The Regulated Product Submission: Progress Update

IMDRF Public Stakeholders Session
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IMDRF RPS Proposal

- Composed of two complementary components:
  - Beta testing of RPS Standard to confirm it is fit for purpose for medical devices
  - Develop common, modular Table of Content (ToC) for device applications (IVD and non-IVD)

- Project takes account of existing work:
  - Beta testing: HL7 RPS WG and ICH
  - ToC: GHTF STED documents

- Project seen as important step towards ultimate goal of common premarket requirements for device applications
The Regulated Product Submission (RPS)

• RPS is a message standard that can be used for the electronic submission of product information between a company and a regulatory agency for the purpose of gaining market authorization.

• Message standard (envelop) is independent of submission content (letter).

• Scope:
  – Meant for worldwide use: same model for all product types, all regulatory agencies.
  – Project charter includes pharmaceuticals, food additives and medical devices.
Why is this important?

• RPS will allow for unprecedented functionality in terms of the review and management of regulated product information over the entire product life cycle
• Use by regulatory agencies across product lines provides for resource savings and greater efficiencies, including with respect to the training of reviewers
• Expected to increase the efficiency and effectiveness of regulatory processes internationally
RPS provides standard definitions and data relationships to help sponsors and regulators communicate about pre-market submissions.
Health Level Seven (HL7)

- Development of RPS being undertaken through HL7, an ANSI accredited Standards Development Organization (SDO)
- Founded in 1987, now has 2,300+ members in over 34 countries
- Develops standards to improve information sharing and interoperability between health care systems
- Many HL7 standards are also ISO TC-215 standards
- RPS one of several projects under the Regulated Clinical Research Information Management (RCRIM) working group
HL7 develops health informatics standards that can become ISO standards via two paths:

- Joint Initiative: standards work is done in both organizations and goes to ballot in both groups simultaneously
- Fast Track: an approved HL7 standard is balloted through ISO as a DIS
Approach

• Focus efforts on potential differences in business requirements between drugs and devices
• Establish minimum test package required for such testing
• Doesn’t rely on common ToC: use existing application formats to test business requirements
• Distinguish between what necessary for 1) testing and 2) eventual implementation
Progress to Date: Beta Testing

- IMDRF RPS WG formed (regulators and industry from various countries/regions represented by IMDRF)
- Project plan developed
- Series of teleconferences held to familiarize WG members with HL7/RPS and gain agreement on approach/plan
- Participated in HL7 RPS teleconferences
- First meeting held in Ottawa, September, 2012
Outcomes of Ottawa Meeting
September 8-9, 2012

• Agreed on list of action items, overall test strategy and formation of 2 subgroups:
  – test strategy
  – implementation guides/controlled vocabularies
• Identified possible test scenarios
• Drafted invitation letter to software vendors
• Discussed plans to implement RPS (Phase 2) and ‘interim’ options
• Agreed that beta test group should serve as forum for broader information sharing related to eBusiness, such as gateways, eReview plans, etc.
• Subsequent update to HL7 RPS WG at annual meeting in Baltimore (Sept. 11)
ToC Work Stream

• Working towards a comprehensive, modular ToC that uses common language for each of the following submission types
  – Non-IVD Market Authorization
  – IVD Market Authorization
  – Non-IVD Clinical Trial Authorization
  – IVD Clinical Trial Authorization

• Meeting in Ottawa included discussions to refine both non-IVD and IVD market authorization ToCs
**Approach**

- Prior to the meeting, using HC ToC as baseline, jurisdictions worked to identify synonymous headings and missing headings.
- Meeting discussions involved understanding general content expected under each heading and discussion of granularity of ToCs.
- **Issues & Challenges**
  - Level of granularity (art not science)
  - Different regional regulatory languages
Outcomes of Ottawa Meeting

• Refined both IVD and non-IVD ToC
• Gained much better understanding of one another’s regulatory language
• Developed more jurisdiction-neutral headings
• Captured some high-level elements that fall within headings
• Assigned modules to participating jurisdictions
Next Steps

• Beta Test Stream:
  – Engage software vendors
  – Develop final test package
  – Conduct Beta testing (January – April 2013)
  – Submit Ballot comments (August 2013) in advance of Normative Ballot (September 2013)
Next Steps

• ToC Work Stream:
  – Conduct review of ToCs against current requirements to ensure no gaps have been created
  – Work to more formally document general elements that belong under headings
  – Continue with refinement to headings and granularity
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Questions?