A Description of the Active Risk Identification and Analysis System of the U.S. Food and Drug Administration

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BACKGROUND

- **The Sentinel System is one of the U.S. Food and Drug Administration (FDA)'s postmarket medical product safety surveillance systems.**
- **The Sentinel System has three centers: Sentinel Operations Center (SOC), Innovation Center (IC) and Community Building and Outreach Center (CBOC), all collaborating to achieve FDA Sentinel's strategic goals.**
- **The Active Risk Identification and Analysis (ARIA) system is a major component of Sentinel coordinated by the SOC for evaluating the use and safety of regulated medical products.**

The FDA Amendments Act of 2007 (FDAAA) Section 905 required that FDA strengthen its existing post-market safety surveillance for drugs and biological products by directing FDA to create an **active post-market risk identification and analysis (ARIA) system**, which FDA operationalized as one component of the Sentinel System.

FDAAA Section 901 required that FDA determine whether **ARIA** is sufficient to identify or assess a serious risk prior to requiring a sponsor conduct post-market studies or clinical trials.

OBJECTIVE

- **To describe the ARIA system, its roles and process for evaluating safety of approved medical products.**

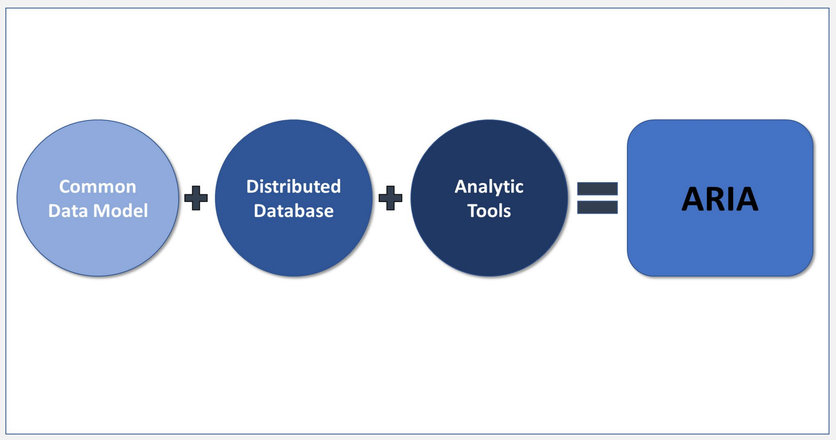
METHOD

- **We identified and described the process for using FDA Sentinel System's ARIA to evaluate the safety of approved medical products.**

RESULTS

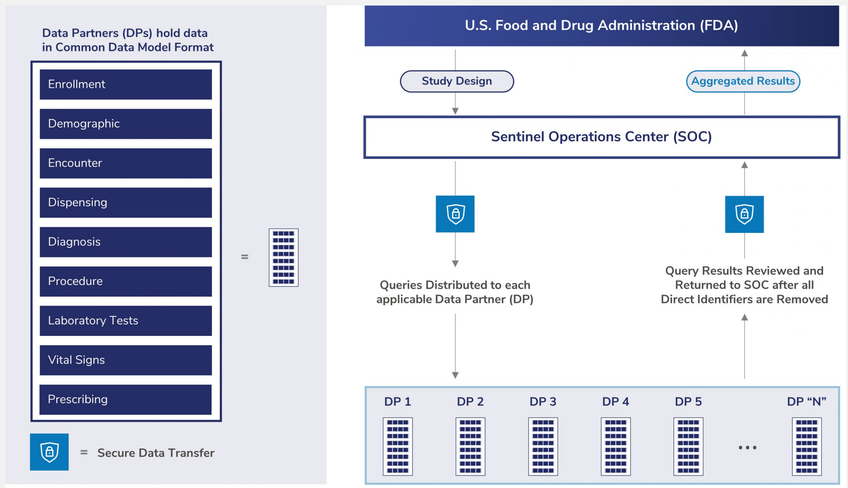
- **The ARIA system comprises the Sentinel Distributed Database (SDD) with data in the Sentinel Common Data Model (SCDM) format, which is queried using routine analytic tools (Figure 1).**

