



Reliable insights regarding medication outcomes from real world data— key principles of an evidence generation framework

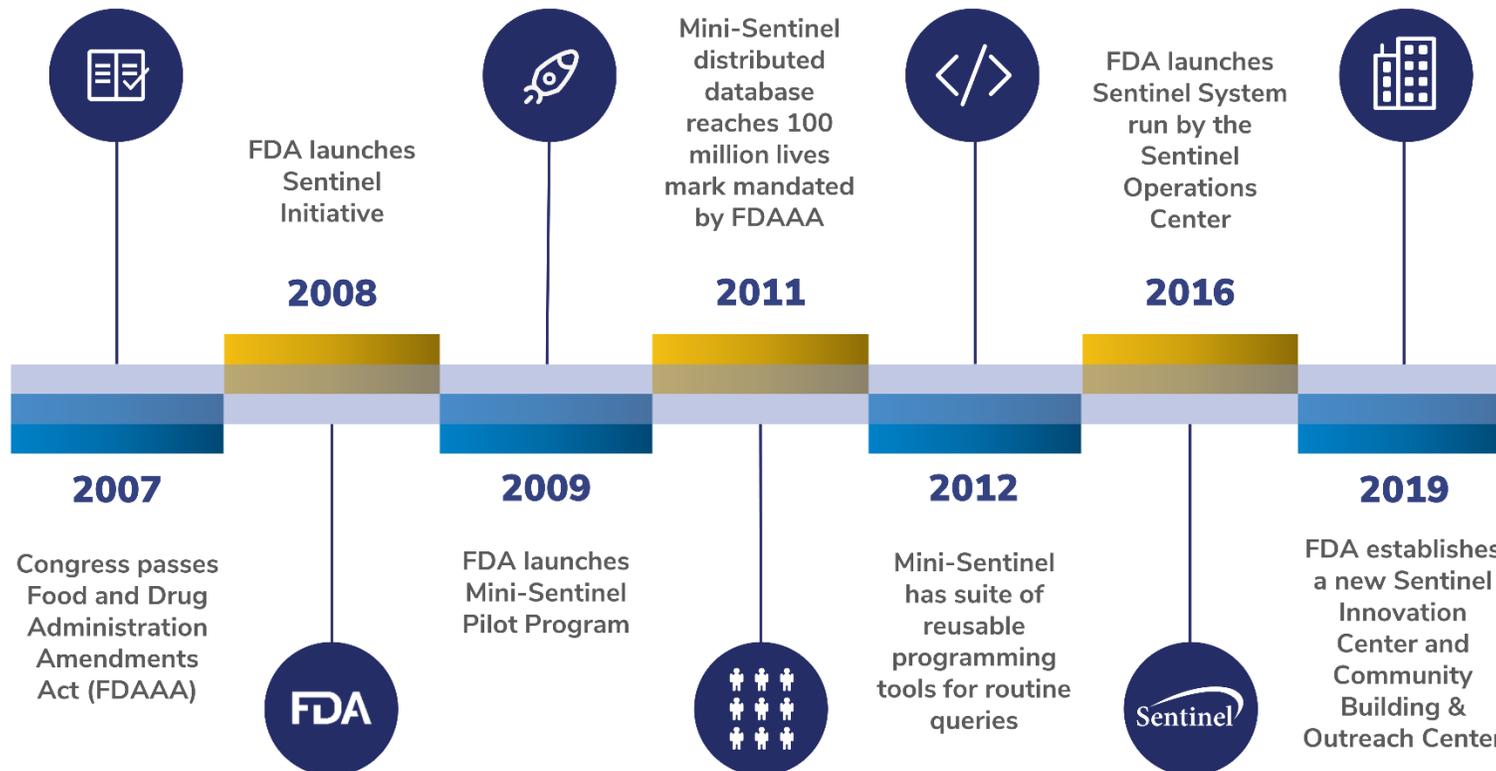
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FDA's Sentinel system

