Interoperability Standards Workgroup Meeting #1

Sarah DeSilvey, Co-Chair

Steven Eichner, Co-Chair

January 23, 2024

Call to Order/Roll Call

Seth Pazinski, Director, Strategic Planning & Coordination Division, ONC

Interoperability Standards Workgroup Roster

Name	Organization	Name	Organization
Sarah DeSilvey* (Co-Chair)	Gravity Project	**Steven Eichner* (Co-Chair)**	Texas Department of State Health Services
Pooja Babbrah	Point-of-Care Partners	Steven Lane	Health Gorilla
Ricky Bloomfield	Apple	Hung Luu*	Children's Health
Medell Briggs-Malonson*	UCLA Health	Anna McCollister*	Individual
Hans Buitendijk*	Oracle Health	Katrina Miller Parrish*	Humana Health Insurance
Keith Campbell**	Food and Drug Administration	Aaron Neinstein*	Notable
Christina Caraballo	HIMSS	Kikelomo Oshunkentan*	Pegasystems
Grace Cordovano	Enlightening Results	Rochelle Prosser*	Orchid Healthcare Solutions
Raj Dash	College of American Pathologists	Mark Savage	Savage & Savage LLC
Derek De Young*	Epic	Fillipe Southerland*	Yardi Systems, Inc.
Lee Fleisher*	University of Pennsylvania Perelman School of Medicine	Shelly Spiro	Pharmacy Health Information Technology Collaborative
Hannah Galvin*	Cambridge Health Alliance	Zeynep Sumer-King*	NewYork-Presbyterian
Rajesh Godavarthi*	MCG Health, part of the Hearst Health network	Naresh Sundar Rajan*	CyncHealth
Jim Jirjis**	Centers for Disease Control and Prevention		

* HITAC Member
** HITAC Federal Representative

Agenda

10:00 AM   **Call to Order/Roll Call**

- Seth Pazinski, Director, Strategic Planning & Coordination Division, ONC

10:05 AM   **Workgroup Introductions**

- Sarah DeSilvey, Co-Chair

- Steven Eichner, Co-Chair

10:20 AM   **IS WG Charge and Timelines**

- Sarah DeSilvey, Co-Chair

- Steven Eichner, Co-Chair

10:25 AM   **Draft USCDI v5 Overview**

- Al Taylor, Office of Technology, ONC

11:20 AM   **Public Comment**

- Seth Pazinski, Director, Strategic Planning & Coordination Division, ONC

11:25 AM   **Workgroup Work Planning**

- Sarah DeSilvey, Co-Chair

- Steven Eichner, Co-Chair

11:30 AM   **Adjourn**

Workgroup Introductions

Sarah DeSilvey, Co-Chair

Steven Eichner, Co-Chair

Interoperability Standards Workgroup Roster
(State name, organization, and title/role – please keep to 30 seconds)

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IS WG Charge and Timelines

Sarah DeSilvey, Co-Chair

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Interoperability Standards Workgroup Charge

Overarching charge: Review and provide recommendations on the Draft USCDI Version 5

Specific charge: Due

Evaluate Draft USCDI v5 and provide ONC with recommendations for: **April 11, 2024**

a. New data classes and elements from Draft USCDI v5 that should be considered for the final USCDI v5 release.
b. Level 2 data classes and elements not included in Draft USCDI v5 that should be considered for the final USCDI v5 release.

