

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

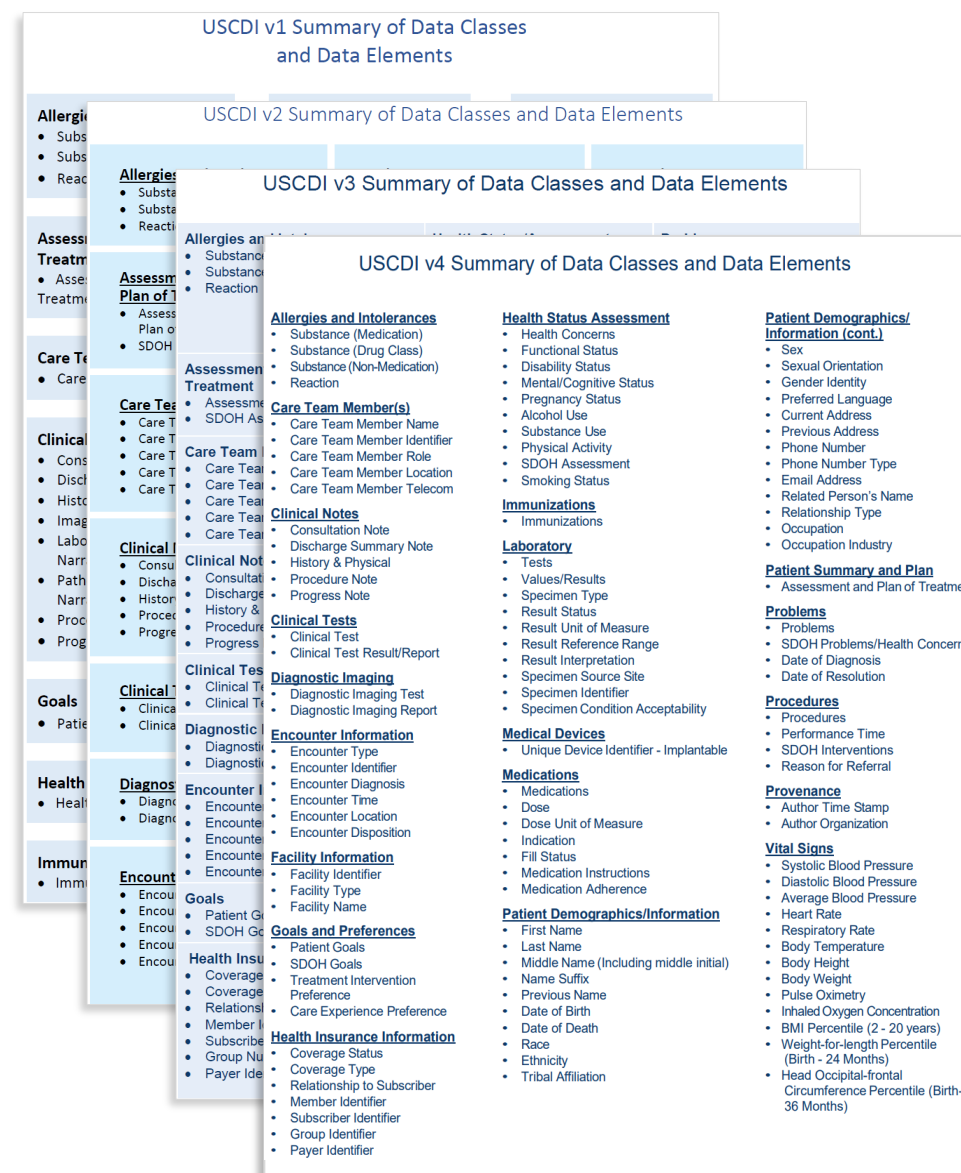
Expands over time via a predictable, transparent, and collaborative **public** process

