#	Project Name and Description	Strategy / Milestones	Status as of May 2008	Current Status
1.	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) **POC:** Alfred Kempski / Sandra Benton	A strategy to support e-platform development over the long-term is being developed in collaboration with the NIH and the NCI. Finalize the MOU between FDA/NCI and CRIX International. Begin the FIREBIRD demonstration project.	In March 2007 the FDA and NIH jointly issued a request for information (RFI) on the formation of a public-private partnership whose goal it would be to establish and maintain the e-platform (http://www.fbo.gov/servlet/Solicitation/R/HHS/FDA/DCASC/e-Platform-RFI). Public comments and responses to the RFI have been reviewed. FDA and NCI will pursue a demonstration project in collaboration with CRIX International to test the e-platform concept. The demonstration project will be a production system for FIREBIRD (see below) and will include an assessment of the viability of the e-platform concept for other types of clinical research and regulatory product information exchange.	• MOA between FDA, NCI and CRIX was finalized and published in the Federal Register on October 1, 2008 to establish a public-private partnership to pilot the use of a nonprofit organization to manage the production instance of FIREBIRD. • A contract to evaluate the business needs of the Agency and outside stakeholders for an ePlatform was posted on FedBizOps and awarded in September 2008. • A needs assessment is in progress. The report of the business needs of the Agency and outside stakeholders for an ePlatform will be finalized in May 2009. A public version will be released thereafter.
2.	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 support the electronic dissemination of clinical research information. FIREBIRD enables investigators to register online with clinical trial sponsors, allows sponsors to electronically maintain and manage 1572 registrations, and eliminates the paper-based, manual process for 1572 forms by providing the FDA with electronic access to the information. **POC:** Alfred Kempski / William Taylor	Complete harmonized FDA requirements for CDER, CBER and CDRH. Functionality includes 1572 data extraction, inspection data entry, query and reporting capabilities, integration with Center application tracking systems, and data migration from existing clinical investigator and bioresearch monitoring systems. 3rd Quarter, 2008 Finalize the MOU Create a project team, define roles, and develop a project plan 4th Quarter, 2008 Design the pilot platform Review and finalize FDA requirements	Pilot completed and limited production implementation in 2007, for NCI/Division of Cancer Prevention DCP and investigator community. Completed draft of harmonized FDA requirements for CDER, CBER and CDRH in 4th quarter 2007. Completed draft of MOU between NIH/NCI, FDA and CRIX International for application and database development, platform design and hosting.	A contract has been let to identify viable business models by FY10. For FIREBIRD, the development of the demonstration project in collaboration with FDA, NCI and CRIX to test the ePlatform is ongoing (see below). The demonstration project will be a production system for FIREBIRD and will include an assessment of the viability of the e-Platform concept for other types of clinical research and regulatory product information exchange. • Completed MOA between NIH/NCI, FDA and CRIX International for application and database development, platform design and hosting in 3rd quarter CY 2008. • Identified project team 3rd quarter CY 2008. • Designed pilot platform 4th quarter CY 2008. • Project approved by FDA's Pre-Market BRB and BioInformatics Board (BiB) in 1st quarter CY 2009. • Demonstrated basic registration software to project team in 1st quarter CY 2009.
3.	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. **POC:** Randy Levin	Prototype will be tested by FDA and industry users starting January 2008. FDA will evaluate the results of the prototype UAT in Q2 2008.	Requirements completed CRADA partner delivered prototype. User Acceptance Testing (UAT) by FDA and industry is underway.	• Continue to evaluate next steps. Functionality needs to be extended to a more holistic strategy.

