United States Core Data for Interoperability: Updates for Versions 2 and 3, USCDI+

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The Office of the National Coordinator for
Health Information Technology

Agenda

- Core Principles

- Why USCDI Matters

- Versions 2 and 3

- Standards Version Advancement Process

- Update on USCDI+

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Core Principles

USCDI

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

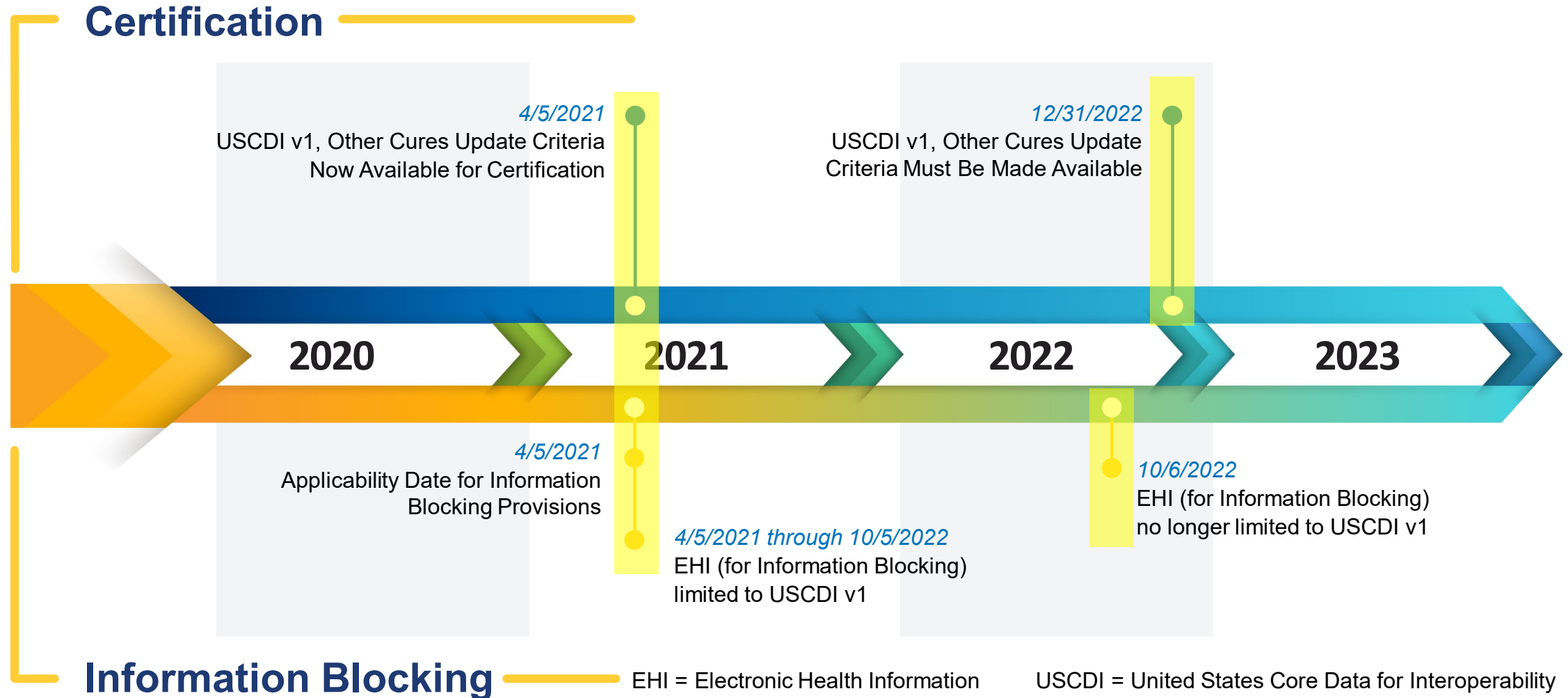Establishes a consistent baseline of data for other use cases

