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Public Meeting

Update on CDISC Study Data Tabulation Model

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Why Standards?

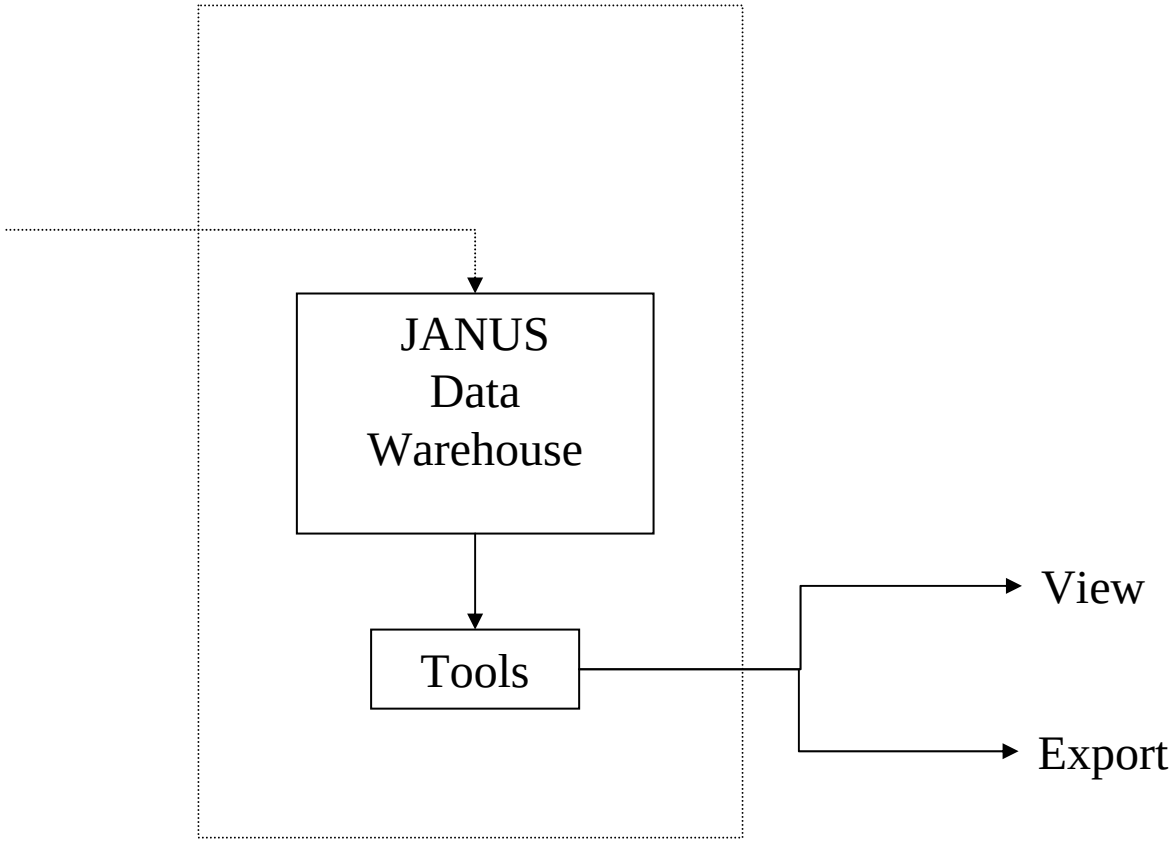
- Improve patient safety and reduced costs by reducing time to market for safe and effective treatments
  - Improve efficiency of evaluation of safety and efficacy of investigational treatments
    - Facilitate communication between regulatory authority and applicant
    - Facilitate development of efficient review environment (e.g., access to data, orientation, redundancy, training, analysis tools)
  - Improve efficiency for clinical research
    - Facilitate design and conduct of clinical trials
    - Facilitate communication between researchers and study sponsor (e.g., between CRO and drug company)
    - Integration with the electronic health record

