

HL7 Standards Lifecycle

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**This session will be recorded*



Agenda

- Welcome from Civitas Networks for Health
- Purpose and Objective of Today's Training
- Part 1 – Standards Lifecycle Overview
- Part 2 – HL7 Standards and Ballot Process
- Questions

Housekeeping Reminders

- This is a Zoom webinar.
- Please make sure you are muted.
- Please feel free to put questions or comments in the Q&A. These will be answered at the end – time permitting.
- This session is being recorded.

For questions following the meeting, reach out to mvalu@civitasforhealth.org





ABOUT CIVITAS

[Civitas Networks for Health](#) is a national collaborative comprised of over 170 member organizations working to use health information exchange, health data, and multi-stakeholder, cross-sector approaches to improve health.

Civitas educates, promotes, and influences both the private sector and policymakers on matters of interoperability, quality, coordination, health equity, and cost-effectiveness of health care. The network supports local health innovators by amplifying their voices at the national level and increasing the exchange of valuable resources, tools, and ideas.



[Civitas Networks for Health](#)



[@civitas4health](#)



Demographic Data Standards Development

Project Team

- This effort is a partnership between Civitas Networks for Health (Civitas), AHIP, and Health Level 7 (HL7) International.

Objective/Scope

- AHIP has funded Civitas to launch a project in partnership with HL7 International to support refinement and development of improved demographic data questions and response choices for race, ethnicity, language, sexual orientation, gender, disability status, military experience, and spirituality.

