Mini-Sentinel Operations Center
Proposal to Reagan-Udall Foundation for the Use of IMEDS Research Lab

This proposal contains a summary of the intended use of the Reagan-Udall Foundation (RUF) IMEDS Research Lab by various members of the FDA Mini-Sentinel Operations Center (MSOC) team at the Harvard Pilgrim Health Care Institute (Boston).

Research Objectives and Aims

Mini-Sentinel is a pilot project sponsored by the U.S. Food and Drug Administration (FDA) to create an active surveillance system - the Sentinel System - to monitor the safety of FDA-regulated medical products. Mini-Sentinel uses existing administrative and electronic health care data from multiple collaborating and Data Partner institutions around the country. Please refer to our public website, Mini-Sentinel.org, for additional information.

Scope/Proposed Approach

A high-level description of two types of activities is included below. For either type of activity, the MSOC would welcome access to the various IMEDS sources of electronic healthcare data (e.g., Commercial, Medicare, Medicaid, Labs) formatted into the Mini-Sentinel Common Data Model (MSCDM) and compliant with Mini-Sentinel Data Quality Assurance – (QA) standards. The MSOC QA team will work with the RUF team to implement the appropriate QA controls before using the data.

1. **IMEDS Research Lab as Mini-Sentinel Testing Environment**

    a. **Quality-testing SAS analytic programs:** To fulfill the requirements of the FDA Sentinel System, the MSOC team has implemented Standard Operating Procedures (SOPs) to ensure quality and consistency of the various analytic programs used in production mode for surveillance activities. Before they can be used for routine queries, all SAS programs are subject to a thorough Quality Compliance (QC) process, during which MSOC staff: (1) run each program within various technical environments (e.g., Operating Systems, SAS versions, volumes and types of data), (2) troubleshoot for errors, and (3) revise programs for efficiency purposes. The IMEDS Research Lab would be invaluable as a testing platform to fulfill these tasks during the development of all analytic programs.

    b. **Simulations and other methods development activities:** The MSOC Methods team would benefit from the IMEDS Research Lab environment for methods development activities, including data-intensive simulations, to evaluate existing statistical methods and new methods under development, thus further enhancing the capabilities of the FDA Sentinel System.

2. **Research & Development**

    As part of ongoing activities at the MSOC, members of the Systems and Analytic Programming teams explore alternatives to the distributed data querying approach currently used within Mini-Sentinel. Example objectives include:

    a. Assess the feasibility of using programming languages other than SAS at various stages of the querying process, e.g.:

- SQL programs executed against raw MSCDM data stored in relational databases instead of in SAS datasets;
- SQL programs embedded into routine SAS;
- R programs to handle the more complex analytics on aggregate data.

b. Assess other approaches for storing raw MSCDM data at Data Partner sites; in particular, assess efficiency gains from partitioning the data into small, independent subsamples at Data Partners with large populations.

Impact

Access to the IMEDS Research Lab, with data transformed to the MSCDM, will benefit MSOC, FDA, and the public:

a. The ability to quality-test SAS analytic programs against the IMEDS data sets will streamline development and free taxpayer funds for higher-value FDA activities.
b. Access to billions of claims and EHR records will improve assessments of existing statistical methods and speed development of new methods, benefitting the research community generally.
c. Access to data in MSCDM format other than through current Data Partners will enable improvements to distributed querying capabilities, advancing the aims of FDA Sentinel as well as PCORI and other outcomes-oriented efforts.

IMEDS Research Lab Configuration

The MSOC technical team will work with the RUF team to determine an appropriate virtual machine configuration and to evaluate which data sets will be of greatest value to ongoing Sentinel activities.

Experience

The MSOC Team will work with the RUF Team to determine an appropriate number of MSOC staff to be given access to the IMEDS Research Lab, so that MSOC can derive the intended benefit from the Research Lab while giving RUF confidence that security protocols are respected. MSOC staff members are trained on patient privacy and HIPAA matters and are knowledgeable about data sharing best practices and compliance restrictions (e.g., Data Use Agreements for Limited Datasets, Data Confidentiality Agreements, End User License Agreements). MSOC proposes that the following people have access:

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Timeline