Altarum Institute Response to ASTP/ONC Standards Bulletin 2026-1

Specific Feedback on Draft USCDI v7

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Submitted by: Altarum Institute

Introduction

Altarum Institute appreciates the opportunity to provide feedback on Draft USCDI v7 in response to the specific questions posed in ASTP/ONC Standards Bulletin 2026-1. Our responses are informed by Altarum's direct, hands-on experience in public health data exchange spanning electronic case reporting, vital records modernization, immunization registry operations, laboratory reporting, and disease surveillance system implementation.

This submission reflects the combined expertise of Altarum's public health technology and informatics team, whose members bring deep experience in FHIR interoperability, standards development leadership through HL7 and the Helios FHIR Accelerator, and multi-state public health data exchange engagements coordinated across HL7, CDC, ASTP, and state health departments. The team's capabilities span eCR implementation, TEFCA adoption analysis, public health software and integration engineering, and over 30 years of collective experience in IT operations, data governance, vital records, birth defects, and newborn screening interoperability—including FHIR-based death messaging with CDC/NCHS, SMART-on-FHIR applications for birth certification, and coordination of IHE and HL7 FHIR Connectathons.

Altarum is broadly supportive of Draft USCDI v7 and its 30 proposed data element additions. Our recommendations are oriented toward strengthening the clinical and public health utility of these data elements to improve patient safety, reduce duplicative clinical burden, and enable the data foundation that supports chronic disease prevention and national health improvement consistent with the administration's Make America Healthy Again priorities.

> **Question 1:** *Suggestions for improvement in the data classes or elements in Draft USCDI v7, including: (a) Data class and element definitions, usage notes, and examples; and (b) Examples of code systems used by health IT developers and implementers to communicate data element scope.*

Response to Question 1

Adverse Event — Vocabulary Alignment with Public Health Reporting

The Adverse Event data element specifies SNOMED CT as the applicable vocabulary standard. While SNOMED CT is appropriate for clinical characterization, the primary public health adverse event reporting systems—the Vaccine Adverse Event Reporting System (VAERS) and the FDA Adverse Event Reporting System (FAERS/MedWatch)—use the Medical Dictionary for Regulatory Activities (MedDRA) terminology. Drawing on direct experience implementing electronic case reporting interfaces at Epic (where eCR pilots required mapping between clinical terminologies and public health reporting vocabularies), Altarum recommends that ASTP/ONC add a usage note acknowledging MedDRA as a commonly used vocabulary for adverse event

reporting to public health and regulatory destinations, and consider adding MedDRA as an optional applicable vocabulary standard.

Adverse Event Outcome — Vocabulary Standard Gap

We note that Adverse Event Outcome does not list an applicable vocabulary standard. While the definition provides examples (hospitalized, recovered, recovered with sequelae, death), the absence of a required vocabulary will likely lead to inconsistent implementation. We recommend specifying a vocabulary standard, such as the HL7 FHIR AdverseEvent outcome value set or a SNOMED CT subset, to ensure interoperable exchange of outcome data across systems.

Tobacco Use — Structured Observation Guidance

We recommend that the usage notes provide implementation guidance supporting the capture of product type, frequency of use, duration of use, and mode of consumption as distinct structured observations rather than a single composite field. This aligns with how population surveillance systems such as the Behavioral Risk Factor Surveillance System (BRFSS) collect tobacco data and enables more granular analysis for state tobacco control programs and clinical quality measures related to cessation counseling. In addition, Altarum supports aligning Tobacco Use with existing USCDI Alcohol Use and Substance Use data elements with the utilization of applicable vocabulary standards to promote consistency across USCDI implementations.

Deceased Indicator — Implementation Guidance

Altarum supports the inclusion of Deceased Indicator in USCDI v7 as this data element is utilized by both healthcare and public health institutions. In healthcare software systems, this indicator is utilized to deprecate patient records for both system efficiency and to prevent awkward situations like appointment reminders for deceased individuals. In both public health and healthcare, the deceased indicator is used for research purposes, to identify and correct deadly trends. It should be noted that, within vital records and FHIR-based mortality exchange, when a date of death is available, systems will typically convey it using Date of Death without a Deceased Indicator present. Altarum recommends that this usage be noted within USCDI guidance, that primarily the Deceased Indicator should be used to indicate that death is known even if the exact date is not yet available or is not being exchanged. This clarification is also important for perinatal and newborn contexts (e.g., birth reporting and birth defect surveillance), where documenting whether an infant is deceased can materially affect downstream reporting workflows, case ascertainment, and interpretation of outcomes—even when the exact date of death may not be present in the exchanging system.

