Janus

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Overview

• Challenge and Vision
• Janus- Enterprise initiative to improve FDA’s management of standardized structured scientific data

• Data Standards Strategy
  – Exchange Standards
  – Analysis Standards
  – Terminology Standards
The Challenge

• The FDA receives **massive** amounts of clinical research data
  – in extremely disparate formats
  – using a variety of proprietary standards

• This makes it extremely difficult, if not impossible, to do cross-study and application reviews
The Vision

• FDA has been working towards a standardized approach to acquire, receive, and analyze study data

• Standardization of study data is vital to integrate pre-marketing study data and post-marketing safety data to improve public health and patient safety
Janus: Central to the Vision

- Enterprise initiative to improve FDA’s management of structured scientific data
  - Standards-based infrastructure that supports the exchange and management of structured scientific data about the products that the FDA regulates
  - Enhance scientific computing
  - Improve scientific knowledge
  - Inform regulatory decisions
  - Improve public health and patient safety.

- Collection of interoperable databases based on well-defined data standards

- Advanced analytic/data visualization tools
Janus will enable FDA

- Establish an enterprise-wide data architecture and standards to facilitate integration of structured scientific data
- Develop the standards-based scientific data exchange networks to ensure the quality, safety, and efficacy of medical and consumer products
- Create structured scientific data repositories that support the acquisition, validation, integration, and extraction of data from the increasingly large and complex datasets received by the Agency
- Make use of enhanced analytical tools and techniques that enable reviewers to search, model, and analyze data to conduct better safety and efficacy analyses.
*The following depicts a conceptual framework for Janus. The final implementation may change as this conceptual framework is further vetted and refined within FDA. As stated in the PDUFA IT Plan 2008.
Janus Functional Components

Comprehensive logical data model for the scientific data

Set of software tools that can be used to extract, validate, transform, and load scientific data into the Janus database.

Janus Data Model

Set of review tools that are capable of using database data either through the export module’s data views or by direct access to the database.

Data Import

Janus Database

Physical database (or multiple physical databases forming a virtual database) that instantiates all or part of the Janus data model.

Analytical Tools

Set of tools that support the creation and maintenance of views or materialized views of standard analytical data sets for use by review tools.

Data Export and Mart
Ultimate Goal of Janus

• Support and improve the regulatory review process through which the FDA can convert scientific data into useful scientific knowledge to inform its regulatory decisions.
Goals of Data Standard Initiatives

• Standardize data – exchange, analysis, and terminology standards to facilitate data aggregation, analysis, data mining and signal detection
  – Improved access to aggregate data
  – Enables user friendly tools for review

• Support of the FDA Critical Path Initiatives supporting regulatory research
  – Safer, effective products
  – More efficient product development
Data Standards

• Data standards can be divided into three broad categories:
  – Exchange standards
  – Analysis standards
  – Terminology standards
Exchange Standards

- Exchange standards provide a consistent way to exchange information between computer systems in various organizations.
- Exchange standards help ensure that the sending and receiving systems both understand unambiguously what information is being exchanged.
  - That is, to exchange information and understand what has been exchanged (semantic interoperability)
- For data exchange standards, the FDA is working with HL7 Reference Information Model (RIM)
Exchange Data Standard Strategy

- FDA encourages other business experts, such as CDISC, ICH, other government agencies, and international regulatory bodies to model their business requirements to HL7 RIM to ensure interoperability among health information exchange standards.
FDA and HL7

Figure 4: Developing Health Information Exchange Standards within HL7

- FDA Data Council
- CDISC (Research data standards)
- Global Regulatory
- International Regulatory Standards (e.g., ICH, VICH, GHTF)
- CHI/HITSP
- Government healthcare and research standards
- HL7 (International healthcare and research standards)
- ISO TC215
Current Study Data Exchange Standards Activities

