CDISC HL7 Project

FDA Perspective

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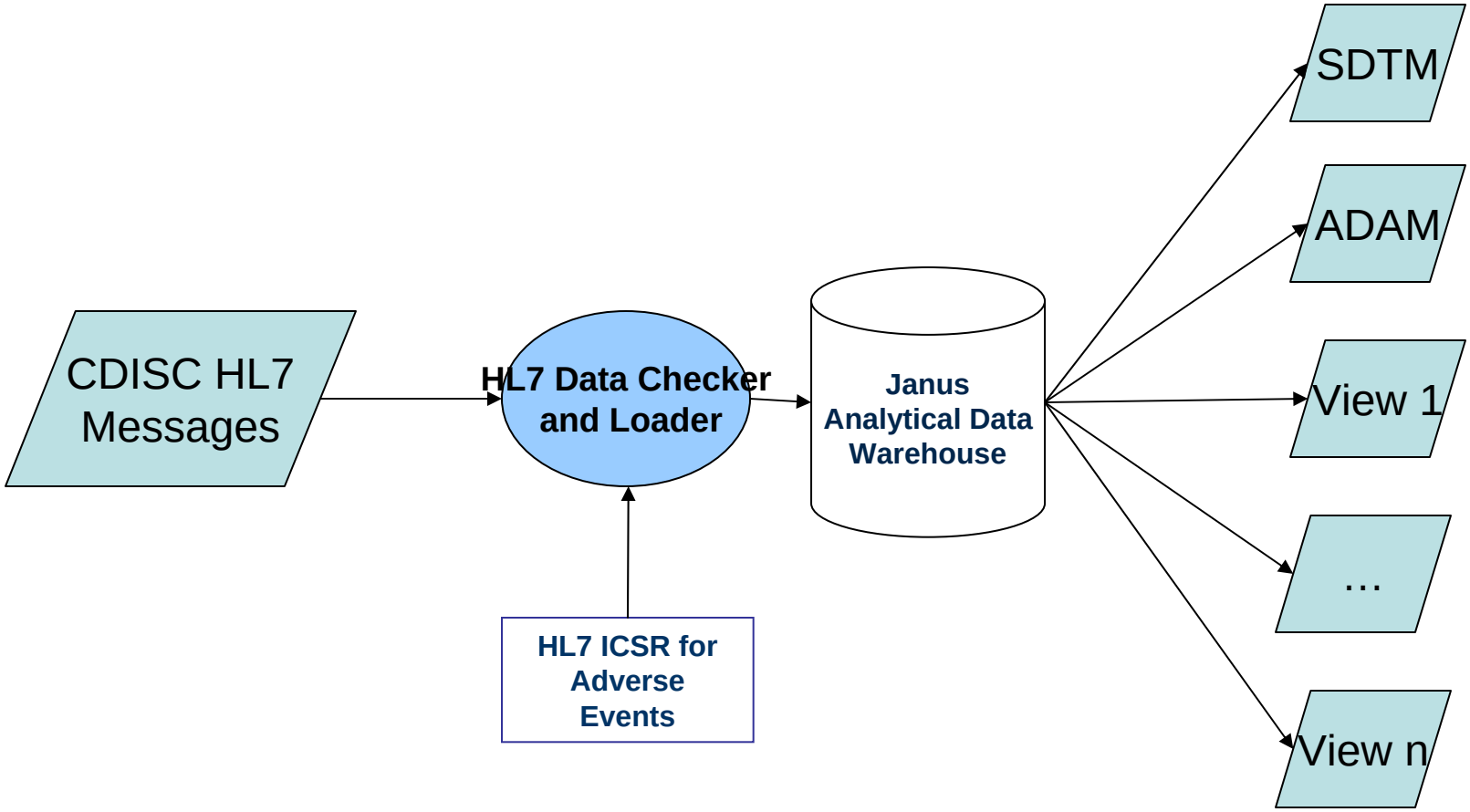
FDA's Strategic Plan

- Use HL7 exchange standards for all data submitted to FDA
  - CDISC HL7 project part of FDA strategic initiatives to improve public health and patient safety

FDA Goal


CDISC HL7 Messages
HL7 Data Checker and Loader
Janus Analytical Data Warehouse
HL7 ICSR for Adverse Events
SDTM
ADAM
View 1
…
View n

Why HL7?