Next Session

- Summary of Draft Revisions + Next Steps | April 11 at 1:30pm ET



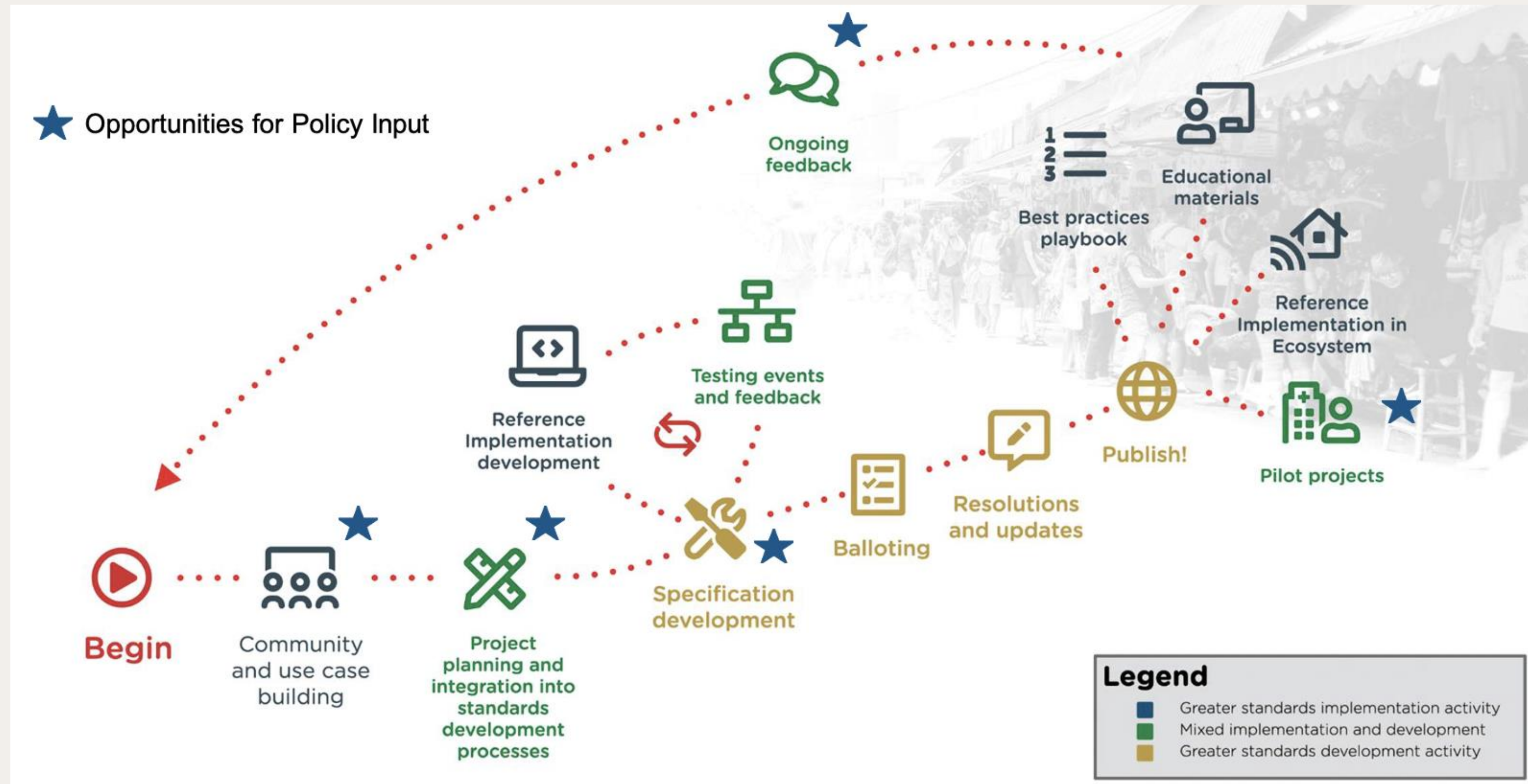
Purpose & Objective

- Provide educational sessions for all interested stakeholders on core topics related to standards development and health information exchange.
- Introduce HL7's processes that guide and promote development of consensus-based health information technology standards.
- This 101-level presentation requires no prior knowledge or experience and is open to anyone who is interested in learning more about HL7's standards development process.



Part 1 - Standards Lifecycle Overview

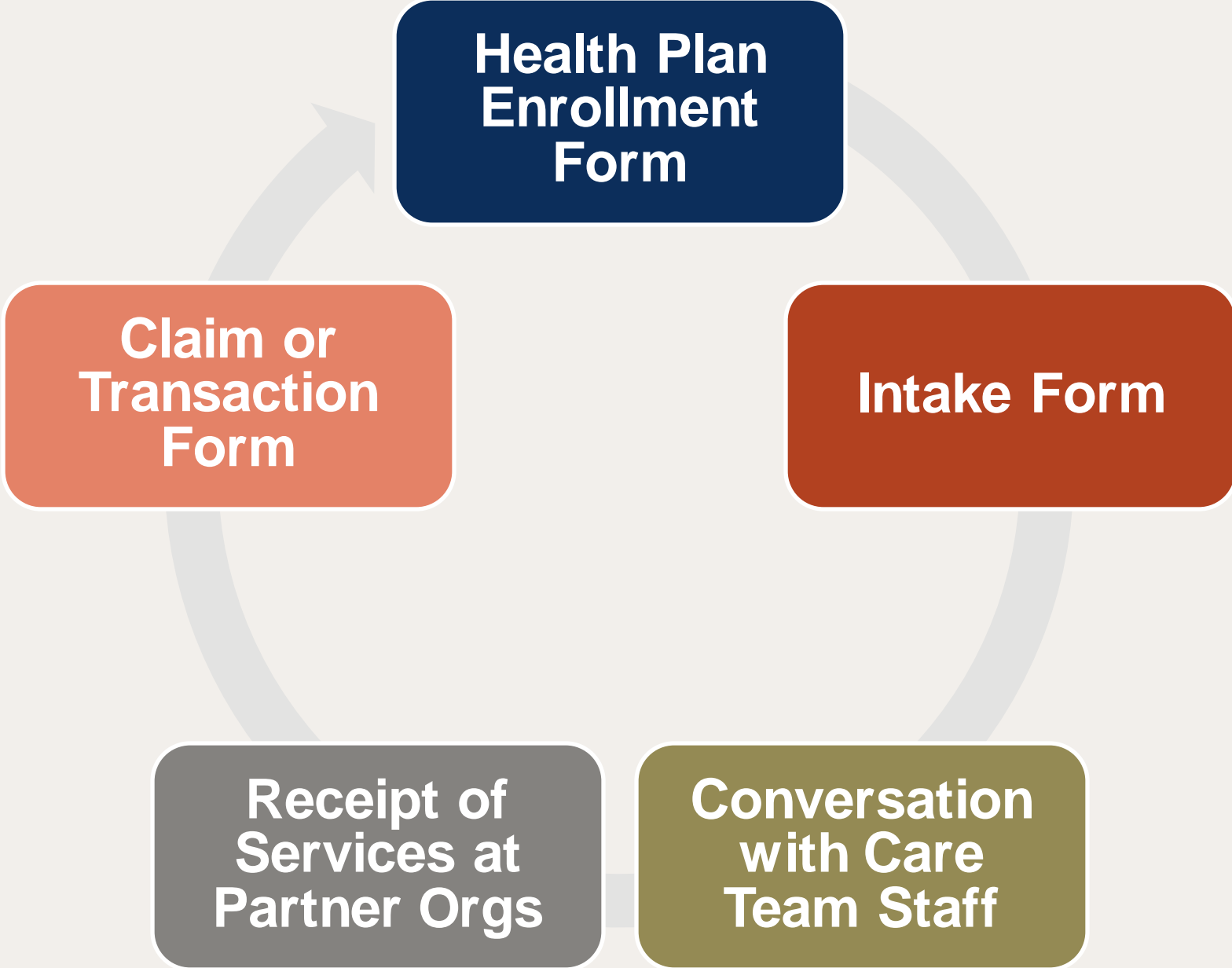
Coordination of Standards Development and Implementation



