

FHIR Profile and IG Balloting

FHIR "Conformance" artifacts (Profiles, Conformance statements, ValueSets, ConceptMaps, etc.) developed and maintained by HL7 can be approved in one of two ways:

1. They can be incorporated as part of the core FHIR specification and balloted as part of that specification (likely with a frequency of every 1.5-2 years)
2. They can be packaged into a distinct implementation guide that is balloted separately from the FHIR spec.

The criteria for deciding between these two approaches as well as the ramifications are as follows:

Part of the FHIR core specification

Reasons to include a conformance package content in the core specification include:

- they are "example" instances (clearly denoted as such), demonstrating how to create Profiles, ValueSets, etc.
- they provide a demonstrations of how a resource can or should be used (e.g. "good practice" profiles)
- they define common extensions and/or search criteria that are outside core but where there's still a desire to provide a standardized approach
- they define "key" clinical concepts that might otherwise have been candidates as distinct resources (e.g. Immunization)

If a conformance artifact is part of the core specification, it will be restricted to being balloted according to the timelines for the overall FHIR specification and will have more limited visibility because it won't be listed as a stand-alone construct. Conformance artifacts that are included as part of the core specification can be labeled as "draft", "DSTU" or "Normative", based on degree of stability

Note: A conformance artifact can't be part of core if it has dependencies that aren't part of core.

As a separate implementation guide

Conformance artifacts balloted as separate implementation guides should have the following characteristics:

- Clear use-cases defining the set of stakeholders and circumstances for which the IG applies
- Be scoped for either international or US-realm use (the constituencies represented by HL7 International) or, when agreed with the affiliate, other realm content
- Include the complete set of profiles and other conformance artifacts necessary to address the specified problem space

Implementation guides can be balloted separately from the FHIR core specification (once the tooling is complete). The only requirement is that they cannot have a ballot level that is more formal than the lowest ballot level of any of the core structures they reference. E.g. If an IG contains profiles on 2 normative resources, 3 DSTU resources and 1 draft resource, the IG cannot have a ballot status higher than "draft". FHIR IGs are encouraged to make use of a DSTU period with an expectation of a minimum level of implementation prior to proceeding to normative status.

Process

All HL7-international maintained conformance package and IG proposals must be submitted to the FMG for review. This ensures cross-organizational awareness, ability to balance work group loads and verification of appropriateness of the proposed conformance package/IG(s) for the desired publication mechanism. When submitting a profile proposal, the submitter should indicate whether they wish to have their profiles balloted as part of the FHIR core specification or as a separate IG. If the FMG approves a separate IG, the ballot timeline and responsibility will be delegated to the responsible work group. If the content is included as part of the FHIR specification, the ballot timeline will be managed by the FMG.

Content balloted as part of the FHIR core specification does not need its own "Notice of Intent to Ballot" or other paperwork as it is covered under the paperwork for the overall FHIR specification. Implementation guides that are published separately from the FHIR specification will need to manage their own NIBs and other processes.

Note that IGs will also be produced by numerous other organizations outside of HL7. No consultation is expected with the FMG in these circumstances. In the case of a jointly created/maintained specification between HL7 and an external organization, consultation with the FMG should occur and adherence to HL7 Int'l guidelines will apply if the content will be published using HL7 publication and balloting processes.