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

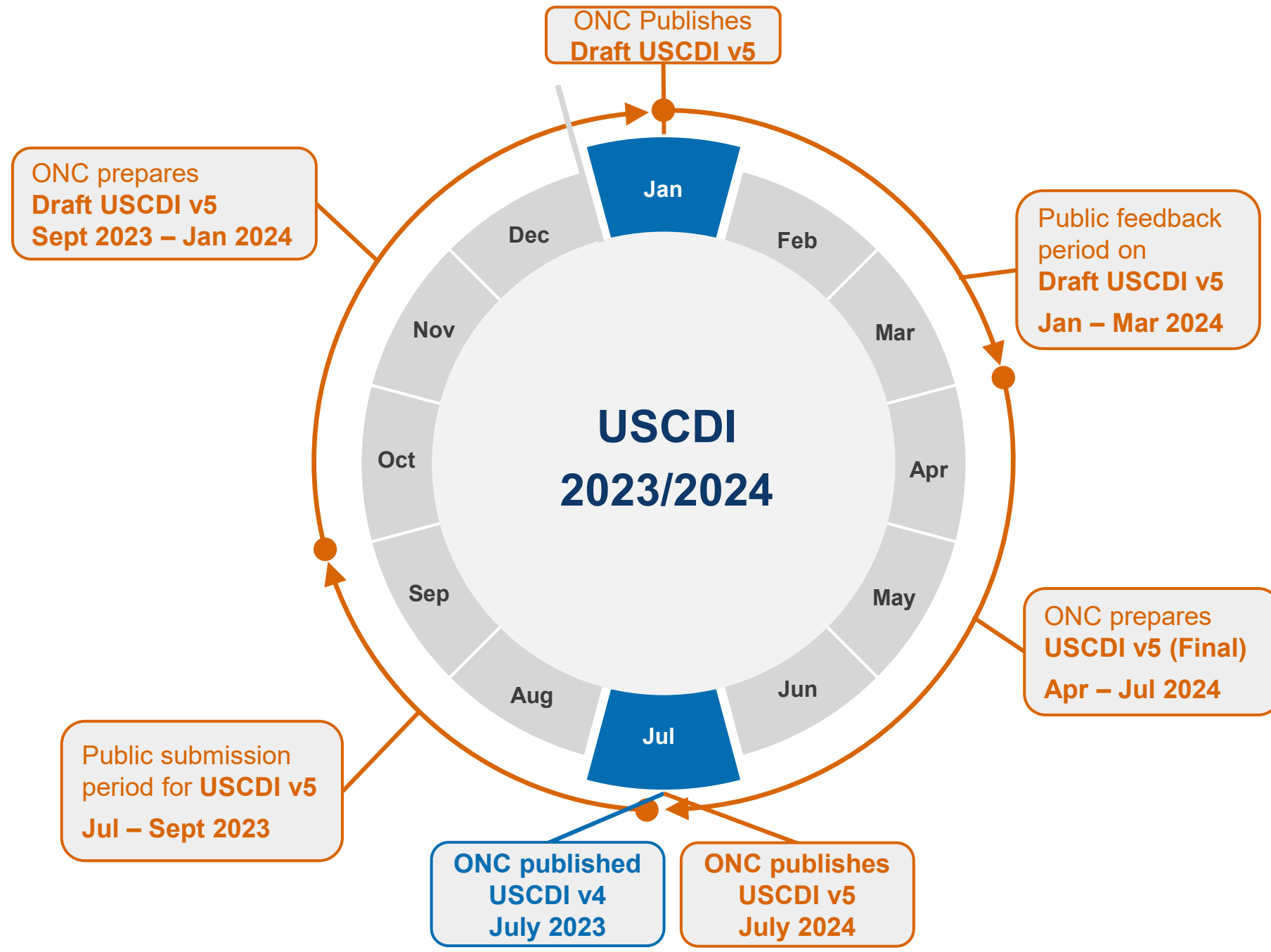
USCDI: Transparent, Predictable, Collaborative

