Health Level Seven International (HL7)
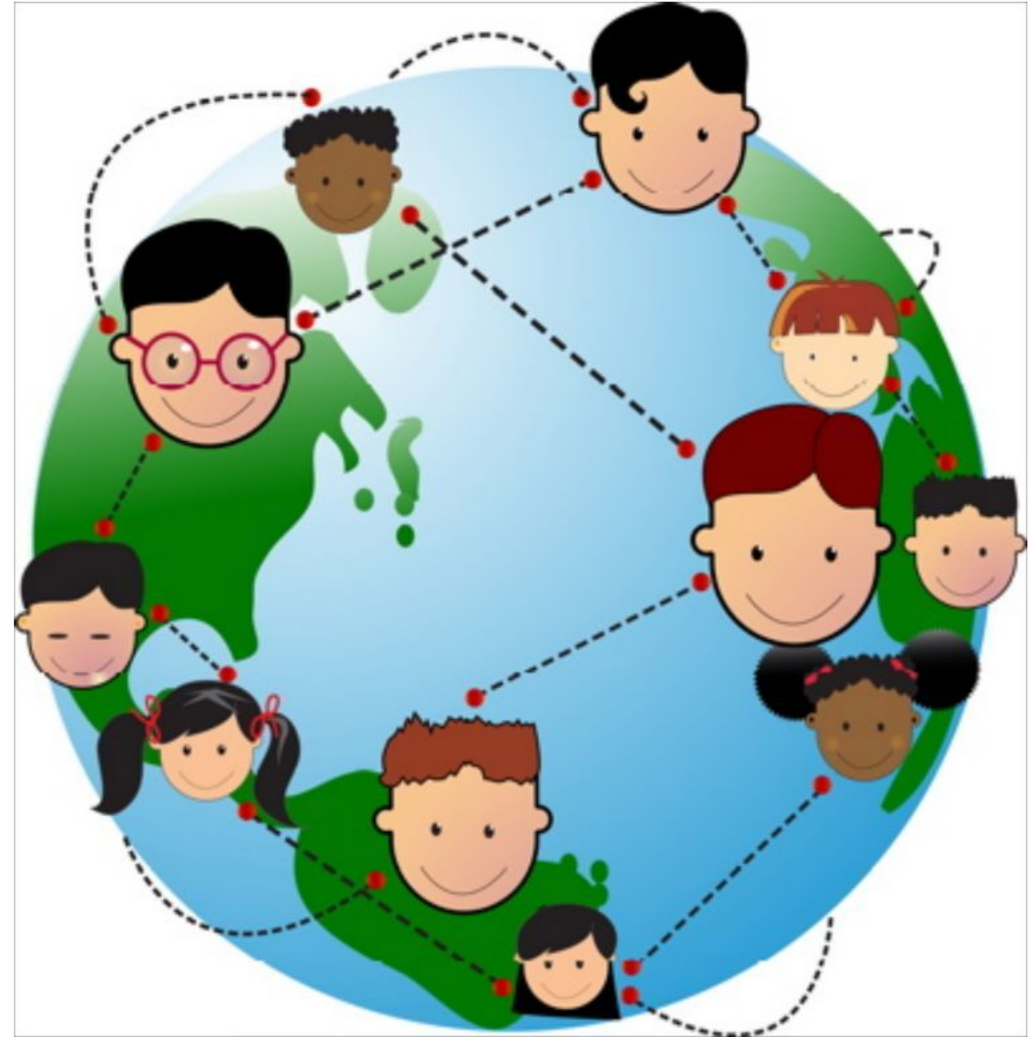
Organization, Process and Governance

Adapted from:

