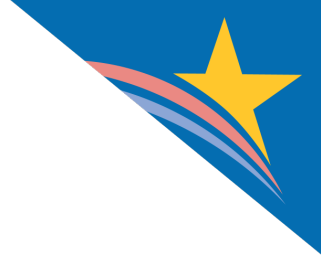


USCDI Version 4

November 3, 2023

Agenda

- Overview of USCDI as ONC Policy
- Review USCDI v4 new data elements
- USCDI Version Cadence
- ONDEC Submission System Update
- USCDI v5 Submission Cycle Update
- USCDI in the ONC Certification Program



Core Principles



Comprises a core set of data needed to support patient care and facilitate patient access using health IT

Establishes a consistent baseline of data for other use cases

Expands over time via a predictable, transparent, and collaborative **public** process

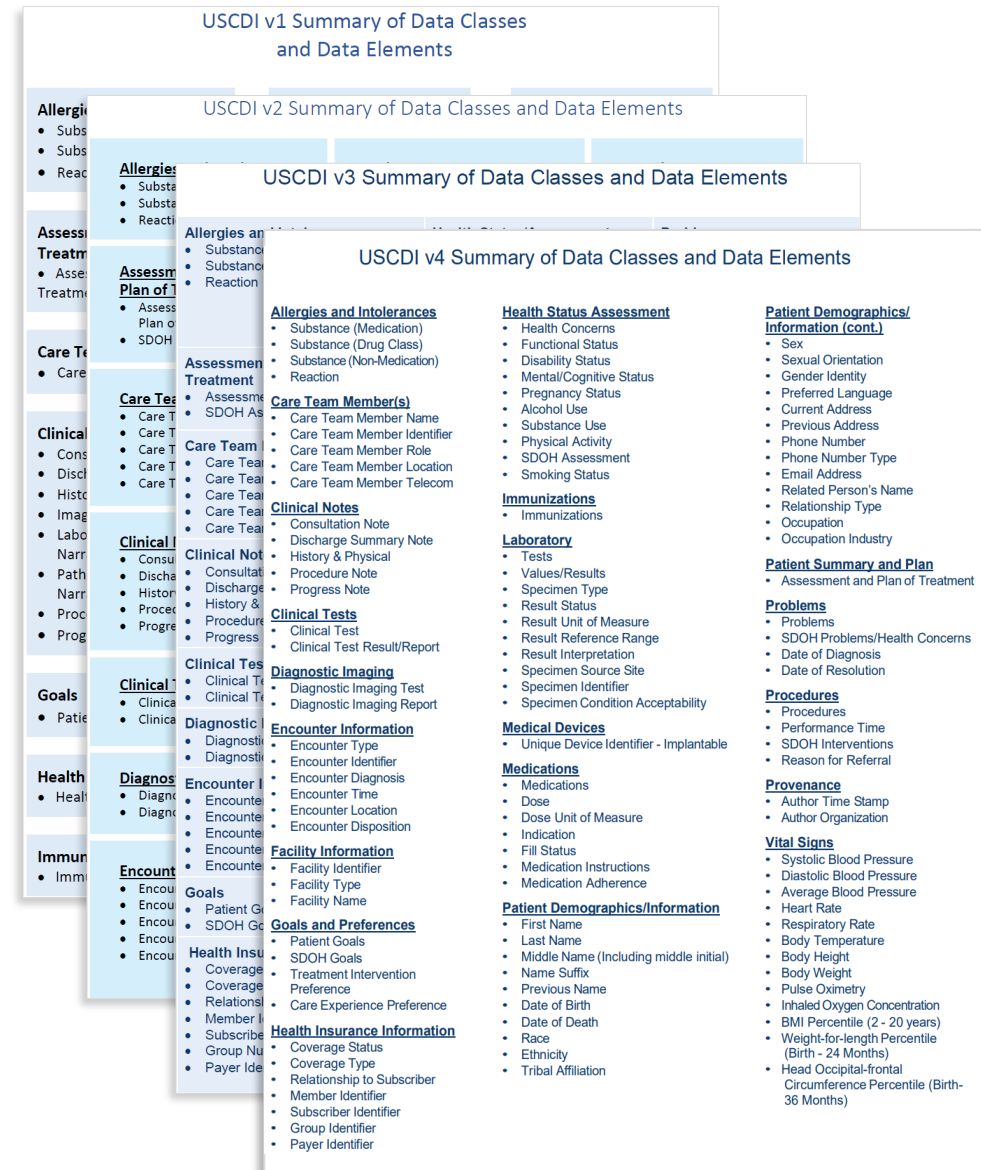
Why USCDI Matters

- Established in the ONC Cures Act Final Rule in 2020
- Required for new Certification Criterion (application programming interface (API) to access patient data, using FHIR® US Core
- USCDI v1 replaces the Common Clinical Data Set in existing Certification Criteria, using HL7® C-CDA or FHIR® US Core:
 - Transitions of Care documents (create, send, and receive)
 - Clinical Information reconciliation and incorporation
 - Patient View, Download, and Transmit their health data to a 3rd party
 - Electronic case reporting to public health agencies*
 - Create C-CDA document
 - Access to data via APIs
- USCDI also defines required data for other uses, such as CMS Patient Access and Payer-to-Payer API
- USCDI v3 proposed to be required in HTI-1 NPRM



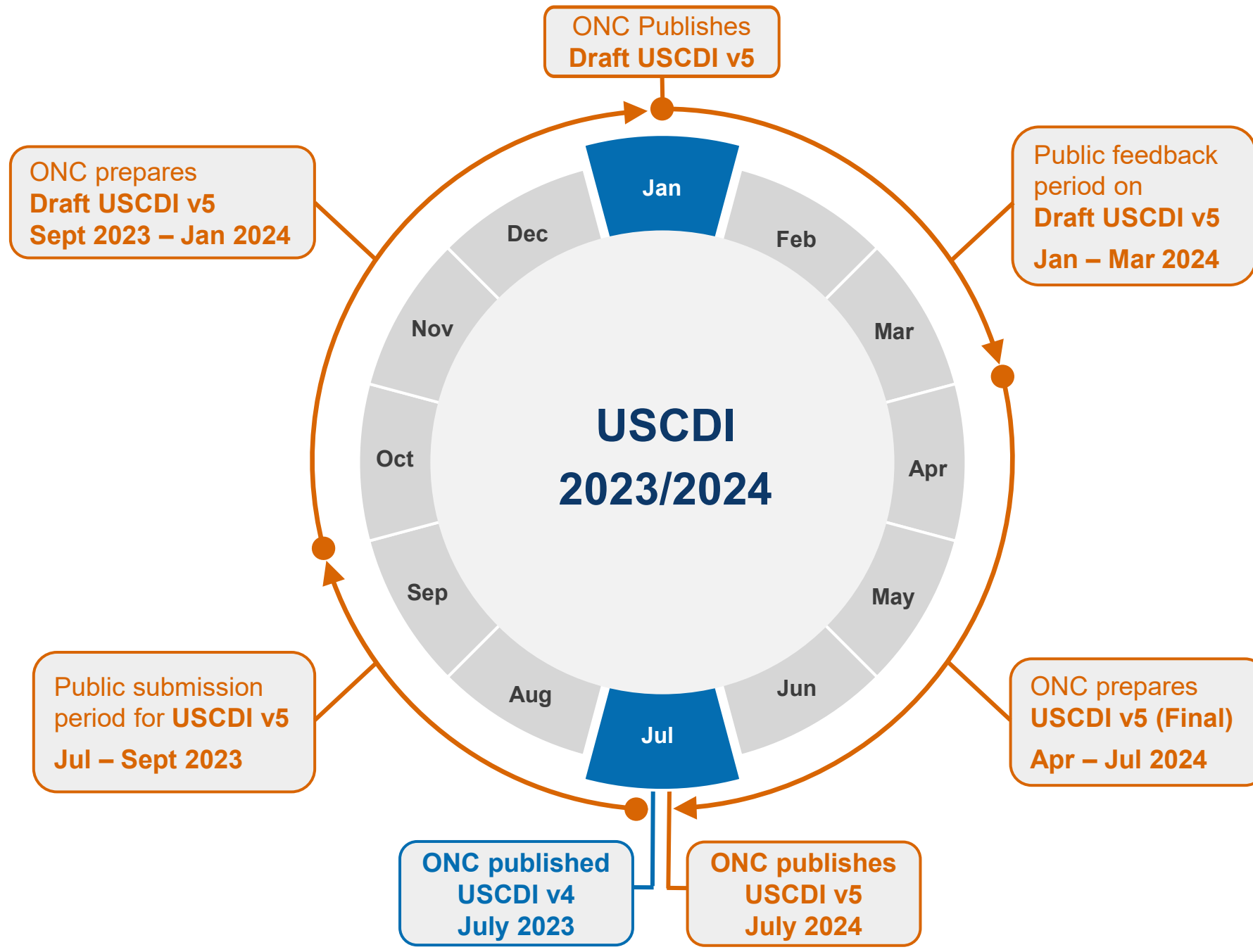
USCDI: Transparent, Predictable, Collaborative

- USCDI v1 is required by Cures Act Final Rule and added data classes clinical notes and provenance, and data elements pediatric vital signs and address
- USCDI v2 added three data classes and 22 data elements in support of advancing health equity (SOGI and SDOH)
- USCDI v3 added 24 data elements focused on factors promoting equity, reducing disparities and supporting public health data interoperability.
 - Proposed as new required version in Health Data, Technology, and Interoperability 1 (HTI-1), with an effective date of December 31, 2024
- USCDI v4 added 20 data elements including Alcohol, Substance Use and Physical Activity Assessments, Treatment Intervention and Care Experience Preferences, and Medication Adherence data elements





