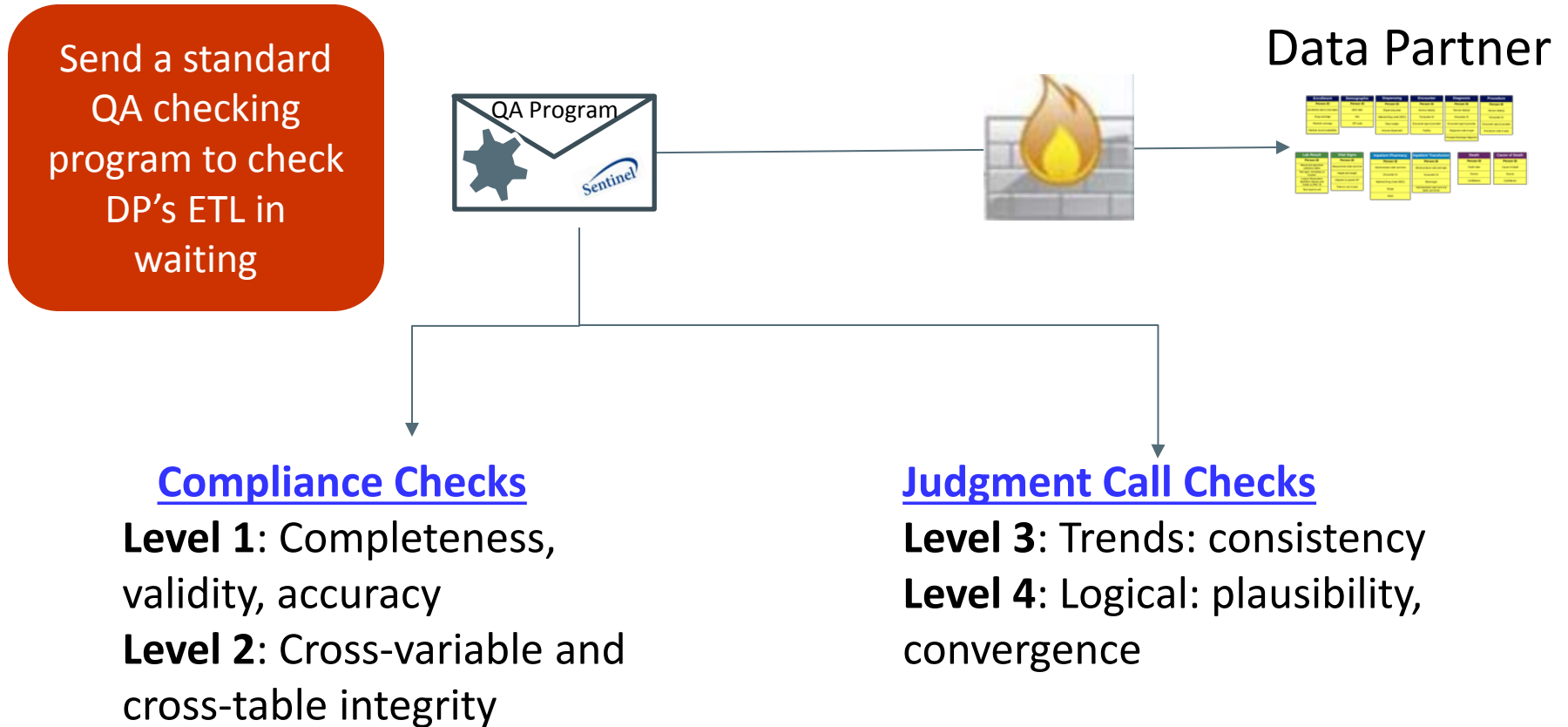


Data Partner's Database Transformed into SCDM Format (DP ETL)

Enrollment	Demographic	Dispensing	Encounter	Diagnosis	Procedure
Person ID	Person ID	Person ID	Person ID	Person ID	Person 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 & provider	Encounter type & provider	Encounter type & provider
Medical record availability		Amount dispensed	Facility	Diagnosis code & type	Procedure code & type
				Principal discharge diagnosis	