Understanding the HL7 International Organization

Lorenzi, Saele – January 2022

Vision

A world in which everyone can securely access and use the right health data when and where they need it
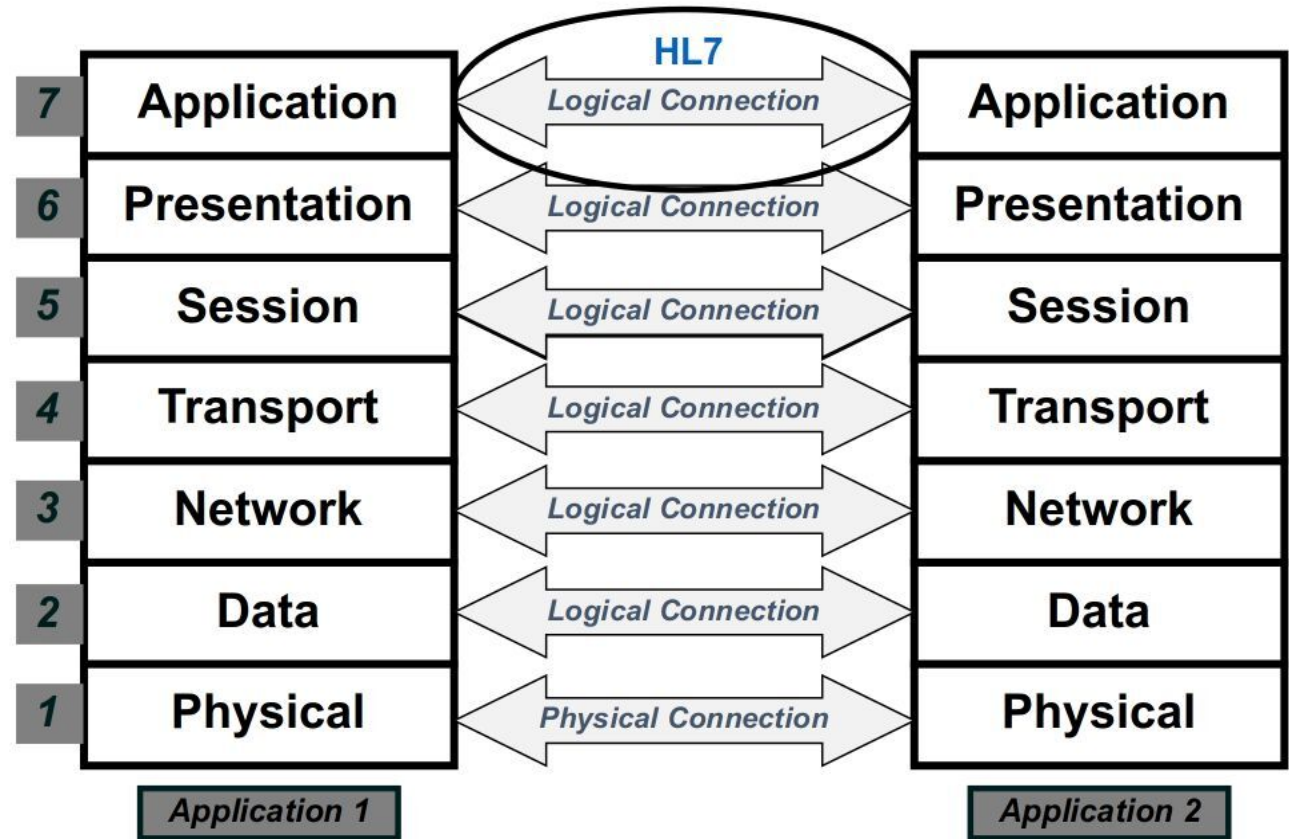
HL7 Mission

HL7 empowers global health data interoperability by developing standards and enabling their adoption and implementation

What is the origin of the name HL7?

