PDUFA IV
Information Technology Plan

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Outline

- What is the PDUFA IV IT Plan?
- What does it say?
- How can CDISC and FDA work together to achieve success?
What is it?

- Rolling 5-year plan
  - how FDA will automate business processes and develop IT systems to support other PDUFA IV performance goals
- Published early Jan 2008 in draft
- Public Comment period now closed
- Finalize by May 2008
- Updated Periodically
- Helps industry align their IT investments with those of the Agency
How did it come about?

- From PDUFA and the PDUFA IV Goals Letter
- PDUFA – Prescription Drug User Fee Act
  - “fee for service”
  - Re-authorized in 2007 for another 5 years – PDUFA IV
  - FDA “services” are described in the PDUFA IV Goals Letter → letter from Secretary of HHS to Congress
PDUFA IV Goals Letter

FDA agrees to meet certain I.T. goals:


1. FDA will develop and periodically update a five-year IT plan for improving the automation of business processes and acquiring and maintaining information systems to achieve the objectives defined above in PDUFA IT Goal A. The plan will include measurable or observable milestones toward achievement of those objectives.

2. The IT plan will be reviewed and approved through the appropriate FDA governance process to ensure it conforms to the Agency’s overall long-term automation strategy.

3. The IT plan will be drafted, published on the FDA web site, and updated as follows:
   a) FDA will publish a draft of the IT plan by December 31, 2007. At that time, FDA will solicit and consider comments from the public on the draft IT plan. The public comment period will be at least 45 calendar days. FDA will complete revisions to the IT plan and publish the final version no later than May 30, 2008.
   b) FDA will conduct an annual assessment of progress against the IT plan and publish on the FDA web site a summary of the assessment within 2 months after the close of each fiscal year.
   c) FDA will publish updates to the IT plan as FDA deems necessary to achieve the objectives defined in PDUFA IT Goal A. FDA will publish on the FDA web site draft revisions to the IT plan; solicit comments from the public on those draft revisions; and consider the public comments before completing and publishing updates to the IT plan.
What does it say?

http://www.fda.gov/ohrms/dockets/dockets/07d0481/07d0481.html

☐ 37 pages
- Introduction
- Purpose
- Vision
- Goals and Objectives
- PDUFA IV IT Strategy
- Programs (Pre-market, Post-market)
- Appendices (actual Projects / Initiatives)
Projects Related to CDISC

- Proposed Rule: Submission of Standardized Electronic Study Data from Clinical Studies Evaluating Human Drugs and Biologics

- Data Standards (p. 23):
  - CDISC for standardized clinical and non-clinical study data content (semantics)
  - HL7 XML for standardized exchange format for all structured regulatory product data (syntax)

- FDA CDISC Communications Team (p. 23) – ensure that CDISC standards meet FDA scientific requirements
Target Data Flow (p. 23)

The diagram illustrates the flow of data from Site to Sponsor, involving various components and tools such as CDISC Content and Interchange, MedWatch AE Reports (ICSR), Sponsor Data Warehouse (ODM), Trial Design, Data Checker and Loader, FDA Reviewers, and Review Tools. The flow includes interactions with CDASH, CDISC, SDTM ADaM, and HL7 output files.
Projects

- CDSIC-HL7 Project – HL7 XML messages for CDISC content
- BRIDG
  - Harmonize all CDISC content in BRIDG
- Janus – study data warehouses (NCI, NCTR)
  - Phase 3 pilot: loading more data, standard terminology/NCI EVS, test loading of CDISC-HL7 messages
  - SEND Phase 2 pilot: accept, load nonclinical data into NCTR Janus
- eCRF Pilot (ODM) – develop ODM eCRF viewer
- CDASH – FDA playing a supporting role
CDISC – FDA Collaboration
Key to Success

- CDISC-FDA Communications Team
  - Enhance/Improve SDTM
  - SDTM critical for the development of standard analytic algorithms and review tools of the future
  - Need more and more consistent FDA involvement in CDISC processes

- Continued FDA-CDISC joint involvement in HL7 and BRIDG

- CDISC Support for ongoing FDA projects and pilots – much appreciated
  - FDA Staff Training Efforts – very popular!!