

#### **Data Usability Workgroup**

August 1, 2024



#### **Agenda**

- Welcome, Introductions, Membership, Agenda Adam Davis, MD 5 minutes
- Data Usability Taking Root Community of Practice Update Didi Davis 5 minutes
- Process and Timeline for Public Comment Phase Didi Davis 15 min
- Highlights for Workgroup Input and Public Comment

   Bill Gregg, MD 30 minutes
- Reminders 5 minutes
  - HL7 Implementation-a-thon August 7-8, 2024
  - Timeline for Phase 4 Final Publication and Save the Date: The Sequoia Project Annual Meeting
- Workgroup Discussion & Q&A Didi Davis, Co-chairs and Workgroup



Adam Davis, MD, Co-chair Sutter Health

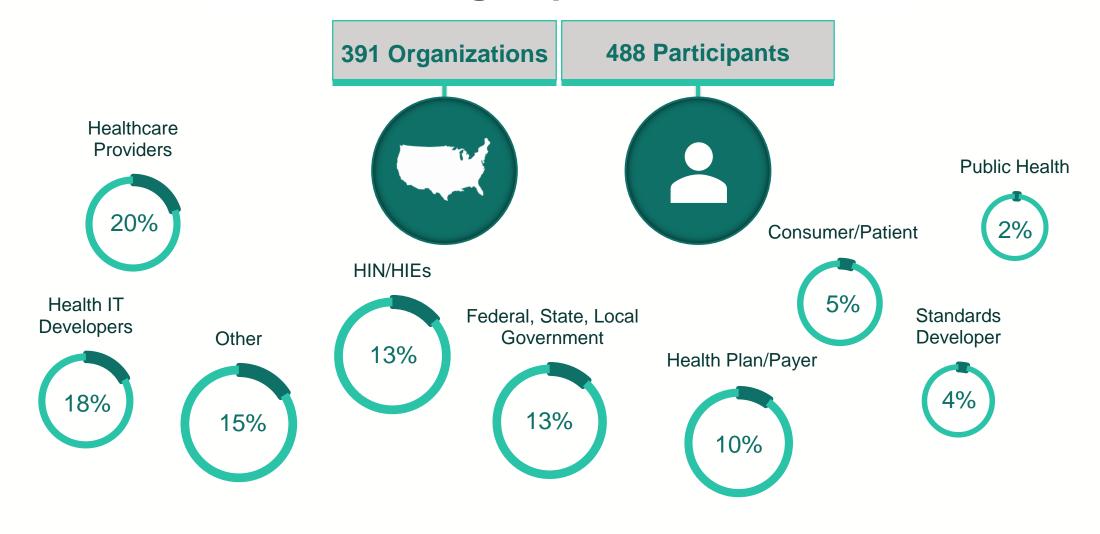


Bill Gregg, MD, Co-chair HCA Healthcare



Didi Davis, VP The Sequoia Project

#### **Workgroup Members**



## Sequoia Members Shape Interoperability for the Public Good







































































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## Sequoia Members Shape Interoperability for the Public Good





