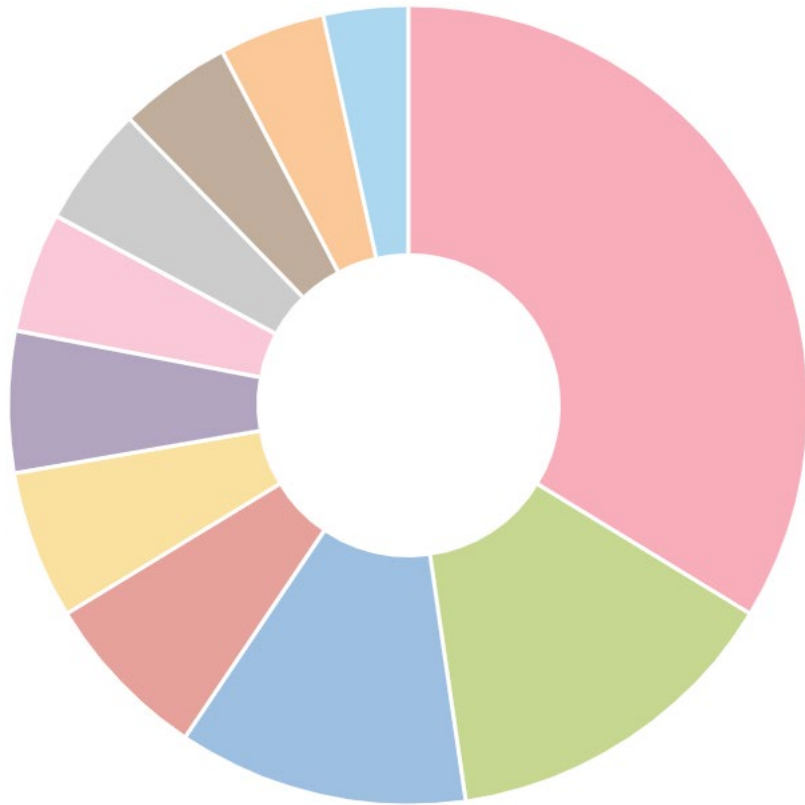
USCDI Update Process





Draft USCDI v5 Comment Process

Public Comments for USCDI Version 5

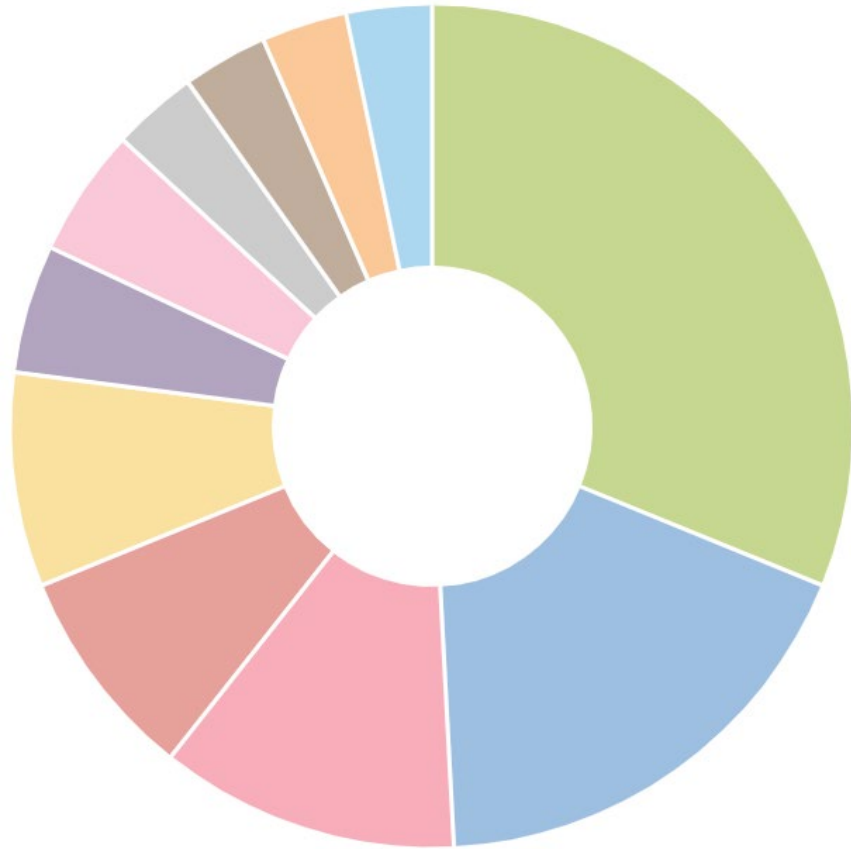


Comments Received
Total: **350**












Medications	49
Laboratory	41
Provenance	24
Patient Demographics/Information	21
Health Status Assessments	20
Pregnancy Information	17
Social Determinants of Health	17
Advance Directives	16
Immunizations	15
Clinical Notes	12
Other...	118



ONDEC Submissions for USCDI Version 5



Comments Received
Total: **61**

 Outcomes	19
 Medical Devices	11
 Health Status Assessments	5
 Vital Signs	5
 Encounter Information	3
 Medications	3
 Cancer Care	2
 Genomics	2
 Patient Demographics/Information	2
 Provenance	2
 Other...	7

Prioritization Criteria for New USCDI Data Elements

- Healthcare disparities and inequities
- Underserved communities
- Behavioral health
- Public health
- Key additions over past USCDI versions
- Modest burden for
 - Standards and implementation guide developers
 - Health IT developers
 - Providers and health systems implementing updates
- Aggregate lift for all new data elements



New Data Elements in USCDI v4

Allergies and Intolerances







- Substance (Non-Medication) 

Encounter Information




- Encounter Identifier  

New Data Class






Facility Information

- Facility Identifier  
- Facility Type  
- Facility Name  













Goals and Preferences

- Treatment Intervention Preference  
- Care Experience Preference  



Health Status Assessments

- Alcohol Use  
- Substance Use  
- Physical Activity  

Laboratory

- Result Unit of Measure  
- Result Reference Range  
- Result Interpretation  
- Specimen Source Site  
- Specimen Identifier  
- Specimen Condition Acceptability  

Medications

- Medication Instructions 
- Medication Adherence 

Procedures

- Performance Time 

Vital Signs

- Average Blood Pressure 

Allergies and Intolerances

- Substance (Medication)
- Substance (Drug Class)
- Substance (Non-Medication) **+**
- Reaction

Care Team Member(s)

- Care Team Member Name
- Care Team Member Identifier
- Care Team Member Role
- Care Team Member Location
- Care Team Member Telecom

Clinical Notes

- Consultation Note
- Discharge Summary Note
- History & Physical
- Procedure Note
- Progress Note

Clinical Tests

- Clinical Test
- Clinical Test Result/Report

Diagnostic Imaging

- Diagnostic Imaging Test
- Diagnostic Imaging Report

Encounter Information

- Encounter Type
- Encounter Identifier **+**
- Encounter Diagnosis
- Encounter Time
- Encounter Location
- Encounter Disposition

Facility Information **+**

- Facility Identifier **+**
- Facility Type **+**
- Facility Name **+**

Goals and Preferences **△**

- Patient Goals
- SDOH Goals
- Treatment Intervention Preference **+**
- Care Experience Preference **+**

Health Insurance Information

- Coverage Status
- Coverage Type
- Relationship to Subscriber
- Member Identifier
- Subscriber Identifier
- Group Number
- Payer Identifier

Health Status Assessments

- Health Concerns
- Functional Status
- Disability Status
- Mental/Cognitive Status
- Pregnancy Status
- Alcohol Use **+**
- Substance Use **+**
- Physical Activity **+**
- SDOH Assessment **>**
- Smoking Status

Immunizations

- Immunizations

Laboratory

- Tests
- Values/Results
- Specimen Type
- Result Status
- Result Unit of Measure **+**
- Result Reference Range **+**
- Result Interpretation **+**
- Specimen Source Site **+**
- Specimen Identifier **+**
- Specimen Condition Acceptability **+**

Medical Devices **△**

- Unique Device Identifier - Implantable **△**

Medications

- Medications
- Dose
- Dose Unit of Measure
- Indication
- Fill Status
- Medication Instructions **+**
- Medication Adherence **+**

Patient Demographics/ Information

- First Name
- Last Name
- Middle Name (Including middle initial)
- Name Suffix
- Previous Name
- Date of Birth
- Date of Death
- Race
- Ethnicity
- Tribal Affiliation
- Sex
- Sexual Orientation
- Gender Identity
- Preferred Language
- Current Address
- Previous Address
- Phone Number
- Phone Number Type
- Email Address
- Related Person's Name
- Relationship Type
- Occupation
- Occupation Industry

Patient Summary and Plan **△**

- Assessment and Plan of Treatment

Problems

- Problems
- SDOH Problems/Health Concerns
- Date of Diagnosis
- Date of Resolution

Procedures

- Procedures
- Performance Time **+**
- SDOH Interventions
- Reason for Referral

Provenance

- Author Organization
- Author Time Stamp

Vital Signs

- Systolic Blood Pressure
- Diastolic Blood Pressure
- Average Blood Pressure **+**
- Heart Rate
- Respiratory Rate
- Body Temperature
- Body Height
- Body Weight
- Pulse Oximetry
- Inhaled Oxygen Concentration
- BMI Percentile (2 - 20 years)
- Weight-for-length Percentile (Birth - 24 Months)
- Head Occipital-frontal Circumference Percentile (Birth - 36 Months)










ONDEC Changes

ONDEC Changes – USCDI v5 and Beyond

USCDI ONDEC (ONC New Data Element and Class) Submission System

The deadline for new submissions for USCDI v5 is September 20, 2023, at 11:59 p.m. EDT. Submissions after this date will be considered for USCDI v6.

How It Works

	<p>Search ONDEC for the same or similar data elements. You can connect with other submitters and collaborate to strengthen a submission by commenting on them rather than submitting a duplicate entry.</p> <p>Search within USCDI <input type="text"/> </p>
	<p>Step 1. Submit new data elements and classes</p> <p>Review Prep Sheet See questions and prepare content for your submission - updated to include more information on ONC's evaluation of submissions</p> <p>Start My Submission Registered ISA users only - login or create account here</p>
	<p>Step 2. ONC evaluates and assigns a level to each data element depending on the overall value, maturity and challenges to implementation</p> <p>• Level 0 • Level 1 • Level 2 View Leveling Criteria</p>
	<p>Step 3. ONC posts submitted data elements on the USCDI page by level</p> <p>Submitters will have an opportunity to add or change information which could change its level determination. Other stakeholders can review these submissions and contribute to their development through comments and collaboration with original submitters.</p>
	<p>Step 4. Deadline for new submissions for USCDI v5 is September 20, 2023 at 11:59 ET.</p>
	<p>Step 5. ONC anticipates publishing Draft USCDI v5 in January 2024.</p>

ONDEC Changes – Level Criteria Language

USCDI Data Element Leveling Criteria

ONC evaluates all submissions and assigns a level based on four criteria.

[Return to ONDEC](#)

- Level 2 data elements are most mature and are considered for future versions of USCDI.
- Level 1 and Level 0 determinations are used to identify areas of additional work needed to meet the criteria for a higher level and consideration for future versions of USCDI.

Submitters can provide updates with additional information to justify a higher level and consideration.

	Criterion #1 Maturity - Current Standards	Criterion #2 Maturity - Current Use	Criterion #3 Maturity - Current Exchange	Criterion #4 Use Case(s) - Breadth of Applicability
LEVEL 2	Data element is represented by a terminology standard or SDO-balloted technical specification or implementation guide.*	Data element is captured, stored, or accessed in multiple production EHRs or other HIT modules from more than one developer.	Data element is electronically exchanged between more than two production EHRs or other HIT modules of different developers using available interoperability standards.	Use cases apply to most care settings or specialties.
LEVEL 1	Data element is represented by a terminology standard or SDO-balloted technical specification or implementation guide.*	Data element is captured, stored, or accessed in at least one production EHR or HIT module.	Data element is electronically exchanged between two production EHRs or other HIT modules using available interoperability standards.	Use cases apply to several care settings or specialties.
LEVEL 0	Data element is not represented by a terminology standard or SDO-balloted technical specification or implementation guide.	Data element is captured, stored, or accessed in limited settings such as a pilot or proof of concept demonstration.	Data element is electronically exchanged in limited environments, such as connectathons or pilots.	Use cases apply to a limited number of care settings or specialties, or data element represents a specialization of other, more general data elements.

*Maturity-Standard criterion is the same for Level 1 and Level 2. Data elements meeting this level of maturity will be assigned Level 2 for this criterion.

USCDI Data Element Submission – Definition vs: Description

Data Element

Data Class Name (or select an existing USCDI Data Class from the drop-down menu) *

Data Element Name *

Data Element Definition *

This field contains a concise definition for this data element. Please enter additional information about the use case(s) in the field(s) below.





USCDI in the ONC Certification Program



USCDI in the ONC Certification Program

- USCDI advances interoperable data exchange for certified health IT by specifying a common set of data classes and elements.
- The ONC Cures Act Final Rule adopted USCDI v1 as a standard for use in the Certification Program.
- **Support for USCDI is included in many criteria in the Certification Program:**
 - § 170.315(b)(1) Transitions of care
 - § 170.315(b)(2) Clinical information reconciliation and incorporation
 - § 170.315(e)(1) View, download, and transmit to 3rd party
 - § 170.315(f)(5) Transmission to public health agencies electronic case reporting
 - § 170.315(g)(9) Application access - all data request
 - § 170.315(g)(10) - Standardized API for patient and population services

Standards Version Advancement Process (SVAP)

- Supporting interoperability with flexibility!
- Certified Health IT developers participating in the Certification Program can *voluntarily* update Health IT modules to updated versions of standards prior to adoption in regulation
- Limited to standards adopted in the certification criteria that meet the Real World Testing Condition and Maintenance of Certification requirement
- Annually, ONC collaborates with stakeholders and elicits public comment in the process to identify and approve newer standards ready for adoption



Source: [2023 SVAP Fact sheet \(healthit.gov\)](https://www.healthit.gov/2023-svap)

USCDI and SVAP 2023

The [Approved SVAP Standards for 2023](#) include the advancement of six standards.