Lab Result	Vital Signs	Inpatient Pharmacy	Inpatient Transfusion	Death	Cause of Death
Person ID	Person ID	Person ID	Person ID	Person ID	Person ID
Result and specimen collection dates	Measurement date and time	Administration date and time	Blood product code and type	Death date	Cause of death
Test type, immediacy & location	Height and weight	Encounter ID	Encounter ID	Source	Source
Logical Observation Identifiers Names and Codes (LOINC ®)	Diastolic & systolic BP	National Drug Code (NDC)	Blood type	Confidence	Confidence
Test result & unit	Tobacco use & type	Route	Administration start and end dates and times		
		Dose			

The quality assurance process

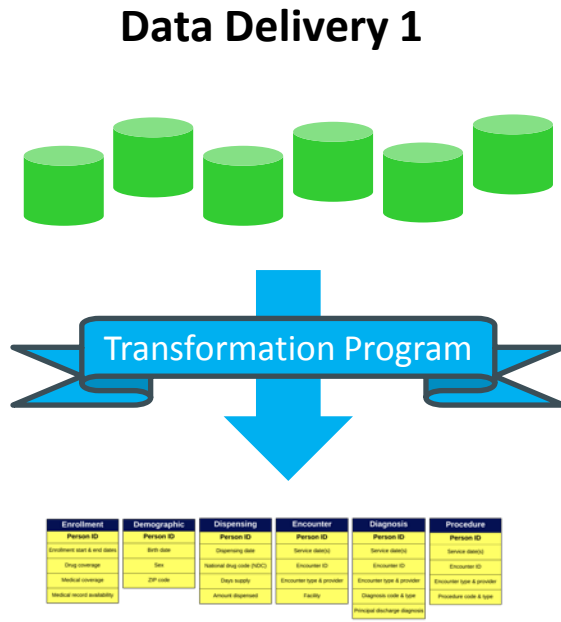


The database is dynamic – updates overwrite the preceding data

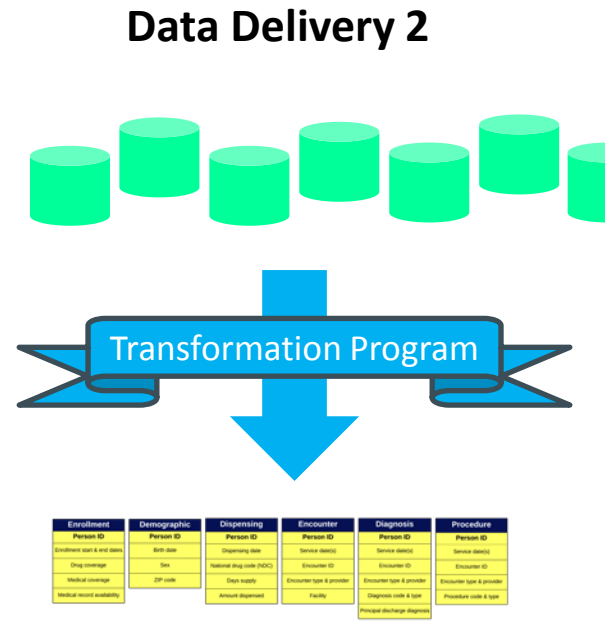
Unique Data Partner Source Database Structure

Data Partner's Database Transformed into SCDM Format

Timeframe of Data Available in Database



Lab Result	Vital Signs	Inpatient Pharmacy	Inpatient Transfusion	Death	Cause of Death
Person ID Result and specimen collection date Test type, methodology & facility Legal Characterization Identifier Number and Code (LINC #) Test result & unit	Person ID Measurement date and time Height and weight Diastolic & systolic BP Tobacco use & type	Person ID Administration date and time Encounter ID National Drug Code (NDC) Route Date	Person ID Blood product code and type Encounter ID Blood type Administration start and end dates and times	Person ID Death date Source Confidence	Person ID Cause of death Source Confidence



Lab Result	Vital Signs	Inpatient Pharmacy	Inpatient Transfusion	Death	Cause of Death
Person ID Result and specimen collection date Test type, methodology & facility Legal Characterization Identifier Number and Code (LINC #) Test result & unit	Person ID Measurement date and time Height and weight Diastolic & systolic BP Tobacco use & type	Person ID Administration date and time Encounter ID National Drug Code (NDC) Route Date	Person ID Blood product code and type Encounter ID Blood type Administration start and end dates and times	Person ID Death date Source Confidence	Person ID Cause of death Source Confidence



Sentinel QA statistics

- Annually, the QA team conducts reviews for approximately 50 data deliveries per year from 17 Data Partners
- Since 1/1/2016, the QA package has had to be re-run in 16 instances to fix an issue
- In the latest data deliveries from the 5 largest DPs, 25 checks were reported in QA that required DP follow-up

What's next?

