HL7® Update

eSolutions Xchange
2023 Conference

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Point of Care Partners

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HL7 International

- A not-for-profit organization, founded in 1987
- ANSI-accredited standards development organization
- Dedicated to providing a comprehensive framework and related standards for the exchange, integration, sharing, and retrieval of electronic health information
- Three Product Families: FHIR, V3/CDA, V2.x

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HL7's Global Reach

- 50+ Countries
- 500+ Corporate Members
- 1600+ Individual Members
- Thousands of contributors

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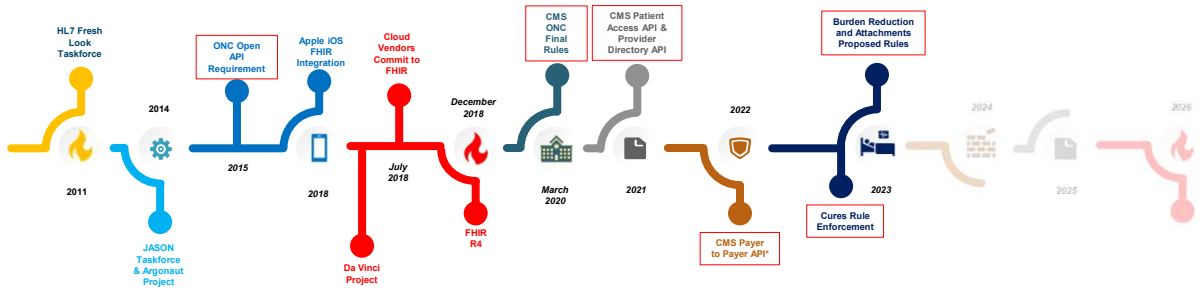
FHIR Timeline and Federal Regulations

CMS and ONC have identified FHIR as the foundational standard to support data exchange via secure application programming interfaces (APIs).



CMS identified FHIR in their final rules to establish a future where data flows freely and securely between payers, providers, and patients and to achieve truly coordinated care, improved health outcomes, and reduced costs.

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Slide 4

JK0 No mention of CCDA requirements.
Jocelyn Keegan, 2023-08-28T12:27:50.293

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S04 Pursue new communities

SID

Outreach

We will proactively reach new communities and leverage opportunities in the industry. Our first focus will be creating events featuring networking opportunities and new content tailored for our growing audience.

FHIR in the Sky	FHIR - The Future of Interoperability. Now!	FHIR Data Science Institute @ HL7	AMIA/HL7 FHIR App Competition	Open Data on FHIR	Cybersecurity for FHIR

Anticipated Outcomes

Outreach: expanding interest in HL7's standards to a broader audience

Implementation: support implementers by focusing on key uses, innovations, best practices, and widely available tools

Advance standards: add new perspectives and bridge the gap between standards development and implementation

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S02

Increase quality, value and reach of HL7 education offerings

SID

Education

Create new education programs to increase the value (through **credentialing**), volume (through **partnering**) and quality (through **certifying education providers**) of HL7 Education

Anticipated Outcomes

HL7 FHIR Credentialing: improve employability of credentialed individuals, assist hiring organizations via a recognizable marker

HL7 FHIR Certified Education Provider: increase the value for participants through recognized expertise of their educators

HL7 Partnering Program: expand training opportunities for the industry, and increase value for the Partners because of HL7 evaluation and further co-branding or recommendations (link from our pages)

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FHIR Education

- Technical and non-technical education for executives, clinicians, analysts, architects and developers
- Hands-on with synchronous, asynchronous and hybrid models
- Expanding partnership programs with academic community and industry organizations
- Expanding FHIR Certification

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S03 Create a platform for discovery and testing of our specifications

SID

The FHIR Foundry

Create an open platform (the ***FHIR Foundry***) where anyone in the world can **discover**, **test/try**, and **install** (reference) implementations of the HL7 specifications.

Anticipated Outcomes

Outreach and Discovery: the Foundry is the recognized place for discovering reference implementations for FHIR specifications

Continuous Testing: the Foundry enables implementers to test apps and servers against reference implementations and test engines with robust sample data *at any time*.

Standards Rigor: Over time, standards development includes Foundry-deployed reference implementation software as part of QA and Publication processes.