"Level Seven" refers to the highest level of the International Standards Organization (ISO) communications model for Open Systems Interconnection (OSI) (i.e., the Application Layer)

HL7 International

- Standards Development Organization (SDO)
- Open and Consensus-based
- Volunteer driven

https://confluence.hl7.org/display/HL7/Understanding+the+Standards+Process

HL7 is ANSI accredited

- One of several American National Standards Institute (ANSI) accredited SDOs in healthcare

- Follows ANSI requirements for consensus-based standards development

HL7 and ISO

- HL7 International's domain is clinical and administrative data

- Many of our Standards are also ISO TC-215 Standards

- ISO TC-215 both adopts specific HL7 International Standards and also works with HL7 International to jointly develop standards

Who participates in HL7?

- Vendor / Manufacturer

- Consultant

- Healthcare Provider / User

- Associations / Government Agencies / Universities

- Payer / Third Party Administrator

- Pharmaceutical

What the Market wants

- Faster implementations
- Conformance & conformability testing
- Computable semantic interoperability
- Better quality, methodology & tools
- Confidentiality / security
- Harmonization with other standards
- Support of the latest communication technologies
- Simplicity

In short

- Interoperability beyond a single point to point interface requires:
  - A profile that includes all of the related SDOs' elements (e.g., terminologies), and other directed references within the primary SDO product (e.g., state names & abbreviations)
  - A resolution of all pre-coordinated decisions to remove all optionality
  - Full specification from Layers 1-7 (not just Level 7)
  - The publication of an implementation guide that is used by all communicating parties
  - A published governance and update process that supports needed fixes and related updates

HL7 primary standards

Name	Description	State
C-CDA (HL7 CDA® R2 Implementation Guide: Consolidated CDA Templates for Clinical Notes - US Realm)	The Consolidated CDA (C-CDA) implementation guide contains a library of CDA templates	Active
CDA® Release 2	The HL7 Version 3 Clinical Document Architecture (CDA®) is a document markup standard that specifies structure and semantics of "clinical documents"	Stable
FHIR® R4 (HL7 Fast Healthcare Interoperability Resources, Release 4)	FHIR is an interoperability standard intended to facilitate the exchange of healthcare information	Active
HL7 Context Management Specification (CCOW), Version 1.6	Being replaced by HL7 FHIRCast Aimed at facilitating the integration of applications at the point of use	Retired
HL7 Version 2 Product Suite	HL7's Version 2.x (V2) messaging standard is the workhorse of electronic data exchange in the clinical domain and arguably the most widely implemented standard for healthcare in the world	Stable
HL7 Version 3 Product Suite	A suite of specifications based on HL7's Reference Information Model (RIM)—provides a single source that allows implementers of V3 specifications to work with the full set of messages, data types, and terminologies needed to build a complete implementation	Retired

https://www.hl7.org/implement/standards/product_section.cfm?section=1

Timeline of HL7
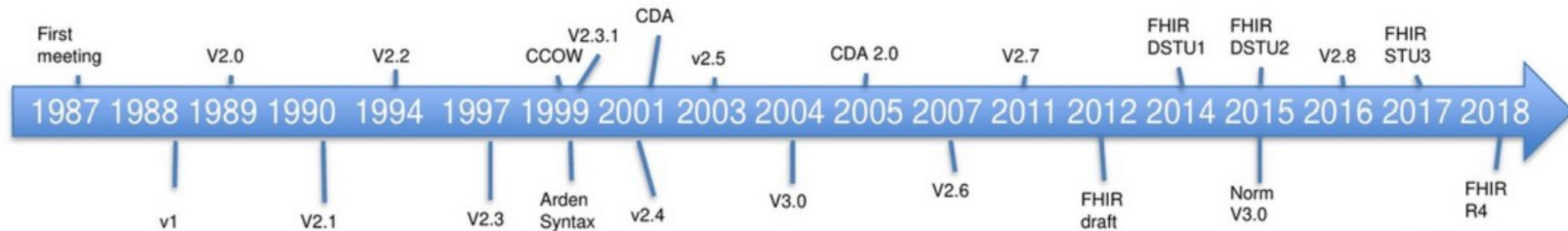
HL7 Affiliate Organizations

