ONC Health IT Certification Program Developer Roundtable

November 15, 2022

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.

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Agenda

1. Opening Remarks
2. 2015 Edition Cures Update: 2022 Requirements
3. Real World Testing
4. § 170.315(g)(10) Standardized Application Programming Interface (API) for Patient and Population Services
    a. General Inquires
    b. Test Procedure Live Demonstration
5. Inferno Strategy Update

Opening Remarks

Rob Anthony, Director, ONC Health IT Certification Program

Today's Speakers:

1. Tony Myers, Branch Chief, Program Administration
2. Asara Clark, Senior Advisor, Program Administration
3. Scott Bohon, IT Specialist, Tools and Testing
4. Keith Carlson, Cyber Security IT Specialist, Tools and Testing
5. John Bender, Public Health Analyst, Tools and Testing

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2015 Edition Cures Update: 2022 Requirements

Tony Myers, Branch Chief, Program Administration

What to Do in 2022

Most new and revised 2015 Edition Cures Update certification criteria must be included in a Certified Health IT Developer's product(s) and **provided to its customers by December 31, 2022**.

2015 Cures Update Requirement	Compliance Deadline
Real World Testing 2023 Plans	December 15, 2022
Standardized APIs for Patient and Population Services	December 31, 2022
Electronic Prescribing	December 31, 2022
USCDI/ Consolidated - Clinical Document Architecture (C-CDA) Companion Guide	December 31, 2022
Clinical Quality Measures (CQMs) - reports	December 31, 2022
ASTM Updates	December 31, 2022
Privacy and Security Transparency Attestations	December 31, 2022
Update to Support Security Tags	December 31, 2022
Application Programming Interfaces Condition and Maintenance of Certification	December 31, 2022

Real World Testing 2023 Plans

- Health IT Module(s) certified to any of the certification criteria outlined in 45 CFR 170.405(a) must have a 2023 Real World Testing Plan approved by their ONC-ACB and made publicly available on the CHPL no later than **December 15, 2022**.

- The following resources are available to help Certified Health IT Developers to fully understand the requirements of the Real World Testing Condition and Maintenance of Certification:
  - Real World Testing Resource Guide
  - Real World Testing–What It Means for Health IT Developers – Fact Sheet
  - Real World Testing Certification Companion Guide
  - Real World Testing Plan Template
  - Real World Testing Results
  - Report Template

Standardized API for Patient and Population Services

- Developers of a Certified Health IT Module previously certified to the §170.315(g)(8) Application access — data category request criterion must provide their customers with Health IT Modules certified to § 170.315(g)(10) Standardized APIs for patient and population services by **December 31, 2022**.

Why it's Important

- **Developers** can integrate a wider array of functionalities into their products and make available standardized data routinely available for access, exchange, and use.
- **Providers** can efficiently transmit electronic health information (EHI) amongst health IT systems and to their patients.
- **Patients** can efficiently access to their EHI using API technology, where and how they want.

Electronic Prescribing

- Heath IT Developers with Health IT Modules certified to the § 170.315(b)(3) Electronic prescribing criterion must update their Health IT to support the use of the National Council for Prescription Drug Programs (NCPDP) SCRIPT Version 2017071 standard by **December 31, 2022**.

Why it's Important

- **Providers** can utilize Certified Health IT to efficiently transmit prescriptions to their patients' pharmacies in a secure and accurate manner
- **Patients** receive their prescriptions in a timelier manner that is less prone to transmission errors.

USCDI/ Consolidated - Clinical Document Architecture (C-CDA) Companion Guide

- Health IT Developers currently certified to affected 2015 Edition certification criteria must **provide their customers** with updated versions of their products that support USCDI by **December 31, 2022.**
- Health IT Developers currently certified to the following 2015 Edition criteria have until December 31, 2022 to **provide their customers** with updated versions of their products that support USCDI and/or C-CDA standards by **December 31, 2022**
  - § 170.315(b)(1): Transitions of Care
  - § 170.315(b)(2): Clinical Information Reconciliation and Incorporation
  - § 170.315(b)(9): Care Plan
  - § 170.315(e)(1): View, Download, and Transmit 3rd Party
  - § 170.315(f)(5): Transmission to Public Health Agencies- Electronic Case Reporting
  - § 170.315(g)(6): Consolidated CDA Creation Performance
  - § 170.315(g)(9): Application Access-All Data Request

Why it's Important

- **Developers** can more easily exchange, use, and leverage USCDI and C-CDA data received from other developers which dramatically improves interoperability.
- **Providers** can consistently and routinely transmit USCDI and C-CDA data elements across all Certified Health IT for patient care.
- **Patients** can more reliably access their EHI and leverage plug-and-play applications using USCDI

Clinical Quality Measures (CQMs)

- The 2015 Edition Cures Update revised the § 170.315(c)(3) Clinical quality measures (CQMs)- report certification criterion to remove the HL7® Quality Reporting Document Architecture (QRDA) standard requirements and in their place require Health IT Modules to support the CMS QRDA Implementation Guides (IGs).

- Developers of affected Certified Health IT must have their updated Certified Health IT Product(s) available to their customers by **December 31, 2022**.

Why it's Important

- **Developers** will face less burden in their certification process by removing certification requirements that do not support quality reporting for CMS programs.
- **Providers** can now utilize a CMS specific IG for CMS program reporting

ASTM Updates

- A Health IT Developer with Health IT certified to the following prior to May 1, 2020 must have their updated Certified Health IT Product(s) available to their customers by **December 31, 2022**.
  - § 170.315(d)(2) Auditable events and tamper-resistance
  - § 170.315(d)(3) Audit report(s)
  - § 170.315(d)(10) Auditing actions on health information

Why it's Important

- **Developers** can now use the most up-to-date ATSM specifications for audit and disclosure logs
- **Providers** can create audit reports for specific time periods and sort entries in the audit log by a standardized set of up-to-date and relevant data elements
- **Patients** can be more confident in the security of their information as the up-to-date standards equate to better tracking which improves patient safety

Privacy and Security Authentication

- Certified Health IT Developers must certify the following criteria by acknowledging “Yes” or “No” to the following certification criteria
  - § 170.315(d)(12) Encrypt Authentication Credentials
  - § 170.315(d)(13) Multi-factor Authentication (MFA)

Update to Support Security Tags

- Certified Health IT Developers may voluntarily update their modules certified to the following criteria to support security tagging at the documents, section, and entry levels by **December 31, 2022.**
  - § 170.315(b)(7) security tags – summary of care – send
  - § 170.315(b)(8) security Tags – summary of Care -- receive

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Real World Testing

Asara Clark, Senior Advisor, Program Administration

What is Real World Testing?

Real World Testing is a process by which Certified 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).

Real World Testing verifies that deployed certified health IT continues to perform as intended by conducting and measuring observations of interoperability and data exchange. These observations are described in a public and transparent way through Real World Testing plans and reported as Real World Testing results.

Successful Real World Testing means…

- Certified health IT continues to be compliant with the certification criteria, including the required technical standards and vocabulary code sets;
- Certified health IT is exchanging electronic health information (EHI) in the care and practice settings for which it is marketed for use; and
- Electronic health information (EHI) is received by and used in the certified health IT

(from 85 FR 25766)

Who is Required to Conduct Real World Testing?

CONDITION OF CERTIFICATION

A developer with Health IT Module(s) certified to one or more of the applicable certification criteria* **must** successfully test the real-world use of the technology for interoperability in the type of setting in which such technology is marketed.