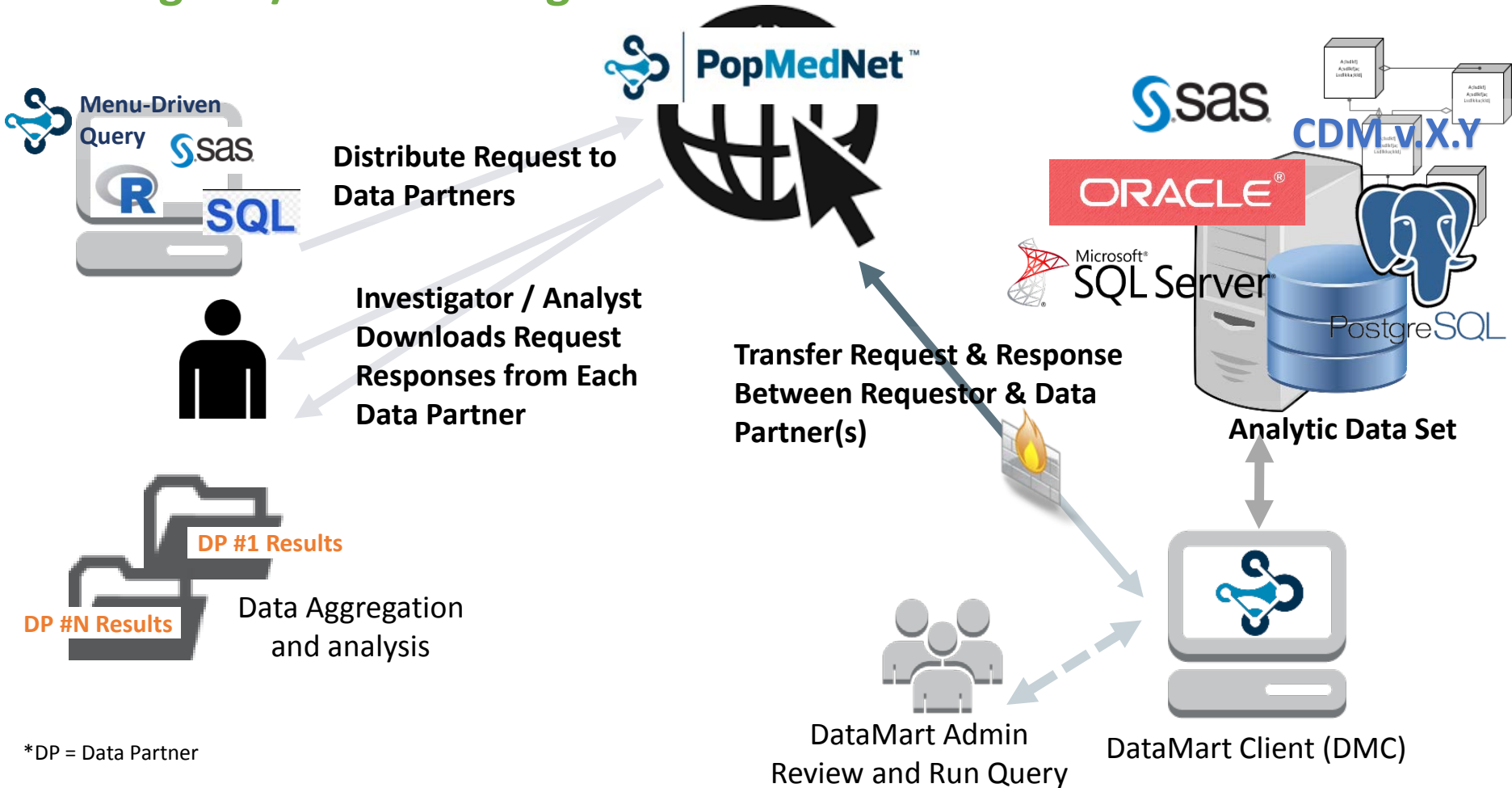
- Incorporate mother-baby linked data for routine analyses
- NLP and other approaches to obtain critical data elements difficult to extract or not available in source data
 - Pregnancy start
 - Family history
 - Treatment regimens
 - Disease progression
 - Radiologic findings
 - Demographics
 - Test results
- Better tools to enable use of dispersed data
 - **Horizontally partitioned distributed regression**
 - Vertically partitioned distributed regression
 - Efficient patient finding and linkage
- Mobile apps to collect patient data

