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.

- US IG
- EU IG
- Brazil IG
- Canada IG
Challenges in Quantifying Cost-Benefit

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

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

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

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