ASTP Assistant Secretary
for Technology Policy

ONC Health IT Certification Program Developer Roundtable

ONC Health IT Certification Program

March 4, 2026

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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1. General Certification Program Updates

2. Prior Authorization in 2026

3. Inferno 101

General Certification Program Updates

Jeffery Smith, Acting Director

ASTP Better health enabled by data

Thank you to all who attended the ASTP 2026 Annual Meeting!

In case you missed or want to revisit our ASTP 2026 Annual Meeting mainstage sessions, recordings are now available to watch on-demand. Slides from our breakout sessions are also available!

➢ Watch the plenary sessions and view the presentation slides →

HTI-1 Certification Criteria Compliance Dates Enforcement Discretion

Several ONC Health IT Certification Criteria were revised by the HTI-1 Final Rule. The HTI-1 Final Rule established that to maintain certification to these criteria a developer needs to update their Health IT Module(s) and provide such updated technology by December 31, 2025.

Due to the laps in appropriations, health IT developers' ability to certify their Health IT Modules to these revised criteria was substantially impacted, so on November 24, 2025, ASTP/ONC issued a notice giving developers until March 1, 2026 to update and provide customers with updated Health IT Modules.

Impacted Certification Criteria

- The "patient demographics and observations" criterion in § 170.315(a)(5);
- The "family health history" criterion in § 170.315(a)(12);
- The "social, psychological, and behavioral data" criterion in § 170.315(a)(15);
- The "transitions of care" criterion in § 170.315(b)(1);
- The "clinical information reconciliation and incorporation" criterion in § 170.315(b)(2);
- The "care plan" criterion in § 170.315(b)(9);
- The "decision support interventions" criterion in § 170.315(b)(11);
- The "clinical quality measures (CQM) - filter" criterion in § 170.315(c)(4);
- The "view, download, and transmit to 3rd party" criterion in § 170.315(e)(1);

- The "transmission to immunization registries" criterion in § 170.315(f)(1);
- The "transmission to public health agencies – reportable laboratory tests and values/results" criterion in § 170.315(f)(3);
- The "transmission to cancer registries" criterion in § 170.315(f)(4);
- The "consolidated CDA creation performance" criterion in § 170.315(g)(6);
- The "application access – all data request" criterion in § 170.315(g)(9); and
- The "standardized application programming interface (API) for patient and population services" criterion in § 170.315(g)(10).

Draft USCDI v7

➢ ASTP/ONC published <u>Draft USCDI v7</u> on January 29, 2026, which includes 30 new data elements.

  ➢ Draft USCDI v7 includes 30 overall proposed data element additions across multiple data classes.

  ➢ Strengthens support for patient safety, nutrition care, and administrative burden reduction in alignment with national health and wellness priorities to Make America Healthy Again

➢ ASTP/ONC welcomes input on future versions during the USCDI feedback period

  o Feedback period will close **April 13, at 11:59 PM ET**.

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Proposed New Data Elements in USCDI v7

➢ ASTP/ONC is accepting new data element submissions through **ONDEC**, and comments on data elements may be entered via the updated commenting feature on the USCDI data element pages.

New Data Class

Adverse Events
- Adverse Event +
- Adverse Event Outcome

Allergies and Intolerances
- Allergy Intolerance Criticality

Care Team Members
- Healthcare Agent +

Clinical Notes
- Referral Note

Diagnostic Imaging
- Diagnostic Imaging Reference +

Encounter Information
- Appointment

Facility Information
- Facility Telecom + S

New Data Class
Healthcare Information Attributes
- Reason Not Performed +
- Diagnostic Report Date + S

Health Insurance Information
- Health Insurance Coverage Period + S
- Health Insurance Payer S
- Health Insurance Plan + S
- Health Insurance Plan Identifier + S

Health Status Assessments
- Nutrition Assessment +
- Tobacco Use*

Immunizations
- Immunization Status + S
- Immunization Record Source + S

Laboratory
- Specimen Collection Method

Medical Devices
- Device Type + S

Medications
- Medication Administration +
- Medication Dispense Quantity + S

Orders
- Medical Device Order +
- Nutrition Order +
- Referral Order

Patient Demographics/Information
- Accommodation
- Deceased Indicator +
- Patient Identifier + S

