IMDRF International Medical Device Regulators Forum

RPS Work Item: Beta Testing of Message Standard

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Recap

- Beta Testing Objective (Phase 1):
  - Assess RPS Standard fitness for use with device submissions
  - Identify areas where the RPS standard may not meet device requirements and provide input to the HL7 standard
- If RPS is found to be suitable for device business requirements, Phase 2 of RPS Work Item, if endorsed by IMDRF MC, would focus on implementation

Software Tool versus Message Standard

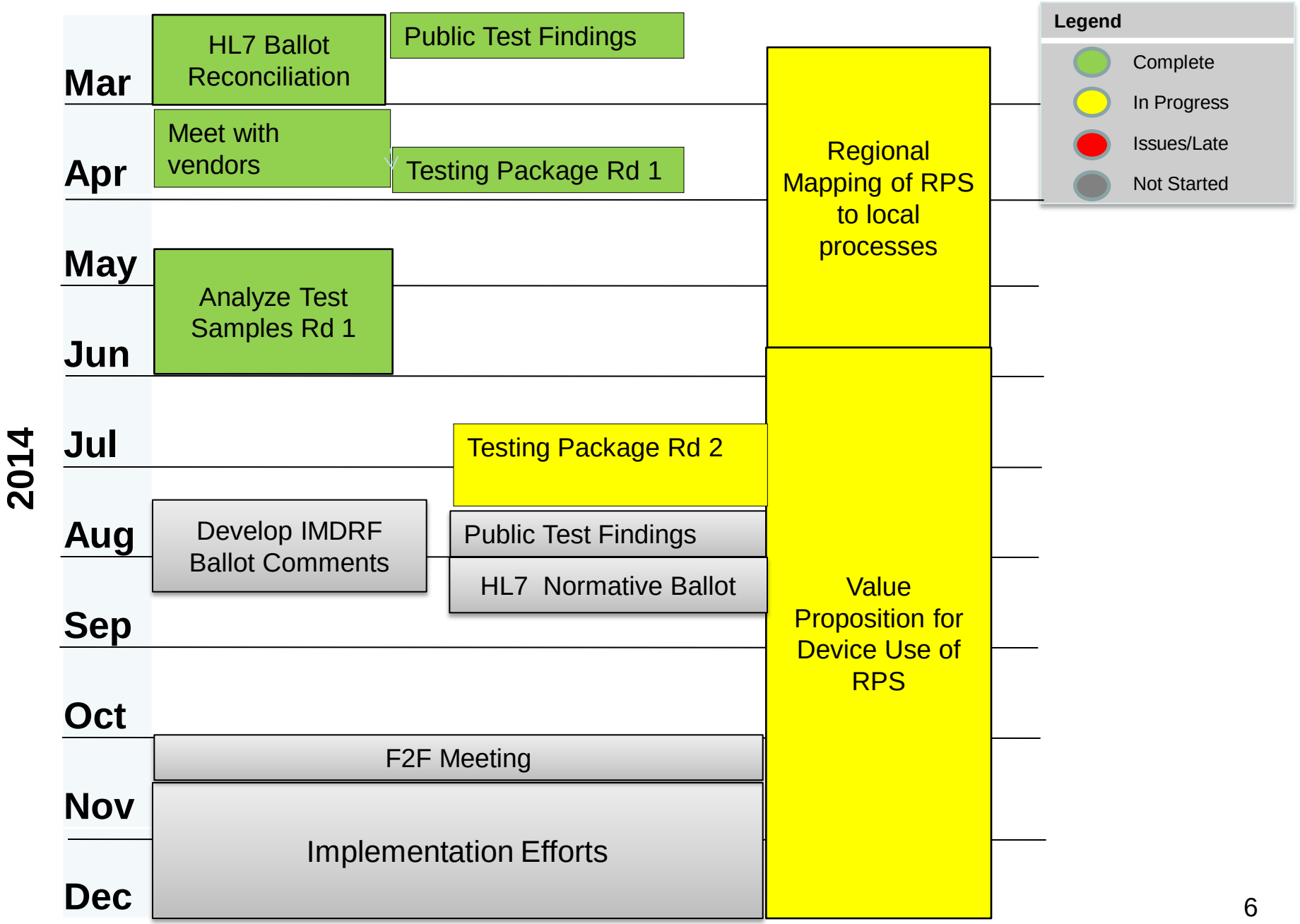
- **Tool:** a business need that can be met with functionality built into publishing and reviewing software tools
- **Message:** Information that must be contained in the RPS message to support the business process
  - The RPS message carries information that software tools can use to enable software functionality
  - Business requirements may be met through tools if the RPS message carries the necessary information to do so

