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TEFCA Technical Monthly Webinar

Agenda

- HL7 C-CDA R2.1 Background
- HL7 C-CDA R2.1 CCDS and USCDI Versioning
- TEFCA & Concise Consolidated CDA: Deploying Encounter Summary and Patient Summary Documents with Clinical Notes
- HL7 CDA/C-CDA Future Publication Roadmap
- Sequoia Data Usability - eHealth Exchange Participant Considerations

HL7 C-CDA R2.1 Background

Consolidated Clinical Document Architecture (C-CDA)

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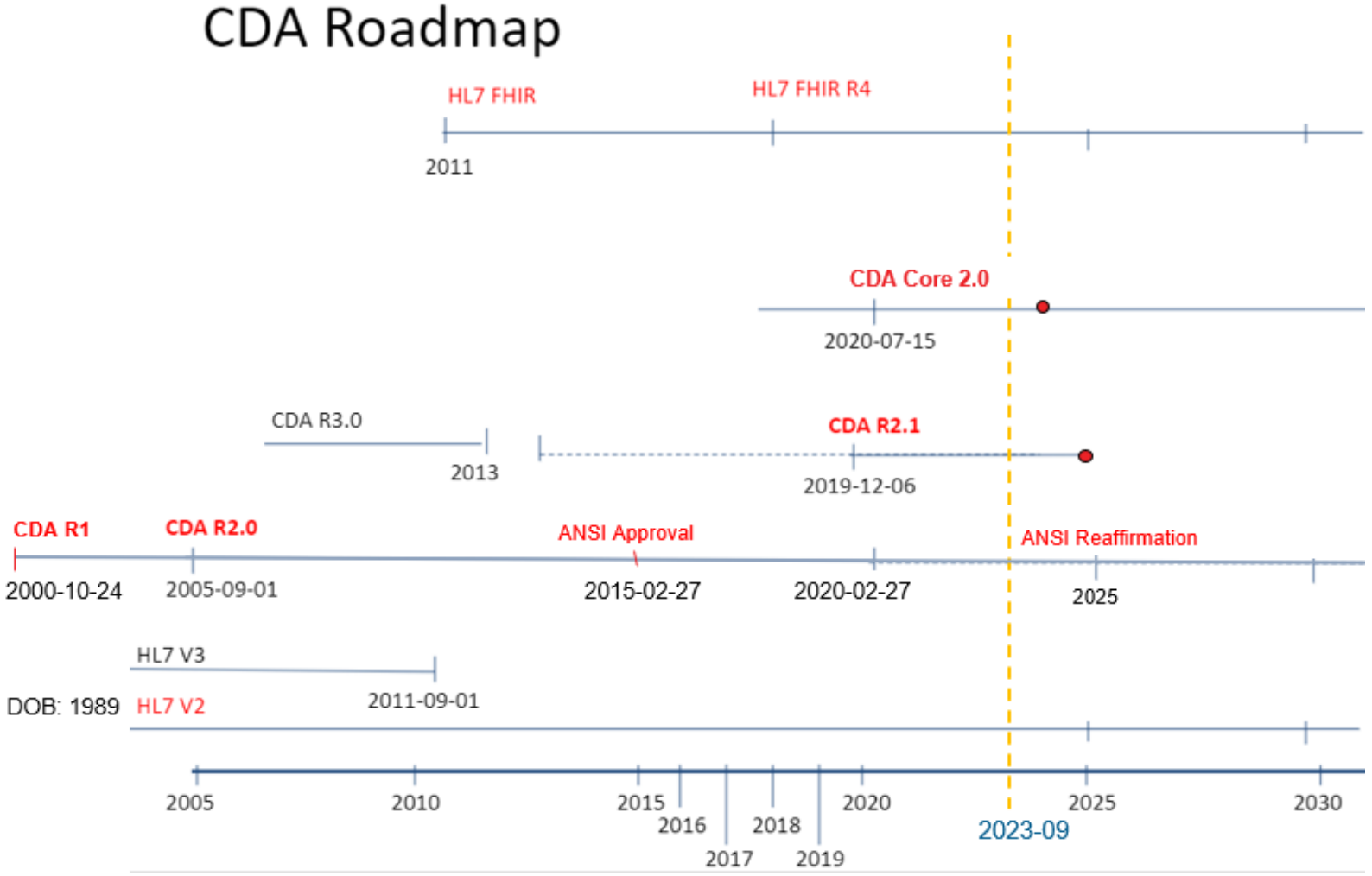
CDA turns 24 in 2024!

CDA DOB: 10/24/2000



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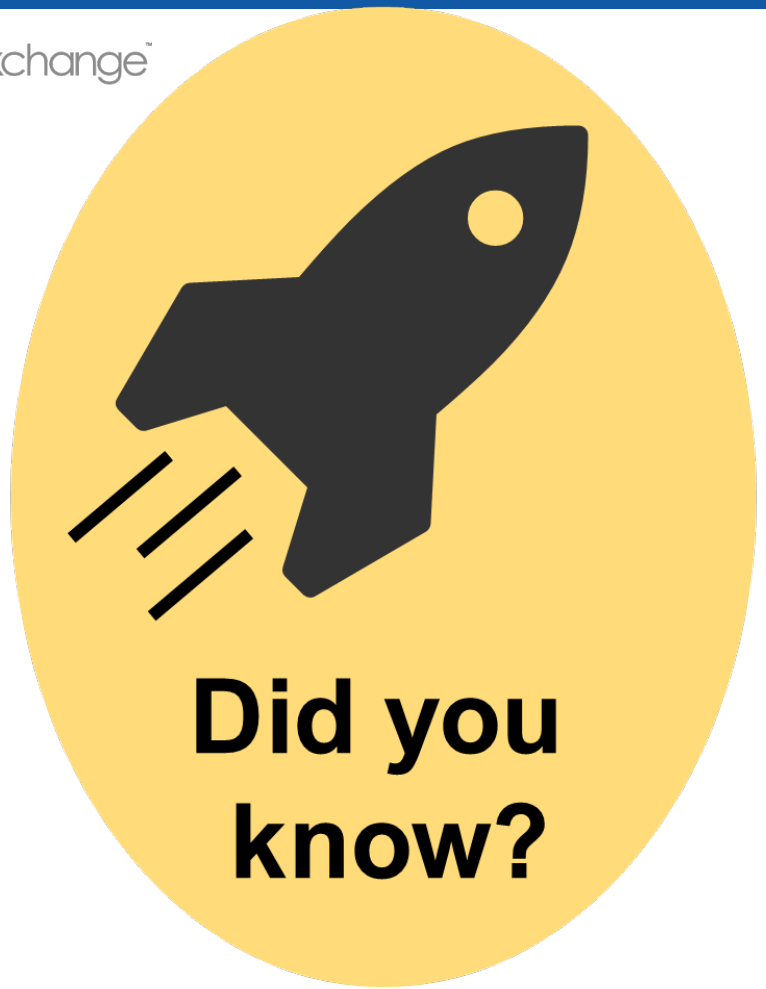
Key Attributes of HL7 CDA

- XML format based on a complex information model*
- Became the primary standard for US and international guides to exchange patient summaries
- 6 dimensions of a clinical document:
  1. Persistence
  2. Stewardship
  3. Potential for authentication
  4. Context
  5. Wholeness
  6. Human readability

- * You can learn more about the HL7 Reference Information Model (RIM) here: https://www.hl7.org/implement/standards/rim.cfm

HL7's CDA vs. C-CDA

- CDA – the schema for structured documents
  - The HL7 Clinical Document Architecture (CDA) is a document markup standard that specifies the structure and semantics of "clinical documents" for the purpose of exchange.
- C-CDA – defines a set of CDA documents
  - The HL7 Consolidated CDA is an implementation guide which species a library of templates and prescribes their use for a set of specific document types.
  - Priority is patient care, facilitate sharing of data to healthcare applications
  - Minimize technical barriers to implementation
  - Promote longevity of clinical records
  - Scoped by exchange, independent of transfer or storage
  - Enable policy-makers to control information requirements



