Harnessing big data for medical product safety surveillance: The experience of the Sentinel Initiative

Judith C. Maro, PhD
Harvard Medical School
and Harvard Pilgrim Health Care Institute, Boston, MA

Agenda

- Sentinel 101
- Answering Safety Questions in Sentinel
- Selected Methods Projects
- Selected FDA-Catalyst Projects

Sentinel and the United States Food and Drug Administration's (FDA) Mandate

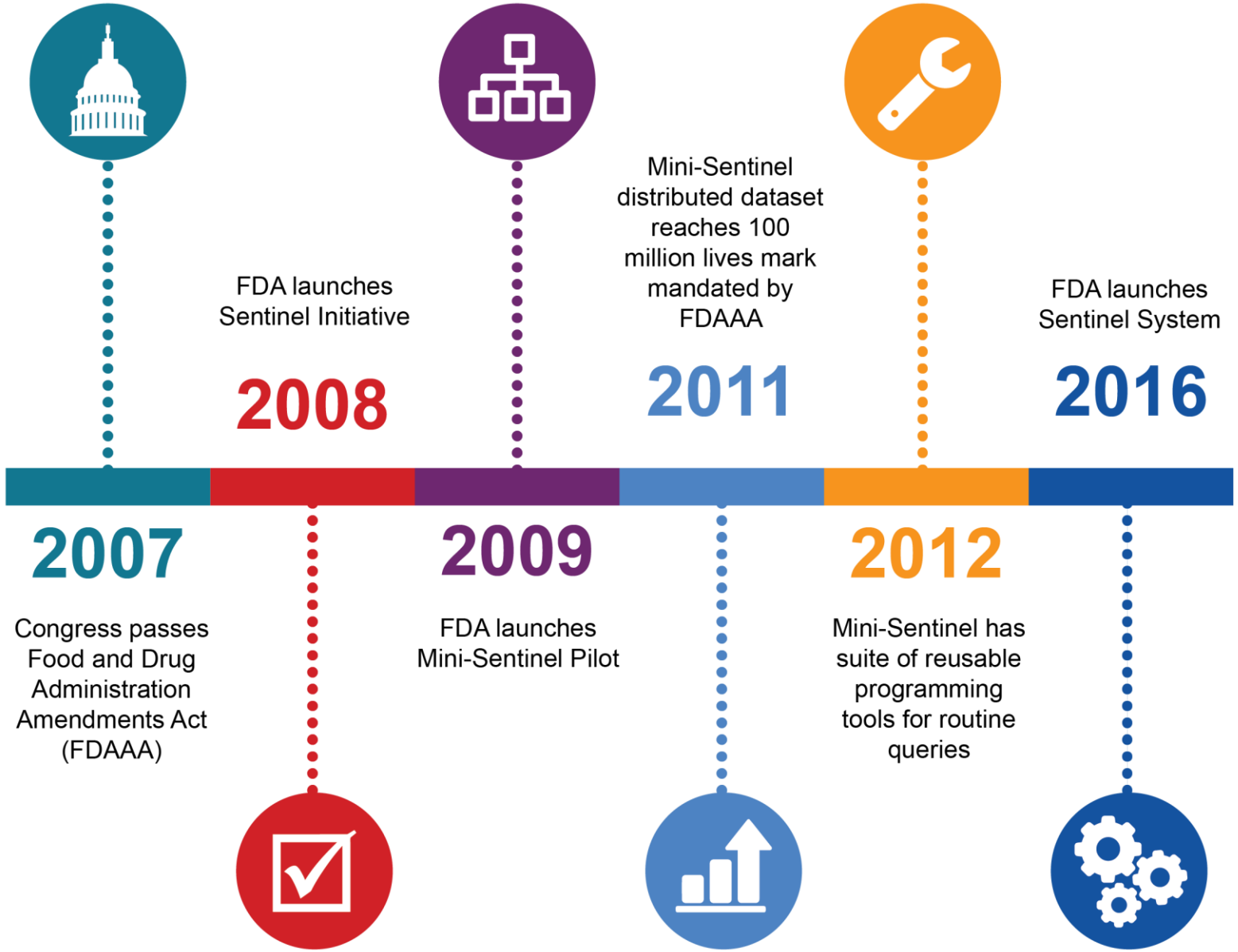
Section 905
Mandates creation of Sentinel

Section 901
New Food and Drug Administration Amendments Act (FDAAA) Postmarketing Requirements (PMR) authority

"The Secretary may not require the responsible person to conduct a study under this paragraph, unless the Secretary makes a determination that the reports under subsection (k)(1) and the **active postmarket risk identification and analysis system** as available under subsection (k)(3) will not be **sufficient** to meet the purposes set forth in subparagraph (B)."

https://www.gpo.gov/fdsys/pkg/PLAW-110publ85/pdf/PLAW-110publ85.pdf

Creation and Evolution of Sentinel

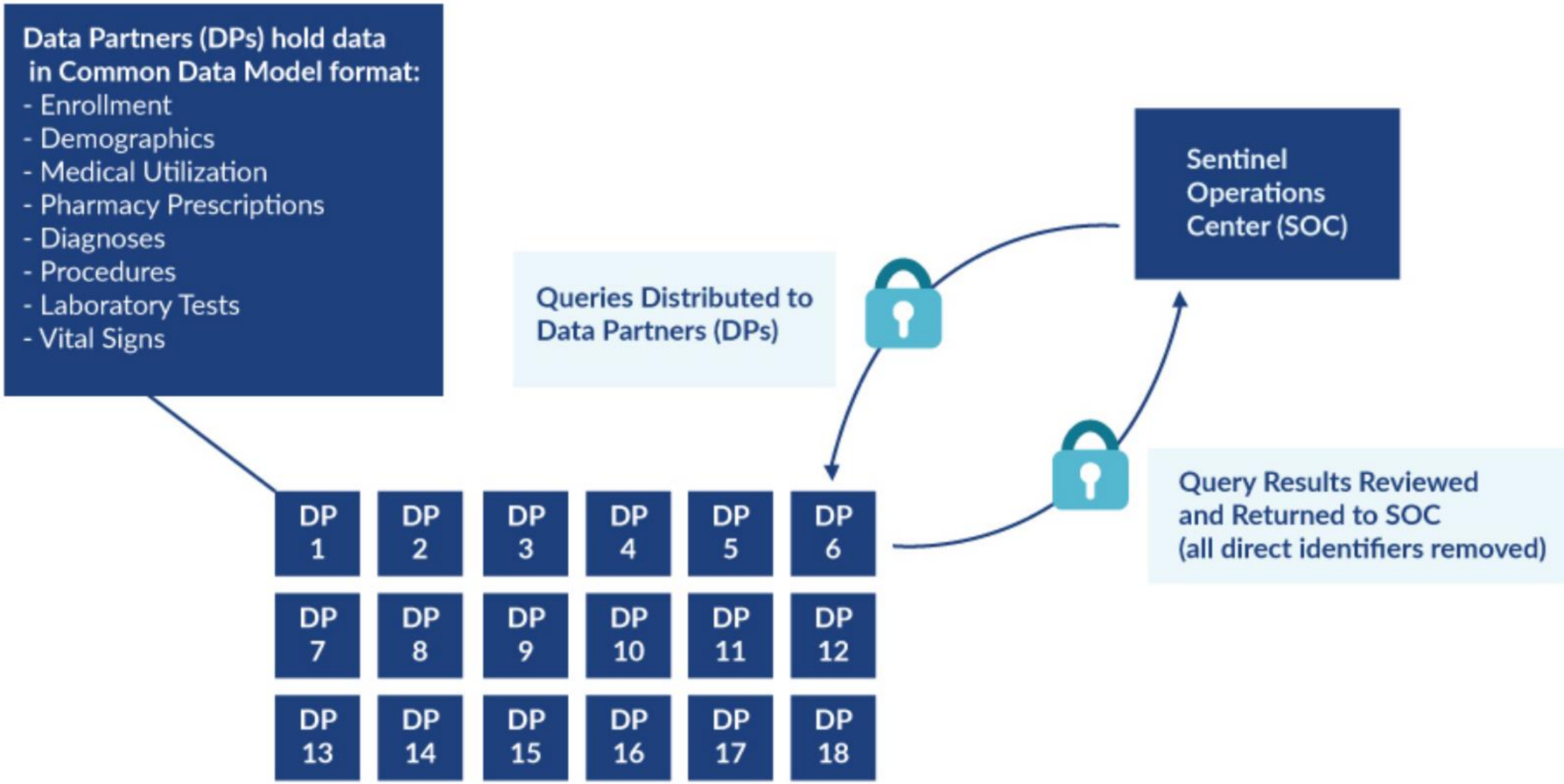


https://www.sentinelinitiative.org/background

Sentinel Design Requirements

- Electronic health data for >100M persons
  - Include special populations (pregnant women, elderly)
  - Ability to link to external sources, e.g., National Death Index
  - Ability to access full text medical records
- Expertise in the way health care delivery and payment influence electronic healthcare data
- Rapid answers to many FDA safety questions
- Accuracy sufficient to support regulatory decision making
- Federal Information Security Management Act (FISMA)-compliant data security
- Ability to protect non-public information and to keep records on all data requests for public record-keeping