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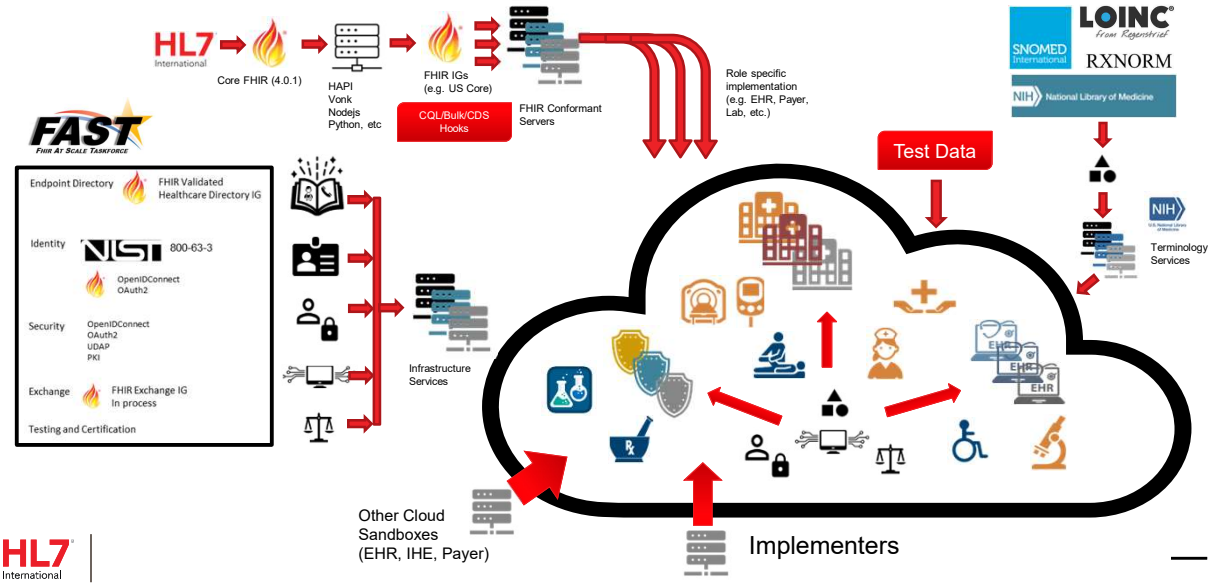
HL7 FHIR Foundry®



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S01 Leverage and expand the success of the HL7 FHIR Accelerator program

SID

Program Management

Based on the best practices learned through our experience, we will develop a standardized and sustainable *Accelerator Blueprint* as the model to grow our community and support the adoption of FHIR around the world.

Anticipated Outcomes

Establish and apply the ***Accelerator Blueprint*** as the model for going from a nascent idea to a thriving group

Increase revenue through the HL7 FHIR Accelerator program with new groups and efficiencies to existing ones

Expand the Accelerator portfolio by proactively pursuing new domains

Increase HL7 membership by demonstrating its value to HL7 FHIR Accelerator participants who are not yet

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HL7 FHIR Accelerator Program

Begun only 6 years ago, the program assists implementers across the healthcare and research spectrum in the creation of FHIR implementation guides and critical public- and private-sector solutions.

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HL7 FHIR ARGONAUT PROJECT

Private sector initiative to advance industry adoption of modern, open interoperability standards.

Prior Initiatives

- SMART on FHIR support
- Data Query and Document Query
- Provider Directory
- Scheduling
- CDS Hooks support
- Bulk Data
- Questionnaire and Questionnaire Response
- Clinical Provenance
- Clinical Notes
- SMART Web Messaging
- Clinical Data Subscriptions
- US Core Argonaut R4 - USCDI
- SMART on FHIR Granular Controls
- Patient List
- FHIR Write

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Argonaut 2023 – Full Projects

HL7 FHIR ARGONAUT PROJECT

API Access to Images

- Make imaging data accessible through the same SMART on FHIR API as clinical data.
- One authorization flow + one access token enables access to clinical + imaging. Bridge to DICOM web services under the hood.

FHIR Write – Vitals

- Provider facing-app or Patient facing-app: sprint focused on writing back Vitals.
- This information is structured in systems today, and Health Systems report they want to bring this discrete data into the EHR.

US Core design to support USCDI v4

- Consistent deployment of USCDI requires, review, testing, and the development of clear FHIR profiles.
- Test new designs for USCDI

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Argonaut 2023 – Minis

- **Enable patient-provider secure messaging from app (4-5 calls!)**
  - Patients using an app who want to share information with their providers need to screenshot or copy that information and then log in to a separate health system app to send a message
- **Testing of Patient Access Brands**
  - FHIR endpoints and associated branding information to create a seamless user experience connecting patients to their health records through various applications.
  - Apps display recognizable cards or tiles representing different healthcare providers, payers, or organizations
- **Assessment Sprint**
  - Mini sprint to test new US Core design of Observation vs QuestionnaireResponse
  - Updated design included in US Core 6.0.0

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Creating Access to Real-time Information Now through Consumer-Directed Exchange

CARIN is a multi-sector Alliance with more than 80 stakeholders, with the goal to advance the adoption of consumer-directed exchange across the U.S.

