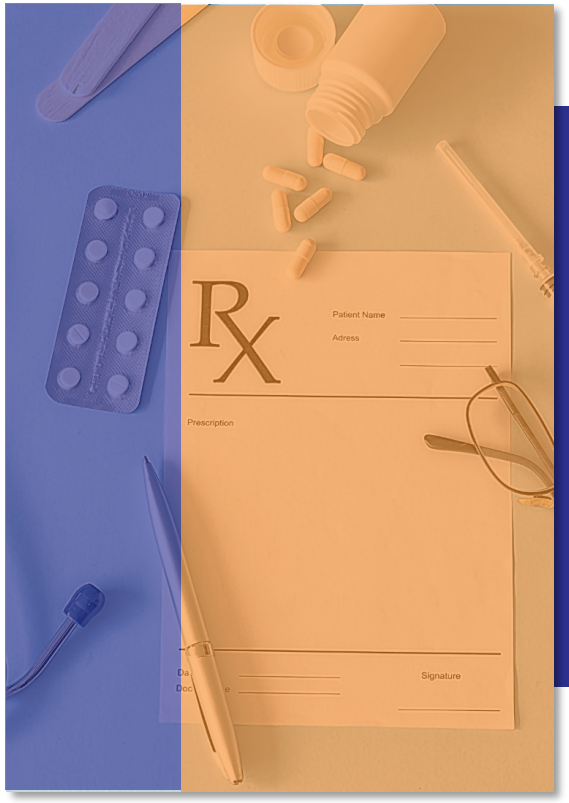

The U.S. Food and Drug Administration's Sentinel System: A Post-Market Active Drug Safety Surveillance System

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June 2024 | PSK@60

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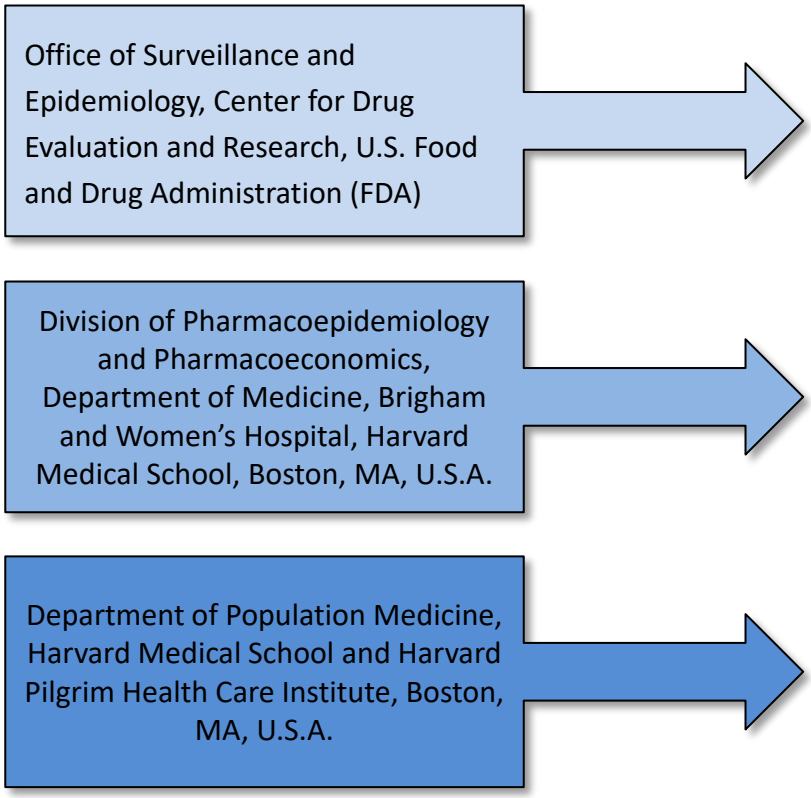

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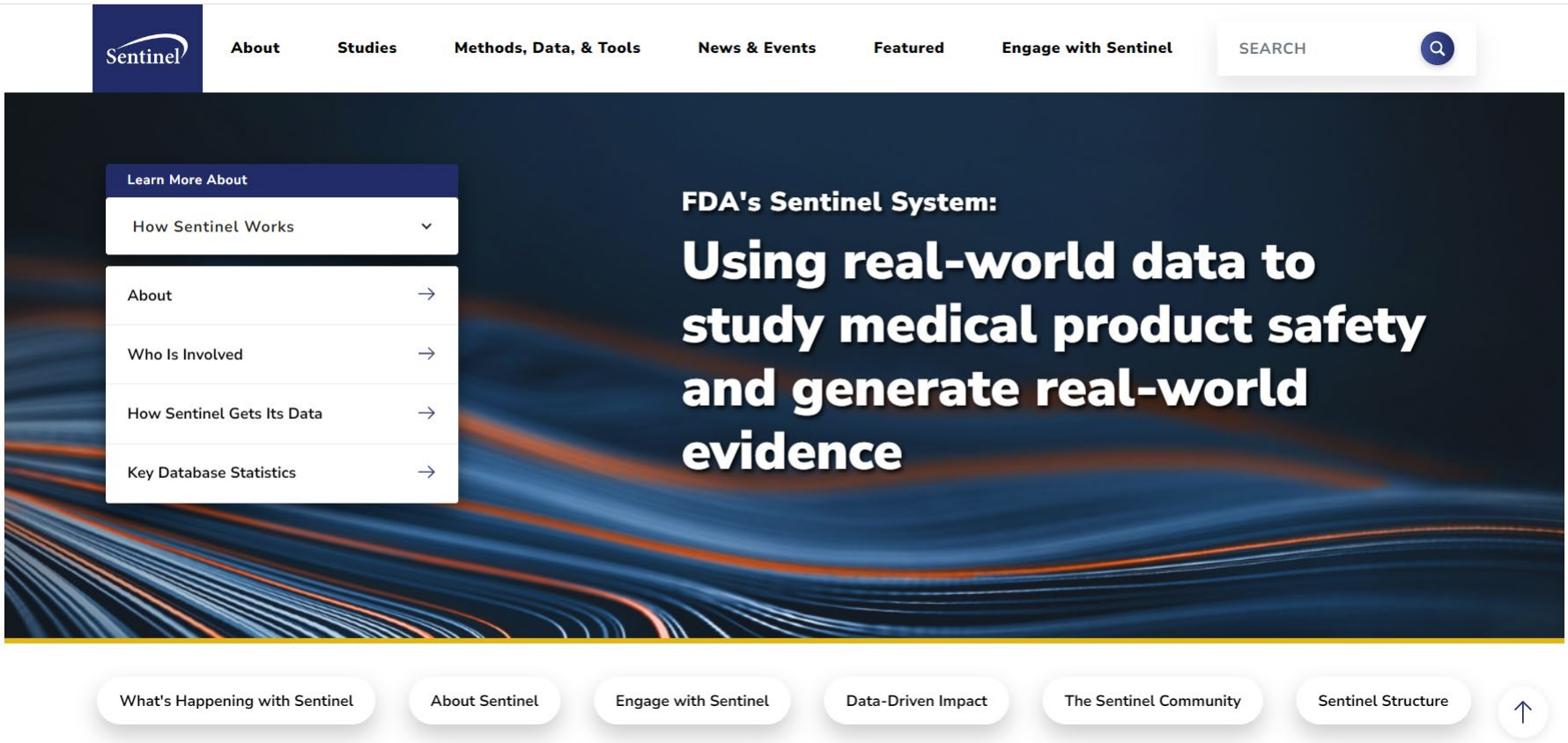
The contents are those of the authors and do not necessarily represent the official views of, nor and endorsement, by FDA/HHS, or the U.S. Government.
Some co-authors on this abstract are employed at organizations which conduct work for government and private organizations, including pharmaceutical companies.

Background

- The U.S. Food and Drug Administration (FDA) ensures the safety, efficacy, and security of regulated medical products.

- An efficient national drug safety surveillance system is needed to support this mission.

The Sentinel System



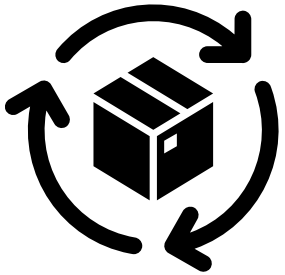
One of FDA's post-market medical product safety surveillance systems for assessing the use and safety of regulated medical products.

Objective

To describe the Sentinel System, its goals, implementation timeline of milestones, key components, and achievements since inception.