Sentinel Distributed Database



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

Sentinel Partner Organizations

Sentinel

Lead – HPHC Institute

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

Data & scientific partners

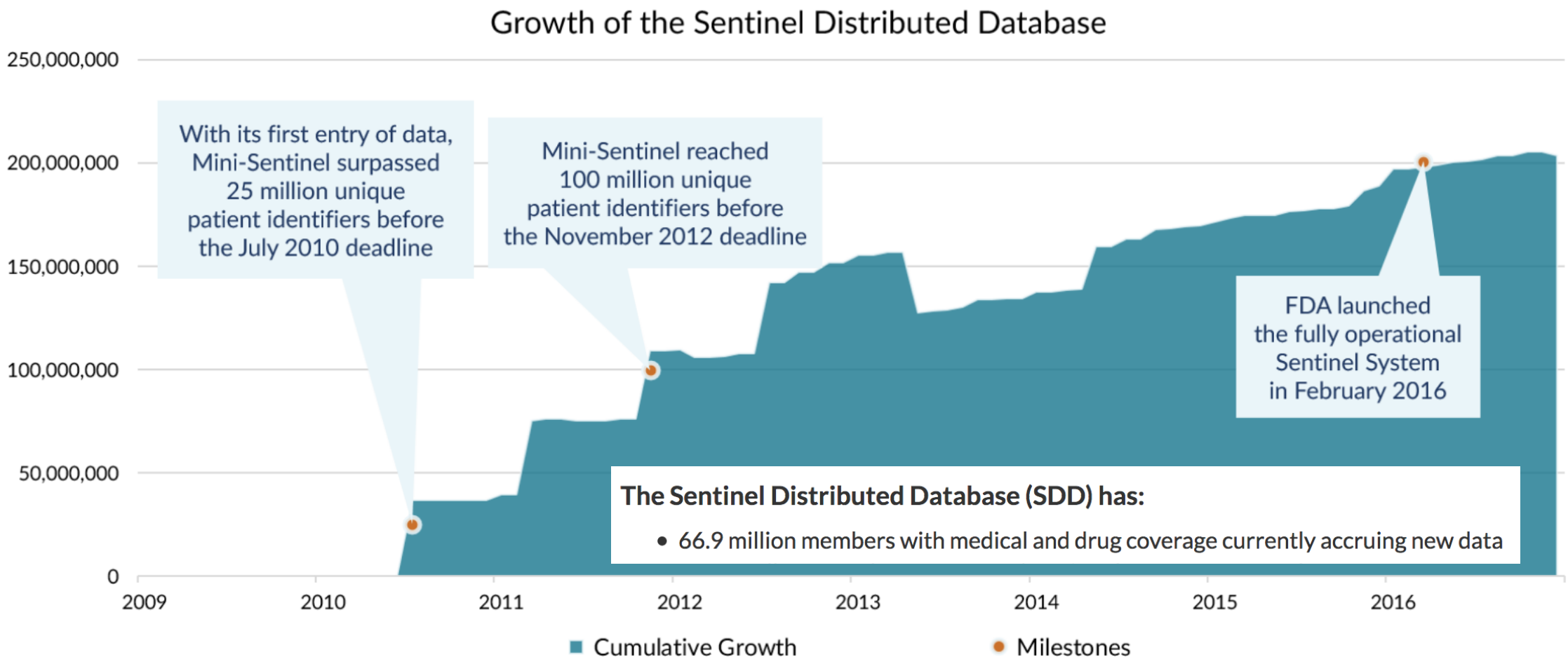
MASSACHUSETTS
HealthCore Anthem
VANDERBILT SCHOOL OF MEDICINE
health care systems research network
HUMANA
HCA Hospital Corporation of America
DukeMedicine
OPTUM
KAISER PERMANENTE
aetna

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/sentinel/data/data-partners

Sentinel Distributed Database Characteristics



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.

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

Sentinel Common Data Model Guiding Principles

- 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.

Sentinel Common Data Model v 6.0

Administrative

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 dates	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 & provider
Medical record availability	Etc.	Amount dispended	Facility	Diagnosis code & type	Procedure code & type
			Etc.	Principal discharge diagnosis	Etc.

Clinical

Lab Result	Vital Signs
Person ID	Person ID
Result and specimen collection dates	Measurement date & time
Test type, immediacy & location	Height & weight
Logical Observation Identifiers Names and Codes (LOINC®)	Diastolic & systolic BP
Test result & unit	Tobacco use & type
Etc.	Etc.

Registry

Death	Cause of Death	State Vaccine
Person ID	Person ID	Person ID
Death date	Cause of death	Vaccination date
Source	Source	Admission type
Confidence	Confidence	Vaccine code & type
Etc.	Etc.	Provider
		Etc.

Inpatient

Inpatient Pharmacy	Inpatient Transfusion
Person ID	Person 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.

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

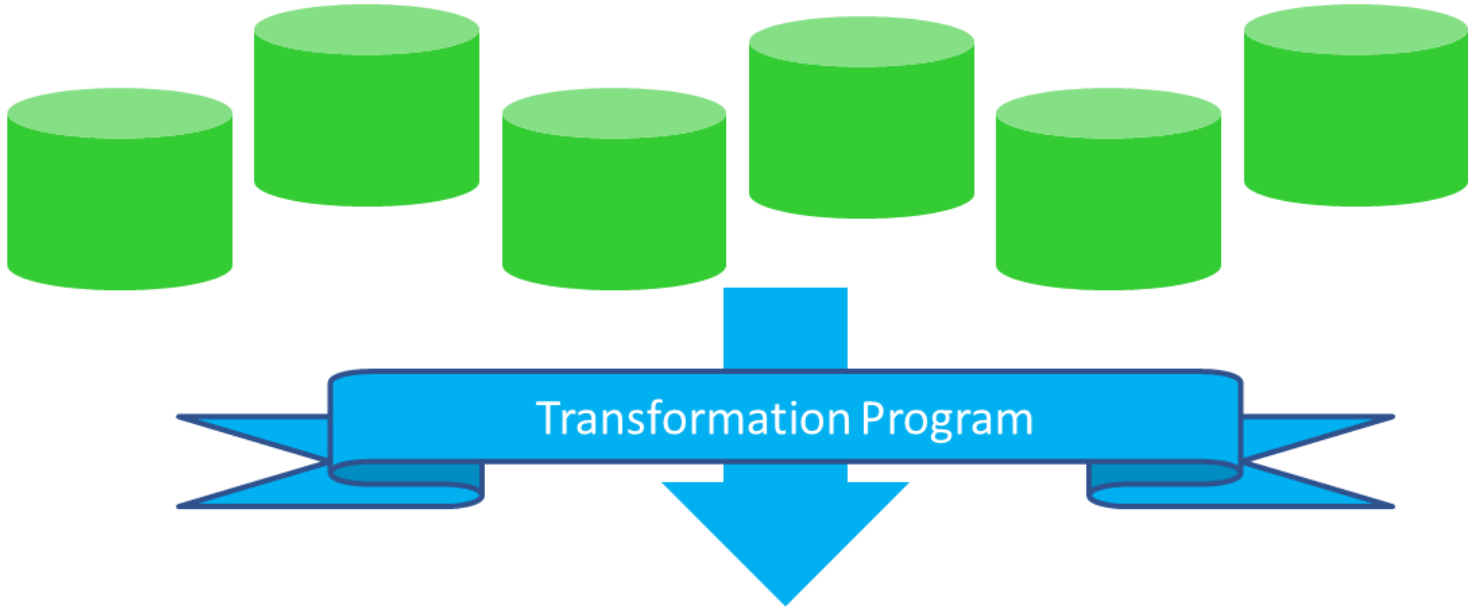
CAUSE OF DEATH

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

Every Data Partner Transforms their Source Data into the Sentinel Common Data Model

Sentinel

Unique Data Partner's Source Database Structure



Data Partner's Database Transformed into SCDM Format (Refresh)

Administrative

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 dates	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 & provider
Medical record availability	Etc.	Amount dispended	Facility	Diagnosis code & type	Procedure code & type
			Etc.	Principal discharge diagnosis	Etc.

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Lab Result	Vital Signs
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Etc.	Etc.	Provider
		Etc.

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Encounter ID	Encounter ID
National Drug Code (NDC)	Transfusion administration ID
Route	Transfusion product code
Dose	Blood type
Etc.	Etc.

Quality Assurance Guidance Before Sentinel…

Sentinel

Guidance for Industry and FDA Staff

Best Practices for Conducting and Reporting Pharmacoepidemiologic Safety Studies Using Electronic Healthcare Data

https://www.fda.gov/downloads/drugs/guidances/ucm243537.pdf

Project-Specific v. System Data Curation

Project-Specific	System
"As needed / as-you go"	"Always Ready"
Ad hoc	Repeatable, systematic
Variable amount of data cleaning	1200+ checks to pass each dataset
Burden on study team	Burden on Quality Assurance team
Cost is included in the cost of a study	Cost is front-loaded for studies that use system

Take-home message: "Making data fit for purpose" at scale entails cost and time trade-offs.

Adaptation of Guidance to a System Basis

Submit Comment

Sentinel Data Quality Assurance Practices

Project Title	**Sentinel Data Quality Assurance Practices**
Date Posted	*Thursday, March 23, 2017*
Status	Complete
Deliverables	Sentinel Data Quality Assurance Practices
Description	The Food and Drug Administration (FDA) set forth its current recommendations for data quality assurance (QA) in the following document: "Guidance for Industry and FDA Staff: Best Practices for Conducting and Reporting Pharmacoepidemiologic Safety Studies Using Electronic Healthcare Data" (Guidance), section IV.E "Best Practices – Data Sources: Quality Assurance (QA) and Quality Control (QC)," in May 2013. This Guidance describes best practices that particularly apply to observational studies designed to assess the risk associated with a drug exposure using electronic healthcare data.

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

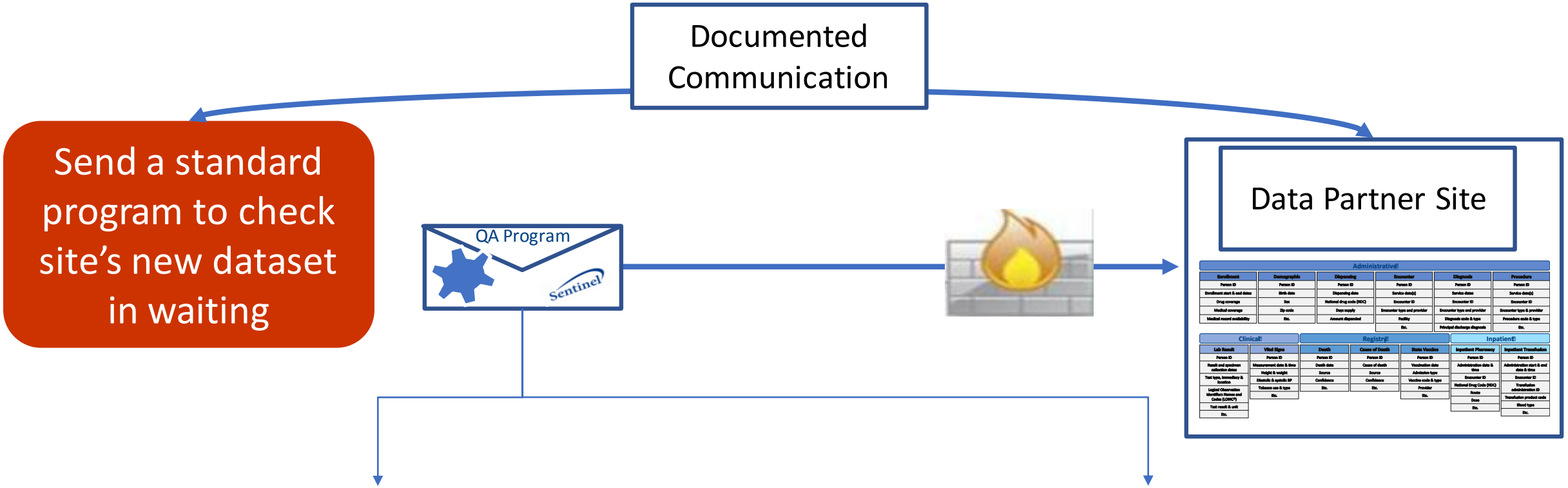
Transparent and Reproducible Quality Assurance