HL7® CDA®

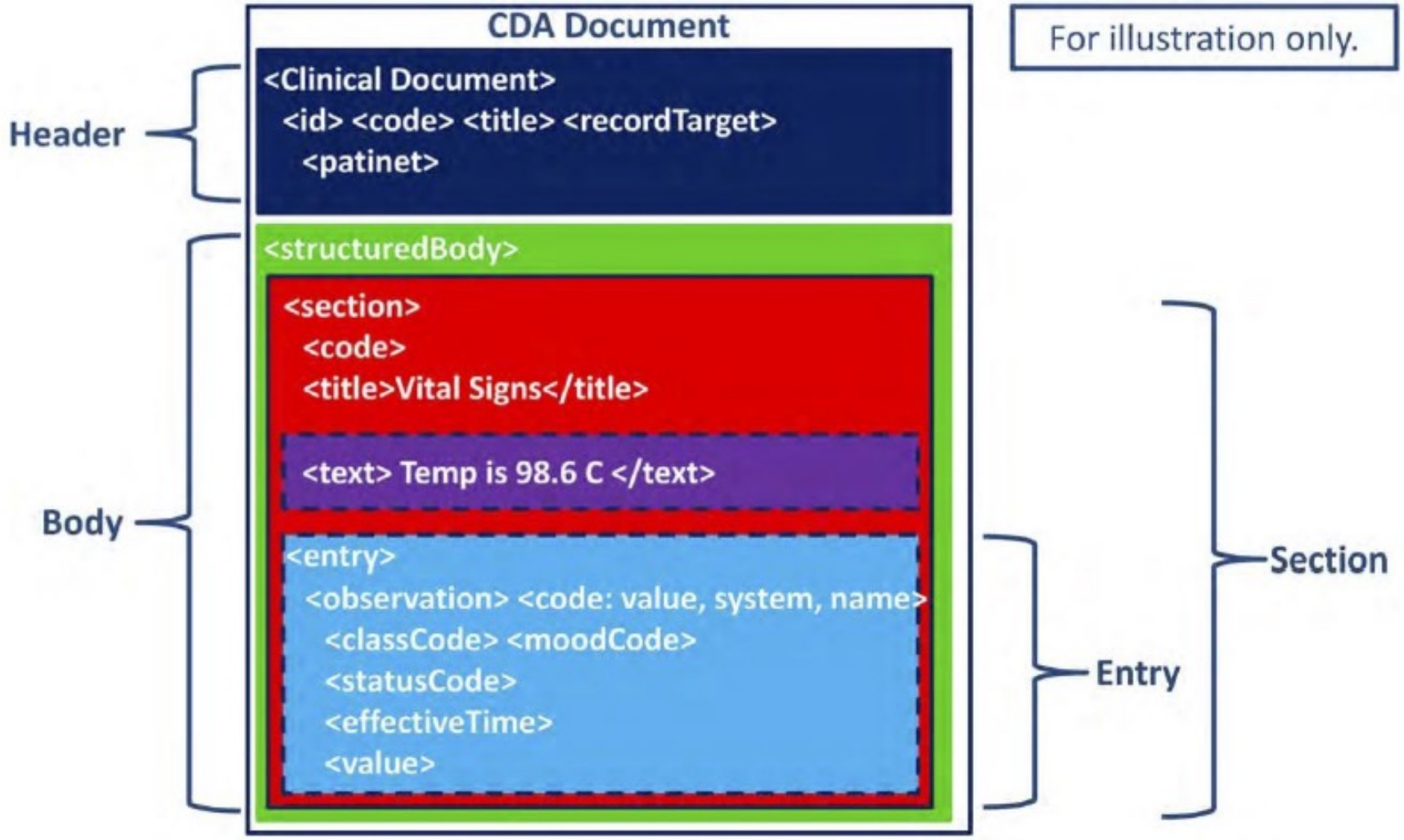
CDA means
Clinical Document Architecture

Since you started reading this slide, **over 500 CDA documents** have been exchanged. It's over 100 documents per second* in the United States alone!!

* C-CDA Volumes reported **over 7 Billion** CDA documents exchanged from Carequality and US national networks, and even more shared through international, regional and administrative exchange.

C-CDA Provides Semantic Building Blocks!

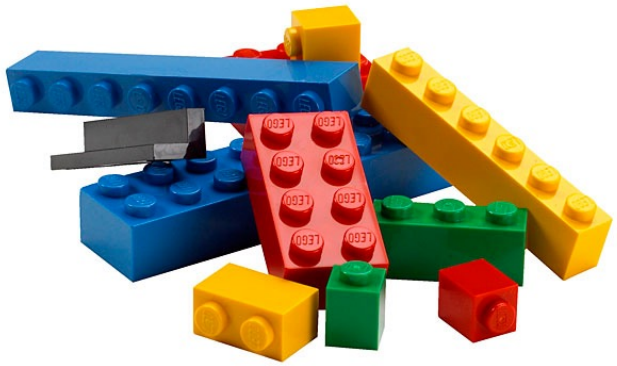
That we can reconfigure for specific purposes



C-CDA R2.1 Document Types (12 Total)

- C-CDA R1.0/R1.1
  - Consultation Note
  - Continuity of Care Document (CCD)
  - Diagnostic Imaging Report
  - Discharge Summary
  - History and Physical
  - Operative Note
  - Procedure Note
  - Progress Note
  - Unstructured Document

- New as of C-CDA R2.0/R2.1
  - Care Plan
  - Referral Note
  - Transfer Summary



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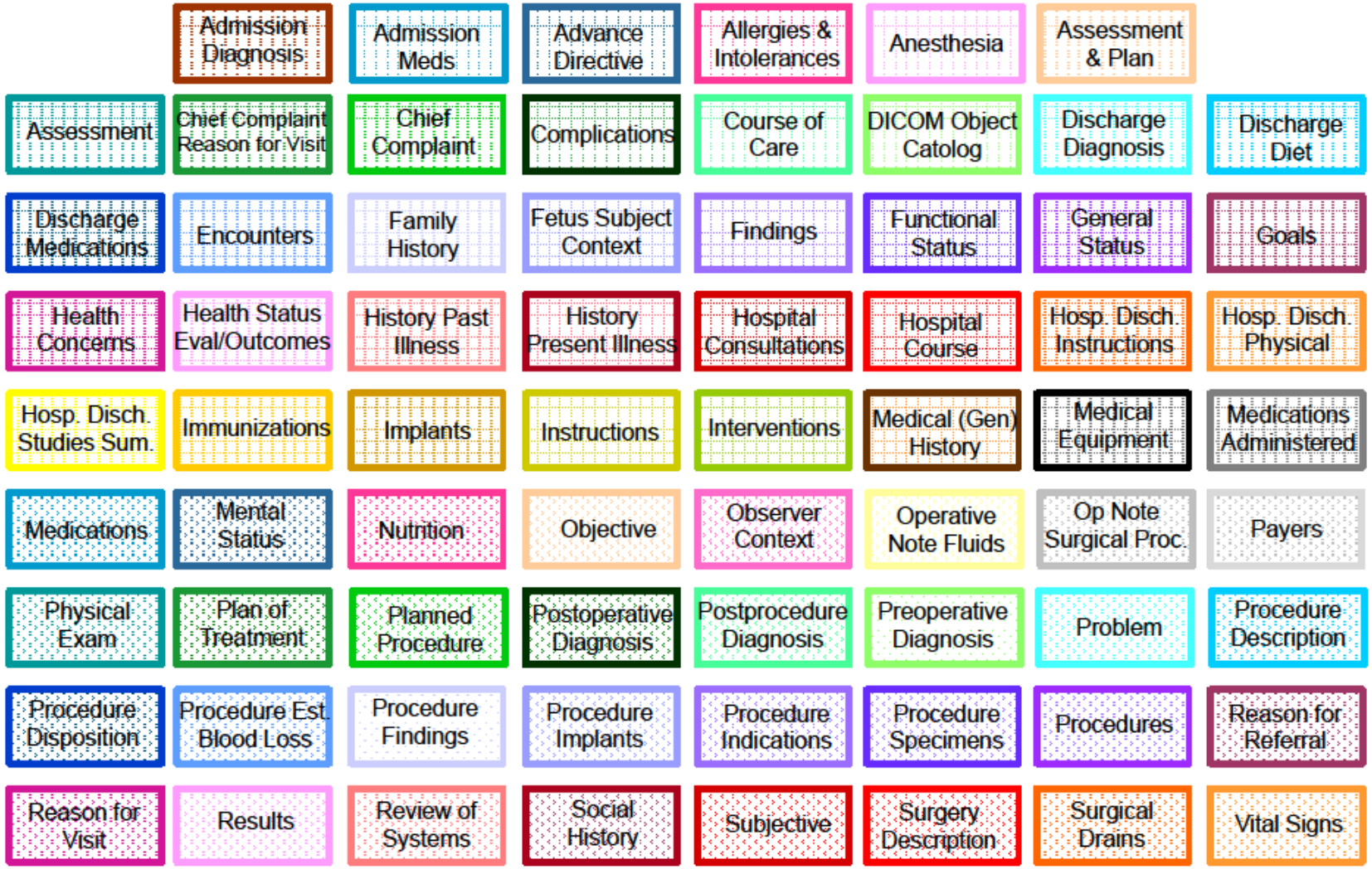
70 Document Sections in C-CDA R2.1



HL7 C-CDA R2.1 CCDS and USCDI Versioning

Common Clinical Data Set (CCDS) and US Core Data for Interoperability (USCDI)

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Common Clinical Data Set (CCDS) = 2015 Edition MU

The Office of the National Coordinator for Health Information Technology

2015 Edition
Common Clinical Data Set (CCDS)
Reference Document

Version 1.3– Last Updated 2/22/18

Please consult the Final Rule entitled: *2015 Edition Health Information Technology (Health IT) Certification Criteria, 2015 Edition Base Electronic Health Record (EHR) Definition, and ONC Health IT Certification Program Modifications* for a detailed description of the certification requirements. We also encourage developers to consult the Certification Companion Guide as they provide clarifications that may be useful for product development and testing.