Methodology

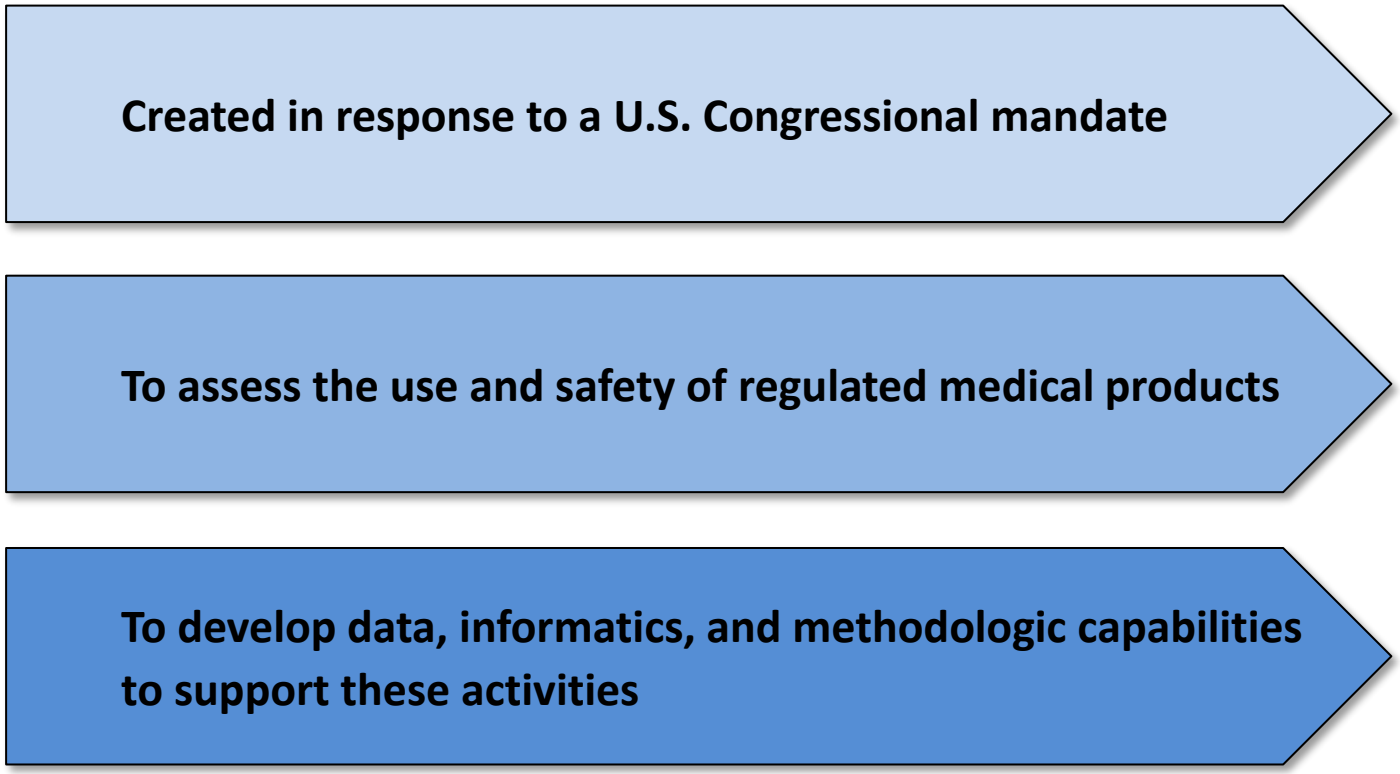
We describe the FDA Sentinel System and report on major achievements