Tool Requirement Example

- Reviewers want to see all documents related to a manufacturing facility grouped together
  - The RPS message allows documents to be tagged with keywords. The tool can then display all documents with the same keyword together
  - All of the required information is in the message, but the use of the keywords for grouping content for display is a tool requirement

Beta Testing Status

- Initial plan to complete testing by July 15 was delayed because changes to the RPS model were not available
- A revised testing approach will allow us to comment on the HL7 RPS Ballot by Sept 8th


2014
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec
HL7 Ballot Reconciliation
Public Test Findings
Meet with vendors
Testing Package Rd 1
Analyze Test Samples Rd 1
Regional Mapping of RPS to local processes
Testing Package Rd 2
Develop IMDRF Ballot Comments
Public Test Findings
HL7 Normative Ballot
Value Proposition for Device Use of RPS
F2F Meeting
Implementation Efforts
Legend
Complete
In Progress
Issues/Late
Not Started

Next Steps

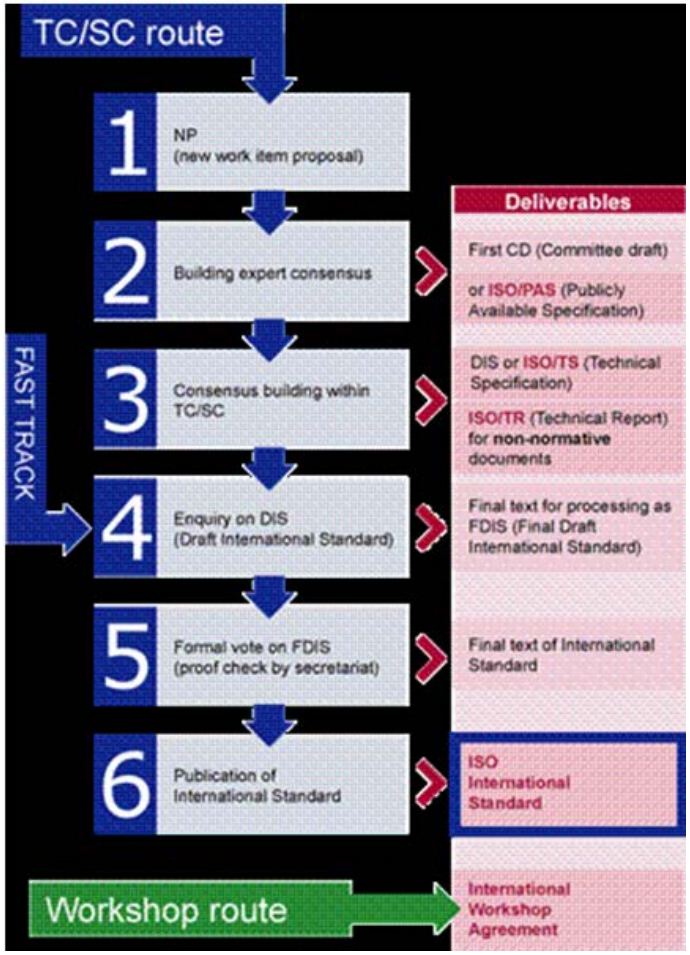
- A F2F meeting will be held in early November to review test results & finalize the business case for proceeding with Phase 2 (Implementation)
- Interim options for encouraging electronic submission of ToC formatted submissions also being developed

RPS as an ISO Standard

Once RPS is at a normative state in HL7, ICH plans to bring RPS forward to ISO TC215

- Approval in ISO will take ~18 months from the time it is proposed.
- Once approved as an ISO standard, changes will take ~24 – 36 months.

RISK: Combination Products may have new requirements that require a revision to the HL7 and ISO standard



Work Item Extension – Common Data Elements

- RPS Work Item Extension endorsed by the IMDRF MC that will:
  - Identify and define common data elements and a structure to support device identification for regulatory purposes at different stages of the product lifecycle. This work will also cover the harmonization of definitions of data fields and sets of UDIDs (Phase 1)
  - Evaluate whether an existing electronic exchange format could accommodate the transmission of device identification information or whether a new data exchange message would be required (Phase 2)

Update on Common Data Elements WG

- Work under this third RPS work stream has started
- Initial step – survey of common data elements that are currently collected/captured by IMDRF members to identify a device through its lifecycle (pre-market/post market) and also those that may be contemplated due to proposed revisions in some regulatory frameworks
- Results from the survey will be discussed at the Face to Face Meeting in November.
- Phase I work is projected to be completed by September 2015.

Thank you!