Project Areas

- Trust Framework, Code of Conduct, and App Registration Guide
- CARIN IG for Blue Button®
- CARIN IG for Consumer-facing Real-time Pharmacy Benefit Check
- CARIN IG for Digital Insurance Card
- Digital Identity & Authentication

https://www.carinalliance.com/

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2023 CARIN ALLIANCE PLANS

CARIN WORKGROUP	PLANS FOR 2023
Trust Framework, Code of Conduct, and App Registration Guide	❖ Continue to ramp up the CARIN code of conduct certification program with more applications getting certified.
CARIN IG for Blue Button®	❖ Continue testing the IG STU2. ❖ Launching a pilot with the ONC and CMS to include a test kit on the ONC's Inferno test suite for the CARIN IG for Blue Button®.
CARIN IG for Consumer-facing Real-time Pharmacy Benefit Check	❖ Advance the adoption of the IG, including encouraging PBMs to consider this standard in conjunction with the NCPDP standard for MAPD and Part D plans.
CARIN IG for Digital Insurance Card	❖ Held a developer seminar on 2/28 to discuss an approach for integrating the CARIN IG for Digital Insurance Card with SMART Health Cards. ❖ CARIN helda testing event at the CMS July Connectathon.
Digital Identity & Authentication	❖ Incorporate the lessons learned from the Digital Identity Federation Proof of Concept into a production pilot ❖ A new workgroup within CARIN will be addressing an open framework for how to identity proof minors with their consent and their legal guardian's/parent(s) consent

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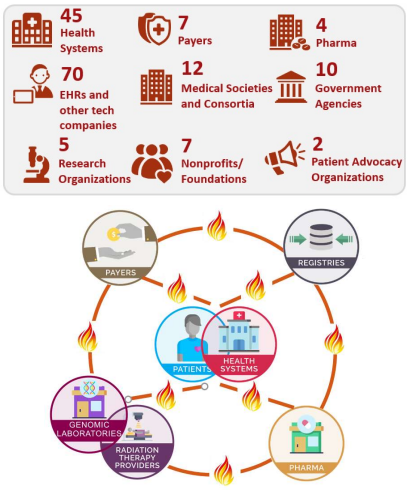
CodeX™
Common Oncology Data Elements eXtensions

Member-driven HL7 FHIR Accelerator, building a community to accelerate interoperable data modeling and applications leading to step-change improvements in cancer patient care and research

mCODE: Implemented by Epic + 14 other systems (so far)



https://confluence.hl7.org/display/COD/CodeX+Home

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CodeX Oncology Use Cases

Focus of 2023 is on expanding patient impact

EHR Endpoints for Cancer Clinical Trials (ICAREdata)

Building foundation to transform clinical trials by capturing trial results in a standard way. When oncology patient data is consistently captured during trials, clinical researchers can learn more and help more patients with standard trial results. Three clinical sites participating.

Integrated Trial Matching for Cancer Patients and Providers

Automates existing clinical trial matching process, allowing eligibility screening to be completed in one step. Demonstrated feasibility of program with a 300% to 800% increase in matched trials with plans for a prospective approach including 2-3 implementation sites.

Cancer Registry Reporting

Enables automated reporting of cancer data to registries, expediting researchers' ability to identify better treatments. Completed the pilot and currently preparing to extend testing before transitioning to production in the future.

Radiation Therapy (RT) Treatment Data for Cancer

Enables exchange of radiation therapy data for enhanced patient care coordination and data reuse, such as quality management, research, and payer-required reporting. Currently, proof of concept testing the exchange of treatment summary information between oncology information systems.

Prior Authorization (PA) in Oncology

Automates PA for cancer treatment utilizing FHIR® CRD, DTR, PAS IGs to **expedite patient care, reduce manual processes for providers and payers** with the target of 80% of determinations that do not require manual review. Currently preparing proof of concept for radiation oncology for prostate cancer.

Quality Measures for Cancer

Demonstrates ability to **author and evaluate oncology quality measures using FHIR® data model and mCODE for value-based programs and quality improvement**. Currently, developing and testing conversion of oncology-based quality measures to FHIR® as a proof-of-concept.

Each CodeX Use Case progresses through three stages of development.

CodeX

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gravity PROJECT

To create and maintain a consensus-building community to expand available SDOH core data for interoperability and accelerate standards-based information exchange by using HL7® FHIR®.