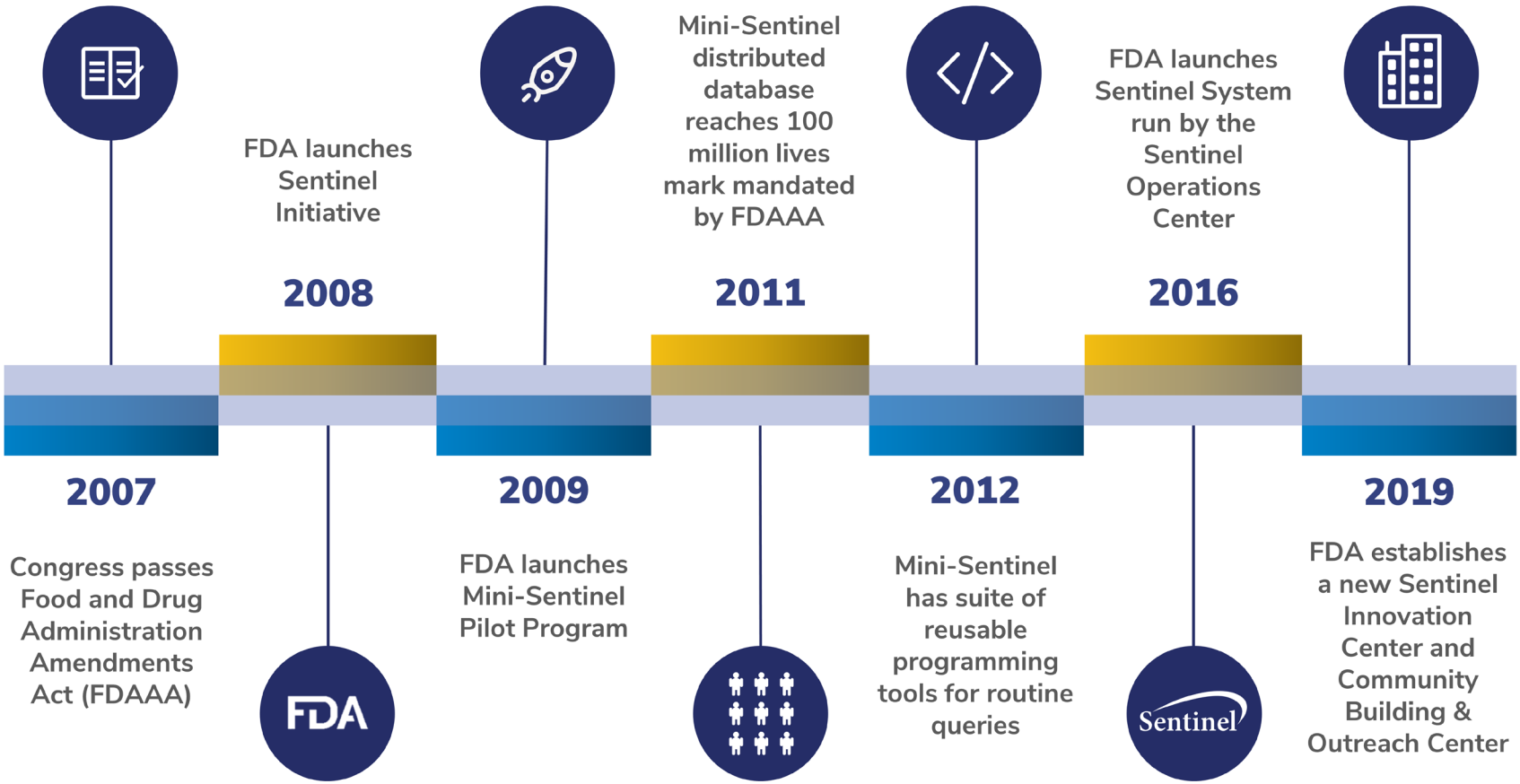
RESULTS

The Sentinel System

- FDA's medical product active safety surveillance system



The Sentinel System Timeline



https://www.sentinelinitiative.org/about

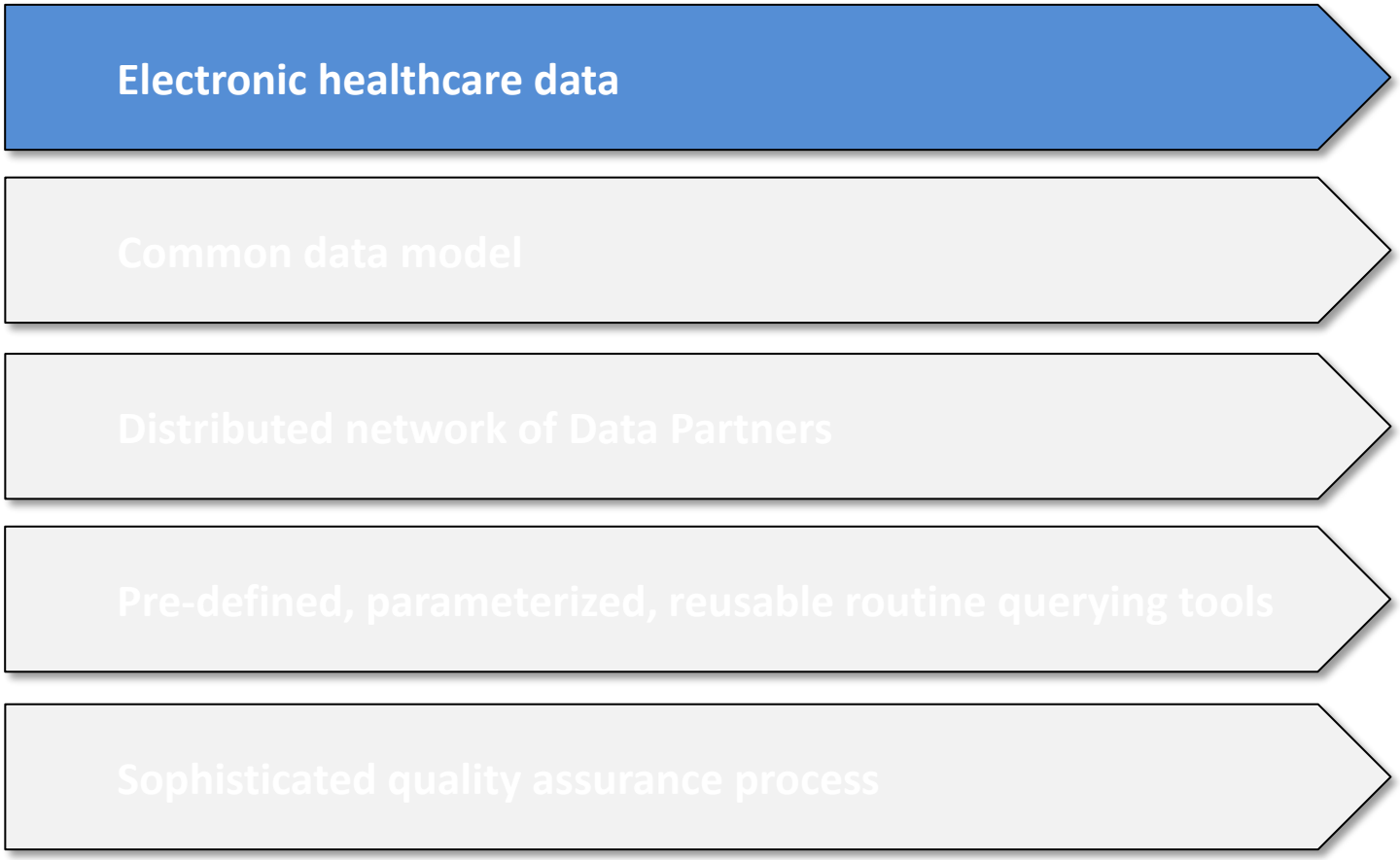
The Sentinel System

Key components

- Electronic healthcare data
- Common data model
- Distributed network of Data Partners
- Pre-defined, parameterized, reusable routine querying tools
- Sophisticated quality assurance process