Data Quality Review and Characterization Programs v4.1.0

Project Title	Data Quality Review and Characterization Programs v4.1.0
Description	The Sentinel Data Quality Review and Characterization Programs are used by the Sentinel Operations Center (SOC) for data quality review and characterization of the Sentinel Distributed Database (SDD). To create the SDD, each Data Partner transformed local source data into the Sentinel Common Data Model (SCDM) format. The SOC created a set of data quality review and characterization programs to ensure that the SDD meets reasonable standards for data transformation consistency and quality and that the SDD data meets expectations needed for a distributed health data network.
Link	Sentinel Data Quality Review and Characterization Programs v4.1.0 – Overview Sentinel Data Quality Review and Characterization Programs v4.1.0 – Appendix A Sentinel Data Quality Review and Characterization Programs v4.1.0 – Appendix B Sentinel Data Quality Review and Characterization Programs v4.1.0 – SAS Programs View more details here.

https://www.sentinelinitiative.org/sentinel/data/distributed-database-common-data-model/data-quality-review-and-characterization

Data Quality Review and Characterization Process



Compliance Checks

Level 1: Completeness, validity, accuracy

Level 2: Cross-variable and cross-table integrity

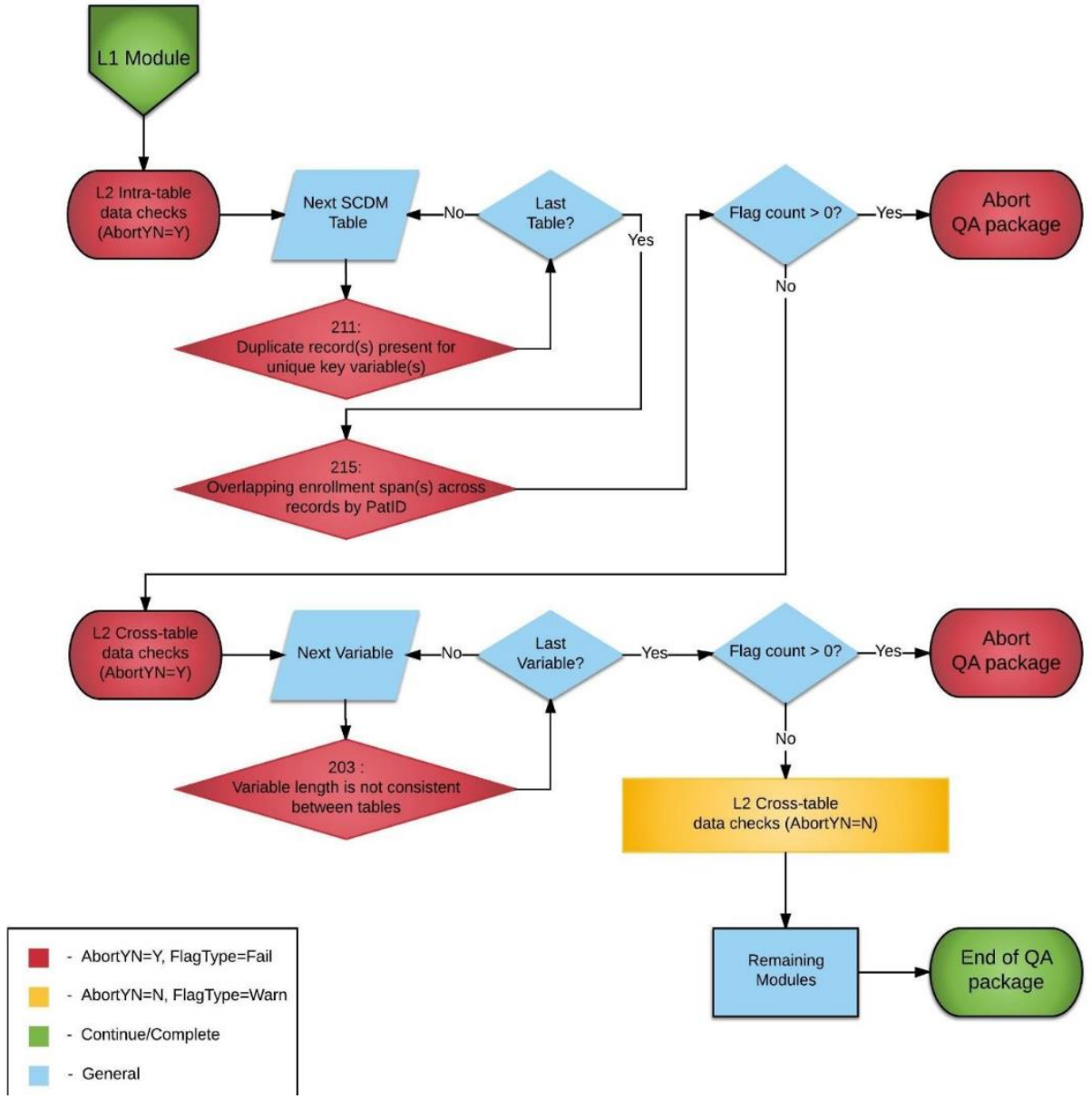
Judgment Call Checks

Level 3: Trends: consistency

Level 4: Logical: plausibility, convergence

Quality Review and Characterization Program Logic

- Compliance checks for all tables are mandatory.
- Quality Review and Characterization Program will abort after it runs through all compliance checks, producing an automatically created report on failures.



Available Data in Common Data Model Format

ABOUT

- Background
- Coordinating Center
- Privacy and Security
- The Sentinel System Story

MEDICAL PRODUCT ASSESSMENTS

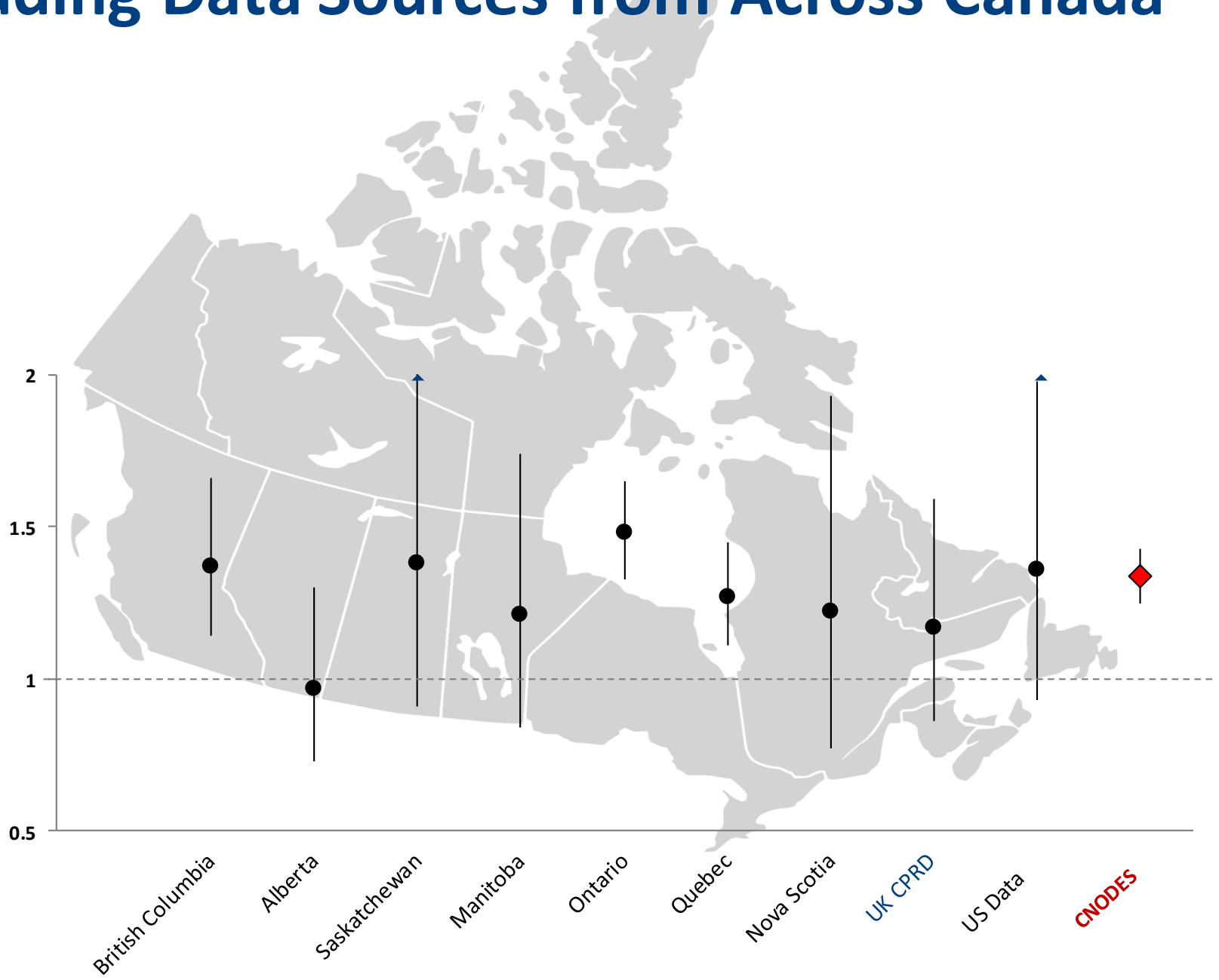
- Active Risk Identification and Analysis System
- Ongoing ARIA Assessments
- Assessments of Drugs