FHIR Implementation Guide

- SDOH Clinical Care for Multiple Domains (STU 2 Published November 2022)

Inclusion of SDOH in USCDI V2

- SNOMED CT US Ed. March 2022
- ICD-10-CM 2022

Pilots Affinity Workgroup

- Peer-to-peer learning forum for real-world testing of Gravity terminology and technical standards

https://confluence.hl7.org/display/GRAV/The+Gravity+Project

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Terminology Workstream — Scope

- **Develop data standards** to represent and exchange patient level social risk data documented across four clinical activities:
  - Screening,
  - Assessment/diagnosis,
  - Goal setting, and
  - Intervention/treatment
- **Test and validate** standardized social risk data for use in patient care, care coordination between health and human services sectors, population health management, public health, value-based payment, and clinical research

SDOH Domains

Domains grounded by those listed in the NASEM "Capturing Social and Behavioral Domains in Electronic Health Records" 2014

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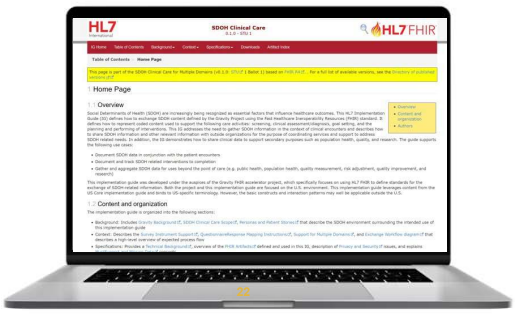
Technical Workstream — Scope HL7 SDOH Clinical Care FHIR Implementation Guide (IG)

1. This is a framework Implementation Guide (IG) and supports multiple SDOH domains.
2. IG support the following clinical activities:
   - Assessments
   - Health Concerns/Problems
   - Goals
   - Interventions including referrals
   - Consent
   - Aggregation for exchange/reporting
   - Exchange with patient/client applications
   - Draft specifications for race/ethnicity exchange
3. Standard for Trial Use 2 (STU2) published November 2022!



Click to access Gravity SDOH Implementation Guide (STU2)

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Pilot Workstream — Scope

- **Goal:** Drive implementation of Gravity Project terminology and technical standards and evaluate these standards for continuous improvement
- **Gravity Pilots Affinity Group**:
  A peer-to-peer learning forum for entities participating in the real-world testing of Gravity standards
- ***Supported Pilots***: Intentional relationships offering technical assistance to pilot teams and direct feedback on Gravity deliverables

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HELIOS

The goal of Helios is to help overcome barriers to adoption, promote market-based solutions that are compatible with nationwide interoperability priorities, and ensure scalability and long-term sustainability of data modernization

- **Diverse teams** across public health, healthcare, philanthropic organizations, and the private sector work together to tackle longstanding challenges and explore new opportunities to advance interoperability.
- Align with and address known gaps in the FHIR standard to help **promote more flexible and effective data exchanges** with healthcare, the public, and other sectors beyond public health.
- **Prioritize** a small set of **use cases** that complement what exists today and make it easier for public health officials to act swiftly, share insights effectively, and have a greater impact in their communities.

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Deliver Aggregate Information

Goal

Provide mission-critical situational awareness information to public health to support both emergency response and ongoing monitoring needs

Partners

- HIT/EHR Vendors
- Tech Partners
- STLTs
- Federal Partners

Key Steps

1. Identify priority measures for proof-of-concept work
2. Test FHIR-native and/or CSV to FHIR approach to sharing data
3. Recruit key partners and plan activities for piloting the exchange of measure data

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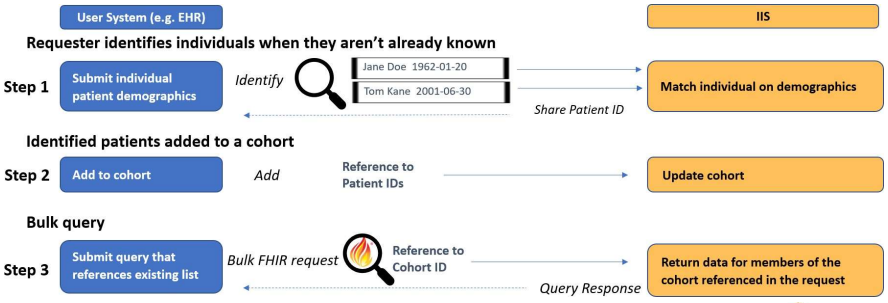
Make Public Health Data Accessible in Bulk

Progress

- Success with an initial round of Connectathon testing
- Development of a Minimum Viable Product for next round of testing



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The FAST Accelerator will identify FHIR resources, scalability gaps and possible solutions, as well as analyses that will address current barriers and accelerate FHIR adoption at scale.