- Represents their country / territory at HL7 International:
  - Participates in Governance of HL7
    - International Council
  - Participates in HL7 standards development

- Represents HL7 within their country / territory:
  - Promotes and trains on the use of HL7 standards
  - Fosters local HL7 community
  - Translates and localizes the HL7 specification

HL7 Affiliates

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Countries with HL7 Affiliates in 2020

Argentina	France	Poland
Australia	Germany	Portugal
Austria	Greece	Romania
Belgium	Hong Kong	Russia
Bosnia & Herzegovina	India	Saudi Arabia
Brazil	Italy	Singapore
Canada	Japan	Spain
Chile	Korea	Sweden
China	Netherlands	Switzerland
Croatia	New Zealand	Taiwan
Czech Republic	Norway	UAE
Denmark	Pakistan	UK
Finland	Philippines	Ukraine

FHIR Accelerators

- Communities and collaborative groups across the global health care spectrum working within HL7 to create and adopt FHIR Implementation Guides in focused areas

HL7 Board

- **Overall governance of HL7 – strategic focus**
- Committees and Councils
  - International Council
  - Advisory Council
  - Executive Committee
  - Leadership Development and Nominations Committee
  - Finance Committee
  - Governance and Operations
  - Policy Advisory Council
  - Awards and Recognition
  - Technical Steering Committee

HL7 Organizational chart
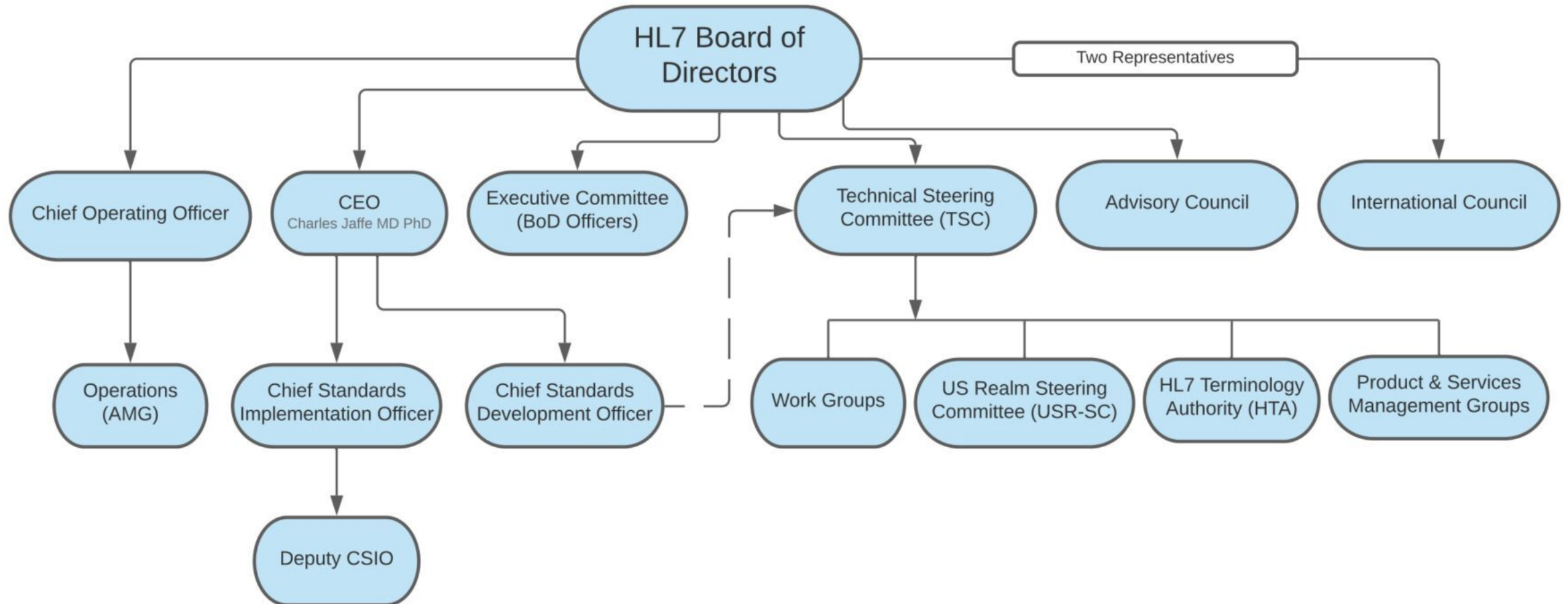
Technical Steering Committee