Problems
- Condition Status + S

Procedures
- Procedure Status + S

+ In USCDI+

S US Core Must Support

* Significantly modified data element (see more information below)

HTI-5 Proposed Rule

- The HTI-5 proposed rule enables ASTP/ONC to reset the Certification Program's regulatory scope and establish a new foundation on which to build Fast Healthcare Interoperability Resources (FHIR®)-based API requirements in the future.
  ‣ Collectively, the proposals in the HTI-5 Proposed Rule directly align with President Trump's goals as outlined in Executive Order (EO) 14192 (Unleashing Prosperity through Deregulation) and EO 14267 (Reducing Anti-Competitive Regulatory Barriers).

- The proposed rule includes deregulatory actions that update the ONC Health IT Certification Program to:
  ‣ Reduce burden on health IT developers by streamlining ASTP/ONC's voluntary Health IT Certification Program by removing redundant requirements;
  ‣ revise definitions to better promote electronic health information access, exchange, and use so that patients' access to their data is not blocked; and
  ‣ advance a new foundation of AI-enabled interoperability solutions through modernized standards and certification.

- The public comment period closed on February 27th.
  ‣ ASTP is currently reviewing all submitted comments.

HTI-5 Proposed Rule Resources

❖ Proposed Rule Overview Factsheet
❖ Proposed Rule Information Session Recording

❖ Proposed Rule Information Session Presentation
❖ Key Provisions

RFIs: Diagnostic Imaging Interoperability Standards and Certification & HHS Health Sector AI RFI

- Diagnostic Imaging RFI
  - ASTP/ONC is seeking public input on whether the adoption of technical standards and certification criteria would improve how diagnostic images are accessed, exchanged, and used through certified health IT. Feedback will help inform potential future rulemaking.
    - Diagnostic images, such as X-rays, CT scans, MRIs, and ultrasounds, are an important part of many people's electronic health records.
    - Patients and health care providers still face challenges specific to access, exchange, and use of these diagnostic images across different health care settings.
    - Public comments will be accepted until March 16, 2026
      - ➢ Read the RFI and Submit Comments

- HHS Health Sector AI RFI
  - HHS Office of the Deputy Secretary in collaboration with ASTP/ONC has published this Request for Information (RFI) to seek broad public comment on what HHS can do to accelerate the adoption and use of AI as part of clinical care.
    - Input sought across (1) regulation; (2) reimbursement; and (3) research and development
  - Public comment period closed Feb. 23 and comments are publicly available at https://www.regulations.gov/document/HHS-ONC-2026-0001-0001/comment

Reminder 2026 Attestation Period

- The first 2026 attestation submission window will open on April 1, 2026, and will remain open through April 30, 2025.

- Certified Health IT developers should 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 contact your ONC-Authorized Certification Body (ONC-ACB) directly.

- Developers are also encouraged to reference the ASTP/ONC Attestations Resource Guide.

2025 Real World Testing Results

- Real-world testing results must be publicly available on the Certified Health IT Product List (CHPL) by March 15 of the year following the testing year 1.

- Test results for testing year 2025 must be made publicly available by March 15, 2026.

Real World Testing Enforcement Discretion	
For CY 2025	For CY 2026
1. ONC will not exercise its direct review authority under 45 CFR 170.580 for any non-conformity, potential or actual, that arises solely from a health IT developer not complying with 45 CFR 170.405(b)(1). This means that a developer with a Health IT Module(s) certified to one or more of the criteria referenced in 45 CFR 170.405(a) is **not expected to submit an annual real world testing plan to its ONC-Authorized Certification Body (ONC-ACB) for the 2026 real world testing year**. 2. ONC will not conclude that an ONC-ACB has failed to adhere to 45 CFR 170.523(p)(1) and (3), find a violation of 45 CFR 170.560(a), or take any enforcement action under 45 CFR 170.565 against an ONC-ACB for not reviewing CY 2026 real world testing plans and submitting the plans to ONC for public availability.	1. ONC will not exercise its direct review authority under 45 CFR 170.580 for any non-conformity, potential or actual, that arises solely from a health IT developer not complying with 45 CFR 170.405(b)(2), except with respect to Health IT Modules certified to the certification criteria specified in 45 CFR 170.315(g)(7) through (10). This means that **ONC only expects a developer with a Health IT Module(s) certified to the (g)(7) through (10) certification criteria, as of August 31, 2024, will submit a CY 2025 real world testing results report to its ONC-ACB by March 2026**. 2. ONC will not conclude that an ONC-ACB has failed to adhere to 45 CFR 170.523(p)(2) and (3), find a violation of 45 CFR 170.560(a), or take any enforcement action under 45 CFR 170.565 against an ONC-ACB if an ONC-ACB does not review and confirm that applicable health IT developers submit real world testing results reports, except with respect to Health IT Modules certified to the criteria specified in 45 CFR 170.315(g)(7) through (10).

