



Office of the National Coordinator  
for Health Information Technology

# ONC Health IT Certification Program Developer Roundtable



October 25, 2023



## Please Note:

- The materials contained in this presentation are based on the provisions contained in 45 C.F.R. Parts 170 and 171. While every effort has been made to ensure the accuracy of this restatement of those provisions, this presentation is not a legal document. The official program requirements are contained in the relevant laws and regulations. Please note that other Federal, state and local laws may also apply.
- This communication is produced and disseminated at U.S. taxpayer expense.



# Today's Speakers

1. Robert Anthony, Director, Certification and Testing
2. Shawn Spurlock, Public Health Analyst, Program Administration
3. Ashley Hain, Acting Branch Chief, Tools and Testing
4. Scott Bohon, Public Health Analyst, Tools and Testing
5. Jiuyi Hua, IT Specialist, Tools and Testing
6. Erin Little, Public Health Analyst, Tools and Testing
7. Keith Carlson, Health IT Specialist, Tools and Testing
8. John Bender, Public Health Analyst, Tools and Testing



# Agenda

1. Opening Remarks
2. ONC Health IT Certification Program Updates
3. § 170.315(b)(10) Electronic Health Information Export
4. CHPL: CMS EHR Certification ID Updates
5. ONC Tooling 101





# ONC Health IT Certification Program Updates

Shawn Spurlock, Public Health Analyst, Program Administration

# 2023 SVAP Timeline

- 2023 SVAP Public Comment Period
  - Opened: February 21, 2023
  - Closed: May 22, 2023
- 2023 SVAP Announcement
  - July 12, 2023
- 2023 SVAP Effective
  - **September 11, 2023**
- 2024 SVAP Public Comment Period
  - Opens: February 2024
  - Closes May 2024 (90 days)

## SVAP Annual Process

<https://www.healthit.gov/SVAP>



# Standards Version Advancement Process (SVAP)

The SVAP allows health IT developers participating in ONC's Health IT Certification Program to voluntarily update their Health IT Modules to use approved newer versions of standards than are adopted in regulation so long as certain conditions are met.

## Why Is This Important?

- Provides flexibility to approve newer versions of adopted standards without rulemaking.
- Institutes a predictable and timely approach within the Certification Program to keep pace with the industry's standards development efforts.
- Supports interoperability in the real world as updated versions of standards reflect insights gained from real-world implementation and use.

**ONC established the voluntary SVAP flexibility as part of the “Real World Testing” Condition and Maintenance of Certification requirement of the 21st Century Cures Act.**

# Real World Testing Deadlines

- Real World Testing is a process by which Health IT developers demonstrate interoperability and functionality of their Certified Health IT in real world settings and scenarios, rather than in a controlled test environment with an ONC-Authorized Testing Lab (ONC-ATL).
  - 2024 Real World Testing Plans are due December 15, 2023
  - 2023 Real World Testing Results are due March 15, 2024





# Attestation Period Closing

The attestations submission window opened October 1, 2023, and remains open for Certified Health IT developers to submit their attestations through **October 31, 2023**.

Certified Health IT developers will submit their attestations to ONC-Authorized Certification Bodies (ONC-ACBs) for review using the Certified Health IT Product List (CHPL). For any questions about Attestations requirements or CHPL registration, please visit the [Attestations Resource Guide](#) or contact your ONC-ACB directly.



# ONC's 2023 Annual Meeting


**We're back!** For the first time since 2020, ONC will be hosting our Annual Meeting in-person in Washington, DC for two days of conversation, learning, and networking. Join us to hear about the key issues at the intersection of health care, public health, policymaking, and technology through a variety of keynote speakers, including National Coordinator Micky Tripathi, and main stage & breakout sessions.

**December 14-15, 2023**

For more information, including registration, please visit [www.oncannualmeeting.com](http://www.oncannualmeeting.com)

## § 170.315(b)(10) EHI Export

- The 2015 Cures Update includes the § 170.315(b)(10) EHI export criterion that replaces the 2015 Edition § 170.315(b)(6) Date export criterion
- Replacing § 170.315(b)(6) with § 170.315(b)(10) enables:
  - Providers to export all EHI stored in a Certified Health IT product for a single patient or for an entire patient population
  - Individual patient access to EHI
- Required to be certified and made available to end users by December 31, 2023



## **§ 170.315(b)(10) Electronic Health Information (EHI) Export**

Robert Anthony, Director, Certification and Testing

# Who Is Required to Be Certified to § 170.315(b)(10)?

- The Assurances Maintenance of Certification requires Certified Health IT that electronically stores EHI to certify to the Cures Update § 170.315(b)(10) EHI Export criterion.
- What about:
  - Certified Health IT that is part of a larger product that stores EHI?
  - Certified Health IT that uses relied upon software (RUS) to export EHI?
  - Certified Health IT that leverages 3<sup>rd</sup> party EHI storage?
- What should developers submit to their ONC-ACB if they feel as if § 170.315(b)(10) does not apply to them?
- *Can a developer just direct customers to a 3<sup>rd</sup>-party solution and not have to certify to § 170.315(b)(10) themselves?*
- *Do customers have to accept the (b)(10) update and/or use it?*

# What Is EHI?

- Electronic Health Information (EHI) refers to “electronic protected health information” (ePHI) to the extent that it would be included in a designated record set as defined in 45 CFR 164.501
- EHI does not include:
  - Psychotherapy notes
  - Information compiled in a reasonable anticipation or, for use in, a civil, criminal, or administrative action/ proceeding.
- *“Does [X data need] to be included in the EHI Export?”*
  - Ask yourself these 2 questions:
    - Is it stored by the product of which the Certified Health IT Module is a part?
    - Would it qualify under the EHI definition above?
- Can information outside of the EHI definition be included in the EHI Export?
  - The ONC Health IT Certification Program does not place requirements on the EHI that can be exported under the § 170.315(b)(10) functionality beyond what is defined in regulation as EHI.

## § 170.315(b)(10) & Information Blocking

- Do hospitals or providers need to have § 170.315(b)(10) functionality in place to comply with Information Blocking requirements?
  - § 170.315(b)(10) is not explicitly designed to fulfill Information Blocking requirements.
  - § 170.315(b)(10) is a developer requirement, not a provider requirement.
  - ONC regulations only place requirements on developers to make the functionality available to its end users. There are no ONC regulatory requirements on end users or providers related to the use of the functionality.



## § 170.315(b)(10) Resources

For more information regarding the § 170.315(b)(10) EHI export criterion, please refer to the following resources:

1. [§ 170.315\(b\)\(10\) EHI Export Factsheet](#)
2. [§170.315\(b\)\(10\) Certification Companion Guide](#)
3. [Blog: Getting Ready for EHI Export: A Quick Guide](#)





**CHPL: CMS EHR Certification ID Updates**

# CHPL: CMS EHR Certification ID Updates

## Only 2015 Cures Update listings can be used to generate CMS IDs, and they will include a “15C” syntax within the ID

- With the introduction of the 2015 Edition Cures Update, ONC started issuing CMS EHR Certification ID's of "15C" to identify EHRs are certified to the 2015 Edition Cures Update for CMS Programs. The CMS Quality Payment Program's Promoting Interoperability Performance Category, Promoting Interoperability Program, and Inpatient Quality Reporting Program submission period is closed for the last reporting period (2022) that accepted 2015 Edition Certified Products with the "15E" syntax.
- Effective for reporting periods starting in 2023, the IQR Program, Promoting Interoperability Program, and Quality Payment Programs Promoting Interoperability Performance Category require the use of 2015 Edition Cures Update certified technology. Because CMS reporting programs will only accept 2015 Edition Cures Update certified technology, ONC's CHPL will only generate CMS EHR Certification IDs with the "15C" syntax. 2015 Edition and hybrid Certification IDs are no longer permitted by CMS.
- For questions regard the CMS policy, please contact the Inpatient Value, Incentives, and Quality Reporting Outreach and Education Support Contractor at [https://cmsqualitysupport.servicenowservices.com/qnet\\_qa](https://cmsqualitysupport.servicenowservices.com/qnet_qa) for eligible hospital eCQM and Hybrid measures.