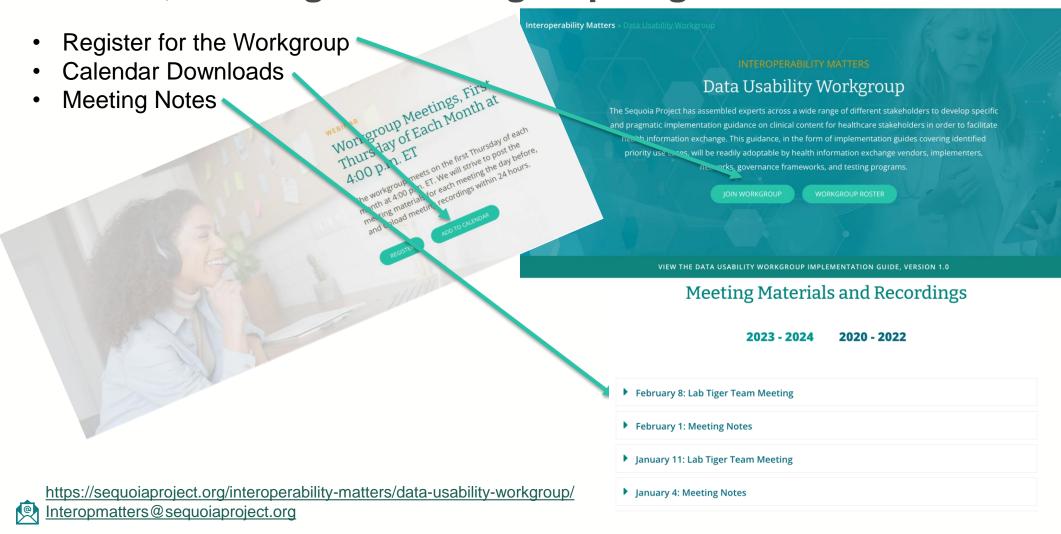








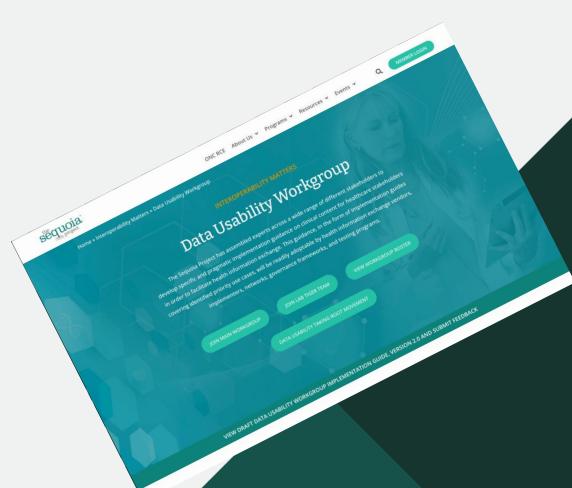
#### Website, Meeting and Workgroup Logistics



#### **Meeting Logistics and Timeline**

- 2023 2024 Planned Schedule Kickoff Call: February 2, 2023
  - Ongoing calls: 1<sup>ST</sup> Thursday each month
  - Next Phase of Activities Process & Timeframe
    - Phase 1 Administration and Prioritization
      - February 2023 June 2023
    - Phase 2: Developing Initial Draft Guidance
      - July 2023 July 2024 This meeting ends Phase 2
    - Phase 3: Public Comment Period/Recommended Next Steps
      - July 23, 2024 August 23, 2024
    - Phase 4: Finalizing Implementation Guide and Call to Action
      - August 26, 2024 December 11, 2024





Public Comment Open: Implementation Guide v2.0 Published July 23, 2024

#### **DUWG Implementation Guide Version 2.0**

The implementation guide covers the identified priority use cases that can be readily adopted within health information exchange vendors, implementers, networks, governance frameworks, and testing programs with 18 months. Some key changes in this version include:

- Added guidance for receiving systems in addition to sending systems
- Advancing the baseline requirements from USCDI V1 (Problem, Allergy, Medications, Immunizations ONLY) to all data classes within USCDI V3
- Expanded guidance to be technology agnostic with added requirements for HL7® FHIR®, HL7 v2.x and HL7 C-CDA across the topic categories
- Added an additional topic category for laboratory

#### **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
  - Seven Topic Categories
  - Guidance with SHALL, SHOULD, MAY
- References
- Appendix A High Priority Lab Results
- Appendix B A Priority list of documents for information sharing















#### **Use Cases**

- Provider-to-provider health information exchange
- Provider-to-public health agency information exchange
- Healthcare entity-to-consumer information exchange

## **Section / Chapter Structure**

- Problem statement
- Use Cases
- Existing Published Work
- Guidance
- Future Efforts



#### **Phase 3: Public Comment Website Navigation**

- The <u>Implementation Guide was published</u> July 23, 2024 for a 33 day public comment period ending August 23, 2024
- The Implementation Guide and Comment form can be found <u>here</u>
- At the top of this page you will find two buttons
  - Download the Implement Guide PDF using the first button
  - The second button takes you to the Sequoia form Tool used to Submit Feedback by August 23, 2024
- Scroll past the Executive Summary to find the <u>press release</u> issued July 23, 2024



#### **Phase 3: Public Comment Process**

Comments require a name and email reference

Page xx, line xx, comment, suggested edit

- When ready to comment you will need to do the following:
  - Page # and Line # for comments in the appropriate section on the form (line numbers are included in the published IG)
  - There is a comment box for each section 1-7
    - General comments not specific to one topic category should be included in the *Additional Feedback* section of the form with page & line #s

Don't forget to Click Submit!