*Any of the certification criteria outlined in § 170.405(a); summarized on next slide

MAINTENANCE OF CERTIFICATION

ONC- ACB - Authorized Certification Body
CHPL - Certified Health IT Product List

A Certified Health IT Developer **must**:

(1) Submit its Real World Testing plan to its ONC-ACB by a date that enables the ONC-ACB to publish the plan on the CHPL no later than December 15 of each calendar year.

(2) Submit its Real World Testing results to its ONC-ACB by a date that enables the ONC-ACB to publish the results on the CHPL no later than March 15 of each calendar year.

(3) Notify the responsible ONC-ACB of any non-conformity with Certification Program requirements.

Applicable Real World Testing Certification Criteria

Care Coordination

- ✓ § 170.315(b)(1) Transitions of care
- ✓ § 170.315(b)(2) Clinical information reconciliation and incorporation
- ✓ § 170.315(b)(3) Electronic prescribing
- ✓ § 170.315(b)(6) Data export
- ✓ § 170.315(b)(7) Security tags – summary of care – send
- ✓ § 170.315(b)(8) Security tags – summary of care – receive
- ✓ § 170.315(b)(9) Care Plan
- ✓ § 170.315(b)(10) Electronic Health Information export

Patient Engagement

- ✓ § 170.315(e)(1) View, download and transmit to 3rd party

Clinical Quality Measures

- ✓ § 170.315(c)(1)—record and export
- ✓ § 170.315(c)(2)—import and calculate
- ✓ § 170.315(c)(3)—report

Electronic Exchange

- ✓ § 170.315(h)(1) Direct Project
- ✓ § 170.315(h)(2) Direct Project, Edge Protocol, and XDR/XDM

Application Programming Interfaces (APIs)

- ✓ § 170.315(g)(7) Application access—patient selection
- ✓ § 170.315(g)(8) Application access—data category request
- ✓ § 170.315(g)(9) Application access—all data request
- ✓ § 170.315(g)(10) Standardized API for patient and population services

Public Health

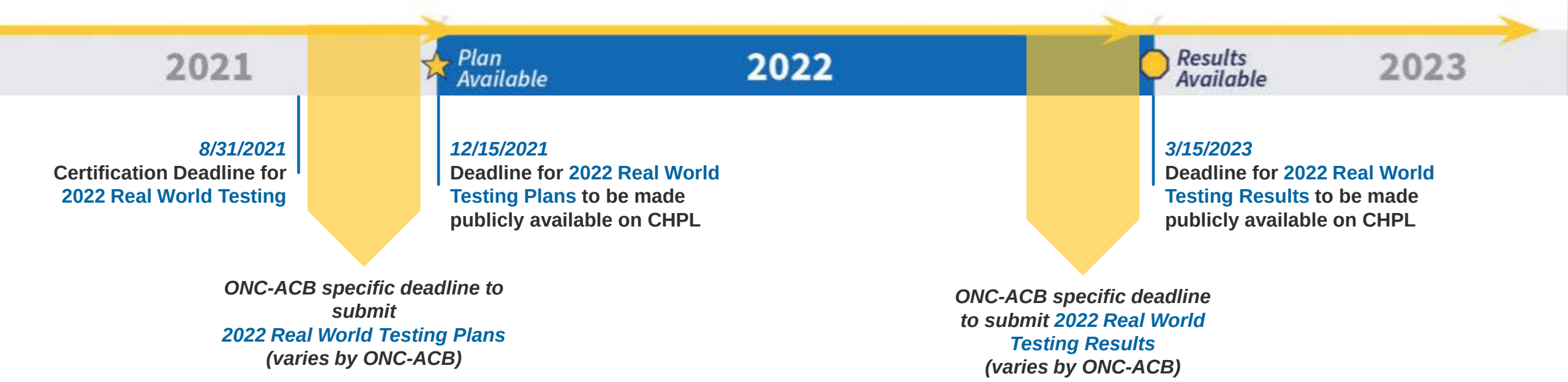
- ✓ § 170.315(f)(1) Transmission to immunization registries
- ✓ § 170.315(f)(2) Transmission to public health agencies – syndromic surveillance
- ✓ § 170.315(f)(3) Transmission to public health agencies – reportable laboratory tests and value/results
- ✓ § 170.315(f)(4) Transmission to cancer registries
- ✓ § 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

Real World Testing Plan and Results Deadlines

Real World Testing plans must be publicly available on the CHPL **by December 15th of each year.** Developers have one year to complete their testing of their submitted plan(s).

Real World Testing results must then be publicly available on the CHPL **by March 15th of each year** following their year of testing.

NOTE: For both testing plans and results ONC-ACBs will determine a date by which the plans and results report must be submitted in order to allow time to review for completeness before making publicly available.



Real World Testing Lifecycle

Real World Testing occurs on a yearly cycle, but planning, conducting, and reporting Real World Testing for each given year means that a developer's Real World Testing activities from different years can overlap.

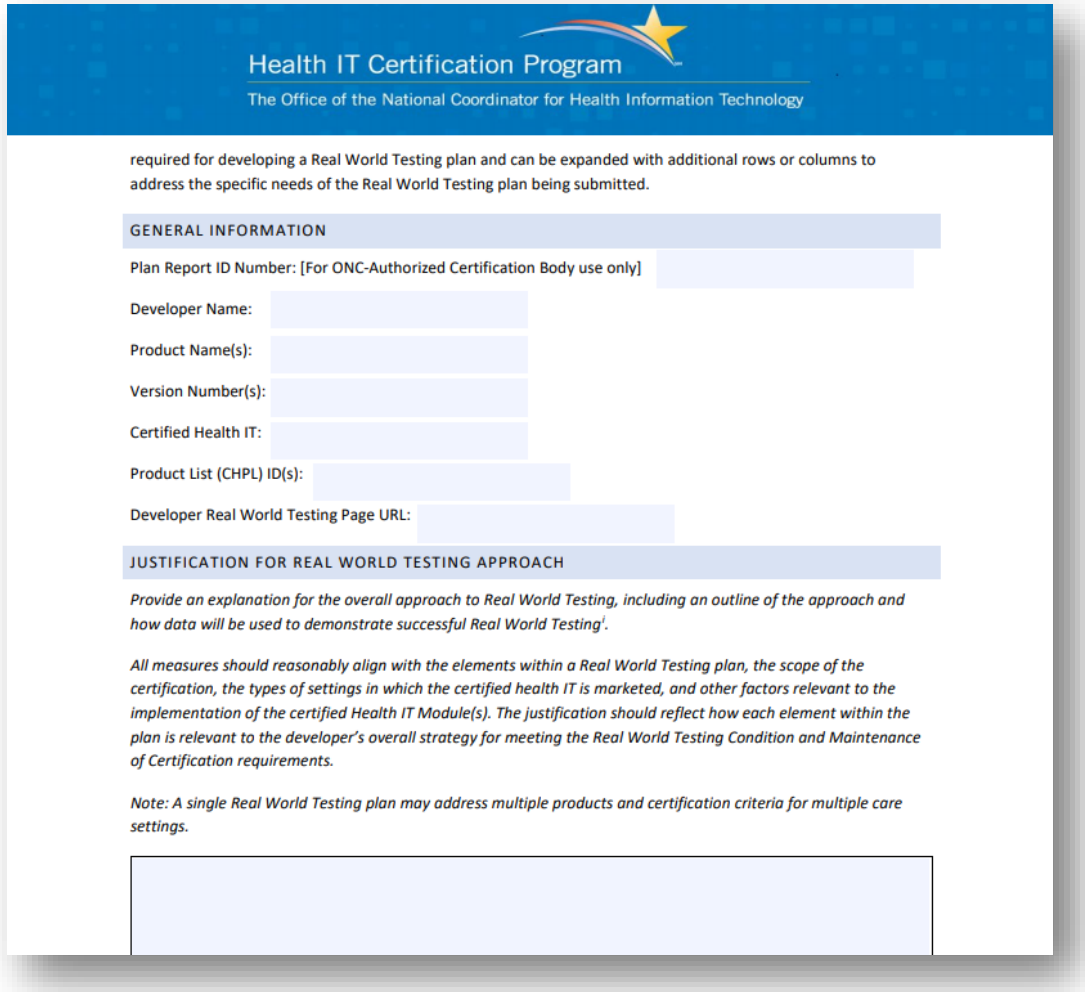
Designing and Submitting a Real World Testing Plan

Real World Testing Resources – Plan Template

This **optional** template is available to assist developers with the creation of their Real World Testing plan by outlining all necessary elements required for submission.

