Interoperability Standards Workgroup (IS WG) 2025

Sarah DeSilvey, Co-Chair

Steven Eichner, Co-Chair

January 21, 2025

Call to Order/Roll Call and Workgroup Member Introductions

Seth Pazinski, Designated Federal Officer, ASTP

Interoperability Standard Workgroup 2025 Roster

Name	Organization
Sarah DeSilvey* (Co-Chair)	Gravity Project
Steven (Ike) Eichner* (Co-Chair)	Texas Department of State Health Services
Shila Blend*	North Dakota Health Information Network
Ricky Bloomfield	Apple
Hans Buitendijk*	Oracle Health
Christina Caraballo	HIMSS
Rajesh Dash	College of American Pathologists
Derek De Young*	Epic
Lee Fleisher*	University of Pennsylvania Perelman School of Medicine
Rajesh Godavarthi*	MCG Health, part of the Hearst Health network
Bryant Thomas Karras*	Washington State Department of Health
Steven Lane	Health Gorilla
Hung S. Luu*	Children's Health
Meg Marshall**	Department of Veterans Health Affairs

Name	Organization
Katrina Miller Parrish*	Patient.com
Liz Palena Hall	Centers for Medicare & Medicaid Services
Randa Perkins*	H. Lee Moffitt Cancer Center & Research Institute
Rochelle Prosser*	Orchid Healthcare Solutions
Mark Savage	Savage & Savage LLC
Naresh Sundar Rajan*	Neantix Inc.
Wilson Washington	Substance Abuse and Mental Health Services Administration

* HITAC Member   ** HITAC Federal Representative

Opening Remarks

Sarah DeSilvey, Co-Chair

Steven Eichner, Co-Chair

Agenda

10:00 AM   **Call to Order/Roll Call and Workgroup Member Introductions**
- Seth Pazinski, Designated Federal Officer, ASTP

10:20 AM   **Opening Remarks**
- Sarah DeSilvey, Workgroup Co-Chair
- Steven Eichner, Workgroup Co-Chair

10:25 AM   **IS WG Charge**
- Sarah DeSilvey, Workgroup Co-Chair
- Steven Eichner, Workgroup Co-Chair

10:30 AM   **USCDI Background**
- Sara Armson, Office of Standards, Certification, and Analysis, ASTP
- Ashley Ashworth, Office of Standards, Certification, and Analysis, ASTP
- Liz Turi, Office of Standards, Certification, and Analysis, ASTP

11:20 AM   **Public Comment**
- Seth Pazinski, Designated Federal Officer, ASTP

11:25 AM   **Next Steps**
- Sarah DeSilvey, Workgroup Co-Chair
- Steven Eichner, Workgroup Co-Chair

11:30 AM   **Adjourn**

IS WG Charge

Sarah DeSilvey, Co-Chair

Steven Eichner, Co-Chair

Interoperability Standards Workgroup 2025 Charge

Overarching Charge: Review and provide recommendations on Draft USCDI Version 6.

- **Specific Charge:** Evaluate Draft USCDI v6 and provide ASTP with recommendations for:
  - New data elements included in Draft USCDI v6 and whether they should be changed or excluded in the final USCDI v6 release.
  - Level 2 data elements not included in Draft USCDI v6 that should be considered for the final USCDI v6 release.