Requirements

The following table is a complete list of the 2015 Edition of the Common Clinical Data Set (CCDS) and their associated standards. The complete list of the 2015 CCDS and the associated standards may be found in Table 8 of the Final Rule.

Standard(s):

§ 170.205(a)(4) HL7 Implementation Guide for CDA® Release 2: Consolidated CDA Templates for Clinical Notes, Draft Standard for Trial Use, Release 2.1
§ 170.207(a)(4) International Health Terminology Standards Development Organization (IHTSDO) Systematized Nomenclature of Medicine Clinical Terms (SNOMED CT®), U.S. Edition, September 2015 Release
§ 170.207(b)(2) Current Procedural Terminology/Healthcare Common Procedure Coding System CPT-4/HCPCS
§ 170.207(b)(3) Current Dental Terminology (CDT)
§ 170.207(b)(4) International Classification of Diseases ICD-10-PCS
§ 170.207(c)(3) Logical Observation Identifiers Names and Codes (LOINC®) Database version 2.52, Released June 2015, a universal code system for identifying laboratory and clinical observations produced by the Regenstrief Institute, Inc.
§ 170.207(d)(3) RxNorm, a standardized nomenclature for clinical drugs produced by the United States National Library of Medicine, September 8, 2015 Release
§ 170.207(e)(3) HL7 Standard Code Set CVX—Vaccines Administered, updates through August 17, 2015
§ 170.207(e)(4) National Drug Code (NDC) Directory– Vaccine NDC Linker, updates through August 17, 2015
§ 170.207(f)(1) The Office of Management and Budget Standards for Maintaining, Collecting, and Presenting Federal Data on Race and Ethnicity, Statistical Policy Directive No. 15, as revised, October 30, 1997
§ 170.207(f)(2) CDC Race and Ethnicity Code Set Version 1.0 (March 2000)
§ 170.207(g)(2) Request for Comments (RFC) 5646, "Tags for Identifying Languages", September 2009
§ 170.207(h) Smoking status must be coded in one of the following SNOMED CT® codes:
(1) Current every day smoker. 449868002
(2) Current some day smoker. 428041000124106
(3) Former smoker. 8517006
(4) Never smoker. 266919005
(5) Smoker, current status unknown. 77176002

1

https://www.healthit.gov/sites/default/files/ccds_reference_document_v1_1.pdf

USCDI V1

https://www.healthit.gov/isa/sites/isa/files/2020-10/USCDI-Version-1-July-2020-Errata-Final_0.pdf

HL7 C-CDA R2.1 Meaningful Use to USCDI v1.0 Background

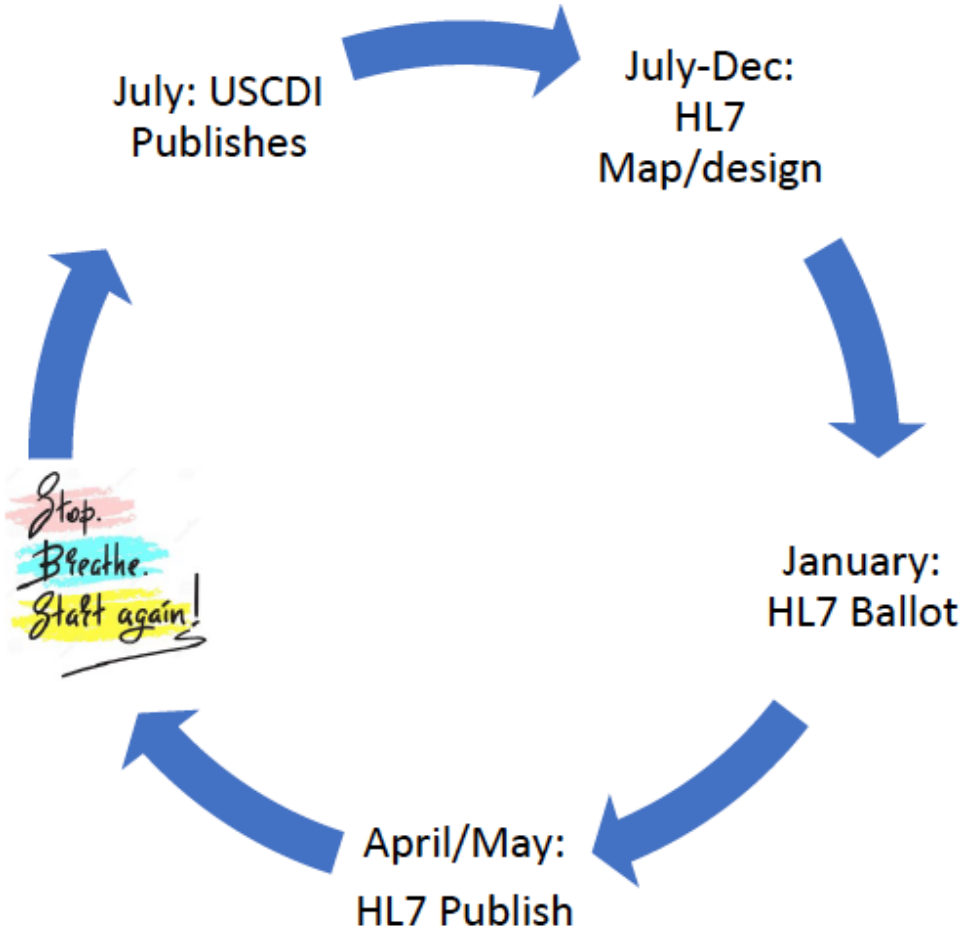
- Meaningful Use 2015 Edition – Common Clinical Data Set (CCDS)
  - CCDS was the foundation for USCDI v1.0
  - https://www.healthit.gov/sites/default/files/ccds_reference_document_v1_1.pdf
- **21st Century Cures Act transitions from CCDS to adopt USCDI v1.0**
- USCDI V1.0 Added 3 Data Classes and Expanded Patient Demographics
  - Allergies and Intolerances
  - Clinical Notes
  - Expanded Patient Demographics (Current/Previous Address, Phone Number and Type, Email Address, Previous Name)
  - Provenance

Cures Act Final Rule Information

- All ONC Cures Rule Materials can be found at www.healthit.gov/topic/oncs-cures-act-final-rule
- USCDI V1 available at www.healthit.gov/uscdi
- ONC Cures Act Final Rule
  - https://www.federalregister.gov/documents/2020/05/01/2020-07419/21st-century-cures-act-interoperability-information-blocking-and-the-onc-health-it-certification

HL7 Response to USCDI Annual Expansion Process

- **January:** Ballots C-CDA (and US Core) design of USCDI version published prior July
- **April-May:** Publishes C-CDA (and US Core) design of USCDI version published prior July
- **July-December:** Design sessions for the next January ballot begin



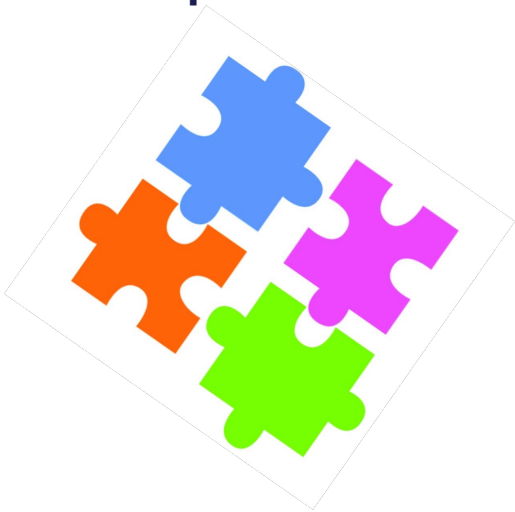
DRAFT US Core C-CDA Alignment Principles (Value Sets):

Update all C-CDA value sets to use value sets developed or used in US Core where possible

- Considerations:
  - FHIR vs V3 value sets
  - CDA and nullFlavor construct

Change C-CDA design to accommodate using/aligning with value sets **developed** or **used** in US Core

- Considerations:
  - Can't change underlying CDA design
  - Primarily how/where value sets are bound
  - C-CDA Vendor and Implementer burden



Reference value set in VSAC, or the value set in US Core directly

- Considerations:
  - Move US Core defined value sets to VSAC
  - If code system not present (or not able to be added) in VSAC, will reference US Core, FHIR or THO set

If US Core adds FHIR Data Absent Reasons to a value seet, C-CDA will also-ELSE, C-CDA will CONTINUE with nullFlavor construct.