# ONC Tooling 101

Tools and Testing Branch

# Agenda: ONC Certification Program Tooling 101

- Overview
- HL7 FHIR Testing
- SITE / Edge Testing
- Electronic Prescribing Testing
- Clinical Quality Measures (CQMs) Testing
- Public Health Testing



# ONC Conformance Test Tools page

Official Website of The Office of the National Coordinator for Health Information Technology (ONC)

HealthIT.gov

[TOPICS](#) [BLOG](#) [NEWS](#) [DATA](#) [ABOUT ONC](#)

HealthIT.gov > [Topics](#) > [Certification of Health IT](#) > [Certification Process](#) > [ONC Conformance Test Tools](#)

**Certification of Health IT** ▾

About the Health IT Certification Program

**Certification Process** ▾

Conformance Methods

**ONC Conformance Test Tools**

ONC-Authorized Certification Bodies (ONC-ACBs)

ONC – Authorized Testing Laboratories (ONC-ATLs)

ONC Approved Testing Partners

Certification Criteria >

Conditions & Maintenance of Certification

Real World Testing

Certified Health IT Products List (CHPL)

Oversight and Surveillance >

**Key Links**

[Certified Health IT Product List \(CHPL\)](#)

[2015 Edition Cures Update Criteria](#)

[§ 170.315\(b\)\(10\) Electronic Health Information \(EHI\) Export Fact Sheet](#)

[Conditions & Maintenance of Certification](#)

**ONC Conformance Test Tools**

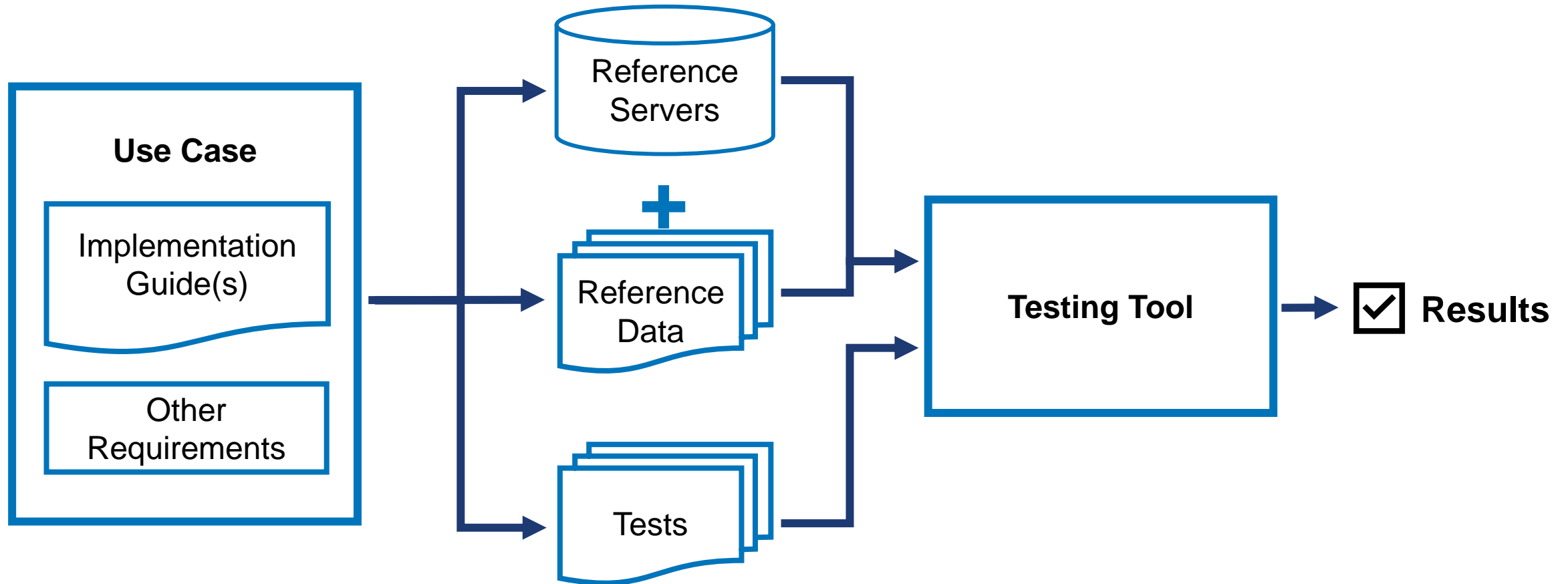
The following tools are ONC-approved Conformance resources to help developers implement standards to enable health information interoperability.

**Inferno**

Test Tools	Use in ONC Health IT Certification Program	Base Standards Under Test for the ONC Health IT Certification Program
<b>Inferno Framework</b>	§ 170.315(g)(10) Standardized API for patient and population services	<p><b>HL7<sup>®</sup> FHIR<sup>®</sup></b></p> <ul style="list-style-type: none"> <li>◦ <a href="#">US Core Implementation Guide STU V3.1.1</a> ☞</li> <li>◦ <a href="#">HL7<sup>®</sup> FHIR<sup>®</sup> Version 4.0.1, October 30, 2019</a> ☞</li> <li>◦ <a href="#">SMART Application Launch Framework Implementation Guide Release 1.0.0</a> ☞</li> <li>◦ <a href="#">Bulk Data Access (Flat FHIR<sup>®</sup>) (V1.0.1: STU 1)</a> ☞</li> </ul> <p><b>Other standards</b></p> <ul style="list-style-type: none"> <li>◦ <a href="#">OpenID Connect Core 1.0 incorporating errata set 1</a></li> </ul>

<https://www.healthit.gov/topic/certification-ehrs/onc-conformance-test-tools>

# ONC Certification Testing Workflow

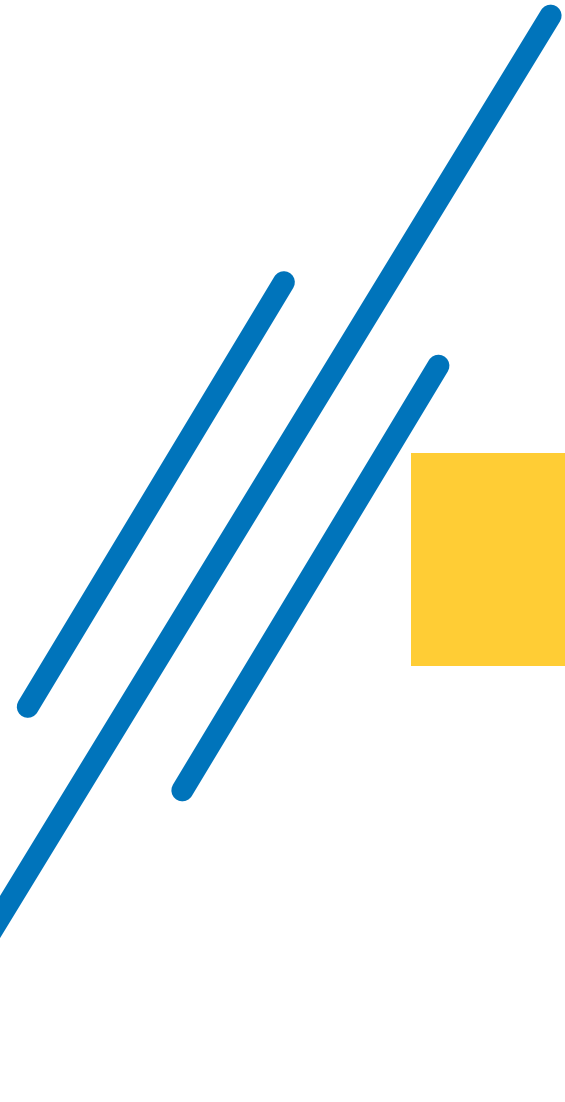


**Step 1:**  
Define  
Requirements

**Step 2:**  
Establish baseline  
artifacts

**Step 3:**  
Test system

**Step 4:**  
Verify  
conformance



# HL7 FHIR Tooling

Scott Bohon, Public Health Analyst

# FHIR Testing Tools



- FHIR APIs are required as part of certification to the § 170.315(g)(10) "Standardized API for patient and population services" criterion
- **Inferno**
  - Supports ONC Certification Program and FHIR community testing
  - Open-source code, with documentation available for writing your own tests
  - Uses the Ruby programming language for executing tests