1. Data Provenance & Traceability of Changes

Provide page number and line number

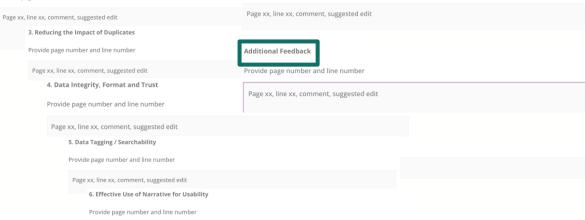
Page xx, line xx, comment, suggested edit

2. Effective Use of Codes

Provide page number and line number

Provide page number and line number

Provide page number and line number



Data Usability Workgroup Implementation Guide Version 2 Draft

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1.3.5.2 Center for Medicare and Medicaid Services Medicare Learning Network "Complying with Medicare Signature Requirements"

1.3.6. The DIRECT Standard - Implementation Guide for Direct Edge Protocols

#### 0 Guidance

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- 1.4.1. This second version of the guide focuses on requiring provenance attributes to be included in health data exchange transactions for ALL USCDI V3 data classes or elements exchanged via HL7 C-CDA, HL7 v2.x or HL7 FHIR.
- 1.4.1.1. The workgroup acknowledges the complexity of the provenance space, particularly recording and sharing the full chain of trust for healthcare data. Our aim is to keep this end in mind, while incrementally improving the content and manner that provenance data is shared. Note that this Guidance does not apply to Laboratory Data, which has its own Provenance requirements mandated by CLIA. For Guidance on Provenance for Laboratory Data, please see Section 7.4
- 20 1.4.1.2. A sending system SHALL include provenance information, when available, for all transactions as specified by USCDI v3. This information SHALL include author organization and time stamp.
  - 1.4.1.2.1. A sending system SHALL conform to the <u>U.S. Core</u> Implementation Guide Basic Provenance requirements.
  - 1.4.1.2.2. FHIR Transactions: A sending system SHALL record Provenance records on all Create, Update and Delete actions on any resource other than Provenance or AuditEvent.
  - 1.4.1.2.3. FHIR Transactions: A sending system SHALL record Provenance records on all Create, Update and Delete actions on any resource other than Provenance or AuditEvent.
  - 1.4.1.2.4. FHIR Transactions: A sending system SHALL record Audit Event records on all Create, Update and Delete actions as well as all GET operations (read, search, etc.).
  - 14.1.2.5. C-CDA 2.1 Documents:Provenance Author Participation: A sending system SHALL use this template at any place C-CDA allows an author. For example, at the CDA Header, CDA Section, CDA Entry, or within a CDA entry (e.g. Organizer and contained Observation(s)). This template is used to identify primary authorship for an entry.

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#### **Phase 3: Public Comment Links**

- Multiple forms may be submitted from one person and/or organization until August 23, 2024
- Sequoia will be reaching out to socialize with industry partners through the comment period
- Share with your colleagues comments are welcome from all and encouraged
  - Press Release Issued July 23, 2024
  - Implementation Guide
  - Comment Form
  - Workgroup Roster
    - Join the Workgroup



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#### **Phase 3: Public Comment Process Example**

Data Usability Workgroup Implementation Guide Version 2 Draft 1.3.5.2 Center for Medicare and Medicaid Services Medicare Learning Network "Complying with Medicare Signature Requirements" 1.3.6. The DIRECT Standard - Implementation Guide for Direct Edge Protocols 10 Guidance **1.4.1.** This second version of the guide focuses on requiring provenance attributes to be included in health data exchange transactions for ALL USCDI V3 data classes or elements exchanged via HL7 C-CDA, HL7 v2.x or HL7 FHIR. 1.4.1.1. The workgroup acknowledges the complexity of the provenance space, particularly recording and sharing the full chain of trust for healthcare data. Our aim is to keep this end in mind, while incrementally improving the content and manner that provenance data is shared. Note that this Guidance does not apply to Laboratory Data, which has its own Provenance requirements mandated by CLIA. For Guidance on Provenance for Laboratory Data, please see Section 7.4 1.4.1.2. A sending system SHALL include provenance information, when available, for all transactions as specified by USCDI v3. This information SHALL include author organization and time stamp. 1.4.1.2.1. A sending system SHALL conform to the U.S. Core Implementation Guide - Basic Provenance requirements. 1.4.1.2.2. FHIR Transactions: A sending system SHALL record Provenance records on all Create, Update and Delete actions on any resource other than Provenance or AuditEvent. 1.4.1.2.3. FHIR Transactions: A sending system SHALL record Provenance records on all Create, Update and Delete actions on any resource other than Provenance or AuditEvent. 1.4.1.2.4. FHIR Transactions: A sending system SHALL record Audit Event records on all Create, Update and Delete actions as well as all GET operations (read, search, etc.). 14.1.2.5. C-CDA 2.1 Documents:Provenance - Author Participation: A

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is used to identify primary authorship for an entry.