The following SVAP 2023 approved standards related to USCDI are available for voluntary certification on September 11, 2023:

- United States Core Data for Interoperability (USCDI), Version 3, October 2022 Errata
- HL7® FHIR® US Core Implementation Guide STU 6.1.0 (June 2023)
- HL7 CDA® R2 Implementation Guide: C-CDA Templates for Clinical Notes R 2.1 Companion Guide, Release 4.1 (June 2023)



Testing USCDI in the Certification Program

The ONC Certification Program supports testing USCDI and related standards

Many certification criteria require support for USCDI

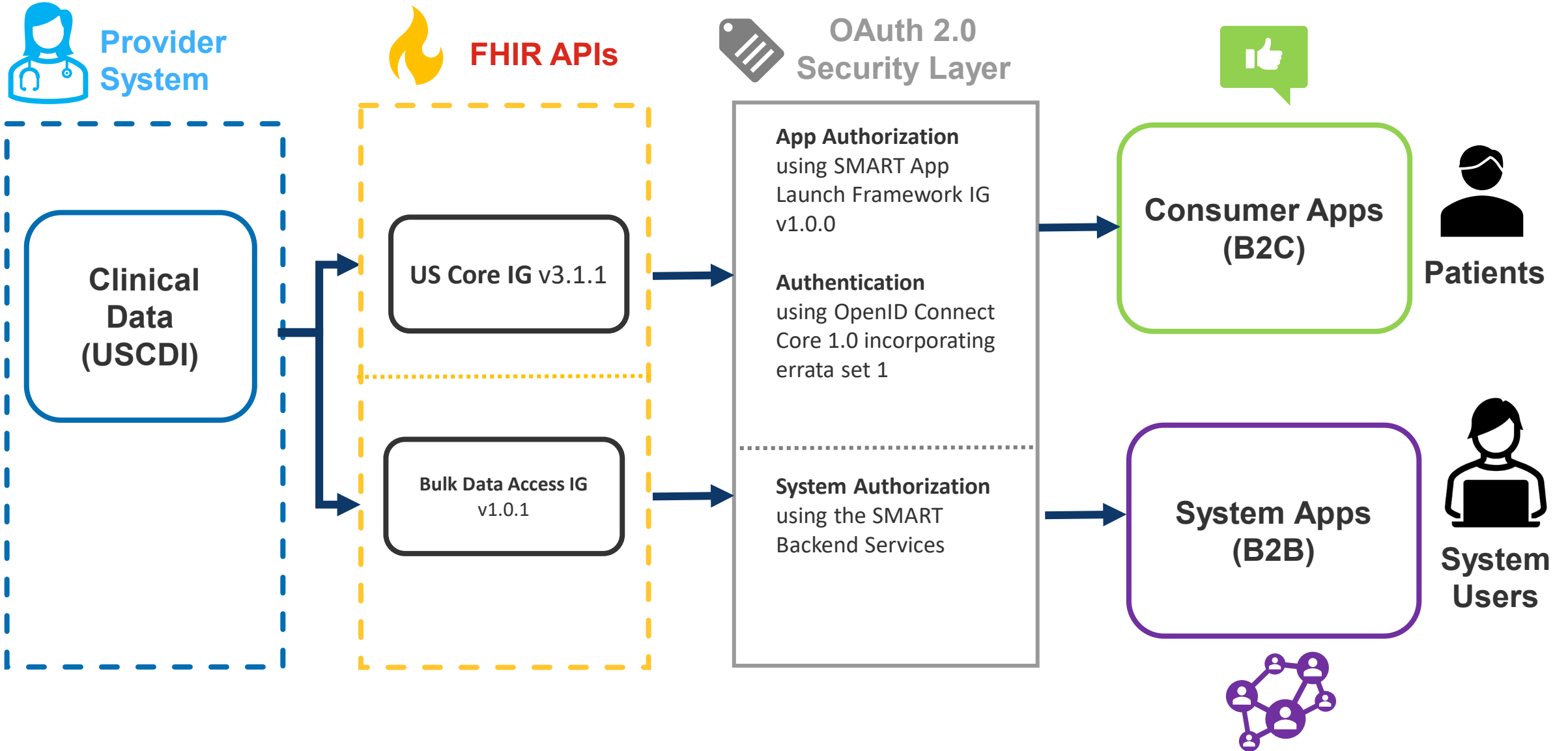
For example, § 170.315 (b)(1) "Transition of care" and § 170.315(g)(10) "Standardized API for patient and population services"

ONC maintains testing tools for testing support for USCDI and related standards

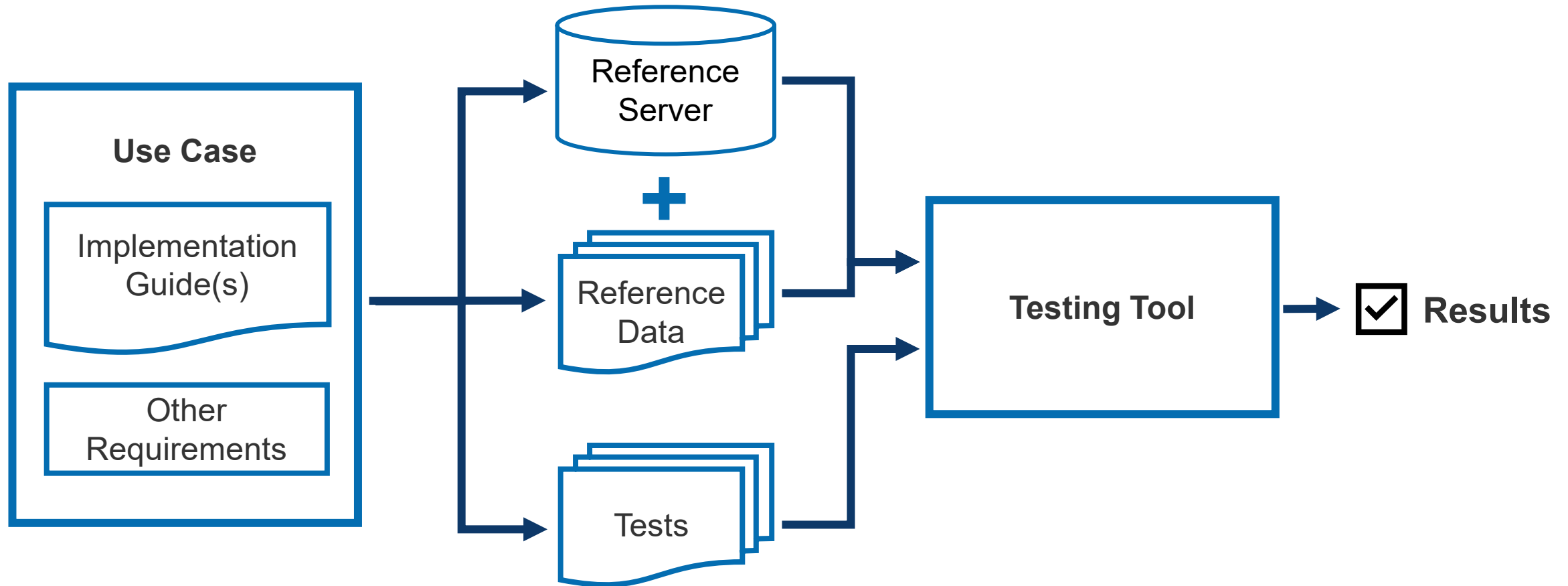
These testing tools include the [Inferno Framework](#) for FHIR testing and the [Edge Testing Tool](#) for C-CDA testing



Example criterion with USCDI: §170.315(g)(10) Standardized API for patient and population services



Testing Workflow



Step 1:
Define
requirements

Step 2:
Establish baseline
artifacts

Step 3:
Test system

Step 4:
Verify
conformance

Testing Tool Example: Inferno, part 1

ONC CERTIFICATION (G)(10) STANDARDIZED API

The ONC Certification (g)(10) Standardized API Test Kit is a testing tool for Health Level 7 (HL7®) Fast Healthcare Interoperability Resources (FHIR®) services seeking to meet the requirements of the Standardized API for Patient and Population Services criterion § 170.315(g)(10) in the 2015 Edition Cures Update rule.

Systems may adopt later versions of standards than those named in the rule as approved by the ONC Standards Version Advancement Process (SVAP). Please select which

Options

←

US Core Version

- US Core 3.1.1 / USCDI v1
- US Core 4.0.0 / USCDI v1
- US Core 5.0.1 / USCDI v2

SMART App Launch Version

- SMART App Launch 1.0.0
- SMART App Launch 2.0.0

Bulk Data Version

- Bulk Data 1.0.1
- Bulk Data 2.0.0

START TESTING

Figure: This screen for the Inferno test kit for the § 170.315(g)(10) criterion allows the tester to select which combinations of standards to test.

Testing Tool Example: Inferno, part 2

ONC Certification (g)(10) Standardized API V.3.8.1
US Core 3.1.1 / USCDI v1, SMART App Launch 1.0.0, Bulk Data 1.0.1

NEW SESSION

Preset: None

(g)(10) Standardized API

- 1 Standalone Patient App
- 2 Limited Access App
- 3 EHR Practitioner App
- 4 Single Patient API
- 7 Multi-Patient API
- ▼ 9 Additional Tests
 - 9.1 SMART Public Client Launch
 - 9.3 Token Revocation

1 Standalone Patient App - Full Access RUN TESTS ▶

This scenario demonstrates the ability of a system to perform a Patient Standalone Launch to a SMART on FHIR confidential client with a patient context, refresh token, OpenID Connect (OIDC) identity token, and use the GET HTTP method for code exchange. After launch, a simple Patient resource read is performed on the patient in context. The access token is then refreshed, and the Patient resource is read using the new access token to ensure that the refresh was successful. The authentication information provided by OpenID Connect is decoded and validated, and simple queries are performed to ensure that access is granted to all USCDI data elements.

- [SMART on FHIR \(STU1\)](#)
- [SMART on FHIR \(STU2\)](#)
- [OpenID Connect \(OIDC\)](#)

1.1 SMART on FHIR Discovery ▼

1.3 Standalone Launch With Patient Scope ▼

INFERN BUILT WITH V.0.4.18 | API

[Report Issue](#) | [Open Source](#) | [Download](#)

Figure: This screen shows the primary testing interface for the Inferno test kit for the § 170.315(g)(10) criterion.

Testing Tool Example: Inferno, part 3

11/1/23, 2:13 PM (g)(10) Standardized API Test Session

ONC Certification (g)(10) Standardized API Report - US Core 3.1.1 / USCDI v1, SMART App Launch 1.0.0, Bulk Data 1.0.1

PENDING	3.8.1	Nov 1, 2023, 2:13 PM
FINAL RESULT	VERSION	REPORT DATE

https://inferno.healthit.gov/suites/g10_certification/j7dK8heWFY3

✓ 1 Standalone Patient App - Full Access

INPUT	VALUE
url	https://inferno.healthit.gov/reference-server/r4
standalone_client_id	SAMPLE_CONFIDENTIAL_CLIENT_ID

Figure: This is an example of part of a testing results report generated by the Inferno test kit for the § 170.315(g)(10) criterion.



Office of the National Coordinator
for Health Information Technology

Contact ONC

Al Taylor, MD, Albert.Taylor@hhs.gov

Scott Bohon, Scott.Bohon@hhs.gov

Erin Little, Erin.Little@hhs.gov



Phone: 202-690-7151



Health IT Feedback Form:

<https://www.healthit.gov/form/healthit-feedback-form>



Twitter: [@onc_healthIT](https://twitter.com/onc_healthIT)



LinkedIn: [Office of the National Coordinator for Health Information Technology](https://www.linkedin.com/company/office-of-the-national-coordinator-for-health-information-technology)



Youtube:

<https://www.youtube.com/user/HHSONC>

HealthIT.gov

Subscribe to our weekly eblast
at [healthit.gov](https://www.healthit.gov) for the latest updates!



Enabling USCDI with FHIR US Core and C-CDA

USCDI Design Now and Future

Brett Marquard

Gay Dolin



Agenda

USCDI and HL7 Standards Development

US Core Enables USCDI

- History
- Mapping USCDI V4 and Profiling FHIR
- Terminology in Profiles
- Capabilities, Testing and Validation

C-CDA Enables USCDI

- History
- Mapping USCDI V4 and Templating C-CDA
- US Core and C-CDA Alignment
- Re-Balloting of C-CDA and New Publication Format

Speaker #1

Brett Marquard

- Principal, WaveOne Associates
- Extensive EHR experience
- Primary Editor, Argonaut Data Query IG / US FHIR Core IG
- Primary Editor, C-CDA, C-CDA Companion Guides
- Project Manager Argonaut
- brett@waveoneassociates.com



US Core Team

Gay Dolin MSN, RN

- Principal, Namaste Informatics LLC
- HL7 US Realm Program Manager
- Primary Editor, C-CDA, C-CDA Companion Guides, US Core
- gdolin@Namasterinformatics.com



Eric Haas MS, DVM

- President Health eData Inc
- Primary Editor US FHIR Core IG
- ehaas@healthedatainc.com



US Core Data for Interoperability



The USCDI is a standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange.

USCDI v4 Summary of Data Classes and Data Elements

Allergies and Intolerances

- Substance (Medication)
- Substance (Drug Class)
- Substance (Non-Medication)
- Reaction

Care Team Member(s)

- Care Team Member Name
- Care Team Member Identifier
- Care Team Member Role
- Care Team Member Location
- Care Team Member Telecom

Clinical Notes

- Consultation Note
- Discharge Summary Note
- History & Physical
- Procedure Note
- Progress Note

Health Status Assessment

- Health Concerns
- Functional Status
- Disability Status
- Mental/Cognitive Status
- Pregnancy Status
- Alcohol Use
- Substance Use
- Physical Activity
- SDOH Assessment
- Smoking Status

Immunizations

- Immunizations

Laboratory

- Tests
- Values/Results
- Specimen Type

Patient Demographics/ Information (cont.)