Each section provides a field for submitting responses and/or explanations for how the Health IT Developer will address each required element in their Real World Testing approach.

Note: ONC-ACBs may have additional requirements for submission. Confirm all requirements with your respective ONC-ACB before submission.



Health IT Certification Program

The Office of the National Coordinator for Health Information Technology

required for developing a Real World Testing plan and can be expanded with additional rows or columns to address the specific needs of the Real World Testing plan being submitted.

GENERAL INFORMATION

Plan Report ID Number: [For ONC-Authorized Certification Body use only]

Developer Name:

Product Name(s):

Version Number(s):

Certified Health IT:

Product List (CHPL) ID(s):

Developer Real World Testing Page URL:

JUSTIFICATION FOR REAL WORLD TESTING APPROACH

Provide an explanation for the overall approach to Real World Testing, including an outline of the approach and how data will be used to demonstrate successful Real World Testing[i].

All measures should reasonably align with the elements within a Real World Testing plan, the scope of the certification, the types of settings in which the certified health IT is marketed, and other factors relevant to the implementation of the certified Health IT Module(s). The justification should reflect how each element within the plan is relevant to the developer's overall strategy for meeting the Real World Testing Condition and Maintenance of Certification requirements.

Note: A single Real World Testing plan may address multiple products and certification criteria for multiple care settings.

https://www.healthit.gov/sites/default/files/page/2021-07/Real-World-Testing-Plan-Template.pdf

Real World Testing Plan – Included Health IT Modules

Real World Testing plans are intended to describe measurement approaches for the year immediately following the plan's submission. The plan should address any Health IT Modules certified **by or before August 31** of the year in which the plan is submitted.

This process is required on an ongoing, yearly basis for all Health IT Modules certified to applicable certification criteria. See below for a review of the cycle from plan to results report.

Real World Testing Plan – Included Health IT Modules

FAQ: Can I submit a testing plan for the following calendar year for a Health IT Module and/or certification criteria certified after August 31?

- At a minimum, developers must include in their Real World Testing plan for the following calendar year all health IT certified as of August 31.
- Developers may include in their Real World Testing plan for the following calendar year any Health IT Modules and/or certification criteria certified after August 31, but this is not required.
- Developers that choose to include updates made after the August 31 deadline in their testing plan for the following calendar year, must also include those Modules and/or certification criteria as part of requirements in their next cycle of Real World Testing.
- Real World Testing is required for all health IT Modules certified as of August 31 of each year regardless of whether they were included in previous years' Real World Testing Plans.
- Updates made after the August 31st deadline using the Inherited Certified Status flexibility will still be subject to Real World Testing the following year.

Real World Testing – Plan Elements

Health IT Developers must address the following elements for each certification criterion applicable to the Health IT Module's scope of certification in their Real World Testing plan.

Standards Updates

Justification for Approach

Description of Measurement/Metric(s) Used

Key Real World Testing Milestones

Testing Methodology(ies)

Associated Certification Criteria

Expected Outcomes

Care Setting(s)

FR §170.405(b)(1)(iii)

Landing Page for Real World Testing Plans

- Developers must make past and current plans and results reports available via a URL hosted on the CHPL.
- The CHPL allows for publication of one link for plans and one link for results report.
- **To ensure continued access to current and previous years' plans and results reports, developers should provide a single link on the CHPL that directs to a landing page with access to all documents.**
- Developers have the option to include plans and results reports at the same link or may create two separate links if appropriate. Links can also host plans/results reports for all products that are eligible for Real World Testing.

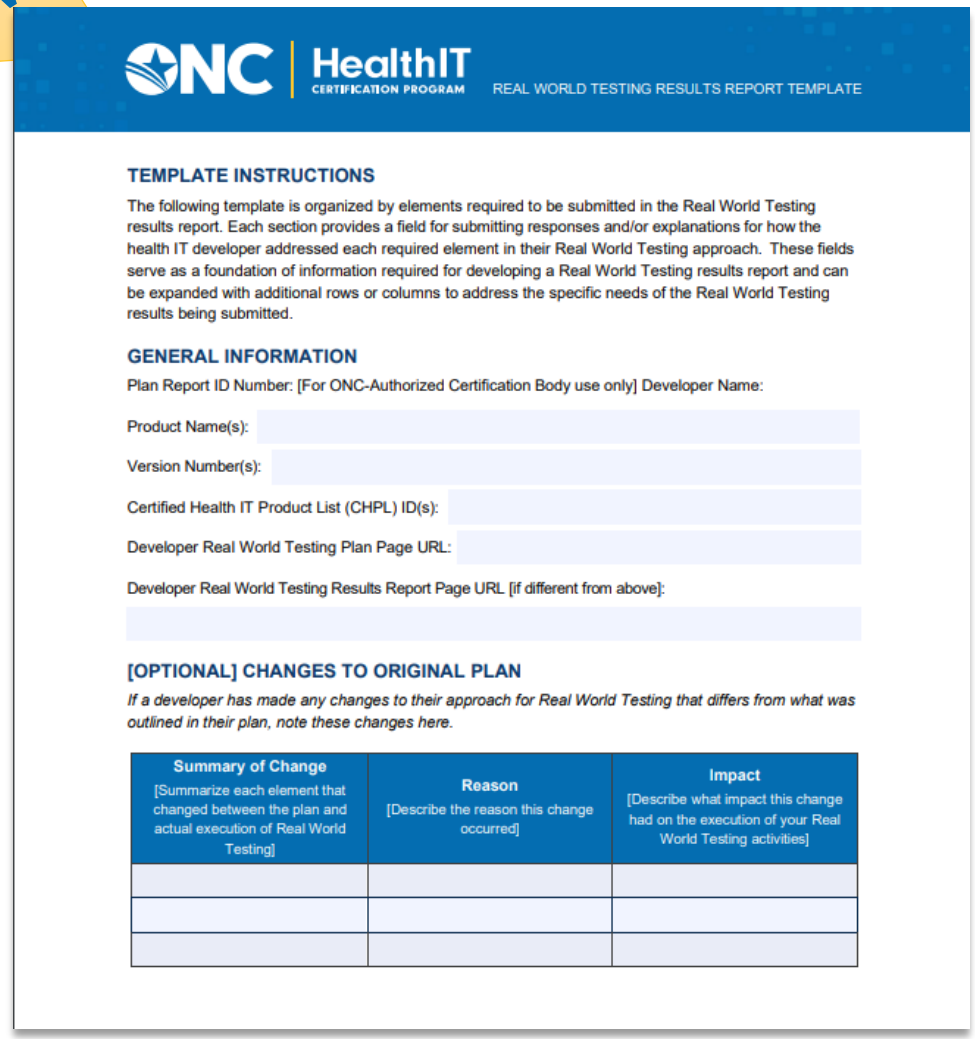
Post-Plan Submission: Considerations during Testing and Creation of Results Report

Real World Testing Resources – Results Report Template

This **optional** template is available to assist developers with the creation of their Real World Testing results report by outlining all necessary elements required for the submission of a complete results report.

