Veeva

**May 9, 2025**

Steven Posnack
Acting Assistant Secretary for Technology Policy
Acting National Coordinator for Health Information Technology
Assistant Secretary for Technology Policy
Department of Health and Human Services
330 C St. S.W.
Washington, D.C. 20201

Dear Acting Assistant Secretary Posnack,

Veeva Systems appreciates the opportunity to comment on the Assistant Secretary for Technology Policy's (ASTP) "*United States Core Data for Interoperability (USCDI) Draft Version 6*."

Veeva Systems is a global leader in cloud-based software for the life sciences industry, supporting over 1,000 pharmaceutical, biotechnology, and medical device organizations. Our solutions span clinical operations, regulatory data exchange, quality, safety, and the generation of real-world evidence. By enabling structured, connected data across sponsors, research sites, and regulatory authorities, we help streamline development and strengthen interoperability across the research ecosystem.

Veeva Systems supports ASTP's continued efforts to advance interoperability and simplify data standardization through the development of the USCDI data element set. As a technology partner to life sciences organizations conducting clinical trials and submitting regulated data globally, we see the value in a unified, structured data standard that reduces the burden on sites, improves data reusability, and supports real-world evidence, regulatory submission, and digital quality measurement. By harmonizing critical data across systems, USCDI can help standardize and simplify how research is conducted, documented, and reported. This will accelerate the generation of high-quality and interoperable data across the healthcare and research ecosystem.

To support greater interoperability in life sciences, we respectfully submit the following recommendations for improving future versions of the USCDI standard:

**1.** Introduce data elements that support clinical trial participation and eligibility.

USCDI currently includes many foundational data points used in clinical trial eligibility, such as diagnosis codes (ICD-10-CM) and clinically relevant terminologies (e.g., SNOMED CT, LOINC). However, it does not provide a standardized way to represent trial-specific eligibility logic or indicate whether a patient meets criteria for a particular study. We recommend the addition of the following elements to support research workflows, trial matching, and real-world evidence generation:

- Clinical trial participation status (e.g., enrolled, completed, withdrawn).
- Study identifiers, including ClinicalTrials.gov NCT numbers or sponsor-assigned IDs.
- Eligibility indicator or computable linkage, allowing relevant patient data (e.g., diagnoses, labs, demographics) to be grouped and queried to assess trial eligibility status.
- Consent for research use, capturing whether an individual has authorized participation or data sharing for research purposes.

These additions would allow healthcare organizations, sponsors, and regulatory bodies to align care delivery with research infrastructure, facilitate just-in-time recruitment, and support compliant real-world data reuse.

**2.** Align USCDI with regulatory submission standards used across global health authorities.

To support the growing convergence between clinical operations, real-world data, and regulatory submission requirements, we recommend that USCDI evolve to better align with data standards commonly used in regulatory contexts. This includes:

- CDISC standards such as SDTM and ADaM, which are required for clinical trial data submissions to the U.S. FDA and Japan's PMDA, and recommended by regulatory authorities in other regions.
- HL7 Structured Product Labeling (SPL) and emerging SPL-on-FHIR models used for electronic labeling submissions.
- EMA Product Information (EPI), which is required in Europe for electronic structured product submissions.

Establishing clearer alignment between USCDI and these regulatory frameworks would improve interoperability across the drug development lifecycle, reduce duplication in data collection, and enable more efficient use of real-world and clinical trial data in global regulatory submissions.

**3.** Expand facility metadata to include research and regulatory-relevant entities.

USCDI currently captures limited metadata about healthcare facilities. To better support regulatory inspections, clinical trial operations, and product lifecycle oversight, we recommend expanding facility-related data elements to include:

- Facility type, with support for identifying research sites, contract manufacturing organizations (CMOs), compounding pharmacies, and importers.
- Facility identifiers, such as DUNS numbers or other persistent organizational identifiers used in regulatory tracking systems.
- Facility contact information, with a focus on roles related to research coordination, quality assurance, or regulatory communication.

These additions would support both clinical and regulatory use cases, including pre-approval inspections, trial site audits, and post-market surveillance activities.

**4.** Reinforce and expand the use of Unique Device Identifiers (UDI).
We support the inclusion of UDI in USCDI Version 6 and recommend continued efforts to operationalize and expand its use across relevant data classes. Specifically, we encourage:

- Consistent capture of both Device Identifier and Production Identifier components, as defined in the FDA UDI Rule.
- Application of UDI across additional data classes, such as procedures, adverse events, and clinical outcomes, where medical devices are relevant.
- Alignment with postmarket surveillance and clinical evaluation frameworks, including safety signal detection and device performance tracking.

Enhancing the representation and exchange of UDI data will support improved traceability, regulatory compliance, and real-world device evaluation across care and research settings.

**5.** Harmonize overlapping data elements and reduce implementation burden.

We recommend ongoing efforts to streamline the USCDI element set by consolidating functionally similar data elements and promoting consistency across domains. Specifically:

- Align time-based metadata elements (e.g., “Performance Time,” “Date Medication Administered,” “Vital Signs Timestamps”) to avoid duplication and simplify implementation.
- Standardize the use of rationale or exception indicators (e.g., “Negation Rationale”) across applicable classes, rather than introducing unique variations.
- Consider merging overlapping encounter-related fields, such as Admission/Discharge DateTime and Encounter Time, into unified representations where clinically and operationally appropriate.

This type of harmonization will reduce interpretive variation, lower the burden of adoption for data submitters, and improve data quality and consistency across use cases.

Veeva supports the goals of the USCDI to create a more connected and interoperable health data ecosystem. As a trusted partner to life sciences organizations worldwide, we see significant opportunity to better align healthcare and research data through structured, standards-based approaches. *The Common Data Architecture (CDA) for Life Sciences™,* developed by Veeva, enables standardized and reusable data models across clinical development and regulatory workflows. It demonstrates how the industry

is already operationalizing these concepts at scale. We would welcome the opportunity to collaborate with ASTP on future iterations of USCDI, provide implementation insights from our work with research sponsors and sites, and support continued alignment between care delivery, research, and regulatory data exchange.

We would be pleased to answer any questions you may have regarding these comments. Please feel free to contact me directly at Anthony.Corso@veeva.com or (614) 401-2914 Ext. 102950.

Sincerely,

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