USCDI

United States Core Data
for Interoperability

Draft USCDI Version 5
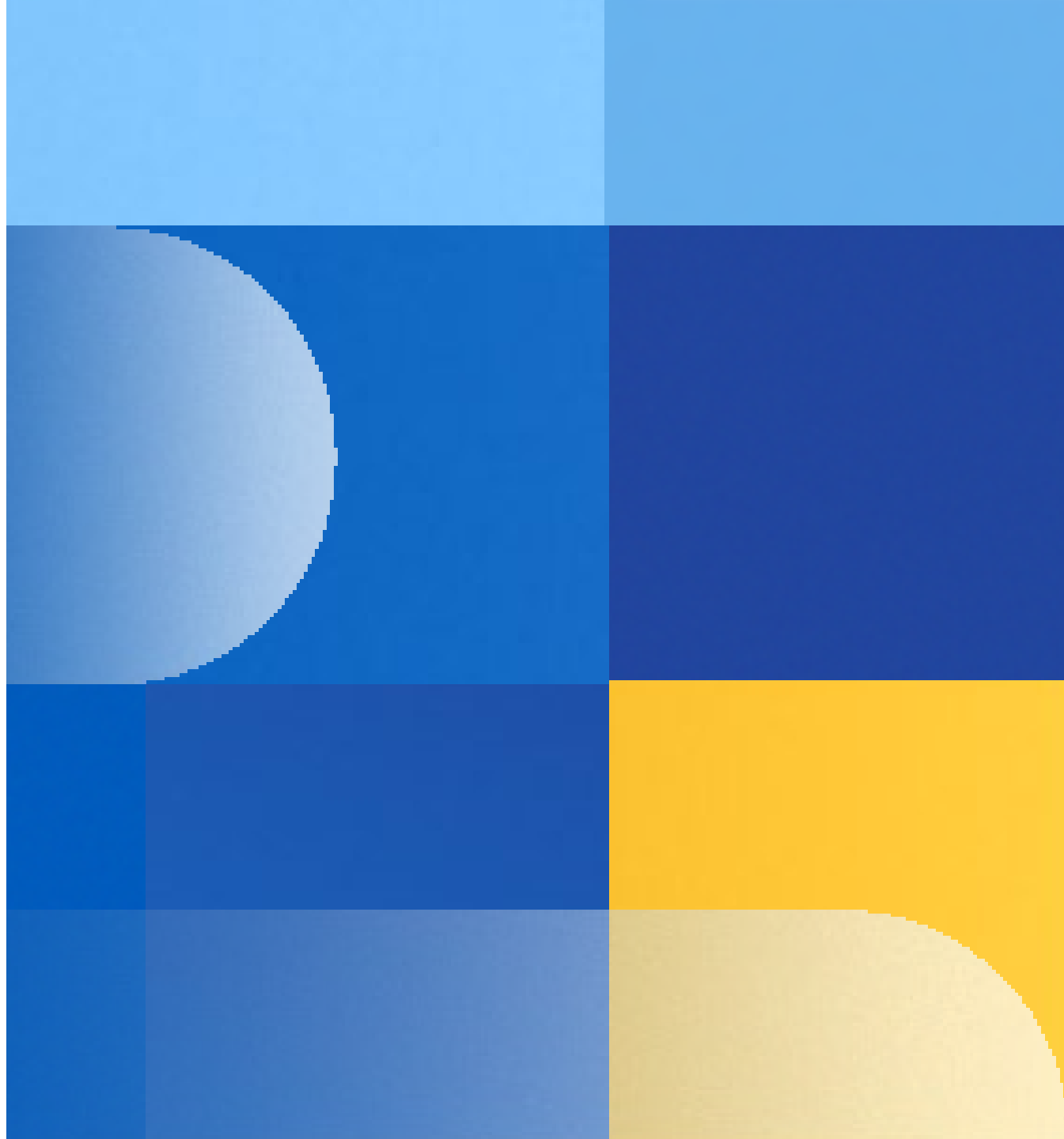
Agenda

- USCDI overview

- Overview of submissions and comments received for Draft USCDI v5

- Review Draft USCDI v5 new data elements

- Timeline

Core Principles

USCDI
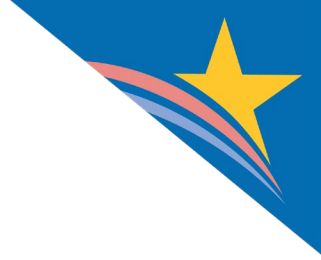
Core set of data needed for patient care and facilitate patient access and data exchange using health IT

Establishes a consistent baseline of data for other use cases

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

Why USCDI Matters

- ONC Cures Act Final Rule established USCDI v1 in 2020, and replaced the Common Clinical Data Set

- HTI-1* Final Rule establishes USCDI v3 as the new baseline data set for these criteria
  - Compliance date January 1, 2026

- Certain certification criteria reference USCDI v3 in HTI-1 Final Rule:
  - Care Coordination - Transitions of Care documents (create, send, and receive)
  - Clinical Information reconciliation and incorporation
  - Patient Engagement - View, Download, and Transmit to 3rd party
  - Create C-CDA document
  - Request and Access data via APIs

- USCDI also defines required data for other uses, such as CMS Patient Access and Payer-to-Payer API, TEFCA, and California Data Exchange Framework (v2)

*Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing

Why USCDI Matters

- ONC Cures Act Final Rule also established the Standards Version Advancement Process (SVAP)
  - SVAP allows health IT developers to:
    - Voluntarily update their products to newer versions of standards
    - Provide those updates to their customers
  - USCDI v2 was available for update until December 2023
    - At least 7 developers updated at least 22 products to USCDI v2
  - US Core 5.0.1 and C-CDA R2.1 Release 3 also available through SVAP
    - Both support implementation of USCDI v2
- ONC Certified Health IT Product List shows "SVAPed" products

USCDI v5 Submission and Comment Summary

ONDEC Leveling Criteria

	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.
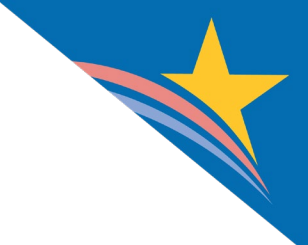
ONDEC Submissions Draft USCDI Version 5
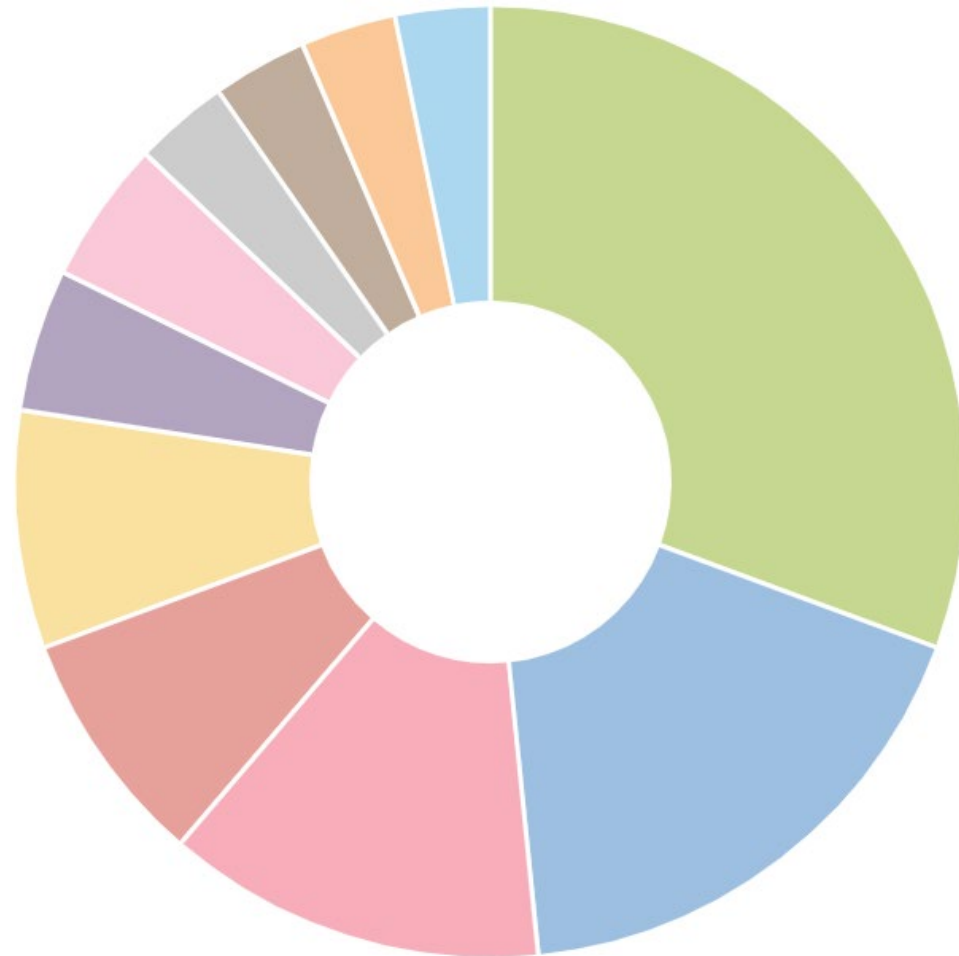
Submissions Received
Total: **62**