The Data Usability Workgroup is seeking public feedback on the Implementation Guide, Version 1 through October 14, 2022. Please include the page number and line number for all comments.

<b>DUWG Implementation Guide Feedback</b>				
Name (Required)				
Didi	Davis			
First	Last			
Email (Required)				
ddavis@sequoiaproject.org				
Organization	Organization URL			
The Sequoia Project	www.sequoiaproject.org			
1. Data Provenance & Traceability of Changes				
Page 11, line 12 - Add hyperlink for quick reference to HL7 Implementation Guide Page 11, line 19 - Add internal document link to Appendix A  Enter commen	ts for specific sections  Once all comments a bottom of form and o	•		
Provide page number and line number  2. Effective Use of Codes  Page xx, line xx - Comment, suggested edits	DUWG Implementation Guide Version 2 Feedback Form  This form is open through Friday, August 23, 2024. Please make sure you provide the page number and line number for the feedback you're providing in each section.  Thanks for contacting us! We will get in touch with you shortly.			

### Phase 4: Finalizing Implementation Guide for Publication

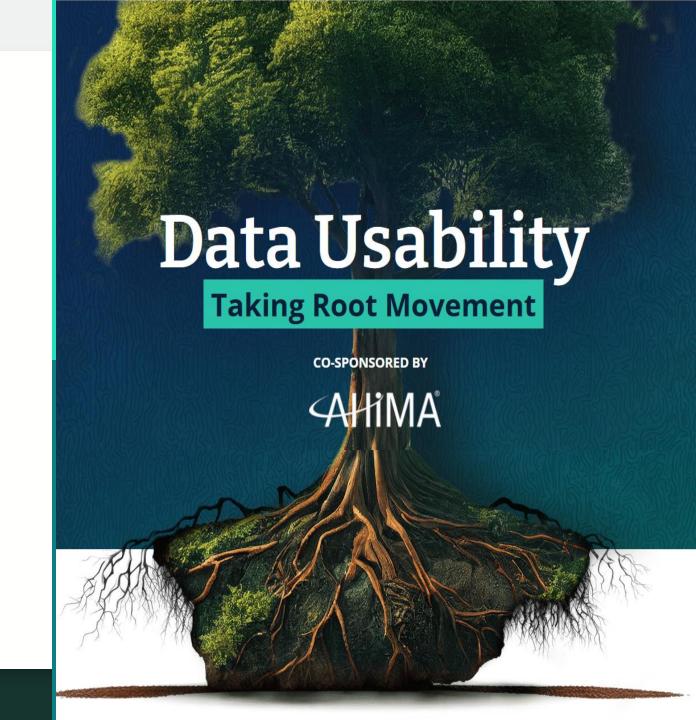
- Comments will be disposed as they are received by the Leadership team and socialized on the monthly workgroup meetings (first Thursday of each month) through December 5, 2024
- The Final Version 2 of the Implementation Guide will be published December 11, 2024
- The Implementation Guide will be highlighted at the in-person Sequoia Annual Member Meeting in Downtown, Nashville, TN
  - Embassy Suites by Hilton
  - Register and Subscribe for Updates
  - https://sequoiaproject.org/2024-annual-meeting/