The Sentinel System

Key components

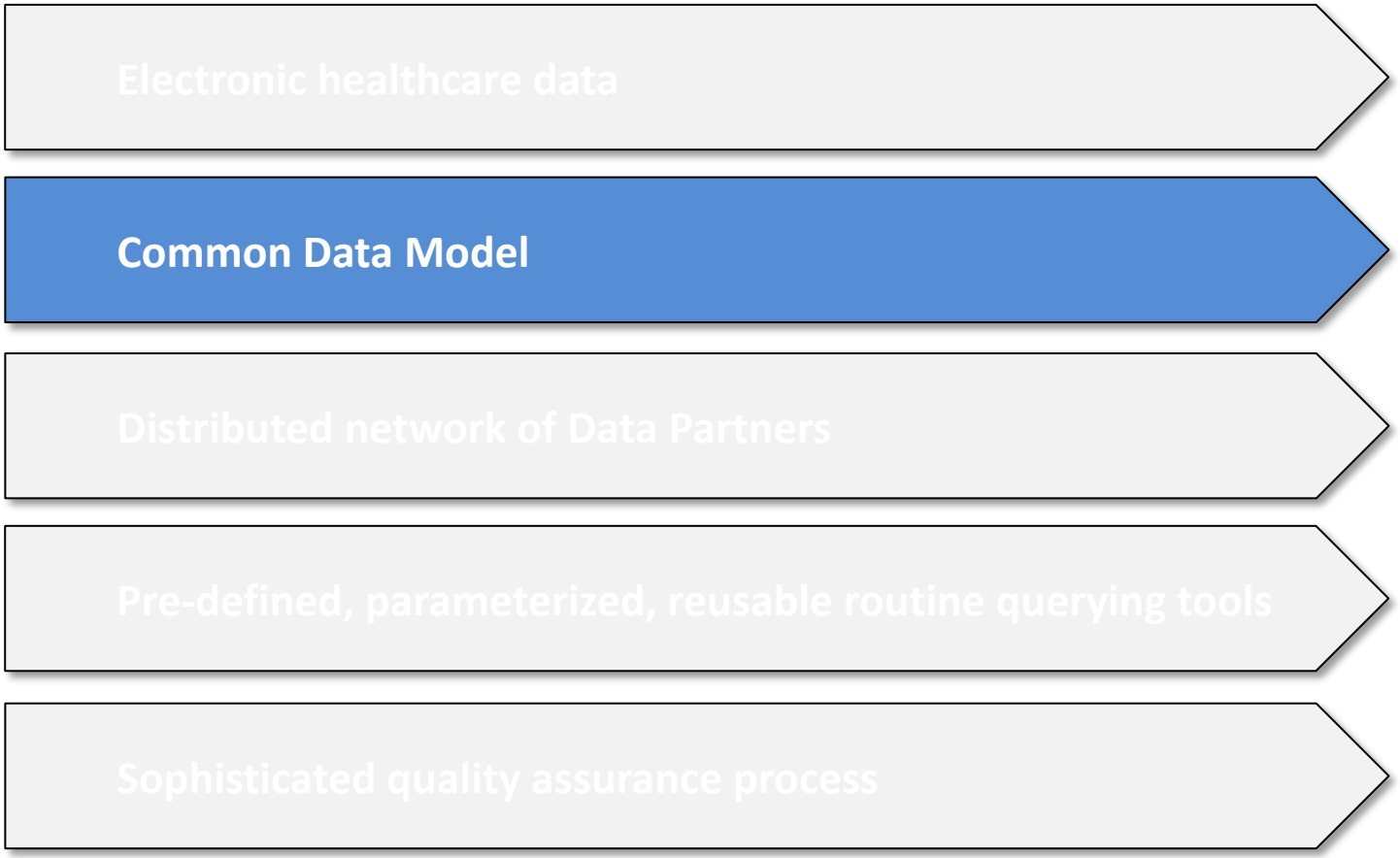


Electronic Healthcare Data

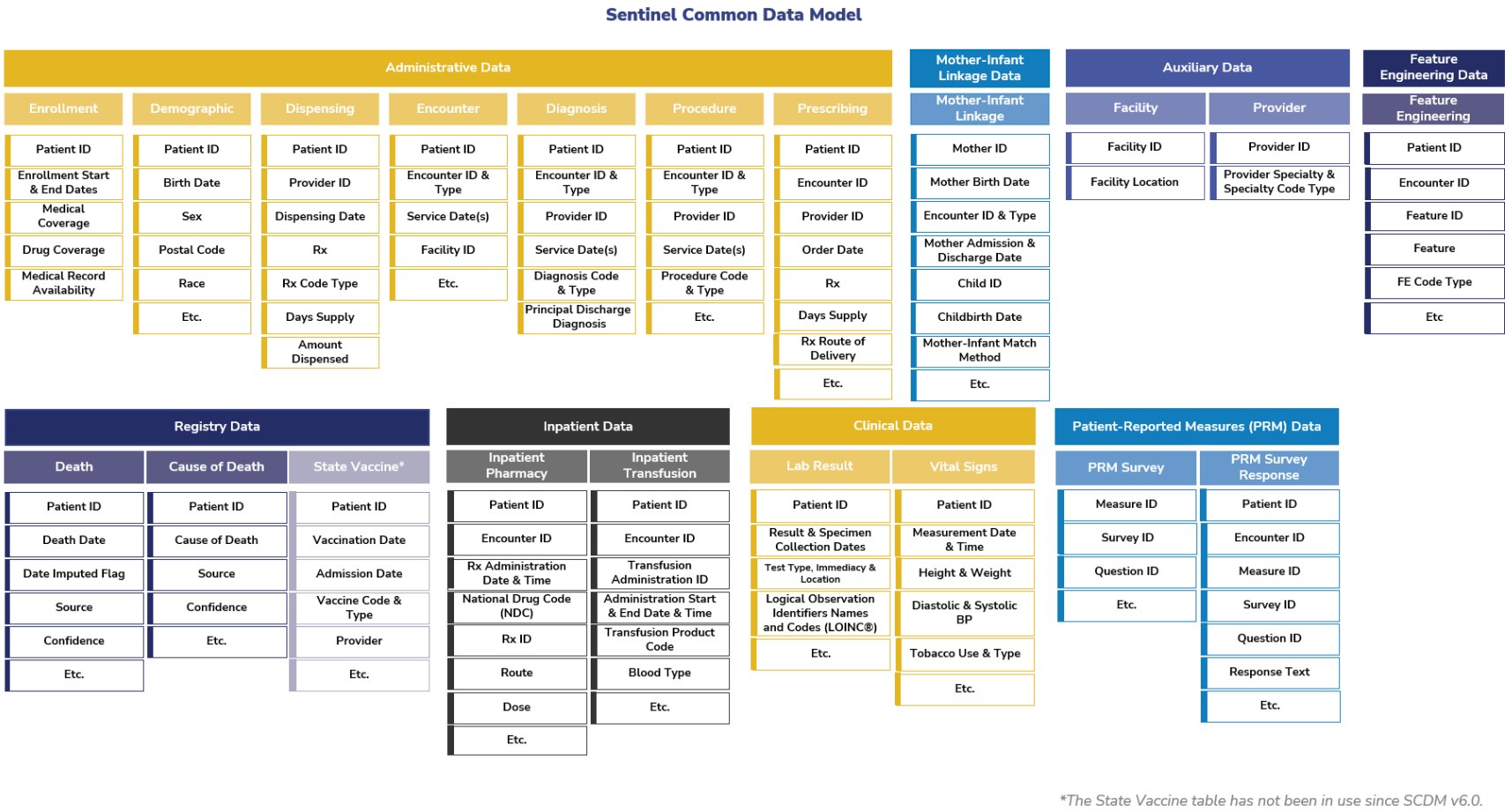
- Sentinel relies on data generated from patient interactions with the U.S. healthcare system through health insurers and providers
- Principal source of data used in Sentinel is healthcare administrative claims data
- Additional types of healthcare data that complement the claims data in Sentinel include:
  - Electronic Health Records (EHRs), immunization registries, disease registries, birth and death registries

The Sentinel System

Key components



Sentinel Common Data Model

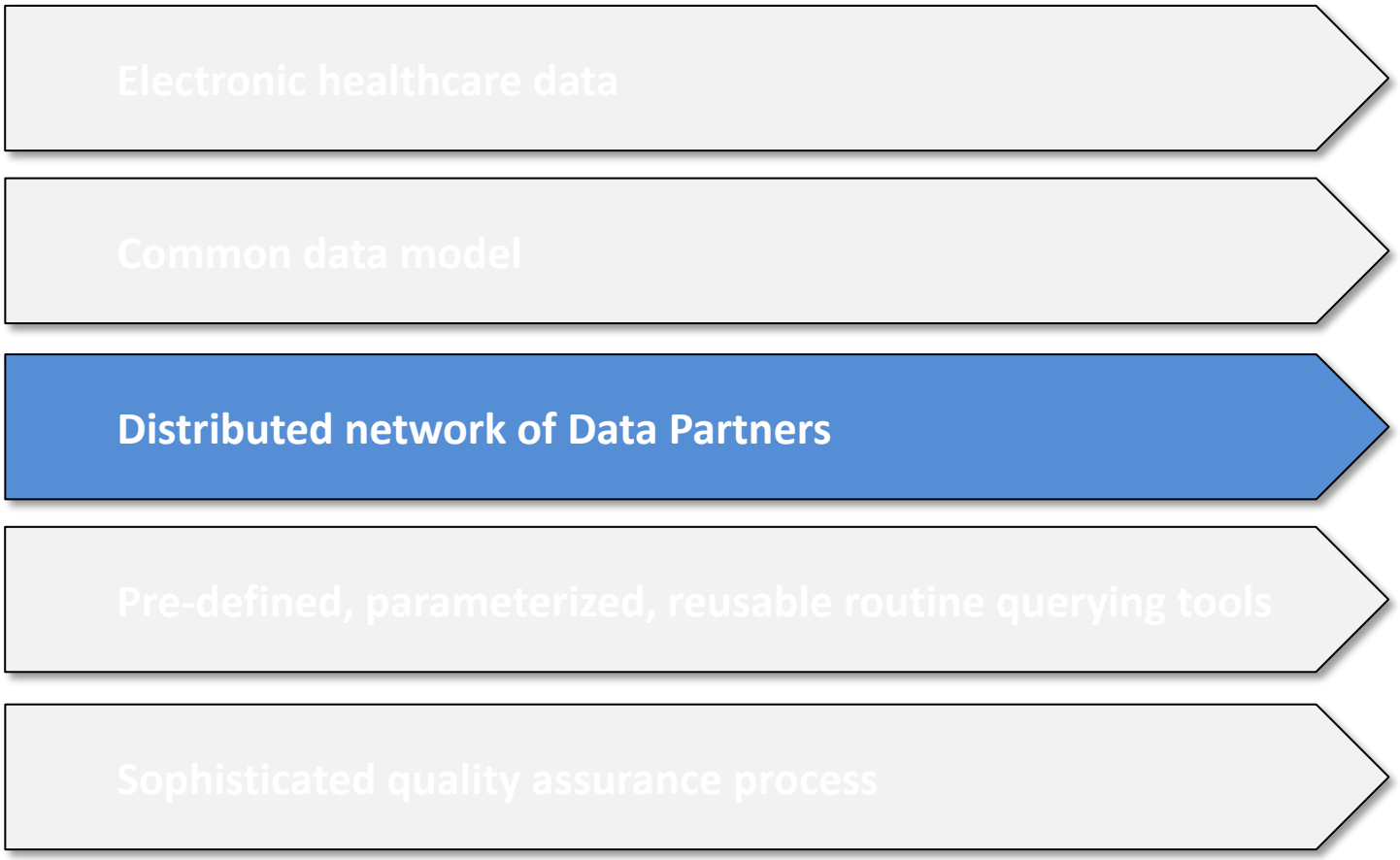


*The State Vaccine table has not been in use since SCDM v6.0.

https://www.sentinelinitiative.org/methods-data-tools/sentinel-common-data-model

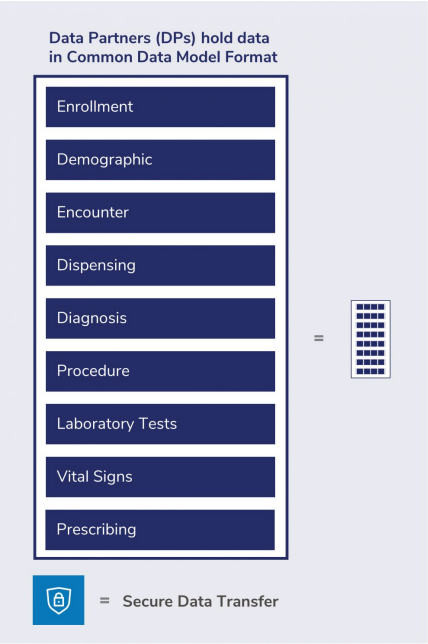
The Sentinel System

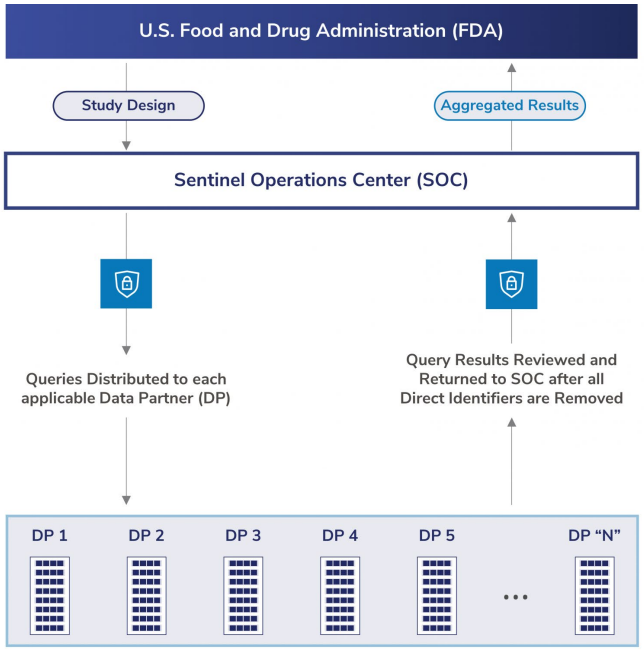
Key components



Sentinel's Distributed Database

- Data Partners maintain physical and operational control over their data
- Data Partners execute standardized queries against their own data and return aggregated results to the Sentinel Operations Center
- Preserves patient privacy and institutional proprietary interests

