IMDRF International Medical Device Regulators Forum

Regulated Product Submission Update

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RPS History

- In Kyoto, the IMDRF MC endorsed the recommendation that WG continue efforts to work towards implementation of RPS as the future electronic information exchange format to be used for medical device submissions; and that the MC charter additional efforts within the RPS WG to develop a harmonized, device specific implementation of the RPS standard

RPS History

- Should be noted that implementation of RPS is a long term undertaking and efforts will most likely take several years

- WG recommends that gradual steps be taken to implement the HL7 RPS Message Standard (e.g. use of a harmonized folder structure as a transition format, etc.)

RPS Implementation Work

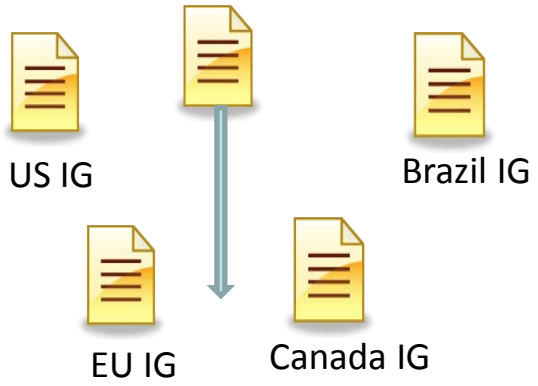
RPS STANDARD
Defines all possible data and relationships

Implementation Guide
Technical Requirements - specifies which parts of the standard will be used and how.

Software tools
Built based on the implementation guide. Presents a customized user view to the submission information

IMDRF Harmonized Implementation Guide (IG)

The harmonized IG is the basis for the regional IGs.



Challenges in Quantifying Cost-Benefit

Implementation Guide

RPS Implementation Complexity

- Technical RPS Requirements (final IG)
- Level of regional variability in implementation

Software Tools

Software Tools

- Number of Vendors offering software to create RPS submissions
- Vendor pricing and solution approach
- Regulator implementation plans (will free tools be provided?)

Organizational variations

Each regulator & company's needs & approach

- Each company's internal IT implementation requirements
- Current state of document and RA Data management at each company
- Internal company requirements for the software (beyond the RPS IG)

Benefits of RPS

- Multiple regions using a harmonized, consistent format
  - reducing IT burden on industry
- Minimal revisions needed to address regional differences and/or requirements in content
- IT harmonization
  - End result is an IT format that can be reused for multiple regions, saving time and resources by mitigating the risk of significantly different methods being developed amongst regulators

Implementation Phases

Work Phase & Outcome	Timing	Information Available/Stakeholder Engagement
Scope & Process Definition:	Ongoing	• Types of submissions in scope by region • High level understanding of structured information required in an RPS submission
Draft IG Preparation	March 2018	• Harmonized IG available for open consultation • Harmonized controlled vocabulary available for open consultation • Vendor discussions / engagement
Testing	Sept 2018	• Ongoing vendor discussion / engagement • Visibility to test scenarios & results
Implementation Approach & Governance Process	TBD	• Final IG • Regional IGs available for review & comment • Regulator implementation plans available for open consultation • Draft IMDRF Governance process for discussion / review

Benefits of RPS

- While initial implementation may be limited to basic structural functionality, RPS supports extensive business requirements that may be used in the future (e.g. document re-use, keywords on headings, etc.)

Progress

- Technical resources have been secured from industry to reassess the workplan developed in June 2016 with some key deliverables scheduled in 2017.
- Sub-working group has rescoped project and shared with larger working group for approval
- Plan to progressively set milestones and deliverables with new workplan

Table of Contents Update

- No new applications have been received into the pilot since March 2017.
- Applications that have been received and reviewed to-date by region:
  - Australia: 1
  - Brazil: 7
  - Canada: 2
  - China: 4
  - EU: 1
  - USA: 2

Table of Contents Update

- Pilot scheduled to end fall 2017
- Working group will analyze results and feedback from both manufacturers and reviewers to determine if revisions to the structure are necessary
- Publish revise Table of Contents (March 2017) and discuss implementation plans

Questions & Discussion