The enforcement discretion will remain in effect until December 31, 2026, or until the Department of Health and Human Services completes a deregulatory action to revise 45 CFR 170.405 and 45 CFR 170.523(p), whichever comes first.

Standards Version Advancement Process (SVAP)

- The Standards Version Advancement Process (SVAP) allows Health IT developers participating in ONC's Health IT Certification Program to voluntarily update their Health IT Modules to use newer versions of standards than are adopted in regulation so long as certain conditions are met.

- ASTP/ONC is currently accepting comments for the 2026 SVAP Cycle
  - Please submit comments to the ASTP Interoperability Standards Platform

How Versions Get Approved

Consider Available Updates → Public Comments → Comment Review → Determinations Published → (cycle continues)

Ongoing Dialogue

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.

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Prior Authorization in 2026

Jeffery Smith, Acting Director

Electronic Prior Authorization (New)

BENEFITS

- Supports HHS agency-wide approach to electronic prior authorization that meets the Department's interoperability and burden reduction goals.

- Addresses processes that have contributed significantly to patient and provider burden, for instance, delays experienced by patients and clinicians as they seek to satisfy the requirements associated with prior authorization rules set by payers.

- Multiple criteria support certification flexibility for developers wishing to support only a part of electronic prior authorization technology stack.

- Use of technology meeting the certification criteria for electronic prior authorization will help to enable exchange of information that promotes a more effective marketplace, increases competition, and provides benefits to patients.

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Electronic Prior Authorization (New)

PROVISION

- ASTP/ONC adopted three new certification criteria in 45 CFR 170.315(31-33) to support more efficient management of electronic prior authorization tasks and reduce administrative burden for providers.

- These criteria are based on Fast Healthcare Interoperability Resources (FHIR®) implementation specifications developed by the HL7® Da Vinci project

  ‣ Provider Prior Authorization API – Coverage Requirements Discovery: Defines a workflow to allow health care providers to request information from payers about coverage requirements.

  ‣ Provider Prior Authorization API – Documentation Templates and Rules: Provides a mechanism for clinicians and other EHR users to navigate and quickly assemble the information needed to support a prior authorization request according to a payer's requirements.

  ‣ Provider Prior Authorization API – Prior Authorization Support: enables direct submission of prior authorization requests from health IT systems using FHIR, as well as supporting follow-up tasks such as checking the status of a previously submitted request.

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Modular API Criteria (New)

PROVISION

ASTP/ONC finalized two supporting certification criteria (and two FHIR specifications) referenced by other criteria for electronic prior authorization included in HTI-4.

- 45 CFR 170.315(j)(20) *Workflow Triggers for Decision Support Interventions — Clients*

- 45 CFR 170.315(j)(21) *Subscriptions — Client*

BENEFITS

- These criteria establish minimum requirements to support CDS Hooks and Subscriptions FHIR capabilities for prior authorization, though these capabilities may be applicable to many other use cases

- CDS Hooks provides a framework for fast decision support in provider workflows (e.g., payer coverage at order sign).

- Subscriptions enable a user to be proactively notified of an event or data update of interest.

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Certification to § 170.315(g)(31-33) and the (j)-criteria

➤ Certification to (g)-criteria that cross-reference (j)-criteria in regulation text demonstrates conformance to both criteria

   ➤ Example: A Health IT Module certified to § 170.315*(g)(31) provider prior authorization API – coverage requirements discovery* requires support for the capabilities in paragraph § 170.315(j)(20) for CDS Hooks and specifies support for the "order-sign" CDS Hook.

   ➤ Certifying to § 170.315(g)(31) means the Health IT Module also supports § 170.315(j)(20) thus does not need to separately certify to § 170.315(j)(20).

