CRISP

Use Case Pilot: FDA Adverse Event Investigation

Overview

The U.S. Food and Drug Administration (FDA) is responsible for protecting the public health by assuring the safety and efficacy of drugs, biologics, medical devices, tobacco products, and our nation's food supply. The 2007 FDA Amendments Act (FDAAA) required FDA to develop an active risk identification and analysis system to monitor and analyze post-market performance of regulated medical products, including drugs, vaccines, and other biologics. To support the FDAAA mandate, FDA created and led the Sentinel Initiative, including the Biologics Effectiveness and Safety (BEST) System, to conduct post-market safety surveillance of biologic products through analyses of large healthcare databases. A critical aim is to improve the current passive biologic surveillance reporting system, which faces challenges related to the under-detection of adverse events and limited access to EHR to perform validations of detected cases. To address these limitations, FDA is piloting an infrastructure to efficiently obtain EHR data for previously identified AE cases through its participation in the eHealth Exchange. This will provide more complete data to guide regulatory decisions as part of the FDA's post-authorization safety and effectiveness surveillance mission.

Permitted Purpose Category

For a Public Purpose, as permitted or required by Applicable Law and consistent with the mission of the HIE to advance the health and wellness of patients in the CRISP service area (Permitted Purpose #2).

Use Case Description

The FDA's current surveillance system for adverse event relies partially on passive reporting systems – specifically the Vaccine Adverse Event Reporting System (VAERS) and FDA Adverse Event Reporting System (FAERS). In these systems, healthcare care providers and manufacturers are required to submit adverse event reports for specific reportable adverse events. In addition, these systems accept reports from anyone, including patients and their relatives; thus, the database contains information on unverified reports of adverse events. This use case is focused on enhancing the ability and efficiency of FDA authorized public health investigators to validate that these adverse events meet established case definitions (e.g., Brighton Collaboration Case Definitions for COVID-19 vaccine-related adverse events). This additional information is currently obtained through calls to physicians and other healthcare providers. The use of CRISP services for adverse event investigation would, if anything, alleviate

some of the administrative challenges the providers face in providing requested information to public health investigators.

Public health investigators, authorized by the FDA, will utilize CRISP data to support adverse event investigations. For previously identified adverse events, FDA will request patient records to review whether case information meets the most up to date case definition requirements.

With regard to data flow, these data will be requested of CRISP members by FDA through its participation in the eHealth Exchange network – as permitted public health use under the eHealth Exchange Data Use and Reciprocal Support Agreement (DURSA). These data will be retrived from CRISP members where a case match is found and sent to the eHealth Exchange Hub. From the hub, these data will flow to the FDA-authoized participant node – the secure BEST platform. Case data will be reviewed within the BEST platform by FDA-authorized reviewers. Once a case validation is complete, the report will be submitted securely to the FDA-authorized Electronic Submission Gateway (ESG).

Opt-Out Applicability

Any patient that opts-out of CRISP will not have their data included in data provided for this use case.

Eligible Participants

Information will only be available to FDA investigators. FDA may only use the CRISP Services for adverse event investigation and case reporting purposes as defined in this use case. These investigators will maintain any information obtained via CRISP Services confidential in accordance with FDA applicable law, Maryland statues and regulations, and CRISP policies.

Patient Impact Statement

Individuals may have their data viewed by the FDA if they have had an adverse event that was reported to the FDA by one of their healthcare providers. Patients may or may not understand that the FDA currently has the authority to view their information for this purpose, but health care providers who are treating these individuals can be expected to explain the adverse event reporting process and the availability of patient PHI in order to facilitate the investigation. As this information is required to be made available by healthcare providers currently, this use case does not extend any additional data to new entities.

Approval

DocuSigned by:
Jonathan Thierman, MD, PhD
602198D0FB35450...

Chairperson

11/22/2021

Dated