Sentinel Approach to Analysis

Distributed querying

Investigator/Coordinating Center

Data Partner N



Analytic framework (one-off)

Identify health plan members aged ≥ 18 years in year 2001-2014



Restrict to patients with a dispensing of oral ACEIs or β -blockers



Restrict to patients with ≥ 183 days health plan enrollment



Restrict to patients with no diagnosis of angioedema during baseline



Follow patients from index date until diagnosis of angioedema or end of treatment

Analytic framework (re-usable)

Identify health plan members aged ≥ 18 years in year 2001-2014



Restrict to patients with a dispensing of oral ACEIs or β -blockers



Restrict to patients with ≥ 183 days health plan enrollment



Restrict to patients with no diagnosis of angioedema during baseline



Follow patients from index date until diagnosis of angioedema or end of treatment

Analytic framework (re-usable)

Identify health plan members aged in year



Restrict to patients with a dispensing of or



Restrict to patients with days health plan enrollment

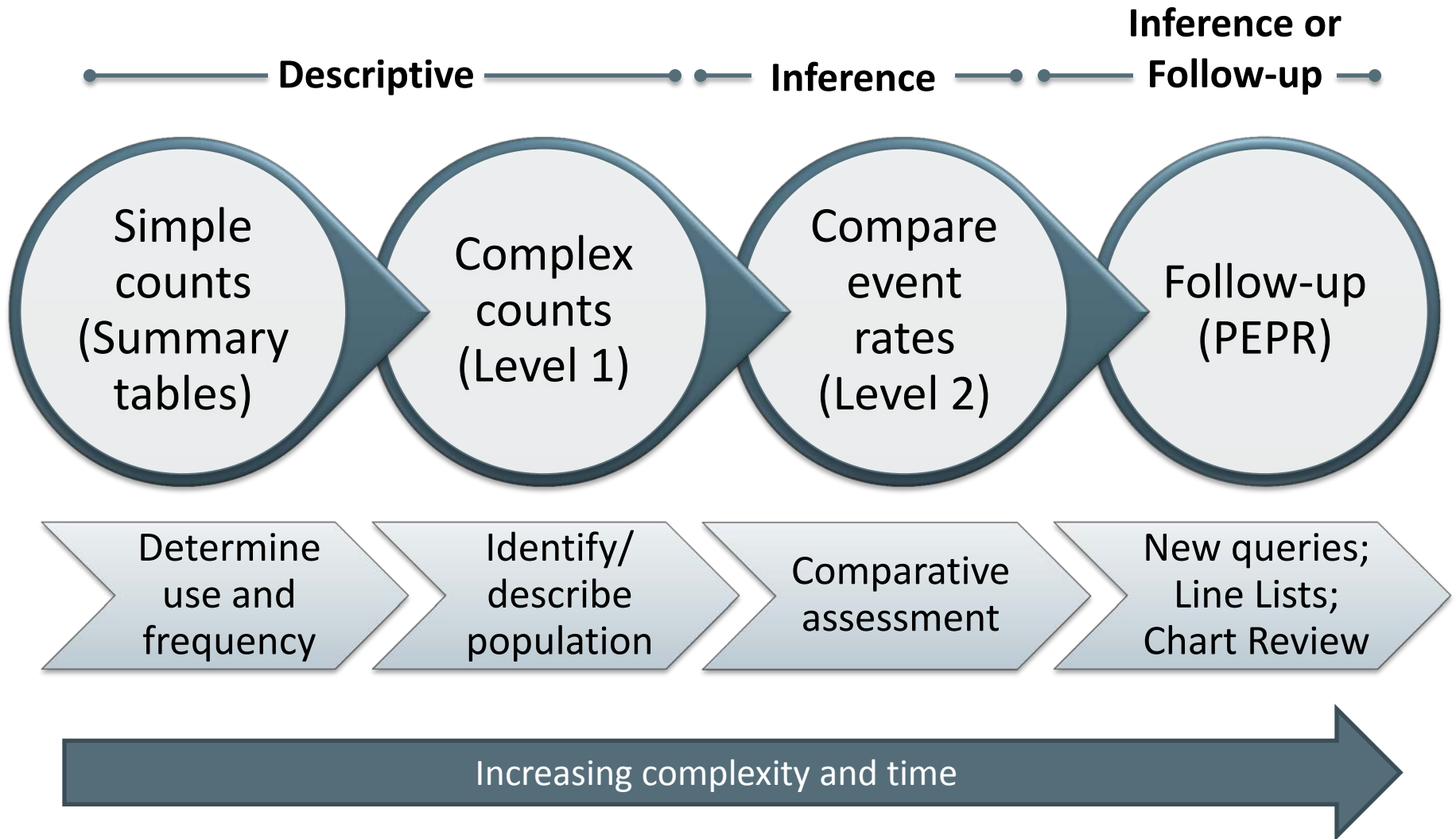


Restrict to patients with no diagnosis of during baseline

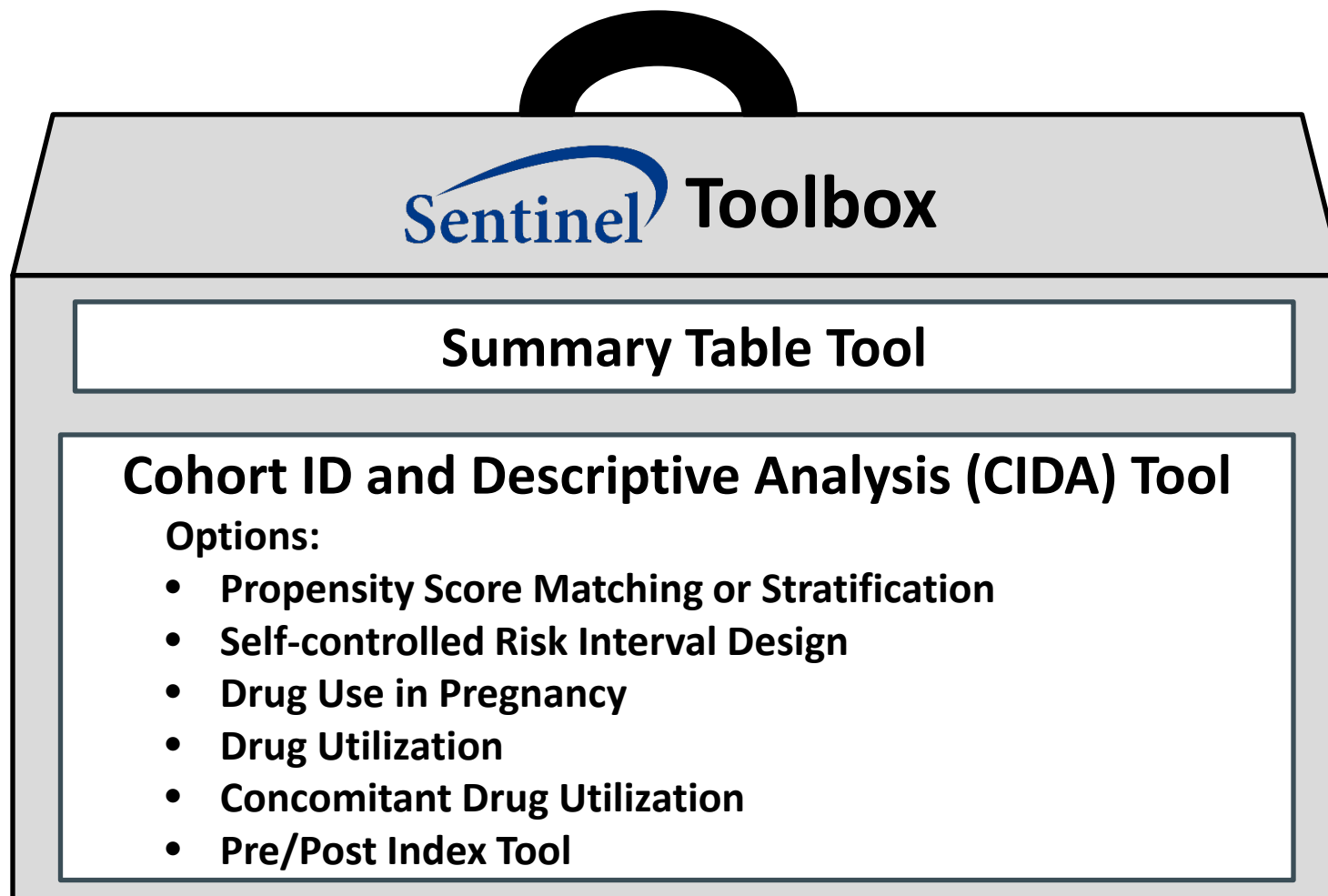


Follow patients from index date until diagnosis of or

Rapid analysis querying sequence



Sentinel's Tools



Sentinel analytic approach

- Prioritizes flexibility to assess individual exposure/outcome relationships
- Investigators can customize exposure and outcome definitions for each assessment
- Tools provide flexibility to address many possibilities