   ➤ (j)-criteria are "modular" and standalone:

   ➤ If a Certified Health IT developer wishes to certify only to § 170.315(j)(20) (or any other (j)-criterion), they may do so without certifying to any (g)-criterion that cross references that (j)-criterion

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Technical Documentation Requirements

Developers certifying to **§ 170.315(g)(31)** and **§ 170.315(g)(33)** specifically have additional expectations related to the publication of accompanying technical documentation, as defined in the criteria regulation text. These criteria describe the requirements of such technical documentation that must be published as part of the Certified API developer's complete business and technical documentation.

For the purposes of these documentation requirements, complete accompanying technical documentation includes as applicable:

- API syntax, function names, required and optional parameters supported and their data types, return variables and their types/structures, exceptions and exception handling methods and their returns;

- The software components and configurations that would be necessary for an application to implement in order to be able to successfully interact with the API and process its response(s); and

- All applicable technical requirements and attributes necessary for an application to be registered with a Health IT Module's authorization server.

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Key Considerations for § 170.315(g)(31-33) and the (j)-criteria

	§ 170.315(g)(31) ePA CRD	§ 170.315(g)(32) ePA DTR	§ 170.315(g)(33) ePA PAS	§ 170.315(j)(20) Workflow triggers	§ 170.315(j)(21) Subscriptions
Deadline Considerations	There are no Certification Program-associated deadlines for these criteria. However, developers with clients leveraging Medicare incentive programs, measures tied to ePA go into effect in 2027.				
Dependencies	➢ § 170.315(j)(20) ➢ § 170.315(g)(4) ➢ § 170.315(g)(5)	➢ § 170.315(g)(4) ➢ § 170.315(g)(5)	➢ § 170.315(j)(21) ➢ § 170.315(g)(4) ➢ § 170.315(g)(5)	➢ § 170.315(g)(4) ➢ § 170.315(g)(5)	➢ § 170.315(g)(4) ➢ § 170.315(g)(5)
	No new privacy and security criteria requirements				
Additional Considerations for CHPL	Documentation requirements		Documentation requirements		
Test Tool	Inferno (available for testing at TBD)				

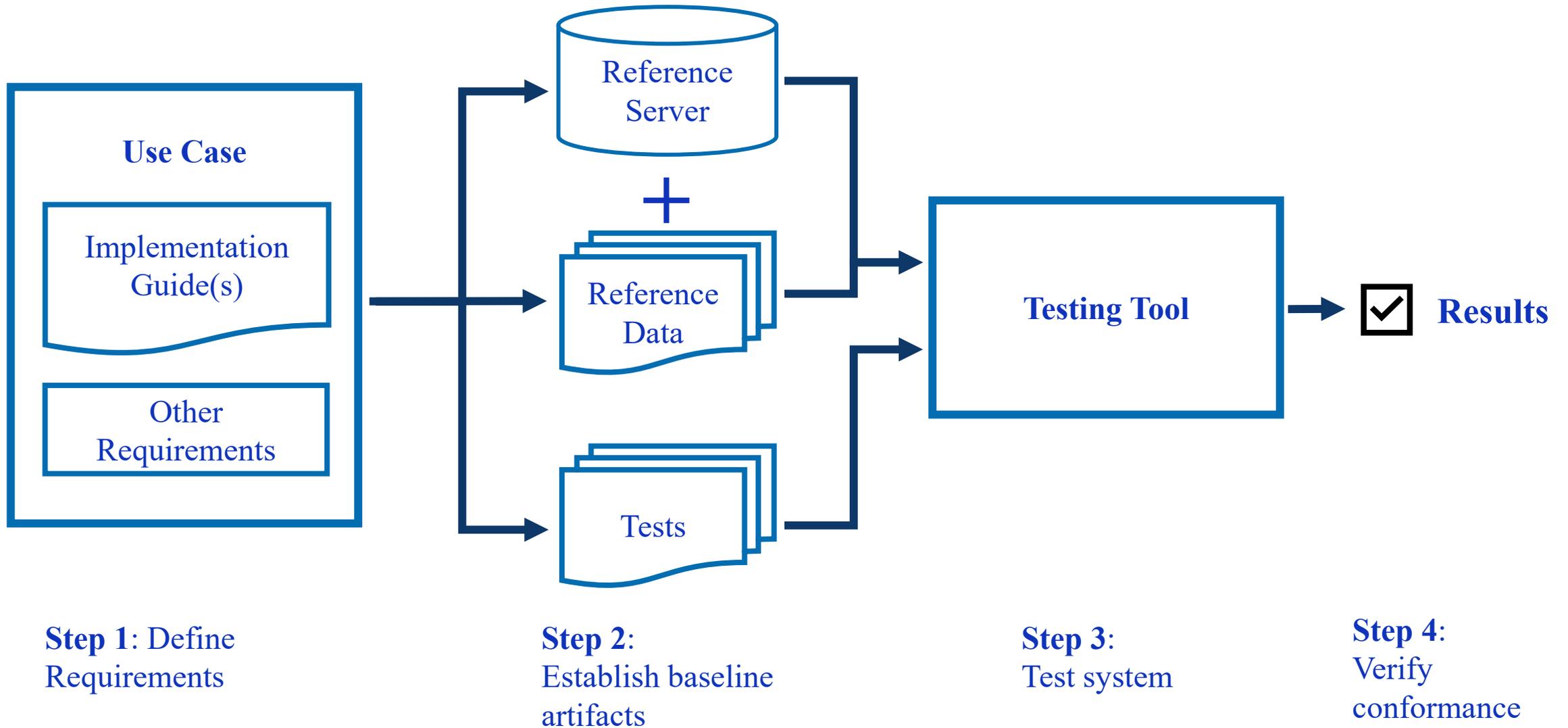ASTP Assistant Secretary for Technology Policy