- Exchange format of choice for health care information
  - ANSI accredited, open, consensus based Standards Development Organization
  - Integration with health care related exchange standards and mandates
    - Reference Information Model (HL7 version 3)
    - Electronic Health Record
    - Consolidated Health Informatics
    - Healthcare Information Technology Standards Panel
    - Health Insurance Portability and Accountability Act
  - Integration with other FDA HL7 standards
    - Individual Case Safety Report
    - Structured Product Labeling
    - Regulated Product Submission
    - Product Stability Data

Why CDISC?

- Defines content for research data
  - Open, consensus based standard development organization
    - Liaison Status A with ISO TC 215
    - Charter Agreement with HL7
  - Protocol information and observations from research studies
    - Study Data Tabulation Model
    - Standard for Exchange of Non Clinical Data
    - Analysis Dataset Model
    - Trial Design Model
    - Laboratory Data Model
    - Operational Data Model
    - Define.xml
    - Production Controlled Terminology (with HL7 RCRIM, FDA and NCI)
    - Developing Acquisition Standards (CDASH)
  - Initiated BRIDG model

CDISC HL7 Project

- Based on HL7 Reference Information Model
  - Leverages existing HL7 standards (e.g., EHR, ICSR)
- Contains CDISC content
- Harmonized with the BRIDG
  - Initial requirements gathered from the BRIDG analysis project.
  - Additional requirements identified during development incorporated into the BRIDG

CDISC HL7 Project
FDA Use Cases

- What is going to be done in the study?
  - Example FDA use case
    - Investigational application new Protocol submission
- Who is involved in the conduct of the study?
  - Example FDA use case
    - Investigational application annual report
    - Marketing application study report
- What was observed during the study?
  - Example FDA use case
    - Marketing application study report
    - Investigational application expedited adverse event reports
- What expedited adverse reactions were reported?
  - Example FDA use case
    - Expedited adverse event reports

CDISC HL7 Project Standards

- *Study Design*
  - What is going to be done?
- *Study Participation*
  - Who is involved in the conduct of the study?
- *Subject Data*
  - What was observed during the study?
- *Individual Case Safety Report*
  - Study AE Reports

CDISC HL7 Project Proposed Organization

Standard	Reference	Information	Use
Study Design	•CDISC SDTM/CDASH •HL7 Clinical Statement CMET •Clinical Trial Enrollment •HL7 SPL| •define.xml	•Encounters (Visits) •Interventions •Observations (Assessments) •Inclusion Criteria •Study Characteristics	•Study Protocol •Clinical Trial Registry
Study Participation	•CT Lab •Clinical Trial Enrollment •define.xml	•Sites •Investigators •Subjects	•Add/changes to participant information •Annual reports •Study result submission
Subject Data	•CDISC SDTM •ADaM •Clinical Statement CMET •ICSR •SPL •define.xml	•Encounters •Interventions •Observations •AE •Link to Trial Design	•Study result submission
ICSR	•SPL	•AE Reports	•AE reporting

Summary

- Improve data management (Janus)
- Leverages
  - HL7 version 3 Reference Information Model to allow compatibility with other HL7 standards
  - CDISC standards for content (SDTM)
- Proposed CDISC HL7 Project supports FDA use cases

Next Steps

- Initiate CDISC HL7 Project
- Continue BRIDG Harmonization

Proposed Timeline*

	Phase, Major Deliverable, Activity or Milestone	Date
	Create Project Charter	October 16, 2007
	Create storyboards (iterative process)	Sept 07 - Jan 08
	Create CIM from BRIDG / HL7 artifacts (iterative process)	Sept 07 - Jan 08
	BRIDG harmonization (iterative process)	Jan 08 - Feb 08
	Prepare ballot documentation	Dec 07 – Feb 08
	Quality verification to go to DSTU ballot	February 2008
	Conduct DSTU ballot (work with Publishing Committee)	March 2008
	DSTU Ballot reconciliation	May 2008
	Quality verification to go to Normative ballot	October 2008
	Conduct Normative ballot (work with Publishing Committee)	November 2008
	Normative Ballot reconciliation	January 2009

* Preferably, all messages developed concurrently