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BACKGROUND

- The Sentinel System of the U.S. Food and Drug Administration (FDA) was created to assess drug use and safety and to develop the relevant data capabilities to support these activities.
- The Sentinel System functions through the Sentinel Operations Center (SOC), Innovation Center (IC), and Community Building and Outreach Center (CBOC), all collaborating towards achieving Sentinel's mission.
- The Sentinel IC is tasked with developing and evaluating innovative methods for studying drug safety using real-world data (RWD). Although Sentinel's focus is on drug safety, these methods can also be applied to evaluating drug effectiveness.

OBJECTIVE

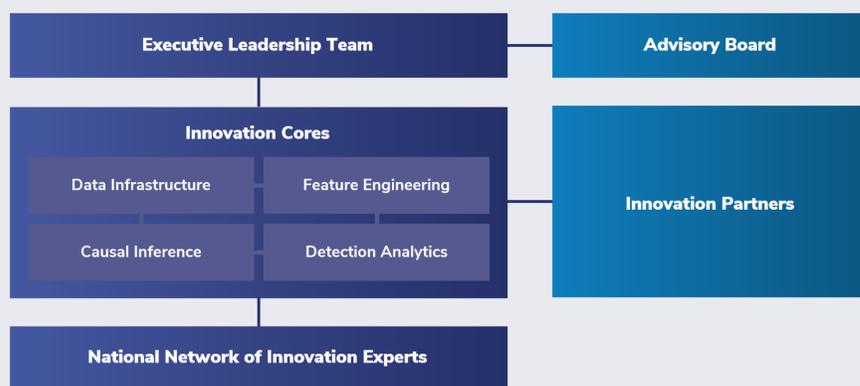
To describe the Sentinel Innovation Center, its structure, and projects.

METHOD

We examined and described the FDA Sentinel System's Innovation Center.

Figure 1: Sentinel Innovation Center Structure

Sentinel Innovation Center (IC)



- The IC involves collaboration between academia, healthcare institutions and the technology industry, to develop innovative methods to advance Sentinel's capabilities (Figure 1).
- It leverages novel data sources, real-world evidence innovation, advanced analytics, and informatics.

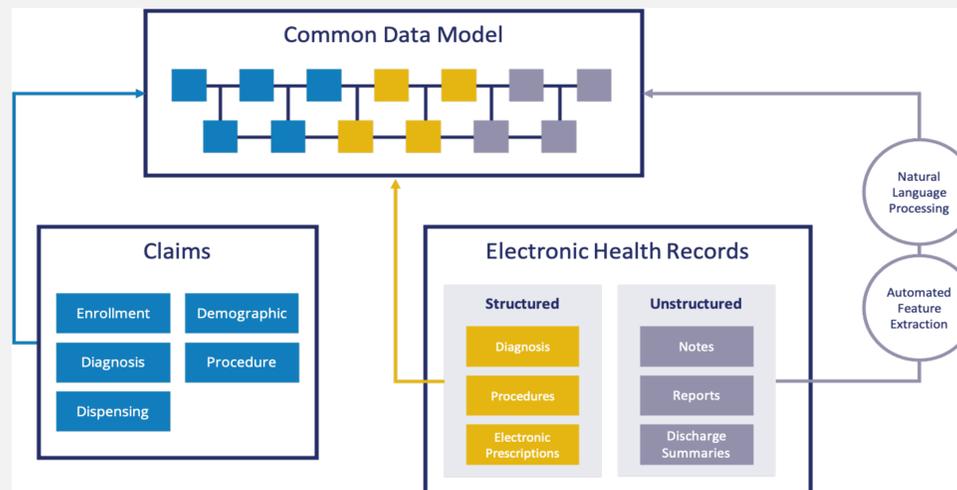
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RESULTS

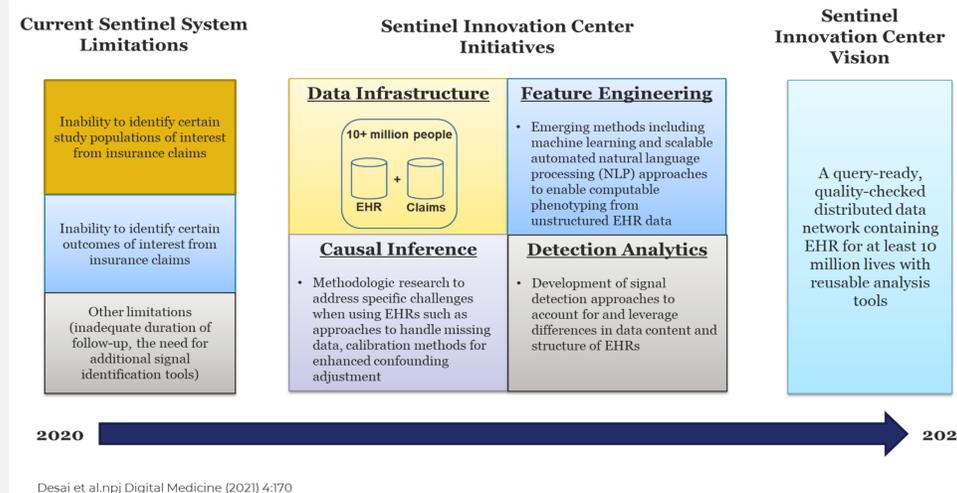
- To align with Sentinel's strategic goals, the IC develops and implements methods to extract, standardize, and quality check clinical data and free text from electronic health record (EHR) data (Figure 2).