- 2007 FDA Amendments Act mandates FDA to establish **active surveillance system** for monitoring drugs using electronic healthcare data
- Through the Sentinel Initiative, FDA aims to assess the post-marketing safety of approved medical products

History of the Sentinel Initiative



Sentinel data partners

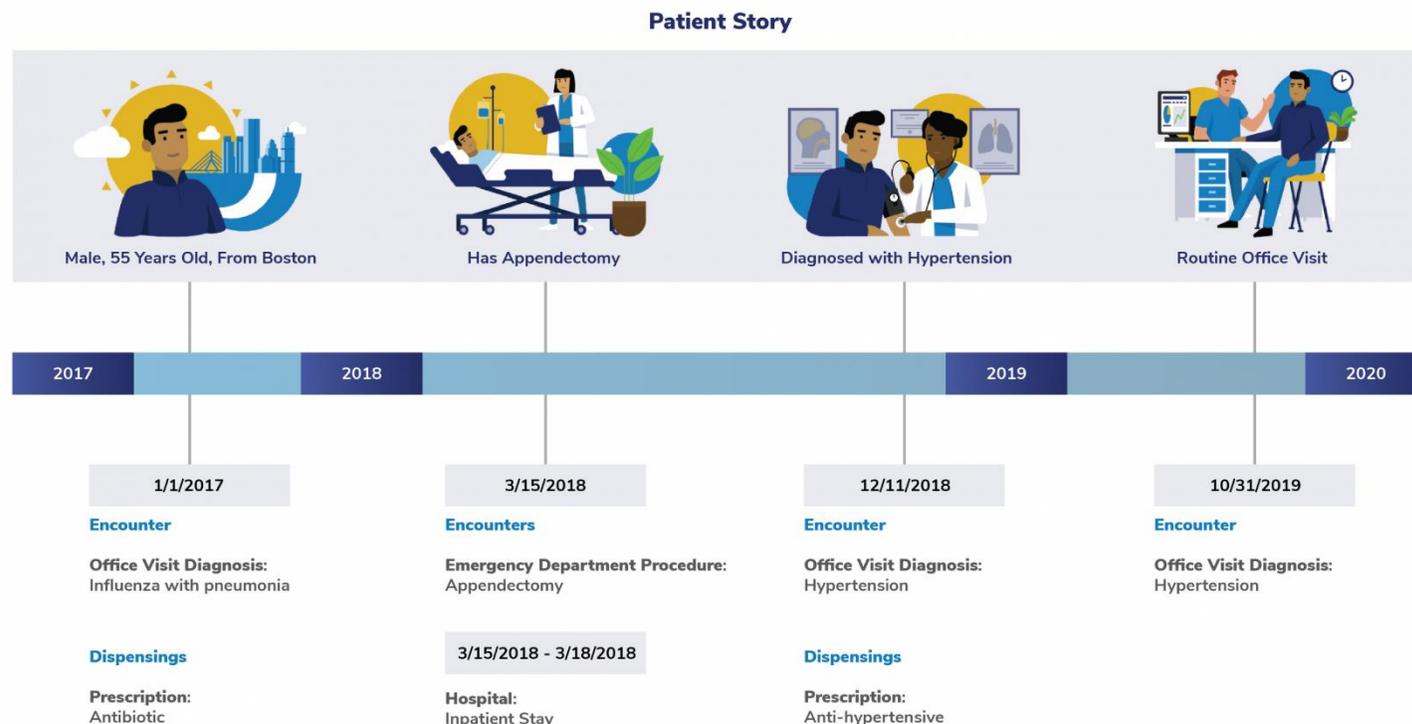
1. [Aetna, a CVS Health company](#)
2. [Duke University School of Medicine: Department of Population Health Sciences \(Medicare Fee-for-Service data\)](#)
3. [Harvard Pilgrim Health Care Institute](#)
4. [HCA Healthcare](#)
5. [HealthCore, Inc. \(Anthem, Inc. data\)](#)
6. [HealthPartners Institute](#)
7. [Humana, Inc.](#)
8. [Kaiser Permanente Colorado Institute for Health Research](#)
9. [Kaiser Permanente Hawaii Center for Integrated Health Care Research](#)
10. [Kaiser Foundation Health Plan of the Mid-Atlantic States, Inc.](#)
11. [Kaiser Permanente Northwest Center for Health Research](#)
12. [Kaiser Permanente Washington Health Research Institute](#)
13. [Marshfield Clinic Research Institute](#)
14. [Optum \(OptumInsight Life Sciences Inc. and Optum Labs®\)](#)
15. [Vanderbilt University Medical Center, Department of Health Policy \(Tennessee Medicaid data\)](#)