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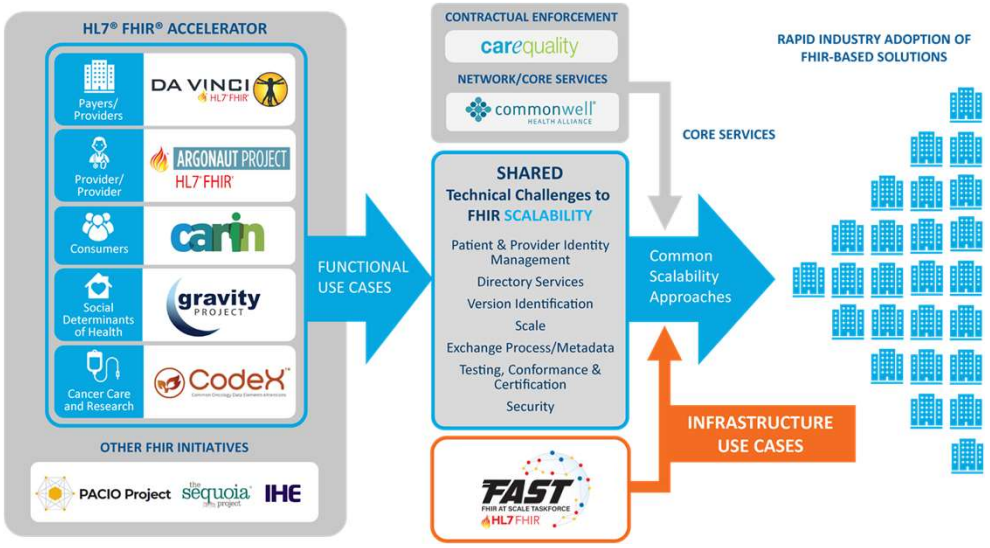
FAST in Ecosystem



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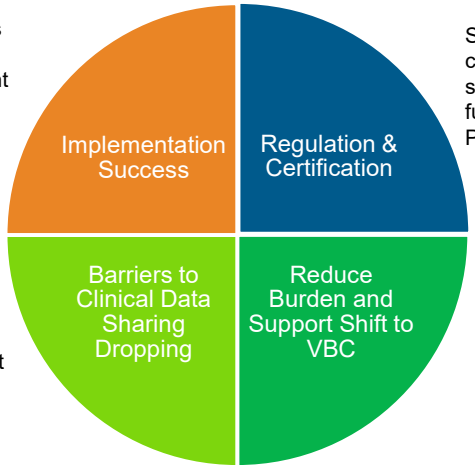
Da Vinci: Why Now, What is Different

Real world progress across implementers demonstrating improvement and benefit of automating critical workflows for provider and payer teams alike



Shift driven by ONC and CMS coordinated acceleration to shift the industry to APIs across functional areas across Providers, Payers and Vendors

Payers and Providers include clinical data sharing as base contract agreement with reality better tools to scale. Shared agreement to do this with standards

Real world progress across implementers demonstrating improvement and benefit of automating critical workflows for provider and payer teams alike

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Convergence of Policy, Technology and Industry Alignment

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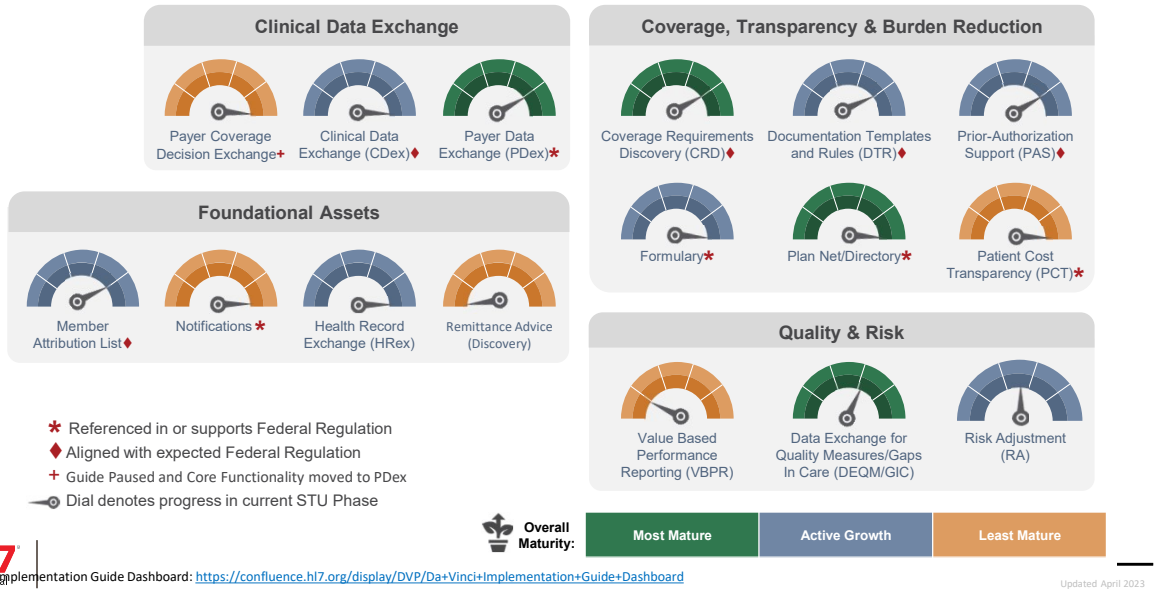
Da Vinci Use Case & IG Readiness