- **Technical leadership to the HL7 organization**
- Primarily made up of representatives from workgroup leadership
- Related Governance Groups
  - US Realm Steering Committee
  - Standards Governance Board (and product management groups)
  - Steering Divisions
  - Architectural Review Board
  - HL7 Terminology Authority
  - Education Advisory Council

Work Groups

- Members of Health Level Seven International are known collectively as the "Working Group", which is organized into individual work groups

- The work groups are directly responsible developing and maintaining the standards

- Work groups can also serve as a source for exploring new areas that need to be covered by HL7 International's published standards

- All work groups are open to participation

HL7 Work Groups

- Arden Syntax
- BR&R
- CIMI
- Clinical Decision Support
- Clinical Genomics
- Clinical Interoperability Council
- Clinical Quality Information
- Community Based Care and Privacy
- Conformance
- Cross-Group Projects Home
- Devices (DEV)

- EHR
- Emergency Care
- FHIR-I
- Financial Management
- Imaging Integration
- Implementable Technology Specifications
- Infrastructure and Messaging (InM)
- Learning Health Systems
- Mobile Health
- Modeling and Methodology (MnM)
- Orders and Observations

- Patient Administration
- Patient Care
- Patient Empowerment
- Payer/Provider Information Exchange
- Pharmacy
- Public Health
- Publishing, Electronic Services, & Tooling
- Security
- Service Oriented Architecture
- Structured Documents
- Vocabulary

Workgroup collaboration

- Meetings
  - Weekly conference calls
  - Tri-annual Working Group Meeting
  - Connectathon Participation
  - Joint meetings
  - Meeting times, Agendas and minutes all on Confluence

- Between Meetings
  - Confluence.hl7.org
  - Chat.fhir.org and Email (list server)
  - E-votes