CDISC SDTM in Health Information Technology Initiatives

- Regulatory electronic submissions
- Critical Path
- Health IT Strategic Framework
- Electronic Health Record
- Others

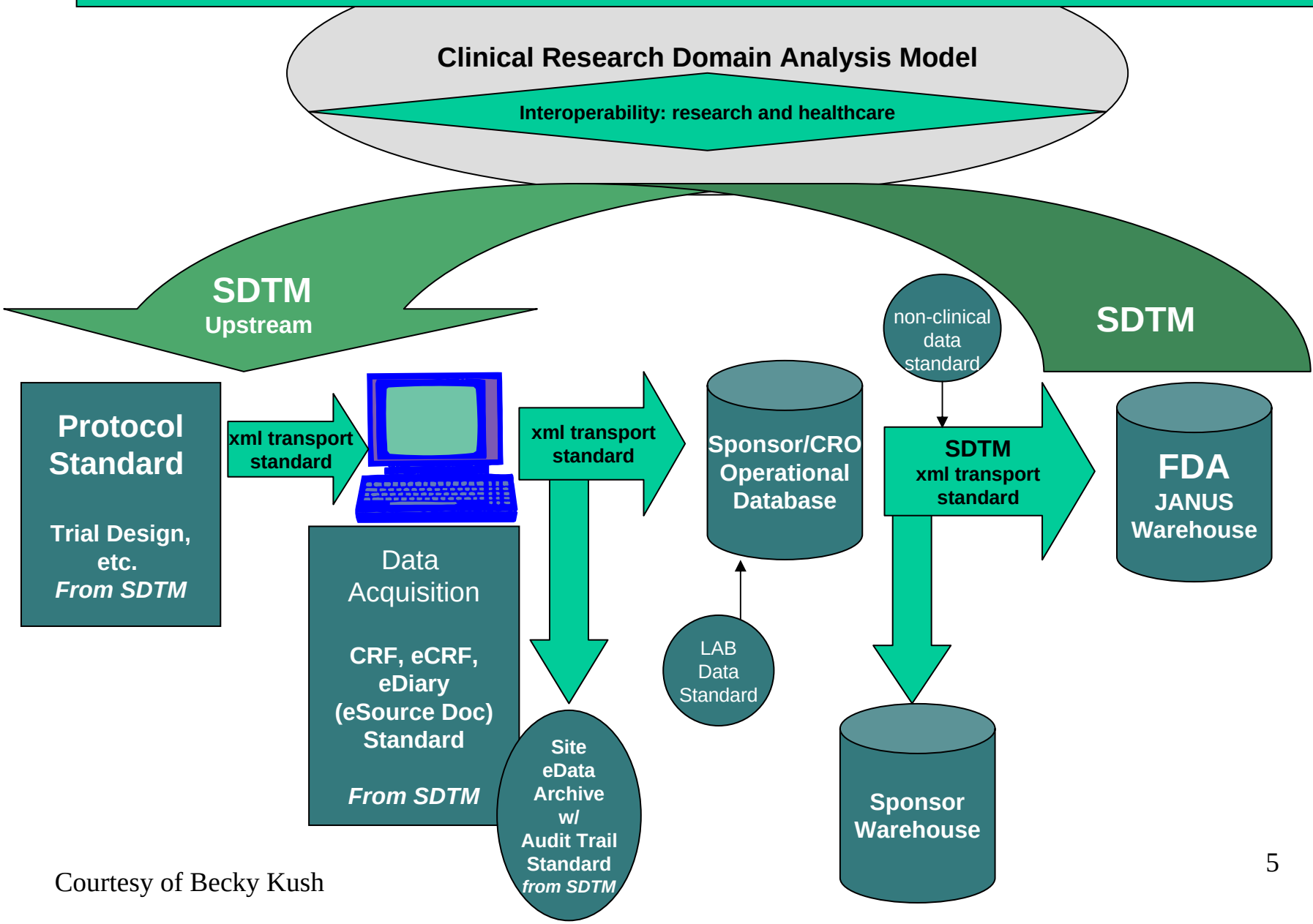
Target
Study Data Environment

SDTM
CDISC/HL7 XML
- Protocol details
- Observations
- Metadata
- Audit trail
- Terminology



