

## HL7 Process for projects and standards

### **Project Scope Statement**

- All HL7 formal activities start with a Project Scope Statement (PSS)
- It requires, at a minimum, one sponsoring HL7 workgroup (WG)
- The PSS allows for multiple co-sponsoring WGs
- The PSS defines the scope and intent of the project and the responsible individuals

#### PSS approval process

- Must be approved by the sponsoring WG
- Must be approved by the co-sponsoring WG(s)
- Must be approved by the steering committee for the sponsoring WG (e.g. clinical)
- If it is specific to the US, must be approved by the US Realm Steering Committee
- If it contains external content (e.g. from other SDOs), must be approved by the Area Review Board (ARB)
- If it is a FHIR artifact, must be approved by FMG
- Final approval must be given by Technical Steering Committee (TSC) after which, it is assigned a project number

### **Notice of Intent to Ballot (NIB)**

- Indicates that artifacts from the PSS are intended to be part of the next ballot cycle.
- Must be submitted at least 5 weeks before the start of the ballot (see current ballot calendar)

#### Approval process

- Requires an approved PSS
- Must be approved by the sponsoring WG and submitted by the co-chairs of the WG to TSC
- Must be approved by TSC

### **Ballot Process**

- This is the formal ANSI/HL7 process by which the community of interested parties can comment on the proposed standard to improve the standard prior to publication.
- Any HL7 member and any individual paying the current non-member ballot fee may “sign-up” to participate in the ballot process. A separate signup is required for each balloted artifact (e.g. sign up for CRD and MRP)
- The signup process occurs in the 30-days prior to the start of the ballot period.
- The ballot period is the 30-days prior to the week before the HL7 working group meeting which occurs in January, May and September of each year. During this ballot period any one that has signed up for a balloted artifact may submit both a vote for the artifact (Positive, Negative, or Abstain). Any negative vote must include specific ballot comment that may be addressed during the reconciliation.

## **Ballot Reconciliation**

- During the ballot reconciliation process, all ballot comments are address with a specific disposition. The commenter may request to be present during the discussion regarding their specific comment. Ultimately interested HL7 members vote on the disposition. The disposition may or may not result in changes to the HL7 artifact.
- When all comments are reconciled, the dispositions and the revised artifact are posted for review. The individuals that voted negatively are given the opportunity to withdraw their negative votes. If 60% (for the initial phase of a standard) of the individuals that voted now support the standard, then the workgroup may vote to move the artifact into the publishing process (requires the review and approval of the TSC) to become a “standard”. Initial standards are called Standards for Trial Use Level 1 (STU 1). When the standard has been tested it may move on to a normative standard or a higher level of STU (e.g. STU 2). Each movement of the standard requires a new ballot process.