 - 100+ specification decisions (e.g., incidence, exclusions)
 - Stockpiling algorithms (eg, % overlap)
 - Complex outcome definitions that couple relationships between diagnoses, procedures, dispensings, demographics, and relative time-windows
- Tools use the most granular data available

Sentinel's approach to creating medication exposure episodes

- Use the most granular data
- Build episodes based on the specific needs of the analysis and characteristics of the products
- Sentinel tools have multiple flexible ways to create treatment episodes
- Main point: Sentinel designed to allow the investigator to decide on query specifications and implement at program execution

Sentinel stockpiling algorithm

- Evaluates outpatient pharmacy dispensing dates and adjusts to reflect active treatment days
 - Adjusts data to ensure non-overlapping days supply
 - Options for implementation:
 - Adjust all dispensing dates with overlapping days supply (default)
 - Adjust dispensings based on % overlap of days supply
 - No adjustment

Allowable episode gaps

- Specify a maximum number of days between two spans of active treatment where:
 - Separate spans should be “bridged” to create a single episode of treatment
 - Maximum number of days for gap is a tool parameter
- FDA chooses the gap appropriate for the analysis
 - Common choices are 7, 14, and 30 days
 - Amoxicillin with a 20 day interval for acute otitis media represents a new event; amlodipine with the same pattern represents a Caribbean vacation...

Allowable episode gaps