DRAFT US Core C-CDA Alignment Principles (Profiles):

Eliminate or add C-CDA templates/profiles where needed to mirror US Core

- Considerations:
  - Discovery will be iterative during the march to ballot with both USCDI design and non-USCDI ballot changes
    - Current Decisions:
      - Keep only one C-CDA Procedure Template/Profile
      - Remove DIR Templates
    - C-CDA Vendor and Implementer burden

Profile/Template Element Changes

- To accommodate value set binding changes
- To accommodate USCDI Design

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

- Adopts USCDI v3 as new baseline as of January 1, 2026
  - Combined 42 new data elements from V2 (18) and v3 (24)
  - C-CDA Companion Guide

- C-CDA Companion Guide
  - HL7® CDA R2 Implementation Guide: C-CDA Templates for Clinical Notes R2.1 Companion Guide, Release 4.1-US Realm

TEFCA & Concise Consolidated CDA: Deploying Encounter Summary and Patient Summary Documents with Clinical Notes

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Concise Consolidated CDA – Version History

Guide developed through a joint effort of Carequality and CommonWell

- Initial Release – February 2018
- Version 1.1 Release – February 2019
  - Clarified use of IHE query parameters, added conformance verbs, moved content to appendix
- Version 2.0 Release – March 2022
  - Added document sharing details, dynamic generation, versioning, labs, pain points, reorganized content.
  - Renamed document to add ”and Patient”
    - Concise Consolidated CDA: Deploying Encounter Summary and Patient Summary Documents with Clinical Notes

Qualified Health Information Network (QHIN) Technical Framework (QTF) V2.0 references to Concise CDA Whitepaper

- **QTF-051** - Responding QHINs **SHOULD** provide C-CDA 2.1 documents that follow recommendations as presented in Concise Consolidated CDA: Deploying Encounter Summary CDA Documents with Clinical Notes
- **QTF-058** - $XDSDocumentEntryServiceStartTimeTo and $XDSDocumentEntryServiceStopTimeFrom are optional parameters that **MAY** be included in the FindDocuments query to limit the number of documents returned. Usage **MUST** follow the guidance of Concise Consolidated CDA: Deploying Encounter Summary CDA Documents with Clinical Notes Appendix A.3 IHE XDS Query Parameters. serviceStartTime and serviceStopTime are defined ITI TF-3 Table 4.1.3.2-1. These query parameters are among the metadata parameters that **MUST** be returned with objects in all LeafClass Query for Documents responses. serviceStartTime and serviceStopTime **MUST** be requested as UTC in DTM format.
- **QTF-098** - A Responding Actor **SHOULD** provide C-CDA 2.1 documents that follow recommendations as presented in Concise Consolidated CDA: Deploying Encounter Summary CDA Documents with Clinical Notes26, when the information held by that Responding Actor is organized around a clinical encounter construct.

QTF V2.0 C-CDA R2.1 and USCDI V1 References

- **QTF-048:** When a Responding Source is unable to generate C-CDA 2.1 format documents, QHINs **MAY** offer document conversion services, except where the use of another format is consistent with QTF-050 and QTF-052.
- **QTF-049:** A QHIN converting a document to C-CDA 2.1 format **MUST** convert to one of the templates as defined in HL7 CDA® R2 Implementation Guide: Consolidated CDA Templates for Clinical Notes - US Realm.
- **QTF-052:** All C-CDA 2.1 format documents adhering to the Continuity of Care Document template **MUST** include all appropriate data classes and elements from the United States Core Data for Interoperability (USCDI) V1 when data are available.23 The RCE will update the QTF to enable the use of future versions of USCDI that are consistent with ONC rules for health IT certification compliance.
- **QTF-100:** All C-CDA 2.1 format documents adhering to the Continuity of Care Document template **MUST** include all appropriate data classes and elements from USCDI V127 when data are available. The RCE will update the QTF to enable the use of future versions of USCDI that are consistent with ONC rules for health IT certification compliance.
- **QTF-117:** The test patient data **MUST** include at least one C-CDA 2.1 document with fictional clinical data that can be queried and retrieved.
- **QTF-118:** All QHINs **SHOULD** create at least one C-CDA Discharge Summary and Progress Note template document for the test patient. QHINs serving outpatient clinics and inpatient hospitals **MUST** create such documents. Any encounters, etc. **MUST** be linked to the clinician created for QTF-122.
- **QTF-123:** A “Document Query Nominal Flow” of the test data per QTF-113 **MUST** return the C-CDA 2.1 document(s) associated with a test patient.

HL7 CDA/C-CDA Future Publication Roadmap

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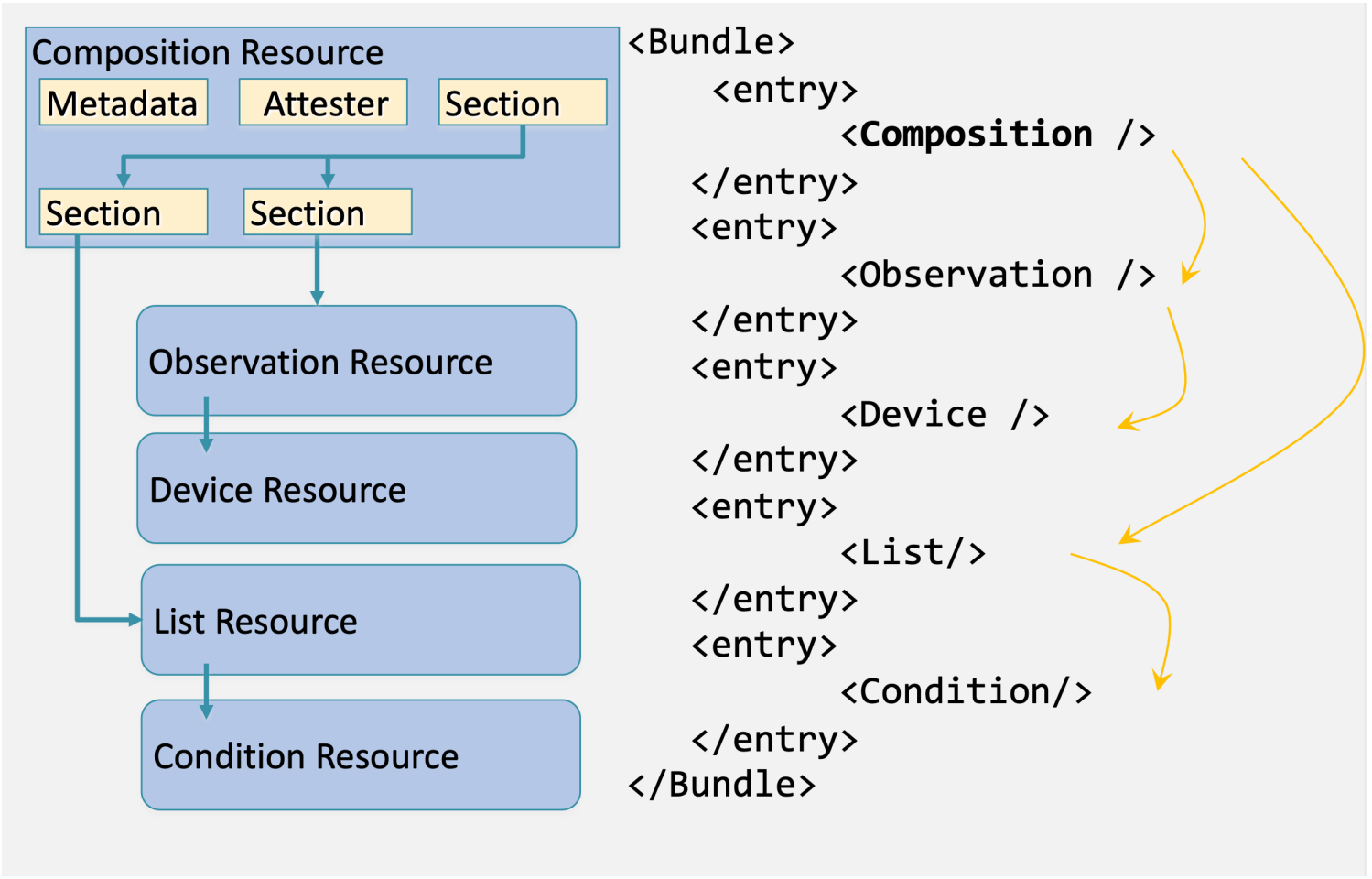
FHIR – FAST Healthcare Interoperability Resources

- FHIR is fast for implementers, why?
  - Community and based on modern IT standards
  - Licensing issues/web-based standard which is searchable with examples
  - Reference implementations
  - Test servers
  - Validation Tools
  - Publishing Tools
- How this can be applied to implement CDA with FHIR tool stack?

