RPS Work Item:
Beta Testing of Message Standard

IMDRF Stakeholder Forum
San Francisco
March 26, 2014

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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
Jan
- HL7 Ballot Reconciliation

Feb
- Regional Mapping of RPS to local processes

Mar
- Meet with vendors
- F2F Meeting
- Public Test Findings

Apr
- Testing Package Complete

May
- Analyze Test Samples

Jun
- Develop Business Case for proceeding with Phase 2: Elements necessary for RPS implementation
- Public Test Findings

Jul
- Develop IMDRF Ballot

Aug
- Comments

Sep
- HL7 Normative Ballot

Oct
- Implementation Efforts
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!