Featured Postings

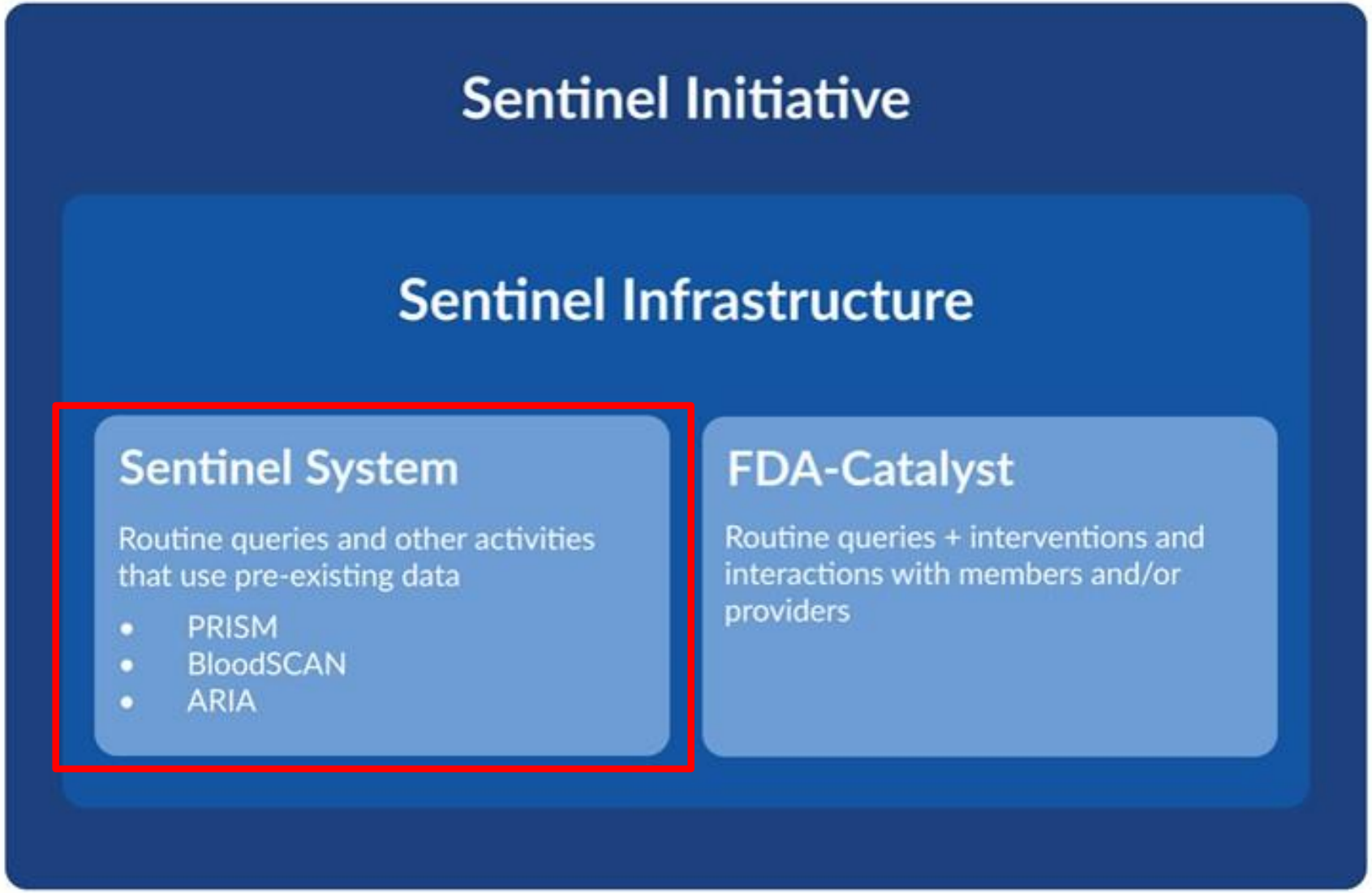
- Medicare Claims Synthetic Public Use Files in Sentinel Common Data Model Format: User Documentation, Demonstration Routine Querying Package, and Data Files
  Wed, 04/25/2018

https://www.sentinelinitiative.org

Adding Data Sources from Across Canada



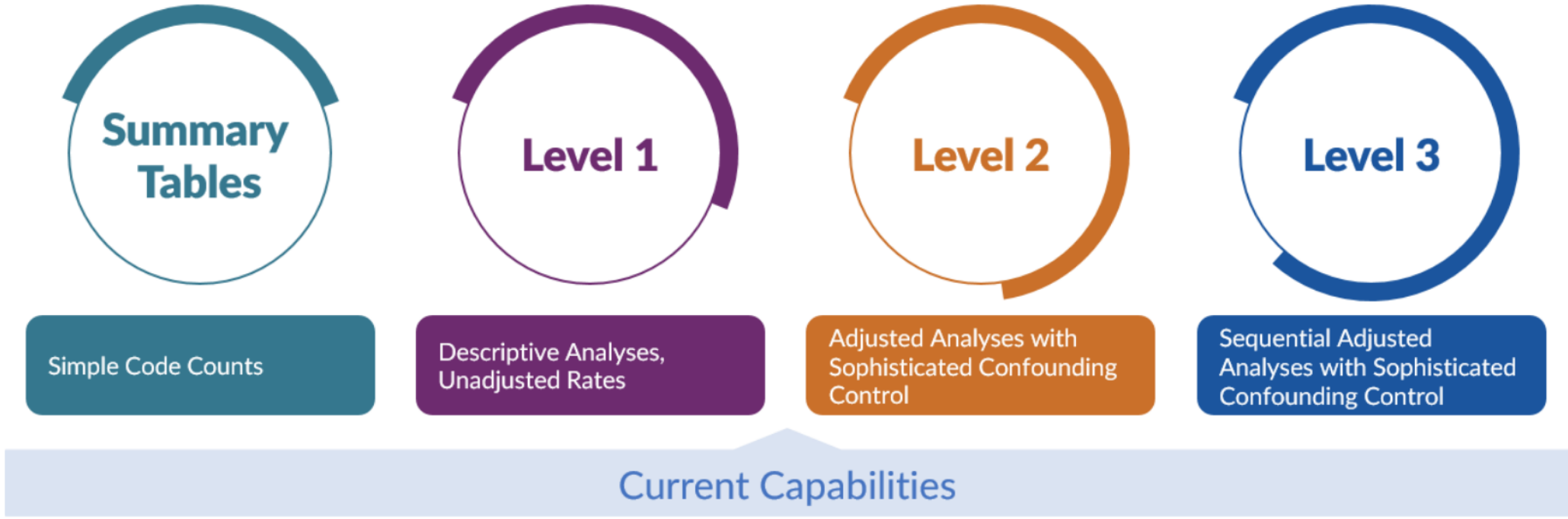
Answering Questions in Sentinel



https://www.sentinelinitiative.org/sentinel/about

Active Risk Identification and Analysis (ARIA)

ARIA is FDA's active post-market risk identification and analysis system, which is comprised of pre-defined, parameterized, reusable routine querying tools, combined with the electronic data in the Sentinel Common Data Model. Because ARIA uses parameterized tools and a trusted multi-site distributed database that undergoes continuous quality checks and refreshes, safety analyses can be done more efficiently to conduct medical product safety surveillance to fulfill the mandate in the FDA Amendments Act of 2007.



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

Sentinel

Type here to search...

Sentinel | Drugs | Vaccines, Blood & Biologics | Devices and Radiologic Health | Communications | Report Finder

FDA-Catalyst

Sentinel is a National Medical Product Monitoring System

LEARN MORE

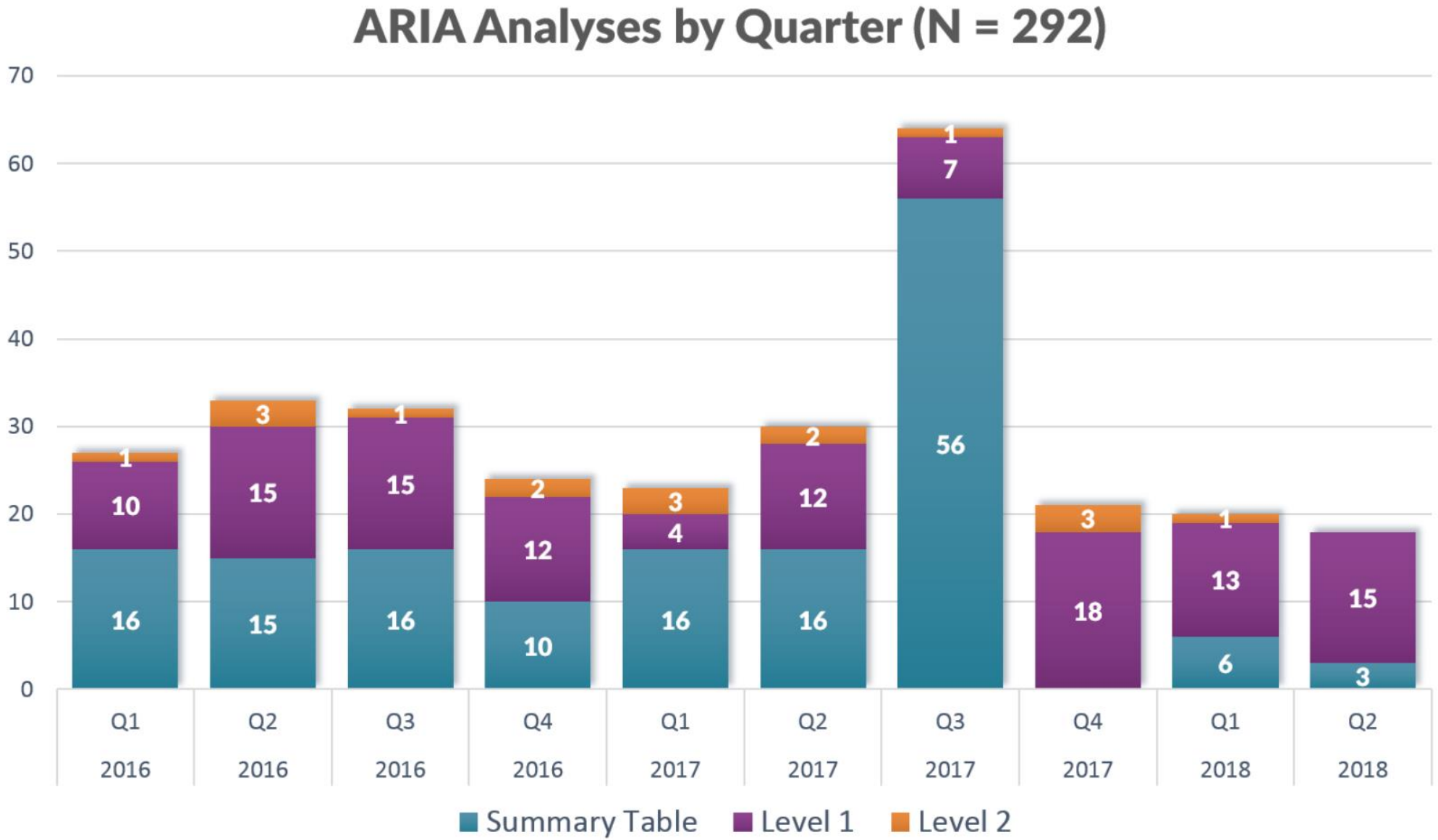
DATA AND TOOLS

- Routine Querying System Documentation (version 5.4.4)
  Fri, 08/17/2018
- Data Quality Review and Characterization Programs v4.1.0
  Wed, 02/28/2018
- Sentinel Common Data Model v6.0.2
  Wed, 10/04/2017