- **Workgroup Recommendations Due:** April 10, 2025

ASTP | Health IT Advisory Committee

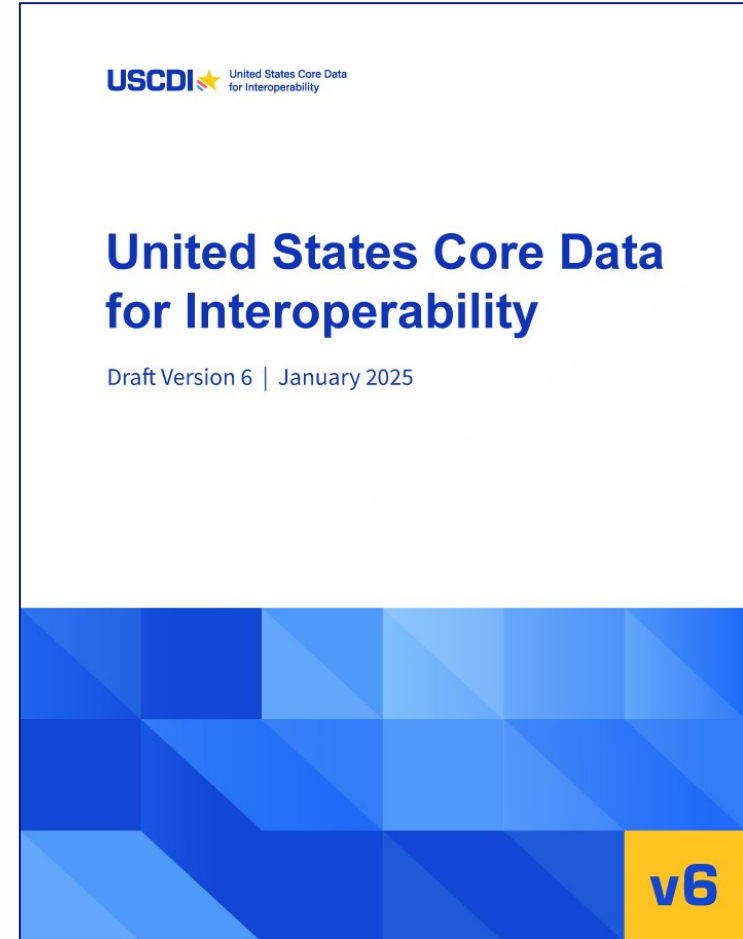# USCDI and USCDI+ Background

Sara Armson, Office of Standards, Certification, and Analysis, ASTP

Ashley Ashworth, Office of Standards, Certification, and Analysis, ASTP

Liz Turi, Office of Standards, Certification, and Analysis, ASTP

US Core Data for Interoperability (USCDI)

The Minimum Dataset of the Health Care Delivery System

v6

USCDI ★ United States Core Data for Interoperability

United States Core Data for Interoperability

Draft Version 6 | January 2025

v6

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

Why USCDI Matters

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

‣ HTI-1* adopted USCDI v3 and established as the new baseline data set for these criteria

  • Compliance date January 1, 2026

‣ HTI-2** NPRM **proposes** to adopt USCDI v4 and set it as the baseline for applicable certification criteria

‣ 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
**Health Data, Technology, and Interoperability: Patient Engagement, Information Sharing, and Public Health Interoperability Proposed Rule

Standards Version Advancement Process (SVAP)

- ONC Cures Act Final Rule also established the [Standards Version Advancement Process (SVAP)](#)
  - SVAP allows health IT developers to:
    - Voluntarily update their products to use newer versions of standards
    - Provide those updates to their customers
  - USCDI v4 was included in the 2024 SVAP standards
  - US Core 7.0.0 and C-CDA 3.0 also available through 2024 SVAP standards
    - Both support implementation of USCDI v4
- [ONC Certified Health IT Product List shows "SVAPed" products](#)

How does USCDI, US Core, and C-CDA make health data interoperable?