Source: Diego Kaminker 3/6/2023 FHIR 101

Community and Use Case Building

Opportunities for Demographic Data Collection across Healthcare Ecosystem



Source: AHIP/Civitas/HL7 National Convening reference

HL7 Work Groups Involvement in Standards Development

A

- Affiliate Engagement Committee
- Arden Syntax

B

- Biomedical Research and Regulation
- Board Motions

C

- CDA Management Group
- Clinical Decision Support
- Clinical Genomics
- Clinical Information Modeling Initiative
- Clinical Interoperability Council
- Clinical Quality Information
- Community-Based Care and Privacy (CBCP)
- Conformance
- Cross-Group Projects

D

- Devices

E

- Education
- Electronic Health Records
- Emergency Care

F

- FHIR Community Process Coordination Committee
- FHIR Infrastructure
- FHIR Management Group
- Financial Management

G

- Governance and Operations

H

- Helios
- HL7 Europe
- Human and Social Services

I

- Imaging Integration
- Implementable Technology Specifications
- Infrastructure and Messaging
- International Council

L

- Leadership Development and Nomination Committee
- Learning Health Systems

M

- Mobile Health

O

- Orders and Observations

P

- Patient Administration
- Patient Care
- Patient Empowerment
- Payer/Provider Information Exchange Work Group
- Pharmacy
- Policy Advisory Committee
- Public Health
- Publishing - Electronic Services and Tooling

R

- Recognition and Awards

S

- Security
- Services Oriented Architecture
- Structured Documents

T

- Technical Steering Committee
- Terminology Authority
- Terminology Infrastructure Work Group
- Terminology Services Management Group (TSMG)

U

- US Realm Steering Committee

V

- V2 Management Group

Source: <https://www.hl7.org/Special/committees/>

Part 2 - HL7 Standards and Ballot Process

Background: What is HL7?

- Consensus based framework (and related standards) for the exchange, integration, sharing, and retrieval of electronic health information.
- Support clinical practice and the management, delivery, and evaluation of health services.
- Standards define
 - how information is packaged and communicated between a sending system and receiving system
 - the language, structure and data types required for seamless integration between systems (e.g. FHIR, V3, C-CDA)
- HL7 encompasses the complete life cycle of a standards specification including authoring, registration, publishing, adoption, market recognition, utilization, and adherence.

Background: Say What? Acronyms

Acronym	In other words	Definition
ANSI	American National Standards Institute	Main organization supporting the development of technology standards in the US. Goal is to support development of standards in collaboration with industry and government stakeholders. (https://www.techtarget.com/searchdatacenter/definition/ANSI#)
DSTU	Draft Standard for Trial Use	Historical term that has been replaced with Standard for Trial Use
FHIR [®]	Fast Healthcare Interoperability Resources	Standard that defines the exchange of healthcare information between computer using the concept of Resources to identify the data for exchange
HL7 [®]	Health Level Seven	Standards organization that provides a framework for the exchange, integration, sharing, and retrieval of electronic health information
IG	Implementation Guide	The mechanism/documentation that describes how FHIR is used to meet a specific Use Case or cases.
SDO	Standards Development Organization	HL7
STU	Standard for Trial Use	Indicator of the adoption and use as well as maturity level of an Implementation Guide (STU1 – Normative)

All About Standards: Why Use a Standard?