- A project in HL7 to develop exchange standards for study data
  - Sponsored by HL7, FDA, and CDISC
  - Approved by the Regulated Clinical Research Information Management (RCRIM) Working Group within HL7 - Fall 2007

- Four standards:
  - Study Design (What will be done?)
  - Study Participation (Who is involved?)
  - Subject Data (What was observed?)
  - HL7 ICSR (expedited AE reporting)

- Covers CDISC content
- Leverages existing HL7 standards (e.g. HL7 ICSR, SPL)
Analysis Standards

• Data analysis standards provide presentations used for evaluation
  – For example, CDISC Study Data Tabulation Model (SDTM) provides presentation for evaluation of clinical safety and efficacy data
Analysis Standard Strategy

- Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTM) standardizes the content for analysis.
  - CDISC SDTM is a view for clinical study data
  - CDER has been accepting SDTM datasets since July 2004
  - CBER is evaluating SDTM in a pilot setting
  - Continued interest in ADaM; awaiting implementation guide
  - Evaluation and Implementation of new analysis tools such as jReview and WebSDM
  - Continued partnership with CDISC to evolve SDTM to support a broader range of products

- Nonclinical requirements will be included in CDISC Standard for Exchange of Nonclinical Data (SEND) model that is being harmonized with the SDTM.
  - CDISC SEND is a view for non-clinical data
  - Phase 2 SEND Pilot is underway in CDER
  - CVM intends to pilot SEND for animal data
  - Gathering requirements in other FDA Centers
Terminology Standards

• Terminology standards provide a consistent way to describe concepts.
  – For example, the Unique Ingredient Identifiers (UNII), developed by FDA, provides a consistent way to describe substances in foods and drugs.
Terminology Strategy

• Ongoing need for development and maintenance of terminology standards to support Janus
• Will continue to work with CDISC, HL7, NIH and other stakeholders on terminology standards
• FDA plans to incorporate all terminology developed into NCI Enterprise Vocabulary Services (EVS)
• FDA anticipates benefits from CDISC SHARE project
Future Exchange and Analysis Standard Strategy

• Vision is to allow users to create analysis views based on study data content
• Study data content exchanged in XML files modeled using the HL7 Reference Information Model (RIM)
The Vision

• Receiving data electronically in a standardized format can
  – Enhance the efficiency and effectiveness of the safety review process
  – Enable the development of standard tools to access, query, and view the tabulations
  – Benefit industry by streamlining the flow of data from collection through submission, and facilitating data interchange within the industry (e.g. between investigators and sponsors)
  – Support the FDA’s efforts to develop a repository for all submitted study data (Janus)
Current Study Data Submission

Biopharma/Device Company

Data Manager

Analytics Server

XPT File

FDA

CDISC SDTM Standard

Reviewer
Future Study Data Submission

1. Exchange Layer
   - Biopharma/Device Company
   - Data Manager
   - Analytics Server
   - HL7 Study Data Exchange Standard
   - HL7 V3 RIM Database

2. Source Layer
   - Janus Database
   - e.g. CDISC SDTM/SEND Views

3. Database Layer
   - Datasets
   - Any

4. Analysis Layer
   - Software Tools
   - Reviewer

5. Tool Layer

6. Review Layer

Reviewer
Concluding Remarks

- Janus: an enterprise initiative to improve FDA’s management of structured scientific data
  - Based on standards to support the exchange and management of structured scientific data about the products that the FDA regulates
  - Enhance scientific computing and knowledge
  - Inform regulatory decisions and improve public health and patient safety

- The FDA is working with the HL7 RIM to develop exchange standards for regulated product structured data
  - Ensures unambiguous exchange of healthcare information (including clinical research information) between computer systems to promote interoperability

- Study data content for creation of SDTM views will be sent to FDA as an XML files modeled using the HL7 RIM

- FDA recognizes an ongoing need for development and maintenance of terminology standards to support Janus and plans to continue to work with CDISC, HL7, NIH and other stakeholders on terminology standards