



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2017-N-0001]

Sentinel Training at the Food and Drug Administration; Public Workshop

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public workshop entitled "Sentinel Training at FDA." The purpose of the public workshop is to provide training to understand the kinds of questions that can be asked using health care claims data generally and within the FDA Sentinel System specifically, allowing an understanding of the capabilities of the Sentinel System.

DATES: The public workshop will be held on July 10, 2017, from 10 a.m. to 4 p.m.

ADDRESSES: The public workshop will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31, rm. 1503 (the Great Room), Silver Spring, MD 20993. Entrance for the public workshop participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to

<https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

FOR FURTHER INFORMATION CONTACT: Kayla Garvin, Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 51, rm. 6314, Silver Spring, MD 20993, 301-796-7578, [Kayla.Garvin@fda.hhs.gov](mailto:Kayla.Garvin@fda.hhs.gov).

## SUPPLEMENTARY INFORMATION:

### I. Background

The Sentinel Initiative began in 2008 as a multiyear effort to create a national electronic system for monitoring the performance of FDA-regulated medical products. The Sentinel Initiative is FDA's response to the Food and Drug Administration Amendments Act of 2007 (FDAAA) requirement that FDA work with public, academic, and private entities to develop a system to obtain information from existing electronic health care data from multiple sources to assess the safety of FDA approved medical products.

The Sentinel System uses a distributed data approach in which Data Partners maintain physical and operational control over electronic health care data in their existing environments. The distributed approach is achieved by using a standardized data structure referred to as the Sentinel Common Data Model. Data Partners transform their data locally in accordance with the Common Data Model, which enables them to execute standardized computer programs that run identically at each Data Partner site. Data Partners are able to review the results of the queries before sending them back to the Sentinel Operations Center. Queries are distributed and results are returned through a secure portal to preserve privacy.

### II. Topics for Discussion at the Public Workshop

This full-day seminar, targeting clinical researchers and others without direct experience using health care claims data, will provide an overview of data that are and are not available in the Sentinel Distributed Database, the Sentinel Common Data Model, and a description of the distributed tools available to work with the data. This seminar will help those in attendance understand the kinds of questions that can be asked using health care claims data generally and within the Sentinel System specifically. Attendees will leave with an understanding of the

capabilities of the Sentinel System. The Sentinel System can help the public, academia, and private entities better understand potential safety issues associated with FDA-approved medical products. Importantly, users can get responses to their questions in a matter of weeks, as compared to months, or even longer using traditional surveillance methods.

### III. Participating in the Public Workshop

Registration: To register for the public workshop, please visit the following Web site: <https://www.eventbrite.com/e/sentinel-training-at-food-and-drug-administration-registration-32503315291>. Please provide required contact information for each attendee, including name, title, affiliation, and email.

Registration is free and based on space availability, with priority given to early registrants. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. If time and space permit, onsite registration on the day of the public workshop will be provided beginning at 9 a.m.

If you need special accommodations due to a disability, please contact Kayla Garvin no later than June 30, 2017.

Streaming Webcast of the public workshop: This public workshop will also be Webcast at: <https://collaboration.fda.gov/sentineltraining2017/>.

If you have never attended a Connect Pro event before, test your connection at [https://collaboration.fda.gov/common/help/en/support/meeting\\_test.htm](https://collaboration.fda.gov/common/help/en/support/meeting_test.htm). To get a quick overview of the Connect Pro program, visit [https://www.adobe.com/go/connectpro\\_overview](https://www.adobe.com/go/connectpro_overview). FDA has verified the Web site addresses in this document, as of the date this document publishes in the Federal Register, but Web sites are subject to change over time.

Transcripts: Please be advised that transcripts will not be available.

Dated: April 19, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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