- Facilitate the exchange of data in an interoperable way
 - Know how to exchange the data (format)
 - And what data is being exchanged (content)
- Supports Semantic (exchange) and Semantic (meaning) of data
- HL7 is an ANSI and ISO 9001 recognized standard
 - Complies with the procedures outlined by ANSI and ISO in the development of standards

All About Standards: Why a Standards Development Organization (SDO)?

- **Interoperability:** Format of exchange and content of datasets/resources.
 - Definitions and structures of the data clearly articulated for use across a wide variety of health and system-based use cases.
- **Legitimacy:** Provide a level of validity and formality.
- **Curation of Standards:** Identify, and publish global standards for the exchange, integration, sharing and retrieval of electronic information.
- **Regulatory Inclusion:** Published standards can be referenced and enforced by regulatory specifications.
- **Business Strategy:** Standards are business tools which technology vendors can adopt from in response to market trends.
 - SDOs provide solutions that can be incorporated into a product offering.

The HL7 Ballot Process: What You Need to Know?

- Process is rigorous and outlined by HL7.
 - Those who ballot are required to adhere to the HL7 process.
- HL7 is ANSI and ISO accredited and as such must maintain strict processes.
- Projects typically introduced to HL7 leadership and potential sponsoring workgroups at HL7 Face-to-Face Workgroup Meetings.
 - HL7 has 3 ballot cycles per year which follow the Face-to-Face Workgroup Meetings (January, May, September)

The HL7 Ballot Process: Timeline from STU to Normative

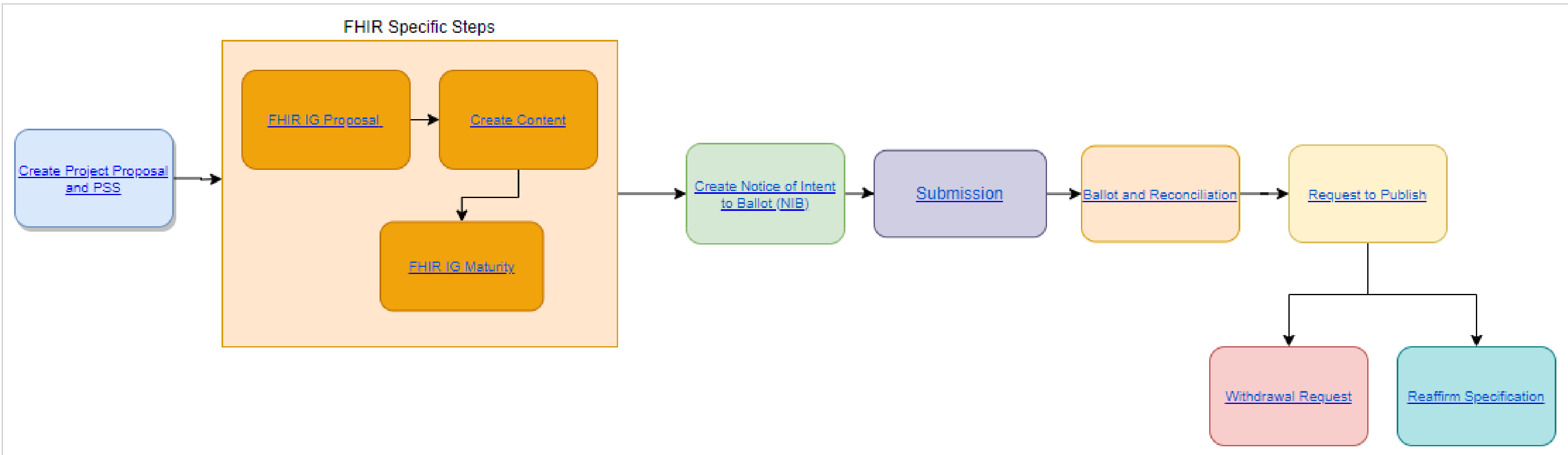
- A typical project takes 12-18 months to complete the entire ballot cycle (STU 1).

- Project identification
- Use Case
- Ballot Process
- Publication



- Moving from Standard for Trial Use (STU) to Normative.
 - 2-4 ballot cycles
 - Demonstrated testing, industry use, and community feedback
- Normative ballots are the final ballots before the standard becomes a sanctioned/formally recognized standard.
- To date, standards noted in regulation have not been required to reach “Normative” status to be referenced in regulation(s).