🟩	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…	8

Public Comments on Draft USCDI Version 5
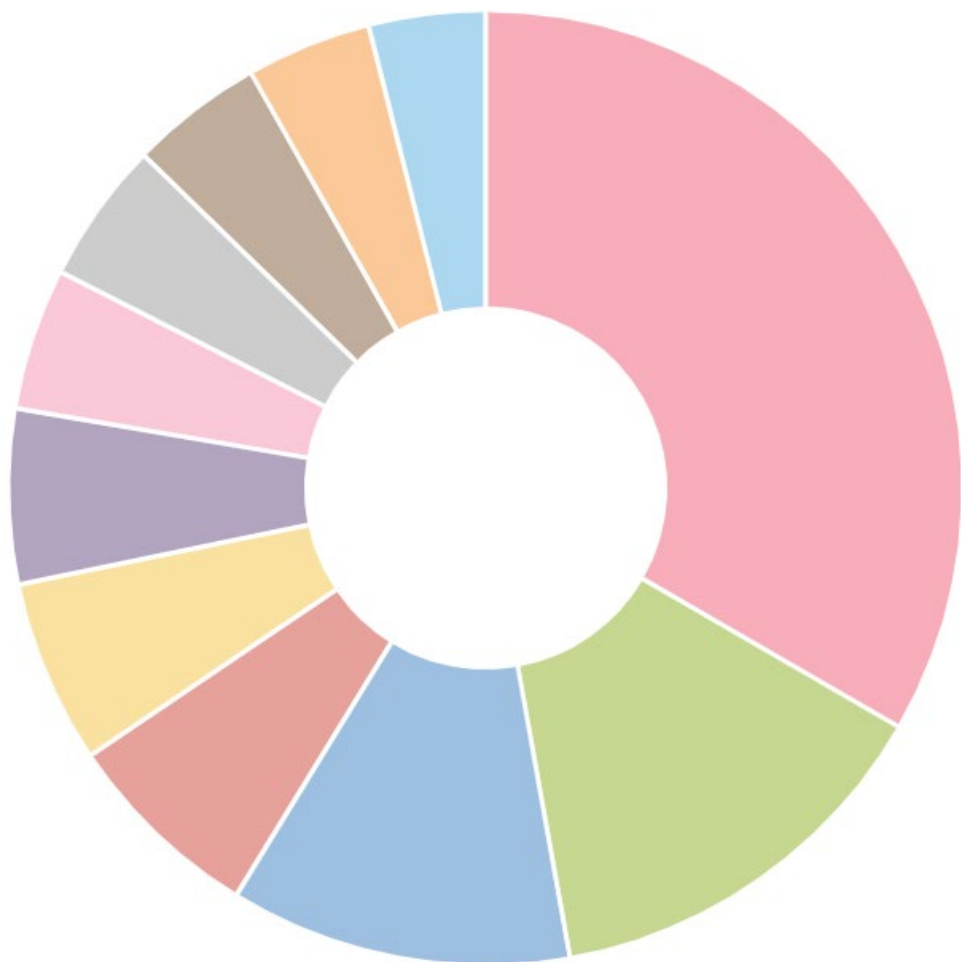
Comments Received
Total: **354**

	Medications	49
	Laboratory	41
	Provenance	24
	Patient Demographics/Information	22
	Health Status Assessments	21
	Pregnancy Information	17
	Social Determinants of Health	17
	Advance Directives	16
	Immunizations	15
	Clinical Notes	14
	Other...	118

USCDI ⭐ Data Elements Considered for v5 (All Level 2)

Advance Directive
- Advance Directive Observation **H**

Allergies and Intolerance
- Substance (Food) **H**
- Criticality

Biologically Derived Product
- Product Code
- Unique Identifier
- Source Identifier
- Division
- Processing Facility

Clinical Notes
- Operative Note **H**
- Emergency Department Note **H**
- Antepartum Summary Note
- Postpartum Summary Note
- Maternal SDOH Note

Diagnostic Imaging
- Accession Number **H**
- Imaging Reference **H**
- Requested Procedure ID **H**

Exposure/Contact Info
- Agent
- Date
- Direction
- Source/Target Participant
- Type

Facility Information
- Facility Address **H**
- Facility Contact Info
- Facility GPS Coordinates
- Facility Managing Org ID

Family Health History
- Family Health History **H**

Health Insurance Information
- Coverage Period
- Policy Number
- Medicare Patient Identifier
- Payer Name
- Plan Name
- Plan Identifier
- Group Name

Health Status Assessments
- Incontinence
- Health Literacy Status
- Pain Assessment
- Mental/Cognitive Status