API Condition and Maintenance of Certification – New Criteria Updates

➢ **Updated Applicability of API Conditions and Maintenance of Certification requirements at 45 CFR 170.404 to include ePA-related g-criteria**

- ➢ General requirements
- ➢ Transparency conditions
- ➢ Fees conditions
- ➢ Openness and pro-competitive conditions

➢ **Updated Maintenance of Certification Requirements (45 CFR 170.404(b)(1)):**

- ➢ Authentication verification and registration for production use (for (g)(31) and (g)(33) only)

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Inferno 101

Scott Bohon, Information Technology Specialist

Testing Workflow

Step 1: Define Requirements

Step 2: Establish baseline artifacts

Step 3: Test system

Step 4: Verify conformance

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Inferno Testing Overview

Certification Testing

Inferno is an official testing tool for the ONC Certification Program

HL7® FHIR® Testing

Designed to test FHIR®, including US Core, Da Vinci Burden Reduction, and more!

Interactive & Automated

Inferno tests support both graphical user interfaces and automated machine interfaces

Open Source & Transparent

Freely available code and documentation for open and accessible testing

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# Writing Health API Tests with Inferno Framework

Inferno testing is built using the "Inferno Framework" including:

- a programming language tailored to writing FHIR ® tests

- web, API, and command line interfaces for accessible testing

Inferno's extensive testing capabilities are enabled using the fully-featured Ruby programming language