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4.	Regulated Product Submission, RPS, is 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. Release 2 will incorporate the following requirements; • Two-way communication o Minutes and general correspondence (related to two-way communication) including pre-submission information • Referencing o in backbone (Master Files, Other submission/application, Pre-submission) o Hyperlink content to other content • Provide information about the submission (e.g. information currently collected on application forms) o information about the product o Contact Information As of January 1, 2008 CDER only accepts electronic submissions in the eCTD format. To facilitate the transition to the CTD format FDA will start accept CTD submissions based on the RPS standard for a limited set of submissions. These submissions have been part of a paper submission with the electronic portion submitted in the eNDA format. Applicants and sponsors will be permitted to submit RPS using the CTD format for the following types of submissions; • SPL to a paper NDA/BLA • Electronic datasets to a paper IND/NDA/BLA • Single Investigator IND FDA will provide applicants/sponsors access to web-based forms to create and submit the submission types above. This strategy will allow the PDUFA program to start to transition to the RPS standard and permit current applicants/sponsors using the eNDA format or paper to move to the CTD format. **POC:** Alfred Kempski / Mark Gray	Implement/accept RPS submissions in the 2nd Quarter of 2008 for: o SPL submissions to a paper NDA/BLA o Electronic datasets to a paper IND/NDA/BLA o Single Investigator IND Target for addressing PDUFA requirements RPS DSTU Release 2 – HL7 ballot 2nd Quarter, 2009. Test RPS Release 2 submissions with completion of the testing targeted for 2nd Quarter, 2010. Develop PDUFA RPS Implementation Guide and modify standard (based on test results) with completion targeted for the 4th Quarter, 2010. Target for accepting RPS Release 2 submissions in the 2nd Quarter, 2011.	HL7 RCRIM Approval, May 2008, of the RPS Release 1 Implementation Guide as a HL7 Informative Document. HL7 approval of the RPS release 2 project, with PhRMA and FDA co-sponsorship.	**HL7 RPS R2 Status:** HL7 RPS2 timeline approved with the requirements gathering divided into three iterations. The timeline for RPS Release 2 DSTU was moved from the 2nd quarter CY 2009 to the 1st quarter of CY 2010 (January 2010). Iteration 1 Status (Two-way communication / submission information). • Completed requirements and development. • Currently finalizing test case to move into testing of the Iteration 1 requirements. Iteration 2 Status (Multi-regulator / Multi-product). • Requirements and development completed for multi-regulator. • Need to address how to handle multi-product requirements. **FDA Projected Implementation Timelines:** • Develop PDUFA RPS Implementation Guide – 4th quarter CY 2010. • Conduct RPS2 pilot – 1st quarter CY 2011. • RPS2 production – 4th quarter CY 2011.

#	Project Name and Description	Strategy / Milestones	Status as of May 2008	Current Status
5.	The FDA Electronic Submissions Gateway (ESG), 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 fully 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 receipt 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. **POC:** Michael Fauntleroy	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 this area in 2008. Depending on the progress garnered as well as the uptake by interested parties, the FDA could expand the ESG in several areas during 2008. Begin planning for testing of VAERS infrastructure capability. Begin limited testing in support of the use of the SPL standard version 4 for registration and listing.	In FY2007, the ESG received and processed over 147,000 pre-market and post-market submissions. Most of these submissions were post-marketing safety reports, during the last six months of FY2007 the ESG was processing over 13,800 post-market safety reports per month. In the pre-market area, the ESG was averaging over 1100 submissions per month. Information on the ESG process and requirements is at: http://www.fda.gov/esg. The FDA upgraded their software to provide a method to include the Center & Submission Type attributes in the AS2 Routing ID. This upgrade will enable the FDA to decrease support cost and the cost on behalf of Industries to migrate to the more robust AS2 standard for AERS reporting. This upgrade enabled FDA to phase out the AS1 submission method for drug safety reporting on March 1, 2008. The FDA is currently planning to upgrade their production system software to version 5.5.2 – 3. FDA successfully upgraded the ESG pre-production environment to version 5.5.2_3 of Axway Interchange on April 12, 2008. The Axway Activator software was upgraded and tested before that date. We will continue to engage in testing as well as monitoring of the pre-production environment. After one month of testing and monitoring the new software versions will be mounted in the production environment. Axway software version 5.5.2_ 3 addresses almost all of the un-addressed FDA concerns with the original Axway software package. At present the keep alive issue with the Axway software has not been rectified in the latest enterprise release. The FDA is working with the sponsor to address this issue. Once this item has been addressed, work a rounds will no longer be needed to deliver a stable and dependable service. The FDA is presently working with the CDC and their vendor Constella/SRA to develop and implement a receipt, store, and forward paradigm for electronic VAERS reporting. The plan is to deliver this capability in late 2008 early 2009. Additional discussions regarding capabilities and timeline with Constella/SRA/CDC are ongoing. Delivered the infrastructure piece necessary to support the use of SPL version 4 for registration and listing.	In CY 2008, the ESG received and processed approximately 300,000 pre-market and post-market submissions. Many of these submissions were post-marketing safety reports; during CY 2008 the ESG was processing over 21,000 post-market safety reports per month. In the pre-market area, the ESG was averaging over 2,750 submissions per month. Information on the ESG process and requirements are located at: http://www.fda.gov/esg. • The FDA is currently planning to upgrade their production system software to version 5.5.2 – 3. • FDA successfully upgraded the ESG pre-production environment to version 5.5.2 - 3 of Axway Interchange on April 12, 2008. The Axway Activator software was upgraded and tested before that date. We will continue to engage in testing as well as monitoring of the pre-production environment. • We have run into a series of issues with the Axway enterprise software. We are actively discussing the issues with the Axway enterprise software in an attempt to resolve the anomalies experienced with their enterprise software.