Immunizations
- Immunization Status
- Lot Number
- Vaccination Administration Date
- Vaccination Event Record Type **H**
- Reason Immunization Not Performed
- Immunization Code

Laboratory
- Laboratory results: date and timestamps **H**
- Laboratory Test Performed Date **H**
- Specimen collection date/time
- Accession number
- Test Kit Unique Device Identifier **H**
- Laboratory Test/Panel Code
- Specimen Collection Method

Medical Devices
- Device Used
- UDI-Production Identifier-Serial or UDI-PI-Serial
- UDI-Device Identifier or UDI-DI
- UDI-Production Identifier-Lot or UDI-PI-Lot
- UDI-Production Identifier-Manufacturing Date or UDI-PI-Manufacturing Date
- UDI-Production Identifier Expiration Data or UDI-PI-Expiration Date
- UDI-Production Identifier-Distinct Identification Code or UDI-PI-DIC

Medications
- Medication Administration Route **H**
- Medication Administration
- Medication Administration Status **H**
- Medication Knowledge
- Medication Prescription Patient
- Medication Prescription Status
- Negation Rationale

Nutrition and Diet H
- Oral Diet Type
- Oral Diet Fluid Consistency
- Oral Diet Texture Modifiers
- Oral Nutritional Supplement
- Enteral Nutrition Type
- Enteral Nutrition Volume
- Enteral Nutrition Rate
- Enteral Nutrition Frequency
- Enteral Nutrition Additive
- Enteral Nutrition Flush
- Eating/drinking assistive device
- Oral Diet Nutrient Modifiers

Observations
- Observation Value
- Observation Code
- Observation Timing
- Observation Subject
- Observation Performer

Orders
- Orders

Draft v5 Data Elements **H** HITAC Recommended

USCDI Data Elements Considered for v5 (All Level 2)

Patient Demographics/ Information
- Name To Use **H**
- Pronouns**H**
- Interpreter Needed
- Address Use Period
- Birth time
- Multiple Birth Order
- Mother's Maiden Name
- Identifier
- Patient Identifier Type

Patient Summary and Plan
- Care Plan **H**

Problems
- Date of Onset **H**

Procedures
- Location of Procedures
- Procedure Sequence

Provenance
- Author **H**
- Author Role **H**

Referral
- Referral Category

Sex Parameter for Clinical Use
- Sex Parameter for Clinical Use **H**
- Clinical Test SPCU
- Laboratory SPCU
- Procedure SPCU
- Diagnostic Imaging SPCU
- Medication SPCU

Social Determinants of Health
- Outcomes

Social History
- Social History Observation **H**
- Sexual Activity
- Refugee Status
- Congregate Living

Special Alerts for Care Handoffs
- Risk Scores

Travel Information **H**
- Travel History Location
- Travel History Dates
- Travel Plans Location
- Travel Plans Dates

Vital Signs
- BMI
- Vital sign results: date and timestamps
- Oxygen delivery device
- Urine Output
- Total Intake
- Total Output

Work Information
- Job Employer Address
- Job Employer Name
- Job End Date
- Job Start Date
- Job Supervisory Level or Pay Grade
- Job Work Classification
- Job Work Schedule
- Usual Industry
- Usual Occupation
- Usual Occupation Duration
- Usual Occupation Start Date

Draft v5 Data Elements **H** HITAC Recommended

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 Draft USCDI v5

Clinical Notes
- Emergency Department Note ➕⬆️**H**
- Operative Note ➕⬆️**H**

Immunizations
- Lot Number 🔍➕**§**

Laboratory
- Test Kit Unique Device Identifier **H** 🔍➕

Medications
- Route ➕**H**

New Data Class

Observations
- Advance Directive Observation ⬆️**H**
- Sex Parameter for Clinical Use **§ H**

New Data Class

Orders
- Orders ➕**§**

Patient Demographics/Information
- Interpreter Needed ➖⬆️
- Pronoun ➖⬆️**§**
- Name to Use ➖⬆️**§**

Provenance
- Author ➖⬆️**H**
- Author Role ➖⬆️**H**

➖ Equity Based ⬆️ Underserved 🔍 Public Health ➕ Add'l USCDI Needs **§** ONC Cert

USCDI ★ United States Core Data for Interoperability

Draft USCDI Version 5

Allergies and Intolerances
- Substance (Medication)
- Substance (Drug Class)
- Substance (Non-Medication)
- Reaction