Specimen Collection Method — Missing Vocabulary Standard

We note that Specimen Collection Method does not list an applicable vocabulary standard. This is a significant gap that will result in inconsistent coded representation across laboratory information systems and public health electronic laboratory reporting (ELR) destinations. Altarum's team, including engineers who have implemented HL7 v2 and FHIR-based laboratory interfaces at organizations ranging from individual hospitals to national health systems—has observed firsthand that the distinction between a nasopharyngeal swab and an anterior nares swab affects the sensitivity profile of respiratory pathogen tests. Without a standardized vocabulary, receiving public health systems cannot reliably interpret or validate specimen

metadata. We recommend specifying SNOMED CT as the applicable vocabulary standard, which includes a mature hierarchy for specimen collection procedures.

Immunization Status and Immunization Record Source — Value Set Guidance

We recommend that ASTP/ONC provide explicit guidance on the expected value sets for both Immunization Status and Immunization Record Source. For Status, the guidance should align with the FHIR Immunization resource status value set (completed, entered-in-error, not-done). For Record Source, the guidance should specify at minimum: provider-reported (new administration), historical (from external record), and patient-reported. This distinction is critical for immunization information system (IIS) deduplication logic and coverage rate estimation and should be harmonized with the HL7 v2 immunization messaging standard (VXU) field OBX-5 for information source and the FHIR Immunization.reportOrigin element.

> **Question 2:** *Should other existing Level 2 data elements be added to USCDI v7 instead of, or in addition to, those in Draft USCDI v7? If so, why?*

Response to Question 2

Yes. Altarum recommends the following Level 2 data elements be added to USCDI v7 in addition to those already proposed:

Travel History Location and Travel History Dates

Altarum strongly agrees with CDC and CSTE support for the inclusion of Travel History Location and Travel History Dates in USCDI standards. Travel history is foundational for healthcare and public health workflows. Within healthcare, travel history data elements support treatment and care coordination by providing critical context of potential disease exposures, to care providers when individuals move across settings (e.g., primary care to specialist care, surgery, ED/ICU). Travel history documents international and regional travel-associated risks (e.g., valley fever in the Southwest/California, regionally concentrated tickborne diseases, malaria exposure, and other geographically linked conditions) and can materially change diagnostic and treatment decisions. Within public health, Travel History is built into investigation and outbreak response as part of the national case notification messaging for 25+ reportable conditions enabling epidemiologists to better track disease outbreaks. The HL7 electronic case reporting (eCR) Implementation Guide supports travel history as structured data, and these elements are exchanged in production by thousands of eCR implementations sending tens to hundreds of thousands of thousands of records across the U.S. every day. For these reasons, Travel History Location and Travel History Dates should be included in a future version of USCDI.

Vaccination Administration Date

While Draft USCDI v7 commendably adds Immunization Status and Immunization Record Source, the discrete date of vaccine administration remains absent as a named data element. Although Performance Time in the Healthcare Information Attributes class could theoretically cover this case, it could also be interpreted to refer to when the order was placed or when the encounter occurred. A dedicated Vaccination Administration Date element would eliminate ambiguity for implementers and align with the specificity expected by immunization information systems. In addition to public health surveillance and compliance use cases, having an accurate administration date is important for clinical care because patients often do not remember when a vaccine was given. Exchanging the Vaccination Administration Date facilitates the appropriate

scheduling of follow-on doses and helps avoid unnecessary repeat vaccination. CDC has strongly supported this element across multiple USCDI comment cycles, emphasizing its importance for vaccination schedule tracking, public health surveillance, international travel compliance, and school entry requirements. The element is universally captured in production EHRs and exchanged via HL7 v2 immunization messages and FHIR Immunization resources.