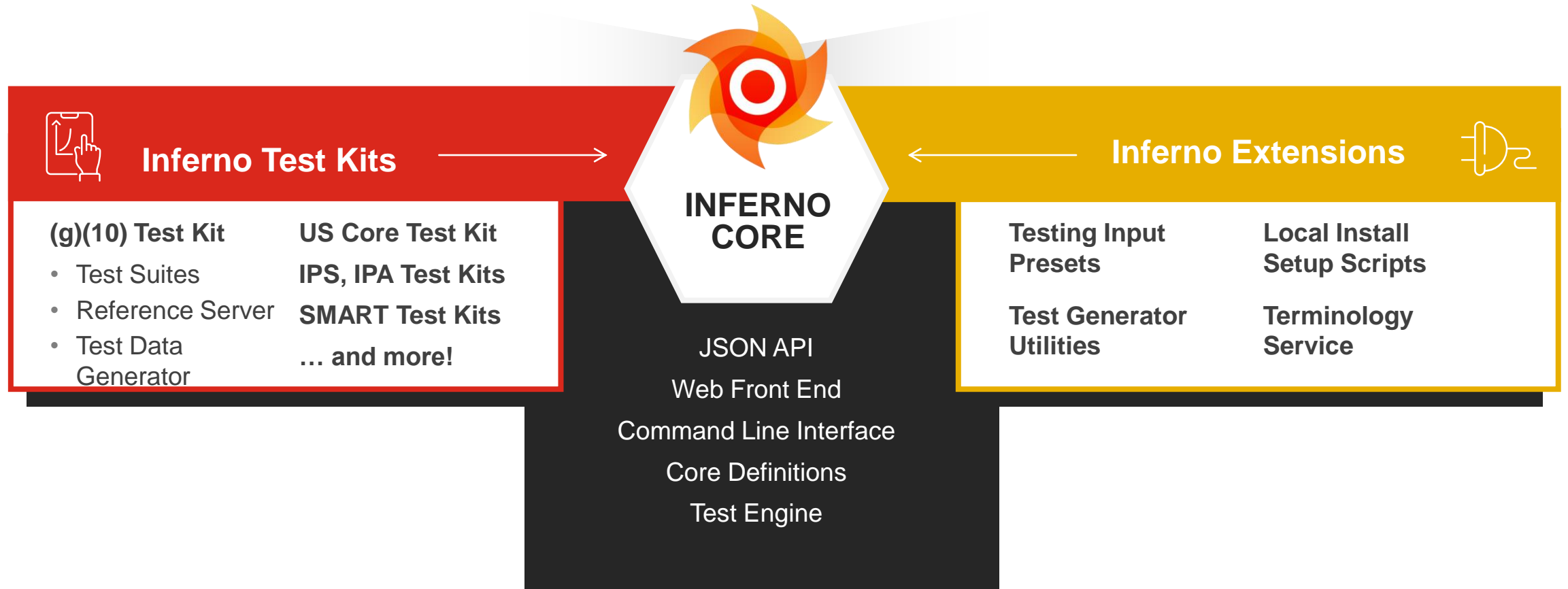


- **AEGIS Touchstone**
  - Supports variety of FHIR implementation guides
  - Used in an Alternative Test Method for API testing in the ONC Certification Program
  - Executes tests via FHIR "TestScript" resource plus extensions





Helping developers implement the FHIR standard consistently.



### Additional Resources

US Core  
Synthea Generator

Template  
Reference Server

Template Test Kit

FHIR Validator

Lantern

# Inferno Examples: (g)(10) Test Kit Standards Selection

## ONC CERTIFICATION (G)(10) STANDARDIZED API

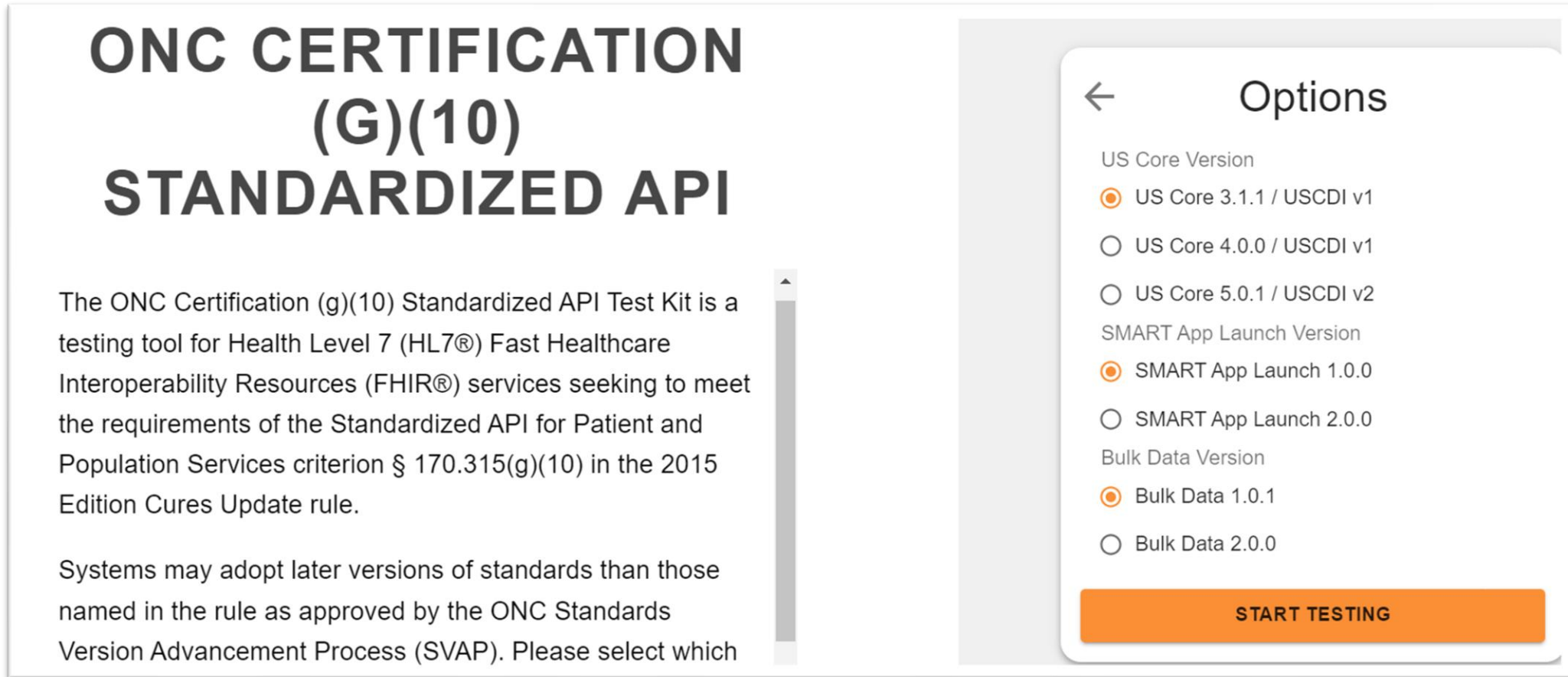
The ONC Certification (g)(10) Standardized API Test Kit is a testing tool for Health Level 7 (HL7®) Fast Healthcare Interoperability Resources (FHIR®) services seeking to meet the requirements of the Standardized API for Patient and Population Services criterion § 170.315(g)(10) in the 2015 Edition Cures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

The image shows a screenshot of the Inferno test kit interface. On the left, there is a text box with the title "ONC CERTIFICATION (G)(10) STANDARDIZED API" and a paragraph of text explaining the test kit's purpose and a note about adopting later versions of standards. On the right, there is a modal window titled "Options" with a back arrow. It lists three categories of standards: "US Core Version", "SMART App Launch Version", and "Bulk Data Version". Each category has radio buttons for different versions, with the first option in each category selected. At the bottom of the modal is an orange button labeled "START TESTING".