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Implementation Guide Dashboard: https://confluence.hl7.org/display/DVP/Da+Vinci+Implementation+Guide+Dashboard

Updated April 2023

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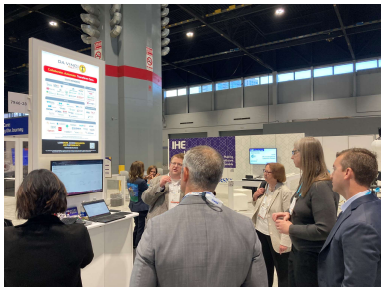
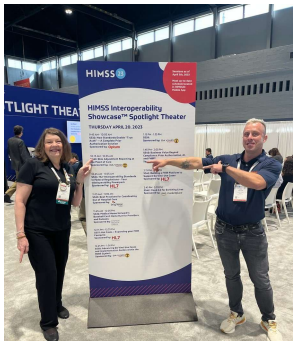
HIMSS23





Members delivered 30+ presentations, demonstrations, and panel discussions

Standards + FHIR + Da Vinci use cases (APIs) underpinning industry progress

Seeing momentum from 21st Century Cures related regulations

Garnering value

AI buzz + criticality of data quality

Pragmatic storytelling of incremental improvement

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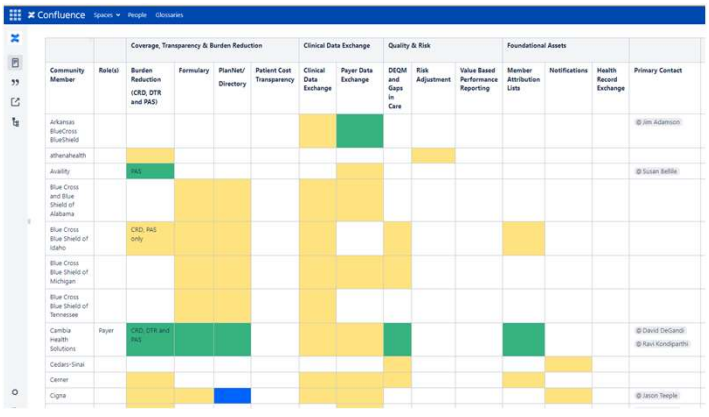
Da Vinci in Action: Implementations Dashboard

Da Vinci In Action Interactive:

View and update the interactive chart to denote progress on HL7 FHIR and Da Vinci Use Cases

- Depict three levels of progress
  - Development
  - Testing
  - Production
- **Open to all**

Use the chart to **locate community members** to who are in active development, ready for partners and want to connect with the community



Share your progress at: https://confluence.hl7.org/display/DVP/Da+Vinci+In+Action+Interactive+-+Implementations+To+Date

Updated 8/28/23

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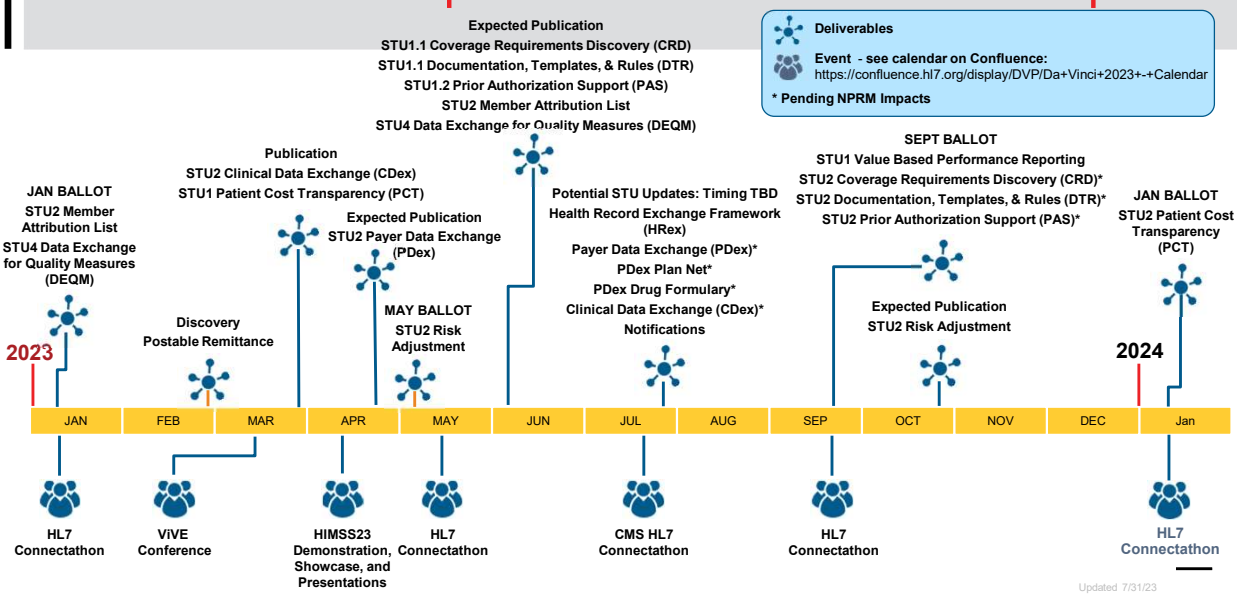
2023 Da Vinci Implementation Guide Roadmap