HL7 standards development

5/20/2021
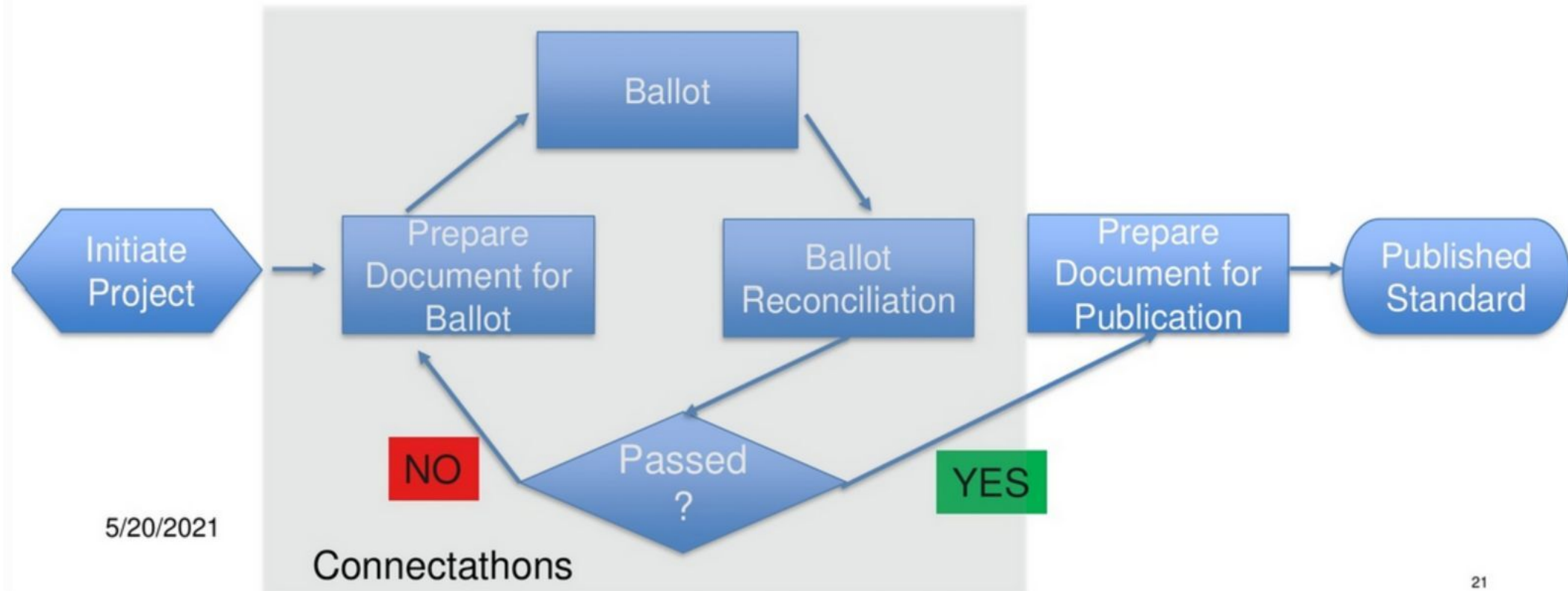
Ballots

- Balloted documents can be:
  - Informative
  - Draft Document for Comment Only
  - Draft Standards for Trial Use (DSTU)
  - Normative Standard
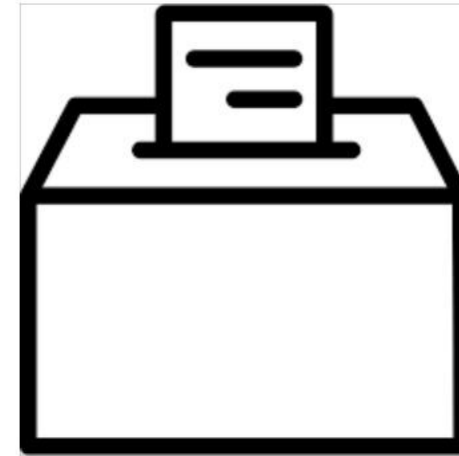
Ballots

- All members in HL7 can participate in ballots (non-members can too, for a fee)

- Your chance to review, comment and impact proposed standards

- Ballots occur three times a year about a month before each working group meeting

- Negative votes must be accompanied with a specific reason justifying the negative vote

ALL HL7 Balloted Standards are introduced first as a DSTU and must show some successful implementations before being advanced as a Normative Standard.

Ballots

- Work Groups must resolve negative votes:
    - Accept the voters comment and recommended solution
    - Negotiate with the voter and get them to agree to withdraw their negative
    - Declare the vote non-persuasive
    - Voters may appeal to the TSC and Board. They can also re-vote their same negative vote on the next round of balloting
    - Substantive changes to a ballot (either to fix a negative or add new material) merit another round of balloting
- When 75% (for normative documents) of the responses are registered as affirmatives...and hopefully all negatives withdrawn, a document is ready for publication as an HL7 International Standard

Balloting uses Jira

- Jira.hl7.org

The Working Group Meeting (WGM)

- A convening of all the HL7 workgroups for an intensive week of standards development work
  - Discuss Project Scope Statements (PSS's)
  - Ballot reconciliation
  - Collaborate with other work groups
  - Group logistics and strategy
- Sunday through Friday
- General sessions ...
- Plenary WGM once per year (Fall)
- Lots of educational opportunities (tutorials)
- Connectathon immediately before

Thank you!

António Martins

Membership Has Its Advantages

MORE THAN YOU THINK