Note: ONC-ACBs may have additional requirements for submission. Confirm all requirements with your respective ONC-ACB before submission.

NEW!



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REAL WORLD TESTING RESULTS REPORT TEMPLATE

TEMPLATE INSTRUCTIONS

The following template is organized by elements required to be submitted in the Real World Testing results report. Each section provides a field for submitting responses and/or explanations for how the health IT developer addressed each required element in their Real World Testing approach. These fields serve as a foundation of information required for developing a Real World Testing results report and can be expanded with additional rows or columns to address the specific needs of the Real World Testing results being submitted.

GENERAL INFORMATION

Plan Report ID Number: [For ONC-Authorized Certification Body use only] Developer Name:

Product Name(s):

Version Number(s):

Certified Health IT Product List (CHPL) ID(s):

Developer Real World Testing Plan Page URL:

Developer Real World Testing Results Report Page URL [if different from above]:

[OPTIONAL] CHANGES TO ORIGINAL PLAN

If a developer has made any changes to their approach for Real World Testing that differs from what was outlined in their plan, note these changes here.

Summary of Change [Summarize each element that changed between the plan and actual execution of Real World Testing]	Reason [Describe the reason this change occurred]	Impact [Describe what impact this change had on the execution of your Real World Testing activities]

https://www.healthit.gov/sites/default/files/page/2021-08/Real-World-Testing-Results%20Report-Template_2022.pdf

Real World Testing Results Reports – Key Elements

There are specific elements that developers must include in their Real World Testing results report for it to be considered complete.

- Any changes to the Real World Testing plan that occurred during the execution of the plan, why those changes occurred and the impact on the intended outcomes of the testing (if applicable)
- Testing method(s)/ methodology(ies) that were used to demonstrate real world interoperability and conformance to the full scope of the certification criterion's required capabilities
- Care setting(s) that were tested for real world interoperability
- Voluntary updates to the standards and implementation specifications approved through SVAP (if applicable)
- List of key Real World Testing milestones
- Description of the outcomes of Real World Testing, including any challenges encountered
- Measurement/metric (at least one) associated with the Real World Testing

Real World Testing Resources

Real World Testing Resources

Visit https://www.healthit.gov/topic/certification-ehrs/real-world-testing for access all the materials discussed and more.

- **Fact Sheet – What it Means for Health IT Developers**
- **Plan Template – *Updated!***
- **Results Report Template – *New!***
- **Resource Guide – *Updated!***
- **Real World Testing Certification Companion Guide**
- **Previous Webinar Recording and Slides**

Real World Testing Resources – Resource Guide

Certain scenarios specific to your Health IT Module may inform what measures you select to include in your Real World Testing plan.

Resellers of Certified Products

Relied Upon or Third Party Software

Cloud-based Products

Products with Non-deployed Capabilities or Low Adoption of Capabilities

Real World Testing Resources – Resource Guide

This Resource Guide aims to assist developers in organizing the required elements related to the submission of a Real World Testing plan to support the Conditions and Maintenance of Certification for their applicable Health IT Modules.

Items outlined in the guide include:

- Timeline requirements
- Details on the plan elements needed to meet requirements
- Guidance on special considerations for unique product(s), customer(s) and/or setting(s)
- Sample scenarios to illustrate the creation of a Real World Testing plan to support testing for:
  - Health IT Modules that must complete Real World Testing for a single certification criterion
  - Health IT Modules that must complete Real World Testing for multiple certification criteria

2022 Resource Guide Updates include:

NEW IN 2022!

- Clarity on inclusion of ICS products in Real World Testing
- Importance of creating a landing page for plans/results reports
- More examples on what to include in metrics
- Initial guidance on considerations for the creation of results reports, including:
  - How to document changes to your plan
  - How to address products that had been withdrawn since the initial plan submission

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§ 170.315(g)(10) Standardized API for Patient and Population Services

§ 170.315(g)(10): General Inquires

Scott Bohon, IT Specialist, Tools and Testing

§ 170.315(g)(10) Rollout

Inquiry: What is the requirement regarding rollout of (g)(10)-certified APIs?

API § 170.315(g)(10) Rollout Condition: A Certified API Developer with certified API technology previously certified to the certification criterion in § 170.315(g)(8) must provide all API Information Sources with such certified API technology deployed with certified API technology certified to the certification criterion in § 170.315(g)(10) by no later than December 31, 2022.

Response: For this Maintenance of Certification requirement, 12/31/2022 is the specific date for Certified Health IT Developers by which API technology certified to § 170.315(g)(10) needs to be provided to the appropriate API Information Sources.

Non-compliance:

- ONC may initiate the Direct Review process to ensure compliance
- ONC could terminate certification(s) and/or issue ban if not corrected

§ 170.315(g)(10) Inquiries: USCDI and US Core "Must Support"

Inquiry: What is the intent for requiring "Must Support" data elements from US Core when such elements are not explicitly specified in USCDI?

Response:

- US Core may enforce stricter requirements than USCDI
- Generally, it is not ONC's intent to override "shall" or "must support" standard requirements unless otherwise specifically stated
- All "shall" and "must support" elements in US Core must be supported even if not specified in the minimum required data elements in USCDI

Native Apps

Inquiry: What does "native application" mean? What will be tested?

- RFC 6749: *A native application is a public client installed and executed on the device used by the resource owner. Protocol data and credentials are accessible to the resource owner. It is assumed that any client authentication credentials included in the application can be extracted. On the other hand, dynamically issued credentials such as access tokens or refresh tokens can receive an acceptable level of protection.*

Testing requirements for native apps:

1. grant a refresh token valid for a period of no less than three months to native applications capable of securing a refresh token.
2. publish the method(s) by which secure issuance of an initial refresh token to native applications is supported, according to the technical documentation requirements at § 170.315(g)(10)(viii) and transparency conditions at § 170.404(a)(2)

Note: The Inferno testing tool does not include an automated test for this test step. Instead, the ONC-ATL inspects the Health IT Module and its documentation to verify the fulfillment of the requirement.

API Terms of Use and Product Version

Inquiry: Is there a requirement in the § 170.315(g)(10) documentation requirements at 45 CFR § 170.315(g)(10)(viii) for API Terms of Use to include a specific product and/or version?

- There is not an explicit requirement at 45 CFR § 170.315(g)(10)(viii) for API Terms of Use to include a specific product and/or version.

US Core $docref support

Inquiry: Can you please clarify if the Health IT Module needs to support the US Core $docref operation?

- The § 170.315(g)(10) "Standardized API for patient and population services" certification criterion does not require support for the US Core $docref operation.

Bulk export for only specific patients

Inquiry: For Bulk Data group export, is there a way for a client to restrict the data exported to only specific patients?

- Health IT developers may choose to implement the SVAP approved standard of Bulk Data Access 2.0.0 instead of Bulk Data Access 1.0.1. Bulk Data Access 2.0.0 defines an experimental, optional "patient" parameter for the "group-export" operation which restricts the returned resources to the Patient Compartments associated with the patients specified within the parameter.