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6.	eCTD review system – The current FDA eCTD review system was implemented in 2005, and allows reviewers to review submissions submitted in the ICH eCTD format. The review system provides search capabilities and reviewers are able to track the progress of the eCTD submission review at the section level. The eCTD review system functionality includes a validation component that provides a log of the submission errors. **POC:** Gary Gensinger	The FDA is currently testing the updated validation component and anticipates its implementation by the end of the 3rd Quarter, 2008. FDA is reviewing potential changes to the Module 1 specifications.	The current review system is in operations and maintenance, with the latest release providing the FDA with the capability to integrate the eCTD review system with the CBER and CDER submission tracking databases. The current activity is focused on the validation component of the software. The FDA plans to use this to validate individual eCTD submissions and to gather statistics on the number of submissions in compliance with the FDA standards, along with a distribution of the submission failures by problem type. In relation to the RPS strategy, the FDA plans on using the eCTD review system to review RPS based submissions.	• Currently upgrading validation components. • Review of potential changes to the Module 1 specifications – in progress. • Updating validation rules and, Global Submit for requirements for next release - tentative 1st quarter of CY 2010.
7.	Workflow tracking and information management system (DARRTS) - Is a flexible, integrated, fully electronic workflow tracking and information management systems to receive, log, track, assign, process, and manage official submissions with internal and external stakeholders. The system maintains the official submission records and will manage and track all communications and documentation concerning a submission. **POC:** Gary Gensinger	Release 3.0 requirements completed application development, reports development and data migration underway. Release 3.0 - 1st Quarter, 2009 for all CDER NDAs and ANDAs. Release 3.x for CBER and CDER BLAs.	Release 1.0 on 1/28/2006, for Therapeutic Biologic Product INDs. Release 1.4 on 1/29/2007 for Safety Issues, and Releases 1.1 through 1.6 also provided system enhancements and bug fixes. Release 2.0 implemented 11/13/07 for all CDER INDs, Master Files and Emergency Use Authorizations plus system enhancement and bug fixes. Release 3.0 requirements baselined.	• Release 3 includes CDER NDA's \ANDA's expected in 3rd Quarter CY 2009. • Release 4 will include CBER and CDER BLAs. • Consolidating NDA and ANDA systems in Release 4.
9.	Information and Computer Technologies for the 21st Century, ICT21, 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. **POC:** Michael Stoos	IDIQ contract will supply the data center design and strategy for Application migrations, award 4th Quarter, 2008. Data Center Design Complete 1st Quarter, 2009. Application Migration Wave one 2nd Quarter, 2009. Bioinformatics Pilots Started 2nd Quarter, 2009. Application Migration Wave two 1st Quarter, 2010. Application Migration Wave Three 2nd Quarter, 2011. Complete New Bioinformatics Platform in 2012.	Completed Baseline Analysis and Alternatives and started PMO functions. Performed Risk assessment of White Oak Data Center 2nd Quarter of CY 2008. Completed RFP for Data Center Design and Application Migrations 2nd Quarter of CY 2008. Data Center Design Phase Began 2nd Quarter of CY 2008.	• Completed Business Impact Analysis and critical applications ranking – finalizing. • Beginning Application Migration to datacenters.