- 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





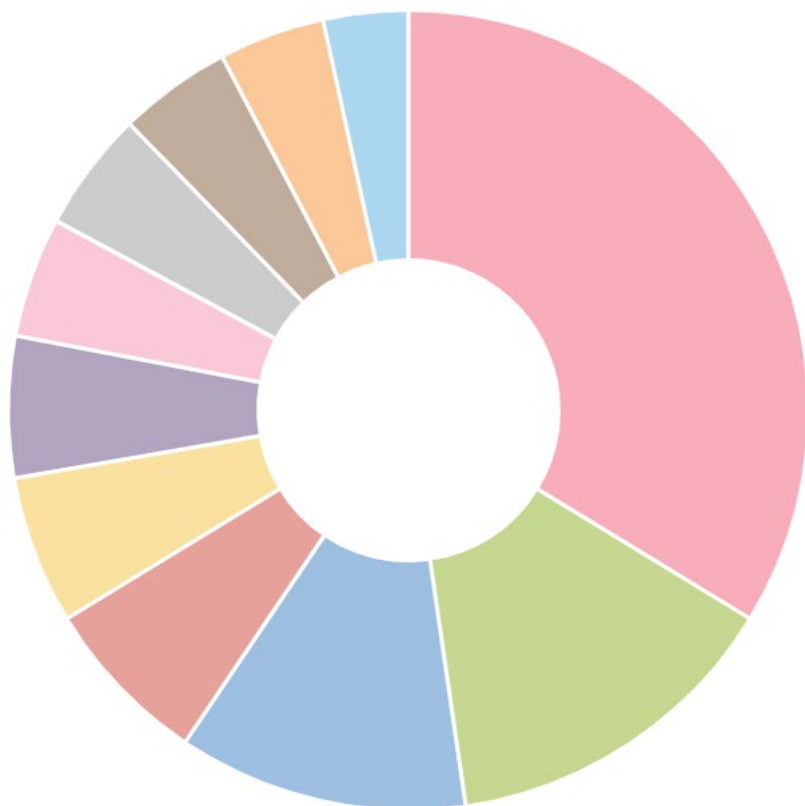
Draft USCDI v5 Comment Process



Public Comments for USCDI Version 5

Comments Received

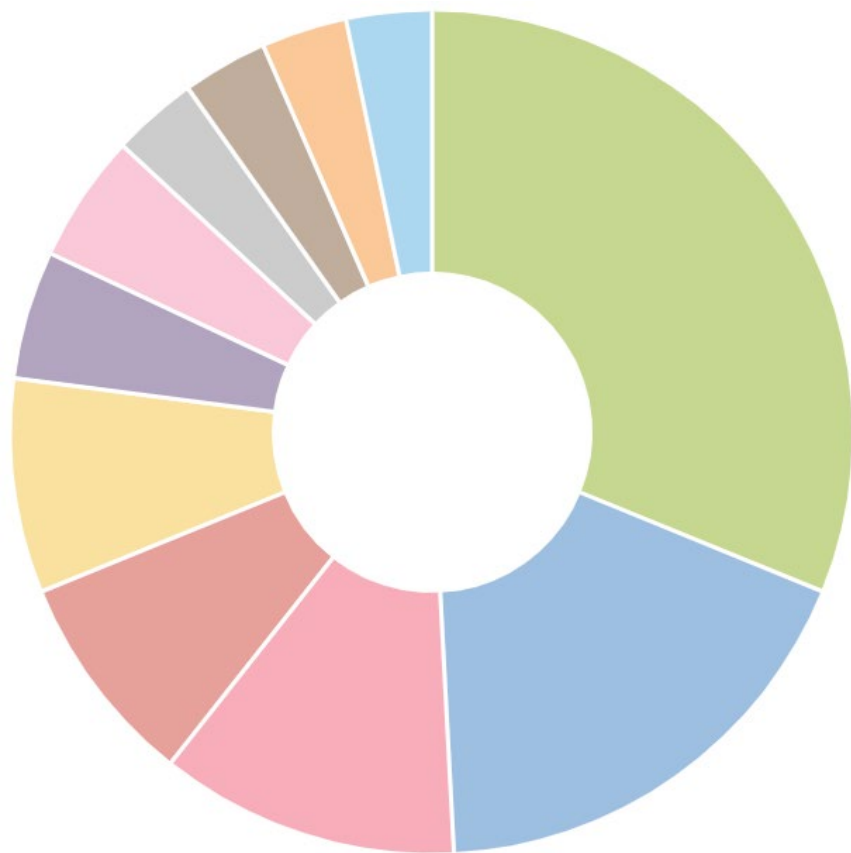
Total: **350**



	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 Δ

- 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 Δ

- Unique Device Identifier - Implantable Δ

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 Δ

- 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



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.