Data Absent Reason and Must Support

Inquiry: Our server returns an Observation resource for the Inferno Pulse Oximetry Tests (4.18). The resource returned includes a "Data Absent Reason" extension, and Inferno fails the test because of this. Please clarify why the test failed.

- "Data Absent Reason" is an extension which provides a reason why the expected value or elements in the element that is extended are missing.
- In the Pulse Oximetry Tests, as in many of the other US Core conformance tests, Inferno checks that a server implementation demonstrates that it supports the "MustSupport" element in a meaningful way.
- Inferno "MustSupport" tests check that each "MustSupport" element is present in at least one resource from all resources returned from the server.
- It is not necessary that one resource contain all "MustSupport" elements.
- Inferno does not consider using a "Data Absent Reason" (DAR) extension on a "MustSupport" element as supporting the element "in a meaningful way," so Inferno ignores elements with DAR extensions when looking for "MustSupport" elements.

FHIR Search Responses

Inquiry: For FHIR searches, our server provides relevant "Provenance" resources in the response by default. However, our server fails Inferno search tests because these "Provenance" resources are included in the response. The FHIR specification provides flexibility for the server to include other relevant resources in a FHIR search response.

- Inferno ONC Certification (g)(10) Standardized API Test Kit v2.2.2, released on 7/11/2022, relaxes the constraint that prevented systems from returning additional resource types in search responses. Systems may return other resource types if they believe them to be relevant, and tests now provide informational messages in this case.

Bulk Data Scopes

Inquiry: Inferno requires for Bulk Data Access 1.0.1 scopes that information returned is no greater than scopes pre-authorized for multi-patient queries. Can you explain what this means?

- As per the Bulk Data Access 1.0.1 implementation guide, clients negotiate out of band the scopes which the client is authorized to access. That is, the developers of the client and the Health IT Module pre-coordinate which scopes the client has access to on the Health IT Module's bulk FHIR server before using the Bulk Data Access protocol. In this test, the health IT developer is attesting that its Health IT Module's bulk data server only provides access to scopes which were negotiated out-of-band with the client.

Inferno support for SVAP

Inquiry: Does Inferno support the 2022 SVAP standards?

- The Inferno **ONC Certification § 170.315(g)(10) Standardized API Test Kit** supports the approved 2022 SVAP standards.
- The test kit update on 08/26/2022 added support for the following standards:
  - US Core 4.0.0 / USCDI v1
  - US Core 5.0.1 / USCDI v2
  - SMART App Launch 2.0.0
  - Bulk Data Access 2.0.0

Use DataAbsentReason to "mask"

Inquiry: Can developers use the FHIR "Data Absent Reason" extension with code value of “masked” for observations deemed as restricted information (i.e., HIV lab results, behavioral health observations, etc.)?

- Health IT developers are permitted to use the "Data Absent Reason" extension to implement security and privacy mechanisms for their § 170.315(g)(10) "Standardized API for patient and population services" certified Health IT Module.
- The health IT developer and their Health IT Module must continue to meet the requirements of the § 170.315(g)(10) "Standardized API for patient and population services" criterion and the §170.404 "Application programming interfaces" Condition and Maintenance of Certification requirements.
- Additionally, the health IT developer should be mindful to not take any action inconsistent with any other Condition and Maintenance of Certification requirement. This includes the Information Blocking Condition, Assurances Condition and Maintenance, and Communications Condition and Maintenance requirements.

TLS 1.2 Enforcement

Inquiry: Can TLS be enforced at the application layer rather than the connection layer?

- TLS version 1.2 or above must be enforced for the appropriate connections.
- Health IT developers are encouraged but not required to follow TLS Best Current Practice (BCP 195) for TLS version enforcement, referenced in section 6.1.0.3 of the HL7 4.0.1 Fast Healthcare Interoperability Resources Specification (FHIR) Release 4, October 30, 2019, which recommends TLS 1.2 or above to be used for all production data exchange and limits support for lower versions of TLS.
- As of **ONC Certification (g)(10) Standardized API Test Kit v3.2.0**, TLS tests will now issue a warning for systems that accept TLS 1.0 or TLS 1.1 connections, instead of failing the system.
- For systems that do not deny TLS 1.0 or 1.1 connections, testers will be required to describe how they enforce use of TLS 1.2 or above in test 9.10.15 "TLS version 1.2 or above must be enforced".

Clarification: Subsequent Connections & Tokens

Clarification: *For subsequent connections of applications capable of storing a client secret, Health IT Modules are required to issue a refresh token valid for a new period of no shorter than three months per the API certification criterion requirement finalized in § 170.315(g)(10)(v)(A)(2)(ii).*

- This clarification reiterates the existing requirement that, on subsequent connections from an app, the Health IT Module must support issuance of a refresh token valid for a new period of no shorter than three months without requiring re-authentication and re-authorization when a valid refresh token is supplied.
- An update to the Inferno ONC Certification (g)(10) Standardized API Test Kit is forthcoming to specifically address this requirement.

Clarification: "DocumentReference.custodian"

Clarification: *For the purposes of testing and certification, health IT developers are not required to demonstrate Health IT Module support for the "custodian" data element in the "DocumentReference" US Core 3.1.1 IG Profile.*

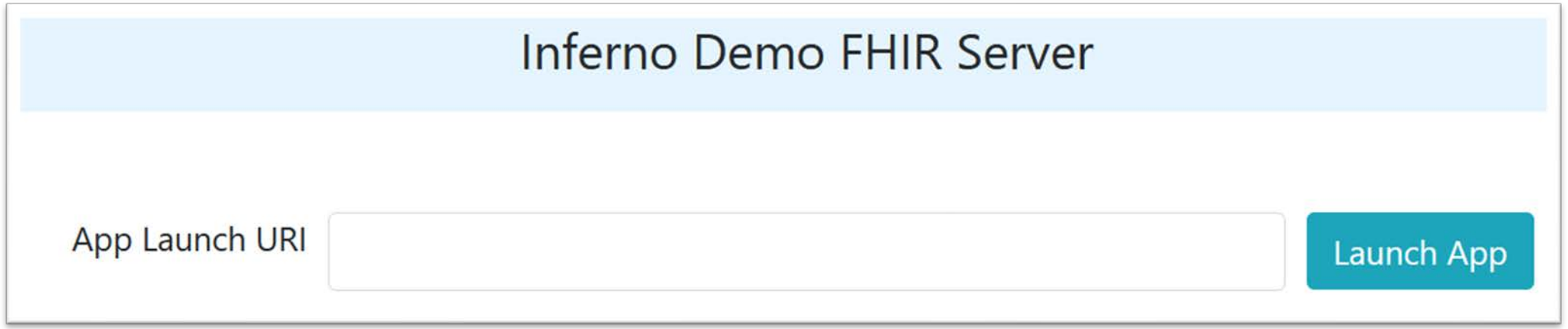
- The HL7 Cross-Group Projects work group approved patching US Core 3.1.1 to remove "must support" from the "DocumentReference.custodian" data element. This update follows the US Core 'Patch' Process, and the details for the patch can be found in HL7's Jira ticket FHIR-28393.
- The Inferno **ONC Certification § 170.315(g)(10) Standardized API Test Kit v3.3.0** implements this update.

SMART App EHR Launch (part 1)

Inquiry: For purposes of certification testing, how can a health IT developer demonstrate that their Health IT Module supports a user launching an app from an EHR as per the SMART App Launch "EHR Launch"?