#	Project Name and Description	Strategy / Milestones	Status as of May 2008	Current Status
10.	FDA's Common Electronic Document Room (EDR) initiative is intended to establish one common, Agency-wide, standards-based EDR as a single platform database for all FDA-regulated product documents. Having a single platform database that contains all documents related to the FDA-regulated products 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. In addition, having an Agency-wide EDR offers the opportunity to reduce redundancy and related costs and complexities associated with maintaining multiple electronic document rooms. Benefits/Strategy: A Common EDR provides the FDA with the capability to streamline the submission process, provide reviewers' additional collaboration capabilities, provide reviewers access and search for information across traditional organizational boundaries, and position the FDA to share and interact with external networks/systems as an Agency (e.g. e-Platform).	4th Quarter, 2008 Requirements, alternatives analysis, concept of operations Development and Testing of the Common EDR Functionality 3rd Quarter, 2009 Phase I Implementation	Concept Proposal and Project Boundary Document approved by the Bioinformatics Board. Project Charter and IT Project Team was formed to define and document the current (as-is) environment. Metrics have been collected on current environment. Common EDR boundary document (scoping document) has been developed and approved. Current activity is to develop project planning documents and to model and establish the business functional requirements.	• Requirements gathering in progress.
	The Facts@FDA program is part of the broader US effort to achieve electronic prescribing and other e-health information technology initiatives: ELIPS, e-List, CP, and SRSID **POC:** Randy Levin			
11.	Electronic Labeling Review System – The Electronic Labeling Review System receives and processes electronic labeling information through the Structured Product Label (SPL) standard format. The Data Warehouse (DW) functionality provides users ad-hoc report and query capability on transmitted SPLs. **POC:** Randy Levin	Continue with operation and maintenance. Evaluate incorporation of SPL schema Release 4 into the software.	Release 1.0 on October, 2005 to support receipt, store, review, and transmission of SPLs to NLM. Release 3.0 on February, 2007 to support PLR SPLs. DW release 1.0 on October, 2006 provides initial query and report capability via an Agency Reporting tool.	• ELIPS has been consolidated into e-List.
12.	Electronic Listing – Electronic listing has been expanded to provide for both registration and listing based on SPL schema release 4 and will provide the ability to automate drug registration and listing information and validation processes. The SPL data elements will be extracted and reused. The listing information will be available to the public through DailyMed and other electronic means. **POC:** Randy Levin	CRADA partner to deliver electronic registration and listing release 1 supporting SPL schema release 4 during 3rd Quarter, 2008.	CRADA partner delivered Collaboration Portal (CP) prototype. User Acceptance Testing (UAT) by FDA was completed.	• Draft guidance document published. • Electronic registration and listing submissions began July 2008. • Consolidation efforts, new user requirements planned for CY 10. • System for validation, storage and processing of SPL file in place.