- Sex
- Sexual Orientation
- Gender Identity
- Preferred Language
- Current Address
- Previous Address
- Phone Number
- Phone Number Type
- Email Address
- Related Person's Name
- Relationship Type
- Occupation
- Occupation Industry

Patient Summary and Plan

- Assessment and Plan of Treatment

+ many more!

Our view on USCDI

It is **Data Policy**

- standards agnostic
- use case agnostic
- sets a **floor** for standardization
- allows for further standards development for specific use cases

US Core Implementation Guide

Foundational US guide that maps USCDI to FHIR

The screenshot displays the 'US Core Data for Interoperability USCDI V3' page. It features a blue header with the HL7 logo and 'US Core Implementation Guide 6.1.0 - STU6' text. A search icon and 'HL7 FHIR' logo are in the top right. A 'USCDI' badge is also present. The main content is a table with two sections: 'Allergies and Intolerances' and 'Assessment and Plan of Treatment'. The 'Allergies and Intolerances' section lists three categories: Substance (Medication), Substance (Drug Class), and Reaction, each linked to the 'US Core AllergyIntolerance Profile'. The 'Assessment and Plan of Treatment' section lists two categories: Assessment and Plan of Treatment, linked to the 'US Core CarePlan Profile', and SDOH Assessment, linked to the 'US Core Simple Observation Profile' and 'US Core Condition Problems and Health Concerns Profile'. A 'See Screening and Assessments Guidance' link is also provided. At the bottom, there are two numbered points regarding profile support and a reference to the Conformance Requirements page.

Category	US Core Profile
Allergies and Intolerances	US Core AllergyIntolerance Profile
•Substance (Medication)	US Core AllergyIntolerance Profile
•Substance (Drug Class)	US Core AllergyIntolerance Profile
•Reaction	US Core AllergyIntolerance Profile
Assessment and Plan of Treatment	US Core CarePlan Profile
•Assessment and Plan of Treatment	US Core CarePlan Profile
•SDOH Assessment	US Core Simple Observation Profile US Core Condition Problems and Health Concerns Profile

1. Profile Only Support: Systems may support *only* the US Core Profiles to represent clinical information.
2. Profile Support + Interaction Support: Systems may support *both* the US Core Profile content structure *and* the RESTful interactions defined for a resource.
For a detailed description of these different usages of US Core, see the [Conformance Requirements](#) page.



US Core

USCDI





ONC's Cures Act Final Rule

21st Century Cures Act: Interoperability, Information Blocking, and the ONC Health IT Certification Program

The patient is at the center of the 21st Century Cures Act. Putting patients in charge of their health records is a key piece of patient control in health care, and patient control is at the center of HHS' work toward a value-based health care system.

The ONC Cures Act Final Rule implements interoperability requirements outlined in the Cures Act. Patients need more power in their health care, and access to information is key to making that happen.

...in the rule...

Considering this and commenters' recommendations, we have adopted the **HL7 FHIR US Core Implementation Guide STU 3.1.0 (US Core IG)** implementation specification in § 170.215(a)(2). We note that we adopted the latest version of the US Core IG at the time of the final rule publication. The US Core IG defines the minimum conformance requirements for accessing patient data using **FHIR Release 4** (adopted in § 170.215(a)(1)), including profiled resources, operations, and search parameters for the Data Elements required in the USCDI implementation specification (adopted in § 170.213)

..



Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Proposed Rule

ONC's HTI-1 proposed rule seeks to implement provisions of the [21st Century Cures Act](#) and make updates to the [ONC Health IT Certification Program](#) (Certification Program) with new and updated standards, implementation specifications, and certification criteria. Implementation of the proposed rule's provisions will advance interoperability, improve transparency, and support the access, exchange, and use of electronic health information.

Key provisions of the proposed rule include:

- Implementing the Electronic Health Record Reporting for developers of certified health information technology
- Modifying and expanding exceptions in the [information sharing](#)

**Proposed rule
published: 4/18/2023**

We also propose to adopt the FHIR US Core Implementation Guide STU version 5.0.1 in § 170.215(b)(1)(ii). Based on the annual US Core release cycle, we believe US Core IG v6.0.0 will be published before ONC issues a final rule.^[13] Therefore, it is our intent to consider adopting the updated US Core IG v6.0.0 that supports the data elements and data classes in USCDI v3 since we propose to adopt USCDI v3 in this rule. Health IT systems that adopt this version of the US Core IG can provide the latest consensus-based capabilities for providing access to USCDI data classes and elements using a FHIR API.

Standards Version Advancement Process (SVAP)

2023 Approved SVAP Versions

The 2023 approved SVAP versions were announced July 12, 2023 and will be available for voluntary certification under the Certification Program on September 11, 2023. Once effective, any newer versions of approved standards replace existing approved standards from previous years. Updated test tools and test procedures for the criterion that leverage these standards will be made available in December 2023 for any developers looking to explore new certifications that will include these SVAP versions within their tested criteria.

§ 170.315(g)(10) - Standardized API for patient and population services	HL7® FHIR® US Core Implementation Guide STU 3.1.1, August 8, 2020	HL7® FHIR® US Core Implementation Guide STU 6.1.0, June 30, 2023  New 2023 SVAP Approved!	§ 170.215(a)(2)
	United States Core Data for Interoperability (USCDI), Version 1, July 2020 Errata	United States Core Data for Interoperability (USCDI), Version 3, October 2022 Errata New 2023 SVAP Approved!	§ 170.213

US CORE ENABLES USCDI



Profile-less FHIR



- You don't need profiles to interoperate with FHIR
 - Resources are “discrete” enough that mechanism to populate most elements is clear
- Approach
 - Populate/consume all elements you know, use HL7 or country-standard extensions for extras
 - Map to/from “recommended” terminologies as much as possible, populate CodeableConcept.text
 - Expose capabilities in Conformance resource

Base Condition Resource vs.



Name	Flags	Card.	Type
Condition	I TU		DomainResource
identifier	Σ	0..*	Identifier
clinicalStatus	?!	0..1	CodeableConcept
verificationStatus	?!	0..1	CodeableConcept
category	Σ I	0..*	CodeableConcept
severity	Σ I	0..1	CodeableConcept
code		Σ 0..1	CodeableConcept
subject	Σ	1..1	Reference(Patient Group)
encounter	Σ	0..1	Reference(Encounter)
onset[x]	Σ	0..1	
onsetDateTime			dateTime
onsetAge			Age
onsetPeriod			Period
onsetRange			Range
onsetString			string

abatement[x]	I	0..1	
abatementDateTime			dateTime
abatementAge			Age
abatementPeriod			Period
abatementRange			Range
abatementString			string
recordedDate	Σ	0..1	dateTime
recorder	Σ	0..1	Reference(Practitioner PractitionerRole Patient RelatedPerson)
asserter	Σ	0..1	Reference(Practitioner PractitionerRole Patient RelatedPerson)
assessment	I	0..*	Reference(ClinicalImpression DiagnosticReport Observation)
type		0..1	CodeableConcept
evidence	I	0..*	BackboneElement
code	Σ I	0..*	CodeableConcept
detail	Σ I	0..*	Reference(Any)
note		0..*	Annotation

Identification of the condition, problem or diagnosis
Condition/Problem/Diagnosis Codes (Example)

US Core Condition



Name	Flags	Card.	Type	Description & Constraints
Condition		0..*	Condition	Detailed information about conditions, problems or diagnoses
condition-assertedDate	S	0..1	dateTime	Date the condition was first asserted URL: http://hl7.org/fhir/StructureDefinition/condition-assertedDate
clinicalStatus	S	0..1	CodeableConcept	active recurrence relapse inactive remission resolved Binding: ConditionClinicalStatusCodes (required)
verificationStatus	S	0..1	CodeableConcept	unconfirmed provisional differential confirmed refuted entered-in-error Binding: ConditionVerificationStatus (required)
Slices for category	S	1..*	CodeableConcept	category codes Slice: Unordered, Open by pattern:\$this
category:us-core	S	1..*	CodeableConcept	problem-list-item health-concern Binding: US Core Problem or Health Concern (required)
category:sdoh	S	0..1	CodeableConcept	problem-list-item encounter-diagnosis Required Pattern: At least the following
coding		1..*	Coding	Code defined by a terminology system Fixed Value: (complex)
system		1..1	uri	Identity of the terminology system Fixed Value: http://hl7.org/fhir/us/core/CodeSystem/us-core-tags
code	S	1..1	CodeableConcept	Identification of the condition, problem or diagnosis Binding: US Core Condition Codes (extensible): Valueset to describe the actual problem experienced by the patient
onset[x]	S	0..1	Core Patient Profile	Estimated or actual date, date-time, or age
onsetDateTime			dateTime	S
onsetAge			Age	
onsetPeriod			Period	
onsetRange			Range	
onsetString			string	

US Core Implementation Guide

- Built from Argonaut requirements
- US Core profiles *supersede* Argonaut Data Query profiles for FHIR R4
 - Version 3.1.1 published June 2020
- HL7 balloted US Realm FHIR profiles
 - Supports *United States Core Data for Interoperability (USCDI)* which superseded the *Common Clinical Data Set*
 - Used by US stakeholders when implementing FHIR
 - Basis for creating further US Realm profiles.


...fun fact: the [Data Access Framework \(DAF\)](#) = ONC sponsored DAF effort on FHIR preceded the Argonaut guide!

US Core 6.1.0


- Support for **ONC's USCDI v3**
- Resolved 100+ trackers
- Updated [Change Log](#)
(6.1.0 errata to 6.0.0 to improve Sex guidance)
- Improved Conformance and Guidance sections

<http://hl7.org/fhir/us/core/>

US Core Data for Interoperability USCDI V3



Allergies and Intolerances	US Core AllergyIntolerance Profile
•Substance (Medication)	US Core AllergyIntolerance Profile
•Substance (Drug Class)	US Core AllergyIntolerance Profile
•Reaction	US Core AllergyIntolerance Profile
Assessment and Plan of Treatment	US Core CarePlan Profile US Core Simple Observation Profile US Core Observation Screening Assessment Profile US Core QuestionnaireResponse Profile
•Assessment and Plan of Treatment	US Core CarePlan Profile



16

USCDI to US Core Profile Mapping



USCDI Data Class/Element	US Core Profile
Patient Demographics	US Core Patient Profile US Core Observation Sexual Orientation Profile US Core Observation Sexual Orientation Profile US Core Observation Sexual Orientation Profile US Core Observation Occupation Profile
•First Name	US Core Patient Profile
•Last Name	US Core Patient Profile
•Previous Name	US Core Patient Profile
•Middle Name (including middle initial)	US Core Patient Profile
•Suffix	US Core Patient Profile
•Birth Sex	US Core Patient Profile US Core Birth Sex Extension
•Sex	US Core Patient Profile US Core Birth Sex Extension
•Date of Birth	US Core Patient Profile
•Date of Death	US Core Patient Profile
•Race	US Core Race Extension
•Ethnicity	US Core Patient Profile US Core Ethnicity Extension
•Tribal Affiliation	US Core Patient Profile US Core Tribal Affiliation Extension

