RPS WG Update
September 2015
Open Stakeholder Session

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RPS Strategic Assessment
Strategic Assessment Scope

**IN SCOPE**

- Technical Exchange format for medical device pre-market submissions

**OUT OF SCOPE**

- TOC (implementation of the TOC is assumed)
- Combination product submissions*
- Any submissions other than pre-market

*combination products are referenced as a strategic consideration
Process

Evaluation to determine which technical submission exchange format is the right direction to meet stakeholder business objectives

- Business Objectives
- Stakeholders
- Format Options
- Scoring Discussions
- Tabulation of scores & weighting
- Scoring discussion feedback and other strategic factors
- RECOMMENDATION
Scoring

Each technical format option was scored for each business objective as a comparison to the current state. Options are also scored based on implementation and maintenance cost.

- A score of 1-5;
- Current state is scored as 3 which is the comparison point;
- Scores >3 are better than current state, Scores <3 are worse.

<table>
<thead>
<tr>
<th>Objective</th>
<th>Current State (option 1)</th>
<th>Option 2 Folder Structure</th>
<th>Option 3 IMDRF Standard</th>
<th>Option 4 RPS</th>
</tr>
</thead>
<tbody>
<tr>
<td>FOR EXAMPLE</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enable a clear view to the lifecycle of Application content over time, as well as the ability to quickly see the most current version of an Application.</td>
<td>3</td>
<td>2</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

Scores for each option weighted by stakeholder group and totaled across all objectives. Current state has a total score of 45 (when all objective scores are totaled).
Stakeholders & Weighting

Multiple stakeholder groups were identified to insure all diverse perspectives were considered in the analysis.

**REGULATORS**
- Regulators with electronic review tools and experience reviewing structured content in submissions
- Regulators who don’t currently have review tools

**INDUSTRY**
- Companies that currently support eCTD or have publishing software in-house
- Companies that support multiple complex submissions
- Companies that have primarily simple submissions
## Technical Format Options

<table>
<thead>
<tr>
<th>Format Option</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Option 2: Harmonized Folder Structure</td>
<td>A harmonized hierarchical folder structure housing e-files, and possibly a harmonized eForm that captures some metadata about the submission.</td>
</tr>
<tr>
<td>Option 3: Custom IMDRF Message Standard</td>
<td>An IMDRF developed Messaging Standard that allows management of submission content lifecycle</td>
</tr>
<tr>
<td>Option 4: RPS</td>
<td>HL7 RPS XML Messaging Standard</td>
</tr>
</tbody>
</table>

Each option was compared to the current state (Option 1 – maintain the status quo and do nothing).
## Final Scores

<table>
<thead>
<tr>
<th>Stakeholder Sub-Group</th>
<th>Option 1 Status Quo (Baseline)</th>
<th>Option 2 Harmonized Folder structure</th>
<th>Option 3 Custom IMDRF Message Standard</th>
<th>Option 4 HL7 RPS Message Standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>INDUSTRY - Companies with eCTD publishing software</td>
<td>45.0</td>
<td>50</td>
<td>48.5</td>
<td>54.3</td>
</tr>
<tr>
<td>INDUSTRY - complex submissions</td>
<td>45.0</td>
<td>48.9</td>
<td>50.4</td>
<td>50.3</td>
</tr>
<tr>
<td>INDUSTRY - Companies with primarily simple submissions</td>
<td>45.0</td>
<td>50.6</td>
<td>49.4</td>
<td>48.5</td>
</tr>
<tr>
<td>REGULATORS – jurisdictions with electronic review tools</td>
<td>45.0</td>
<td>44.1</td>
<td>53.2</td>
<td>56.5</td>
</tr>
<tr>
<td>REGULATORS - jurisdictions without review tools</td>
<td>45.0</td>
<td>50.5</td>
<td>53.8</td>
<td>54.6</td>
</tr>
<tr>
<td>TOTAL SCORE (Weighting Applied)</td>
<td>45.0</td>
<td>48.9</td>
<td>51.5</td>
<td>52.3</td>
</tr>
</tbody>
</table>
Recommendation

..... it is recommended that the IMDRF MC endorse 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.....

..... It should be noted that implementation of RPS is a long term undertaking, and efforts will most likely take several years.....

.....the RPS 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.)....

.....the full implementation of RPS that will require establishment of an ongoing governance model to maintain harmonization and address proposed changes.....

As a first step, the RPS WG should develop a public strategy outlining a project plan and key milestones to implement RPS
Questions & Discussion
Common Data Elements WG - Update

• July 1, MC endorsed CDE WG Proposed Document “Common Data Elements for Medical Device Identification” for Public Consultation

• Comment Period Closes September 15, 2015
Common Data Elements WG - Update

• Proposed Document Contents include:
  – Introduction
  – Scope
  – Common Data Elements
    • Definition
    • Data Format
    • Value Set
    • Usage Notes (for life cycle)
    • Implementation Considerations
    • Examples
Common Data Elements WG – Project Plan

• October 27-30, 2015
  – WG Meeting will be held in Brussels to review all comments (i.e., both regulator and industry)
  – First 2 days will include Industry Stakeholders

• Post Brussels Meeting
  – Review, revise and gain consensus on the final draft of the document

• December 15, 2015
  – WG will finalize document and deliver to the Management Committee