The HL7 Ballot Process: Balloting at-a-Glance

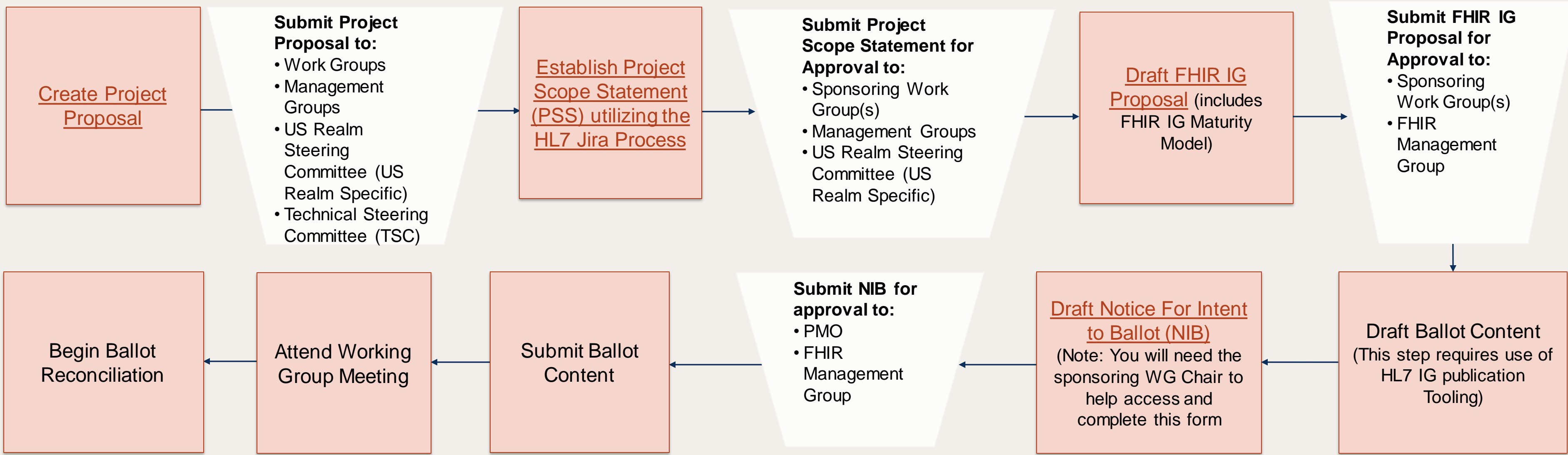


Source: <https://confluence.hl7.org/pages/viewpage.action?pageId=111117149>

The HL7 Ballot Process: Ballot Flow

Ballot Types

- Comment Only
- Informative
- Standards for Trial Use
- Normative
 - Submitted to ANSI



Repeat Process Until “Normative Status” is achieved (24 - 48 months)

Steps to Success

Step	Link
Project Proposal	https://confluence.hl7.org/display/TPTF/Project+Proposals+Home
Project Scope Statement (PSS)	https://confluence.hl7.org/display/HL7/How+to+Create+and+Review+a+Project+Proposal
FHIR IG Proposal	https://confluence.hl7.org/pages/viewpage.action?pageId=76162146
Notice for Intent to Ballot (NIB)	https://www.hl7.org/special/committees/tsc/specialuploads/NIB_Instructions.pdf

Milestones and Due Dates: HL7 Calendar

HL7 Calendars - HL7 - Confluence

HL7 Calendars

Created by Joshua Prociou, last modified by Lynn Laakso on Oct 30, 2023

The HL7 calendars page provides a one-page view of the high level HL7 deadlines for the current month; please use the navigation to move forward and backward by month. The calendar includes the Working Group Meeting dates, the Ballot dates, ballot content submission dates, the New Project Scope submission deadlines, Harmonization dates, Work Group co-chair responsibility dates and the dates for Working Group Meeting registration.

Ballot Content calendar refers to the important deadlines Work Groups need to meet if they are balloting any standards or documents.

Ballot Voting calendar reports important dates in the current ballot cycle. This calendar lets voters know when ballot sign up begins and ends, when voting opens and closes for the cycle, and when after the voting closes the Working Group Meeting opens. Please note that the actual ballot open and close dates for specific ballots may vary by a few days. Voters should always refer to the Ballot Announcement document posted on the [Ballot Desktop](#) where exceptions are noted.

