IMDRF International Medical Device Regulators Forum

Regulated Product Submission Update

Nancy Shadeed

Health Canada

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

- The RPS WG has been developing 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, keywords on headings, etc.)

Progress

- Progress Technical resources have been secured from industry to reassess the workplan developed in June 2016 with some key deliverables scheduled in 2017.

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

- Document was created that focused on Steps 4 and 5 of the workplan slides above
- Intended to provide guidelines to other IMDRF Working Groups to consider when developing implementation specifications for a specific regulatory activity
- Document has been finalized and is awaiting endorsement by Management Committee as an Information Document.

Table of Contents Update

- 0 new devices accepted into Pilot since last update
- 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