FDA PDUFA IV IT Initiatives

	A	B	C	D	E	F	G	H	I	J	K	L	M
1	**Initiative Type**	**Name**	**Description**	**Goal**	**Release**	**1q 08**	**2q 08**	**3q 08**	**4q 08**	**1q 09**	**2q 09**	**3q 09**	**4q 09**
2	Standard	BRIDG Model	The Biomedical Research Integrated Domain Group, BRIDG Model, is a domain analysis model representing protocol-driven biomedical/clinical research. The BRIDG Model is a collaborative effort of stakeholders from the Clinical Data Interchange Standards Consortium (CDISC), the HL7 Regulated Clinical Research Information Management Technical Committee (RCRIM TC), the National Cancer Institute (NCI) and the FDA to produce a shared view of the dynamic and static semantics that collectively define the shared domain of clinical and pre-clinical protocol-driven research and its associated regulatory artifacts. To date, content has come from the following: SDTM, caXchange, RPS, CTOM, TDM.	Any content identified as part of the CDISC - HL7 Project will be harmonized with the BRIDG Model in coordination with the BRIDG scheduled releases.										
3	Standard	CDASH	CDISC CDASH (Clinical Data Acquisition Standards Harmonization) - The project goal is to develop a set of "content standards" (element same, definition, and related	The next steps are for the CDASH project team to assemble the comments on each of the 4 packages. After there is agreement on		x							
4	Standard	CDISC - HL7 Project	The FDA plans to transition to HL7 exchange messages for submission of all study data. To identify HL7 exchange message content for submission to a regulatory authority that	The FDA is proposing the development of four messages that map to content areas: 1. Study design, 2. study participation, 3.									
5	Standard	CDISC ADaM	The ADaM datasets are designed to provide a clear and unambiguous communication of the content, source and quality of the datasets supporting the statistical analyses performed in a clinical study. They provide a standard for transferring analysis datasets between sponsors and FDA.	No goals listed									
6	System	CP	The Collaboration Portal will provide a web-based collaboration platform where applicants and the FDA can review and negotiate SPL-based labels. This online collaboration should enhance the FDA's ability to approve final labeling at the time of the application approval.	Prototype will be tested by FDA and industry users starting January 2008. If approved by business stakeholders, Release 1.0 will be in Production late 2nd quarter of 2008. A CRADA initiative.	1	x	x						
7	Standard	eCRF Pilot	The purpose of the eCRF pilot project is to obtain experience with the CDISC Operational Data Model (ODM) based CRFs, with the goal of replacing the existing portable document format (PDF)-based CRFs derived from clinical trials that use EDC and, therefore, lack paper CRFs. A successful pilot will	The Agency is seeking sponsors willing to provide CRFs in ODM format to test our capabilities to review these files. However, data supplied during the pilot project will not replace any regulatory requirements for									
8	System	eCTD Review System	...allows reviewers to review submissions submitted in the ICH eCTD format. Provides search capabilities and reviewers are able to track the progress of the eCTD submission review at the section level. Includes a validation component that provides a log of the submission errors. The latest release provides the FDA with the capability to integrate the eCTD review system with the CBER and CDER submission tracking databases.	In relation to the RPS strategy, the FDA plans on using the eCTD review system to review RPS based submissions.		n/a	n/a	n/a	n/a				

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9	System	EDR	Common Electronic Document Room. Intended to establish one common, Agencywide, standards-based EDR as a single platform database for all FDA-regulated product documents. Having a single platform will improve access to all FDA documents, data, and metadata across center lines, thus enhancing the ability of Agency pre-market reviewers and others to perform their jobs. ... offers the opportunity to reduce redundancy and related costs and complexities associated with maintaining multiplc electronic document	Current activity is to define the scope of the Common EDR.		x							
10	System	EDR		Development and Testing of the Common EDR Functionality -4" quarter of 2008.					x				
11	System	EDR		Full Implementation -3d quarter of 2009								x	
12	System	Electronic Labeling Review System	Receives and processes electronic labeling information through the Structured Product Label (SPL) standard format. The labels	Interface with the workflow and information management system to access (migrated)		?	?	?	?				
13	System	Electronic Labeling Review System		Address the system performance issue		?	?	?	?				
14	System	Electronic Listing	Will provide the ability to automate drug listing information and validation processes. The SPL data elements from the labels will be extracted and reused. The listing information will be available to the public through DailyMed and other electronic means.	Prototype will be tested by FDA and industry users starting in 1st quarter of 2008. If approved by business stakeholders, Release 1.0 will be in Production in 2nd quarter of 2008. A CRADA initiative.	1	x	x						