Voters and balloters interested in specific ballots may need to refer to the global calendar or the text descriptions of some entries in the calendar for the full meaning of a deadline entry. For example, FHIR ballot developer needs to know that the Reconciliation deadline occurs three weeks before ballot opening, but not worry about the V3-specific initial content deadline four weeks before ballot opening.

[All HL7 Calendars](#) [2024 May Ballot Cycle](#) [2024 September Ballot Cycle](#) [Health Informatics Standards Event Calendar](#) [ANSI Standards approaching expiration](#) [STUs Expiring in Next 6 Months](#) [Active Standards for Trial Use](#) ...

HL7 Calendars and Deadlines

Today ◀ ▶ **March 2024** ▼

[Print](#) [Week](#) [Month](#) [Agenda](#) ▼

Sun	Mon	Tue	Wed	Thu	Fri	Sat
25 HL7 Terminology (THO) Content Freeze	26	27	28	29	30 2024SEP WG-approved PSS in Jira to consensu	1 2
3 2024MAY NIB Deadline 12am 2024MAY Ballot NIB Deadline 12am 2024MAY FHIR IG Proposal Approval deadl 12am 2024MAY FHIR IG Publisher/Validator issue	4 2pm TSC appeal deadline for missed 2024MAY N	5	6	7	8	9
10 HL7 Terminology (THO) Approximate Publicatic	11 2024MAY Consensus Group (ballot pool) Signu	12	13	14	15	16
17	18	19 12am 2024MAY FHIR Connectathon Proposals Du	20	21	22	23
24 12am 2024MAY Reconciliation Deadline	25	26 WG approves FHIR IG 12am FHIR Ballot Content freeze 2pm 2024MAY TSC appeal deadline for missed R	27	28	29	30
31	Apr 1	2	3	4	5	6

Implementation Guide Registry

Once the IG completes the ballot process

- All code, IG information, contacts are registered and posted on the [FHIR Implementation Guide Registry](#)

The screenshot shows the HL7 FHIR Foundation website's Implementation Guide Registry. The header includes the HL7 FHIR logo and navigation links for FHIR Foundation, Community, and Chat. The main content area is titled "Implementation Guide Registry" and contains an introductory paragraph about the FHIR Specification and a list of implementation guides. Below the text is a search and filter interface with dropdown menus for Authority, Country, Release, Product, Category, and Contents, and a checkbox for "Hide Descriptions". A table lists 249 implementation guides, with the following entries visible:

Specification	Category	Authority
US Core : Base US national implementation guide STU7 Ballot (7.0.0-ballot R4) CI Build Test Server Source Code	National Base	HL7/us
AU Base : AU Base implementation guide provides support for the use of FHIR® in an Australian context. Trial Use (4.1.0 R4) CI Build	National Base	HL7/au
AU Core : AU Core implementation guide provides support for the use of FHIR® in an Australian context, and defines the minimum set of constraints on the FHIR resources to create the AU Core profiles. Preview (0.2.1-preview R4) CI Build	National Base	HL7/au
NZ Base : Base New Zealand national implementation guide Release 2 (2.0.0 R4) CI Build	National Base	HL7/nz
CCDA on FHIR : US Realm Implementation Guide (IG) addressing the key aspects of Consolidated CDA (C-CDA) required for Meaningful Use (MU). This IG focuses on the clinical document header and narrative constraints necessary for human readability, and references the Data Access Framework (DAF) implementation guide for coded data representation STU 1 (1.2.0 R4) CI Build	Clinical Documents	HL7/us

Questions?

References

Resource	Link
Standards Process	https://confluence.hl7.org/display/HL7/Understanding+the+Standards+Process
Project Proposal	https://confluence.hl7.org/display/TPTF/Project+Proposals+Home
Project Scope Statement (PSS)	https://confluence.hl7.org/display/HL7/How+to+Create+and+Review+a+Project+Proposal
FHIR IG Proposal	https://confluence.hl7.org/pages/viewpage.action?pageId=76162146
Notice for Intent to Ballot (NIB)	https://www.hl7.org/special/committees/tsc/specialuploads/NIB_Instructions.pdf
HL7 Calendar	HL7 Calendars - HL7 – Confluence
FHIR IG Registration	https://www.fhir.org/guides/registry/