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

Overall Status of Phase 1 Work

- Following device scenarios tested to date:
  - Bundled PMA Supplement (US)
  - Bundled Submission (Canada)
  - Submission covering many products (Australia)
  - Modular PMAs (US)
- HL7 Ballot Reconciliation ongoing and will result in changes to the RPS model
- Delays experienced in HL7 schedule, in part related to ongoing discussions within ICH on business requirements for pharmaceuticals
- Next opportunity for RPS to become a normative HL7 standard is following ballot in Sept 2014

Update since Brussels

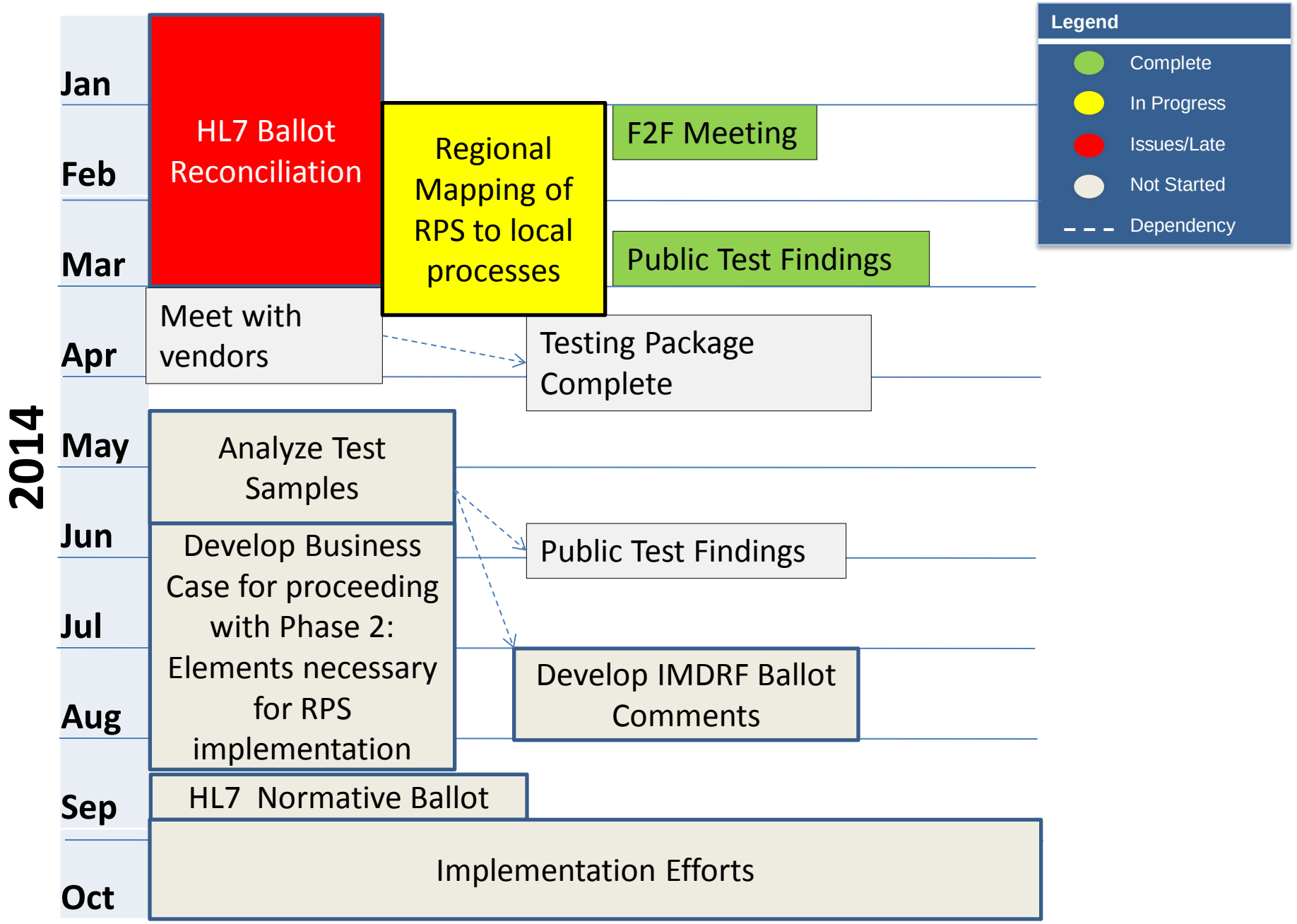
- Public test results from first round of testing by software vendors finalized and ready for posting together with initial Draft Implementation Guide (IG) for Testing
- Training conducted at recent meeting in Washington to improve stakeholder knowledge and input
- Work in progress within each region to determine how RPS fits into their current business processes
- Master Glossary of Terms and Business/Message requirements in preparation

Outstanding Phase 1 Testing

- Additional business scenarios to be tested:
  - Brazil Laboratory Certificate
  - EU Quality Systems Certificate and Design Examination Certificate
  - US Manufacturing Supplements
  - Other?
- Some re-testing of modular PMAs and/or bundled submissions also anticipated
- Testing focused on message requirements that need to be tested for device-specific requirements

Next Steps

- Working towards March 31 meeting with tool vendors and testing of additional business requirements by mid-end May using a simplified testing procedure
- Will require completion of testing package (test case scenarios and revised IG for testing) by mid-April
- Business case for proceeding with Phase 2 (Implementation) under development
- Interim options for encouraging electronic submission of IHS formatted submissions also being developed


2014
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
HL7 Ballot Reconciliation
Regional Mapping of RPS to local processes
F2F Meeting
Public Test Findings
Meet with vendors
Testing Package Complete
Analyze Test Samples
Public Test Findings
Develop Business Case for proceeding with Phase 2: Elements necessary for RPS implementation
Develop IMDRF Ballot Comments
HL7 Normative Ballot
Implementation Efforts
Legend
Complete
In Progress
Issues/Late
Not Started
Dependency

Work Item Extension

- RPS Work Item Extension previously 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 (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)

Work Item Extension

- Work Item Extension will build upon and complement work undertaken by the UDI and RPS working groups
- Work under this third RPS work stream was to begin once RPS message standard became a normative HL7 standard
- Given delays caused by reconciliation of HL7 RPS ballot comments, discussed launch of preliminary work at recent meeting in Washington

Thank you!