June 19, 2025

The Honorable Martin A. Makary, MD
Commissioner
Food and Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993

Submitted electronically via regulations.gov

RE: Docket No. FDA-2025-N-0287; Exploration of Health Level Seven Fast Healthcare Interoperability Resources for Use in Study Data Created from Real-World Data Sources for Submission to the Food and Drug Administration; Establishment of a Public Docket; Request for Comments

Dear Administrator Makary:

On behalf of the American Academy of Family Physicians (AAFP), representing 128,300 family physicians and medical students across the country, I write in response to the Food and Drug Administration's (FDA) request for comments on the various available approaches to optimize the submission of structured and standardized clinical study data collected from real-world data (RWD) sources. The AAFP strongly believes in the importance of real-world data and testing, and we appreciate the agency seeking input on how to best standardize clinical study data that is collected from RWD sources.

The AAFP is extremely supportive of real-world testing and the use of RWD sources in clinical study data submissions, and we believe it is critical to ensure products and standards facilitate their intended uses without negative, unintended uses.[i] Health care is a complex, adaptative system that cannot always be predicted, which means real-world testing must be conducted, and RWD must be considered. We appreciate FDA working with the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP/ONC) to align health

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information technology (IT) policies throughout the Department of Health and Human Services (HHS), including how data derived from RWD sources might be accurately and consistently submitted to FDA. We believe aligning these submissions with current standards adopted by ASTP/ONC for Health Level Seven Fast Healthcare Interoperability Resources (HL7 FHIR)-based exchange should be a priority, and we consider this request for comments a significant step toward that alignment.

What are your suggestions on how, from a data standards perspective, FDA might reach a future state of clinical study data submissions collected from RWD sources that aligns with ASTP/ONC health IT goals for HL7 FHIR-based exchange? Does the US Core Data for Interoperability (USCDI) version 3 provide enough information for collecting RWD for research purposes? Is there information that USCDI version 3 does not sufficiently address?

To ensure a seamless integration and interchange of clinical study data derived from RWD sources, the AAFP recommends that the core clinical data be transmitted in alignment with USCDI. While USCDI Core covers substantial parts of the necessary data, it is important to recognize that not all data required for clinical studies will be included. The additional data is likely to fall into two major categories:

1. Meta-data about the clinical data: This includes information such as the context of the data collection, the provenance of the data, and other administrative details that are not typically part of the core clinical data set.
2. Data types not covered by USCDI Core: Clinical study data often requires specific types of data that extend beyond the standardized data elements found within the USCDI Core. These might include specialized measurements, patient-reported outcomes, or other study-specific data elements.

We recommend that the FDA consider leveraging the USCDI expansion process to standardize these additional data elements that are essential for clinical studies but currently fall outside the scope of the USCDI Core. This approach can help establish a more comprehensive framework for data standardization in the future, potentially incorporating some of these elements into the USCDI Core over time.

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The AAFP has long supported HHS and ASTP/ONC's efforts to advance interoperability of health IT. Interoperability is essential for ensuring family physicians have access to meaningful, actionable data at the point of care, which in turn enables them to provide comprehensive, patient-centered care. Truly interoperable health records will also reduce administrative burdens for physicians and facilitate patients' access to their health data. It is crucial that any implementation of clinical study data interoperability must be carefully managed to avoid increasing the burden on physicians and health care organizations. **Smooth, efficient data exchange processes are paramount to achieving and maintaining efficient workflows and ensuring that the primary focus remains on patient care**.

In conclusion, the AAFP reiterates its strong support for utilizing RWD sources and aligning that data with current health IT standards. By focusing on comprehensive data standardization and minimizing additional burdens on physicians and their care teams, we can achieve meaningful progress in the future state of clinical study data submissions. We appreciate the opportunity to provide comments and are eager to collaborate with FDA and other HHS agencies on the development of related policies and guidance. Should you have any questions, please contact Mandi Neff, Regulatory and Policy Strategist, at mneff2@aafp.org.

Sincerely,

Steve Furr, M.D., FAAFP

Steven P. Furr, MD, FAAFP
Board Chair
American Academy of Family Physicians

[i] Health IT End Users' Alliance. September 2022. https://hitenduser.org/wp-content/uploads/2022/09/Real-world-testing-consensus-statement_FINAL.pdf

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