*Figure: This screen shows standards combinations available for certification testing in the Inferno test kit for the § 170.315(g)(10) criterion.*

# Inferno Examples: (g)(10) Test Kit Test Interface

**HealthIT.gov**

These reference applications are provided by ONC for demonstration only. Do not use to access sensitive data or Protected Health Information (PHI). Test sessions without testing activity for two months are removed. [HHS Privacy Policy](#) | [HHS Vulnerability Disclosure Policy](#)

**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
  - 9.4 SMART Invalid AUD Launch
  - 9.5 SMART Invalid Token Request

**ONC Certification (g)(10) Standardized API** RUN ALL TESTS ▶

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.

To get started, please first register the Inferno client as a SMART App with the following information:

- SMART Launch URI: <https://inferno.healthit.gov/suites/custom/smart/launch>
- OAuth Redirect URI: <https://inferno.healthit.gov/suites/custom/smart/redirect>

For the multi-patient API, register Inferno with the following JWK Set Url:

- [https://inferno.healthit.gov/suites/custom/g10\\_certification/.well-known/jwks.json](https://inferno.healthit.gov/suites/custom/g10_certification/.well-known/jwks.json)

Systems must pass all tests in order to qualify for ONC certification.

- 1 [Standalone Patient App - Full Access](#)
- 2 [Standalone Patient App - Limited Access](#)
- 3 [EHR Practitioner App](#)

**INFERN** BUILT WITH V.0.4.18 | API Report Issue | Open Source | Download

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

# FHIR Testing Links

- ONC hosted instance of Inferno for FHIR testing
  - [Inferno.HealthIT.gov](https://Inferno.HealthIT.gov)
- ONC GitHub for Certification Program FHIR testing code
  - [ONC Certification \(g\)\(10\) Standardized API Tests \(github.com\)](https://github.com/ONC-Certification-Program/Standardized-API-Tests)
- Inferno Framework GitHub for general FHIR testing code
  - [Inferno Health API Testing Framework \(github.com\)](https://github.com/Inferno-Health-API-Testing-Framework)
- Inferno Documentation for writing FHIR tests
  - [Inferno Framework Documentation](#)
- Touchstone Platform for FHIR testing
  - [The Touchstone Platform for HL7® FHIR® – AEGIS.net, Inc.](#)
- Alternative Test Method for § 170.315(g)(10) criterion
  - [Drummond G10+ FHIR® API powered by Touchstone tool](#)



# SITE / Edge Testing

Jiuyi Hua, IT Specialist  
Erin Little, Public Health Analyst

## SITE/ETT

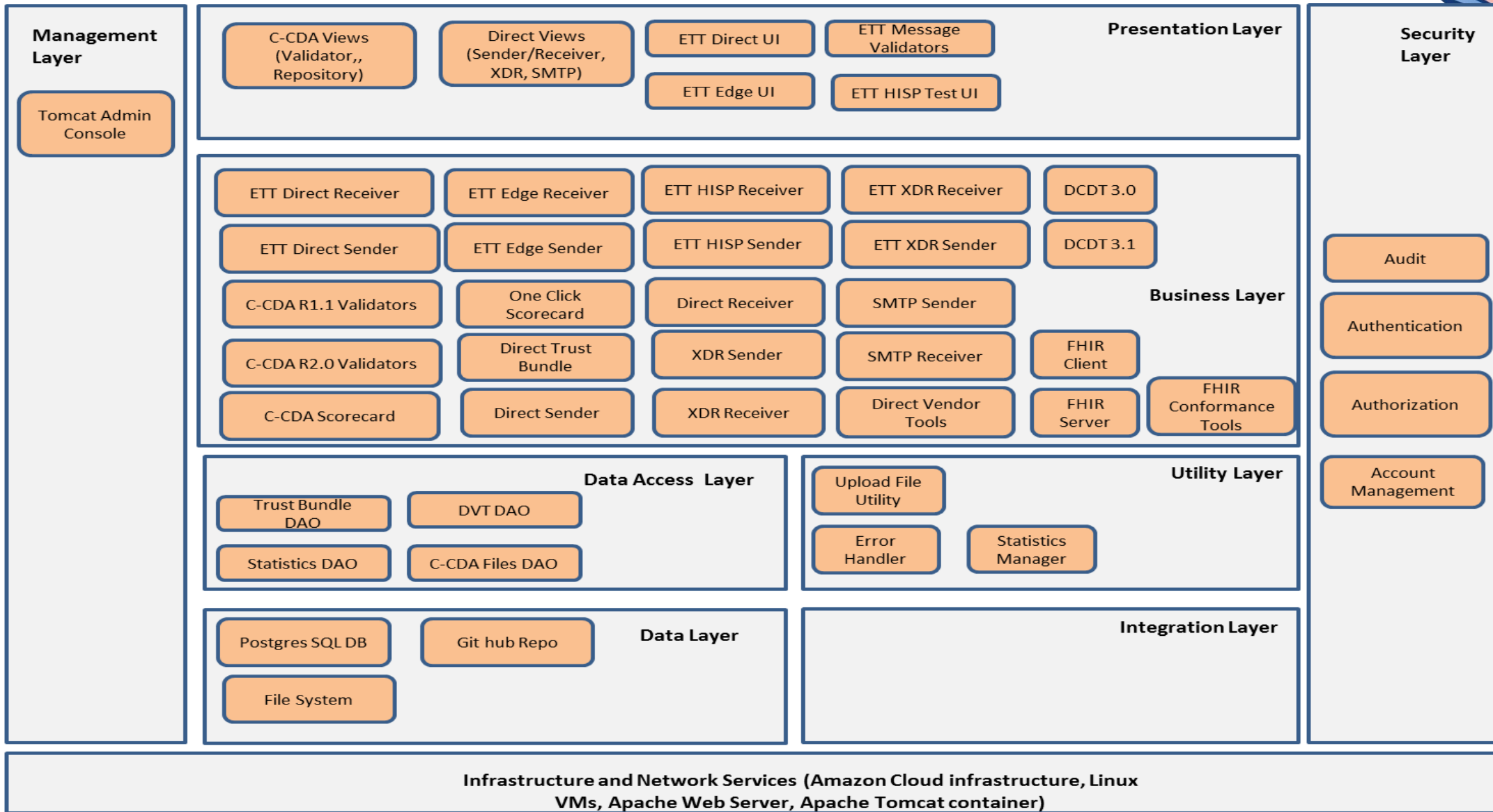
### SITE

- Standard and Interoperability support. Organized in a collection of sandboxes that provide test tools, sample data, resources, services and useful links. <https://site.healthit.gov/home>

### ETT

- Set of testing tools. Testing utilities created to validate the requirements of the 2015 Edition and the 2015 Edition Cures Update Health IT Certification Program.

# SITE Architecture

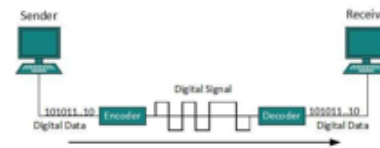


# The h Criteria = Transport Protocols

- ❖ 2015 Edition health IT certification criterion § 170.315 h regulates **Health Data Transport Methods and Protocols**



## h(1) Direct Project, HISP



- Secure Messaging
- HIPPA Compliant
- Interoperable
- Nationwide clinic data exchange

## h(2) Direct, Edge Protocol, XDS



- XDM – MIME message type – Email + WWW
- IHE XRD Permit direct message interchange between EHRs, PHR, other Health IT system



# Message Validators

- Validators test conformance of artifacts to industry standards and specific criteria, and include:
  - C-CDA
  - XDM
  - XDR
  - Direct Message
- There are context-free validators for general testing and validators for the criteria of the 2015 Edition
- <https://ett.healthit.gov/ett/#/validators>

## C-CDA R2.1 Validator for 2015 Edition Cures Update and SVAP 2022

### R2.1 and USCDI v2 Validation

To validate with the C-CDA Implementation Guide attach or drag your C-CDA into the tool and press Validate.

Upload generated C-CDA file and click validate.

OR Drag And Drop your file here

Click to Validate your Document:

To validate your C-CDA for 2015 Edition Cures Update and SVAP 2022.