13.	CP (Collaboration Portal) – Please refer to the e-Platform Initiatives in Section 5.2			See item #3 above.

#	Project Name and Description	Strategy / Milestones	Status as of May 2008	Current Status
14.	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. **POC:** Lawrence Callahan / Frank Switzer	Continue with operation and maintenance. Enhancements to the SRS over the next 6 months will allow release of synonyms in addition to preferred terms and Unique Ingredient Identifiers.	Release 1.0 on September, 2005 to support registration and review of substances and ingredient names. This release provides Unique Ingredient Identifier (UNII) standard terminology for use in SPL. Release 1.4 allows all FDA personnel to query and view approved substances. Release 1.5 enhances change notification and search capabilities.	Synonyms are now available to public from data standards web site. Working with NLM Chemid to make chemical structures, definitions available to public. Updated USP Dictionary in 2009, over 8000 UNII's listed. Working with ISO, UNII is a candidate for IDMP standard for the Identification of Substances. See FDA Data Standards Council web page for latest updates. http://www.fda.gov/oc/datacouncil/
15.	CDISC - HL7 Project - The FDA plans to transition to HL7 exchange messages for submission of all study data. This initiative is based on the outcomes of the CDISC Content to HL7 Message Exploratory Project. **The objective of the Exploratory Project was to:** Harmonize the SDTM into the BRIDG model (see below). To identify HL7 exchange message content for submission to a regulatory authority that addresses; a) study summary (clinical trial registry), b) eligibility criteria, c) trial design (including parts I and II: arms, elements visits, planned assessments, and planned intervention(s)), d) statistical analysis plan, e) collected data/study data tabulations and f) derived data/analysis datasets, all of which are currently defined by the CDISC standard. **POC:** Patty Garvey	Message development is underway in HL7. Plan is to go to DSTU (draft standard for trial use) ballot at the end of 3rd Quarter of CY 2008 and to test the messages as part of the Janus phase 3 pilot (see Janus Initiative). Additional milestones: 3rd Quarter of CY 2008 - HL7 DSTU Ballot 2008 – 2009 - Testing 3rd Quarter CY 2009 - HL7 Normative Ballot 2009-2012 - FDA accepts both CDISC-HL7 XML and SAS transport files 2013 and Beyond - FDA accepts only CDISC-HL7 XML	CDISC Content to Message Project initiation was approved by the HL7 Regulated Clinical Research Information Management (RCRIM) Technical Committee 11/2007. The FDA is proposing the development of four messages that map to content areas identified above. Study Design Study Participation Subject Data Individual Case Safety Reporting (ICSR) This process also includes the completion of the BRIDG Model harmonization, to ensure that all content has been identified and harmonized with the model before achieving normative status.	• Study Participation and Study Design Messages passed the draft standard for trial use (DSTU) in May 2009. • Subject Data Message will be submitted for DSTU ballot September 2009. • FDA is proceeding with testing the messages and has established a RIM database test environment at NCTR for this purpose.

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16.	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. In the case of the BRIDG model, the domain is defined as: *Protocol-driven research and its associated regulatory artifacts, i.e. the data, organization, resources, rules, and processes involved in the formal assessment of the utility, impact, or other pharmacological, physiological, or psychological effects of a drug, procedure, process, or device on a human, animal, or other biologic subject or substance plus all associated regulatory artifacts required for or derived from this effort.* The BRIDG Model serves to bridge standards, as well as organizations and various communities, including academic research institutions and pharmaceutical product development organizations and related service and technology providers. It is also bridging the gap between clinical research and healthcare. **POC:** Patty Garvey	BRIDG Release 2.0 is being released in April 2008. Release 2.0 includes: • All semantic content from Release 1.1 plus new semantic content for adverse events and participant registration • Full binding of all static attributes to HL7 V3 data types • Candidate terminology / value sets for attributes with a Coded Descriptor (CD) data type • Mapping from BRIDG to HL7's RIM Evaluation of strategy for incorporating BRIDG Model 'sub-domains' (e.g. cancer-specific semantics) using NCI's Clinical Trials Object Model. The next release of BRIDG is expected in 4th Quarter, 2008 or 1st Quarter, 2009. It will include complete harmonization of Protocol Representation Version 1, which consists of Trial Design and Clinical Trial Registry. This release will support the CDISC-HL7 messages.	As of Release 1.1, in October 2007, the content has been drawn from six projects: • Study Data Tabulation Model (SDTM) – CDISC • caXChange/LabHub (including Periodic Reporting of CT Laboratory Results and Lab Model) -- NCI/HL7/RCRIM TC/CDISC • Regulated Product Submission (RPS) -- HL7 RCRIM TC • Cancer Trial Object Model (CTOM) – NCI (approximately 50% of the total content) • Trial Design Model (TDM) – CDISC • Patient Study Calendar, Phase II (PSC) – NCI Content identified as part of the CDISC - HL7 Project will be harmonized with the BRIDG Model in coordination with the BRIDG scheduled releases.	• The FDA has determined that BRIDG is of limited value in achieving FDA's IT goals. FDA believes that existing HL7 processes and artifacts are sufficient to develop standards that serve the needs of academic research institutions, regulated industry and related services and technology providers, as well as bridge the gap between clinical research and healthcare.

