The Regulated Product Submission: Progress Update

IMDRF Public Stakeholders Session
Sydney, Australia
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IMDRF RPS Proposal

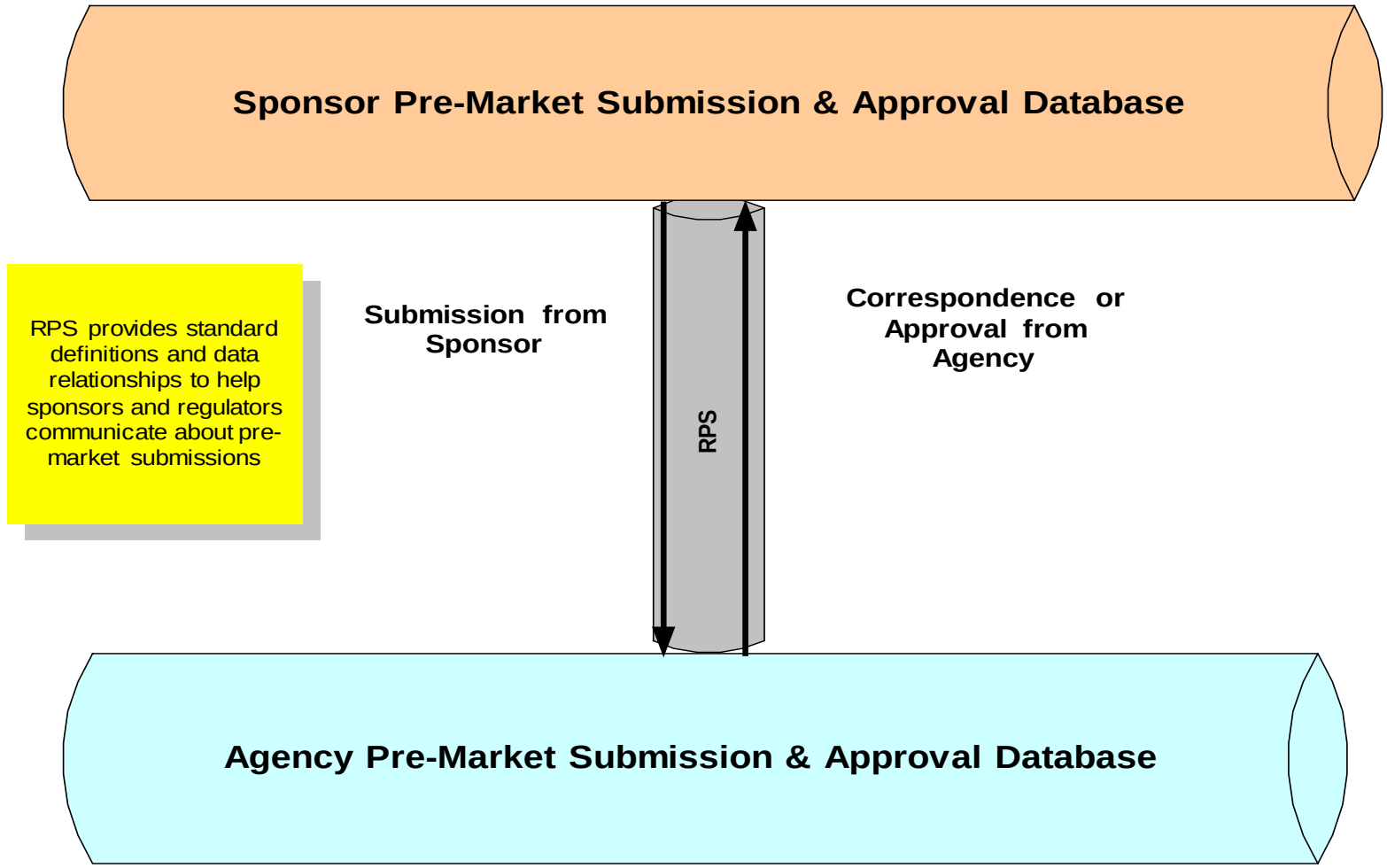
- Composed of two complementary components:
  - Beta testing of RPS Standard to confirm it is fit for purpose for medical devices
  - Develop common, modular Table of Content (ToC) for device applications (IVD and non-IVD)
- Project takes account of existing work:
  - Beta testing: HL7 RPS WG and ICH
  - 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?

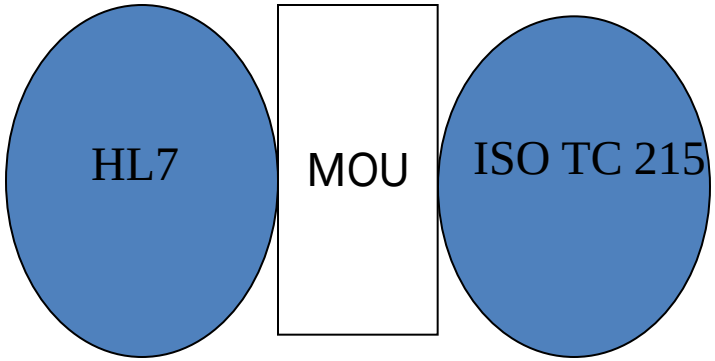
- RPS will allow for unprecedented functionality in terms of the review and management of regulated product information over the entire product life cycle
- Use by regulatory agencies across product lines provides for resource savings and greater efficiencies, including with respect to the training of reviewers
- Expected to increase the efficiency and effectiveness of regulatory processes internationally


Sponsor Pre-Market Submission & Approval Database
RPS provides standard definitions and data relationships to help sponsors and regulators communicate about pre-market submissions
Submission from Sponsor
RPS
Correspondence or Approval from Agency
Agency Pre-Market Submission & Approval Database

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

Developing ISO Standards via HL7



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?