IMDRF International Medical Device Regulators Forum

Regulated Product Submission Update

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RPS History

- In Kyoto, the IMDRF MC endorsed the recommendation that WG continue efforts to work towards implementation of 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

RPS History

- Should be noted that implementation of RPS is a long term undertaking and efforts will most likely take several years

- 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.)

RPS History

- Full implementation of RPS 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

Benefits of RPS

- Multiple regions using a harmonized, consistent format
  - reducing IT burden on industry
- Minimal revisions needed to address regional differences and/or requirements in content
- IT harmonization
  - End result is an IT format that can be reused for multiple regions, saving time and resources by mitigating the risk of significantly different methods being developed amongst regulators

Benefits of RPS

- While initial implementation may be limited to basic structural functionality, RPS supports extensive business requirements that may be used in the future (e.g. document re-use, two-way messaging, keywords on headings, etc.)

Progress

- F2F meetings held June 2-3, 2016, in Ottawa on the project plan that was developed in March 2016
- Discussions centred on the need for technical experts from industry and deliverables (controlled vocabulary, implementation guide, vendor engagement)
- Communication Strategy/Outreach

Challenges

- Identification and allocation of resources and technical expertise a challenge for all regions
- Project risks stalling or discontinuation without proper resources
- Opportunity for industry to contribute and continue collaboration with regulators on moving project forward

Next Steps

- Identify potential technical expert(s)
- Lack of movement may result in individual regions charting their own path without harmonized approach
  - Increased compliance burden on industry

Common Data Elements Update Phase 2 Workplan

1. Analysis and documentation by each regulatory region of existing regulatory usage and allowable values of each common data element.
2. Compilation of regulatory region data element specifications and mapping to data types and controlled vocabularies.

Common Data Elements Update Phase 2 Workplan

3. Documentation of existing exchange messages that are available for regulatory reporting.
4. Mapping of common data elements to existing exchange messages.
5. Recommendations for data exchange guidelines of common data elements.

Common Data Elements Update

- F2F meeting held May 31-June 1, 2016, in Ottawa
- Work and discussions focused on completing Steps 4 and 5 identified in the workplan slides above.
- Draft document outlines the data exchange guidelines for the common data elements published in IMDRF RPSWG N19 document.

Common Data Elements Update

- Document is meant to provide guidelines to other IMDRF Working Groups to consider when developing implementation specifications for a specific regulatory activity
- WG is consulting with industry prior to finalization of the document
- Anticipated timeline for finalization of the document is November 2016

Table of Contents Update

- 1 new device accepted into Pilot since last update, bringing total to 12
- Application breakdown by region:
  - Australia: 1
  - Brazil: 11
  - Canada: 4
  - China: 4
  - EU: 3
  - USA: 6

Table of Contents Update

- Pilot ongoing but some manufacturers delaying submitting
- Positive feedback from applicants and reviewers but some concerns about technical limitations
- Differences in interpretation amongst regions?
- Concerns about the viability of ToC without buy-in from all regions towards future implementation as the new standard

Table of Contents Update

- In communication with manufacturers to follow up on delayed submissions
- Anticipate receiving delayed submissions shortly
- Small sample size, need more applicants to ensure implementation is successful
- Full benefits of ToC cannot be realized until set up as part of electronic format of RPS

Questions & Discussion