Draft USCDI Version 6

ASTP   Better health enabled by data
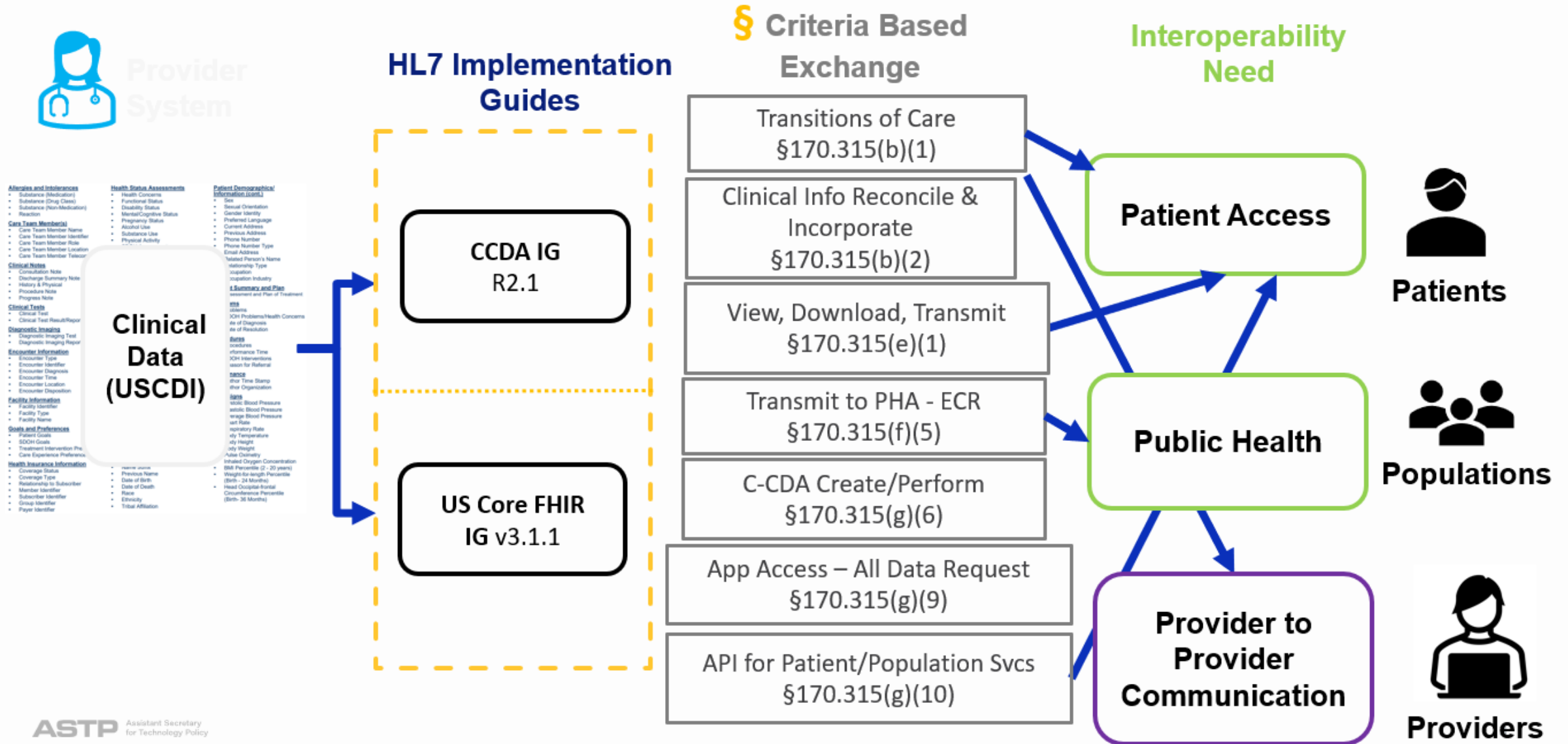
Draft USCDI v6 Development

- Draft USCDI v6 submission cycle ran from July to September 2024

- ASTP received over 130 comments on existing data elements and almost 80 submissions recommending new data elements

- Recently, ASTP has been able to use feedback from our USCDI+ datasets to help inform the technical maturity and breadth of applicability of data elements

- ASTP reviewed and considered these comments and submissions in the development of the Draft USCDI v6, which includes six next data elements

Draft USCDI Version 6

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
- Facility Address

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
- Result Interpretation
- Specimen Source Site
- Specimen Identifier
- Specimen Condition Acceptability

Medical Devices
- Unique Device Identifier

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

Observations
- Advance Directive Observation
- Sex Parameter for Clinical Use

Orders
- Medication Order
- Laboratory Order
- Diagnostic Imaging Order
- Clinical Test Order
- Portable Medical Order

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
- Care Plan

Problems
- Problems
- Family Health History
- SDOH Problems/Health Concerns
- Date of Onset
- 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 Data Elements for Draft USCDI v6

Facility Information
- Facility Address

Medical Devices
- Unique Device Identifier ⭐

Orders
- Portable Medical Order

Patient Summary and Plan
- Care Plan

Problems
- Date of Onset
- Family Health History

⭐ Significantly modified data element

New Data Elements

USCDI Data Elements can include:

- Name

- Description
  - ‣ Usage Notes
  - ‣ Examples

- Applicable standard

Facility Information

Physical place of available services or resources.

DATA ELEMENT	APPLICABLE VOCABULARY STANDARD(S) Standards listed are required. If more than one is listed, at least one is required unless otherwise noted. Where an applicable vocabulary standard has not been identified, this field will remain empty.
Facility Address Physical location of available services or resources.	

Medical Devices

An instrument, machine, appliance, implant, software, or other article intended to be used for a medical purpose.