Step 1: Select whether your system is a SENDER or RECEIVER of C-CDA's:

Step 2: Select the ONC 2015 Edition Cures Update criteria objective or other C-CDA IG conformance criteria:

Select validation criteria...

Step 3: Select the scenario file that you used to generate the C-CDA:

Select scenario file...

Step 4: Upload generated C-CDA file and click validate.

OR Drag And Drop your file here

Step 5: Click to Validate your Document:

To validate your C-CDA for 2015 Edition Cures Update and SVAP 2022.

**Step 1: Select whether your system is a SENDER or RECEIVER of C-CDA's:**

Sender Receiver

**Step 2: Select the ONC 2015 Edition Cures Update criteria objective or other C-CDA IG conformance criteria:**

Select validation criteria...

170.315\_b1\_ToC\_Amb

170.315\_b1\_ToC\_Inp

170.315\_b2\_CIRI\_Amb

170.315\_b2\_CIRI\_Inp

170.315\_b7\_DS4P\_Amb

170.315\_b7\_DS4P\_Inp

170.315\_b9\_CP\_Amb

Upload File OR Drag And Drop your file here

**Step 5: Click to Validate your Document:**

Validate



# Electronic Prescribing Testing

Erin Little, Public Health Analyst

# Electronic Prescribing (eRx) Testing

- Certification criteria: § 170.315(b)(3) Electronic prescribing
- Testing tool developed by the National Institute of Standards and Technology (NIST) and currently managed by the National Council for Prescription Drugs Programs (NCPDP)
  - ONC-Approved Testing Partner
- NCPDP SCRIPT Standard 2017071
  - Developed for transmitting prescription information electronically between prescribers, pharmacies, payers, and other entities
- NCPDP eRx testing suite supports transport, messaging and functional testing
- [tools.ncpdp.org/erx/#/home](https://tools.ncpdp.org/erx/#/home)

Test Plan Type: [Private](#) [Public](#) Test Plan: 

## Test Cases

- ▼ **ONC Certification Test Plan**
  - ▼ Cancel Prescription Tests
    - ▼ Cancel Scenario 1 - Pharmacy successfully cancels t
      - ▼ XML
        - 1.Prescriber creates a NewRx message and s
        - ← 2.Pharmacy acknowledges receipt of the New
        - ← 3.Pharmacy creates a Verify message in resp
        - 4.Prescriber acknowledges receipt of the Verif
        - 5.Prescriber creates a CancelRx message an
        - ← 6.Pharmacy acknowledges receipt of the Can
        - ← 7.Pharmacy creates a CancelRxResponse me
        - 8.Prescriber acknowledges receipt of the Can
      - ▶ Cancel Scenario 2 - (Optional) Immediate cancelation
      - ▶ Cancel Scenario 3 - (Optional) Discontinuation of exis
      - ▶ Cancel Scenario 4 - Discontinuation of an existing the
    - ▶ Change Prescription Tests
    - ▶ Medication History Tests (Complete either PBM or Pharm
    - ▶ Renewal Prescription Tests
    - ▶ DrugAdministration Tests (Optional)
    - ▶ Fill Indicator Change Tests (Optional)
    - ▶ NewRxRequest Transaction Tests (Optional)
    - ▶ Prior Authorization Tests (Optional)
    - ▶ Recertification Tests (Optional) LTC
    - ▶ REMS Transaction Tests (Optional)
    - ▶ Resupply Tests (Optional) LTC
    - ▶ Transfer Prescription Tests (Optional) Pharmacy Only

TestStep: Prescriber creates a NewRx message and sends to the pharmacy.

[▶Load Test Step](#)
[Test Story](#)
[Test Data Specification](#)
[Example Message](#)
[Download PDF](#)

## Title

Immediate cancellation of a new prescription. The pharmacy cancels the prescription.

## Description

Susanne Adirondack (Patient 6), with a diagnosis of hypertension, is coming to see Doctor Anna Bates (Provider 1) for a checkup. Susanne has been taking medication for hypertension for two years, and her blood pressure was well controlled. Since first being diagnosed with hypertension she has measured her blood pressure regularly. In the last few weeks, she has noticed some deviations in her blood pressure that are not responding to the therapy. Doctor Anna Bates examines her and concludes that her blood pressure is elevated, even with the medication therapy. Doctor Bates also notices the patient's legs are a little swollen. Doctor Bates decides to prescribe Hydrochlorothiazide 50 mg (MU2-01), one tablet every morning and sends a prescription to the NYC Pharmacy (Pharmacy 4). The doctor instructs Susanne to take the medication and keep track of her blood pressure as usual. After reviewing the patient's information and the medication order more closely, Doctor Bates notices that she prescribed a higher dose of hydrochlorothiazide than needed. Doctor Bates sends to the pharmacy a cancel request for the prescription. The pharmacy recognizes the Susanne and cancels the order for the Hydrochlorothiazide 50 mg tablets.

**ICD-10 Diagnosis Code:** I10 - Essential (primary) hypertension

## Precondition

Vendor has pre-configured the test prescribers, pharmacies, and patients, and has used one of each in this test.

## Postcondition

NCPDP SCRIPT V2017071 NewRx, Verify, CancelRx and CancelRxResponse messages have been generated by the test system.

## TestObjectives

Confirm correct population of the NCPDP SCRIPT V2017071 NewRx message.  
 Confirm correct population of the NCPDP SCRIPT V2017071 Verify message.  
 Confirm correct population of the NCPDP SCRIPT V2017071 CancelRx message.  
 Confirm correct population of the NCPDP SCRIPT V2017071 CancelRxResponse message.

## Notes

Visually compare &lt;DrugDescription&gt; to the RxNorm name and synonyms.

## NIST Developed ERX Validation Tool

[Home](#)
[Context-free](#)
[Context-based](#)
[Documentation](#)
[About](#)

Hello erinlitt2 -

[Test Selection](#)
[Test Execution](#)
 Current Test Step: Prescriber creates a NewRx message and sends to the pharmacy.

[ONC Certification Test Plan](#) / 
 [Cancel Scenario 1 - Pharmacy successfully cancels the prescription.](#) / 
 [XML](#) / 
 Prescriber creates a NewRx message and sends to the pharmacy.

Name	Description	Test Step Outcome	Comments	Report
→ 1. Prescriber creates a NewRx message and sends to the pharmacy.	Prescriber --> Pharmacy	Passed		<a href="#">Download</a>

[Validation](#)
[Report](#)

[Test Story](#)

[Test Data Specification](#)

[Example Message](#)

Message Tree

Message

Message Content

4s

[Validate](#)

[Load Example](#)

[Browse](#)

[Clear](#)

```

1 <?xml version="1.0" encoding="utf-8"?>
2 <Message DatatypesVersion="20170715" TransportVersion="20170715" TransactionDomain="SCRIPT" TransactionVersion="20170715" StructuresVersion="20170715" ECLVersion=
3   <Header>
4     <To Qualifier="P">1013988328</To>
5     <From Qualifier="D">1356602296</From>
6     <MessageID>50000000</MessageID>
7     <SentTime>2022-01-01T10:00:23</SentTime>
8     <SenderSoftware>
9       <SenderSoftwareDeveloper>NCPDP Conformance Tool</SenderSoftwareDeveloper>
10      <SenderSoftwareProduct>443</SenderSoftwareProduct>
11      <SenderSoftwareVersionRelease>12.1</SenderSoftwareVersionRelease>
12    </SenderSoftware>
13    <PrescriberOrderNumber>ORDMU201</PrescriberOrderNumber>
14  </Header>
15  <Body>
16    <NewRx>
17      <ReturnReceipt>1</ReturnReceipt>
18      <Patient>
19        <HumanPatient>
20          <Identification>
21            <PatientAccountNumber>PBMC-ONC MU-6006F</PatientAccountNumber>
22          </Identification>
23          <Name>
24

```

Message Validation Result [Help](#)

[Remove Duplicates](#)


[Report](#)

0 Errors

0 Warnings

0 Alerts

No errors found.