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15	System	E-platform	A common electronic platform for the exchange of clinical research data (i.e.the data normally collected during the course of a clinical trial, as well as the submission, receipt, and management of regulatory product information). A public-private partnership.	Finalize strategy in the first quarter of 2008 in conjunction with NIH and NCI		x							
16	System	ESG	Electronic Submission Gateway. An FDA-wide solution that enables the secure submission of electronic regulatory submissions has been in production since May 2006, the ESG provides the single point of entry for the receipt and processing of all PDUFA submissions. Both CBER and CDER fullv automated the electronic submission process by implementing automated systems to expedite the processing and increase the availably of properly formatted ESG submissions. The electronic submission process encompasses the receipt, acknowledgment of receip; and any processing errors (to the sender), routing, notification (to a receiving Center or Office), and providing access to the review team of the electronic submission.	In the 1st quarter of 2008 the FDA plans to upgrade the ESG, by providing a method to include the Center & Submission Type attributes in the AS2 Routing ID. This upgrade will enable the FDA to phase out the AS I submission method for drug safety reporting.		x							
17	System	ESG		As stated in the PDUFA IT Goals, the FDA will extend the capability of the secure single point of entry to include two-way transmission of regulatory correspondence. The FDA has had preliminary planning discussions on expanding the ESG functionality to meet this goal. The FDA does not plan on expanding the ESG functionality in 2008		n/a	n/a	n/a	n/a				

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18	System	Facts@FDA	The Facts@FDA program is part of the broader US effort to achieve electronic prescribing and other e-health infmation technology inttiatives: ELIPS, e-List, CP, and SRSID	[No goals listed]									
19	System	FIREBIRD	Federal Investigator Registry of Biomedical Informatics Research Data, is a partnership between the National Cancer Institute (NCI) and the FDA to create an infrastructure to	Begin requirements gathering for FDA functionality		?	?	?	?				
20	System	ICT21	Information and Computer Technologies for the 21st Century investment will enable the FDA, through the development of an Agency-wide bioinformatics initiative, to strengthen product development and approval, improve manufacturing and product quality, strengthen post-approval surveillance and safety support electronic prescribing, and improve clinical decision support. The FDA expects to see mature electronic health records, personal health records, and networks that connect them. To meet these challenges and requirements, the FDA must modernize its capacity and communication capabilities by establishing a standardized approach for delivering IT services through this Agency-wide bioinformatics initiative to fulfill its core public health responsibilities and respond to emerging challenges.	1.Establish and implement Program Management Office, 2. Complete detailed Alternatives Analysis, 3. Complete Phase 2 of Bioinformatics Transfer Plan, 4. Complete Bioinformatics design, 5. Complete First Phase of Bioinformatics Platform migration.		?	?	?	?				
21	Standard	JANUS Data Warehouse	The JANUS data warehouse for both animal and human study data is being developed by NCI with the FDA participating through its Interagency Oncology Task Force activities. The NCI and the FDA are collaborating to implement a common, standards-based electronic infrastructure for regulatory data and document submission, review, and analysis. The standard for the submission of study data for Janus is the CDISC Study Data Tabulation Model (SDTM) which includes the standard for animal toxicity data being developed by CDISC's SEND Team. SEND data is designed to work with data viewer (ToxVision) developed through a CRADA with PharmQuest, Inc. (PharmQuest is now Pointcross).	Plan for and implement a Phase 3 pilot that includes extensions of the Janus logical data model and a service-oriented architecture designed to support the submission of HL7 messages and leveraging of NCI's Enterprise Vocabulary Service (EVS) to begin to address controlled vocabulary issues.									
22	Standard	JANUS Data Warehouse		Establish two-way data exchange between FDA and NCI using FDA's electronic gateway.									