What is StructureDefinition Publishing?

- CDA Structures are defined as Logical Models
- Templates are authored as Profiles on underlying CDA Logical Models
- Both Logical Models and Profiles are defined as FHIR StructureDefinition instances
- All of the templates are combined into a C-CDA Implementation Guide
- IG Publisher is run on IG and produces Web content similar to the FHIR IGs

Documents are Bundles



Source: https://github.com/FHIR/documents/tree/master/presentations/2019-01%20Webinars

Mapping from CDA to FHIR

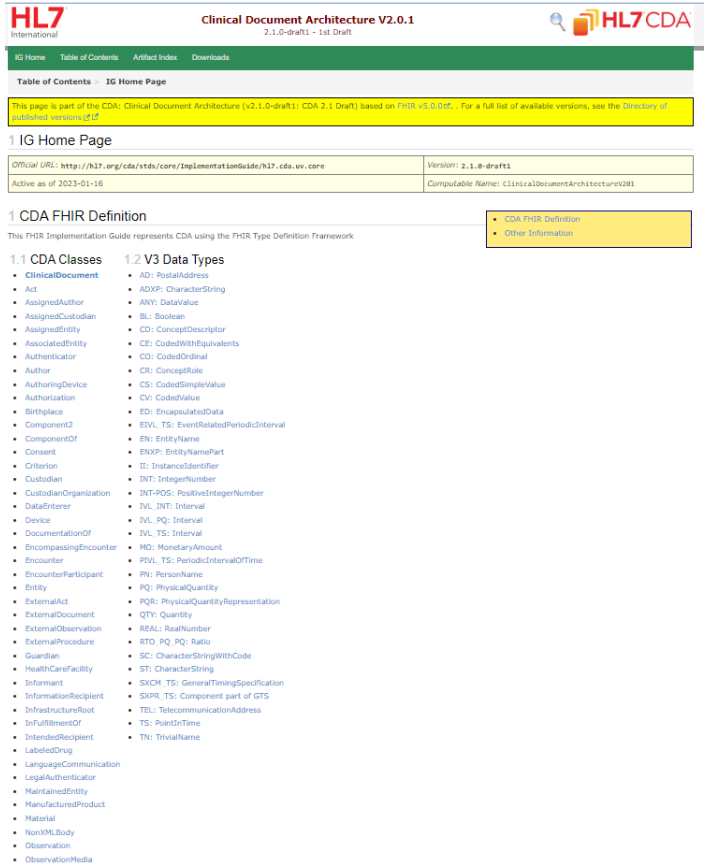
- CDA Level 1: (Just metadata and text), map to Bundle/Composition
- CDA Level 2: Coded sections, map to Bundle/Composition
- CDA Level 3: Structured entries, map to entries in Bundle

Level 1, Level 2 can be done maybe 70% generic, there are some different or missing concepts or too general to map

Level 3 general mapping hardly possible, can only be done on a profiled CDA (template), like C-CDA

Mappings should be done at the CDA template level rather than at the CDA specification

CDA 2.0 (Base specification) Informative Ballot

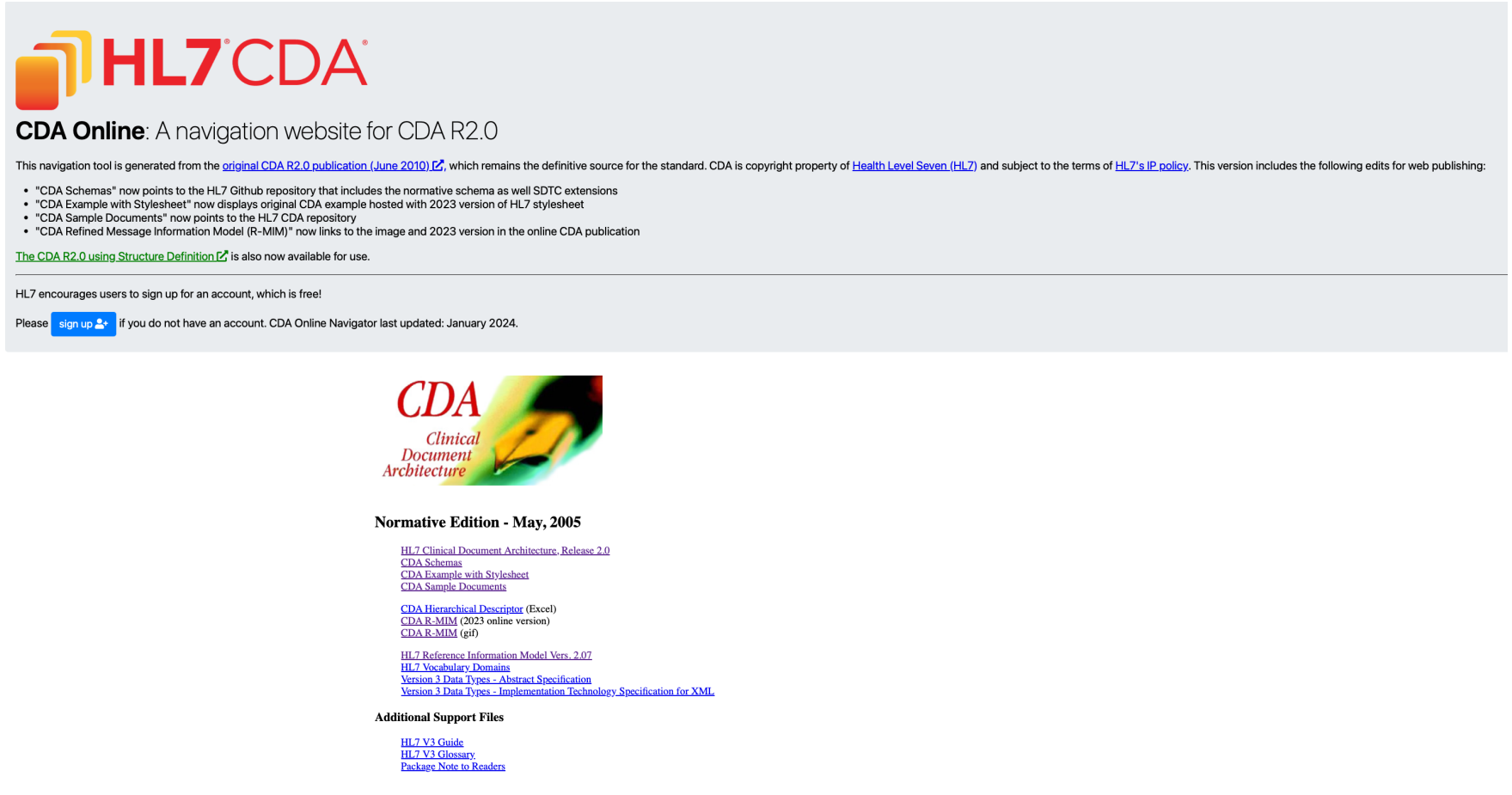


http://hl7.org/cda/stds/core/draft1

- Out of Cycle Ballot – November 2023
- A FHIR Logical Model based on CDA R2.0 Schema
- **Enables CDA IG creation using FHIR IG Publisher**
- Drive progress on **alignment of CDA with FHIR**;
  - Continue to perform work needed to create a CDA Profile on Composition, Bundle (Document), DocumentReference
- Seek resources to begin new "relay approach" for alignment of FHIR US Core, C-CDA and V2 for USCDI data
- Funding for engagement of **C-CDA to FHIR US Core mapping representative: CDA Templates mapped!**
  - Expand funding for Annual Value Set Update project to include resolving Value Set Alignment issues across US Core, C-CDA and V2 **Use same Value Sets as FHIR**

30

CDA Online: A navigation website or CDA R2.0



HL7 CDA

CDA Online: A navigation website for CDA R2.0

This navigation tool is generated from the original CDA R2.0 publication (June 2010), which remains the definitive source for the standard. CDA is copyright property of Health Level Seven (HL7) and subject to the terms of HL7's IP policy. This version includes the following edits for web publishing:

- "CDA Schemas" now points to the HL7 Github repository that includes the normative schema as well SDTC extensions
- "CDA Example with Stylesheet" now displays original CDA example hosted with 2023 version of HL7 stylesheet
- "CDA Sample Documents" now points to the HL7 CDA repository
- "CDA Refined Message Information Model (R-MIM)" now links to the image and 2023 version in the online CDA publication

The CDA R2.0 using Structure Definition is also now available for use.