https://www.sentinelinitiative.org/

Training Materials

https://www.sentinelinitiative.org/communications/sentinel-initiative-events



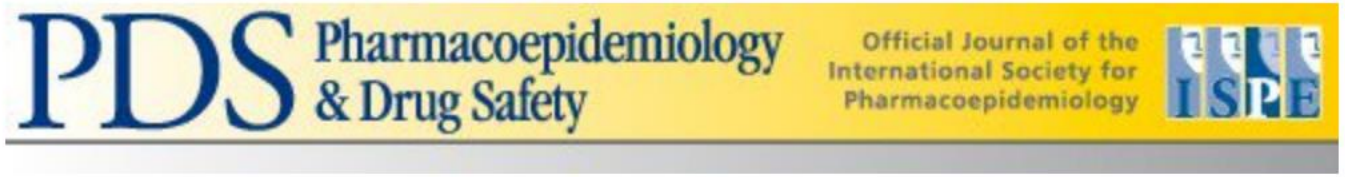
https://www.sentineliniative.org/active-risk-identification-and-analysis-aria

How ARIA Analyses Have Been Used by FDA

This page summarizes how select analyses conducted in Sentinel's Active Risk Identification and Analysis (ARIA) system have been used by FDA since Sentinel's official launch in February 2016. ARIA can contribute to FDA's regulatory process in a variety of ways, such as contributing evidence to support a label change, respond to a Citizens Petition, or become part of an Advisory Committee deliberation. Information from ARIA can also provide evidence that alleviates concerns about a particular safety issue and might lead FDA to determine that no regulatory action is necessary based on the available information.

Recent Published Safety Studies

Sentinel

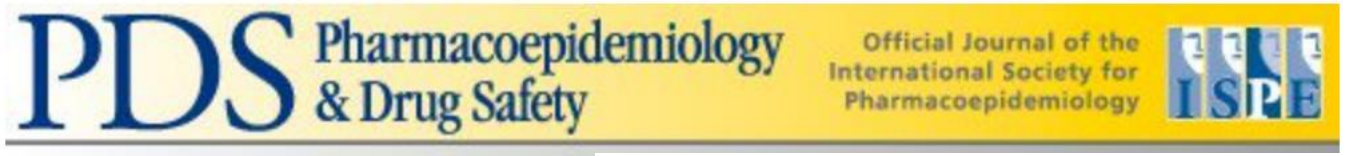


ORIGINAL REPORT

Safety asses
Administrati

Joshua J. Gagne, Sengwee Toh

First published: 06 N



ORIGINAL REPORT

Prospective surveilla
Food and Drug Admi

Elizabeth A. Chrischilles, Joshua Azadeh Shoaibi, Marsha E. Reichn

First published: 10 January 2018

Original Investigation

ONLINE FIRST

October 1, 2018

Association of Risk for Venous Thromboembolism With Use of Low-Dose Extended- and Continuous-Cycle Combined Oral Contraceptives

A Safety Study Using the Sentinel Distributed Database

Jie Li, PhD[1]; Genna Panucci, SM[2]; David Moeny, RPh[1]; et al

» Author Affiliations

JAMA Intern Med. Published online October 1, 2018. doi:10.1001/jamainternmed.2018.4251

Recently Published Descriptive Work

Sentinel

Influenza and other respiratory viruses
Open Access
isirv

SHORT ARTICLE

Outpatient
influenza s

Noelle M. Cocoro

First published: 2

PDS Pharmacoepidemiology & Drug Safety
Official Journal of the International Society for Pharmacoepidemiology
ISPE

ORIGINAL REPORT

Utilization of drugs with pregnancy exposure registries during pregnanc

Onyekachukwu
Kate Gelperin, l

Journal of Clinical Psychopharmacology. 38(5):505–508, OCT 2018
DOI: 10.1097/JCP.0000000000000939, PMID: 30102629
Issn Print: 0271-0749
Publication Date: 2018/10/01

Print

First published:

Incidence of Heart Failure and Cardiomyopathy Following Initiation of Medications for Attention-Deficit/Hyperactivity Disorder: A Descriptive Study

Andrew D. Mosholder; Lockwood Taylor; Glenn Mannheim; Lisa Ortendahl; Tiffany S. Woodworth; Sengwee Toh

Methods Development: Summary Scores

Sentinel

Relative Performance of Propensity Score Matching Strategies for Subgroup Analyses

Shirley V Wang ✉, Yinzhu Jin, Bruce Fireman, Susan Gruber, Mengdong He, Richard Wyss, HoJin Shin, Y Sara Karami, Jacqueline M Major, Sebastia Joshua J Gagne

American Journal of Epidemiology, Volume Pages 1799–1807, https://doi.org/10.1093/

Published: 15 March 2018 **Article histo**

Extension of Disease Risk Score–Based Confounding Adjustments for Multiple Outcomes of Interest: An Empirical Evaluation FREE

Rishi J Desai ✉, Richard Wyss, Yinzhu Jin, Justin Bohn, Sengwee Toh, Austin Cosgrove, Adee Kennedy, Jessica Kim, Clara Kim, Rita Ouellet-Hellstrom, ... Show more

American Journal of Epidemiology, kwy130, https://doi.org/10.1093/aje/kwy130

Published: 26 June 2018 **Article history ▾**

Methods Development: Privacy Preserving Regression

Sentinel

eGEMs The Journal for Electronic Health Data and Methods

Model / Framework

A Query Workflow Design to Perform Automata in Large D

PDS Pharmacoepidemiology & Drug Safety — Official Journal of the International Society for Pharmacoepidemiology — ISPE

Authors: Qou

Jessica Young

ORIGINAL REPORT

Comparison of privacy-protecting analytic and data-sharing methods: A simulation study

Kazuki Yoshida ✉, Susan Gruber, Bruce H. Fireman, Sengwee Toh

First published: 18 July 2018 | https://doi.org/10.1002/pds.4615

Methods Development: Signal Detection

Epidemiology. 29(6):895–903, NOV 2018
DOI: 10.1097/EDE.0000000000000907, PMID: 30074538
Issn Print: 1044-3983
Publication Date: 2018/11/01

Print

Data Mining for Adverse Drug Events With a Propensity Score-matched Tree-based Scan Statistic

Shirley V. Wang; Judith C. Maro; Elande Baro; Rima Izem; Inna Dashevsky; James R. Rogers; Michael Nguyen; Joshua J. Gagne; Elisabetta Patorno; Krista F. Huybrechts; Jacqueline M. Major; Esther Zhou; Megan Reidy; Austin Cosgrove; Sebastian Schneeweiss; Martin Kulldorff

+ Author Information

Methods Development in Sentinel: Machine Learning

PDS Pharmacoepidemiology & Drug Safety
Official Journal of the International Society for Pharmacoepidemiology
ISPE

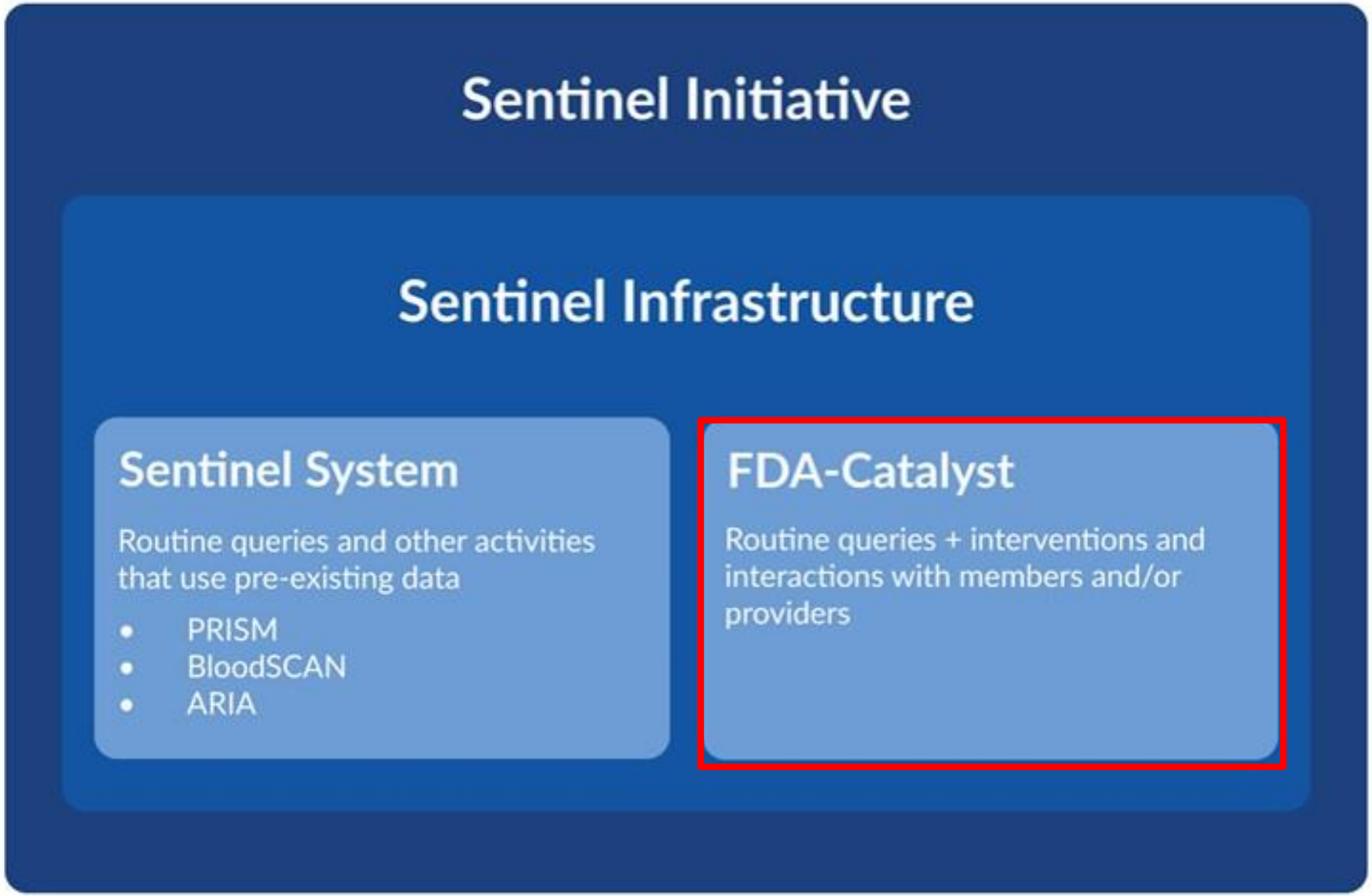
ORIGINAL REPORT

Evaluating automated approaches to anaphylaxis case classification using unstructured data from the FDA Sentinel System