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

USCDI Version 1

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Allergies and Intolerances • Substance (Medication) • Substance (Drug Class) • Reaction	**Goals** • Patient Goals	**Patient Demographics** • First Name • Last Name • Middle Name (Including middle initial) • Suffix • Previous Name • Birth Sex • Date of Birth • Race • Ethnicity • Preferred Language • Current Address • Previous Address • Phone Number • Phone Number Type • Email Address	**Smoking Status** • Smoking Status
Assessment and Plan of Treatment • Assessment and Plan of Treatment	**Health Concerns** • Health Concerns		**Unique Device Identifier(s) for a Patient's Implantable Device(s)** • Unique Device Identifier(s) for a patient's implantable device(s)
Care Team Member(s) • Care Team Members	**Immunizations** • Immunizations		**Vital Signs** • Systolic blood pressure • Diastolic 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 - 36 Months) • Head Occipital-frontal Circumference Percentile (Birth - 36 Months)
Clinical Notes • Consultation Note • Discharge Summary Note • History & Physical • Imaging Narrative • Laboratory Report Narrative • Pathology Report Narrative • Procedure Note • Progress Note	**Laboratory** • Test • Values/Results	**Problems** • Problems	
	Medications • Medications	**Procedures** • Procedures	
		Provenance • Author Organization • Author Time Stamp	

Why USCDI Matters

- New standard 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 these Certification Criteria, using C-CDA or US Core:
  - Transitions of Care documents (create, send, and receive)
  - Clinical Information reconciliation and incorporation
  - Patient View, Download, and Transmit of their health data
  - Electronic case reporting to public health agencies
  - Create C-CDA document
  - Access to data via APIs

- USCDI defines "Electronic Health Information" (for now)

Why USCDI Matters: EHI and Information Blocking

Certification

4/5/2021
USCDI v1, Other Cures Update Criteria
Now Available for Certification

12/31/2022
USCDI v1, Other Cures Update
Criteria Must Be Made Available

2020 **2021** **2022** **2023**

4/5/2021
Applicability Date for Information
Blocking Provisions

4/5/2021 through 10/5/2022
EHI (for Information Blocking)
limited to USCDI v1

10/6/2022
EHI (for Information Blocking)
no longer limited to USCDI v1

Information Blocking EHI = Electronic Health Information USCDI = United States Core Data for Interoperability

USCDI Version 2

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USCDI v2: ONDEC (ONC Data Element and Class) Submission System

How It Works

Step 1. Submit new data elements and classes (registered ISA users only - login or create account here)

Provide information on the use cases, applicable standards, existing use and exchange, and potential challenges of data elements. Submission may contain more than one data element.

Please note: submissions must be completed in a single session - ONDEC does not allow for saving progress and returning at a later time.

Step 2. ONC evaluates and assigns a level to each data element depending on the overall value, maturity and challenges to implementation

• Comment • Level 1 • Level 2

Step 3. ONC posts submitted data elements on the USCDI page by level

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.

Step 4. Submissions achieving Level 2 by October of each year will be considered for inclusion in the draft of the next version of USCDI. ONC will present the draft to the Health IT Advisory Committee and the public for comment.

Step 5. ONC finalizes the next version of USCDI in July.

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USCDI v2 Prioritization Criteria

ONC prioritized the most mature and impactful data element submissions in order to:

- Represent important data needs not included in USCDI v1

- Require only modest standards or implementation guide developmental burden

- Require only modest developmental burden on health IT modules

- Create only modest implementation burden on providers and health systems

- Result in only modest aggregate lift for all new data elements combined

USCDI Version 2

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

Clinical Tests ⭐
- Clinical Test ⭐
- Clinical Test Result/Report ⭐

Laboratory
- Test
- Values/Results

Medications
- Medications

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

Unique Device Identifier(s) for a Patient's Implantable Device(s)
- Unique Device Identifier(s) for a patient's implantable device(s)