Packaging Tests into Inferno Test Kits
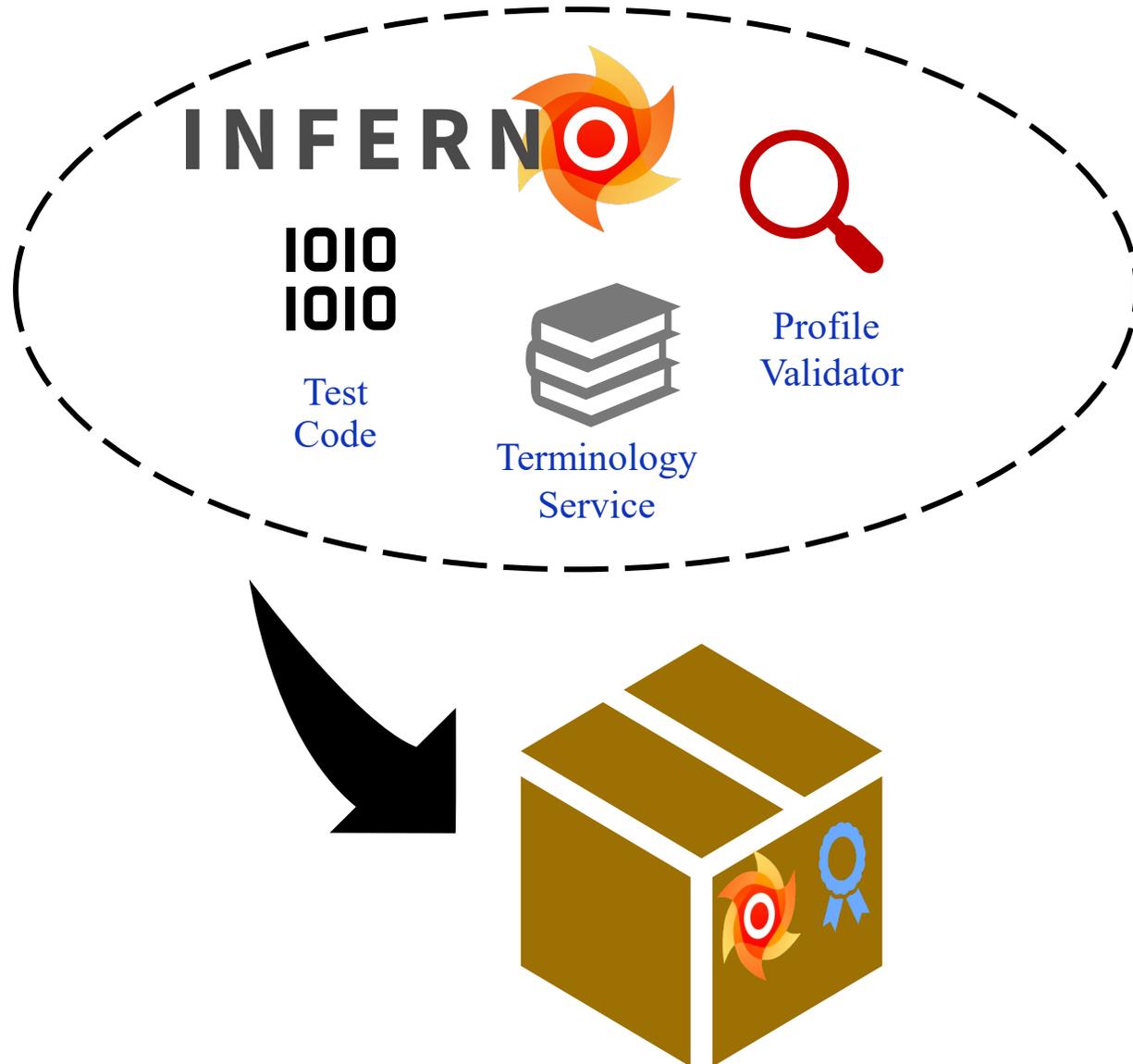
Inferno tests are packaged into "Test Kits" for specific use cases

Usually focus on FHIR ® IGs or ONC Certification Program requirements

Examples:

- US Core Test Kit
- (g)(10) certification criterion Test Kit

Test Kits can be deployed locally or available online at:
https://inferno.HealthIT.gov