Robert Ball ✉, Sengwee Toh, Jamie Nolan, Kevin Haynes, Richard Forshee, Taxiarchis Botsis

First published: 28 August 2018 | https://doi.org/10.1002/pds.4645

The Sentinel Initiative: Patient Interventions

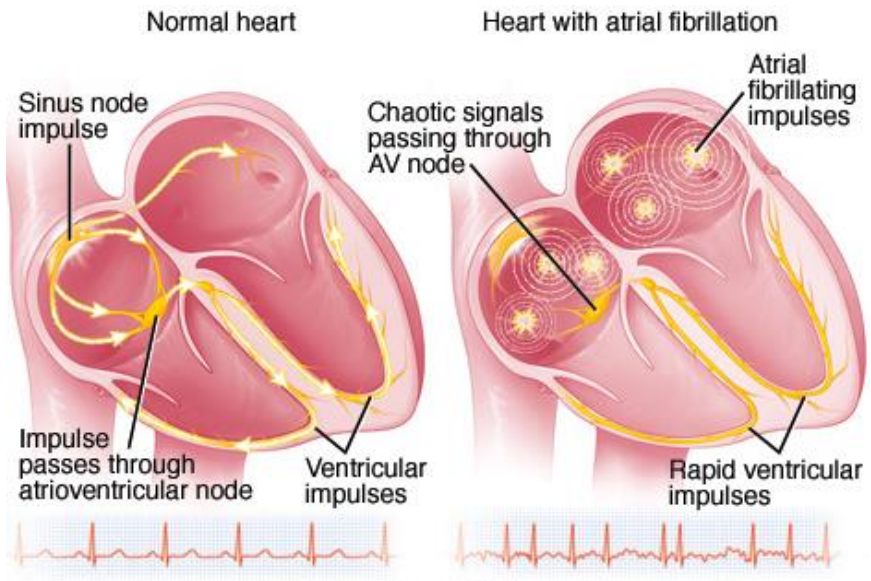


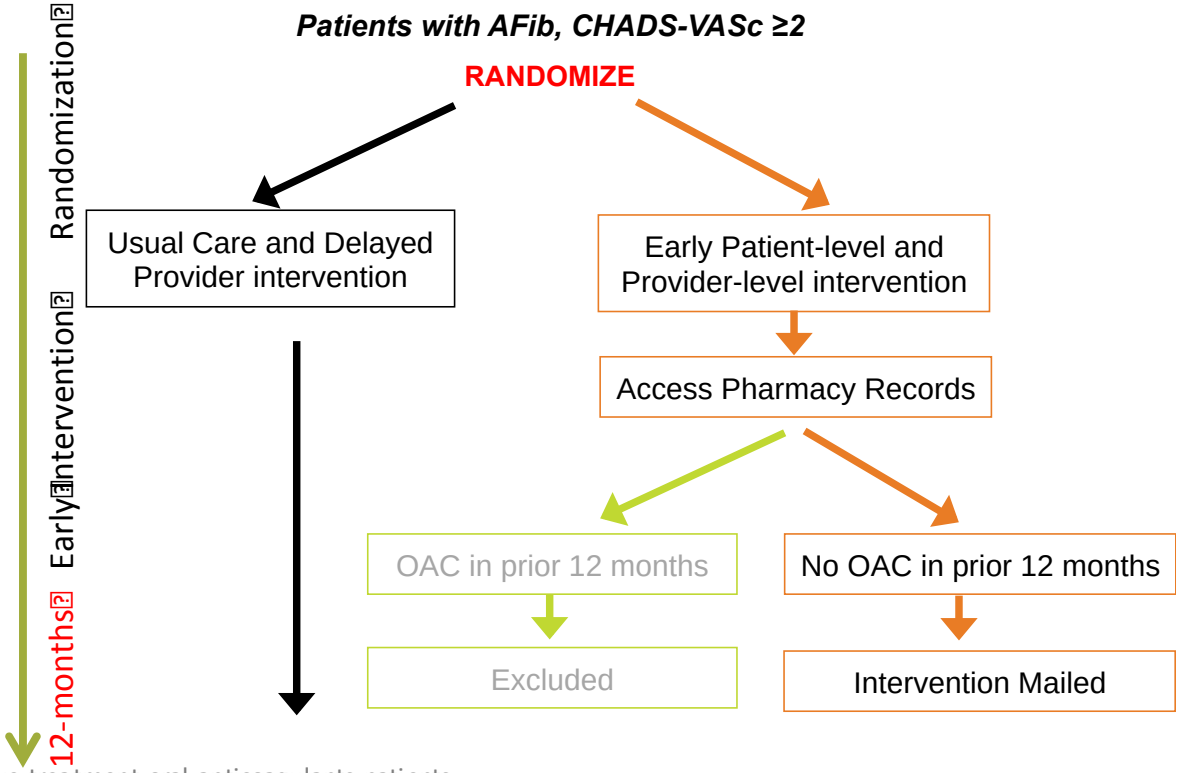
https://www.sentinelinitiative.org/sentinel/about

Pragmatic Trial in Sentinel – IMPACT AFib

IMplementation of a randomized controlled trial to im**P**rove treatment with oral **A**nti**C**oagulan**T**s in patients with **A**trial **Fib**rillation

- Direct mailer to health plan members with AFib, high risk for stroke and no oral anticoagulant (OAC) treatment, and to their providers, to encourage consideration of OACs



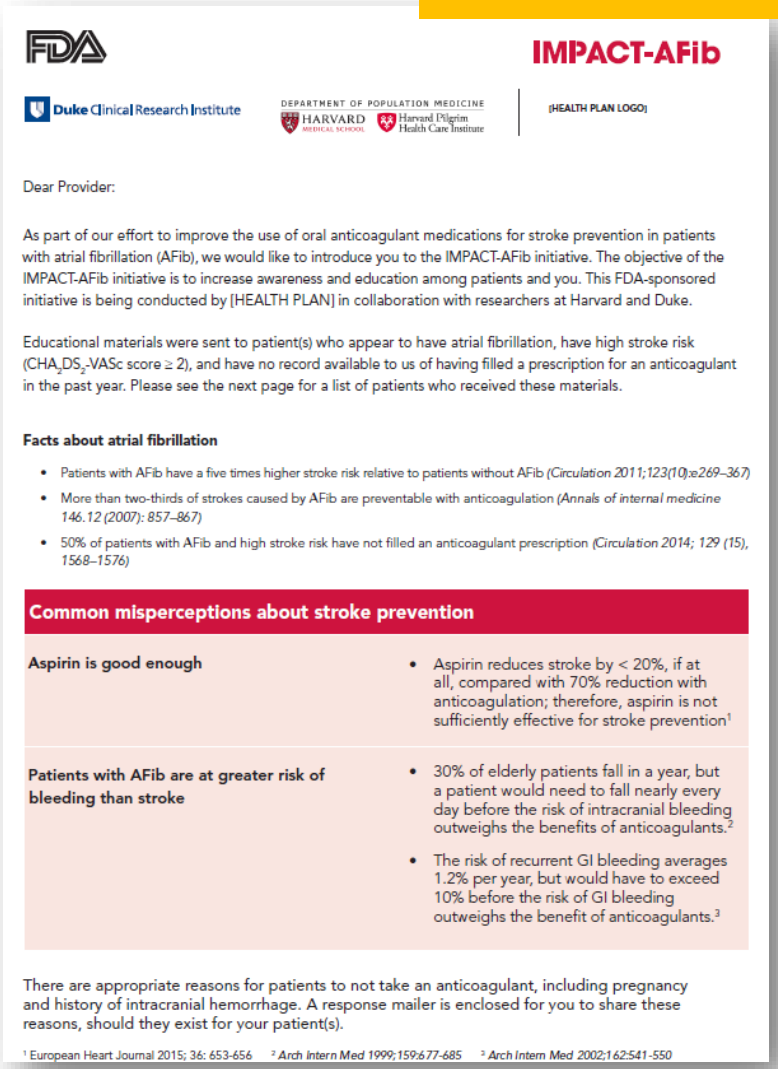


https://www.sentineliniti ative.org/FDA-catalyst/projects/implementation-randomized-controlled-trial-improve-treatment-oral-anticoagulants-patients

39,230 Letters Mailed to Early Intervention Group

Sentinel

PROVIDER LETTER



FDA

IMPACT-AFib

Duke Clinical Research Institute

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

[HEALTH PLAN LOGO]

Dear Provider:

As part of our effort to improve the use of oral anticoagulant medications for stroke prevention in patients with atrial fibrillation (AFib), we would like to introduce you to the IMPACT-AFib initiative. The objective of the IMPACT-AFib initiative is to increase awareness and education among patients and you. This FDA-sponsored initiative is being conducted by [HEALTH PLAN] in collaboration with researchers at Harvard and Duke.

Educational materials were sent to patient(s) who appear to have atrial fibrillation, have high stroke risk (CHA_2DS_2-VASc score ≥ 2), and have no record available to us of having filled a prescription for an anticoagulant in the past year. Please see the next page for a list of patients who received these materials.