- The § 170.315(g)(10) Test Procedure includes a step (AUT-PAT-2) which tests that the health IT developer demonstrates the ability of the Health IT Module to initiate a “launch sequence” as per SMART App Launch Framework "EHR Launch".
- As per the SMART App Launch implementation guide, the start of the "EHR Launch" sequence involves a user launching an app from an EHR session.
- If the module being certified is an EHR, then the developer can demonstrate a user launching an app from their EHR session interface.
- However, some developers are interested in certifying a module to § 170.315(g)(10) which is not a complete EHR by itself and lacks an EHR session interface.
- In this case, the developer can use software (e.g., POSTMAN) to emulate the first step of a user launching an app from an EHR. In this context, the emulation software would NOT be "relied upon software". Another option is the developer could adapt the code from the Inferno Reference Server to have an EHR user interface from which to launch an app for testing purposes.

SMART App EHR Launch (part 2)



Picture of the Inferno Reference Server EHR interface from which a user launches an app as part of the SMART App Launch "EHR Launch" sequence. This user interface can be adapted by a health IT developer as part of demonstrating their Health IT Module supports initiation of the "EHR Launch" sequence.

Publication of Service Base URLs

Inquiry: Who is responsible for publishing § 170.315(g)(10) service base URLs?

- The API Maintenance of Certification requirement at § 170.404(b)(2) requires a Certified API Developer to publish the service base URLs for all Health IT Modules certified to § 170.315(g)(10) that can be used by patients to access their electronic health information.
- This includes publishing the service base URLs for all of its customers regardless of whether the Health IT Modules certified to § 170.315(g)(10) are centrally managed by the Certified API Developer or locally deployed by an API Information Source.
- ONC provides discussion regarding Certified API Developer publication of service base URLs in the ONC Cures Act Final Rule (85 FR 25765).
- See ONC Cures Act Final Rule (85 FR 25813) for an example which discusses API Information Sources providing Certified API Developers service base URLs in the context of Information Blocking.

Now Available: 30+ Anonymized ONC Feedback Portal Questions & Responses

- Official ONC responses to API inquiries may be helpful to the broader community beyond the original inquirer. These are highly researched and official ONC responses to questions about our API certification requirements

- API Inquiries include inquiries related to:
  - § 170.315(g)(10) Standardized API for Patient and Population Services
  - § 170.404 API Conditions & Maintenance of Certification

- Questions & Responses are:
  - Published in the API Resource Guide
    - § 170.315(g)(10) Inquiries: https://onc-healthit.github.io/api-resource-guide/inquiry-portal/g10-inquiries/
    - § 170.404 Inquiries: https://onc-healthit.github.io/api-resource-guide/inquiry-portal/404-inquiries/
  - Organized by paragraph in the same way CCG clarifications are organized
  - Anonymized to remove any implementation or inquirer specific details

- We hope these responses will provide more official background and information that is helpful to Certified Health IT Developers

§ 170.315(g)(10) Test Procedure: Live Demonstration

Keith Carlson, Cyber Security IT Specialist, Tools and Testing

§ 170.315(g)(10) Test Procedure v2.2

Overall Updates

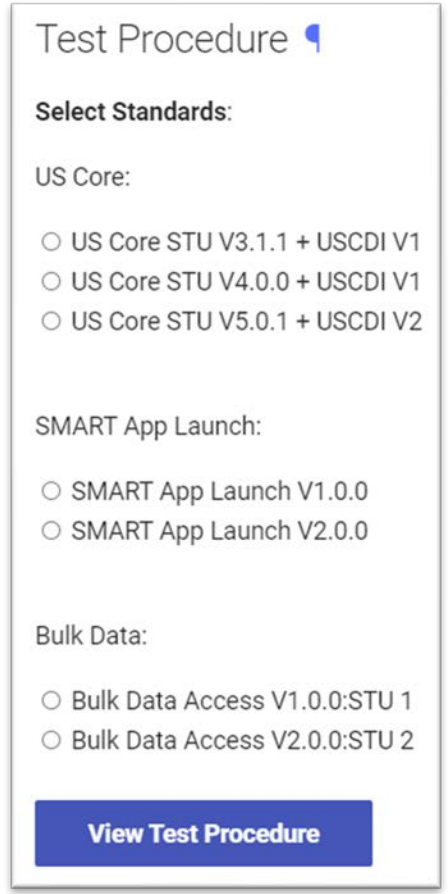
- Unique ID's added to each step (e.g., "APP-REG-1") these IDs are unique across all the steps for all the standards in the § 170.315(g)(10) test procedure
- Steps are grouped based on the standard(s) they are applicable to
- Some steps are applicable to multiple standards and are thus copied in multiple places

Test Procedure Access

- HealthIT.gov: https://www.healthit.gov/test-method/standardized-api-patient-and-population-services#test_procedure
- API Resource Guide: https://onc-healthit.github.io/api-resource-guide/g10-criterion/#test-procedure
- Feedback welcome!

Healthit.gov

API Resource Guide



Inferno Framework Updates & Future

John Bender, Public Health Analyst, Tools and Testing

Inferno Framework released March 8, 2022

- Inferno Framework documentation: https://inferno-framework.github.io
  - Improved backend architecture
  - Easier to maintain and extend
  - Extensible Ruby domain-specific language
  - Easier for developers to create their own tests
  - Flexible default user interface to accommodate a variety of tests
  - JSON API for custom user interfaces / easier integration
- Inferno Framework
  - Inferno Core
  - Test Kits

Test Kits

- **US Core**
- **SMART App Launch**
- **(g)(10) Standardized API**
- **SMART Health Cards**
- **International Patient Summary**
- **International Patient Access**
- **FAST Security**
- **TLS**
- **+ Additional use cases**

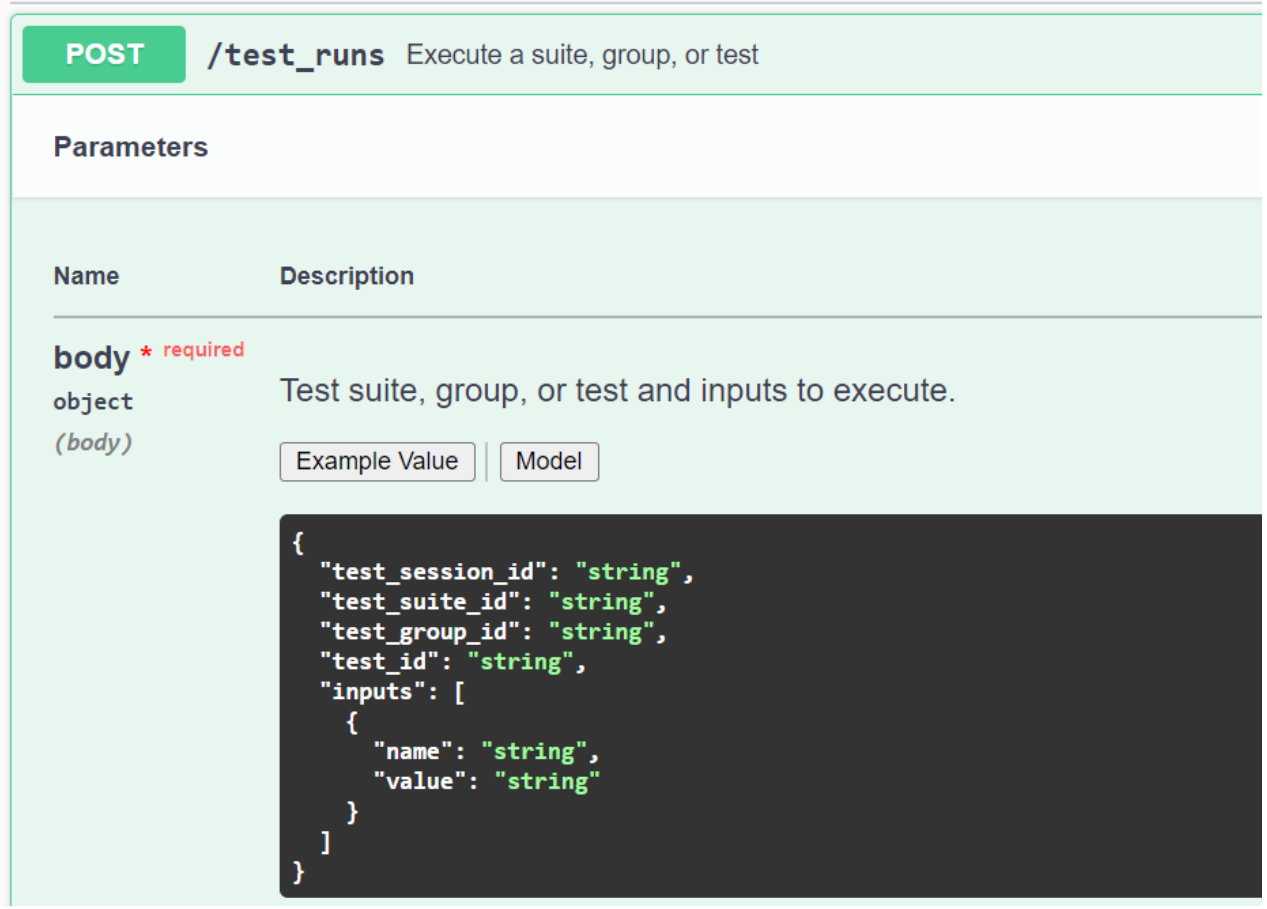
Now you can:

- Use the Inferno Framework **Ruby Domain Specific Language (DSL)** to write tests
  - Complicated interactions and assertions are simplified to a few lines of code
  - For example:
    - Perform a READ request on a FHIR API with patient ID "123"
    - Make sure the READ request returns a status of "200" (successful)
    - Make sure the resource returned is a HL7 FHIR Patient resource
    - Make sure the resource is valid according to the HL7 validator

```
1  test do
2    run do
3      fhir_read(:patient, '123')
4
5      assert_response_status(200)
6      assert_resource_type(:patient)
7      assert_valid_resource
8    end
9  end
```

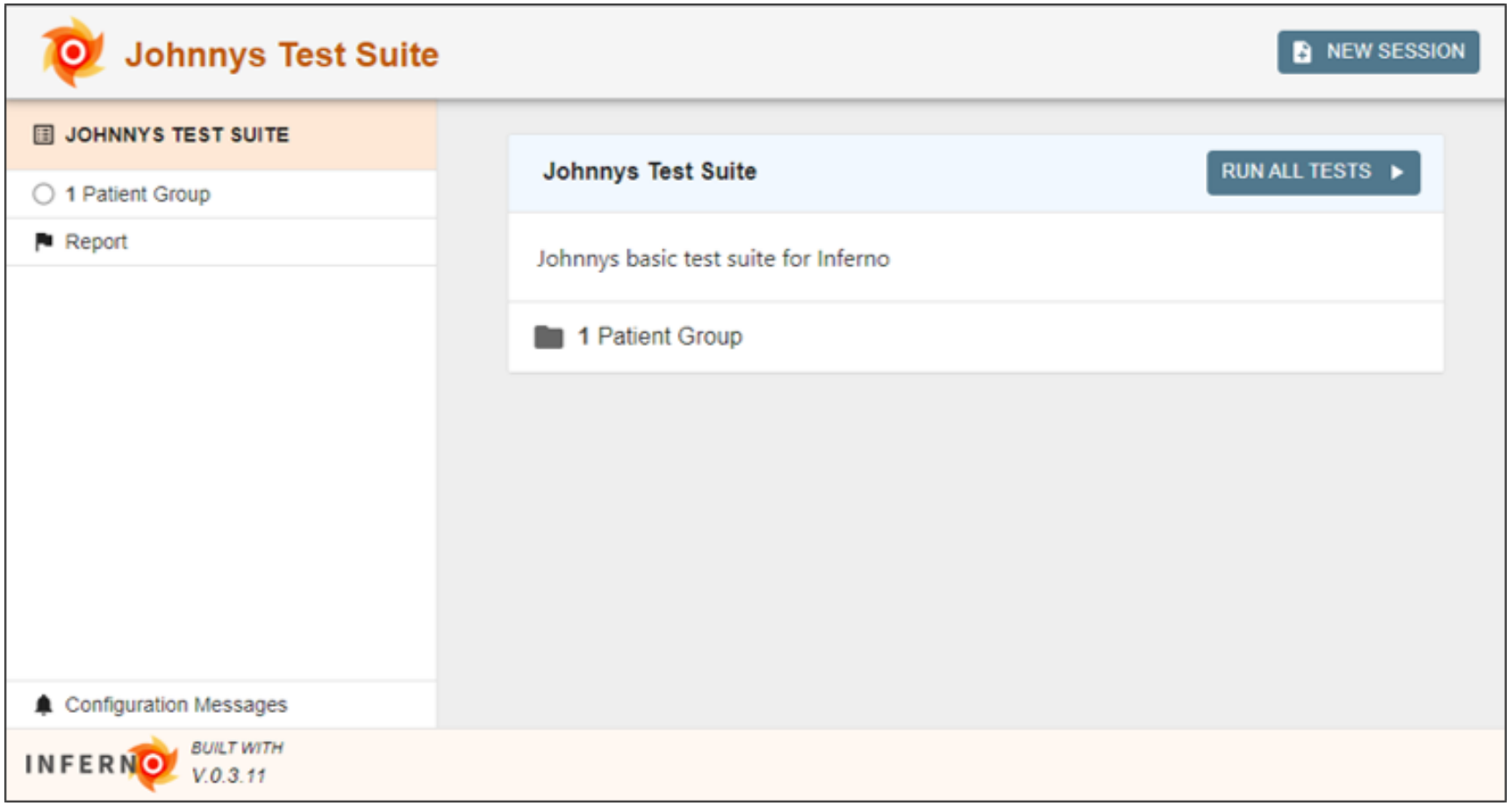
Now you can:

- Integrate with Inferno using the first-class JSON API
  - Leverage Inferno Framework JSON API operations in your software or build your own user interface for tests