Step 1. Submit new data elements and classes

[Review Prep Sheet](#)

See questions and prepare content for your submission - updated to include more information on ONC's evaluation of submissions

[Start My Submission](#)

Registered ISA users only - [login](#) or [create account here](#)



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

• Level 0 • Level 1 • Level 2

[View Leveling Criteria](#)

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. Deadline for new submissions for USCDI v5 is September 20, 2023 at 11:59 ET.



Step 5. ONC anticipates publishing Draft USCDI v5 in January 2024.

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.

Three parallel blue diagonal lines of varying lengths are positioned on the left side of the slide, slanting upwards from left to right.

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-fact-sheet)

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

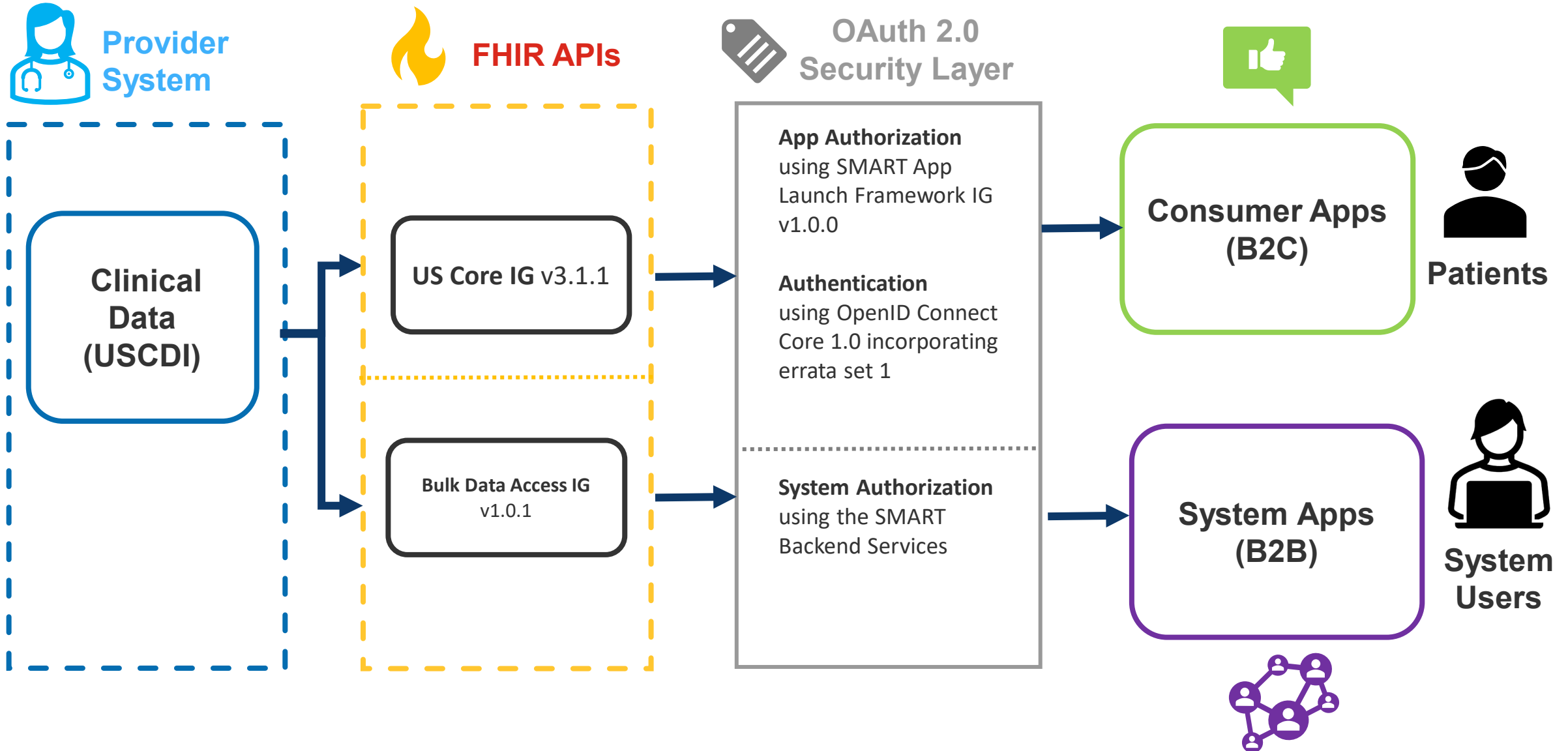
For example, § 170.315 (b)(1) "Transition of care" and § 170.315(g)(10) "Standardized API for patient and population services"