Submission **Repository** **Review**

Healthcare Standards – HL7 Electronic Health Record



Courtesy of Becky Kush

Timeline to Target

- Steps
  - Step 0 – No standards
  - **Step 1 – SDTM v3.1← we are here**
  - Step 2 - JANUS and Smart Tools
  - Step 3 – SDTM enhancements
- Timeline dependencies
  - JANUS implementation
  - Smart tool development and implementation
  - SDTM enhancements and associated JANUS and tool enhancements
  - Reviewer requirements

Timeline Dependencies Status

- JANUS
  - Physical database model completed (IBM CRADA)
  - Negotiations to set up database underway
- Smart Tools
  - Patient profile available to work off of SAS XPT files (PPD Informatics - Patient Profiles)
  - SDTM v 3.1 data validation tool available in mid 2005 (Lincoln Technologies - WebSDM)
  - Prototype loader and front end for clinical reviewers (Lincoln Technologies - WebSDM)
  - Viewing tool for pharm/tox under development (PharmQuest - ToxVision)
  - Loader, viewing and export tools from JANUS under development
  - Terminology server (NCI Enterprise Vocabulary Services)

Timeline Dependencies Status

- Exchange format
  - Metadata exchange format available 2005 (CDISC Define.xml)
  - Data, metadata and audit trail transport format under development (CDISC/HL7 XML)
- SDTM enhancements
  - Terminology under development (FDA, NCI, CDISC, HL7)
  - Additional protocol details under development (FDA, CDISC, NIH, HL7)
  - Analysis variables under development (FDA, CDISC)
  - Implementation guides under development - Animal Tox (FDA, CDISC/SEND), Microbiology (FDA, CDISC), Pharmacokinetics (FDA, CDISC)
- Reviewer requirements
  - Training on SDTM implementation guides, define.xml
  - Training as tools become available

Recommendations

- Provide SDTM v 3.1 datasets
- Discuss the need for additional datasets with the reviewers by discipline
  - Pharm/tox
  - PK/PD
  - Micro
  - Medical
  - Statistical

Requirements

- HHS Regulatory Agenda - inventory of all rulemaking actions under development or review (December 2004 Federal Register – 69 FR 73119)
  - Submission of Standardized Electronic Study Data from Clinical Studies Evaluating Human Drugs and Biologics
    - Proposal would revise FDA regulations to require clinical study data to be provided in electronic format and require the use of standard data structure, terminology and code sets.
  - Legal authority: 21 USC 355; 21 USC 371: 42 USC 262
  - CFR Citation: 21 CFR 314.50; 21 CFR 601.12; 21 CFR 314.94
  - Timetable
    - Action – NPRM
    - Date – June 2005

Agenda

- 8:30 - FDA Plans for Implementing SDTM - Randy Levin
- 8:55 - Current Status of the CDISC SDTM and enhancements - Wayne Kubick
- 9:20 - Current State of Trial Design Model - Diane Wold
- 9:40 - Applying the SDTM for non clinical and PK: Sponsor Perspective - Fred Wood
- 10:00 - Break
- 10:20 - SDTM Submission: Sponsor perspective - Bill Qubeck
- 10:50 - Implementing SDTM -Tom Guinter and Dan Godoy
- 11:30 - Applying SDTM for the JANUS Data Warehouse - Norman Stockbridge
- 12:00 - Lunch
- 1:00 - FDA reviewer perspective – Medical Officer - Armando Oliva
- 1:30 - FDA reviewer perspective – Pharm/Tox reviewer - Tom Papoian
- 1:50 - FDA reviewer perspective – Statistician - Steve Wilson
- 2:30 - Break
- 2:40 - Q&A Panel Discussion - All speakers