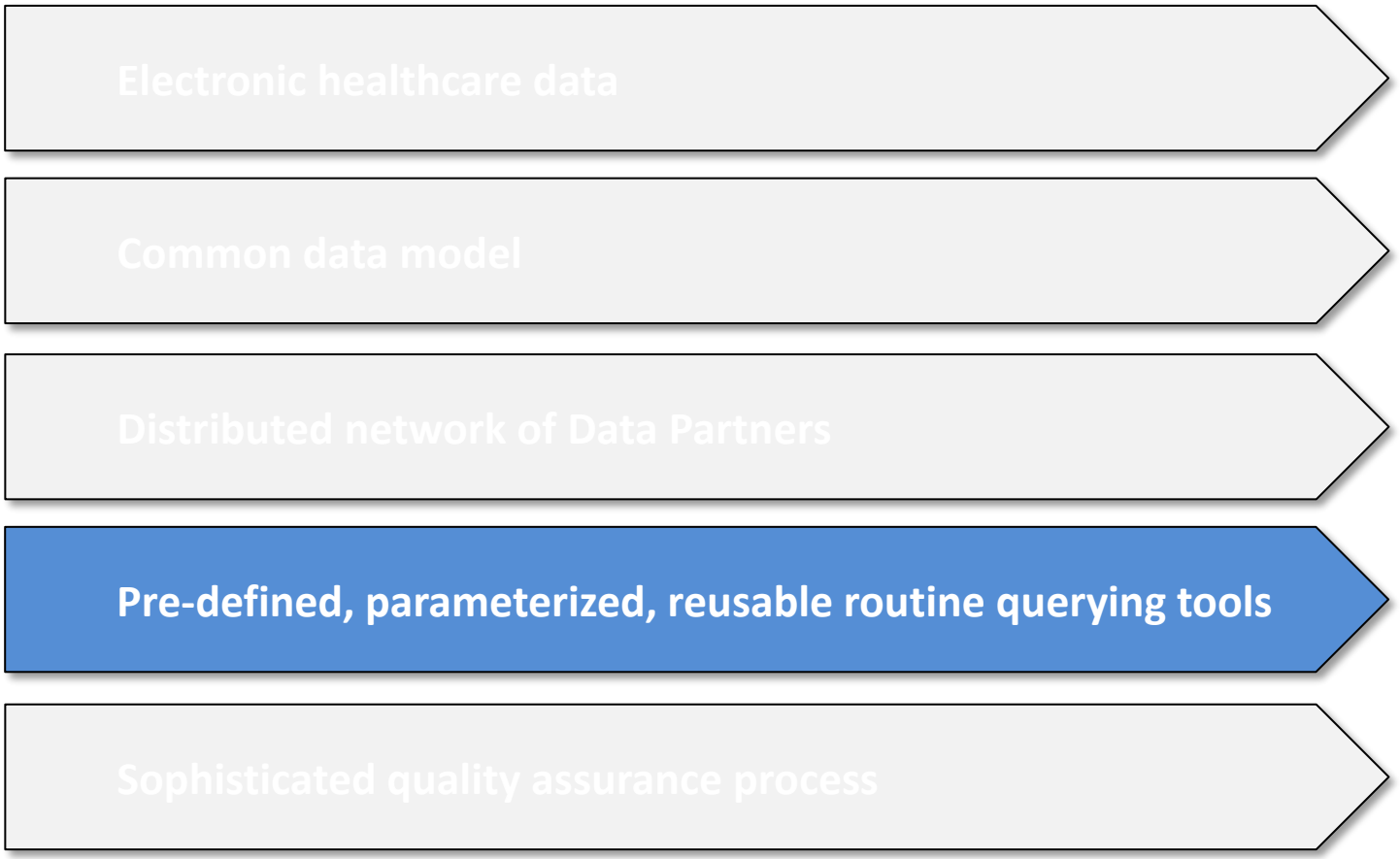




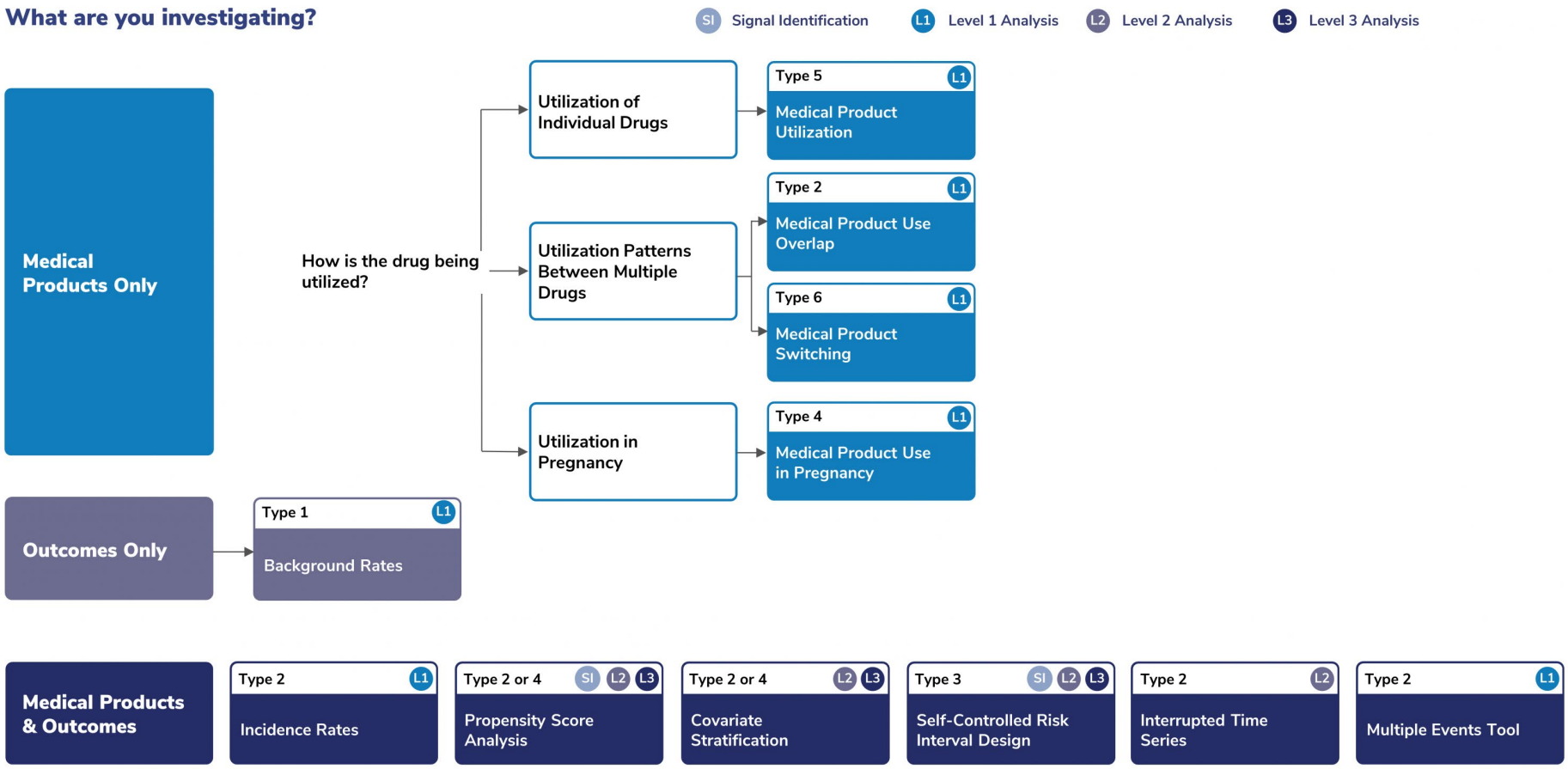
https://www.sentinelinitiative.org/about/how-sentinel-gets-its-data