Facts about atrial fibrillation

- Patients with AFib have a five times higher stroke risk relative to patients without AFib *(Circulation 2011;123(10):e269–367)*
- More than two-thirds of strokes caused by AFib are preventable with anticoagulation *(Annals of internal medicine 146.12 (2007): 857–867)*
- 50% of patients with AFib and high stroke risk have not filled an anticoagulant prescription *(Circulation 2014; 129 (15), 1568–1576)*

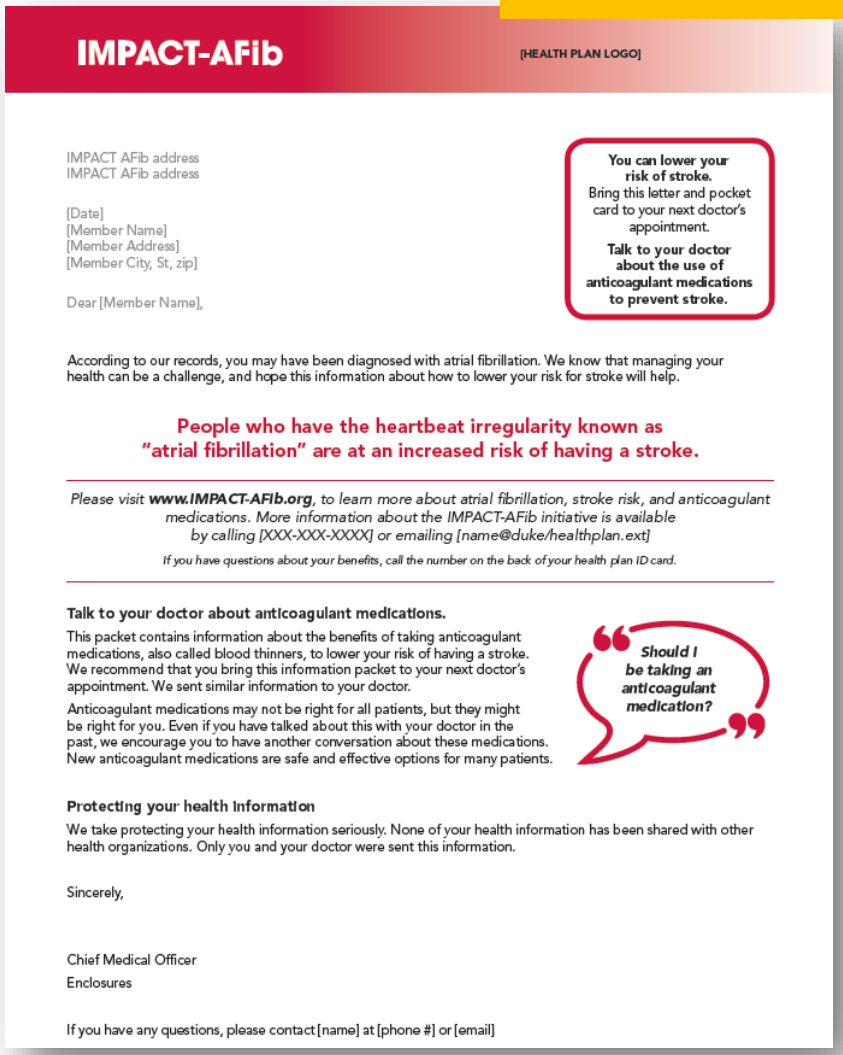
Common misperceptions about stroke prevention

Aspirin is good enough	• Aspirin reduces stroke by < 20%, if at all, compared with 70% reduction with anticoagulation; therefore, aspirin is not sufficiently effective for stroke prevention[1]
Patients with AFib are at greater risk of bleeding than stroke	• 30% of elderly patients fall in a year, but a patient would need to fall nearly every day before the risk of intracranial bleeding outweighs the benefits of anticoagulants.[2] • The risk of recurrent GI bleeding averages 1.2% per year, but would have to exceed 10% before the risk of GI bleeding outweighs the benefit of anticoagulants.[3]

There are appropriate reasons for patients to not take an anticoagulant, including pregnancy and history of intracranial hemorrhage. A response mailer is enclosed for you to share these reasons, should they exist for your patient(s).

[1] European Heart Journal 2015; 36: 653-656 [2] Arch Intern Med 1999;159:677-685 [3] Arch Intern Med 2002;162:541-550

MEMBER LETTER



IMPACT-AFib

[HEALTH PLAN LOGO]

IMPACT AFib address
IMPACT AFib address

[Date]
[Member Name]
[Member Address]
[Member City, St, zip]

Dear [Member Name],

You can lower your risk of stroke.
Bring this letter and pocket card to your next doctor's appointment.
Talk to your doctor about the use of anticoagulant medications to prevent stroke.

According to our records, you may have been diagnosed with atrial fibrillation. We know that managing your health can be a challenge, and hope this information about how to lower your risk for stroke will help.

People who have the heartbeat irregularity known as "atrial fibrillation" are at an increased risk of having a stroke.

*Please visit **www.IMPACT-AFib.org**, to learn more about atrial fibrillation, stroke risk, and anticoagulant medications. More information about the IMPACT-AFib initiative is available by calling [XXX-XXX-XXXX] or emailing [name@duke/healthplan.ext]*

If you have questions about your benefits, call the number on the back of your health plan ID card.

Talk to your doctor about anticoagulant medications.

This packet contains information about the benefits of taking anticoagulant medications, also called blood thinners, to lower your risk of having a stroke. We recommend that you bring this information packet to your next doctor's appointment. We sent similar information to your doctor.

Anticoagulant medications may not be right for all patients, but they might be right for you. Even if you have talked about this with your doctor in the past, we encourage you to have another conversation about these medications. New anticoagulant medications are safe and effective options for many patients.

"Should I be taking an anticoagulant medication?"

Protecting your health information

We take protecting your health information seriously. None of your health information has been shared with other health organizations. Only you and your doctor were sent this information.

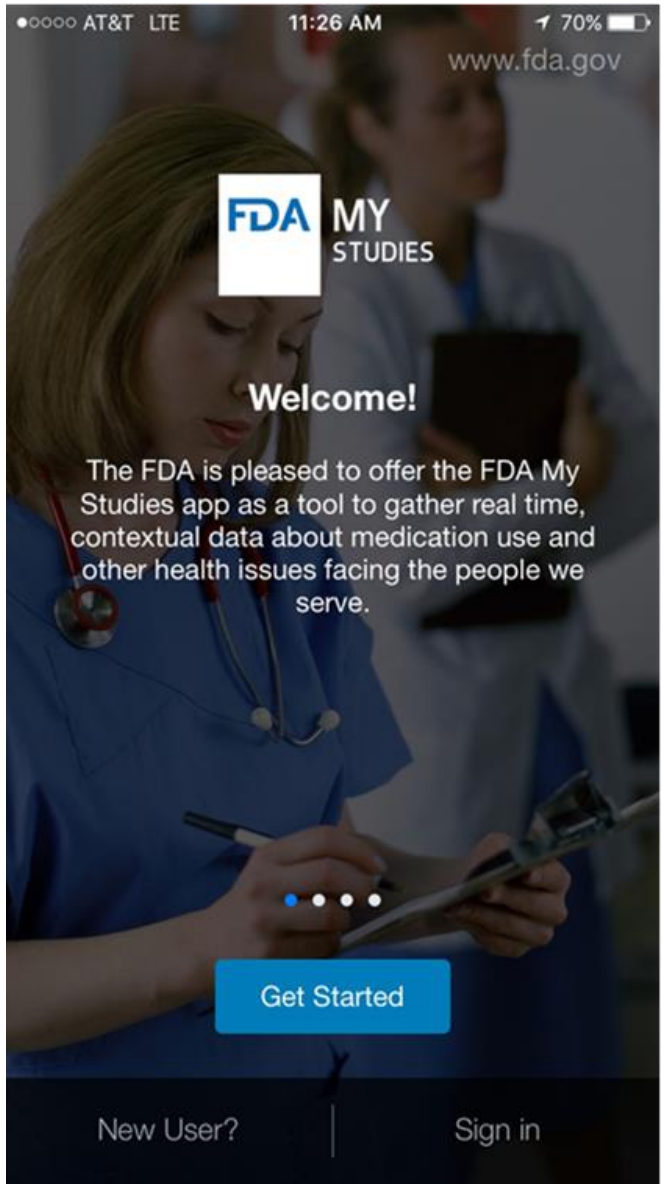
Sincerely,

Chief Medical Officer
Enclosures

If you have any questions, please contact [name] at [phone #] or [email]

https://www.sentineliniti ative.org/FDA-catalyst/projects/implementation-randomized-controlled-trial-improve-treatment-oral-anticoagulants-patients

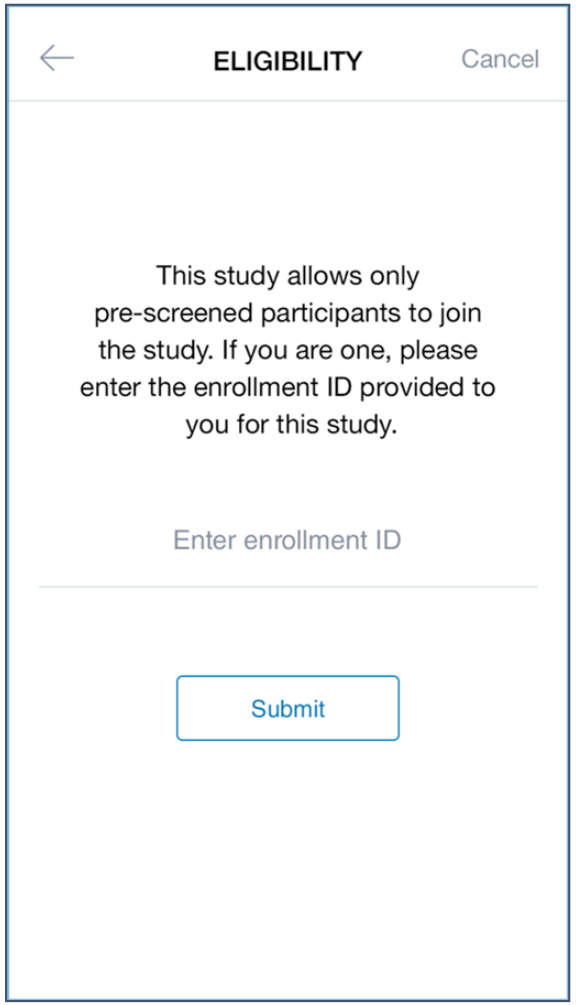
MyStudies App: Collecting Patient-reported Outcomes