US Core Terminology to Align with USCDI



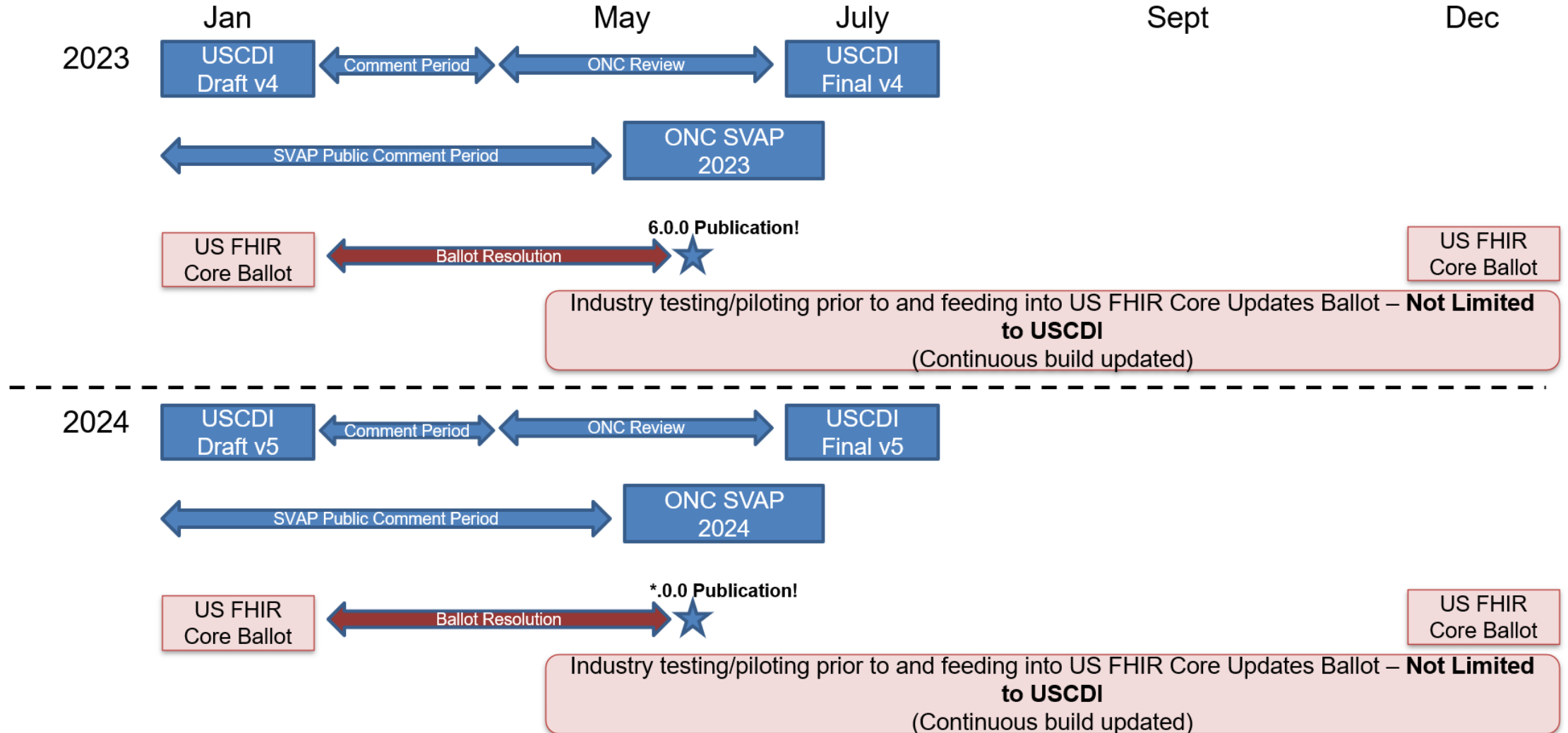
US Core Publication History

USCDI Version	US Core Version
v1	3.1.1
v1	4.0.0
v2	5.0.1
v3	6.1.0 – June 30, 2023!

<http://hl7.org/fhir/us/core/history.html>



- US FHIR Core will ballot every January
- The ballot will reflect HL7 update requests (JIRA) and response to USCDI v+1.
- Connect-a-thons/pilot testing precede US FHIR Core Update Ballot.

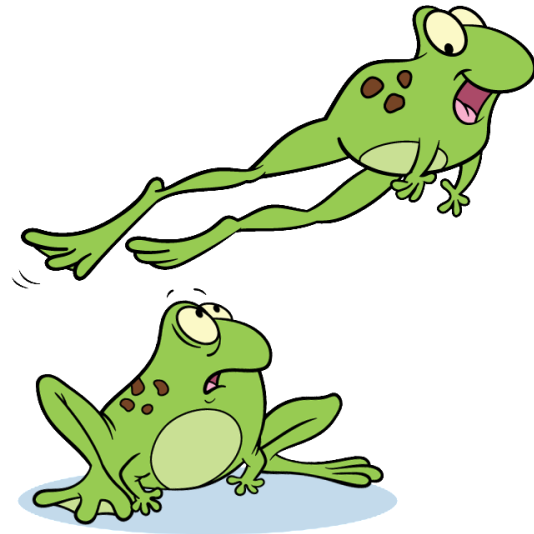




US CORE \neq ONC USCDI

US CORE $>$ ONC USCDI (HL7 new ballot)

US CORE $<$ ONC USCDI (ONC new rule)



Continuous game of leapfrog!

USCDI Patient Demographics -> US Core Patient

1. Start with FHIR Patient Resource
2. Decide which FHIR element need to supported.
3. Add Extensions to fill in gaps
 1. Race
 2. Ethnicity
 3. Gender identity
4. Define Terminology

Name	Flags	Card.	Type	Description & Constraints
Patient		0..*	Patient	Information about an individual or animal receiving health care services
race		0..1	(Complex)	(USCDI) US Core Race Extension URL: http://hl7.org/fhir/us/core/StructureDefinition/us-core-race
ethnicity		0..*	(Complex)	(USCDI) US Core ethnicity Extension URL: http://hl7.org/fhir/us/core/StructureDefinition/us-core-ethnicity
tribalAffiliation		0..*	(Complex)	(USCDI) Tribal Affiliation Extension URL: http://hl7.org/fhir/us/core/StructureDefinition/us-core-tribal-affiliation
birthsex		0..1	code	Birth Sex Extension URL: http://hl7.org/fhir/us/core/StructureDefinition/us-core-birthsex Binding: Birth Sex (required): Code for sex assigned at birth
sex		0..*	code	(USCDI) Sex Extension URL: http://hl7.org/fhir/us/core/StructureDefinition/us-core-sex Binding: Sex (required): Concepts limited to Male, Female, Patient Sex Unknown, asked-declined.
genderIdentity		0..*	CodeableConcept	(USCDI) The individual's gender identity URL: http://hl7.org/fhir/us/core/StructureDefinition/us-core-genderIdentity Binding: Gender Identity (extensible)
identifier		1..*	Identifier	(USCDI) An identifier for this patient
system		1..1	uri	(USCDI) The namespace for the identifier value
value	S	1..1	string	(USCDI) The value that is unique within the system.
name	S C	1..*	HumanName	(USCDI) A name associated with the patient us-core-6: At least name.given and/or name.family are present or, if neither is available, the Data Absent Reason Extension is present.
use		0..1	code	(USCDI) usual official temp nickname anonymous old maiden
family	S C	0..1	string	(USCDI) Family name (often called 'Surname')
given	S C	0..*	string	(USCDI) Given names (not always 'first'). Includes middle names
suffix		0..*	string	(USCDI) Parts that come after the name
period		0..1	Period	(USCDI) Time period when name was/is in use
telecom		0..*	ContactPoint	(USCDI) A contact detail for the individual
system	S	1..1	code	(USCDI) phone fax email pager url sms other Binding: ContactPointSystem (required): Telecommunications form for contact point

US Core Patient Introduction Section

Each Profile page includes a narrative description

13.145.1.1 Mandatory and Must Support Data Elements

The following data-elements must always be present ([Mandatory](#) definition) or must be supported if the data is present in the sending system ([Must Support](#) definition). They are presented below in a simple human-readable explanation. Profile specific guidance and examples are provided as well. The [Formal Views](#) below provides the formal summary, definitions, and terminology requirements.

Each Patient Must Have:

1. a patient identifier (e.g. MRN)
2. a patient name
3. a gender*

Each Patient Must Support:

1. a birth date
2. an address

Additional USCDI Requirements

For ONC's USCDI requirements, each Patient Must Support the following additional elements. These elements are included in the formal definition of the profile and the Patient examples.

1. contact detail (e.g. a telephone number or an email address)
2. a communication language
3. a race
4. an ethnicity
5. a tribal affiliation
6. sex*
7. gender identity*
8. date of death
9. previous address
10. previous name
11. suffix

*see guidance below

US Core Patient Introduction Section

and Profile specific implementation guidance

Profile specific implementation guidance:

- Note that *Previous Name, Suffix, and Previous address* are listed in the U.S. Core Data for Interoperability.
 - Suffix is represented using the `Patient.name.suffix` element.
 - Previous name is represented by setting `Patient.name.use` to "old" and providing an end date in `Patient.name.period` element if known
 - Previous address is represented by setting `Patient.address.use` to "old" and providing an end date in `Patient.address.period` element if known.
 - The patient example below demonstrates the usage of both of these elements.
- *US Core has reviewed and updated value sets based on input from the [HL7 Gender Harmony Project](#) which is modeling gender and sex information which includes data elements, value sets, code systems. When their work is complete, US Core will align with their recommendations. In the interim, the [FHIR specification](#) provides guidance and background for representing Administrative Gender, Sex assigned at Birth, and Gender Identity.
- The Patient's Social Security Numbers **SHOULD NOT** be used as a patient identifier in `Patient.identifier.value`. There is increasing concern over the use of Social Security Numbers in healthcare due to the risk of identity theft and related issues. Many payers and providers have actively purged them from their systems and filter them out of incoming data.

US Core Patient “Quick Start” Section

and supported FHIR RESTful Search API to meet patient access requirements

1. **SHALL** support fetching a Patient using the `_id` search parameter:

```
GET [base]/Patient[id]
```

Example:

1. GET [base]/Patient/1032702
2. GET [base]/Patient?_id=1032702

Implementation Notes: ([how to search by the logical id](#) of the resource)

2. **SHALL** support searching a patient by an identifier such as a MPI using the `identifier` search parameter:

```
GET [base]/Patient?identifier={system|}[code]
```

Example:

1. GET [base]/Patient?identifier=http://hospital.smarthealthit.org|1032702

Implementation Notes: Fetches a bundle containing any Patient resources matching the identifier ([how to search by token](#))

Problem Value Set (compositional)

Compositional : A definition of which codes are intended to be in the value set ("intensional")

12.165.1 ValueSet: US Core Condition Codes	
Official URL: http://hl7.org/fhir/us/core/ValueSet/us-core-condition-code	Version: 5.0.1
Active as of 2019-05-21	Computable Name: USCoreConditionCodes
<i>Copyright/Legal:</i> 1. This value set is based on ICD-9 and ICD-10 (IHTSDO), and distributed by agreement with IHTSDO. 1. ICD-9 and ICD-10 are copyrighted by IHTSDO. IHTSDO has authorized the development and distribution of this value set.	

12.165.1.1 Logical Definition (CLD)

This value set includes codes based on the following rules:

- Include these codes as defined in <http://snomed.info/sct>
 - Code** **Display**
 - [160245001](#) No current problems or disability
- Include codes from <http://snomed.info/sct> where concept is-a 404684003 (Clinical finding (finding))
- Include codes from <http://snomed.info/sct> where concept is-a 243796009 (Context-dependent categories)
- Include codes from <http://snomed.info/sct> where concept is-a 272379006 (Events)
- Include all codes defined in <http://hl7.org/fhir/sid/icd-10-cm>
- Include all codes defined in <http://hl7.org/fhir/sid/icd-9-cm>

Smoking Status (enumerated)

Value Set Members

Expanded Code List

View Toggle Clear Page 1 of 1 20 View 1 - 8 of 8

Code	Descriptor	Code System	Version	Code System OID
~ <input type="text"/> x	~ <input type="text"/> x	~ <input type="text"/> x	~ <input type="text"/> x	~ <input type="text"/> x
266919005	Never smoked tobacco (finding)	SNOMEDCT	2023-09	2.16.840.1.113883.6.96
266927001	Tobacco smoking consumption unknown (finding)	SNOMEDCT	2023-09	2.16.840.1.113883.6.96
428041000124106	Occasional tobacco smoker (finding)	SNOMEDCT	2023-09	2.16.840.1.113883.6.96
428061000124105	Light tobacco smoker (finding)	SNOMEDCT	2023-09	2.16.840.1.113883.6.96
428071000124103	Heavy tobacco smoker (finding)	SNOMEDCT	2023-09	2.16.840.1.113883.6.96
449868002	Smokes tobacco daily (finding)	SNOMEDCT	2023-09	2.16.840.1.113883.6.96
77176002	Smoker (finding)	SNOMEDCT	2023-09	2.16.840.1.113883.6.96
8517006	Ex-smoker (finding)	SNOMEDCT	2023-09	2.16.840.1.113883.6.96

View Page 1 of 1 20 View 1 - 8 of 8

CapabilityStatements

[US Core Server CapabilityStatement](#)

This Section describes the expected capabilities of the US Core Server actor which is responsible for providing responses to the queries submitted by the US Core Requestors.

[US Core Client CapabilityStatement](#)

The Section describes the expected capabilities of the US Core Client which is responsible for creating and initiating the queries for information about an individual patient.

Conforming Server Expectations

7.1.1.2.16 Patient

Supported Profiles: [US Core Patient Profile](#)

Supported Profiles

Reference Policy: `resolves`

Profile Interaction Summary:

- **SHALL** support `search-type`, `read`.
- **SHOULD** support `vread`, `history-instance`.
- **MAY** support `create`, `update`, `patch`, `delete`, `history-type`.