Expanded Pregnancy Information (Estimated Date of Delivery, Pregnancy Outcome)

The current single Pregnancy Status element is insufficient for clinical care coordination and for public health uses including maternal mortality surveillance, birth defect reporting, and vital records modernization. In clinical workflows, pregnancy status plays a critical role in patient care, driving many clinical decisions from appropriate medications to medical imaging. Unfortunately, too often pregnancy status is outdated, which can create patient safety and decision-support issues. Within the public health space, CSTE, CDC, ACOG, and NACHC have all supported obtaining richer pregnancy data, and the HL7 FHIR Vital Records Birth and Fetal Death Reporting IG and the eCR IG support structured pregnancy data elements, demonstrating standards maturity. Adding Estimated Date of Delivery (EDD) and Pregnancy Outcome would better enable clinicians and downstream receiving systems to interpret whether pregnancy information is current and time-relevant, improving care transitions and reducing misclassification. At the same time, these elements materially improve the completeness and interpretability of public health reporting and surveillance by supporting pregnancy-aware case management (e.g., hepatitis B, syphilis, HIV), linking outcomes to pregnancies, and enabling more consistent vital records and birth defects data exchange across jurisdictions. We recommend ASTP/ONC consider establishing a dedicated Pregnancy Information data class for USCDI v7 or v8.

> **Question 3:** *What additional Level 2 data elements or USCDI+ data elements are appropriate for inclusion in USCDI v7, and why?*

Response to Question 3

USCDI+ Public Health Case Reporting and Laboratory Data Exchange

ASTP/ONC has opened USCDI+ datasets for Public Health Case Reporting and Laboratory Data Exchange for comment. Altarum recommends that mature elements from these datasets—particularly those already implemented in production eCR and ELR workflows—be systematically evaluated for USCDI inclusion. Creating a clear pathway from USCDI+ to USCDI Level 2 would signal to implementers that public health data exchange priorities are being addressed in the core standard, not only in domain-specific extensions. This aligns with the CDC's Public Health Data Strategy milestones, which call for defining data elements for core public health data sources in alignment with USCDI.

Exposure / Contact Information

Exposure and contact data are foundational to outbreak investigation, contact tracing, and case notification. The absence of standardized exposure data in EHR exchange has hampered automated case reporting workflows across multiple outbreaks. Investigators have repeatedly been forced to manually extract exposure information from clinical notes, as no structured, interoperable exchange mechanism existed. Recent measles and Legionnaires' disease

outbreaks illustrate the ongoing operational cost of this gap. The eCR Implementation Guide supports exposure data, and the USCDI+ Public Health Case Reporting dataset references these elements. We recommend that ASTP/ONC work with CDC and CSTE to define a minimal set of exposure data elements—prioritizing exposure type, exposure setting, and exposure date—for Level 2 advancement and future USCDI inclusion.

Address Use Period (Begin/End Dates)

CDC has recommended capturing the time period associated with a patient address to support public health reporting when assessing time of exposure. Current Address and Previous Address are in USCDI but lack temporal context. For environmental health investigations, lead exposure assessments, and geocoded disease surveillance, knowing when a patient lived at a particular address is essential. The FHIR Patient.address.period element already supports this concept, demonstrating standards readiness. We recommend advancement toward Level 2.

> **Question 4:** *Are there significant barriers to development, implementation, or use of any of these data elements that warrant a change in the final version of USCDI v7?*

Response to Question 4

Altarum supports inclusion of the 30 proposed data elements in the final USCDI v7, though Altarum does recommend clarification and implementation guidance for several of these data elements to promote consistent interoperability. The considerations below are offered in that spirit—as opportunities to strengthen definitions, vocabulary guidance, and adoption readiness—not as reasons to exclude elements from USCDI v7.

Elements Without Specified Vocabulary Standards (Moderate Risk)

Several proposed elements—including Adverse Event Outcome, Allergy Intolerance Criticality, Specimen Collection Method, Appointment, and Healthcare Agent—do not list applicable vocabulary standards. While this is not a roadblock to the elements themselves, the absence of required vocabularies creates a risk of inconsistent implementation. Different systems may encode the same concept differently, undermining the interoperability goal that USCDI is designed to achieve. We recommend that ASTP/ONC specify vocabulary standards for these elements before finalizing USCDI v7, or at minimum provide implementation guidance identifying commonly used code systems.