Vital Signs
- Systolic blood pressure
- Diastolic 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 - 36 Months)
- Head Occipital-frontal Circumference Percentile (Birth - 36 Months)

Assessment and Plan of Treatment
- Assessment and Plan of Treatment
- SDOH Assessment ⭐

Diagnostic Imaging ⭐
- Diagnostic Imaging Test ⭐
- Diagnostic Imaging Report ⭐

Patient Demographics
- First Name
- Last Name
- Middle Name (Including middle initial)
- Suffix
- Previous Name
- Date of Birth
- Race
- Ethnicity
- Sex (Assigned at Birth)
- Sexual Orientation ⭐
- Gender Identity ⭐
- Preferred Language
- Current Address
- Previous Address
- Phone Number
- Phone Number Type
- Email Address

Procedures
- Procedures
- SDOH Interventions ⭐

Provenance
- Author Organization
- Author Time Stamp

Smoking Status
- Smoking Status

Care Team Member(s)
- Care Team Member Name ⭐
- Care Team Member Identifier ⭐
- Care Team Member Role ⭐
- Care Team Member Location ⭐
- Care Team Member Telecom ⭐

Encounter Information ⭐
- Encounter Type ⭐
- Encounter Diagnosis ⭐
- Encounter Time ⭐
- Encounter Location ⭐
- Encounter Disposition ⭐

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

Goals
- Patient Goals
- SDOH Goals ⭐

Health Concerns
- Health Concerns

Immunizations
- Immunizations

Unique Device Identifier(s) for a Patient's Implantable Device(s)
- Unique Device Identifier(s) for a patient's implantable device(s)

⭐ **New Data Classes and Elements**

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USCDI v2: Changes that Support Health Equity

- Sexual Orientation and Gender Identity (SOGI)
- Social Determinants of Health (SDOH)
  - SDOH Assessment
  - SDOH Goals
  - SDOH Problems/Health Concerns
  - SDOH Interventions

New USCDI v2 Data Elements:
Patient Demographics, SOGI

DATA ELEMENT
Sexual Orientation *A person's identification of their emotional, romantic, sexual, or affectional attraction to another person*
Gender Identity *A person's internal sense of being a man, woman, both, or neither.*

New USCDI v2 Data Elements:
Social Determinants of Health (SDOH)

DATA CLASS	DATA ELEMENT
Assessment and Plan of Treatment	**SDOH Assessment** *Structured evaluation of risk for any Social Determinants of Health domain such as food, housing, or transportation security.*
Goals	**SDOH Goals** *A future desired condition or change in condition related to an SDOH risk established by the patient or provider.*
Procedures	**SDOH Interventions** *A service offered to a patient to address identified SDOH concerns, problems, or diagnoses.*
Problems	**SDOH Problems/Health Concerns** *An SDOH-related condition or diagnosis.*

ONC Standards Bulletin 2021-3

Issue 2021-3

ONC HEALTH IT STANDARDS
BULLETIN

JULY 2021

USCDI v3 Update Cycle

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USCDI v3 Prioritization Criteria

- **USCDI v2 Prioritization Criteria to continue for v3**

- **New USCDI v3 Prioritization Criteria**
  - Further mitigate health and healthcare inequities and disparities
  - Address the needs of underserved stakeholders
  - Address public health reporting, investigation, and emergency response

Draft USCDI Version 3

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

Assessment and Plan of Treatment
- Assessment and Plan of Treatment
- SDOH Assessment

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 Diagnosis
- Encounter Time
- Encounter Location
- Encounter Disposition

Goals
- Patient Goals
- SDOH Goals

Health Insurance Information ★
- Coverage Status ★
- Coverage Type ★
- Relationship to Subscriber ★
- Member Identifier ★
- Subscriber Identifier ★
- Group Number ★
- Payer Identifier ★

Health Status
- Health Concerns ➡
- Functional Status ★
- Disability Status ★
- Mental Function ★
- Pregnancy Status ★
- Smoking Status ➡