# Electronic Clinical Quality Measures (eCQMs) Testing

Keith Carlson, Health IT Specialist



## eCQM certification and testing

- ONC (c) criteria specify import, export, record, report, filter and calculate capabilities for eCQMs used by CMS's Quality Reporting Programs
- eCQMs exist in a fluid environment
  - eCQMs are updated in a yearly cycle to address
    - Changes in clinical practices
    - The addition and removal of codes
    - Bugs in measure logic
    - New and retired measures
    - eCQM standard updates
- Each year, certified systems need to update their systems to comply with the updates to eCQMs and standards
  - Even though recertification is not required, vendors retest their systems to new eCQMs



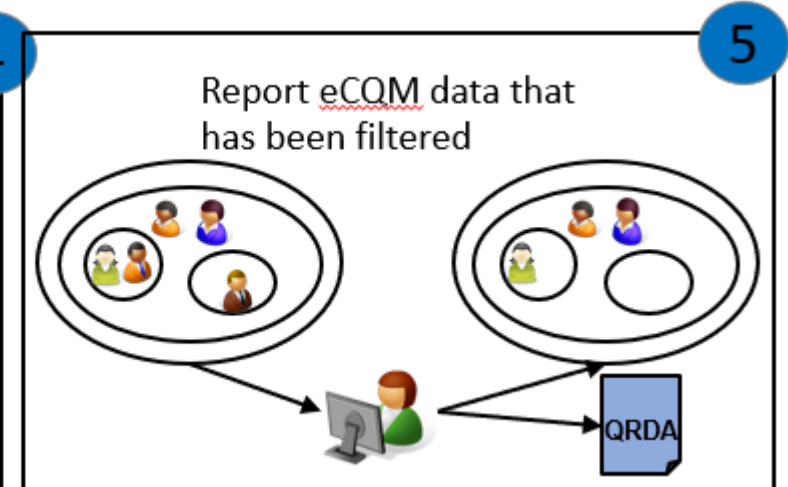
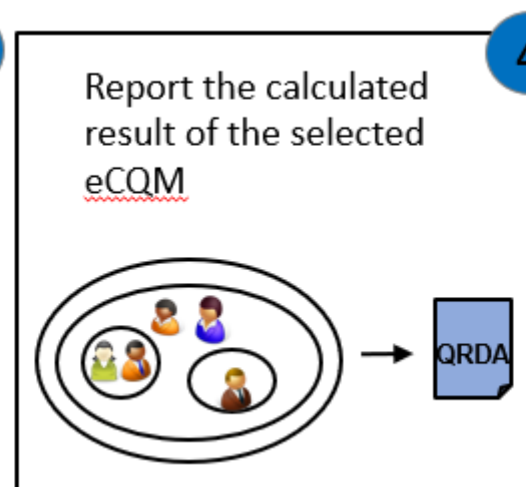
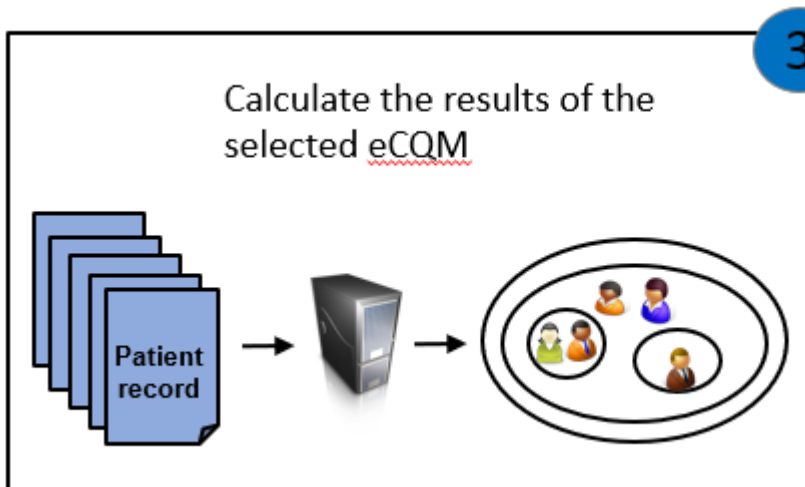
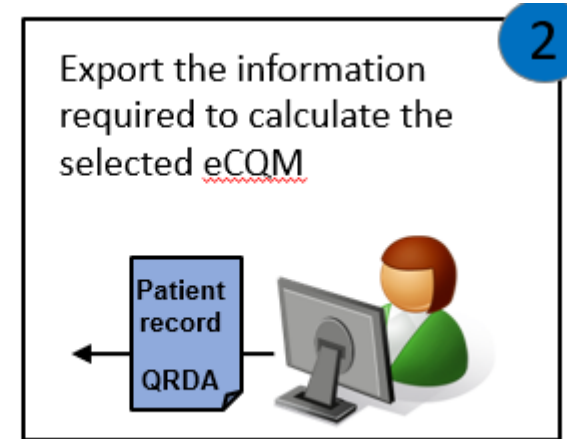
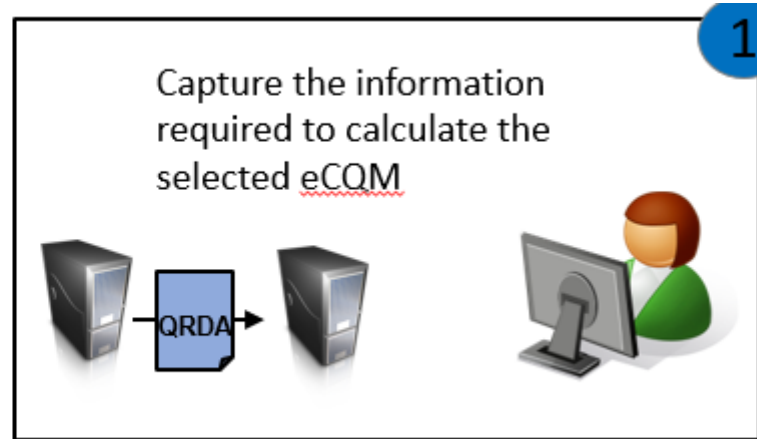
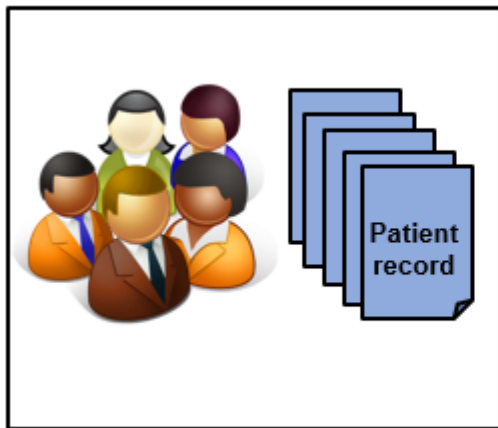
# Cypress

- A testing tool
  - Validates Electronic Health Record (EHR) system's ability to correctly calculate electronic Clinical Quality Measures (eCQMs).
- The official testing tool for the 2015 Edition Cures Update
  - Supported by the Office of the National Coordinator for Health IT (ONC).
- An open-source project
  - Freely available for use or adoption by the Health IT community including EHR vendors and testing labs.