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

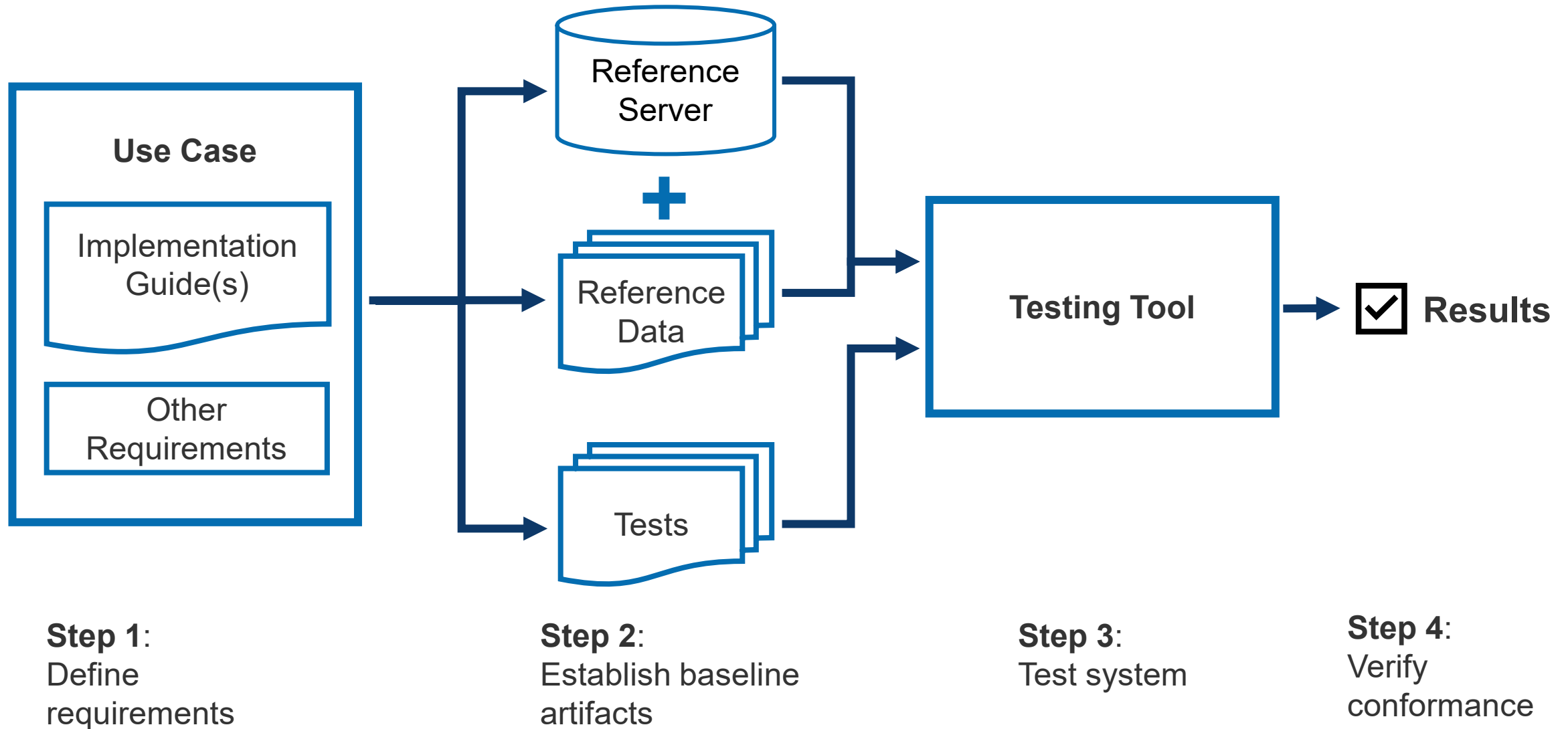
These testing tools include the [Inferno Framework](#) for FHIR testing and the [Edge Testing Tool](#) for C-CDA testing