The Sentinel System

Key components



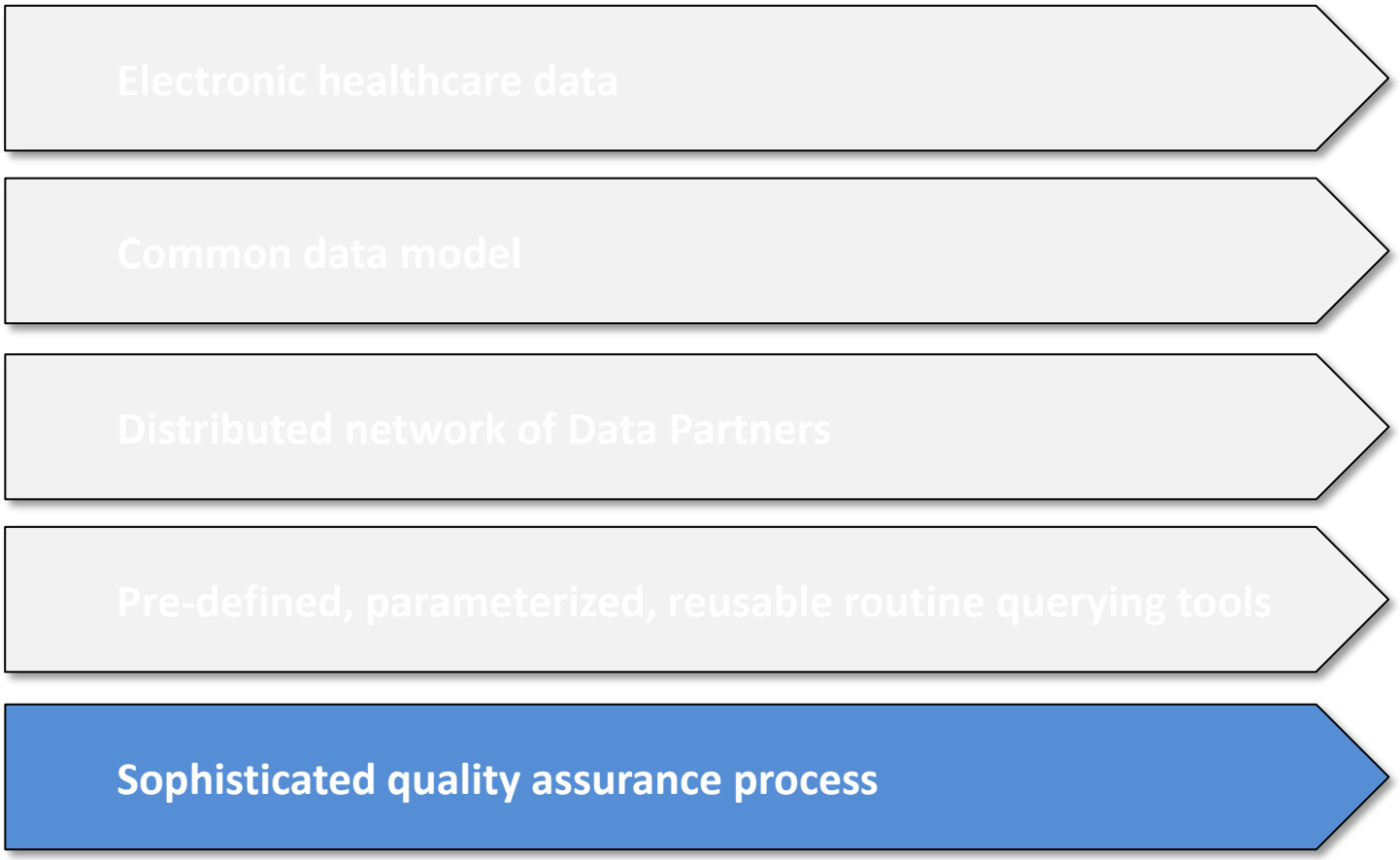
Routine Querying Tools



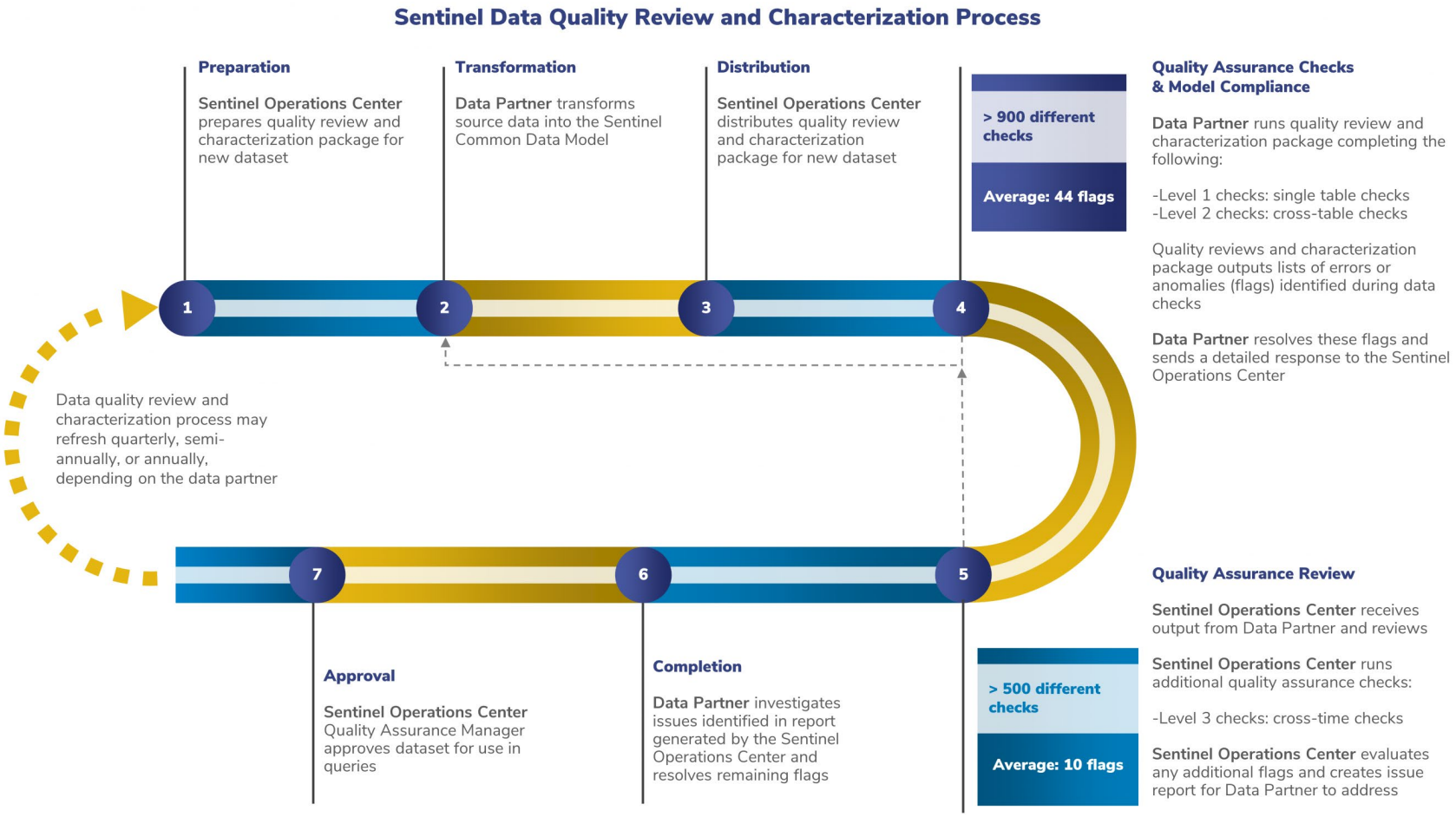
https://www.sentinelinitiative.org/methods-data-tools/routine-querying-tools.