Figure 1: Components of ARIA



- **The SDD comprises Data Partners that contribute longitudinal patient-level data collected from routine healthcare encounters (Figure 2).**
- **Data is largely administrative claims, with some EHR and registry data**
- **Data is maintained by each data partner in the SCDM format, which enables execution of a single analytic program across all Data Partners. ARIA uses pre-tested and validated querying tools.**
- **Deidentified summary-level information is harmonized and collated centrally by the SOC for use to address FDA's regulatory questions.**

Figure 2: The Sentinel Distributed Database (SDD)



- **The SCDM includes 18 data tables capturing a range of administrative, registry, inpatient, clinical, mother-infant linkage, patient reported measures, auxiliary, and feature engineering data (Figure 3).**
- **Currently, 13 Data Partners contribute electronic health data to the SDD with approximately 128.7 million active members accruing new data and 69 million members enrolled in 2023 (Figure 4).**

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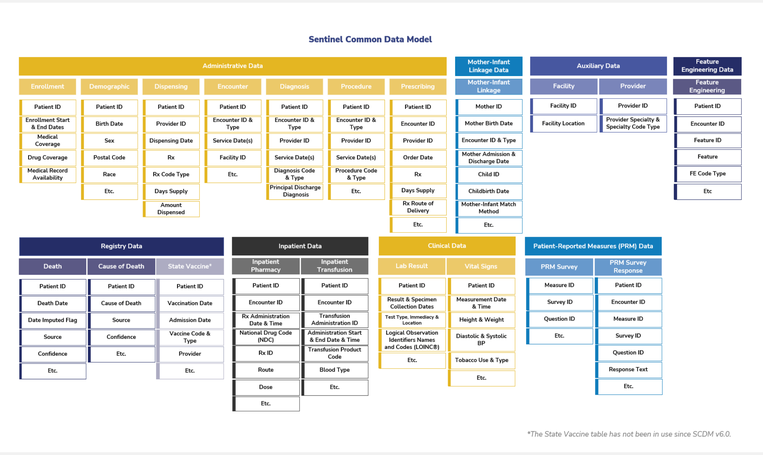
For more information, please visit our website.

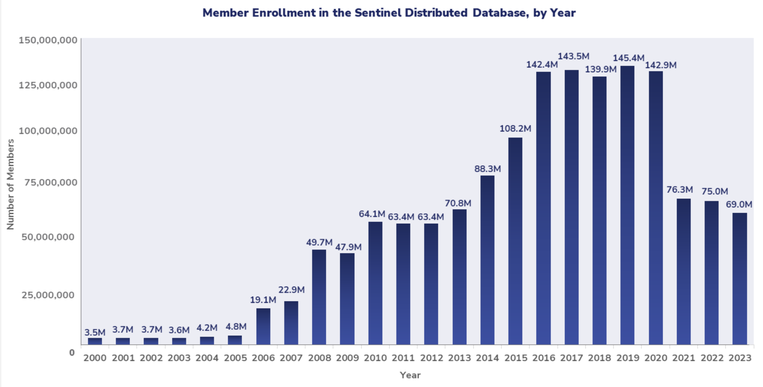
RESULTS

Figure 3: Sentinel Common Data Model



- **From 2016-2023, the FDA has used the ARIA system to evaluate 170 safety concerns, with 75 assessments contributing to FDA regulatory outcomes, including safety-related labeling changes for 12 safety concerns.**
- **In alignment with Sentinel's principle of transparency, FDA notifies applicants of products being studied prior to publicly posting the analytic packages, study results and regulatory outcomes from these analyses.**

Figure 4: Member Enrollment in the Sentinel Distributed Database by Year



CONCLUSION

- **The SOC coordinates the U.S. FDA's ARIA System which comprises a distributed data partner network, a common data model and routine querying tools. The ARIA system allows FDA to evaluate the post-market safety of marketed medical products using real-world data.**