# Community of Practice Update

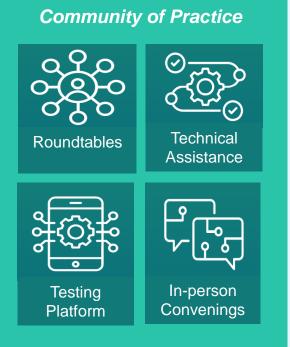
July 24, 2024





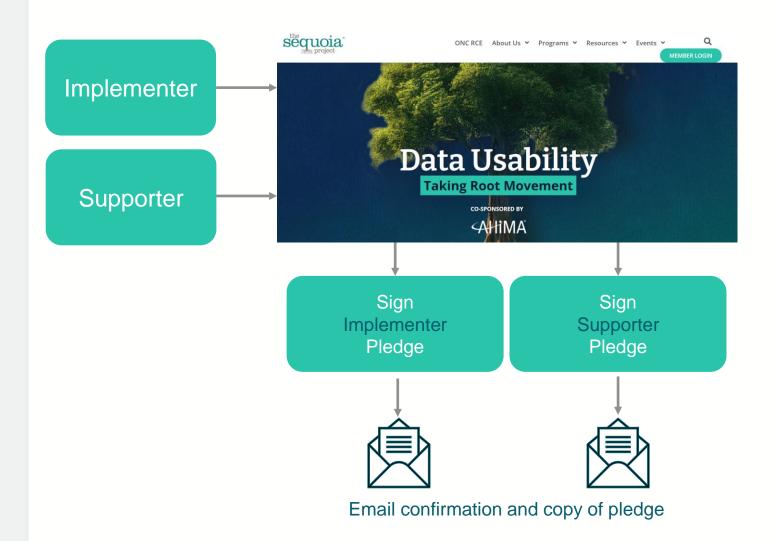
# What is the difference between the Data Usability Taking Root Movement and the Data Usability Workgroup?







#### Pledge Process – Open NOW!



Those who have pledged will have passwordprotected access to **Data Usability Taking Root** Resources on the Sequoia website

#### Organizations that have pledged to participate!



Clinical Architecture Epic Health Gorilla MedAllies Opala Oracle



ADVault, Inc. AHIMA CommonWell DirectTrust Hawai'i Pacific Health LaPortaCare Netsmart Technologies NextGen Healthcare Optum Surescripts Texas Health Services Authority

## Grace Period Extended – August 29, 2024!

Zus Health

ROUNDTABLE
PARTICIPANTS
WHO HAVE NOT
YET PLEDGED

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American Medical Association
Austin Regional Clinic
AthenaHealth
Azuba
Banner
Brevard Health Alliance
Bwell
Carequality
Celeste
Cincinnati Children's Hospital Medical
Center
Civitas
Claim Clarity
CommonSpirit
Complete Health
Delaware Health Information Network
eClinical Works
eHealth Exchange
Elevance Health
FINN Partners
First Genesis, Inc.
Foothold Technology
HCA Healthcare
Health Services of North Texas (HSNT)
HealthElence
HIMSS EHRA Association

IHIE
Intermountain Healthcare
Johnson and Johnson
Kaiser Permanente
Kno2
Meditech
MTC Group LLC
National Institutes of Health, National Institute of
Diabetes & Digestive & Kidney Diseases
New York eHealth Collaborative
OCHIN
Particle Health Inc.
Patientory
Premiere Pointe Podiatry
Santa Cruz Health Information Exchange
Smile Digital Health
Social Security Administration
Stanford Health
Sutter Health
Texas A&M
Texas Department of State Health Services
Texas State University
The Picture of Health
The University of Texas Health Science Center
University of Washington
Veterans Health Information Exchange
Wolters Kluwer Health, Health Language

Access the pledge <u>here</u>



#### Roundtable To Do List

- 1. Sign the pledge
- 2. Complete the Readiness Checklist
- 3. Decide which V1.0 topic areas you will focus on
- 4. Implement change
- 5. Complete and submit Performance Scorecard

## Reminder: Performance Scorecard Reporting

We wanted to remind you all to please report Scorecard metrics to <a href="mailto:takingroot@sequoiaproject.org">takingroot@sequoiaproject.org</a> for any live deployments through June 30, 2024 for any of the topic categories as applicable.

If you could please email those to us by July 31, 2024.



Thank you for your interest in The Sequoia Project's new **Data Usability Taking Root** Initiative.