Fetch and Search Criteria:

- A Server **SHALL** be capable of returning a Patient resource using:
`GET [base]/Patient/[id]`
- A Server **SHALL** be capable of supporting the following `_revinclud`
Provenance:target - `GET [base]/Patient?[parameter=value]&_rev`

Supported Searches

Search Parameter Summary:

Conformance	Parameter	Type
SHALL	<code>_id</code>	token
SHALL	<code>identifier</code>	token
SHALL	<code>name</code>	string

Search Parameter Combination Summary:

Conformance	Parameter Combination	Types
SHOULD	<code>birthdate+ family</code>	date+string
SHALL	<code>birthdate+ name</code>	date+string
SHOULD	<code>family+ gender</code>	string+token
SHALL	<code>gender+ name</code>	token+string

Validation



The Office of the National Coordinator for Health Information Technology



Inferno Framework is a rigorous and extensible testing development framework for HL7[®] FHIR[®] and beyond.

This is an instance of Inferno hosted by ONC for purposes of testing for the ONC Health IT Certification Program and to support community-driven health IT standards development projects. You can build your own tests using Inferno Framework and host your own local instance of Inferno by following the instructions in "Inferno Development Framework" below.

ONC HOSTED TESTS AND UTILITIES

ONC Health IT Certification Program

ONC maintains and hosts an open source certification testing kit for systems seeking to meet the requirements of the Standardized API for Patient and Population Services criterion § 170.315(g)(10) in the 2015 Edition Cures Update.

(g)(10) Standardized API Test Kit

↓ Download

(Legacy) Inferno Program Edition

↓ Download

INFERNO DEVELOPMENT FRAMEWORK

Inferno Framework

The Inferno Framework is a standards conformance testing framework. You can use it to develop tests for your own use cases, like HL7 FHIR implementation Guide conformance testing.

The building blocks of Inferno Framework include 'Inferno Core' and 'Test Kits'. You can get started building your own tests using the 'Test Kit' template repository on Github [here](#).

Learn More



Testing and Community Feedback

- Testing
 - Formal Events at HL7 "Connectathons"
 - Reference Implementations supporting the published profiles
 - Informal pilots
- Feedback
 - Certifiers
 - Testers
 - Other Implementers
 - FHIR Community



United States Core Data for Interoperability (USCDI)

The United States Core Data for Interoperability (USCDI) is a standardized set of health data classes and constituent data elements for nationwide, interoperable health information exchange. Review the [USCDI Fact Sheet](#) to learn more.

A USCDI Data Class is an aggregation of Data Elements by a common theme or use case.

A USCDI Data Element is a piece of data defined in USCDI for access, exchange or use of electronic health information.

USCDI ONC New Data Element & Class (ONDEC) Submission System

With the publication of USCDI v4, ONC is accepting submissions for new data elements. The deadline for USCDI v5 submissions and comments is **September 20, 2023 at 11:59 p.m. ET**. Submissions received after this date will be considered for USCDI v6.



USCDI v4 added 20 data elements and one data class to USCDI v3. Please reference the [USCDI v4 standard document](#) and the [ONC Standards Bulletin 23-2](#) for details. To review the prioritization criteria ONC used to select the USCDI v4 data elements, refer to the [ONC Standards Bulletin 22-2](#). ONC is accepting submissions for new data elements through the **ONDEC** system and feedback on existing data elements until Wednesday, September 20, 2023 at 11:59 p.m. ET.

[USCDI v4](#)



Enabling USCDI with C-CDA

USCDI Design Now and Future

Gay Dolin MSN, RN



Speaker #2

Gay Dolin MSN, RN

- Principal, Namaste Informatics LLC
- HL7 US Realm Program Manager
- HL7 SDWG Co-Chair
- Healthcare Terminologist
- Primary Editor, C-CDA, C-CDA Companion Guides, US Core
- gdolin@NamasteInformatics.com



C-CDA Team



Brett Marquard

- Principal, WaveOne Associates
- Extensive EHR experience
- Primary Editor, Argonaut Data Query IG, US FHIR Core IG
- Primary Editor, C-CDA, C-CDA Companion Guides
- Project Manager Argonaut
- Brett@waveoneassociates.com



Jean Duteau

- CTO, Dogwood Health Consulting
- HL7 TSC Chair
- HL7 Cross Group Projects WG (CGP) Co-Chair
- Primary Editor, C-CDA
- jean.duteau@dogwoodhealthconsulting.com



Benjamin Flessner

- Senior Software Engineer, Availity
- Co-chair HL7 Structured Documents
- Editor, C-CDA, C-CDA on FHIR, C-CDA Companion Guide
- FHIR Data Warehouse Architect
- FHIR IG development
- Care Everywhere Architect
- Benjamin.Flessner@availity.com



Rosemary Hofstede

- Consultant, Duteau Design Inc
- Editor, C-CDA
- rosemary@duteaudeesign.com



C-CDA: Over 4.8 Billion Documents Exchanged Annually!

Statistic Source: CareEquality¹



Image Source: American Nurse Journal²

~ 400 million per month
~ 12 million per day



C-CDA ENABLES USCDI





US Core

USCDI

C-CDA

Consolidated CDA (C-CDA) - History

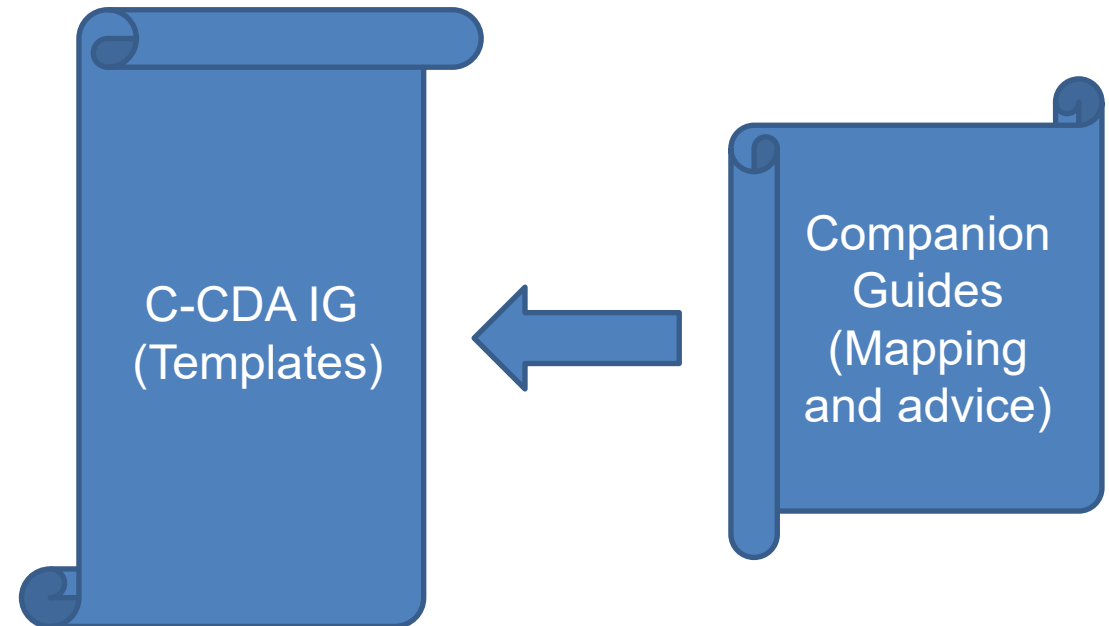
- 2007: Continuity of Care Document (CCD) was first published
- 2007-2010: 10+ Common Clinical Document Types published
- 2011: Consolidated CDA release 1.0 migrated the Common Clinical Document Types into one IG to re-use and align templates
- 3 new versions, 4 Companion Guides, 5 Supplemental Guides, many errata later...

[C-CDA Product Page](#)

....it Grew!

C-CDA and Companion Guides Relationship

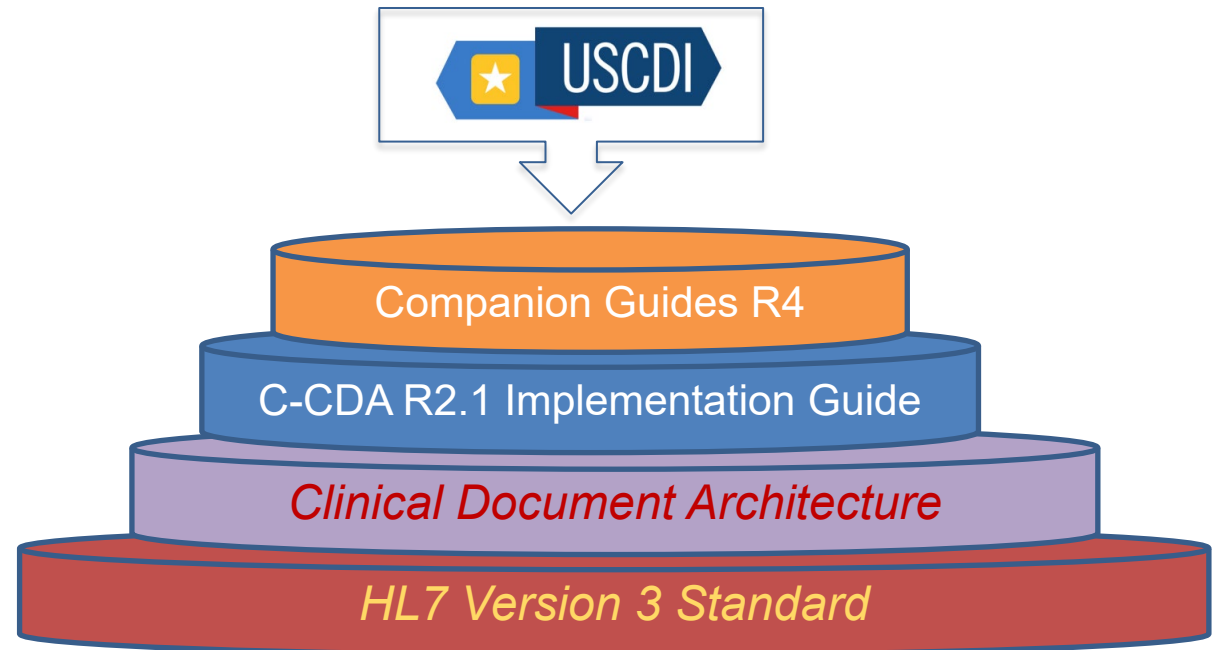
- Companion Guide Release 1 and 1.1 covered MU1 and MU2 guidance
 - Provided CDA Guidance from the base standard and explained the CDA templating approach
 - Provided implementation needed guidance identified through CDA-IATs
 - Pointed to which templates and what elements within the templates met the MU1 and 2 Rulings
 - No new templates



C-CDA and Companion Guides Relationship

Companion Guide Release 4.1 covers USCDI v3 (1-3):

- Bolster base standard, implementation and CDA templating approach guidance
- Provide **mapping to existing C-CDA templates** and elements that represent USCDI Data classes and elements
- Provide additional text guidance
- To more explicitly represent USCDI Data classes and elements:
 - **Contains** specializations or new versions of existing **C-CDA templates**
 - **Contains new templates**



C-CDA Companion Guides

C-CDA guides that maps USCDI to CDA

USCDI Version	Companion Guide Release
v1	<u>C-CDA Companion Guide Release 2</u>
v2	<u>C-CDA Companion Guide Release 3</u>
v3	<u>C-CDA Companion Guide Release 4.1</u>

USCDI v3: C-CDA Companion Guide R4.1

_readme

CDAR2_IG_CCDA_COMPANION_R4.1_STU_2023JUN

CDAR2_IG_CCDA_COMPANION_R4.1_STU_2023JUN_AppxA

CDAR2_IG_CCDA_COMPANION_R4.1_STU_2023JUN_AppxB

- Main Volume:
 - Text Guidance
 - Mapping Tables
- Appendix A:
 - Templates covering USCDI v1-v3 related to C-CDA R2.1 Templates
- Appendix B:
 - Templates covering the USCDI UDI Data Class Elements

CDAR2_IG_CCDA_COMPANION_R4.1_2023JUN



HL7 CDA® R2 Implementation Guide:

C-CDA Templates for Clinical Notes STU Companion Guide

Release 4.1 (US Realm)

Standard for Trial Use

June 2023

Standards Version Advancement Process (SVAP)

2023 Approved SVAP Versions

The 2023 approved SVAP versions were announced July 12, 2023 and will be available for voluntary certification under the Certification Program on September 11, 2023. Once effective, any newer versions of approved standards replace existing approved standards from previous years. Updated test tools and test procedures for the criterion that leverage these standards will be made available in December 2023 for any developers looking to explore new certifications that will include these SVAP versions within their tested criteria.