The Sentinel System

Key components



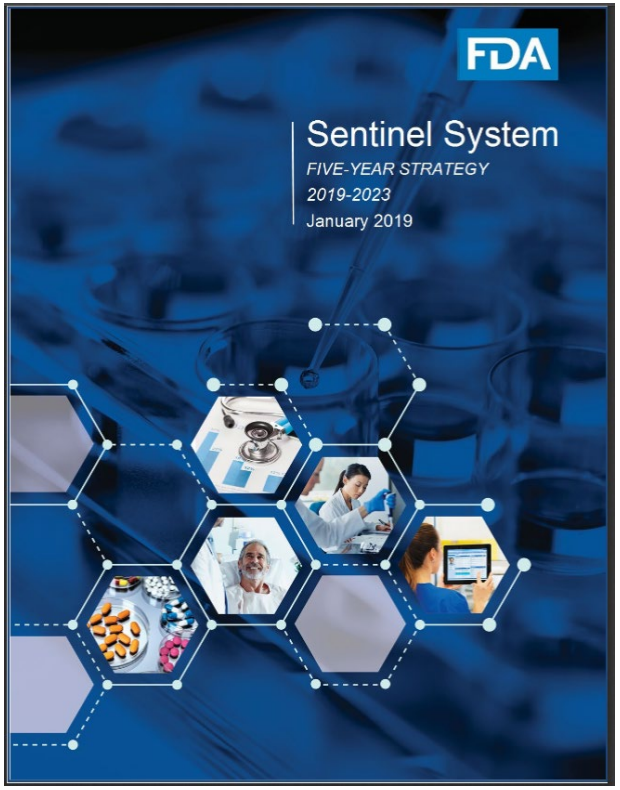
Data Quality Assurance Process



https://www.sentinelinitiative.org/about/how-sentinel-gets-its-data

Sentinel's Strategic Plan 2019-2023

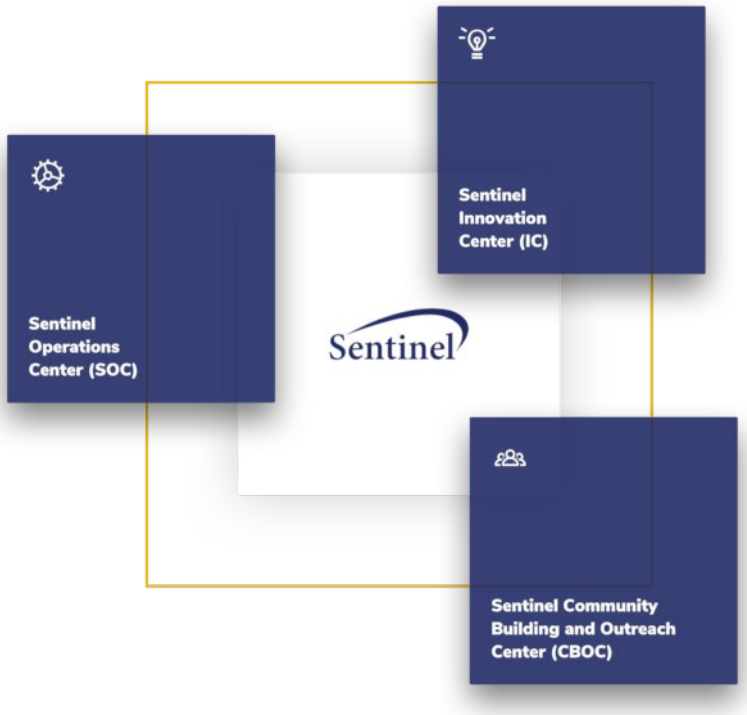
- Maintain and enhance the Sentinel System's foundation, preserving FDA's long-term investment in Sentinel's analysis tools and data infrastructure
- Diversify data sources, especially EHRs and claims linked to EHR
- Selectively incorporate advanced analytics
- Broaden touch points for participating in Sentinel's development
- Establish a Sentinel scientific community and disseminate knowledge to improve public health



https://www.fda.gov/media/120333/download

Sentinel's Three Centers

- In 2019, FDA established three distinct Sentinel centers
  - Sentinel Operations Center (SOC)
  - Innovation Center (IC)
  - Community Building and Outreach Center (CBOC)



Sentinel Operations Center (SOC)

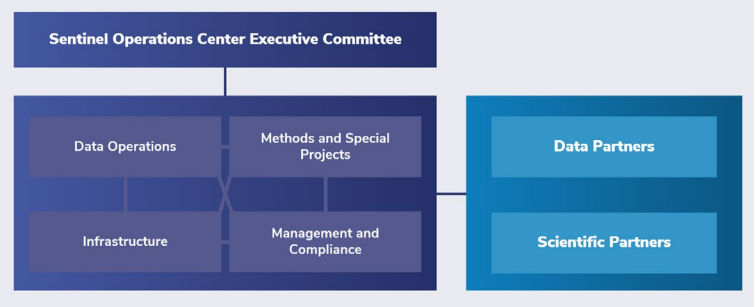
Lead: Harvard Pilgrim Health Care Institute

- Includes >40 collaborating entities, Data Partners, scientific/methods expertise

Roles

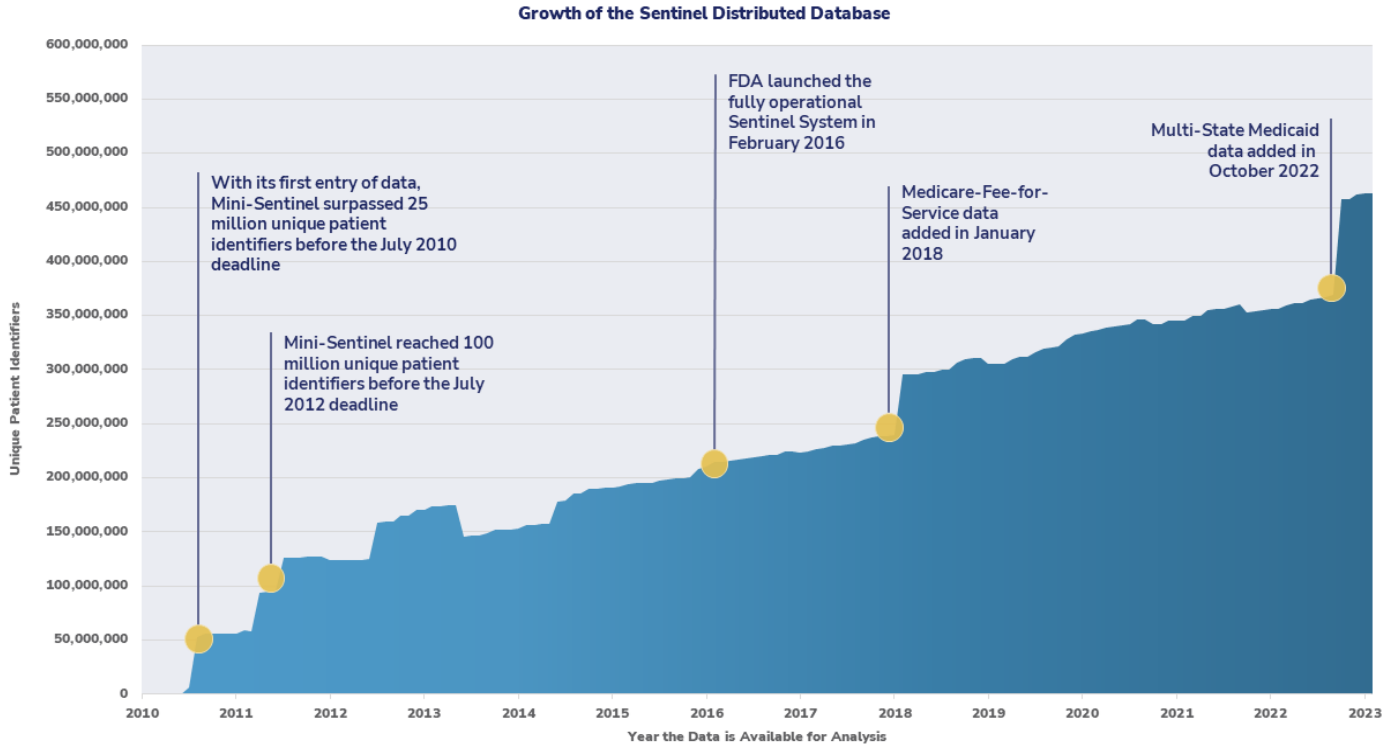
- **ARIA system**
  - Maintain data partner network, Common Data Model, analysis tools
  - Conduct analyses to evaluate the safety and effectiveness of medical products
  - Post analytic packages, results, Regulatory Outcomes

- **Core infrastructure development**
  - Integrate new data sources into the query-ready distributed database
  - Create new analytic tools capable of operating in a distributed environment



Sentinel Operations Center (SOC)

- The SOC maintains the SDD with 13 data partners contributing electronic health data from all U.S. geographic regions to the SDD.
- By 2023, the SDD had accrued 463.3 million unique patient identifiers.