DATA ELEMENT	APPLICABLE VOCABULARY STANDARD(S)
Unique Device Identifier Numeric or alphanumeric code that uniquely identifies a medical device. Usage note: Contains a device identifier (DI) and one or more production identifiers (PI).	• FDA Unique Device Identification (UDI) System

Orders

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

Usage notes: Orders convey a provider's intent to have a service performed on or for a patient, or to give instructions on future care.

DATA ELEMENT	APPLICABLE VOCABULARY STANDARD(S)
Portable Medical Order Provider-authored request for end-of-life or life-sustaining care for a person who has a serious life-limiting medical condition. Usage note: These are meant to follow a person regardless of when and where such an order might be needed (e.g., hospital, care facility, community, home). There are variations in requirements and names for portable medical orders based on jurisdiction.	

Patient Summary and Plan

Conclusions and working assumptions that will guide treatment of the patient, and recommendations for future treatment.

DATA ELEMENT	APPLICABLE VOCABULARY STANDARD(S)
Care Plan Shared plan informed by members of a coordinated care team that details conditions, needs, and goals along with strategies for addressing them. Usage notes: Includes prioritized problems, health concerns, assessments, goals, and interventions from across care settings. Examples include nursing care plan, diabetic care plan, multiple chronic conditions care plan, and long term services and support care plan.	

Problems

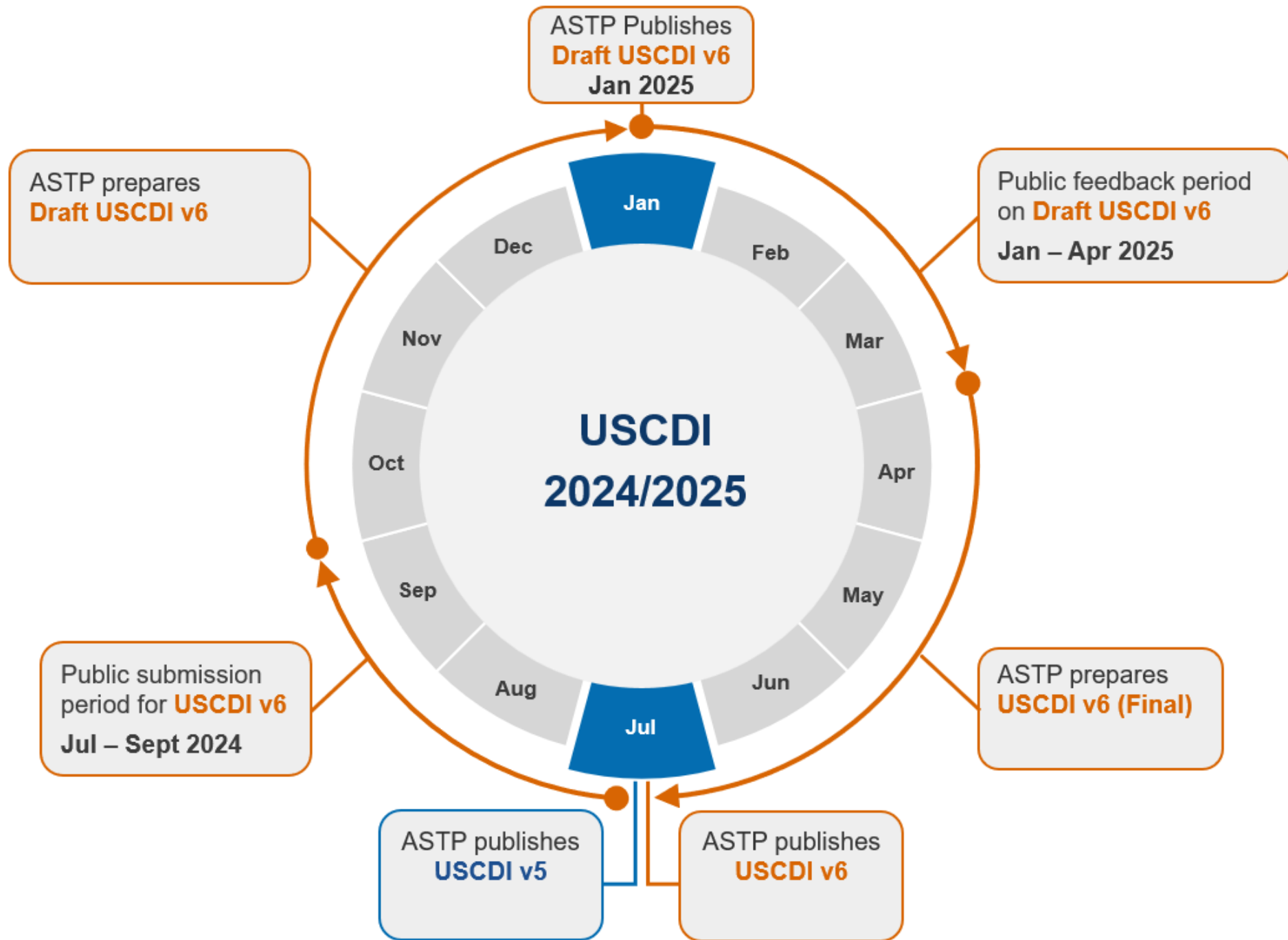Condition, diagnosis, or reason for seeking medical attention.