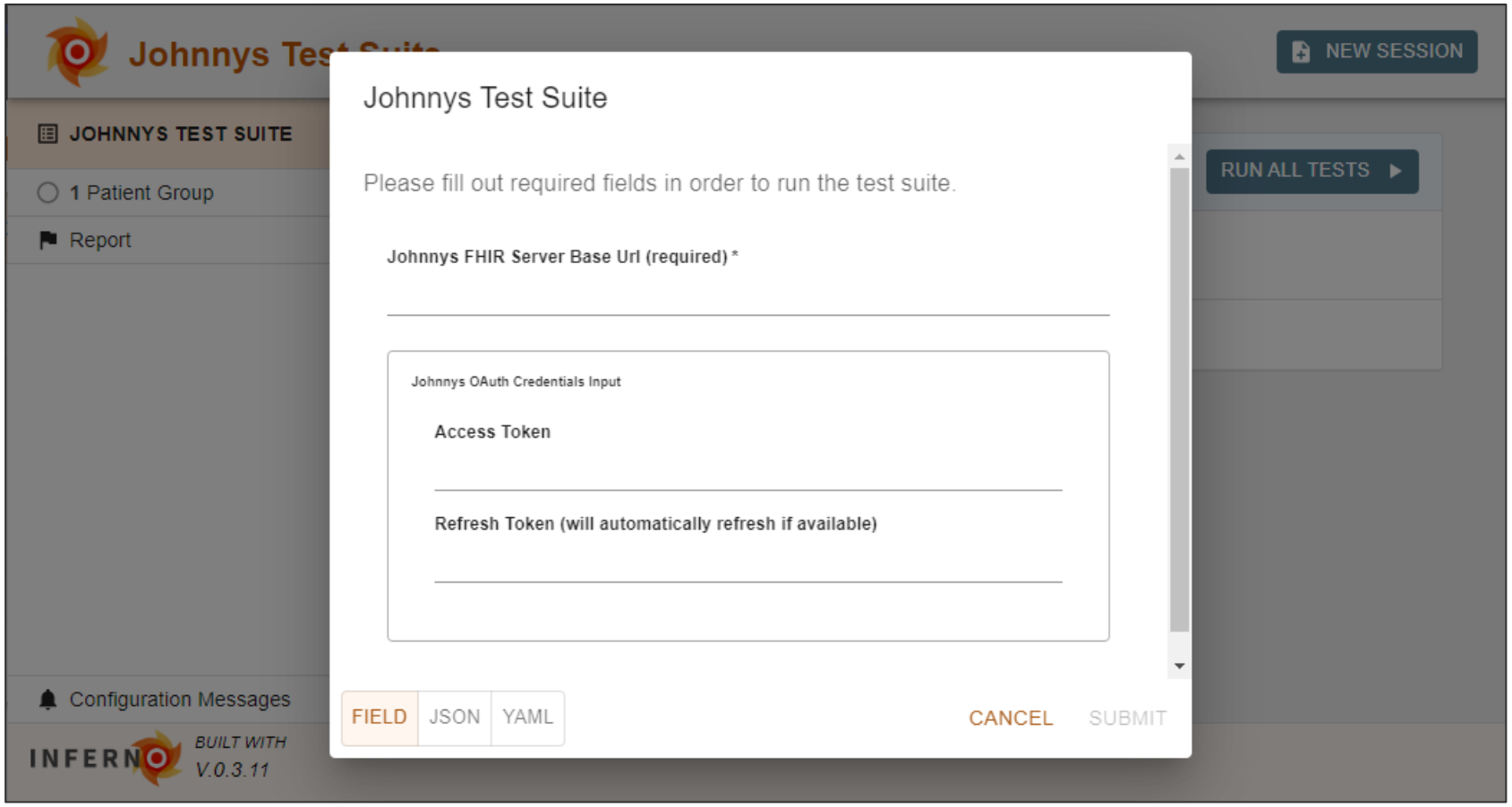
Now you can:

- Write tests that easily render in the default Inferno Core user interface
  - Customize organization, naming, and functionality of tests



Now you can:

- Write tests that easily render in the default Inferno Core user interface
  - Collect customizable input values from end users which can be leveraged in tests



How can Inferno be useful?

- **Writing and testing a system's conformance to an implementation guide**
  - E.g., tests for the International Patient Summary / International Patient Access IGs
  - E.g., tests for Data Exchange for Quality Measures IG
- **Writing and testing a system's conformance to a use case that combines implementation guides**
  - E.g., (g)(10) Test Kit for the ONC Certification Program and the 170.315(g)(10) Standardized API criterion
- **Use testing to monitor interfaces and data**
  - Using the Inferno Framework JSON API, Inferno can be used as part of a continuous integration process
  - E.g., Several vendors and Health IT Developers
- **Use testing to improve an implementation guide or provide clarity for implementations**
  - Test authoring process can uncover issues and assumptions in HL7 FHIR IGs
  - Providing a suite of tests for industry to use can facilitate proper implementation of IGs
  - E.g., US Core IG improvements since 2020

Inferno Framework strategic development

- **Interviews and analysis**
  - Objective: Understand utility of Inferno Framework for the health IT industry and plan future strategy
  - Interviews with 23 individuals / organizations
    - If and how they use Inferno
    - Inferno feedback
    - Thoughts on future utility of Inferno Framework
  - Analysis: Tooling, standards development, and industry analysis
- **Strategic plan development**
  - Vision:
    - Advance a health system that uses information to engage individuals, lower costs, deliver high quality care, and improve individual and population health
  - Values:
    - Be a responsible steward
    - Support open source, transparency and scalability
    - Ensure sustainability, measurability and continuous improvement
    - Build a culture of secure access to health information and protect the privacy and security of individuals' EHI
    - Enable innovation and competition
  - Goal:
    - Position Inferno as a Best-in-Class testing solution for HL7 FHIR-related implementation guides

How can Inferno be helpful to you?

- **Please provide any feedback:**
  - In chat or vocally, Inferno channel via Zulip (chat.fhir.org), GitHub issues, Email (john.bender@hhs.gov)
- **Seeking feedback like:**
  - What has been your experience with Inferno? What has worked well, and what needs improvement?
  - In the next few years, how could Inferno be improved / positioned to help you, or your company better achieve its goals?
  - What can Inferno do in order to help move the needle on health interoperability?
  - How can we foster a community of contributors to Inferno Framework?
- **What we have heard so far:**
  - Positive feedback regarding the level of engagement and support MITRE provides in community forums like Zulip (chat.fhir.org)
  - Inferno error messages could use more clarity
  - Support for payer-related test kits would be helpful in Inferno
  - Would like to see more sharing of user-created Test Kits / Test Suites
  - Inferno Framework documentation could use improvement
  - More clarity regarding test data availability
  - Clear Inferno Core / Test Kit update banner to communicate update frequency and scheduled updates
  - Would be helpful to have FHIR TestScript support in Inferno
  - Would be nice to communicate "best practices" for health standards testing and test development
  - Encourage IG developers to focus on considerations for testing when IGs are developed
  - ... And more!

Inferno Framework focus areas

- **ONC Health IT Certification Program**
  - Tests to support ONC Certification criteria (now & future), SVAP updates, etc.
- **Core and Contributed Libraries**
  - Upgrade core functionalities (e.g., New Ruby DSL concepts, Integrate with other testing platforms)
  - Support community contributions (e.g., Support for FHIR TestScript, Improve user experience)
- **ONC-Stewarded Testing Artifacts**
  - Expand existing library of tests for priority implementation guides that can help advance interoperability with particular focus on foundational IGs, etc.
- **Standards / Implementation Guide Development**
  - Leverage Inferno to support the improvement of standards and implementation guides through their lifecycles; upgrades to Inferno Framework to support this focus area, etc.
- **Governance and Operations**
  - Maintenance, user support, project onboarding, sustainability, etc.

Inferno Resources

- **Inferno Hosted by ONC**
  - Inferno hosted on healthit.gov
- **Inferno Documentation**
  - Inferno Framework Documentation
  - Inferno Test Kit Template Repository on GitHub
  - Inferno Tutorial Repository on GitHub Wiki
  - Inferno Tutorials on Inferno YouTube
- **Communication**
  - https://groups.google.com/forum/#!forum/inferno-testing
    - Announcements & community discussion
  - Chat.fhir.org: https://chat.fhir.org/#narrow/stream/179309-inferno
  - inferno@groups.mitre.org (or rscanlon@mitre.org)

ONC | HealthIT CERTIFICATION PROGRAM

Thank you!

Submit questions, concerns and feedback at https://inquiry.healthit.gov/

HealthIT.gov