Immunizations
- Immunizations

Laboratory
- Test
- Values/Results
- Specimen Type ★
- Result Status ★

Medications
- Medications

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

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

Procedures
- Procedures
- SDOH Interventions
- Reason for Referral ★

Provenance
- Author Organization
- Author Time Stamp

Unique Device Identifier(s) for a Patient's Implantable Device(s)
- Unique Device Identifier(s) for a patient's implantable device(s)

Vital Signs
- Systolic blood pressure
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★ **New Data Classes and Elements** ➡ **Data Element Reclassified**

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Draft USCDI v3 Highlights

- **2 New Data Classes**
  - Health Insurance Information
  - Health Status
- **New Patient Demographics Data Elements**
  - Date of Death
  - Tribal Affiliation
  - Related Person's Name
  - Related Person's Relationship
  - Occupation
  - Occupation Industry

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Health Insurance Information

DATA ELEMENT
Coverage Status *The presence or absence of coverage.*
Coverage Type *Categories of health care payors*
Relationship to Subscriber *Relationship of the person to the insured person.*
Member Identifier *Identifies an individual covered by the benefits.*
Subscriber Identifier *Identifies the individual who selects benefits.*
Group Number *Identifies a specific health insurance plan.*
Payer Identifier *Identifies a payer entity.*

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Health Status

Health-related matter of interest, importance, or worry to a patient, patient's family, or patient's healthcare provider

DATA ELEMENT
Health Concern ➡️
Disability Status *Represents assessments of an individual's physical, cognitive, intellectual, or psychiatric disabilities (e.g., vision, hearing, memory, activities of daily living).*
Mental Function *Observations of cognitive functioning (e.g., alertness, orientation, comprehension, concentration, and memory).*
Functional Status *Assessments of a patient's capabilities or risks of development or worsening of a condition.*
Pregnancy Status *Screening patient for potential pregnancy (e.g., pregnant, not pregnant, unknown) which relate to potential risks and exposures.*
Smoking Status ➡️ *Representing a patient's smoking behavior.*

➡️ Data Element Reclassified

Patient Demographics

DATA ELEMENT
Date of Death
Tribal Affiliation *Self-identified members of Indian entities eligible for US Bureau of Indian Affairs services.*
Related Person's Name *The name of a person involved in the care of a patient, but who is not the target of that care.*
Related Person's Relationship *The relationship between a Patient and a Related Person (e.g., emergency contact,next-of-kin).*
Occupation *The type of work done by a person. For a military position, this is the primary occupational specialty.*
Occupation Industry *Type of business for which a person works, including volunteer work. For a military position, this is the self-reported branch of service.*

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ONC HEALTH IT STANDARDS

BULLETIN

JANUARY 2022

The Office of the National Coordinator for
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Draft USCDI v3 Public Feedback Period

General Feedback on Draft USCDI v3

1. Data class and element improvements:
   - Data class and element names and definitions?
   - Examples or value sets to better define scope of data elements?
2. Other data elements that should be added to USCDI v3
3. Barriers to development, implementation, or use of any data elements that would warrant not including them in USCDI v3?

Specific Feedback sought on several existing data elements:

1. Sex assigned at birth
   - Alignment with Gender Harmony "Recorded Sex or Gender"?
2. Gender Identity
   - Alignment of ONC value set with that of Gender Harmony project?
3. Current and Previous Address (Patient Address)
   - Use of new Unified Specification for Address in Health Care (Project US@)?