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Policy Considerations and Impacts

- ONC and CMS are driving industry towards APIs
- Anticipated certification will expand beyond CEHRT
- Important discussion at HL7 and with industry on versioning base FHIR, Guides, ecosystem support

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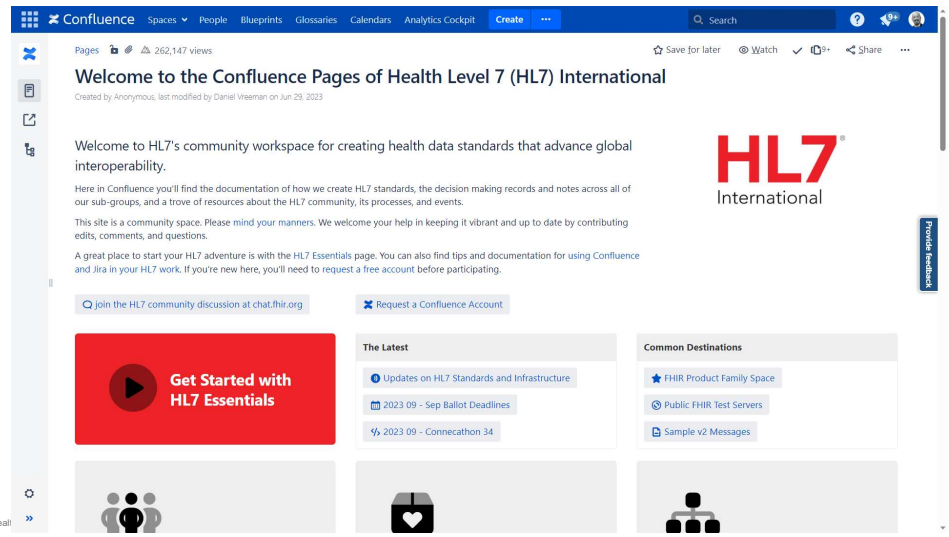
For More Information: Confluence.HL7.org



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ONC Technical Standards

HHS Final Technical Standards in the ONC's 21st Century Cures Act Final Rules

HL7 FHIR R4
Health Level 7 HL7 Version 4.0.1 Fast Healthcare Interoperability Resources FHIR Specification
URL: http://hl7.org/fhir/R4/

SMART IG / OAuth 2.0
SMART Application Launch Framework Implementation Guide Release 1.0.0, November 13, 2018
URL: http://hl7.org/fhir/smart-app-launch/history.html

OpenID Connect
OpenID Connect Core 1.0 Incorporating Errata Set 1, November 8. 2014
URL: http://openid.net/specs/openid-connect-core-1_0.html

Content & Vocabulary Standards

USCDI
United States Core Data for Interoperability USCDI, February 2020, Version 1 v1
URL: https://www.healthit.gov/isa/us-core-data-interoperability-uscdi

FHIR® Bulk Data Access (Flat FHIR®) (v1.0.0: STU 1)
United States Core Data for Interoperability USCDI, February 2020, Version 1 v1
URL: https://hl7.org/fhir/uv/bulkdata/STU1.0.1/

For complete details of certification - https://www.healthit.gov/test-method/standardized-api-patient-and-population-services

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ONC - Health Data, Technology, and Interoperability: Certification Program Updates, Algorithm Transparency, and Information Sharing (HTI-1) Proposed Rule

- Implementing the Electronic Health Record Reporting Program as new Condition and Maintenance of Certification requirements (Insights Condition) for developers of certified health information technology (health IT) under the Certification Program.
- Modifying and expanding exceptions in the information blocking regulations to support information sharing and certainty for regulated actors.
- Revising several Certification Program certification criteria, including existing criteria for clinical decision support (CDS), patient demographics and observations, electronic case reporting, and application programming interfaces for patient and population services.
- **Raising the baseline version of the United States Core Data for Interoperability (USCDI) from Version 1 to Version 3.**
- Updating standards adopted under the Certification Program to advance interoperability, support enhanced health IT functionality, and reduce burden and costs.

