RPS WG Update
March 2015
Open Stakeholder Session

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Health Canada
Background

- RPS WG started trying to catch up with RPS standard development work that was ongoing within other organizations (HL7, ICH)
- Testing concluded the RPS standard can be used for device submissions
- Now we can step back to define the IMDRF business needs for a harmonized electronic submission format

This will allow us to choose the best electronic submission format to meet our business objectives
Business Case

- Efforts underway to produce a final recommended message exchange format for submissions
- A formal business case document will support the recommendation

- Define business objectives
- Define message exchange format options
- Develop and apply evaluation criteria to determine the best message exchange format
- Final recommendation & implementation plan

May 2015
# High Priority Business Objectives

<table>
<thead>
<tr>
<th>Challenge Area</th>
<th>Objective</th>
<th>Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>No harmonized common message exchange format for submissions</td>
<td>Identify a single technical exchange format, or a solution to efficiently support multiple technical exchange formats across different regulators</td>
<td>Industry</td>
</tr>
<tr>
<td>Managing Submission &amp; Content Lifecycle</td>
<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>Regulators and Industry</td>
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<tr>
<td></td>
<td>Include additional metadata on submission content for better discovery in the future (i.e., TOC headings and keywords).</td>
<td>Regulators</td>
</tr>
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<td></td>
<td>Enable regulators and industry to consistently and clearly identify / communicate how a submission relates to previous applications</td>
<td>Regulators &amp; Industry</td>
</tr>
<tr>
<td>Challenge Area</td>
<td>Objective</td>
<td>Impact</td>
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<tr>
<td>Use of Paper by some stakeholders as a preferred format in management of submissions</td>
<td>Enable efficient access (for appropriate parties) to information provided electronically in submissions</td>
<td>Regulators &amp; Industry</td>
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<tr>
<td>Submission log-in / Acknowledgements</td>
<td>Enable reduction of resources / time required for manual login (data entry, record creation) of submissions</td>
<td>Regulators</td>
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Business Case Sections

• Technology Options
• Technology Evaluation Criteria
• Evaluation of Technology Options
• Final Recommendation
• Proposed Next Steps
• Risks / Mitigation
Process

Define technology options

Finalize business objectives and expected benefits

Prioritize business objectives

Evaluate each technology option against the business objectives, and other evaluation criteria (i.e. cost)

Agree on final recommendation & Next Steps

Feb. 28th

Complete

Apr 20

Complete

May 1
Common Data Elements WG - Update

- Survey identifying common data elements for device and manufacturer throughout the product lifecycle was completed by all regions (Oct 2014)
- Results of the survey were discussed at the F2F Meeting (November 2014)
- Survey Findings were consolidated into 2 lists:
  - Harmonized Common Data Elements
  - Additional Elements for Consideration
- List of harmonized common data elements shared with Industry (December 2014)
- Informal consultation with industry (Feb-March) to finalize work item for public consultation
## CDE Workplan

<table>
<thead>
<tr>
<th>Milestone</th>
<th>Target Date</th>
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<tbody>
<tr>
<td>Discuss Common Data Elements</td>
<td>Now – March 31, 2015</td>
</tr>
<tr>
<td>Finalize Common Data Elements for Public Consultation</td>
<td>April 1 – 30, 2015</td>
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<tr>
<td>Documents to MC for endorsement of Public Consultation</td>
<td>May 1, 2015</td>
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<tr>
<td>Public Consultation period</td>
<td>July 1, 2015 – September 15, 2015</td>
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<td>Final Deliverable Due</td>
<td>December 2015</td>
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Thank you