- Examples that require flexibility
 - For antibiotics, date dispensed plus days supply is a reasonable measure of exposure
 - For chronic medications an allowable gap is commonly used
 - For prn medications such as Viagra, days supplied is not useful, but a measure of inter-dispensing intervals might be relevant
 - Migraine medications are dispensed after the headache so exposure based on dispensed date may be misleading

Outcome definitions

- Examples that require flexibility
 - Combine occurrence (or absence) of selected diagnosis, procedure, and medication codes
 - Laboratory result values or occurrence
 - Demographics
 - Relative timing between concepts (before, after, before or after, overlap)
- Any combination of Boolean operators
 - Venous thromboembolism (VTE)
 - (VTE observed in inpatient or emergency department setting) OR (VTE in ambulatory setting AND anticoagulant within 31 days)

Data model adopters and collaborations



In summary

- The Sentinel common data model includes claims, EHR and registry data
- The Sentinel common data model can incorporate other data domains (eg, free text), and is extensible to any data source
- The Sentinel data model supports any type of analysis because the data are stored at the most granular level available
- The Sentinel data model was designed to meet FDA needs for analytic flexibility, transparency, and control
- The Sentinel distributed querying approach allows automated query execution and response
- The Sentinel approach gives FDA maximum control of the network, data, and tools

Thank You