Standards Version Advancement Process

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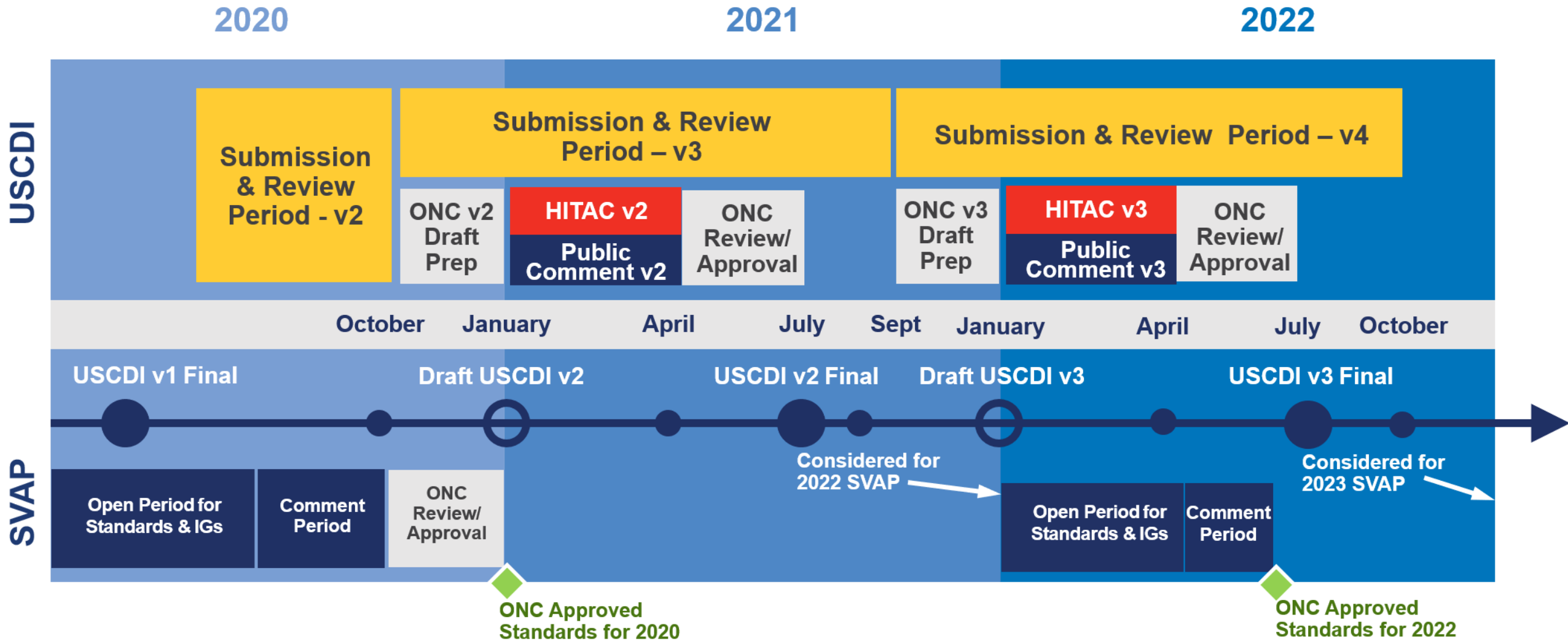# **Standards Version Advancement Process**

- Allows Health IT developers of certified Health IT to <u>voluntarily</u> update their products to newer versions of standards

- Public process to identify versions of standards that are ready for use in the Certification Program.

  - First SVAP Approved Standards for 2020

  - Annual process

  - HealthIT.gov/SVAP

Standards Version Advancement Process

- USCDI v2 will be considered for the Approved Standards for 2022.

- HL7® FHIR US Core and C-CDA implementation guides.

  - These IGs implement exchange of USCDI data elements.