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



Testing Workflow



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

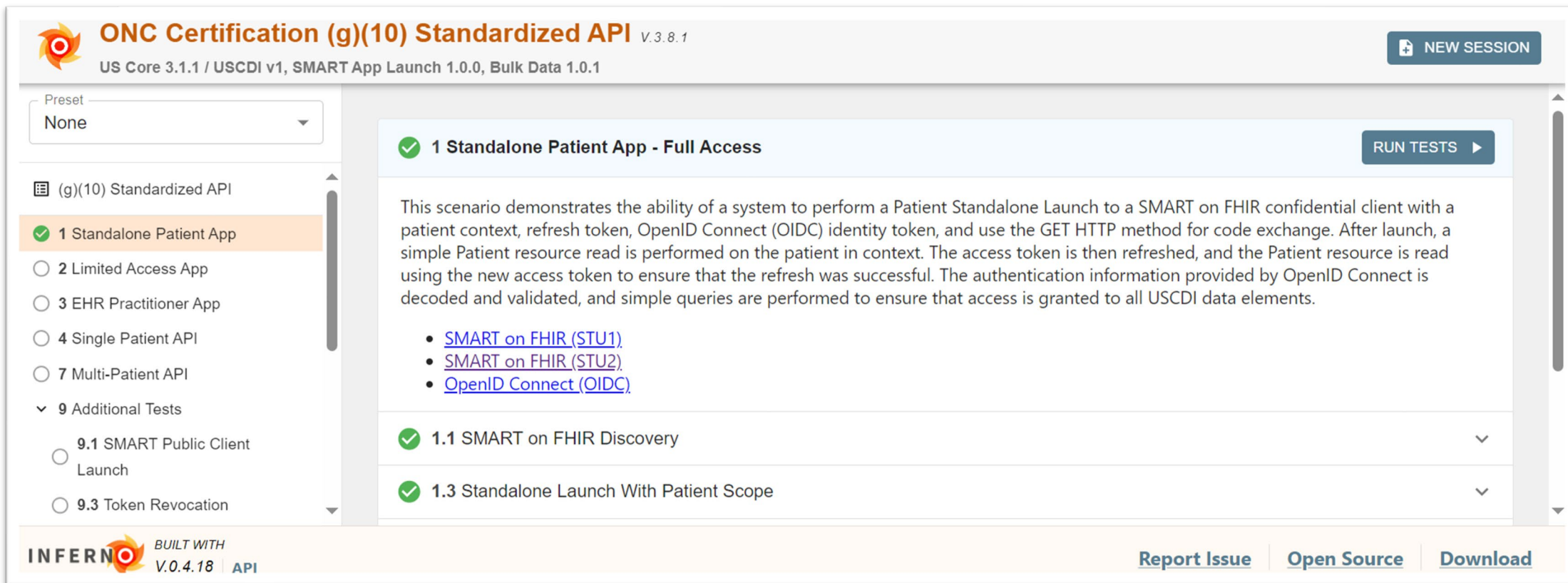
Bulk Data Version

- ☒ 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



The screenshot displays the Inferno testing interface for the ONC Certification (g)(10) Standardized API. The interface is divided into several sections:

- Header:** Features the Inferno logo, the title "ONC Certification (g)(10) Standardized API" with version "V.3.8.1", and a "NEW SESSION" button.
- Left Sidebar:** Contains a "Preset" dropdown set to "None" and a list of test scenarios. The selected scenario is "1 Standalone Patient App", which is highlighted in orange. Other scenarios include "2 Limited Access App", "3 EHR Practitioner App", "4 Single Patient API", "7 Multi-Patient API", "9 Additional Tests" (expanded), "9.1 SMART Public Client Launch", and "9.3 Token Revocation".
- Main Content Area:** Displays the details for the selected test scenario, "1 Standalone Patient App - Full Access". It includes a description of the scenario, a "RUN TESTS" button, and a list of sub-scenarios: "1.1 SMART on FHIR Discovery" and "1.3 Standalone Launch With Patient Scope".
- Footer:** Includes the Inferno logo, the text "BUILT WITH V.0.4.18 API", and links for "Report Issue", "Open Source", and "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

FINAL RESULT

3.8.1

VERSION

Nov 1, 2023, 2:13 PM

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.



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for Health Information Technology

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Health IT Feedback Form:

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



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LinkedIn: [Office of the National Coordinator for Health Information Technology](#)



Youtube:

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

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