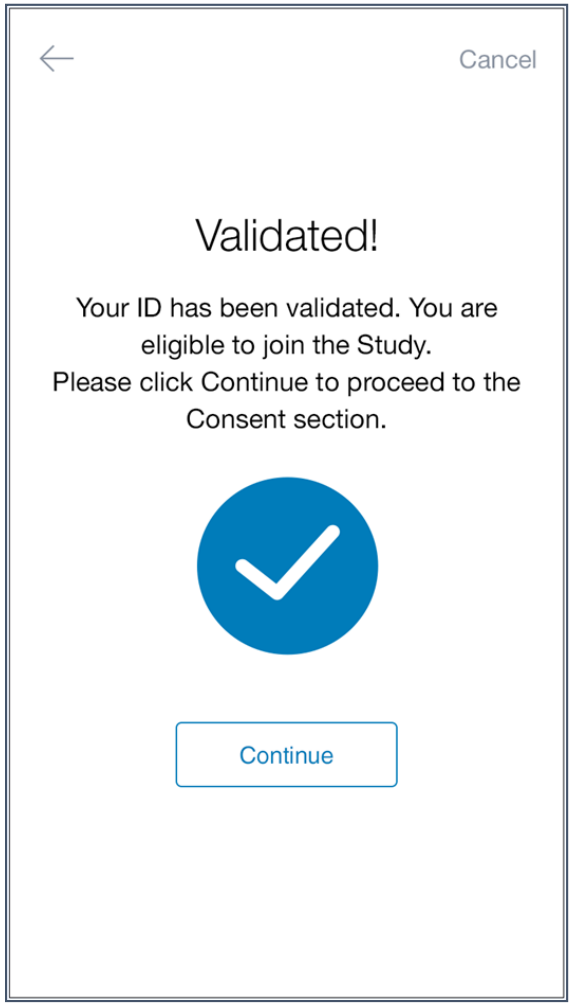


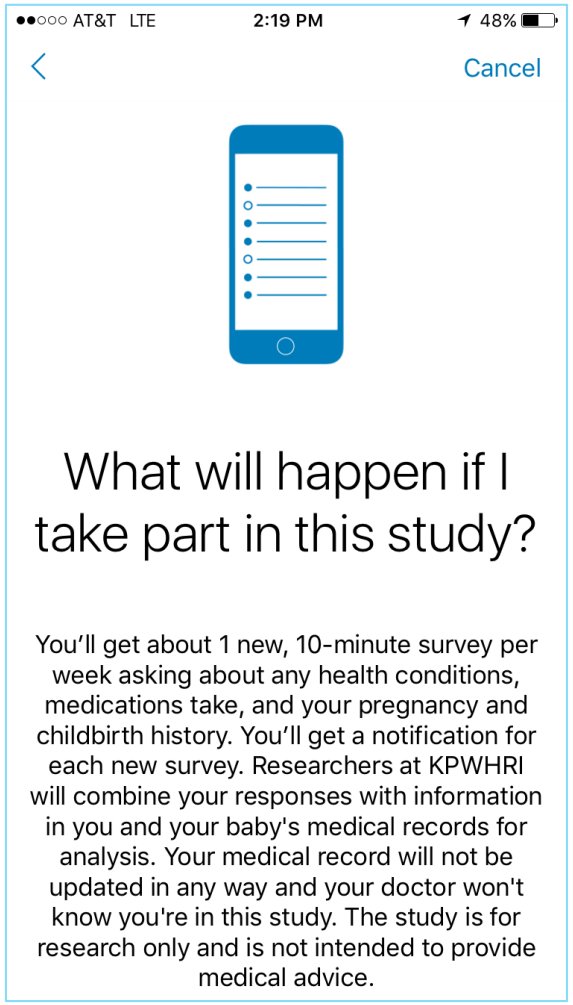
- Mobile App
  - Standard frameworks - ResearchKit (iOS), ResearchStack (Android)
  - Gateway capability
- Web-based configuration portal
- Secure Storage Environment
  - FISMA complaint
  - Partitioned for distributed research
  - Responses can be downloaded in broadly compatible formats (e.g., for use in SAS, Excel, etc.)
- **Linked to the Sentinel Distributed Database**

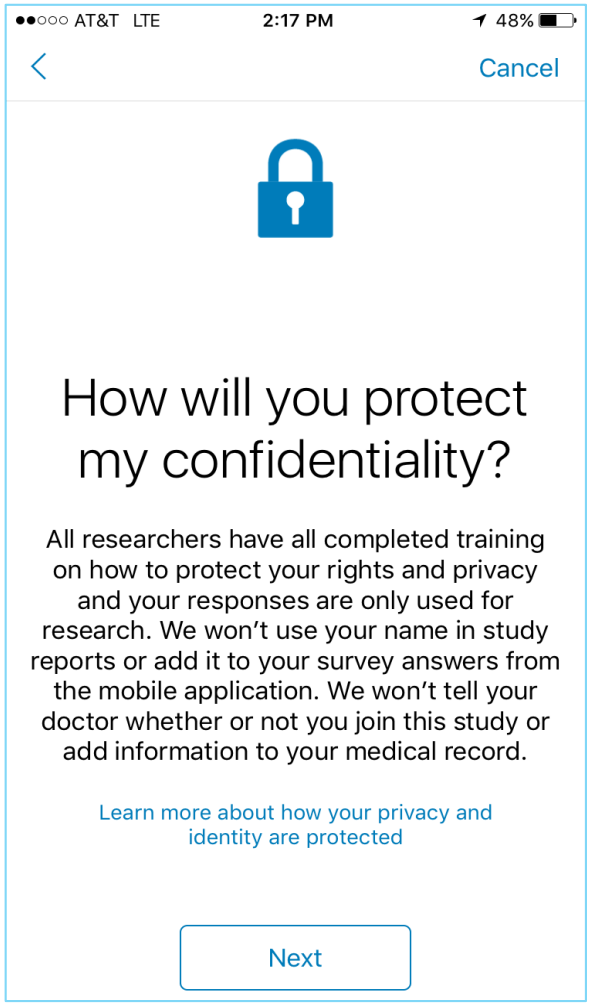
https://www.sentineliniti ative.org/FDA-catalyst/projects/collection-patient-provided-information-through-mobile-device-application-use-comparative

Enroll and Consent Patients

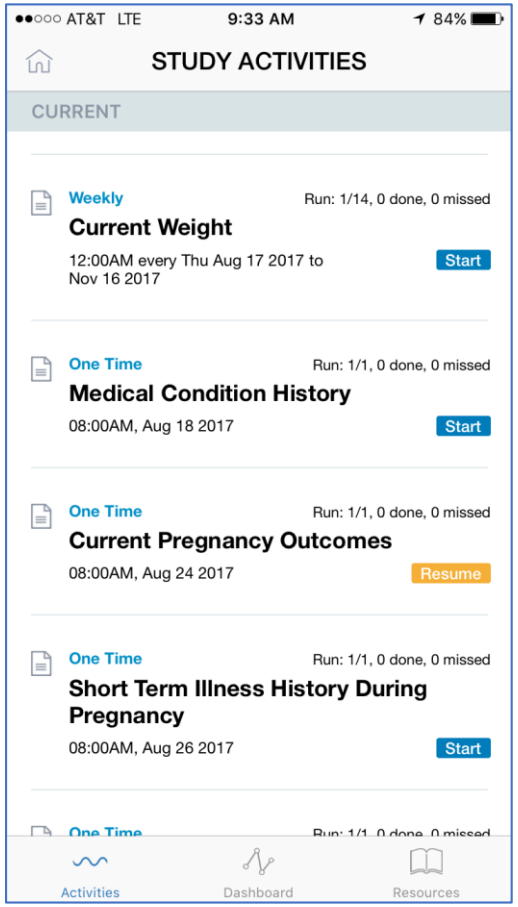


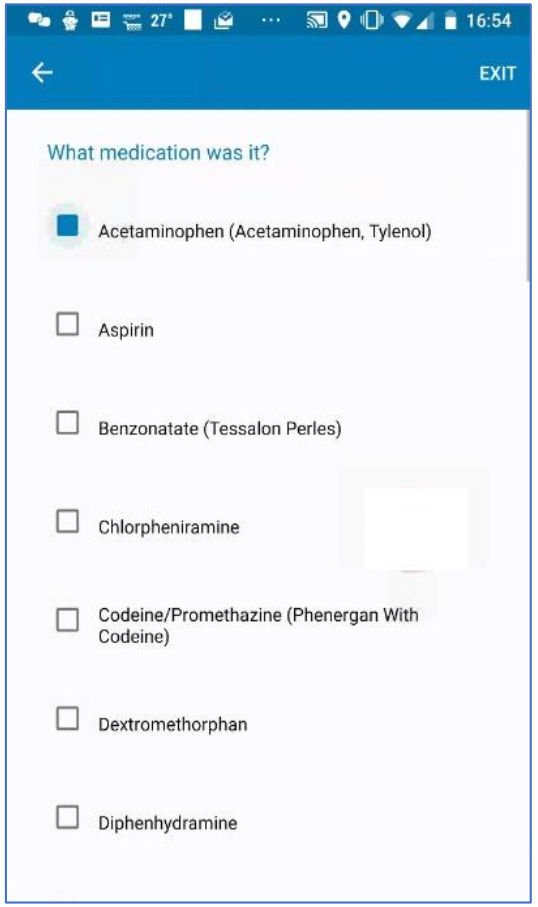






Engage





- Data collected directly from patients
- Participants respond when they choose within the study schedule
- Study Dashboard displays progress as well as highlights from data collection

Looking Ahead: New Infrastructure

Sentinel

Sentinel

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FDA-Catalyst

Home >> Sentinel >> Methods >> Data Infrastructure Expansion: Developing A Mother-Infant Linkage Table In The Sentinel Common Data Model (SCDM)

SENTINEL

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- Methods

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Data Infrastructure Expansion: Developing a Mother-Infant Linkage table in the Sentinel Common Data Model (SCDM)

Project Title	**Data Infrastructure Expansion: Developing a Mother-Infant Linkage table in the Sentinel Common Data Model (SCDM)**

https://www.sentinelinitiative.org/sentinel/methods/data-infrastructure-expansion-developing-mother-infant-linkage-table-sentinel

Looking Ahead: New Challenges/Methods

- How to make best use of EHR data given the large degree of missingness?
  - Especially when missingness is likely Missing-Not-At-Random

- How to incorporate cutting edge machine learning techniques in a **distributed database environment** with a high degree of heterogeneity among databases?

Discussion

Acknowledgements

- Thanks to my many colleagues within the greater Sentinel Initiative including our many collaborating institutions
- Questions: info@sentinelsystem.org