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USCDI Version Update Process

2020 **2021** **2022**

USCDI

Submission & Review Period - v2	Submission & Review Period – v3			Submission & Review Period – v4			
	ONC v2 Draft Prep	HITAC v2 / Public Comment v2	ONC Review/ Approval	ONC v3 Draft Prep	HITAC v3 / Public Comment v3	ONC Review/ Approval	

October January April July Sept January April July October

USCDI v1 Final Draft USCDI v2 USCDI v2 Final Draft USCDI v3 USCDI v3 Final

SVAP

Considered for 2022 SVAP

Considered for 2023 SVAP

| Open Period for Standards & IGs | Comment Period | ONC Review/ Approval | | Open Period for Standards & IGs | Comment Period | |

ONC Approved Standards for 2020

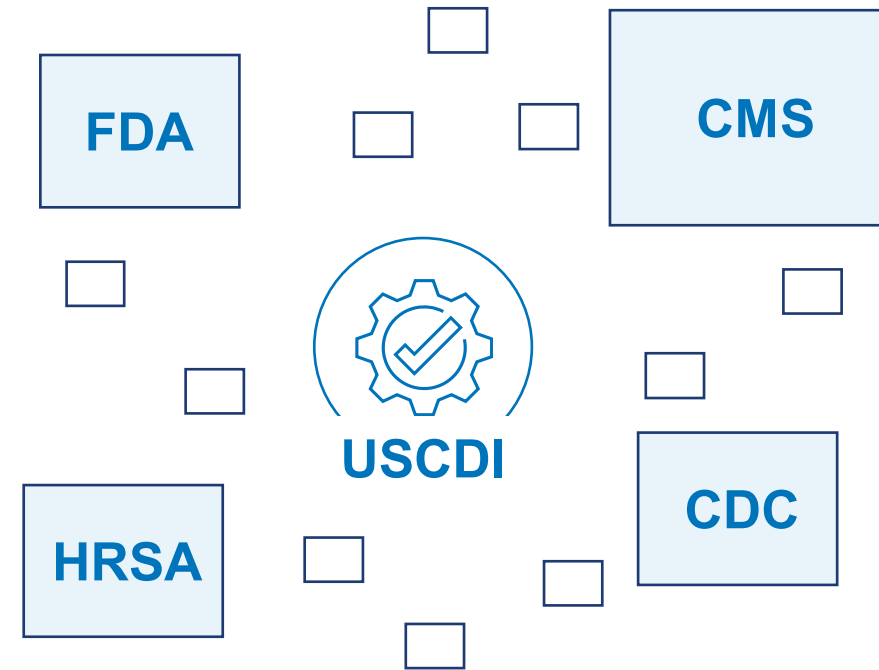**ONC Approved Standards for 2022**

Update on USCDI+

Current State: Data Sets Needed Beyond USCDI

- Unique agency or program-specific data systems and requirements not fully met by USCDI

- Agencies pursue ad hoc approaches to additional data needs

- Creates increasing drift from USCDI, which presents lifecycle maintenance issues, industry resistance, fewer opportunities for synergies across agencies

What is USCDI+?

- Announced October 2021 in the Health IT Buzz Blog: https://www.healthit.gov/buzz-blog/health-it/thinking-outside-the-box-the-uscdi-initiative

- USCDI+ is a service that ONC provides to federal partners who have a need to establish, harmonize, and advance the use of interoperable datasets that extend beyond the core data in the USCDI in order to meet agency-specific programmatic requirements.

- USCDI+ allows ONC to better serve federal partners, assure that extensions build from the same core USCDI foundation, and create the opportunity for aligning similar data needs across agency programs.

- USCDI+ for Quality Measurement and Public Health are beginning with CMS and CDC partners.
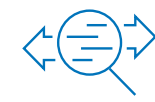
USCDI+ Launch At-a-glance

Discovery

- Determine federal agency/stakeholder commitment

- Identify clear use case and need

- Develop robust implementation plans for agency stakeholders

- Assess regulatory, programmatic, or other requirements for use

- Define resources to support development/stewardship and sustainability of work

Outcomes & Goals

- Nationally-recognized data set that advances program goals via interoperability

- Ongoing maintenance and stewardship of data set that can evolve with program requirements/technology landscape

- Repeatable process for creating robust data sets beyond the USCDI but still leveraging the USCDI core and process

- Harmonization across programs/use cases to reduce fragmentation and data-silos

- Harmonization across federal data sets to optimize investments in interoperability

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Questions & Discussion

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