DI8: Maintaining and Expanding the Reach of the Sentinel EHR and Claims Network

Scoping Review Protocol for FDA Feedback

Sentinel Innovation Center

Version 1.2

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History of Modifications

Version	Date	Modification	Author
1.0	11/30/2023	Original Version	Sentinel Innovation Center
1.1	01/23/2024	SIC Revisions based on FDA feedback	Sentinel Innovation Center
1.2	01/26/2024	SIC Revisions based on FDA feedback	Sentinel Innovation Center

1 Project Overview

To address the Real-World Evidence (RWE) Data Enterprise mandate, the FDA has tasked the Sentinel Innovation Center with establishing a query-ready, quality-checked distributed data network containing electronic health records (EHRs) for at least 10 million lives with reusable analysis tools. A key step in establishing such a network is identifying and assessing potential partners that could contribute the necessary data for this system, including existing data, expansion, and innovation partners, as well as data sources not currently included in Sentinel. Although the FDA's Sentinel System has made substantial progress to this end through partnerships with multiple academic and commercial entities, we are interested in bringing in population-based EHR data (in contrast to the provider-centric views of our existing EHR sources or insurance-centric views of most claims data). Given the potential of Health Information Organizations (HIOs) in characterizing longitudinal care across healthcare data streams regardless of care setting, this project aims to expand the reach of Sentinel's EHR and claims network by evaluating the feasibility of partnering with HIOs to help address limitations of using claims-only data – including data completeness and confounder adjustment – and to incorporate population-based EHR data into Sentinel.

The focus of Aim 1 of this project is to conduct a scoping review of the size and capabilities of the most significant state and regional HIOs to better understand the organizations with a mature data infrastructure ready for Sentinel-specific use. To this end, the Innovation Center has developed a partnership with Civitas Networks for Health – a nonprofit organization that represents HIOs as a multistakeholder collaboration. Civitas Networks for Health, in collaboration with the University of California San Francisco (USCF), conducted the sixth annual HIO survey sponsored by the Office of the National Coordinator (ONC) for Health Information Technology. The 2023 National HIO survey is an electronic survey that includes nationwide state and regional HIOs involved in electronic health information exchange. Apart from the screening questions to ensure eligibility, the survey collected pertinent information on the HIO's organizational demographics, connections with other networks, readiness to participate in Trusted Exchange Framework and Common Agreement (TEFCA), and potential barriers to ongoing development of the HIO network.[1] The next section of this protocol briefly outlines our approach towards the scoping review in three steps as described below.

2 The Stepwise Plan for Conducting the Scoping Review

Step I: Reviewing the 2023 National HIO Survey

As a first step, the workgroup will review questions from the existing 2023 National HIO survey in detail and highlight the questions relevant to our project. This survey has questions covering five broad areas – Organizational demographics; Public Health Reporting; Implementation/Use of Standards; Network-to-Network connectivity and TEFCA; Information Blocking. Some potential questions that might be of interest for assessing feasibility for collaboration with Sentinel include information on participating states, services offered by HIOs to participants, national networks utilized for health exchange, clinical and health-related information made available, methods utilized to electronically send or receive data from participants, etc. A detailed list of survey questions along with the summaries of aggregated

responses will be included in the scoping review as well as the final project report as an Appendix.

Step 2: Reviewing the Aggregated Survey Responses

After Civitas shares the aggregated responses to the specific questions of interest with our team, we will review them in detail and highlight the responses that stand out with respect to narrowing down to the most suitable HIOs for a future partnership. From a Sentinel perspective, we would be interested in connecting with HIOs that meet the following parameters/criteria (along with rationale for each in parentheses) that we deem most important to facilitate queries:

- A reasonably large patient population of more than 4 million unique patients (*provides a population-centric view and access to a wider population*)

- Enable linkage from EHR data to claims data *(provides access to more comprehensive data beneficial for evaluating post-marketing drug safety and surveillance)*

- Collect information on filled medications as well as laboratory results and reports *(provides access to more comprehensive data beneficial for evaluating post-marketing drug safety and surveillance)*

- Provide laboratory results data mapped to LOINC codes (*LOINC is the most widely used controlled vocabulary for laboratory tests and provides granular information on lab tests such as the long name of the test, definition, property, method, test units, etc.)*

- Make clinical notes available such as progress notes, radiology reports, pathology reports, etc. (*EHR-based data sources such as clinical notes facilitate better access to granular patient-level information)*

Table shell for requesting survey responses from Civitas/UCSF

HIO/Question	Q.1 MPI ≥ 4 Million	Q.2 Integrate claims data= Yes	Q3 Filled medications=included	Q4. Laboratory results/ values= Included	Q5. Laboratory report (narrative)=included	Q6. LOINC codes =Yes	Q7. Clinical notes= included
HIO 1	Example: Yes	Example: Yes					
Level	Example: 5,400,000	Example: 15%					
HIO 2	Example: No	Example: No					
Level	Example: 2,400,000	Example: 5%					

HIO 3							
Level							
.							
.							
HIO 15							
Level							

Step 3: Establishing Communication with the HIOs

Once we receive information on the HIOs that meet our parameters of interest from step 2, we will attempt to connect with them depending on their interest in conversing with Sentinel. These will be open-ended conversations to elicit more granular information from the specific HIOs regarding their size and capabilities as well as their readiness for future partnership. To this end, we envision an approach similar to what we followed for establishing a partnership with Oklahoma state's MyHealth Access Network for Aim 2 of this project. The overall purpose of establishing this communication is to make an informed decision in identifying a few HIOs that are most mature for developing a partnership with FDA Sentinel and can contribute to the Sentinel Real World Evidence Data Enterprise (RWE-DE).

References

1. Civitas Networks for Health and Maryland Health Care Commission Release their Health Data Utility Framework. Civitas Networks for Health. Accessed September 14, 2023. https://www.civitasforhealth.org/civitas-networks-for-health-and-maryland-health-care-commission-release-their-health-data-utility-framework/