IMDRF International Medical Device Regulators Forum

RPS WG Update
March 2015
Open Stakeholder Session

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Health Canada

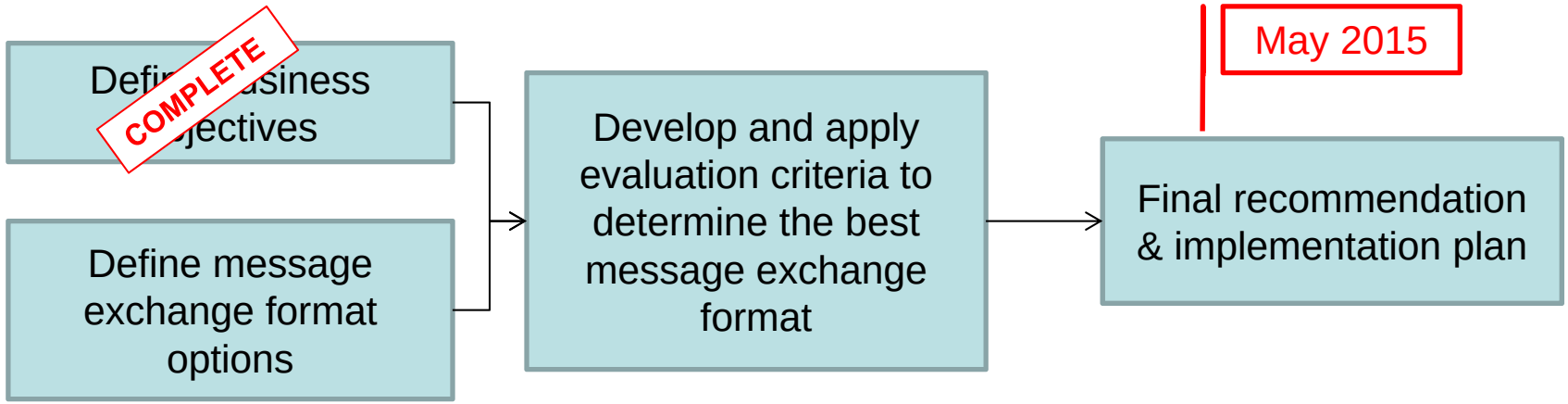
Background

- 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



High Priority Business Objectives

Challenge Area	Objective	Impact
No harmonized common message exchange format for submissions	Identify a single technical exchange format, or a solution to efficiently support multiple technical exchange formats across different regulators	Industry
Managing Submission & Content Lifecycle	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.	Regulators and Industry
	Include additional metadata on submission content for better discovery in the future (i.e., TOC headings and keywords).	Regulators
	Enable regulators and industry to consistently and clearly identify / communicate how a submission relates to previous applications	Regulators & Industry

Challenge Area	Objective	Impact
Use of Paper by some stakeholders as a preferred format in management of submissions	Enable efficient access (for appropriate parties) to information provided electronically in submissions	Regulators & Industry
Submission log-in / Acknowledgements	Enable reduction of resources / time required for manual login (data entry, record creation) of submissions	Regulators

Business Case Sections

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

Process

Finalize business objectives and expected benefits

Complete

Define technology options

Feb. 28th

Prioritize business objectives

Complete

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

Apr 20

Agree on final recommendation & Next Steps

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

Milestone	Target Date
Discuss Common Data Elements	Now – March 31, 2015
Finalize Common Data Elements for Public Consultation	April 1 – 30, 2015
Documents to MC for endorsement of Public Consultation	May 1, 2015
Public Consultation period	July 1, 2015 – September 15, 2015
Final Deliverable Due	December 2015

Thank you