# What Does Cypress Test?

Given a set of patients and eCQMs, Cypress tests the ability of an EHR to:



# How is Cypress made available?

- Cypress is developed as Open Source
  - Source code is made freely available and may be redistributed and modified
- Cypress releases are distributed as a:
  - Virtual Machine
    - A fully enclosed version which can be installed as-is on an organization's network
  - Amazon Machine Image
    - A virtual machine that can be run on Amazon's Elastic Compute Cloud
  - Demo Server
    - Publicly available instances of Cypress
      - <https://cypress.healthit.gov/>
      - <https://cypressvalidator.healthit.gov/>
    - Distribution model allows for EHR's vendors to install and use Cypress locally within their organization's firewalls to prior to certification



# Public Health Testing

Johnny Bender, Public Health Analyst

# Public health context

- **Seven public health criteria**

- 170.315(f)(1) Transmission to immunization registries
- 170.315(f)(2) Transmission to public health agencies — syndromic surveillance
- 170.315(f)(3) Transmission to public health agencies — reportable laboratory tests and value/results
- 170.315(f)(4) Transmission to cancer registries
- 170.315(f)(5) Transmission to public health agencies – electronic case reporting
- 170.315(f)(6) Transmission to public health agencies – antimicrobial use and resistance reporting
- 170.315(f)(7) Transmission to public health agencies – health care surveys

- **Additional information**

- Primarily supports public health reporting for state and federal programs
- Based in HL7 v2 and CDA
- All criteria have software-based testing methods besides (f)(5)
- Most criteria testing leverage the [NIST suite of testing tools](#)

# Public Health Testing: HL7 v2

- **NIST HL7 V2 Resource Portal**
  - Provided by National Institute of Standards and Technology (NIST)
  - Several tools and utilities to support the HL7 v2.x messaging standards
    - Including some tools leveraged by the ONC Certification Program
- **HL7 v2 Tools used in the ONC Certification Program**
  - 170.315(f)(1) Transmission to immunization registries
    - Test Method: **HL7v2 Immunization Test Suite** (ONC steward; NIST)
    - Alternate Test Method: Immunization Integration Program (IIP) (IIP steward; NIST)
  - 170.315(f)(2) Transmission to public health agencies — syndromic surveillance
    - Test Method: **HL7v2 Syndromic Surveillance Test Suite** (ONC steward; NIST)
  - 170.315(f)(3) Transmission to public health agencies — reportable laboratory tests and value/results
    - Test Method: **HL7v2 Electronic Laboratory Reporting** (ONC steward; NIST)

# NIST HL7 V2 Resource Portal


## HL7 V2 Resource Portal 1.0

[Home](#)   [Tools](#)   [Publications](#)   [Resources](#)   [Source Code](#)   [Links](#)   [About](#)

**Welcome to the NIST HL7 V2 Resource Portal!**

NIST provides a number of tools and utilities in support of the HL7 v2.x messaging standard. Conformance testing tools include web applications and web services for validating HL7 v2.x message instances based on message profiles. The foundation of the tool kit is a set of Java APIs that supports testing activities such as automated message generation and message validation. The APIs are organized as a testing framework which can be used to build tools such as web services and web applications. NIST provides the testing tools via these portal or the utilities can be incorporated into 3rd party applications and testing environments. Additionally, NIST is in the process of developing productivity tools to support the creation of HL7 v2 implementation guides (including the message profiles) and to develop test plans (i.e., creating test cases based on message profiles). This site provides access to the NIST HL7 v2 Toolkit.


### TOOLS



Explore NIST HL7 V2 Tools here:

- ▶ Testing Tools
- ▶ Profile Generation
- ▶ Test Case Generation
- ▶ Web Services


### PUBLICATIONS



Explore NIST HL7 V2 Publications here:

- ▶ Papers
- ▶ Presentations and Talks
- ▶ Tutorials


### RESOURCES



Explore NIST HL7 V2 Resources here:

- ▶ Profiles
- ▶ Profile Schemas
- ▶ Value Set Libraries
- ▶ Value Set Schemas

### SOURCE CODE



Access NIST HL7 V2 Source Code here:

- ▶ Testing Framework
- ▶ Validation Tools
- ▶ Productivity Tools
- ▶ APIs



# § 170.315(f)(1) Test Method: HL7v2 Immunization Test Suite

**NIST Immunization Test Suite 2.0.14**

Home | 1 SOAP Envelope | 2 SOAP Connectivity | 3 HL7 Context-free | 4 HL7 Context-based | Documentation | About | Hello Guest

Test Selection | Test Execution

Test Plan: ONC 2015 Test Plan

Test Cases

- ONC 2015 Test Plan
  - Administration Group
    - IZ-AD-1\_Admin\_Child
      - 1. IZ-AD-1.1\_Send\_V04\_Z22**
        - 2. IZ-AD-1.2\_Receive\_ACK\_Z23
      - IZ-AD-2\_Admin\_Adult
      - IZ-AD-3\_No\_Consent
      - IZ-AD-4\_Delete\_Record
      - IZ-AD-5\_Refusal
      - IZ-AD-6\_Update\_Record
      - IZ-AD-7\_Historical\_IIS-Error
      - IZ-AD-8\_Admin\_IIS-Warning
      - IZ-AD-9\_Admin\_IIS-2Warnings
      - IZ-AD-10\_Historical\_IIS-SysError
    - Evaluated History and Forecast Group

TestStep: IZ-AD-1.1\_Send\_V04\_Z22

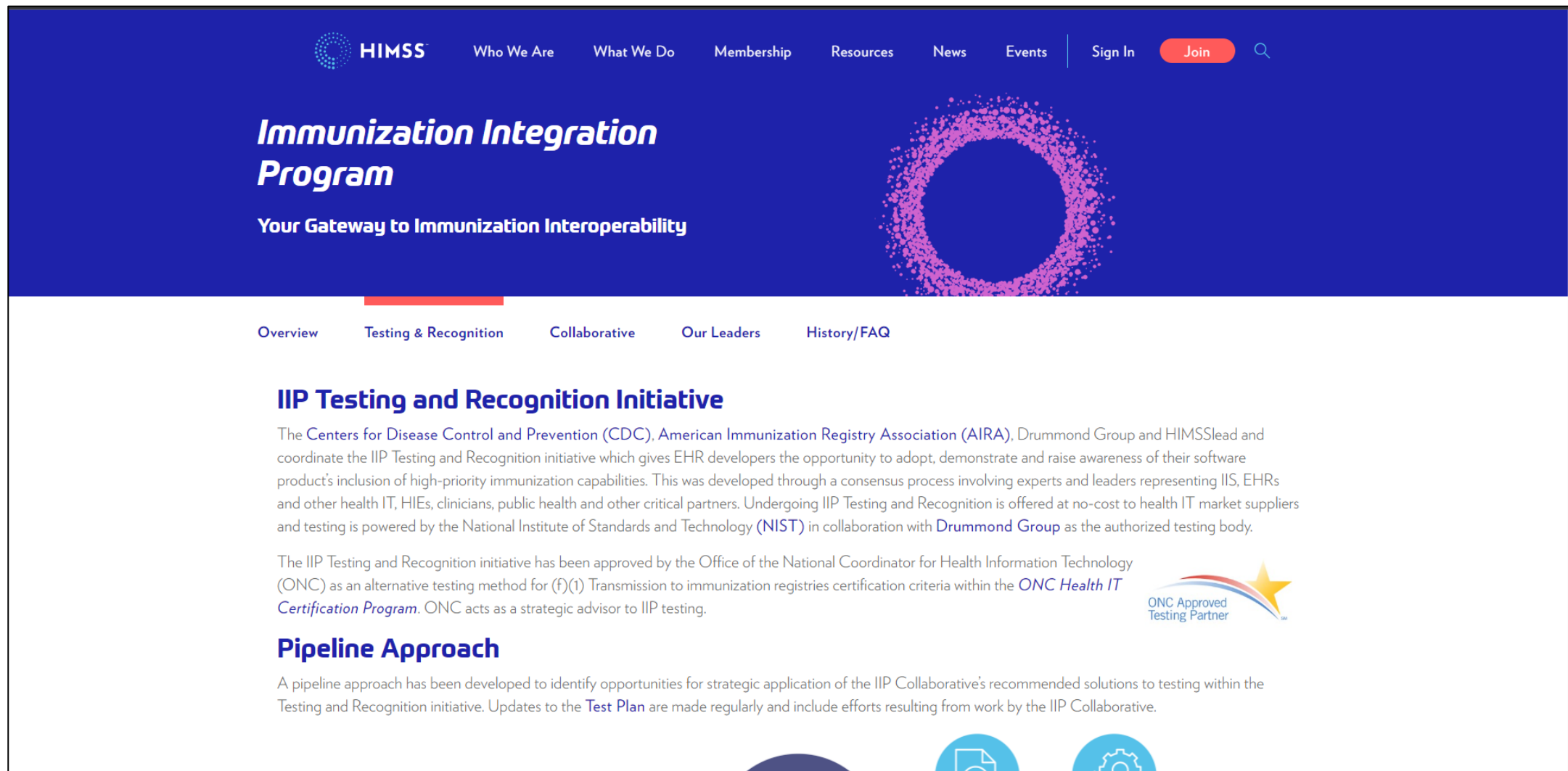
Test Story | Test Data Specification | Message Content | Example Message