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17.	The JANUS data warehouse for human study data is being developed by the National Cancer Institute (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 human study data for Janus is the Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTM). The Janus logical model and validation specifications are public documents and available at http://www.fda.gov/oc/datacouncil/janus_operational_pilot.html **POC:** Bobbie Witczak / Sue Bell	Vocabulary Service (EVS) to begin to address controlled vocabulary issues. Plan to publish FR notice announcing Janus Phase 3 Pilot Q3 CY 2008 to engage interested stakeholders in future Janus development. Establish two-way data exchange between FDA and NCI using FDA's ESG. Have the CDISC-HL7 messages completed and tested within the Janus environment 2008-2009.	Memorandum of Understanding with NCI signed in March 2007. Janus Change Control Board (CCB), with representation from NCI, FDA, CDISC, and industry, was established in July 2007 and meets monthly. Related projects involving the management of structured scientific data, including the Janus pilot at NCI and the SEND pilot described below, will be managed under the BiB and BRB governance structure. Work on the Phase 2 operational pilot was completed in January 2008. This working pilot integrates selected tools with Janus (WebSDM and JReview) and supports an interface with CDER's Electronic Document Room (EDR) as well as the validation, and loading of SDTM datasets from CDER's EDR into the Janus repository. Planning for a Phase 3 operational pilot is ongoing and Phase will begin in 4th Quarter 2008. It will include improving the loading of data into Janus and testing of the CDISC HL7 messages currently under development.	• Scope of work developed for NCI Phase 3 pilot; FDA and NCI have met several times to review this SOW. • FDA is currently working on an Interagency Agreement for the Phase 3 pilot • NCI is moving forward on a task order for the Phase 3 SOW. • Work on Phase 3 is expected to begin during the next several months. • Scope of work developed for CDER Janus CONOPS and implementation plan; work is likely to begin in June 2009.
18.	Standard for Exchange of Nonclinical Data (SEND) Pilot – CDER, in collaboration with NCTR 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, pilot participants, and the CDISC 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 portable document format (PDF), in investigational new drug applications (INDs), new drug applications (NDAs), and biologics licensing applications (BLAs). **POC:** Lilliam Rosario	Update the SEND implementation guide 2nd Quarter, 2008. Begin receiving SEND pilot submissions 3rd Quarter, 2008.	SEND Pilot is ongoing. Enrollment of pilot participants is now closed. Details are provided at http://www.fda.gov/oc/datacouncil/send.html	• SEND pilot (Phase II) continues the evaluation of SEND by CDER. • The SEND Implementation Guide (SENDIG) v3.0 Draft A and the SEND Controlled Terminology for v3.0 Draft A were released on March 14th, 2009. (http://www.cdisc.org/) • SENDIG 3.0 Draft A represents a significant t realignment to the SDTM.

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19.	Electronic Case Report Form eCRF Pilot - The purpose of the eCRF pilot project is to obtain experience with the CDISC Operational Data Model (ODM) based CRFs. Based on our experience, PDF-based CRFs from clinical trials that employ electronic data capture (EDC) are not ideal to support all review activity. Although the PDF-based CRFs for trials that use EDC can provide a record of the observations collected during the trial (i.e., the data) and additional information about what was collected (metadata), they typically do not provide an audit trail. CDER and CBER are interested in adopting a new, standard format that can replace the PDF-based CRF and that can reliably provide all three components of the CRF in an electronic format: Data, metadata, and audit trail. A successful pilot will allow CDER and CBER to routinely accept CRFs from studies that employ EDC in ODM format in marketing applications submitted in electronic format. **POC:** Patty Garvey	Pilot is underway. Additional test ODM submissions expected in 3rd Quarter, 2008. ODM Style sheet will be modified based on comments from FDA and pilot participants.	Six pilot participants have been identified and the first pilot submission of ODM eCRFs has been received.	• FDA has decided to discontinue this pilot - after internal discussions, it's clear that even a successful ODM pilot will not result in FDA adopting ODM as a submission format for eCRFs. The FDA Bioinfomatics Board has decided that all future exchange standards for structured scientific data at FDA will be based on the HL7 Reference Information Model.