DATA ELEMENT	APPLICABLE VOCABULARY STANDARD(S)
Date of Onset Date or estimated date when signs or symptoms of a condition began. Usage note: This may be a specific day, week, month, or year, or it may be an estimate.	
Family Health History Family member's health conditions that are relevant to a patient's care.	• SNOMED Clinical Terms (SNOMED CT) U.S. Edition, September 2024 Release • International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) 2025

Draft USCDI v6 Updates to Existing Data Elements

Added Applicable Standards	•Medication Order
	    •RxNorm
	•Laboratory Order
	    •LOINC
	•Diagnostic Imaging Order
	    •LOINC
	•Clinical Test Order
	    •LOINC

Changed Data Element Definition	•Reaction •Performance Time •SDOH Assessment •Result Unit of Measure •Coverage Type

Draft USCDI v6 Feedback Period

- [Draft USCDI v6](#) is open for public comment until **April 14, 2025 at 11:59 pm ET**

  ‣ Suggestions for improvement in the data classes or elements in Draft USCDI v6, including data class and element definitions, usage notes, examples, and applicable standards

  ‣ Additional data elements from Level 2 or USCDI+ domains to be considered for future versions

  ‣ Significant barriers to development, implementation, or use of any Draft v6 elements

ASTP prepares **Draft USCDI v6**

ASTP Publishes **Draft USCDI v6** Jan 2025

Public feedback period on **Draft USCDI v6** Jan – Apr 2025

ASTP prepares **USCDI v6 (Final)**

ASTP publishes **USCDI v6**

ASTP publishes **USCDI v5**

Public submission period for **USCDI v6** Jul – Sept 2024

USCDI 2024/2025

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

USCDI v5
USCDI v6

USCDI Data Element Levels

Level Criteria Language

USCDI Data Element Leveling Criteria

ASTP 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.
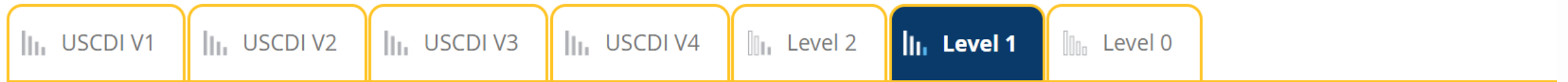
Level Criteria Language – Level 2

|ı. USCDI V1	**|ı.** USCDI V2	**|ı.** USCDI V3	**|ı.** USCDI V4	**|ı. Level 2**	**|ı. Level 1**	**|ı. Level 0**

Level 2 data elements meet the following criteria:

- **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.**
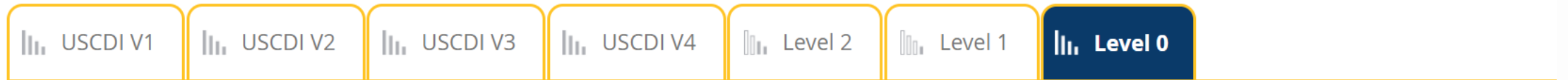- **Use cases apply to most care settings or specialties.**

Level Criteria Language – Level 1

USCDI V1	USCDI V2	USCDI V3	USCDI V4	Level 2	**Level 1**	Level 0

Level 1 data elements meet the following criteria:

- **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 Criteria Language – Level 0

|						
USCDI V1	USCDI V2	USCDI V3	USCDI V4	Level 2	Level 1	**Level 0**

Level 0 data elements meet the following criteria:

- **Not represented by a terminology standard or SDO-balloted technical specification or implementation guide.**
- **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.**

USCDI+

Better health enabled by data

USCDI+: Extending Beyond the USCDI
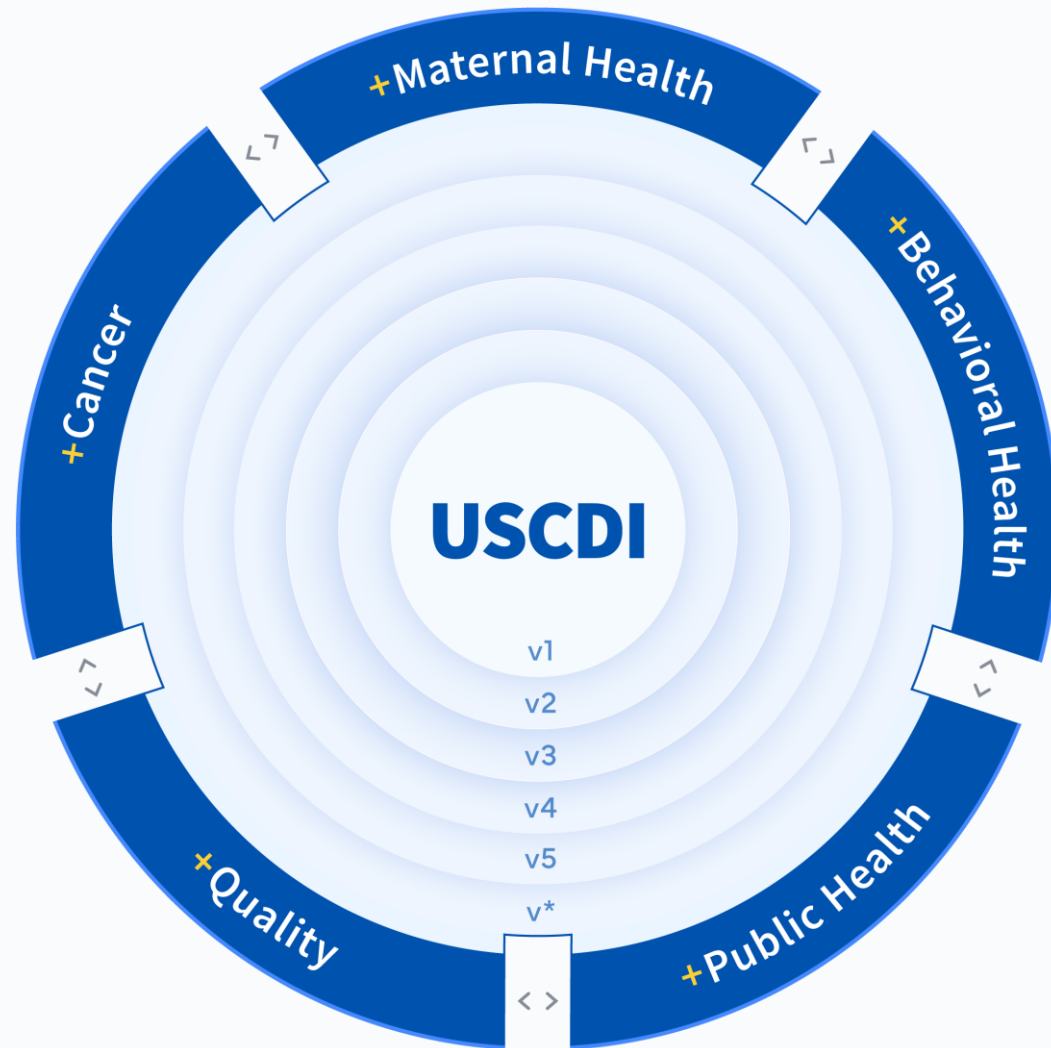
- Unique program and use case-specific data needs are sometimes not fully met by USCDI.

- ASTP's USCDI+ initiative helps government and industry partners build on USCDI to support specific program needs.

- Applies USCDI processes for submission and harmonization while focusing on programmatic priorities.

- Seeks to leverage programs and authorities across HHS to drive adoption.