Da Vinci Project Implementation Guide Inferno Test Kits

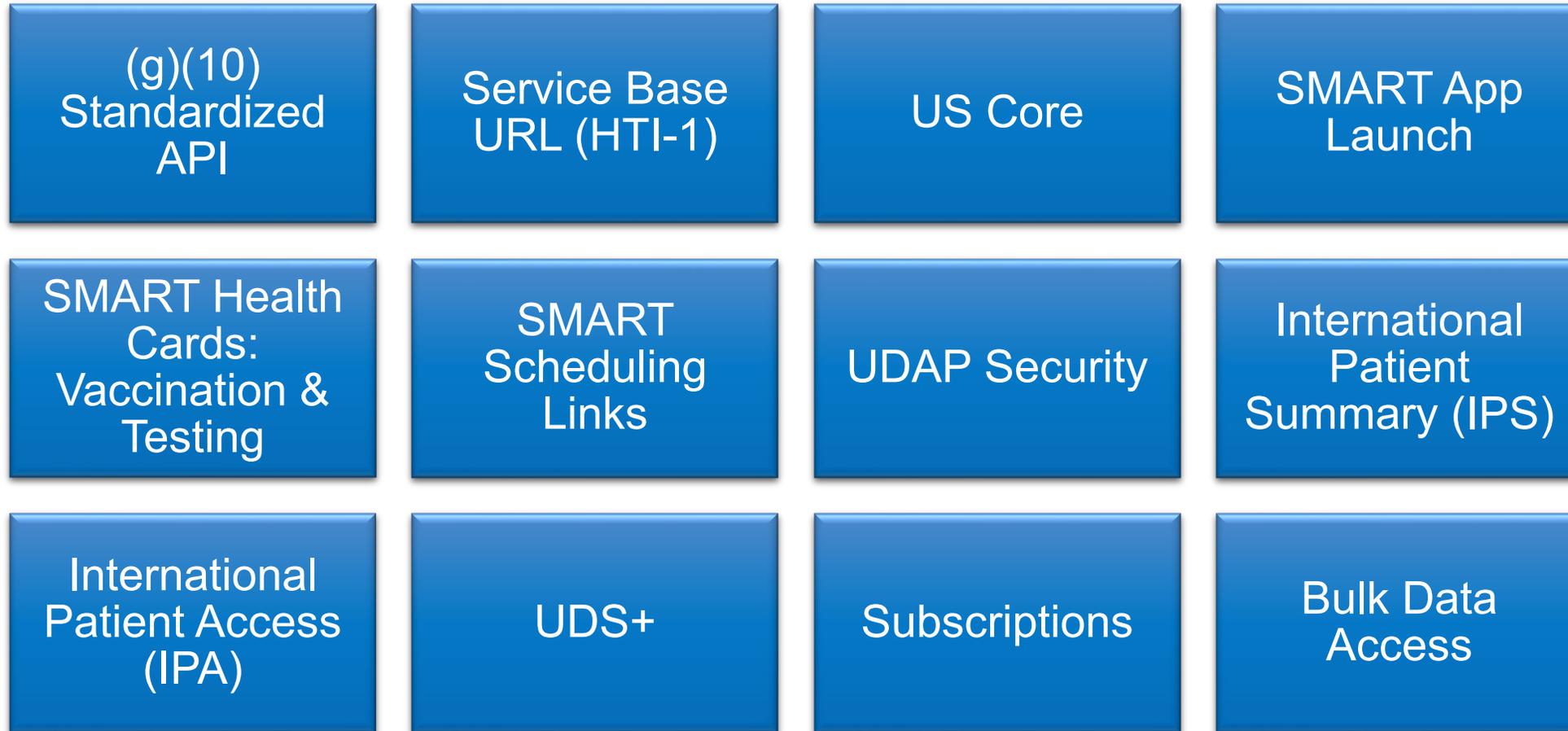|		
Da Vinci Payer Data Exchange (PDEX)	PDEX US Drug Formulary	PDEX Plan Net
Coverage Requirements Discovery (CRD)	Documentation Templates and Rules (DTR)	Prior Authorization Support (PAS)

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Many other Inferno Test Kits Currently Available

(g)(10) Standardized API	Service Base URL (HTI-1)	US Core	SMART App Launch
SMART Health Cards: Vaccination & Testing	SMART Scheduling Links	UDAP Security	International Patient Summary (IPS)
International Patient Access (IPA)	UDS+	Subscriptions	Bulk Data Access

... and more on Inferno Test Kit Registry at https://inferno-framework.github.io/community/test-kits.html

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Inferno Resources and Feedback

Resources for more information

- Unsure of where to start with Inferno? → Inferno.HealthIT.gov

- For list of available Inferno Test Kits → Inferno Test Kit Registry

- For ONC Certification Program related Test Kit source code → ONC GitHub repositories

- For Inferno Framework and voluntary, self-assessment Test Kit source code → Inferno Framework GitHub repositories

- For learning about technology underlying Inferno and writing your own tests → Inferno Framework Documentation

Feedback or questions about an Inferno Test Kit?

- Test Kit technical issue or feedback → submit an issue on the Test Kit GitHub repository

- Alternative channel for discussion and feedback → #inferno channel on chat.fhir.org

- ONC Certification Program testing questions → Health IT Feedback and Inquiry Portal

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Demonstration of Inferno Resources

Reach out via phone or web

📱 202-690-7151

💬 Feedback Form: https://www.healthit.gov/form/healthit-feedback-form

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