Care Team Members
- 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
- Emergency Department Note
- History & Physical
- Operative Note
- 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 Identifier
- Payer Identifier

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
- Lot Number

Laboratory
- Tests
- Values/Results
- Specimen Type
- Result Status
- Result Unit of Measure
- Result Reference Range
- Test Kit Unique Device Identifier
- Result Interpretation
- Specimen Source Site
- Specimen Identifier
- Specimen Condition Acceptability

Medical Devices
- Unique Device Identifier - Implantable

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

Observations
- Advance Directive Observation
- Sex Parameter for Clinical Use

Orders
- Orders

Patient Demographics/ Information
- First Name
- Last Name
- Middle Name (Including middle initial)
- Name Suffix
- Previous Name
- Name to Use
- Pronoun
- Date of Birth
- Date of Death
- Race
- Ethnicity
- Tribal Affiliation
- Sex
- Sexual Orientation
- Gender Identity
- Preferred Language
- Interpreter Needed
- 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
- Author Role
- Author Time Stamp
- Author Organization

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)

New for Draft USCDI v5

New Data Elements and Classes Draft USCDI v5

CLINICAL NOTES

Narrative patient data relevant to the context identified by note types.

DATA ELEMENT	APPLICABLE VOCABULARY STANDARD(S)
Emergency Department Note Summary of care delivered in an emergency department.	• Logical Observation Identifiers Names and Codes (LOINC) version 2.76 • At minimum: Emergency Department Note (LOINC code 34111-5)
Operative Note Summary of a surgical procedure. Usage note: May include procedures performed, operative and anesthesia times, findings observed, fluids administered, specimens obtained, and complications identified.	• Logical Observation Identifiers Names and Codes (LOINC) version 2.76 • At minimum: Surgical operation note (LOINC code 11504-8)

IMMUNIZATIONS

Record of vaccine administration.

DATA ELEMENT	APPLICABLE VOCABULARY STANDARD(S)
Lot Number Sequence of characters representing a specific quantity of manufactured material within a batch.	

LABORATORY

Analysis of clinical specimens to obtain information about the health of a patient

DATA ELEMENT	APPLICABLE VOCABULARY STANDARD(S)
Test Kit Unique Device Identifier Numeric or alphanumeric code representing a collection of materials necessary to perform diagnostic tests.	• FDA Unique Device Identification System (UDI System)

MEDICATIONS

Pharmacologic agents used in the diagnosis, cure, mitigation, treatment, or prevention of disease.

DATA ELEMENT	APPLICABLE VOCABULARY STANDARD(S)
Route Physiological administration path of a therapeutic agent into or onto a patient. Examples include but are not limited to oral, topical, and intravenous.	• Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT) U.S. Edition, September 2023 Release

OBSERVATIONS

Findings or other clinical data collected about a patient during care.

DATA ELEMENT	APPLICABLE VOCABULARY STANDARD(S)
Advance Directive Observation Statement of presence and properties of patient or provider authored documents that record a patient's goals, preferences and priorities should a patient be unable to communicate them to a provider. Usage note: May include whether a person has one or more advance directives, the type of advance directive, the location of the current source document, and whether it has been verified. Examples include but are not limited to indication that a living will is on file, reference to or location of durable medical power of attorney, and validating provider.	
Sex Parameter for Clinical Use Category based upon clinical observations typically associated with the designation of male and female.	

ORDERS

Provider-authored directive for the delivery of patient care services.

DATA ELEMENT	APPLICABLE VOCABULARY STANDARD(S)
Orders Provider-authored directive for the delivery of patient care services. Examples include but are not limited to diagnostic imaging, laboratory tests, interventions, referrals and consultations, and do-not-resuscitate.	

PATIENT DEMOGRAPHICS/INFORMATION
Data used to categorize individuals for identification, records matching, and other purposes.

DATA ELEMENT	APPLICABLE VOCABULARY STANDARD(S)
Interpreter Needed Indication of whether a person needs language interpretation services.	• Logical Observation Identifiers Names and Codes (LOINC) version 2.76 • Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT) U.S. Edition, September 2023 Release
Name to Use Name that should be used when addressing or referencing the patient. Usage note: This information should be provided by the patient. Example includes but is not limited to nickname.	
Pronoun Word that can replace a person's name when addressing or referring to a person. Usage note: This information should be provided by the patient. Examples include but are not limited to she, her, they, them, he, and his.	