Figure 2: Innovation Center Priorities



- Additionally, the IC creates state-of-the-art approaches to identify clinical phenotypes and address issues of confounding and missing data often faced by studies using RWD (Figure 3).

Figure 3: Sentinel Innovation Center Vision



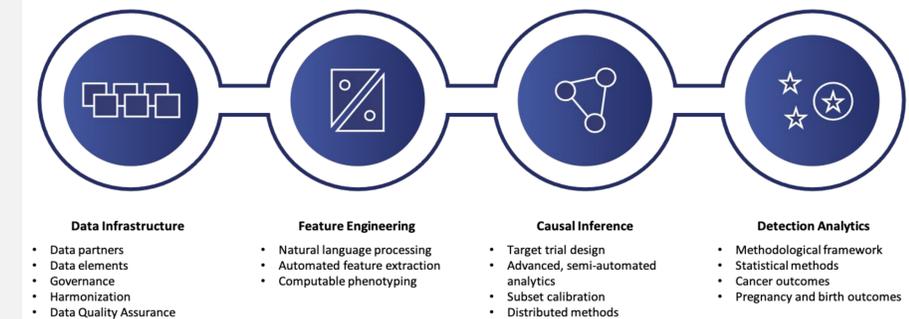
Desai et al. npj Digital Medicine (2021) 4:170



For more information on these projects, please visit our website.

- The IC currently houses over 20 cutting-edge projects in key strategic areas of data infrastructure (DI), feature engineering (FE), causal inference (CI), and detection analytics (DA). See Figure 4.

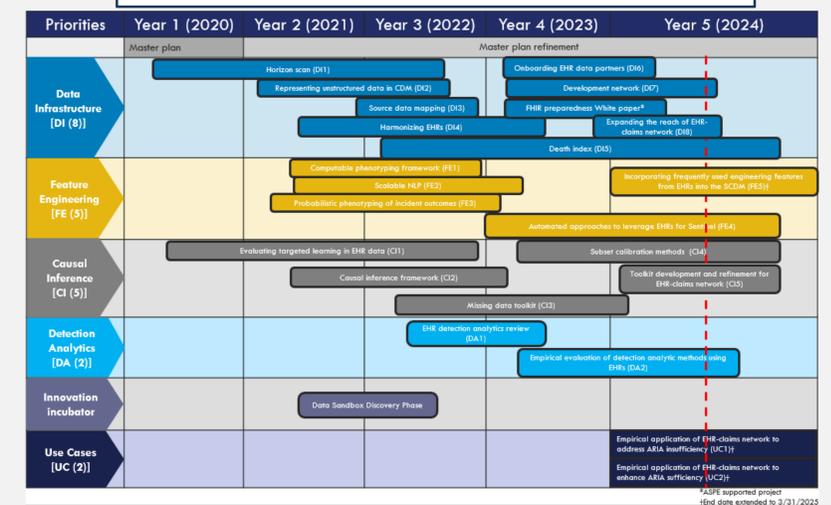
Figure 4: Innovation Center Cores



So far, ongoing or completed projects (Figure 5) include:

- Eight Data Infrastructure projects working to establish a query-ready distributed data network containing EHR
- Five Feature Engineering projects involving machine learning and scalable automated natural language processing approaches.
- Five Causal Inference projects examining approaches for addressing challenges when using EHR data are ongoing or completed.
- Two Detection Analytics projects developing signal detection approaches to deal with differences in EHR data content and structure are completed.

Figure 5: Innovation Center Projects



- Finally, two projects are being implemented in specific use cases to apply learnings from other projects and demonstrate how the EHR-claims network will enhance Sentinel's data capabilities.

CONCLUSION

- The U.S. FDA's Sentinel IC develops and implements innovative methods for studying drug safety using RWD.
- Although Sentinel's focus is on drug safety, these methods can also be applied to evaluating drug effectiveness.