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https://www.healthit.gov/topic/laws-regulation-and-policy/health-data-technology-and-interoperability-certification-program

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US Core 6.1.0

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US Core Implementation Guide
6.1.0 - STU6

HL7 FHIR

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This page is part of the US Core (v6.1.0: STU 6 Update) based on FHIR R4. This is the current published version.
For a full list of available versions, see the Directory of published versions

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Official URL: `http://hl7.org/fhir/us/core/ImplementationGuide/hl7.fhir.us.core`	*Version*: `6.1.0`
Active as of 2023-06-19	*Computable Name*: USCore
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https://www.hl7.org/fhir/us/core/

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CMS Burden Reduction Proposed Rule

Advancing Interoperability and Improving Prior Authorization Processes (CMS-0057-P):

- Impacted Payers
  - Medicare Advantage, Medicaid and CHIP FFS, Medicaid and CHIP Managed Care, QHPs on the FFEs
- Proposed APIs and Recommended IGs (more information)
  - **Patient Access API** – CARIN IG for Blue Button, Da Vinci PDex IG, Da Vinci PDex US Drug Formulary IG, HL7 US Core IG
  - **Provider Access API** – same set as Patient Access API (+ HL7 FHIR Bulk Data Access IG)
  - **Payer-to-Payer API** – same set as Patient Access API (+ HL7 FHIR Bulk Data Access IG)
  - **Prior Authorization Requirements, Documentation, and Decision (PARDD) API** -- Da Vinci Coverage Requirements Discovery (CRD) IG, Documentation Templates and Rules (DTR) IG, and Prior Authorization Support (PAS) IG
- Proposed Required Standards
  - HL7 FHIR Release 4.0.1, US Core 3.1.1/USCDI v1, SMART IG/OAuth 2.0, OpenID Connect 1.0, FHIR Bulk Data Access 1.0.0
- Proposed Compliance Date:
  - January 1, 2026 (or relevant rating period or plan year beginning on or after January 1, 2026

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FHIR Standards and Implementation Guides cited in CMS NPRM 00-57

Highlights

- Top table denotes FHIR standards already referenced in ONC Certification
- Guides by APIs
- Expected shift from Recommendation to Named/Required in Certification over time

Existing FHIR API Requirements

STANDARDS	PATIENT ACCESS API	PROVIDER ACCESS API	PROVIDER DIRECTORY API	PAYER-TO-PAYER API	PARDD API
USCDI at 45 CFR 170.213 (currently V1)	✓	✓	✓	✓	✓
FHIR Release 4.0.1	✓	✓	✓	✓	✓
HL7 FHIR U.S. Core IG STU 3.1.1	✓	✓	✓	✓	✓
HL7 SMART APP Launch Framework IG 1.0.0	✓	✓	✓	✓	✓
HL7 FHIR Bulk Access (Flat FHIR) IG v 1.0.0 STU 1	✗	✓	✗	✓	✗
OpenID Connect Core 1.0	✓	✓	✓	✓	✓

Recommended IGs By API requirement

IMPLEMENTATION GUIDE	PATIENT ACCESS API	PROVIDER ACCESS API	PROVIDER DIRECTORY API	PAYER-TO-PAYER API	PARDD API
CARIN for Blue Button IG Version STU 1.1.0	✓	✓	✗	✓	✗
Da Vinci PDex IG Version STU 1.0.0	✓	✓	✗	✓	✗
Da Vinci PDex U.S. Drug Formulary IG Version STU 1.1.0	✓	✓	✗	✓	✗
Da Vinci PDex Plan Net IG Version STU 1.1.0	✗	✗	✓	✗	✗
Da Vinci Payer Coverage Decision Exchange (PCDE) IG Version STU 1.0.0	✗	✗	✗	✓	✗
Da Vinci Prior Authorization Support (PAS) IG Version STU 1.1.0	✗	✗	✗	✗	✓
Da Vinci Coverage Requirements Discovery (CRD) IG Version STU 1.0.0	✗	✗	✗	✗	✓
Da Vinci Documentation Templates/Rules (DTR) IG Version STU 1.0.0	✗	✗	✗	✗	✓

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