FDA Data Exchange Standards Initiatives

Regulated Product Submission *(RPS)* Standard Status

Outline

- FDA and RPS Goals
- RPS Message
- FDA Implementation Planning
- How to get Involved

The Food and Drug Administration's Goals

- *FDA's goal is to implement a standards-based end-to-end fully electronic receipt, review, dissemination, and archival environment.*

- Meet the PDUFA IV goals:
  - Industry will be able to send in their electronic applications with automated cross-links to previously submitted data and information, so that they only have to submit things once
  - FDA reviewers will be able to retrieve all relevant submissions and related data electronically from their work station, and have efficient tools for searching and analyzing data to support their review
  - FDA will have capability to handle two-way regulatory correspondence with industry, accelerating movement toward all-electronic submission and review environment, and reducing paper submission management systems

Meeting the Goals

- Implemented a new agency-wide governance and communications structure for information management – the Bioinformatics Board
- Approaching business process and information technology decisions more strategically and holistically
- Elevating to the Agency-wide Bioinformatics Board all major funding decisions regarding information technology

Food and Drug Administration's RPS Project Team

- Senior Management Team
  - Charter approved
  - Concept Document approved
  - Boundary Document is under review

  Next Steps
  - Create codes
  - Implement RPS R2

Regulated Product Submission (RPS) Goal

- Create one standard (exchange message) that can be used for the submission of any regulated product
  - Release 1
    - Provide a flexible framework that will allow sponsors to send regulatory information using predefined parameters to identify and catalog their content
      - *Reviewers will be able to consistently locate discipline specific information and data*
      - *Allows for the cross-reference of previously submitted material*
  - Release 2
    - Standardize Submission Response (i.e.; two-way communication)
    - Facilitate the processing of submissions and correspondence

Regulated Product Submission

- Health Level Seven (HL7) exchange standard

- Scope
  - Animal and Human products
    - Including but not limited to food additives, human therapeutics, veterinary products, and medical devices
  - Worldwide use
    - Same model for all product types to all regulatory authorities
  - Out of Scope - Document content

Regulated Product Submission

- Currently working on release 2 of the RPS message
- Next Version of the eCTD will use the RPS exchange message
  - ICH Draft Requirements Review
    - HL7 RPS R2 Development and Requirement Team Leads review draft ICH requirements
    - Most ICH requirements met by RPS R1 & R2
  - ICH meeting the week of June 8th – Next Steps

Regulated Product Submission Standard Release 1 Timeline

- RPS Project initiated June 22nd 2005
  - Leveraged existing Human Pharmaceuticals experience (ICH/eCTD)
- Draft Standard for Trial Use (DSTU)
  - Ballot Passed May 1st 2006
- Testing kick-off June 18th 2006
- HL7 Normative Standard May 2007
- ANSI Standard 2008

RPS Message Capabilities

- **RPS Release 1 provides the capability to;**
  - Standardize submission format/structure
  - Cross-reference previously submitted material owned by the sponsor
  - Handle Submission/Document Lifecycle (e.g.; append, replace, delete)
  - Handle bundled supplements/trans-BLA
  - Correct/modify attributes

Release 2

- Project Approval February 2008
- RPS Project Kick off meeting July 24, 2008
- Project Plan and Schedule on wiki wiki.hl7.org
- Sub-Teams Identified
  - Leadership Team
  - Requirements Team
  - Development Team
  - Testing Team
  - Communication & Education Team
  - HL7 RPS Workgroup
- Phased and Iterative Approach
  - Lifecycle 1 DSTU January 2010

RPS HL7 Release 2 Status

- **Lifecycle One – September 2008 through January 2010**
  - Iteration #1 – Two-way communication / Submission Information
    - Requirements complete
    - Development complete
    - Reviewing Test Case Comments
  - Iteration #2 – Multi-regulator / Multi-Product
    - Requirements
      - Multi-regulator complete
      - Multi-product ongoing – plan is to complete requirements by June 30th
    - Development – Multi-regulator complete
    - Test planning and execution – complete by 8/24/09
  - Iteration #3 – Rework of Iteration #1 and #2 based on testing
    - Iteration 1 & 2 modifications – 8/25/09 – 10/05/09
  - Draft Standard for Trial Use (DSTU) – January 2010
    - Ballot Discussions and Prep – 10/06/09 – 11/27/09
    - Ballot and Reconciliation – 12/28/09 – 1/15/10

RPS Message Capabilities

- **RPS Release 2 will provide the capability to;**
  - Handle two-way communication - standardized message to send regulatory authority (e.g. FDA) correspondence (e.g. request for additional information, meeting minutes, application approval) to the submitter in relation to a regulatory submission
  - Exchange contact information
    - Associate to the submission/submission unit
    - Multiple contacts (e.g. Technical, CMC)
  - Classify submission content/purpose
    - From Sponsor/Applicant (e.g. Meeting Request, New Protocol, Response to Hold)
    - From Regulator (e.g. Information Request, Response to Meeting Request, Approval)
  - Handle Multi-regulator submissions
  - Capture basic product information

Current FDA Implementation Planning

- RPS 2 DSTU - January 2010
- Integration Testing
  - Planning & Industry Coordination 1/2010 – 10/2010
  - Industry Testing 10/2010 – 2/2011
- Production (Dependent on testing outcomes)
  - Pilot 3/2011 – 6/2011
  - Production 9/2011

RPS Release 2 Testing

- HL7 Requirements/Development phase – “Paper” testing
- DSTU Phase
  - Planning (through 10/2010)
    - Work with industry to identify testing partners
    - Identify test scenarios and processes
    - Ensure vendor tools are available
  - Industry Testing (10/2010 – 2/2011)
    - Perform testing
    - Identify issues/questions for implementation
    - Determine if modifications are required to the RPS message

How to Get Involved

- Join the Hl7 Workgroup and/or Subgroup
- Join the HL7 Listserve to receive meeting reminders
- Go to the HL7 wiki for information on the project and project status http://wiki.hl7.org/index.php?title=Regulated_Product_Submissions