Note: If patients move between health plans, they may have more than one patient identifier

https://www.sentinelinitiative.org/about/key-database-statistics

Innovation Center (IC)

Lead: Harvard Pilgrim Health Care Institute

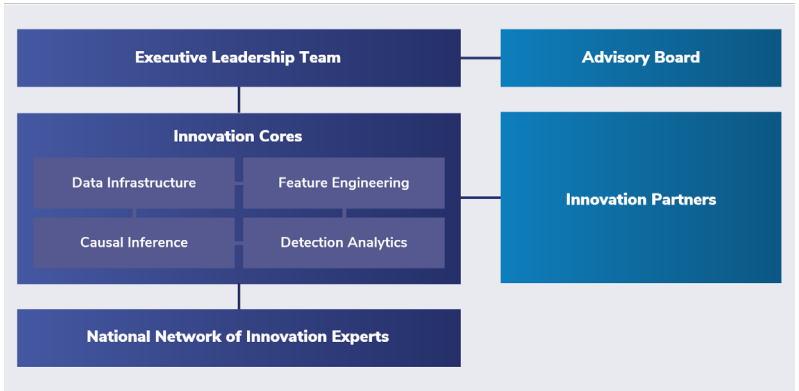
- Includes >50 collaborating entities

Innovation Cores:

1. Data Infrastructure
2. Feature Engineering
3. Causal Inference
4. Detection Analytics

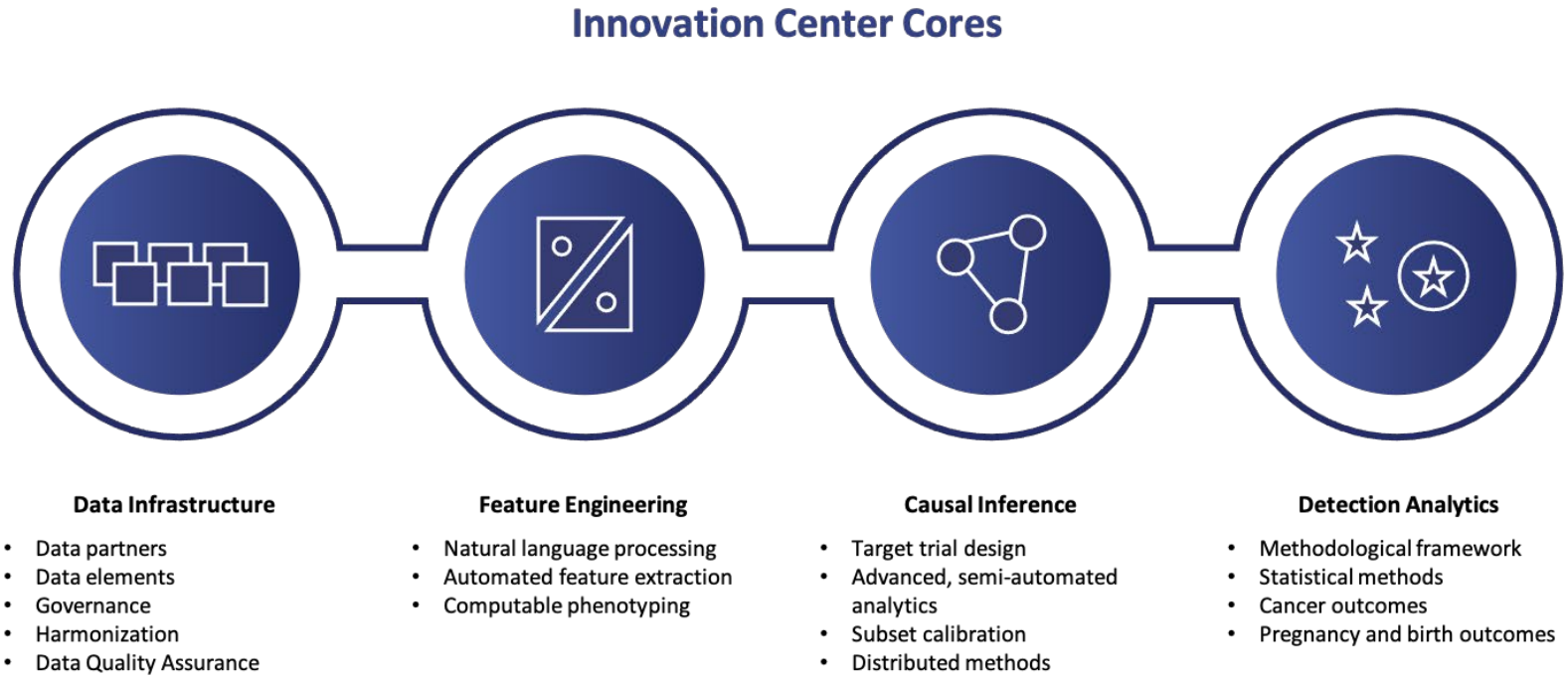
Roles:

- Engage with academia and technology industry to develop innovative methods to further advance Sentinel, with a focus on early phases of methods development
- Develop methods to use EHR data, signal detection, causal inference approaches, and advanced analytics
- Develop a linked claims-EHR data network
- Host an Innovation Day public meeting



Innovation Center (IC)

- The IC has over 20 cutting-edge projects completed or in progress within these four key priority areas



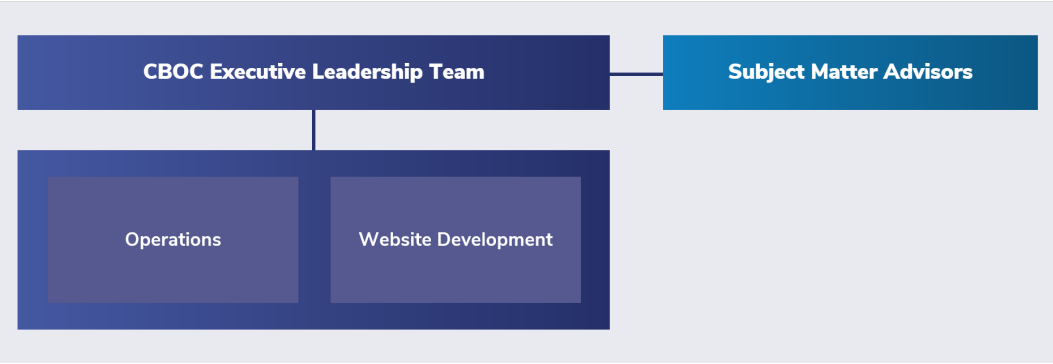
- Two Use Case projects are being implemented to demonstrate how the EHR-claims network will enhance Sentinel's data capabilities

Community Building and Outreach Center (CBOC)

Lead: Deloitte Consulting

Roles

- Transform Sentinel into a vigorous scientific community
- Maintain the Sentinel website and develop novel public portals to enhance usability, search, information management, and community engagement around Sentinel projects, tools, and results
- Increase adoption and use of the Sentinel CDM and tools through external training, direct support, and stakeholder engagement



Community Building and Outreach Center (CBOC)

- Formed a multi-stakeholder workgroup comprising
  - U.S. health agencies
  - Patient advocacy organizations
  - Informatics community
  - Industry
  - International regulatory agencies
  - Academia
  - Additional groups
- Hosted two webinars with a total of 139 attendees
- Attained a wide reach via the Sentinel website and newsletters.

Sentinel System Overall

Safety concerns evaluated from 2016-2023 =170

- 15 Annual Sentinel Initiative Public Workshops (through a cooperative agreement with the Duke-Margolis Center for Health Policy) - with a wide reach of 1000+ participants.
- Sentinel Views, a web-based data visualization application, developed in 2022 to increase access to study results from the Sentinel System

Recent Sentinel Enhancements

- Expanded access to novel data sources
  - EHRs, patient health trackers, disease registries linked with patient reported outcomes and healthcare utilization
  - Via the SOC's Data Partner network and the IC's innovation partners
- Enhanced analytic tools
  - Example topic areas: natural language processing, data model interoperability, machine learning, artificial intelligence, distributed data methods, advanced epidemiologic and biostatistical methods
- Strengthened network of scientific collaborators

Conclusion

- The U.S. FDA's Sentinel System was set up for post-market active monitoring of medical products based on a U.S. congressional mandate
- The Sentinel System has a wide coverage of the U.S. population
- The Sentinel System operates via three centers applying sound scientific expertise and innovative methods to real-world data to advance FDA's mission.

- The Sentinel System is supported by the U.S. Food and Drug Administration (FDA) contract 75F40119D10037.

OPERATIONS CENTER COLLABORATING ORGANIZATIONS

Aetna, part of the CVS Health Family of companies.

Innovation Center Collaborating Organizations: Data & Scientific Partners


FDA
U.S. FOOD & DRUG
ADMINISTRATION