20.	CDISC CDASH (Clinical Data Acquisition Standards Harmonization) - The project goal is to develop a set of "content standards" (element name, definition, and related metadata) for a basic set of global data collection fields (also known as CRF, or Case Report Form, variables) that will support clinical research studies. The initial scope of the project is the development of 16 CRF content 'safety data/domains'; Adverse Events, (Prior and) Concomitant Medications, Comments, Demographics, Disposition/End of Study, Drug Accountability, ECG, Exposure, Inclusion and Exclusion Criteria, Lab, Medical History, Physical Examination, Protocol Violations, Subject Characteristics, Substance Use, and Vital Signs. These safety domains are common to all therapeutic areas. The initial scope is not the physical layout of the CRF or terminology; terminology is incorporated through collaboration with the CDISC Terminology Team. Basic data collection fields identified by CDASH project work streams are mapped into the Study Data Tabulated Model (SDTM) and are compliant with the SDTM Implementation Guide (SDTM IG). FDA's role in this effort is to ensure that the CRF regulatory requirements are being addressed. **POC:** Patty Garvey	The CDASH consolidated final draft has been released for public comments. After the public review period of the consolidated final draft ends 14 May 2008, comments will be consolidated and addressed by the CDASH project team. Comments and responses will be posted on www.cdisc.org along with the final CDASH v 1.0. The goal is to post the final CDASH version 1.0 by the end of 2nd Quarter, 2008. The next step is to identify companies that are interested in becoming "Early Implementers", i.e. applying the CDASH standards in a clinical trial and providing feedback to the CDASH project team. Information attained from "Early Implementers" will be used to further improve the CDASH standard.	These 'safety data/domains' were divided into four separate packages or work streams. The CDASH project has addressed all of the 'safety data/domain' areas and FDA has provided comments to ensure that regulatory requirements will be met.	• CDASH 1.0 published on the CDISC website October 2008. • Sponsors are now able to use CDASH for data collection activities. • The CDASH team is working on developing a CDASH User Guide (CDASHUG). In parallel, two additional groups have started, the CDASH-ODM team and the AdvaMed-CDISC device team. The CDASH-ODM team is working on developing the associated ODM metadata for the 16 domains included in the CDASH standard. • The plan is to publish these ODM files along with CRF examples, with and without annotation, as part of the new CDASHUG. • The AdvaMed-CDISC team has two deliverables, the first is focused on the development of a device properties (DP) domain to complement the SDTM and the second deliverable is focused on identifying the basic device data collection fields for inclusion in the CDASH standard. • The CDASHUG, an update the CDASH standard (incorporating device collection fields) and the new SDTM device properties domain are targeted for completion Q110.

#	Project Name and Description	Strategy / Milestones	Status as of May 2008	Current Status
21.	Product Stability Data Standard To develop a method to provide stability data in a standard electronic format so that it may be viewed as it appears on paper or electronic paper by regulatory agencies and industry. **POC:** Alfred Kempski / Norman Gregory	Release 2 HL7 ballot - 3rd Quarter CY 2008. Implementation Guide HL7 ballot - 3rd Quarter CY 2008. Implement Viewer - 2nd Quarter CY 2009. Accept in place of paper - 4th Quarter CY 2009.	Release 1 HL7 Approved in May 2005. FR Notice of Pilot - May 2006. Pilot Completion Announcement - May 2008.	• Release 2 Implementation Guide passed HL7 ballot in January 2009 and Release 2 published s DSTU with 9 month test period in April 2009.
22.	CDISC ADaM - Analysis Data Model-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. **POC:** Alfred Kempski / Stephen Wilson		ADaM datasets have been pilot tested by CDER review staff.	• ADaM 2.1 and ADaM Implementation Guide 1.0 drafts posted for public comment at. http://cdisc.org/ Public Comment period closed in September 2008.
