

SETTING THE WORLD ON FHIR®

Published by HL7® International, a not-for-profit organization, Fast Healthcare Interoperability Resources (FHIR®) is a standard for exchanging healthcare information electronically

A series of case studies illuminating how HIT professionals are using HL7® FHIR® to improve and advance modern healthcare

FDA BEST IM INITIATIVE

The U.S. Food and Drug Administration (FDA) Center for Biologics Evaluation and Research (CBER) is responsible for ensuring the safety, purity, potency, and effectiveness of biological products (e.g., vaccines, allergenics, blood and blood products, cells, tissues, and gene therapies). CBER protects and advances the public health by regulating biological products (also referred to as biologics) for use in the prevention, diagnosis, and treatment of human diseases, conditions, or injury.

CBER established the [Biologics Effectiveness and Safety](#) Innovative Methods (BEST IM) Initiative with the aim to expand and enhance CBER access to new and better data assets, analytics, and infrastructure for an active, large-scale, efficient post-market surveillance system for evaluating the safety and effectiveness of CBER-regulated biologic products.

IBM

IBM Consulting (US Federal) is the lead contractor working with FDA (CBER BEST IM) on these activities.

GOAL

To improve reporting of adverse events (AEs) to the FDA while minimizing the burden of identification on healthcare practitioners by developing a platform designed to assist with this effort



CASE STUDY

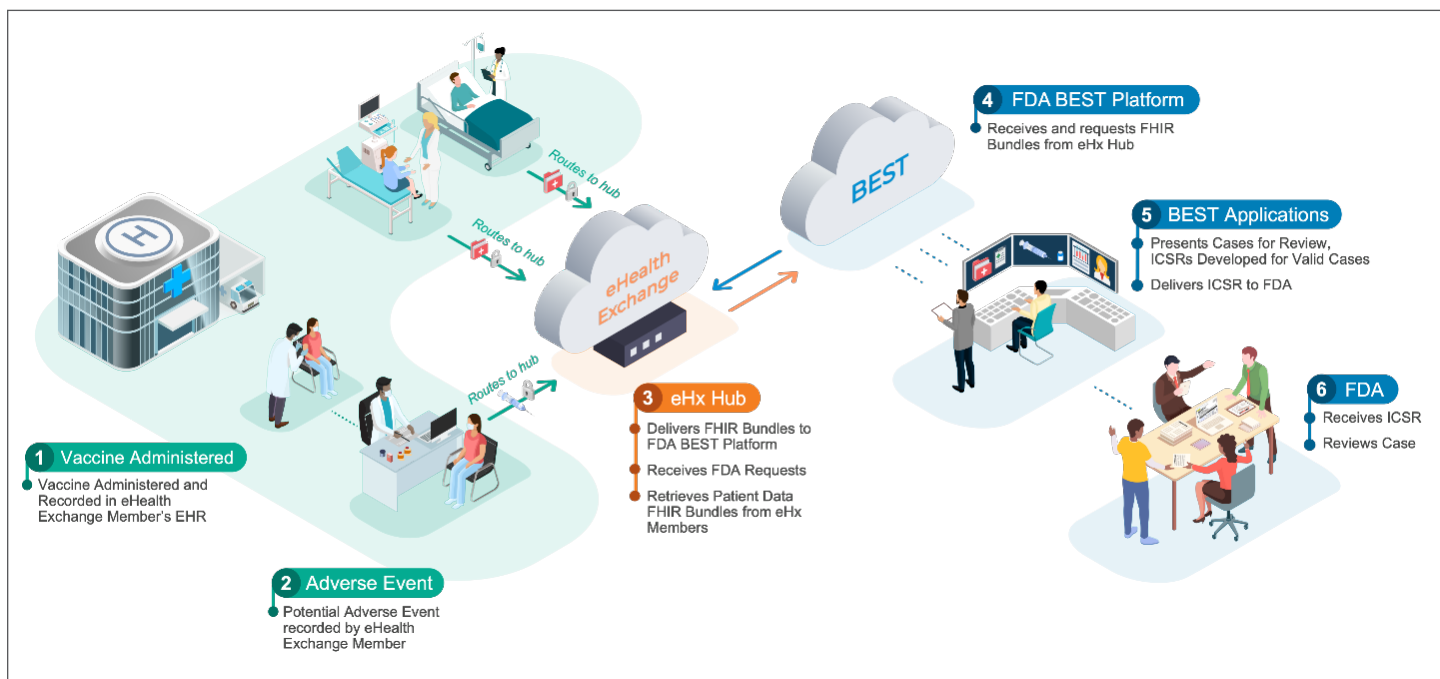


Emerging interoperability-enabled solutions chart the course for BEST to realize CBER's vision of an enhanced nationwide adverse events electronic reporting system.

— Steven Anderson, Ph.D., MPP, Director,
Office of Biostatistics and Pharmacovigilance, FDA

OPPORTUNITY

To develop a platform using HL7® FHIR® to semi-automate AEs detection, validation, and reporting



PROJECT

Currently, identifying AEs following exposure to a biological product is mostly a passive process relying on manual identification, documentation, and submission of AEs reports. Recognizing and determining links between exposures to biological products and outcomes of interest (potential AE) can be hindered by the lack of standardization in capturing and documenting key data elements existing across Electronic Health Record (EHR) systems or in unstructured, clinical notes. The HL7 FHIR standards and technology will address these challenges and provide an opportunity to build a scalable platform, suitable for a nationwide adoption, to fulfill FDA's mission.

The BEST IM Initiative is developing a FHIR-based Platform for automating the detection of potential AEs using AI and FHIR-based algorithms. These potential AEs are reviewed by a clinician via a chart review interface to semi-automate the validation and reporting of AEs to the FDA in an Individual Case Safety Reports (ICSR) format.

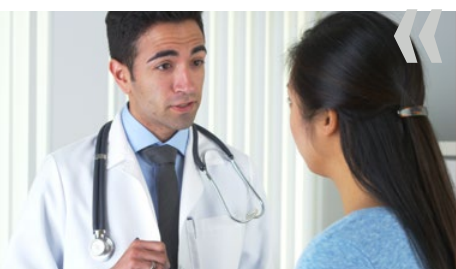
The BEST Platform is in the process of piloting the connection to eHealth Exchange using FHIR R4. Pilot partner healthcare systems will ultimately be able to deploy FHIR-based algorithms to detect potential adverse events following immunizations. Once the BEST Platform is connected to eHealth Exchange, partner healthcare systems will be able to send cases to the BEST Platform to further automate the validation and reporting of AEs, reducing the burden on providers.



PROGRESS

An HL7 FHIR Implementation Guide (IG) has been [published](#) that details the process by which AEs ICSRs are generated from EHR data. The IG currently focuses on post-vaccination and post-transfusion adverse event reporting, and the ICSR data elements are used by the FDA in two systems: the FDA Adverse Event Reporting System (FAERS) and the Vaccine Adverse Event Reporting System (VAERS).

The process will eventually be prospective and will include a provider-facing application. Long-term, the FDA seeks a national electronic reporting system for AEs.



Broad adoption of HL7 FHIR standards is poised to become a critical component in facilitating information exchange with public health agencies, providing rapid access to sufficient quantity and quality of data for regulatory decision making.

— Kathryn Matto, Partner
IBM Consulting - US Federal



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