Current USCDI+ Domains and Initiatives

Behavioral Health
- Comprehensive Care

Cancer
- Cancer Registry
- Clinical Trials Matching
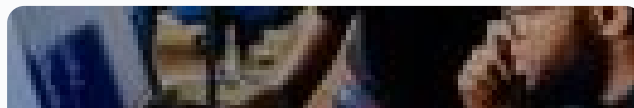- Enhancing Oncology Model
- Immune-related Adverse Events

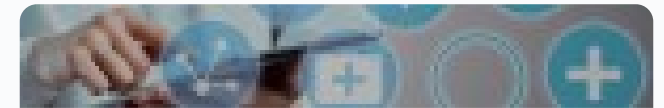## Maternal Health
- Overarching

Public Health
- Case Reporting
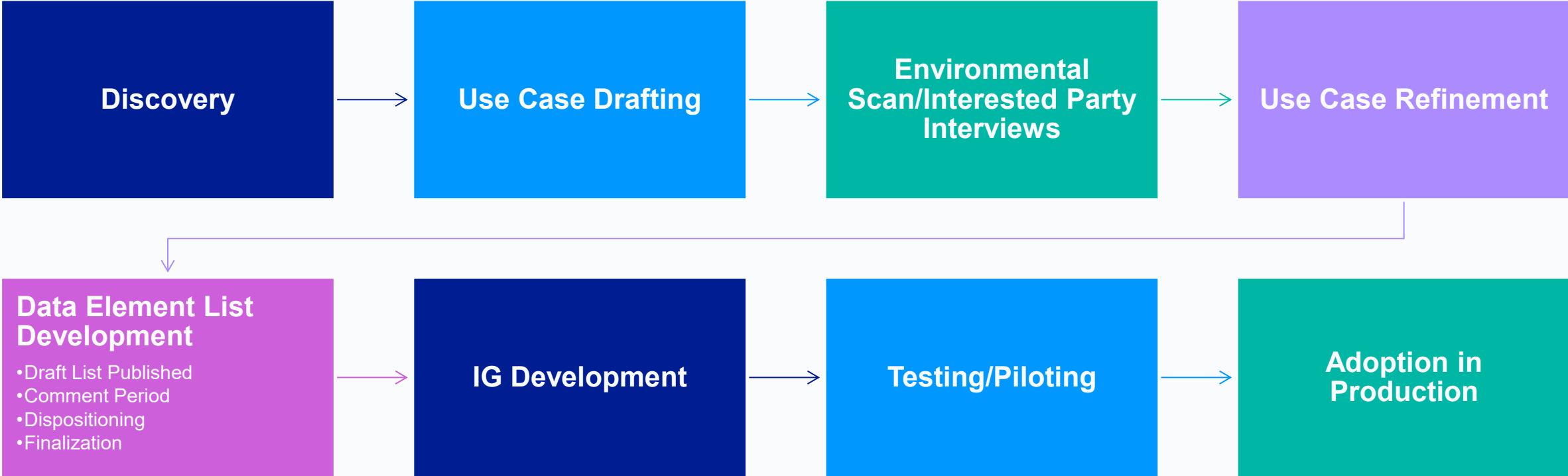- Laboratory Data Exchange

Quality
- Overarching
- Quality Data V1
- UDS+

Other Initiatives
- Respiratory Illness
- Sickle Cell Disease

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Example Lifecycle of a USCDI+ Project

Discovery → **Use Case Drafting** → **Environmental Scan/Interested Party Interviews** → **Use Case Refinement**

Data Element List Development
- Draft List Published
- Comment Period
- Dispositioning
- Finalization

→ **IG Development** → **Testing/Piloting** → **Adoption in Production**

Public Comment

Seth Pazinski, Designated Federal Officer, ASTP

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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 astp-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*

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Next Steps

Sarah DeSilvey, Co-Chair

Steven Eichner, Co-Chair

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Upcoming Meetings

ISWG Meeting Dates
1/28/2025
2/4/2025
2/11/2025
2/18/2025
2/25/2025
3/4/2025
3/11/2025
3/18/2025
3/25/2025
4/1/2025

HITAC Meeting Dates	Task Force Update
2/13/2025	Task Force Update
3/20/2025	Task Force Update
4/10/2025	HITAC Vote

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Meeting Adjourned