IMDRF International Medical Device Regulators Forum

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

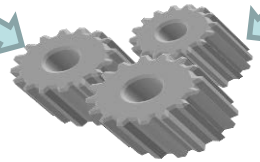
Evaluation to determine which technical submission exchange format is the right direction to meet stakeholder business objectives

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

Objective **FOR EXAMPLE**	Current State (option 1)	Option 2 Folder Structure	Option 3 IMDRF Standard	Option 4 RPS
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.	3	2	3	4

3 = current state

2 = worse than current

3 = no change

2 = better than current

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

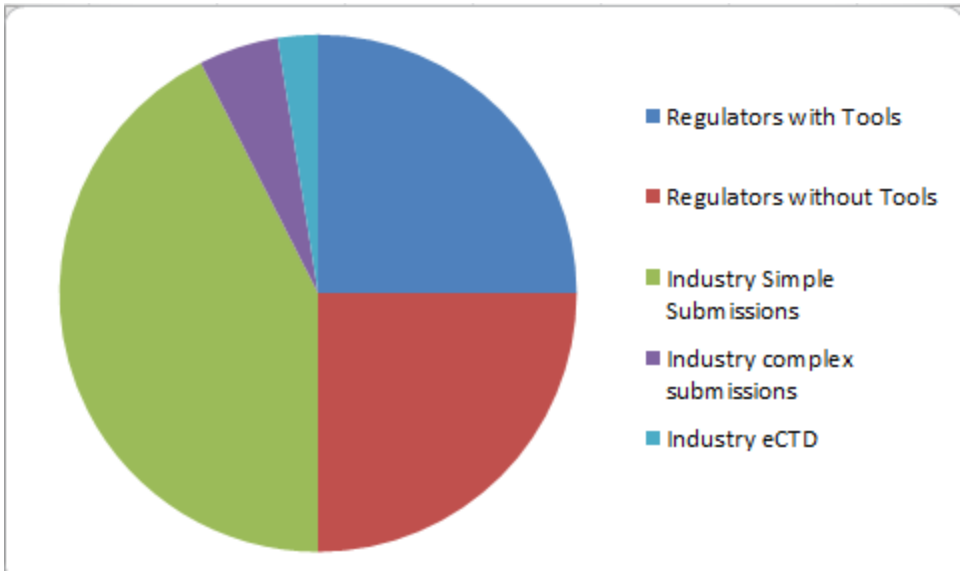
Multiple stakeholder groups were identified to insure all diverse perspectives were considered in the analysis

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

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

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

Final Scores

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

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