If you would like to get in touch you can reach us at:



### takingroot@sequoiaproject.org

To join the Community of Practice Roundtables, please sign up as a Supporter, Implementer or Sponsor here:

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



Highlights for Workgroup Input and Public Comment

## **Summary of Changes Implementation Guide V1.0 to Draft 2.0**

- All sections had additions or edits to each of the original Topic Categories for
  - Problem Statement
  - Use Cases
  - Existing Work
  - Guidance
  - Future Efforts
- Added guidance for receiving systems in addition to sending systems
- Advancing the baseline requirements from USCDI V1 (Problem, Allergy, Medications, Immunizations ONLY) to all data classes within USCDI V3
- Expanded guidance to be technology agnostic with added requirements for HL7® FHIR®, HL7 v2.x and HL7 C-CDA across the topic categories
- Added an additional topic category for laboratory

#### **Table of Contents**

- Looking for your review/comment/input:
  - Executive Summary
  - Statement of Intent
  - All Topic Categories
  - 7. Laboratory Interoperability
  - Appendix A

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#### **Appendix A – High Priority Lab Results**

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#### Appendix A - High Priority Lab Results

The Data Usability Workgroup membership identified Laboratory Interoperability as an area that needed significant improvement during the first cycle (2020 - 2022) that concluded with the publication of the Data Usability Implementation Guide Version 1.0. In Version 1.0, this Appendix A was included to allow HIT Developers, EHR platforms and lab systems to focus on mapping and maintaining codes for this list of preliminary high clinical impact list (for reference only):

#### **Blood Chemistry: Chemistry Results**

- Albumin
  - Alkaline Phosphatase
  - ALT
  - AST
  - Bilirubin, Total
  - Calcium
  - Creatinine

  - Glucos
- Hemoglobin A1
  - Lead Screening
  - Potassium
  - Protein, Total
  - T4
  - Urea Nitrogen (BUN)
  - BNP
  - Troponin
  - Vitamin B1
  - Vitamin B12
     Vitamin D 25.OH

#### Urine Chemistry: • Microalbumin Urine

Microalbumin/Creat Ratio

#### Coagulation

INR

The Data Usability Workgroup would like comments and input on whether providing 15 additional detail for the high priority labs above would be useful to the industry? The Workgroup began drafting a spreadsheet for these Lab that can be found here.

Using Albumin as an example (see rows 3 - 8) in the spreadsheet linked above, many (incorrectly) use the high level LOINC Result code to group Albumins by other methods. There are more suitable LOINC codes for Methods as shown in Column I and J. Clinical values can differ significantly with different methods.

BCG	Albumin [Mass/volume] in Serum or Plasma Bromocresol green (BCG) dye binding method	by
ВСР	Albumin [Mass/volume] in Serum or Plasma Bromocresol purple (BCP) dye binding method	by
Nephelometry	Albumin [Mass/volume] in Serum or Plasma Nephelometry	by
Electrophoresis	Albumin [Mass/volume] in Serum or Plasma Electrophoresis	by
ВСР	Albumin [Mass/volume] in Blood by Bromocresol pur (BCP) dye binding method	rple

The Data Usability Workgroup would like industry comments on whether there is value in including this level of detail in the final publication planned for December 2024?

As referenced by Recommendation 13 in the <u>Synensys report</u>: "Develop formal processes for inclusion of laboratorians in the multidisciplinary teams responsible for decisions about laboratory data needs, representations, and interfaces at care facilities.

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5 For example, medical practitioners are responsible for ordering tests to monitor and diagnose patients, but at the same time have a huge range of responsibilities and could benefit from better communication with laboratories. Laboratorians have up-to-date information on changes to the diagnostic testing environment, including new test options or how test results should be interpreted. However, due to the way many interfaces are set up, laboratorians may not receive sufficient data to fully support practitioners.

What other guidance may be helpful in addressing the flawed communication and coordination within the lab ecosystem to reduce the potential for patient harm?

The Data Usability Workgroup would like comments and input for the yellow highlighted areas of Appendix A and whether providing additional detail for the high priority labs above would be useful to the industry?

Data Usability Workgroup Implementation Guide Version 2 Draft

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Table 1: Laboratory Data Element Code System and Exchange Standards

The table below attempts to highlight the USCDI Data Elements across various specifications, fields, value sets and coding requirements for