23.	The MedWatch Plus 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. **POC:** Deborah Sholtes	• Select FAERS COTS toolset. • Rollout CDER/CBER FAERS release. • Rollout CDRH/Office of Combination Products release. • Complete MedWatch Plus Portal and Core Processing components for both electronic and alternative (fax, telephone, paper) AE reports. • Complete MedWatch Plus Rational Questionnaire Integrate MedWatch Plus portal with FAERS.	MOU with NIH to develop intelligent questionnaire for the Internet portal. High-level and Detailed Business and IT requirements completed for FAERS. Completed MedWatch Plus Portal requirements definition. Awarded MedWatch Plus integration contract.	

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24.	**Sentinel Initiative -** The Sentinel Initiative, a long-term effort to create a national electronic system for monitoring FDA-regulated product safety. The System's goal is to augment the Agency's existing postmarket (primarily passive) safety surveillance systems by enabling the Agency to actively gather information about the postmarket safety and performance of its regulated products. The System will be developed and implemented in stages. As currently envisioned, the Sentinel Initiative will enable the Agency to capitalize on the capabilities of multiple, existing automated healthcare data systems (e.g. electronic health record systems, administrative claims databases, registries). The Sentinel Initiative will enable queries of disparate data sources quickly and securely for relevant product safety information. Data will continue to be managed by its owners, and only data of organizations who agree to participate in this system will be included. Questions would be sent to appropriate, participating data sources, who in turn would, in accordance with existing privacy and security safeguards, evaluate their data and send results for Agency review. **POC:** Melissa Robb	• 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.	Sentinel public meeting held March 7 and 8, 2007 with over 400 pages of transcripts posted to public docket. On May 22, 2008 FDA announced the Sentinel Initiative on public website. http://www.fda.gov/oc/initiatives/advance/sentinel/	• FDA is collaborating in various public and private activities that are exploring the use of observational data to inform the creation of Sentinel. • A series of meetings with all stakeholders is completed. The initial meeting in this series was held in March 2008 and included participants from other Federal Agencies. A Federal Working Group was established to discuss issues related to Sentinel and other complimentary efforts and the first meeting of this group took place June 2008. This group meets quarterly. Additional stakeholder meetings that have taken place include: data holders, April 2008 (two meetings); academics and experts, June 2008; consumer briefing at HHS, July 2008; patient representative telephone conference, August 2008; regulated medical product industry, September 2008; and vendors, October 2008. A public workshop entitled Sentinel Initiative: Structure, Function and Scope, co-sponsored by the FDA and the eHealth Initiative Foundation and convened in cooperation with the Brookings Institution was held on December 16, 2008. Eight solicitations have been issued and awarded to support the development of this Initiative during FY2008. • Developing a Governance and Operations Structure for the Sentinel Initiative- eHealth Initiative Foundation- report completed and available in docket and website • Engagement of Patients, Consumers and Healthcare Professionals in the Sentinel Initiative- eHealth Initiative Foundation- report completed and available in docket and website • Defining and Evaluating Possible Database Models- Harvard Pilgrim Healthcare- report completed and available in docket and website • Evaluation of Existing Methods for Safety Signal Identification- Group Health Cooperative Center for Healthcare Studies- report completed and available in docket and website • Evaluation of Timeliness of Medical Update for Surveillance in Health Care Databases- IMS Government Solutions- report completed • Evaluation of Potential Data Sources- Booz Allen Hamilton • Evaluating Potential Network Data Sources for Blood and Tissue Product Safety Surveillance and Studies- Pragmatic Data

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				• Evaluation of Potential Data Sources for a National Network of Orthopedic Device Implant Registries- Outcome Sciences, Inc. - - report completed and available in docket and website A Request for Information was posted on February 20, 2009 to collect further information on sources to support development of scientific operations for Sentinel. A presolicitation synopsis was posted on May 15, 2009. An Agency-wide Senior Management Team was formed to allow for updates on progress and to provide comment on the scope and direction of Sentinel. This group also enables dissemination of information to update their respective areas on the initiative. Collaborations with CMS, DoD, and VA have been expanded for evaluation of potential safety signals, to include rapid cycle analysis in the various data environments. •