Certification Criteria	Current Standard Version(s)	Approved Standards for 2023	Regulatory Text Citation
§ 170.315(b)(1) - Transitions of care; § 170.315(b)(2) - Clinical information reconciliation and incorporation; § 170.315(b)(9) - Care plan; § 170.315(e)(1) - View, download, and transmit to 3rd party; § 170.315(g)(9) - Application access - all data request	HL7® CDA R2 Implementation Guide: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 2 - US Realm, October 2019	HL7® CDA R2 Implementation Guide: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 4.1 - US Realm, June 2023	§ 170.205(a)(5)

Data Classes and Elements Added in USCDI v3

Health Insurance Info ★ <ul style="list-style-type: none">• Coverage Status = ↑• Coverage Type = ↑• Relationship to Subscriber = +• Member Identifier +• Subscriber Identifier +• Group Number +• Payer Identifier +	Health Status/Assessments ★ <ul style="list-style-type: none">• Functional Status § = ↑• Disability Status = ↑• Mental/Cognitive Status = ↑ §• Pregnancy Status 🗺️ = ↑	Laboratory <ul style="list-style-type: none">• Specimen Type + 🗺️• Result Status + 🗺️
Medications <ul style="list-style-type: none">• Dose § +• Dose Unit of Measure § +• Indication § +• Fill Status § +	Patient Demographics/ Information <ul style="list-style-type: none">• Date of Death §• Tribal Affiliation = ↑• Related Person's Name §• Relationship Type §• Occupation = 🗺️• Occupation Industry = 🗺️	Procedure Reason for Referral §

★ New Data Classes = Equity Based ↑ Underserved 🗺️ Public Health + Add'l USCDI Needs § ONC Cert

C-CDA R3 and USCDI v4

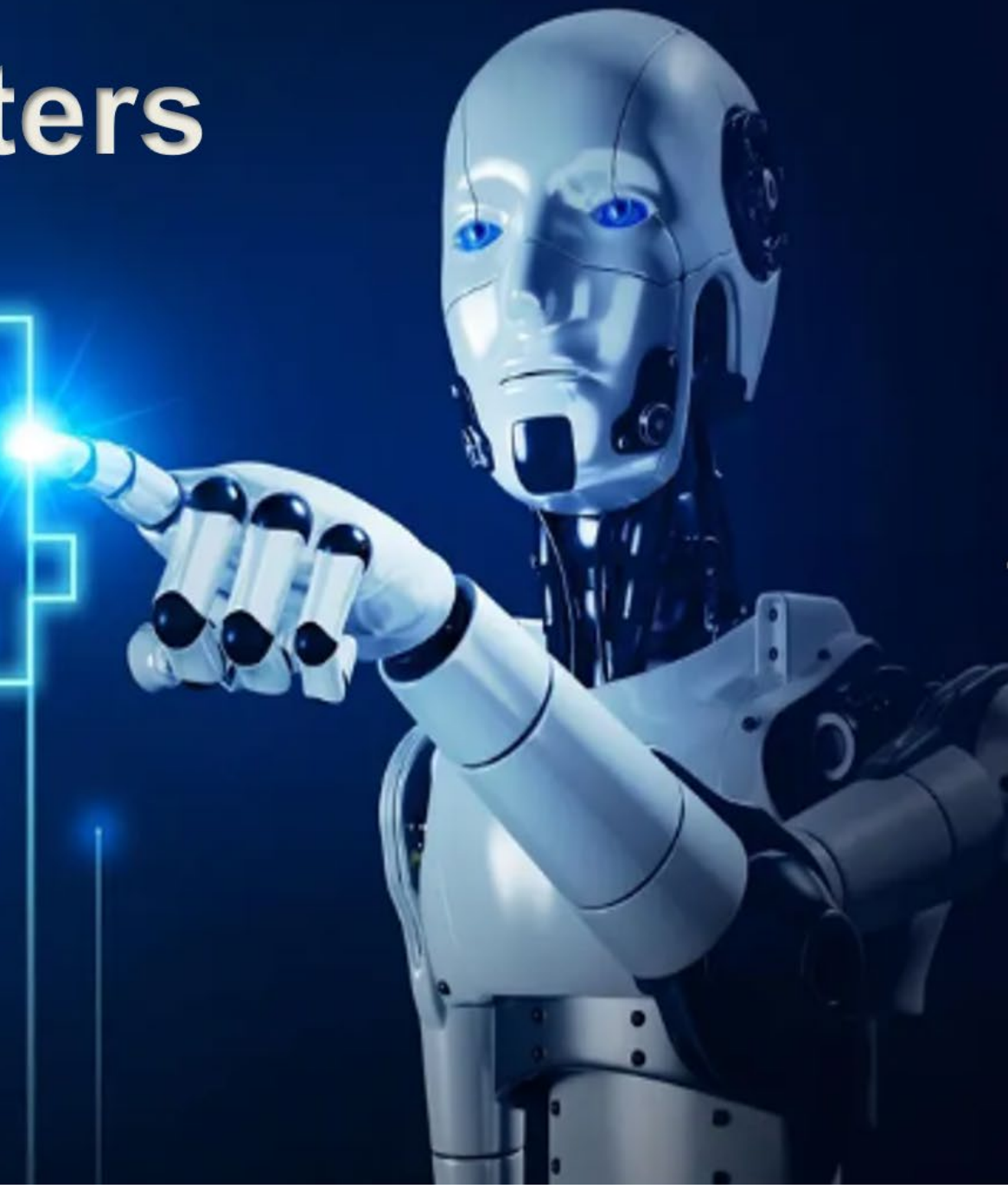
USCDI Version	C-CDA R3 Ballot with USCDI Design through V4
V4	C-CDA 3.0 (New Build Preparing for Ballot – January 2024)

C-CDA Will be balloted for the first time since 2015

- C-CDA + USCDI in one web-based publication
- In a Web Format Similar to FHIR IGs

CDA Publishing Enters

2024



C-CDA and USCDI v4 and Beyond: Web Pub

January 2024: The next ballot of full C-CDA (with USCDI v4 Design) will be in a Web Publication similar to FHIR, using HL7's Structure Definition method

Why?

Structure Definition

- Same underlying tech stack across HL7
- Same Look and Feel across standards
- Inherent Validation
- Logical versioning style
- SD makes (new) implementation easier in systems because SD are computer processable
- Ease updates

Traditional

- **Traditional tooling produces increasingly unwieldy word documents that are transformed to pdfs which often introduce broken links**
- Multiple Documents
- Lack of Same underlying tech stack across HL7

C-CDA R3 Ballot – Re-Organize and Align

- Eliminate or add C-CDA templates/profiles where needed to mirror US Core or industry need/use
- Opportunity to increase alignment with US Core
- Incorporate USCDI v1-v3 design and mappings from Companion Guides R1-4.1
- Add USCDI v4 new design and mappings
- **WEB PUBLICATION!!**



Web Publication Preview

[Consolidated CDA 3.0](#)

The screenshot shows the HL7 International Consolidated CDA 3.0.0 - CI Build web page. The header includes the HL7 logo, the title 'Consolidated CDA 3.0.0 - CI Build', and a search icon. A green navigation bar contains links for IG Home, Table of Contents, Information, How To Read, Downloads, Additional Guidance, Artifact Index, Terminology, and Change Log. Below the navigation bar, there is a breadcrumb trail 'Table of Contents > IG Home Page' and a yellow warning box stating that the content is a continuous build for version 3.0.0 and is based on the current content of a GitHub repository. The main content area is titled '1 IG Home Page' and contains a table with the following information:

Official URL: http://hl7.org/cda/us/ccda/ImplementationGuide/h17.cda.us.ccda	Version: 3.0.0
Draft as of 2023-10-29	Computable Name: CCDA

Below the table, the section '1.1 Introduction' is displayed. It describes the Consolidated Clinical Document Architecture (C-CDA) guide and its purpose. It lists 'Header Constraints' (US Realm Header, Patient Generated Document) and 'Document Types' (Care Plan, Consultation Note, Continuity of Care Document, Discharge Summary, History and Physical, Operative Note, Procedure Note, Progress Note, Referral Note, Transfer Summary, Unstructured Document). A yellow sidebar on the right contains a table of contents for the introduction section, listing: Introduction, Background, This Project, Acknowledgements, and C-CDA Primary Authors.

C-CDA R3 and USCDI V4

Data Classes and Data Elements Added to USCDI v4

Allergies and Intolerances <ul style="list-style-type: none">• Substance (Non-Medication)	Encounter Information <ul style="list-style-type: none">• Encounter Identifier	New Data Class Facility Information <ul style="list-style-type: none">• Facility Identifier• Facility Type• Facility Name
Goals <ul style="list-style-type: none">• Treatment Intervention Preference• Care Experience Preference	Health Status Assessments <ul style="list-style-type: none">• Alcohol Use• Substance Use• Physical Activity	Laboratory <ul style="list-style-type: none">• Result Unit of Measure• Result Reference Range• Result Interpretation• Specimen Source Site• Specimen Identifier• Specimen Condition Acceptability
Medications <ul style="list-style-type: none">• Medication Instructions• Medication Adherence	Procedures <ul style="list-style-type: none">• PerformanceTime	Vital Signs <ul style="list-style-type: none">• Average Blood Pressure

Design and Alignment Approach - Design

Data element understanding process:

- Review Definitions
- Understand the policy intent for healthcare exchange
- Learn what and how vendors currently capture the data element
- Determine what is already defined in the standards
- Detailed mapping analysis to FHIR/US Core
- Detailed mapping analysis to CDA/C-CDA

US Core and C-CDA USCDI Alignment and Design Approach

US Core runs the first 'lap'



Design and Alignment Approach - Implement

Implement:

- Propose designs iteratively
- Build draft US Core profiles
- Build draft C-CDA templates
- Value sets: Re-use or build and bind to common value sets
- Review with work groups
- Revise as per consensus
- Prepare ballot version

C-CDA R3 USCDI v4 Highlights

Existing – Add flag to existing elements

Data Classes and Data Elements Added to USCDI v4

Allergies and Intolerances <ul style="list-style-type: none">• Substance (Non-Medication)	Encounter Information <ul style="list-style-type: none">• Encounter Identifier	New Data Class Facility Information <ul style="list-style-type: none">• Facility Identifier• Facility Type• Facility Name
Goals <ul style="list-style-type: none">• Treatment Intervention Preference• Care Experience Preference	Health Status Assessments <ul style="list-style-type: none">• Alcohol Use• Substance Use• Physical Activity	Laboratory <ul style="list-style-type: none">• Result Unit of Measure• Result Reference Range• Result Interpretation• Specimen Source Site• Specimen Identifier• Specimen Condition Acceptability
Medications <ul style="list-style-type: none">• Medication Instructions• Medication Adherence	Procedures <ul style="list-style-type: none">• PerformanceTime	Vital Signs <ul style="list-style-type: none">• Average Blood Pressure

C-CDA R3 USCDI v4 Highlights

Existing – Add flag to existing elements – Example: Procedure Performance time

This structure is derived from [Procedure](#)

Name	Flags	Card.	Type	Description & Constraints						
Procedure			Procedure	XML Namespace: urn:hl7-org:v3 Elements defined in Ancestors: @nullFlavor, realmCode, typeId, templateId, @classCode, @moodCode, id, code, @negationInd, text, statusCode, effectiveTime, priorityCode, languageCode, methodCode, approachSiteCode, targetSiteCode, subject, specimen, performer, author, informant, participant, entryRelationship, reference, precondition, sdtcPrecondition2, sdtcInFulfillmentOf1 Instances of this type are validated by templateId <i>Slice: Unordered, Open by value:root, value:extension</i>						
Slices for templateId		1..*	II							
templateId:procedure		1..1	II							
@root		1..1	oid, uuid, ruid	Required Pattern: 2.16.840.1.113883.10.20.22.4.14						
@extension		1..1	st	Required Pattern: 2022-06-01						
@classCode		1..1	cs							
@moodCode		1..1	cs	Fixed Value: EVN						
id		1..*	II							
code	C	1..1	CD	Binding: US Core Procedure Codes (preferred) <table border="1"> <thead> <tr> <th>Additional Bindings</th> <th>Purpose</th> <th>Documentation</th> </tr> </thead> <tbody> <tr> <td>Social Determinants of Health Procedures</td> <td>Preferred Binding</td> <td>For Social Determinant of Health Interventions</td> </tr> </tbody> </table>	Additional Bindings	Purpose	Documentation	Social Determinants of Health Procedures	Preferred Binding	For Social Determinant of Health Interventions
Additional Bindings	Purpose	Documentation								
Social Determinants of Health Procedures	Preferred Binding	For Social Determinant of Health Interventions								
originalText	C	0..1	ED	should-originalText: SHOULD contain originalText should-reference: SHOULD contain reference						
reference	C	0..1	TEL	4515-19206: This reference/@value **SHALL** begin with a '#' and **SHALL** point to its corresponding narrative (using the approach defined in CDA Release 2, section 4.3.5.1) (CONF:4515-19206).						
@value		0..1	url							
statusCode		1..1	CS							
@code		1..1	cs	Binding: ProcedureAct.statusCode (required)						
effectiveTime	C	1..1	IVL_TS	(USCDI) Performance Time should-value: SHOULD contain value Indicates historical procedure or an instance of a procedure where precision may be only a date or even a year.						
@value		0..1	ts	Indicates when a procedure started						
low		0..1	IVXB_TS	Indicates when a procedure ended						
high		0..1	IVXB_TS							