HL7 encourages users to sign up for an account, which is free!

Please sign up if you do not have an account. CDA Online Navigator last updated: January 2024.

CDA Clinical Document Architecture

Normative Edition - May, 2005

HL7 Clinical Document Architecture, Release 2.0
CDA Schemas
CDA Example with Stylesheet
CDA Sample Documents

CDA Hierarchical Descriptor (Excel)
CDA R-MIM (2023 online version)
CDA R-MIM (gif)

HL7 Reference Information Model Vers. 2.07
HL7 Vocabulary Domains
Version 3 Data Types - Abstract Specification
Version 3 Data Types - Implementation Technology Specification for XML

Additional Support Files

HL7 V3 Guide
HL7 V3 Glossary
Package Note to Readers

Web Publication: September 2005
Links will open in a new window

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ANSI/HL7 CDA, R2-2005 (R2010)
HL7 Clinical Document Architecture, Release 2
(reaffirmation of ANSI/HL7 CDA, R2-2005)
6/24/2010

ISO/HL7 27932: 2008
HL7 Clinical Document Architecture, Release 2

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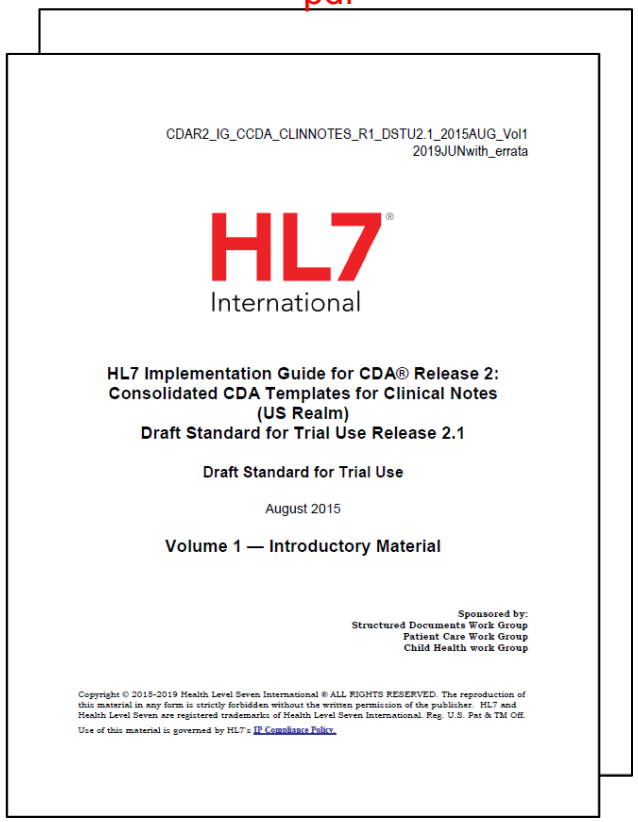
http://www.cda.health

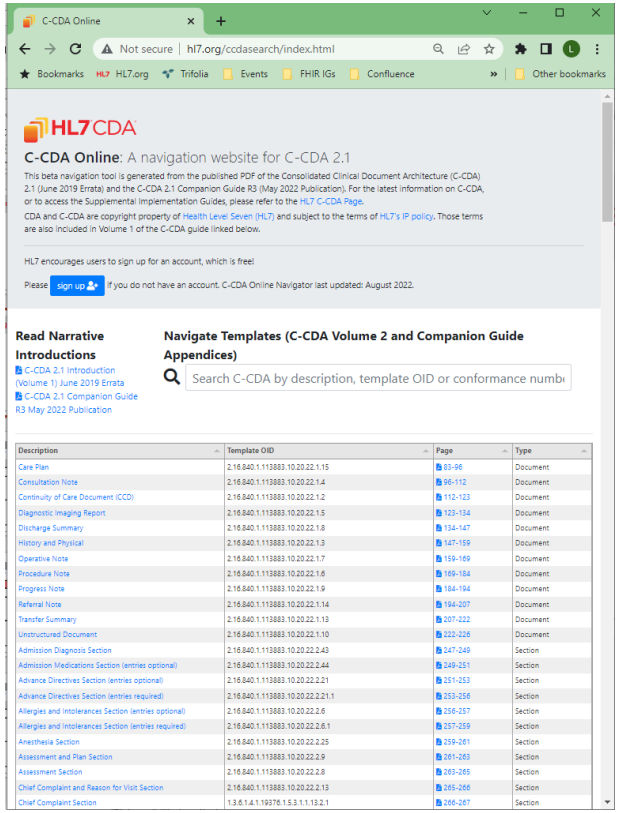
C-CDA R2.1 Web IG Publishing: Bridging Strategy

C-CDA R2.1
pdf



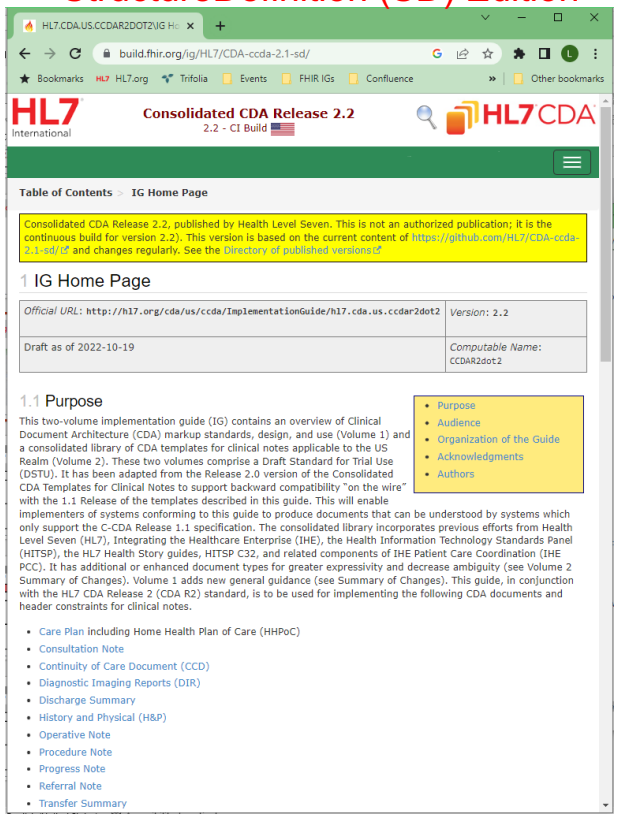
2005 - now

C-CDA R2.1
Online Edition



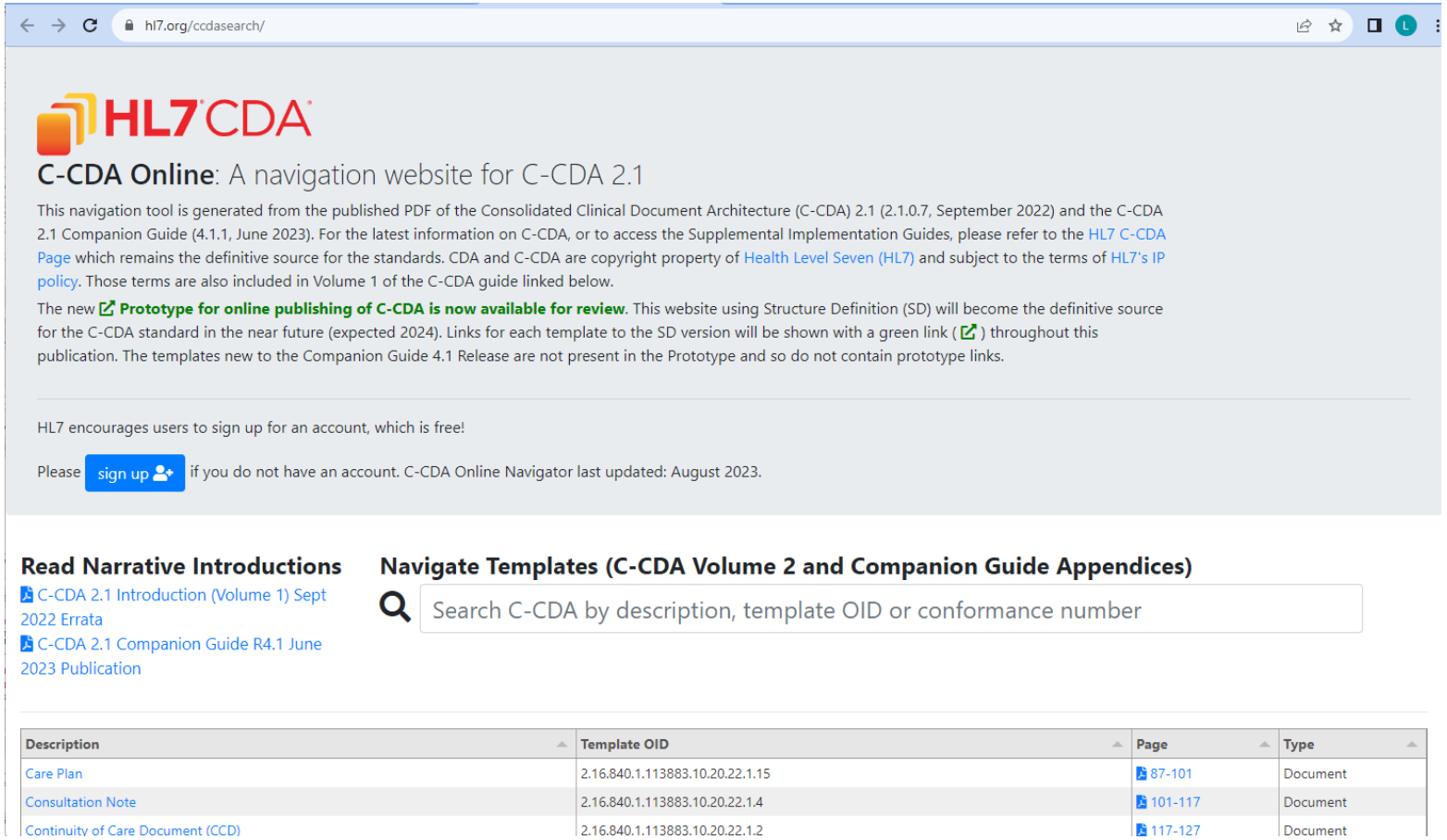
2020 - 2023
Only Available for C-CDA R2.1 ,
Companion Guide 4.1