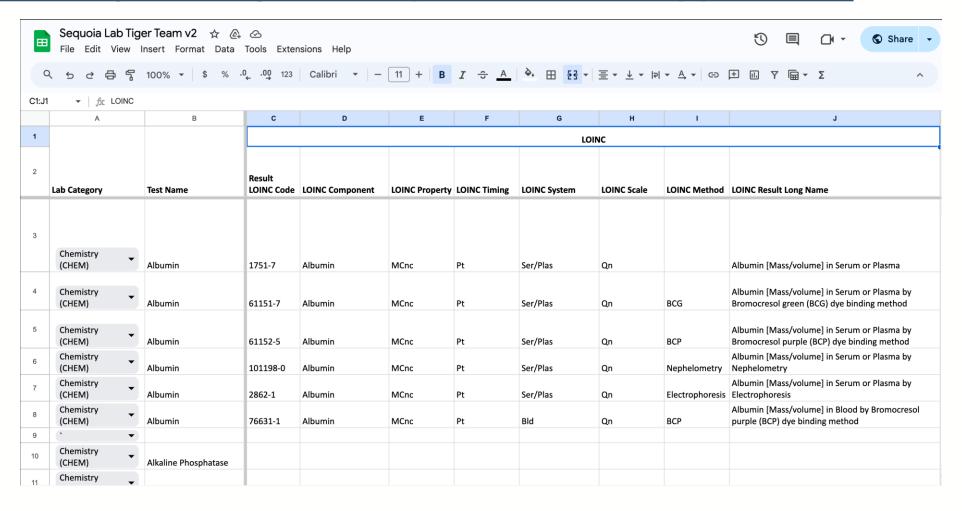
HL7 V2.5.1, HL7 FHIR, HL7 C-CDA and CLIA. This table is non-normative and provided as reference only.

#### The workgroup would welcome feedback on whether this table helpful and how it could be improved

Data Element	Additional Info	Code System	V2.5.1 (LRI, ELR, Genomics)	FHIR Resource	Value Set	CCDA	CLIA
Laboratory Order	May be called Test Procedure or Test Request. Include local test code and information.	LOINC (Order or Both code)	OBR-4	Service Request (preferred) Procedure Observation	HL7 FHIR Value Set (Observation)	ProceduresSection	https://www.ecfr.gou/current/ title-d2/section-493-1241 \$493.1291(c)(4) \$493.1291(c)(3) \$493.1241(c)(3) \$493.1241(c)(6) \$493.1241(c)(7)
Laboratory Result	Also known as test result or observation	LOINC (Both or Observation code)	OBX-3	Observation (preferred) Observation component	HL7 FHIR Value Set (Observation)	Result Organizer  Organizer code  "Laboratory results "SHOULD" be from LOINC (CodeSystem: 2.16.840.1.113883.6.1)	https://www.ecfr.gov/curren// title-42/section-493.1291 \$493.1291(c)(4) \$493.1278 (4)

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#### <u>Laboratory Priority Labs Spreadsheet – Appendix A</u>



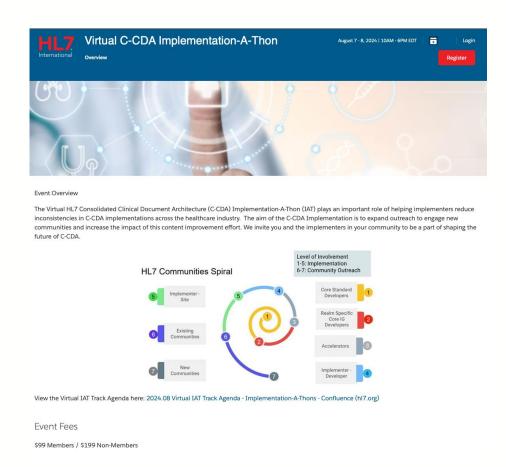


## Reminders



## HL7 Implementation-a-thon (IAT) August 7 – 8, 2024

- Registration is still open <u>here</u>
- NEW There is now an <u>HL7 Zulip</u>
   stream where questions about the ONC
   C-CDA tools can be asked and answered.
   Please have a look at the stream and weigh in with your questions at any time.
- Agenda





# Sequoia Annual Meeting 2024 Embassy Suites Nashville | December 11, 2024

- Save the Date Calendar Invite
- Submit a Topic for Discussion
- Book your hotel
- Consider sponsorship opportunities
   See prospectus
- Easy walk to Broadway







https://sequoiaproject.org/about-us/become-a-member/

#### **Data Usability Work Group**

#### For more information:

www.sequoiaproject.org/interoperability-matters/data-usability-workgroup/





(571) 327-3640

Interopmatters@sequoiaproject.org

Convene

Collaborate

Interoperate







Thank You for your support of Interoperability Matters!