PROVENANCE

The metadata, or extra information about data, regarding who created the data and when it was created.

DATA ELEMENT	APPLICABLE VOCABULARY STANDARD(S)
Author Actor that participated in the creation or revision of data.	
Author Role Category of actor that participated in the creation or revision of data. Examples include but are not limited to provider, patient, family member, and device.	

Changes to Existing Data Elements (USCDI v4)

Summary of Proposed Data Element and Class Changes

Data Element	Change Summary
Encounter Location	Add HSLOC as applicable vocabulary standard
Procedure	Change CDT standard reference
Immunizations	Technical correction-CVX, NDC standards
Discharge Summary Note	Standardized definition
Procedure Note	Standardized definition
Encounter Disposition	Improve definition
Diagnostic Imaging Test	Change examples
Disability Status	Change examples
Mental/Cognitive Status	Change examples
Functional Status	Change examples
Result Unit of Measure	Change examples

Data Class	Change Summary
Care Team Members	Change spelling, improve definition

ENCOUNTER INFORMATION

Activity performed for or on a patient as part of the provision of care.

DATA ELEMENT	APPLICABLE VOCABULARY STANDARD(S)
Encounter Location Place where a patient's care is delivered.	• National Healthcare Safety Network (NHSN) Healthcare Facility Patient Care Location (HSLOC)

PROCEDURES

Activity performed for or on a patient as part of the provision of care.

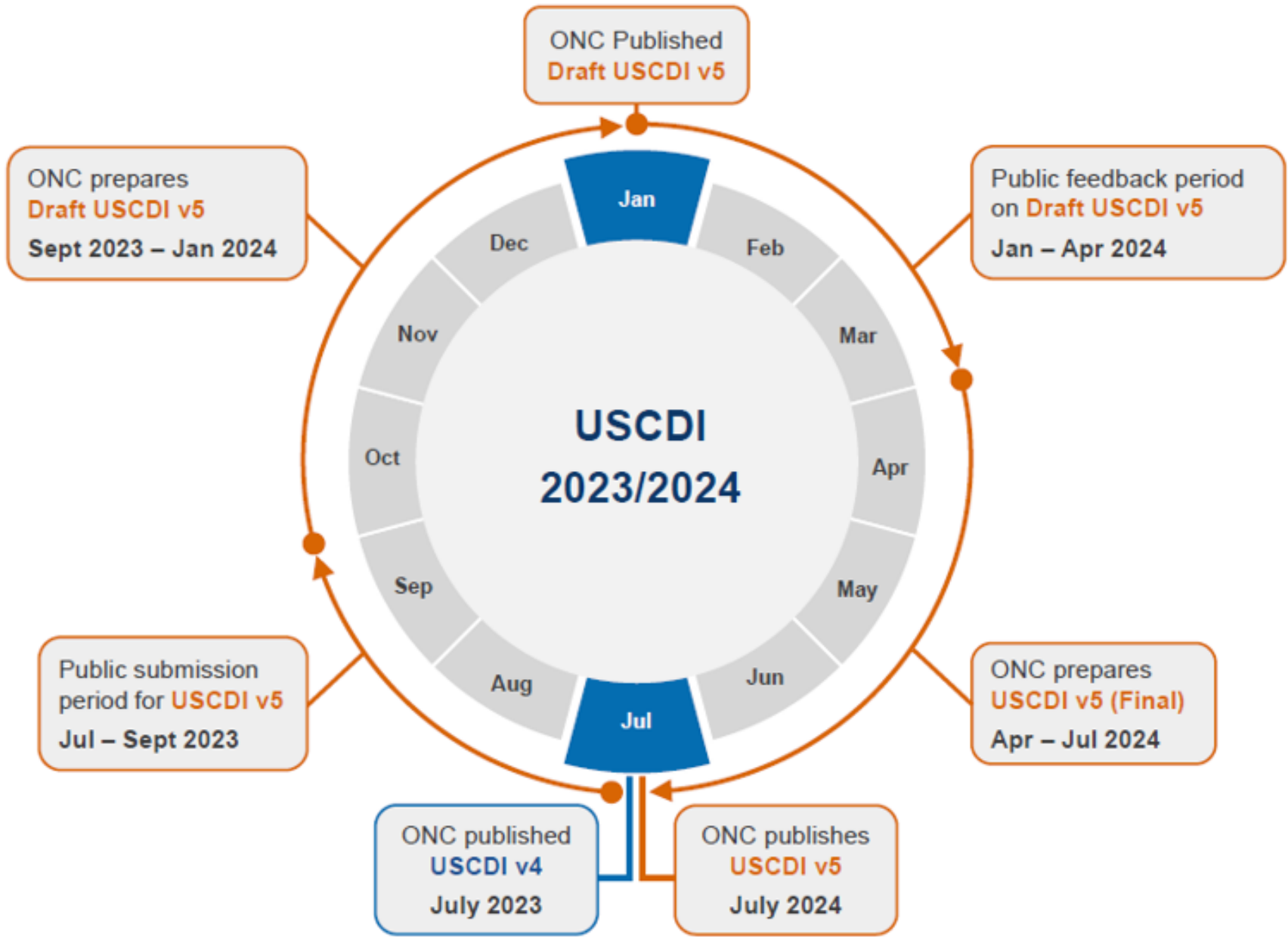| DATA ELEMENT	APPLICABLE VOCABULARY STANDARD(S)
Procedures Activity performed for or on a patient as part of the provision of care.	• SNOMED CT, US Edition • CPT and HCPCS • Code on Dental Procedures and Nomenclature (CDT), maintained and distributed by the American Dental Association Optional: • ICD-10-PCS