C-CDA R3 USCDI v4 Highlights

Derive a new template from an existing one (add vocab bindings and guidance)

Data Classes and Data Elements Added to USCDI v4

Allergies and Intolerances <ul style="list-style-type: none">• Substance (Non-Medication)	Encounter Information <ul style="list-style-type: none">• Encounter Identifier	New Data Class Facility Information <ul style="list-style-type: none">• Facility Identifier• Facility Type• Facility Name
Goals <ul style="list-style-type: none">• Treatment Intervention Preference• Care Experience Preference	Health Status Assessments <ul style="list-style-type: none">• Alcohol Use• Substance Use• Physical Activity	Laboratory <ul style="list-style-type: none">• Result Unit of Measure• Result Reference Range• Result Interpretation• Specimen Source Site• Specimen Identifier• Specimen Condition Acceptability
Medications <ul style="list-style-type: none">• Medication Instructions• Medication Adherence	Procedures <ul style="list-style-type: none">• PerformanceTime	Vital Signs <ul style="list-style-type: none">• Average Blood Pressure

C-CDA R3 USCDI v4 Highlights

Derive a new template from an existing one – Example: Alcohol and Substance Use

- Derive from the Existing Assessment Scale and Assessment Scale Supporting Observation Templates
 - Add vocabulary bindings for Alcohol and Substance Use
 - Bolster guidance for screening and assessments
 - Re-uses Gravity value sets
 - Guidance will align with US Core

20.86.1 Logical Model: Assessment Scale Observation

Official URL: http://hl7.org/cda/us/ccda/StructureDefinition/AssessmentScaleObservation	Version: 3.0
Draft as of 2023-10-21	Computable Name: AssessmentScaleObservation
Other Identifiers: id: urn:hl7ii:2.16.840.1.113883.10.20.22.4.69:2022-06-01	

An assessment scale is a collection of observations that together can yield a calculated or non-calculated summary evaluation of a one or more conditions. Examples include the Braden Scale (assesses pressure ulcer risk), APACHE Score (estimates mortality in critically ill patients), Mini-Mental Status Exam (assesses cognitive function), APGAR Score (assesses the health of a newborn), Glasgow Coma Scale (assesses coma and impaired consciousness), and WE CARE (Well Child Care, Evaluation, Community Resources, Advocacy, Referral, Education - a clinic-based screening and referral system developed for pediatric settings).

When an Assessment Scale Observation is contained in a Problem Observation, a Social History Observation or a Procedure instance that is Social Determinant of Health focused, that Assessment scale **MAY** contain assessment scale observations that represent question and answer pairs from SDOH screening instruments that are represented in LOINC. Note that guidance on the use of LOINC in assessment scales already exists in Assessment Scale Observation constraints and Assessment Scale Supporting Observations constraints.

Usage:

- Use this Logical Model: Disability Status Observation, Functional Status Observation, Functional Status Section, Health Concern Act... [Show 7 more](#)

20.86.1.1 Formal Views of Profile Content

Description of Profiles, Differentials, Snapshots and how the different presentations work.

Name	Flags	Card.	Type	Description & Constraints
Observation			Observation	XML Namespace: urn:hl7-org:v3 Elements defined in Ancestors: @nullFlavor, realmCode, typeId, templateId, @classCode, @moodCode, @negationInd, id, code, derivationExpr, text, statusCode, effectiveTime, priorityCode, repeatNumber, languageCode, value, interpretationCode, methodCode, targetSiteCode, subject, specimen, performer, author, informant, participant, entryRelationship, reference, precondition, sdtcPrecondition2, referenceRange, sdtcInFulfillmentOf1 Instances of this type are validated by templateId <i>Slice: Unordered, Open by value:root, value:extension</i>
Slices for templateId		1..*	II	
templateId:assessment-scale-obs		1..1	II	
@root		1..1	oid, uuid, ruid	Required Pattern: 2.16.840.1.113883.10.20.22.4.69
@extension		1..1	st	Required Pattern: 2022-06-01

C-CDA R3 USCDI v4 Highlights

New Templates

Data Classes and Data Elements Added to USCDI v4

Allergies and Intolerances <ul style="list-style-type: none">• Substance (Non-Medication)	Encounter Information <ul style="list-style-type: none">• Encounter Identifier	New Data Class Facility Information <ul style="list-style-type: none">• Facility Identifier• Facility Type• Facility Name
Goals <ul style="list-style-type: none">• Treatment Intervention Preference• Care Experience Preference	Health Status Assessments <ul style="list-style-type: none">• Alcohol Use• Substance Use• Physical Activity	Laboratory <ul style="list-style-type: none">• Result Unit of Measure• Result Reference Range• Result Interpretation• Specimen Source Site• Specimen Identifier• Specimen Condition Acceptability
Medications <ul style="list-style-type: none">• Medication Instructions• Medication Adherence	Procedures <ul style="list-style-type: none">• PerformanceTime	Vital Signs <ul style="list-style-type: none">• Average Blood Pressure

C-CDA R3 USCDI v4 Highlights

New Template – Example:

Care Experience Preference

- Vocabulary binding only at Observation.code (aka the “Question”)
- Answers allow text to capture the person’s words
- This template could be contained in any location, suggested examples:
 - Advance Directives section or entries
 - Procedure Activity
 - Social History Section

20.93.1 Logical Model: Care Experience Preference

Official URL: http://hl7.org/cda/us/ccda/StructureDefinition/CareExperiencePreference	Version: 3.0
Draft as of 2023-10-21	Computable Name: CareExperiencePreference
Other Identifiers: id: urn:hl7ii:2.16.840.1.113883.10.20.22.4.509:2024-01-01	

This Care Experience Preference template represents a person’s care preferences during their care and treatment. Examples include, but are not limited to religious preferences, dislikes and fears, and thoughts and feelings to be shared. This template does not represent actual order, but holds observations about wishes. These observations may inform the placement of future orders. While observation.code is encoded to support system queries, the answers represented at observation.value are likely to be text. Precondition.Criterion is recommended to represent the situations when a person would prefer the stated care experiences, such as during childbirth or interventional procedures. This template may be used directly in any section, such as Care Plan Document Sections, Social History, or Advance Directives, and may be used inside any entry such as Procedure or Medication Activity.

Usage:

- This Logical Model is not used by any profiles in this Implementation Guide

20.93.1.1 Formal Views of Profile Content

Description of Profiles, Differentials, Snapshots and how the different presentations work [↗](#).

Name	Flags	Card.	Type	Description & Constraints
Observation		1..1	Observation	XML Namespace: urn:hl7-org:v3 Elements defined in Ancestors: @nullFlavor, realmCode, typeId, templateId, @classCode, @moodCode, @negationInd, id, code, derivationExpr, text, statusCode, effectiveTime, priorityCode, repeatNumber, languageCode, value, interpretationCode, methodCode, targetSiteCode, subject, specimen, performer, author, informant, participant, entryRelationship, reference, precondition, sdtcPrecondition2, referenceRange, sdtcInFulfillmentOf1 Base for all types and resources Instances of this type are validated by templateId should-precondition: SHOULD contain precondition <i>Slice: Unordered, Open by value:root, value:extension</i>
<i>Slices for templateId</i>				
templateId:care-experience-pref		1..1	II	
@root		1..1	oid, uuid, ruid	Required Pattern: 2.16.840.1.113883.10.20.22.4.509
@extension		1..1	st	Required Pattern: 2024-01-01
@classCode		1..1	cs	Fixed Value: OBS
@moodCode		1..1	cs	Fixed Value: INT
id		1..*	II	
code		1..1	CD	Care Experience Preference
@code		0..1	cs	Required Pattern: 95541-9
@codeSystem		0..1	oid, uuid, ruid	Required Pattern: 2.16.840.1.113883.6.1
value		1..1		Most of the time, the value will be a string representing the person’s words.
value			ED	
value			CD	

C-CDA R3 USCDI v4 Highlights

New Template – Example:

Medication Adherence

- Vocabulary binding @value (aka “answers”)
- [Medication Adherence](#) (SNOMED CT)
 - Complies with drug therapy (1156699004)
 - Unknown (qualifier value) (261665006)
 - Drugs - total non-compliance (275927006)
 - Drugs - partial non-compliance (275928001)
 - Medication therapy compliance variable (457831000124109)
 - Non-compliance of drug therapy (702565001)
- Contained in the Medication Activity Template

20.144.1 Logical Model: Medication Activity

Official URL: <http://hl7.org/cda/us/ccda/StructureDefinition/MedicationActivity> | Version: 3.0
Draft as of 2023-10-21 | Computable Name: MedicationActivity
Other Identifiers: id: urn:hl7ii:2.16.840.1.113883.10.20.22.4.16:2014-06-09

Element	Cardinality	Type	Base
sequenceNumber	0..1	IVL_I	
act	1..1	SubstanceAdministeredAct	Base for all types and resources
entryRelationship:adherence	0..*	EntryRelationship	(USCDI) Medication Adherence
@typeCode	1..1	CS	Fixed Value: COMP
observation	1..1	MedicationAdherence	Base for all types and resources
entryRelationship:signature	0..*	EntryRelationship	(USCDI) Medication Instructions
@typeCode	1..1	CS	Fixed Value: COMP
substanceAdministration	1..1	MedicationFreeTextSig	Base for all types and resources
precondition	0..*	Precondition	
@typeCode	1..1	CS	Fixed Value: PRCN
criterion	1..1	PreconditionforSubstanceAdministration	Base for all types and resources

...


Element	Cardinality	Type	Base
Slices for templateId	1..*	II	
templateId:med-adherence	1..1	II	
@root	1..1	oid, uuid, ruid	Required Pattern: 2.16.840.1.113883.10.20.22.4.508
@extension	1..1	st	Required Pattern: 2023-05-01
@moodCode	1..1	CS	Fixed Value: EVN
id	1..*	II	
code	1..1	CS	Adherence to prescribed medication instructions [Reported]
@code	1..1	CS	Required Pattern: 71799-1
@codeSystem	1..1	oid, uuid, ruid	Required Pattern: 2.16.840.1.113883.6.1
statusCode	1..1	CS	
effectiveTime	1..1	IVL_TS	
value	1..1	CD	
@code	1..1	CS	Binding: Medication Adherence (extensible)
informant	0..*	Informant	(USCDI) "The person or organization that provided the information about the medication adherence."


USCDI Table



US Core Data for Interoperability USCDI



Allergies and Intolerances 	
•Substance (Medication)	Allergy - Intolerance Observation
•Substance (Drug Class)	Allergy - Intolerance Observation
•Substance (Non-Medication)	Allergy - Intolerance Observation
•Reaction	Allergy - Intolerance Observation

Care Team Members 	
•Name	Care Team Member Act
•Identifier	Care Team Member Act
•Location	Care Team Member Act
•Telecom	Care Team Member Act
•Role	Care Team Member Act

Remaining Timeline

Meeting Coordinates:

Structured Documents Work Group:

Thursdays 10 AM ET – 12 Noon ET

- [Zoom](#)
- Meeting ID: 465 862 913
- Passcode: 310940
- Phone number: +1 929-436-2866

Topic	Date
Review of Draft Designs and Open Design Issues	10/26/2023
Review of Draft Designs and Open Design Issues	11/03/2023
Post for Community QA	11/17/2023
Final IG Content Due	12/04/2023
Sign up to vote by	12/21/2023
Ballot Comment Period	12/8/2023 - 01/08/2023



The Office of the National Coordinator for Health Information Technology



Thank-you!!