Download PDF

FULL	Description	Comments	Pre-condition	Post-Condition	Test Objectives	Evaluation Criteria	Notes
	<p><b>Description</b></p> <p>A two month old male infant, Russell Clinton Richardson, is brought to a clinic for a well child visit by his mother Maria Elizabeth Richardson (nee Billington) and his father John William Richardson. A clinic staff member collects basic patient demographic information including name, date of birth and sex. A clinic provider, Wilma Thomas (physician ID 654) reviews the patient's vaccination history and determines that the child previously received Hepatitis B vaccine 1 day after birth and 1 month after birth. The staff member determines that the patient needs DTaP, Hib, IPV, Rotavirus and Pneumococcal vaccinations. Because of the patient's status of Native American, he qualifies for all Vaccine For Children (VFC) supplied vaccines under the status of VFC eligible - American Indian/Alaska Native. The parents are given 5 Vaccine Information Sheets (VIS) to review. After reading them, they agree that the child should receive all the vaccinations recommended. They also agree that the data should be shared once it is incorporated into the local IIS. They indicate that reminders and recalls may be sent by any method. Appropriate doses of DTaP/Hib/IPV (Pentacel), Rotavirus (RotaTeq) and Pneumococcal (Pnevnar 13) are selected from the clinic's stock of publically funded vaccines. A clinician, Lily Jackson (ID 7824) prepares and administers the doses to the patient and then enters the data into the EHR and transmits it to the IIS.</p>	<p><b>Comments</b></p> <p>No Comments</p>	<p><b>Pre-condition</b></p> <p>No PreCondition</p>	<p><b>Post-Condition</b></p> <p>No PostCondition</p>	<p><b>Test Objectives</b></p> <p>Create an administration message containing historical (using CVX) and new administrations (using NDC)</p> <p>Support for next of kin</p> <p>Support for patient consent</p>		

<https://hl7v2-iz-r1-5-testing.nist.gov/iztool/#/home>

# § 170.315(f)(1) Alt Test Method: Immunization Integration Program



**HIMSS** Who We Are What We Do Membership Resources News Events Sign In Join

## Immunization Integration Program


Your Gateway to Immunization Interoperability

Overview **Testing & Recognition** Collaborative Our Leaders History/FAQ

### IIP Testing and Recognition Initiative

The Centers for Disease Control and Prevention (CDC), American Immunization Registry Association (AIRA), Drummond Group and HIMSS lead and coordinate the IIP Testing and Recognition initiative which gives EHR developers the opportunity to adopt, demonstrate and raise awareness of their software product's inclusion of high-priority immunization capabilities. This was developed through a consensus process involving experts and leaders representing IIS, EHRs and other health IT, HIEs, clinicians, public health and other critical partners. Undergoing IIP Testing and Recognition is offered at no-cost to health IT market suppliers and testing is powered by the National Institute of Standards and Technology (NIST) in collaboration with **Drummond Group** as the authorized testing body.

The IIP Testing and Recognition initiative has been approved by the Office of the National Coordinator for Health Information Technology (ONC) as an alternative testing method for (f)(1) Transmission to immunization registries certification criteria within the **ONC Health IT Certification Program**. ONC acts as a strategic advisor to IIP testing.



### Pipeline Approach

A pipeline approach has been developed to identify opportunities for strategic application of the IIP Collaborative's recommended solutions to testing within the Testing and Recognition initiative. Updates to the **Test Plan** are made regularly and include efforts resulting from work by the IIP Collaborative.

<https://www.himss.org/what-we-do-initiatives/immunization-integration-program>

# Public Health Testing: HL7 CDA

- **NIST General Validation Tool**
  - Provided by National Institute of Standards and Technology (NIST)
  - Testing development framework for HL7v2 and HL7 CDA
- **HL7 CDA Tools used in the ONC Certification Program**
  - 170.315(f)(4) Transmission to cancer registries
    - Test Method: **NIST HL7® CDA Cancer Registry Reporting Validation Tool** (ONC steward; NIST)
  - 170.315(f)(6) Transmission to public health agencies – antimicrobial use and resistance reporting
    - Test Method: **Healthcare Associated Infections CDA Validator** (CDC steward; Lantana Consulting)
  - 170.315(f)(7) Transmission to public health agencies – health care surveys
    - Test Method: **NIST HL7® CDA National Health Care Surveys Validator** (ONC steward; NIST)
    - SVAP Test Method: **NIST General Validation Tool** (ONC steward; NIST)

# § 170.315(f)(4) SVAP Test Method: NIST General Validation Tool - NCHS CDA R3


The screenshot displays the NIST GVT 1.2.0 web application. The interface includes a navigation menu with options like Home, Context-free, Context-based, Documentation, and About. The current page is 'Test Execution' for a specific test step. The test plan is set to 'Public' and 'NHCS30'. A sidebar on the left shows a tree view of test cases under 'NHCS30', with '1.Doctor creates inpatient NHCS with input data and' selected. The main content area shows the configuration for this test step, with tabs for 'Test Story', 'Test Data Specification', and 'Example Message'. The configuration is organized into several sections:

Section	Value
Title	Inpatient
Description	Inpatient.
Comments	No Comments
Precondition	No PreCondition
Postcondition	No PostCondition
Test Objectives	No Objectives
Evaluation Criteria	No evaluation criteria
Notes for Tester	No Note

<https://hl7v2-gvt.nist.gov/gvt/#/home>

# § 170.315(f)(6) Test Method: Lantana Consulting Group CDA Validator

## CDA Validator



This validator is not intended for use with PHI/PII. Only use this validator with test/sample data that contains no PHI/PII.

---

Upload the XML or zip file you wish to validate *(Note: The size of the uploaded zip file must be less than 5Mb):*

No file chosen

Select your desired validation path:

**Base Standard Only**

- CDA\_R2 (Original Normative CDA Edition - No Extensions)
- CDA\_SDTC (CDA XML Schema with SDTC Approved Extensions)

**Base Standard Plus Templated Validation**

**Healthcare Associated Infections (HAI) (HL7 Balloted IGs)**

- Healthcare Associated Infection (HAI) Reporting (DSTU R6) (updated vocabulary Sep 9, 2011)
- Healthcare Associated Infection (HAI) Reporting (DSTU R9) Updated June 2013
- Healthcare Associated Infection (HAI) Reporting (Normative R1; August 2013)
- Healthcare Associated Infection (HAI) Reporting (DSTU R2D1.1; Feb 2014)
- Healthcare Associated Infection (HAI) Reporting (DSTU R2D2.1; Dec 2014)
- Healthcare Associated Infection (HAI) Reporting (DSTU R3D1; December 2015)
- Healthcare Associated Infection (HAI) Reporting (DSTU R3D1.1; September 2016)
- Healthcare Associated Infection (HAI) Reporting (DSTU R3D2; July 2017)
- Healthcare Associated Infection (HAI) Reporting (DSTU R3D3; October 2018)
- Healthcare Associated Infection (HAI) Reporting (DSTU R3D4; October 2019)
- Healthcare Associated Infection (HAI) Reporting (Normative R3; August 2020)
- Healthcare Associated Infection (HAI) Reporting (STU R4D1; June 2021)
- Healthcare Associated Infection (HAI) Reports for Long Term Care Facilities (HAI-LTCF-CDA) (STU R1D1; November 2020)
- Healthcare Associated Infection (HAI) Reports for Long Term Care Facilities (HAI-LTCF-CDA) (R1 STU2.1; April 2023)
- Healthcare Associated Infection (HAI) Reporting (STU R4D2; July 2022)
- Healthcare Associated Infection (HAI) Reporting (STU R4D2.1; July 2023)

**Public Health Case Report - the Electronic Initial Case Report (eICR) (HL7 Balloted IG)**

- Public Health Case Report - the Electronic Initial Case Report (eICR) Release 1, STU Release 1.1

<https://validator-legacy.lantanagroup.com/validator/>



# Thank you!

Please submit questions, concerns, or feedback to  
<https://inquiry.healthit.gov/>