Sentinel distributed database

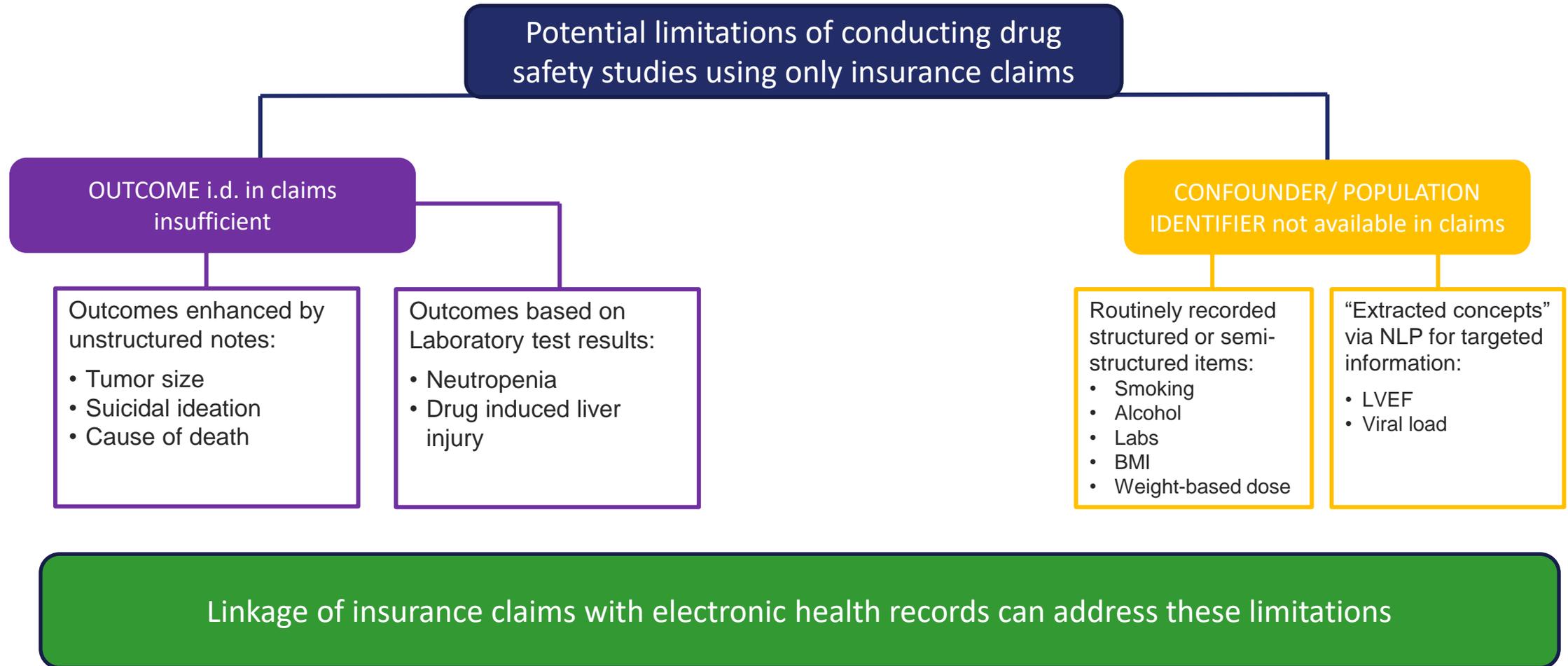
- **351.8 million unique patient identifiers (2000-2020)***
- **70.6 million members** currently accruing new data
- **14.8 billion** pharmacy dispensings
- **13.8 billion** unique medical encounters