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, with an effective date of December 31, 2024

- USCDI v4 added Alcohol and Substance Use Assessments, Physical Activity, Treatment Intervention and Care Experience Preferences, and Medication Adherence data elements

- Draft USCDI v5 proposes to add two new data classes, Orders and Observations, and 13 data elements including Advance Directive Observation, Sex Parameter for Clinical Use, Pronoun, and Name to Use.

USCDI Timeline

ONC Published
Draft USCDI v5

ONC prepares
Draft USCDI v5
Sept 2023 – Jan 2024

Public feedback period
on **Draft USCDI v5**
Jan – Apr 2024

Public submission
period for **USCDI v5**
Jul – Sept 2023

ONC prepares
USCDI v5 (Final)
Apr – Jul 2024

ONC published
USCDI v4
July 2023

ONC publishes
USCDI v5
July 2024

USCDI
2023/2024

Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec

USCDI v4
USCDI v5

USCDI Timeline

- January 18, 2024
  - Draft USCDI v5 publication

- January 18 -April 15, 2024
  - Public feedback period
  - ISWG Charges
  - April 15, 2024 11:59 ET deadline for comments and feedback

- July 2024
  - Anticipated final USCDI v5 publication

- July-September 2024
  - USCDI v6 submission and feedback period

Draft USCDI v5 Feedback Period

- Through [Draft USCDI v5 website](#)
  - April 15, 2024 deadline
  - Draft USCDI v5 data class and element definitions, usage notes, examples, and applicable standards
  - Level 2 data elements to be considered for addition
  - Significant barriers to development, implementation, or use of any Draft v5 elements

- Provenance – Author and Author Role
  - Is there sufficient implementation across health IT developers
  - Compared to 2020 when it was proposed but not adopted in USCDI v1

- Lot Number
  - Should Lot Number apply more broadly to medications and other elements

- Test Kit Unique Device Identifier
  - In what scenarios, settings, and workflows is this element useful
  - What experience do health IT developers have using and exchanging this element.

Thank you!

Contact ONC

Albert Taylor, MD
Medical Informatics Officer
Office of Technology
Albert.Taylor@hhs.gov

HealthIT.gov

Discussion

Public Comment

To make a comment please

Use the Hand Raise Function

If you are on the phone only, press "*9" to raise your hand

*(Once called upon, press "*6" to mute/unmute your line)*

All public comments will be limited to three minutes

You may also email your public comment to onc-hitac@accelsolutionsllc.com

*Written comments will not be read at this time,
but they will be delivered to members of the Workgroup and made part of the public record*

Workgroup Work Planning

Sarah DeSilvey, Co-Chair

Steven Eichner, Co-Chair

Upcoming Meetings

- January 30, 2024

- February 6, 2024

- February 13, 2024

- February 20, 2024

- February 27, 2024

- March 5, 2024

- March 12, 2024

- March 19, 2024

- March 26, 2024

- April 2, 2024

- April 9, 2024

Adjourn