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23	Standard	JANUS Data Warehouse		Have the CDISC-HL7 messages completed and accepted as HL-7 draft standards for trial use Draft Standard for Trial Use (DSTU).									
24	System	MedWatch	The MedWatch initiative will enable the FDA to improve the timeliness, accuracy, and usability of its product safety surveillance data by significantly reducing delays and errors associated with manual data entry and coding of paper reports. It will provide a user-friendly internet portal for anyone to report an adverse event resulting from a FDA-regulated product. The portal will be supported by an Agency-wide repository of adverse event reports (FAERS) with integrated safety signal management and analytical tools.	1.Complete MedWatch requirements definition. 2. Award MedWatch integration contract., 3. Select FAERS COTS toolset. 4. Rollout CDER/CBER FAERS release. 5. Rollout CDRH/Office of Combination Products release. 6. Complete MedWatch Plus portal. 7. Integrate MedWatch portal with FAERS									
25	System	RPS	Regulated Product Submission. A health level seven (HL7) standard to facilitate the processing and review of regulated product information. The next generation of processing the eCTD format will be transitioned to the RPS standard. The FDA plans on using the RPS standard to meet the PDUFA goal to cross reference to previously submitted electronic materials through standardized automated links and to standardize the two-way communication between the sponsor and the FDA by incorporating these requirements into RPS Release 2.	Implement/accept RPS submissions in the first quarter of 2008 for: 1. SPL submissions to paper/NDA/BLA, 2. Electronic datasets to a paper IND/NDA/BLA, and 3. Single Investigator IND.	1	x							
26	System	RPS		RPS Release 1 HL7 Implementation Guide ready for ballot in 2" quarter of 2008.	1		x						
27	System	RPS		Target for addressing PDUFA requirements RPS DSTU Release 2 -HL7 ballot 3d quarter of 2008.		2		x					
28	System	RPS		The Office of Combination Products (OCP) is finalizing the common format for cambination product submissions. Leveraging the CTD format and the PMA & 5lO(k) submission formats. The goal is to complete the submission format in the first quarter of 2008 and to test the submission format in 2008.	1	x	x	x	x				
29	System	RPS		CDRH has defined the submission format for Premarket Approval (PMA) and Premarket Notification 510(k) applications and plans on testing the RPS standard during 2008.	1	x	x	x	x				

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30	System	RPS		CFSAN is currently working on guidance for Food Additive Petition and Color Additive Petition submissions and plans on testing and accepting production submissions in	1	x	x	x	x				
31	Standard	SEND	Standard for Exchange of Nonclinical Data. CDER is conducting a pilot project to test, in a regulatory setting, the electronic submission of nonclinical study data using the CDISC Standard for Exchange of Nonclinical Data (SEND). The purpose of this pilot is to test the ability of a new electronic data format to support nonclinical review activity. The pilot also will involve a collaboration of FDA, available pilot participants, and the SEND team to update and create a new draft SEND implementation guide that will harmonize SEND with SDTM. FDA anticipates that a successful pilot will enable CDER to routinely accept nonclinical study data electronically in SEND format instead of paper or PDF in INDs, NDAs, and biologics licensing applications.	Long term goal of replacing the existing paper/PDF based listings on fonclinical study data. The Phase 2 pilot will include animal toxicity studies. Additional nonclinical study types may be included in the future.									
32	System	Sentinel	Sentinel System - The FDA, in coordination with other Federal agencies, recommends assembling an integrated "virtual" national medical product safety system - the Sentinel System -- which would enable the electronic flow of safety information to and from the point of care. The system will build on existing public and private efforts through multiple, broad-based, public-private collaborations.	Strengthen capability to draw data from sources like electronic health records and medical claims. Establish the ability of the FDA to query other systems quickly and securely for relevant product safety information. Establish methodologies to use Sentinel data to support epidemiology and other safety studies.									
33	System	Substance Registration System	The overall purpose of the joint FDA/USP Substance Registration System is to support health information technology initiatives by generating Unique Ingredient Identifiers (UNII) for substances in drugs, biologics, foods and devices. The UNII is a non-proprietary, free, unique, unambiguous, non-semantic, alphanumeric identifier based on a substance's molecular structure and/or descriptive information.	Interface with the workflow and information management system (release 2.0) to access (migrated) Drug Master File.		?	?	?	?				
34	Standard	Terminology	Terminology binding and RIM harmonization will be done followi& the HL7 Development Framework and applicable stakeholder processes	No goals listed									

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35	System	Workflow tracking and information management system	Is a flexible, integrated, fully electronic workflow tracking and information management systems to receive, log, track, assign, process, and manage official submissions with internal	Release 2.0 on 11/13/2007, for all CDER INDs, Master Files and Emergency Use Authorizations plus system enhancements	2	n/a							
36	System	Workflow tracking and information management system		Release 3.0 end of 2008 for all CDER NDAs and ANDAs.	3				x				
37	System	Workflow tracking and information management system		Release 3.x after 2008 for CBER and CDER BLAs.	3x					?	?	?	?