C-CDA
StructureDefinition (SD) Edition



Jan 2024 Ballot
For C-CDA 3.0

C-CDA On-Line: A navigation website for C-CDA R2.1



- https://www.hl7.org/ccdasearch/
- Latest C-CDA R2.1 Errata Release
  - Consolidated Clinical Document Architecture (C-CDA) 2.1 (2.1.0.7, September 2022)
- Latest C-CDA R2.1 Companion Guide
  - Everything needed for USCDI V3
  - 2.1 Companion Guide (4.1.1, June 2023)
- Viewable pdf pages for C-CDA R2.1 Volume 1 and Volume 2
- Link to the Prototype for the new web-based publishing format for C-CDA

33

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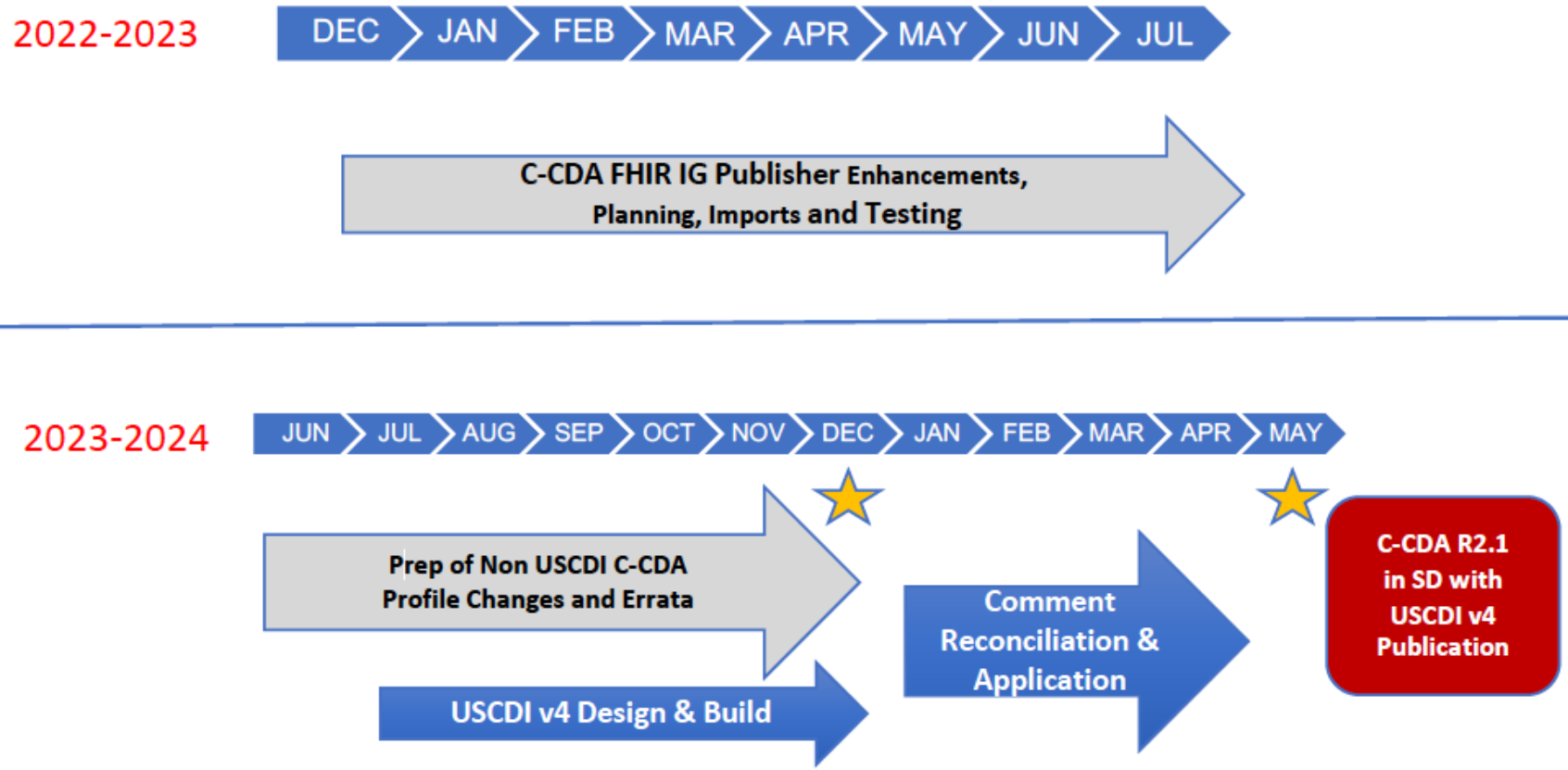
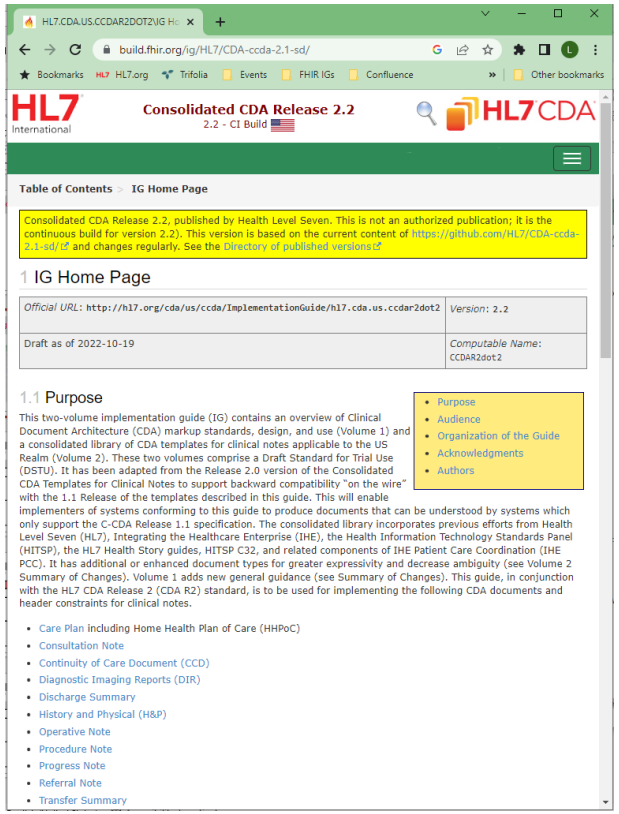
C-CDA Roadmap USCDI v4 and Beyond: Web Pub



2024 IG Creation Capabilities

- C-CDA Web IG Publishing – Validation Capabilities
- Build cross-paradigm IGs that include companion CDA Templates mapped to FHIR Profiles
- HL7 Imperative – alignment with FHIR
  - Fund resources for Profiles on Composition, Bundle (Document), DocumentReference, Provenance
  - Fund additional USCDI advancement work
    - Data element design work: FHIR→CDA→V2 for alignment
    - Value Set alignment; transitioning toward FHIR value sets
- Fund 2 Virtual Implementation-a-thons (IAT's) in 2024
  - Save the Dates: April 17-18, 2024 and August 7-8, 2024
  - Add task for Cross-Community collaboration (Data Usability Taking Roots)
  - Expand task for Outreach to engage specialty EHRs



A mature, productive, thriving product within the HL7 family of interoperability standards

36

Sequoia Data Usability - eHealth Exchange Participant Considerations

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Data Usability Taking Root Movement vs. Data Usability Workgroup?

