US Department of Health and Human Services

Privacy Impact Assessment

Date Signed:

02/12/2014

OPDIV:

FDA

Name:

Mini-Sentinel

PIA Unique Identifier:

P-5376385-342393

The subject of this PIA is which of the following?

Major Application

Identify the Enterprise Performance Lifecycle Phase of the system.

Operations and Maintenance

Is this a FISMA-Reportable system?

Yes

Does the system include a Website or online application available to and for the use of the general public?

No

Identify the operator.

Contractor

Is this a new or existing system?

New

Does the system have Security Authorization (SA)?

Yes

Indicate the following reason(s) for updating this PIA.

Describe the purpose of the system.

Mini-Sentinel is a pilot project sponsored by the FDA as part of an initiative to create an active safety surveillance system - the Sentinel System - to monitor the safety of FDA-approved medical products. To accomplish this purpose, Mini-Sentinel uses pre-existing electronic healthcare data provided by multiple sources.

The overarching Sentinel Initiative is the FDA's response to the Food and Drug Administration Amendments Act of 2007 (FDAAA) requirement that the FDA work with public, academia, and private entities to develop a system to obtain relevant information from existing electronic health care data in order to assess the safety of approved medical products.

Describe the type of information the system will collect, maintain (store), or share.

Mini-Sentinel uses pre-existing, de-identified electronic healthcare data from the various Mini-Sentinel Data Partners. Data Partners include participating health insurers, care providers and academic institutions. Initial data queries are provided to the Data Partners and they provide responses in de-identified, summary format to an Operations Center which aggregates the data and provides it to the FDA. A contractor, Harvard Pilgrim, operates Mini-Sentinel and specifically, the Operations Center. Participating Data Partners are sub-contractors with Harvard Pilgrim.

Most Mini-Sentinel activities focus on safety assessments, evaluation methods, or data. The fact that FDA requests and receives data on a particular product through Mini-Sentinel does not necessarily mean there is a safety issue with the product.

In the event that person-level information is required for analyses, Data Partners remove direct patient/person identifiers from the information conveyed to the Operations Center. If the Operations Center inadvertently receives direct patient identifiers, it will return or destroy the data immediately.

The FDA does not receive, collect, maintain or share personally identifiable information (PII), in the conduct of Mini-Sentinel activities.

Provide an overview of the system and describe the information it will collect, maintain (store), or share,

The Mini-Sentinel pilot provides FDA the ability to (1) work through the "nuts and bolts" of designing safety assessments using multiple existing electronic healthcare data systems; (2) develop and evaluate scientific methods to increase the precision of active safety surveillance efforts; and (3) identify and address barriers and challenges to building a practical, accurate, and timely system for active safety surveillance.

Mini-Sentinel uses pre-existing electronic healthcare data from multiple sources (the Data Partners). FDA may access the data available through Mini-Sentinel for a variety of reasons beyond assessing potential safety risks for a specific product. Some examples include determining a rate or count of an identified health outcome of interest, examining medical product use, or seeking to better understand the capabilities of the Mini-Sentinel pilot.

Mini-Sentinel employs a distributed data approach in which the individual Data Partner entities maintain physical and operational control over electronic data in their existing environments. This approach minimizes the need to share identifiable patient information. Additionally, each health care data system has unique characteristics, and use of a distributed system enables the Data Partner's to perform analyses in their environment. By virtue of this process, unique system characteristics do not present a technical roadblock or require system redesign. The distributed data model thereby ensures an informed approach to interpreting queries and analytical results across multiple Data Partners.

The Operations Center coordinates all activities and queries with the Data Partners. FDA submits queries to the Operations Center who prepares and sends the appropriate analytical program that each Data Partner will run behind their own firewall. Each Data Partner will then submit de-identified aggregated results to the Operations Center. The Operations Center aggregates the data from each of the Data Partners and sends a final aggregated data report to the FDA. After the report has been finalized, it is posted on Minisentinel.org. Data transfer between Data Partners and the Operations Center, and, between the Operations Center and the FDA is done by means of a secure web-based file sharing system.

Does the system collect, maintain, use or share PII?

No