Data needs for generating decision-grade evidence regarding medication outcomes

- To support causal conclusions regarding medication outcomes, establishing a clear temporal sequence of event based on data from sources with near complete longitudinal capture is imperative
- **Health insurance claims** data provide comprehensive capture of outpatient pharmacy dispensing records, medical encounters, and hospitalizations during well-defined periods of health plan enrollment
- Most **EHR sources** in the US lack the ability to capture data when individuals receive care outside of the contributing healthcare systems



Data needs for generating decision-grade evidence regarding medication outcomes



Challenges in developing a robust evidence generation framework utilizing real-world data

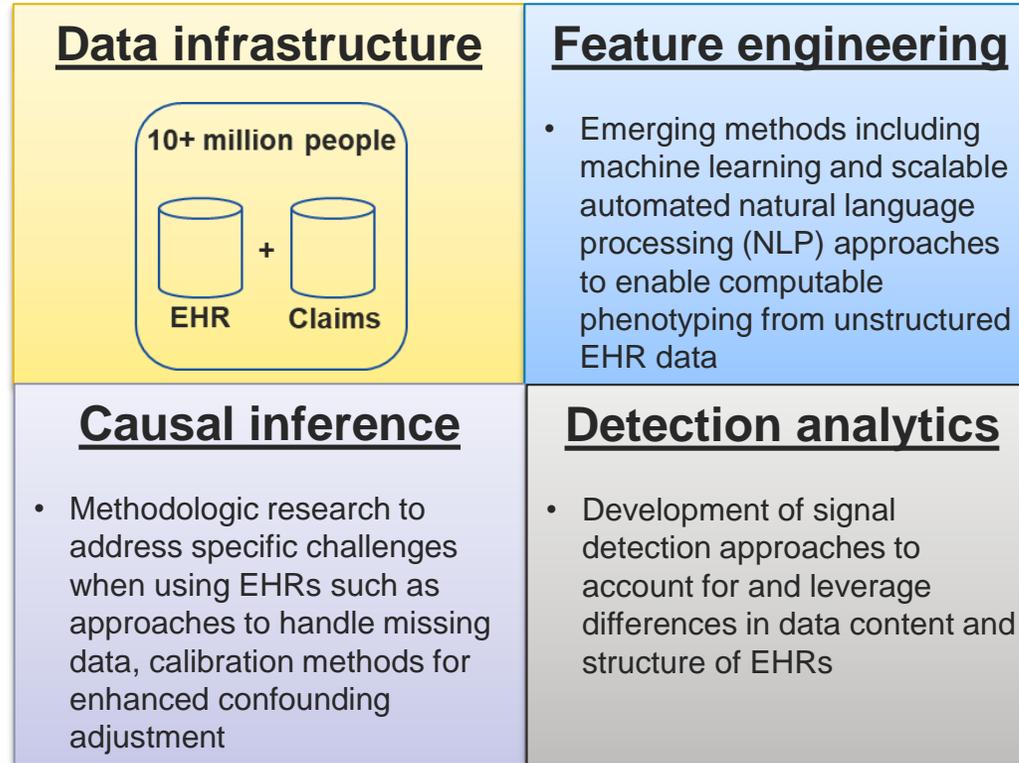
Development of a sustainable infrastructure containing standing linkage between insurance claims and EHRs to support real time querying

Envisioning a framework based on sound causal inference principles and state-of-the art epidemiologic methods to generate regulatory decision-grade evidence generation

Outlining principles of transparent communication to increase confidence in results generated using real-world data

Sentinel innovation center

Initiatives



Vision

A query-ready, quality-checked distributed data network containing EHR for at least 10 million lives with reusable analysis tools

Year 1



Year 5