Data Usability

Workgroup

Develops Guidance

Deployment **Guidance**

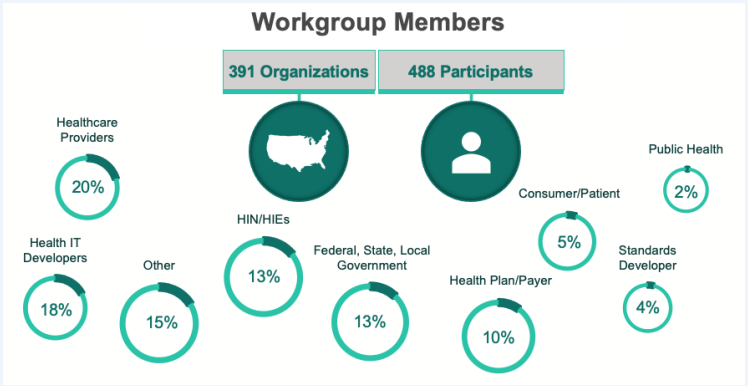
Development **Feedback**

Taking Root

Movement

Implements Guidance

An initiative co-sponsored by AHIMA



Community of Practice

- Roundtables
- Technical Assistance
- Testing Platform
- In-person Convenings

Participation Levels

IMPLEMENTER

SUPPORTER

SPONSOR

eHealth Exchange

Pragmatic Guidance

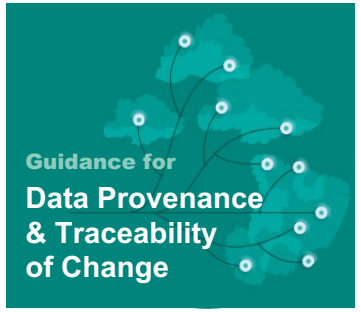
V1.0 Implementation guidance on clinical content for information exchange

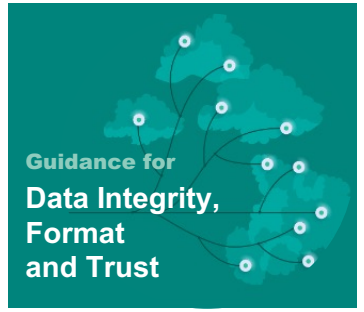
- provider-to-provider
- provider-to-public health
- healthcare entity-to-consumer

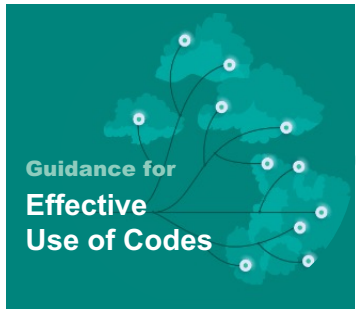
An initiative co-sponsored by AHIMA

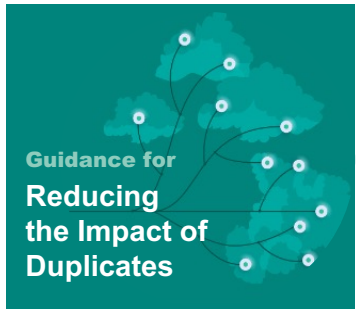
Implementation Guide Table of Contents

- Executive Summary & Phases Timeline
  - Phase 1 - Administration & Prioritization
  - Phase 2 - IG Development
  - Phase 3 - IG Public Comment
  - Phase 4 - IG Publication
- Statement of Intent
- Sections/Chapters
  - Six Topic Categories
  - Guidance with SHALL, SHOULD, MAY
- References
- Appendix A – High Priority Lab Results









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- American Health Information Management Association (AHIMA)
- Carequality & Commonwell Concise Consolidated CDA: Deploying Encounter Summary Patient Summary and Documents with Clinical Notes Whitepaper published March 2022 - referenced as JDCWG C-CDA Whitepaper 2
- Centers for Disease Control and Prevention (CDC)
- Health Level Seven (HL7)
- International Consortium for Harmonization of Clinical Laboratory Results
- LOINC COVID-19 Guidance for mapping to SARS-CoV-2 terms: COVID results
- National Archives Code of Federal Regulations CLIA Requirements
  - CLIA § 493.1291
- National Library of Medicine (NLM) Value Set Authority Center (VSAC)
- Office of the National Coordinator (ONC)
- Sequoia Project Interoperability Matters Data Usability Workgroup
- U.S. Department of Health and Human Services

Data Usability Taking Root

Supporter

Pledges to support the data usability movement as a member of the data usability community of practice. Grants right to Sequoia to include logo in its Taking Root member directory. Participates in Data Usability Roundtables. Supporters that are also Sequoia members are invited to Taking Root Summits.

Implementer

Pledges to implement V1.0 data usability guidance across one or more topics within a defined timeline. Invited to participate in the data usability community of practice, the Data Usability Taking Root Planning Committee, and the Taking Root Summits. Grants right to Sequoia to include logo in its Taking Root member directory.

Sponsor

Pledges to provide sponsorship of the Taking Root Summit(s). Socializes and evangelizes the purpose and power of this work. Co-hosts Taking Root Summits and participates in The Data Usability Taking Root Planning Committee, Roundtables, and Summits.

Levels of Engagement

eHealth Exchange

The Data Usability Taking Root **Movement** – January 2024

IMPLEMENTER — 11

Azuba
Bwell
Celeste
Clinical Architecture
Delaware Health Information Network
Epic
Health Gorilla
National Institutes of Health, National Institute of Diabetes & Digestive & Kidney Diseases
New York eHealth Collaborative
Opala
Santa Cruz Health Information Exchange

SUPPORTER — 40

ADVaultinc
American Medical Association
Austin Regional Clinic
Banner
Brevard Health Alliance
Civitas
Claim Clarity
DirectTrust
eHealth Exchange
Elevance Health
First Genesis, Inc.
Foothold Technology
Hawaii Pacific Health
HCA Healthcare
Health Services of North Texas (HSNT)
HealthElence
Johnson and Johnson
Kaiser Permanente
Kno 2
Meditech
MTC Group LLC

Netsmart
NextGen Healthcare
Optum
Particle Health Inc.
Patientory
PeaceHealth
Premiere Pointe Podiatry
Social Security Administration
Surescripts
Texas A&M
Texas Department of State Health Servic
Texas Health Services Authority
Texas State University
The Picture of Health
The University of Texas Health Science C
University of Washington
Verinovum
Veterns Health Information Exchange
Wolters Kluwer Health, Health Language
Zus Health

SPONSOR — 3

AHIMA

MedAllies

smile DIGITAL HEALTH

OTHER ROUNDTABLE PARTICIPANTS — 8

Carequality
HIMSS EHRA Association
IHIE
OCHIN
Oracle
Stanford Health
Sutter Health
Veterans Administration

An initiative co-sponsored by AHIMA

eHealth Exchange

Optionally: Participants could Implement Additional Guidance Into Practice Individually

- **Identify where to start**
  - Which V1.0 sections are priorities? (Provenance included with USCDI v1)
  - Which can be done quickly?
  - What is the timeframe?
- **Track progress**
  - Potential self-reported score card promotes transparency and healthy competition from Implementers/Vendors/HIEs
  - # elements supported
  - % of customers supporting
- **Incremental approach**
  - Enables rollout in conjunction with other IT projects
  - Elevates data usability for all IT projects - UAP
- **Other Considerations**
  - Leverage for governmental programs (e.g., EHR certification, USCDI, TEFCA, etc)
  - Feedback as part of Data Usability Monthly Round Table

Participants choose their own implementation pathway and pace…

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Roadmap

2024

- Expand participation; develop V2 to include FHIR
- Establish Community of Practice
- Technical Assistance
- Implementation & Conformance Testing begins
- Movement grows and 2nd Taking Root Summit

2025

- Community of Practice expands to include v2.0
- Technical Assistance expands
- Conformance Testing Continues
- Develop of V3 Begins
- Movement grows and 3rd Taking Root Summit

2026

- Community of Practice expands to include v3.0
- Conformance Testing Continues
- Develop of V4 Begins
- Movement grows and 4rd Taking Root Summit

Join the Movement Now!

https://sequoiaproject.org/data-usability-taking-root-movement/

ehealthexchange.org