RPS Next Steps
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
- Canada IG
- Brazil 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)
## Implementation Phases

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

• Preliminary discussion of scope & impact of scope to industry
• Open discussion and active review of the draft harmonized IG and draft controlled vocabulary.
  • Provide feedback to the WG.
  • Each company begin to assess impact based on information required in an RPS message and the information they currently track & store
• During testing:
  • industry may begin to have discussions with vendors to assess plans and potential tools that will be available for purchase
  • Review test results for insights into how RPS will be used and potential challenges
• Open dialog and comment on regulator implementation plans & the governance process
• Individual companies do their own cost analysis as part of the implementation plan review