Nutrition Order — Implementation Maturity Consideration

While Nutrition Assessment and Nutrition Order address important clinical and public health needs, the FHIR NutritionOrder resource is less widely implemented in production systems than more commonly exchanged order patterns (for example, medication orders captured and exchanged via MedicationRequest and related medication workflows). For many implementers, medication ordering provides a familiar baseline for what a “minimum viable” order should include (e.g., who ordered it, what is being ordered, timing/schedule, status, and any patient-specific instructions). To reduce confusion and accelerate adoption, ASTP/ONC should consider adding brief usage guidance that clarifies the intended scope of Nutrition Order (e.g., enteral/parenteral nutrition vs. diet orders), the minimum set of fields expected for exchange, and how Nutrition Order relates to or differs from other order types in USCDI (particularly medication orders) so that organizations can implement consistently across care settings and during transitions between acute and post-acute care.

> **Question 5:** *ASTP/ONC seeks input on the Tobacco Use data element, including the optimal approach for representing this information in USCDI.*

Response to Question 5

Altarum strongly supports the expansion of Smoking Status into the broader Tobacco Use data element. The evolution reflects the changing landscape of nicotine and tobacco product use and is critical for chronic disease prevention, clinical quality measurement, and population health surveillance. We offer the following specific input on the optimal representation:

Structured Multi-Observation Approach

Tobacco Use should be represented as a set of distinct structured observations rather than a single composite field. At minimum, the following dimensions should be separately capturable: product type (cigarette, e-cigarette/vape, smokeless, cigar, hookah, nicotine pouch, etc.), frequency of use (daily, some days, former, never), duration of use (years of use, quit date if applicable), and mode of consumption (smoked, vaped, chewed, dissolved, etc.). This multi-observation approach aligns with how the Behavioral Risk Factor Surveillance System (BRFSS) tobacco use modules collect data at the population level and supports the granularity needed for state tobacco control program evaluation and resource allocation.

Dual Vocabulary Binding Is Appropriate

The proposed dual binding to LOINC and SNOMED CT is appropriate. LOINC provides observation codes (assessment panels and individual questions), while SNOMED CT provides the answer values (specific product types, use patterns). We recommend that ASTP/ONC provide specific guidance on recommended LOINC panels—such as the Tobacco Use panel (LOINC 72166-2 and related codes)—and the SNOMED CT hierarchies that differentiate between product types, to reduce variability in implementation.

Cannabis / Marijuana Scope Boundary

The expansion of Tobacco Use to include e-cigarettes and vaping devices raises an important boundary question: cannabis products that are smoked or vaped share delivery mechanisms with tobacco products but are classified differently for surveillance and regulatory purposes. As legal cannabis markets expand across states, clinicians and systems will encounter patients who use cannabis via the same devices used for nicotine delivery (vape pens, edibles with nicotine/cannabis combinations). We recommend that ASTP/ONC provide explicit scope guidance in the Tobacco Use usage notes:

- Tobacco Use should be scoped to nicotine and tobacco products consistent with the FDA's definition of tobacco products, which does not include cannabis/marijuana.
- Cannabis use (including smoked, vaped, and edible forms) should remain under the existing Substance Use data element.
- Combined-use products (e.g., tobacco wraps containing cannabis) should be documented under both elements as applicable, and implementation guidance should address this overlap.

This clarification is important because public health surveillance systems track tobacco and cannabis through different mechanisms and reporting frameworks. Conflating them in a single USCDI element would create data quality issues for both tobacco control programs and substance use monitoring.

Alignment with FDA Tobacco Product Definition

We recommend that the Tobacco Use definition explicitly reference the FDA's regulatory definition of tobacco products under the Family Smoking Prevention and Tobacco Control Act, which provides an authoritative scope boundary. This alignment ensures that USCDI's definition of tobacco use is consistent with the regulatory framework that governs product labeling, marketing, and surveillance at the federal level.

Closing

Altarum Institute appreciates ASTP/ONC's continued commitment to the transparent, collaborative USCDI expansion process and the opportunity to contribute public health perspectives to Draft USCDI v7. We are available to provide additional technical details, implementation evidence, or use case documentation for any of the areas identified in this response.

We look forward to continued collaboration through the ONDEC system, the HL7 standards development process, and the USCDI+ Public Health datasets to advance interoperable health data exchange in support of public health modernization.

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