PDUFA IV Information Technology Plan

Revision Index

This is the first revision made to the original PDUFA IV IT Plan published in May 2008.

It provides an abbreviated version of the formal PDUFA IV IT Plan Update.

The Revision Index lists the sections of the PDUFA IV IT Plan that have been updated.

Section		Description
1.0	Introduction	Revised
2.0	Purpose	Revised
3.0	Vision	No change
4.0	Goals and Objectives	No change
5.0	PDUFA IV IT Strategy	Revised
6.0	Programs	Revised
7.0	Appendices	No change

1.0 Introduction

As a part of the Department of Health and Human Services (DHHS), the Food and Drug Administration's (FDA's) mission is to advance the public health by helping to speed innovations that make products more effective, safer, and more affordable, and to monitor products for continued safety after they are in use. Decisions made by the FDA affect every single American every day. Consumers spend more than 20 percent of all consumer expenditures on FDA regulated products. Operating as a modern, scientifically up-to-date, responsive, and efficient Agency, the FDA can provide better protection for consumers and more effectively promote their health.

In the last decade, the FDA has achieved great success in reforming and modernizing its regulatory processes and responsibilities as a result of changes and improvements driven by the requirements of the Prescription Drug User Fee Act (PDUFA), the 1997 FDA Modernization Act (FDAMA), and other legislation. The additional resources provided by user fees, when combined with appropriations, have enabled the FDA to modernize its information technology infrastructure and begin a monumental transformation from a paper-based to an electronic work environment. With the reauthorization of PDUFA, the FDA plans to make even greater progress during the PDUFA IV timeframe (FY2008 – FY2012), building on the foundation established in previous years.

The Prescription Drug User Fee Act, or as it is commonly called, PDUFA, allows the Agency to help fund the review of new human drugs through fees paid by the sponsors/applicants that develop and market human drugs and therapeutic biologics. PDUFA was first enacted in 1992, and has been reauthorized, each time for five years, in 1997, 2002, and 2007. The drugs user fee program was reauthorized by the Food and Drug Administration Modernization Act of 1997, by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002, and recently by the FDA Amendments Act of 2007.

PDUFA authorizes the FDA to collect fees from companies that produce certain human drug and biologic products. To market a new drug or biologic, a company must submit an application along with a fee. In addition, companies are assessed annual fees for each prescription drug product marketed and for each manufacturing location of the product. Under PDUFA, industry provides funding that is added to the FDA's appropriated budget, and the FDA commits to certain performance goals. More information on the PDUFA program and performance goals is available at http://www.fda.gov/oc/pdufa/.

The PDUFA III re-authorization included the Electronic Applications and Submission Goals that included FDA's commitment to implement the electronic Common Technical Document (eCTD) and a common solution for the secure exchange of content including secure email and electronic submissions. The FDA met these requirements by implementing a review system for the evaluation of submissions in the eCTD format http://www.fda.gov/cder/regulatory/ersr/ectd.htm and the implementation of the Electronic Submissions Gateway (ESG) http://www.fda.gov/esg/. In addition, the FDA implemented the first phase of the electronic labeling rule in the Center for Drug Evaluation and Research (CDER) that will be expanded to the Center for Biologics Evaluation and Research (CBER) http://www.fda.gov/oc/datacouncil/spl.html.

The Prescription Drug User Fee Act (PDUFA) program has enabled the Food and Drug Administration (FDA) to make significant progress toward achieving the long-term FDA vision of a fully electronic submission and review environment of all regulatory documents and data; and the elimination of future paper-based submissions. To reinforce this vision, the PDUFA IV Commitment Letter, Section XIV, Information Technology Goals states, "FDA is committed to achieve the long-term goal of an automated standards-based information technology (IT) environment for the exchange, review, and management of information supporting the process for the review of human drug applications throughout the product life cycle."

In May 2008 PDUFA IV Information Technology Plan FDA stated that first year of the PDUFA IV timeframe would, "be a period of considerable transition" and "In the first 12 to 24 months of PDUFA IV, the FDA will focus on completing these plans to ensure that they are developed, published, and widely understood." Over the first two years of PDUFA IV the FDA has continued to move forward on data standards initiatives, embarked on a data center modernization effort, establish the Computational Science Center, and enhancing the post-marketing system. FDA is using this opportunity to provide an interim update on a number of these important (e.g. CDISC – HL7 project) initiatives. In other areas, FDA is continuing to explore the e-Platform concept and the establishment of modular review for labeling changes. For these areas additional business process planning

and strategic decisions are in discussion and the FDA will provide more detail in the next version of the PDUFA IT Plan.

2.0 Purpose

This Plan demonstrates how the FDA will improve the automation of business processes and acquire and maintain information systems to achieve the objectives defined in the PDUFA IV Commitment Letter transmitted from the Secretary of Health and Human Services to Congress http://www.fda.gov/oc/pdufa4/pdufa4goals.html . This plan also provides a future-state vision for the FDA standards and technical infrastructure supporting the process for the review of human drugs throughout the product lifecycle. Specifically, this Plan details how the FDA intends to:

- strengthen and improve information management within the new drug and biologic products review processes;
- strengthen the IT infrastructure to improve capacity for post market safety data management and analysis;
- improve the FDA's ability to communicate, share, and disseminate information more clearly within the Agency and with other government organizations, the regulated industry, and the American Public; and
- seek more efficient and effective means for supplying technology tools and services to the FDA user community.

This plan will help guide the direction and implementation of IT projects initiated to meet Agency program objectives and specific PDUFA IV IT goals. Among the principal IT planning documents to be developed by the Agency during the PDUFA IV timeframe, this plan will be the mechanism to communicate the steps the FDA plans to take to achieve its objectives to stakeholders, both internal and external to the Agency.

The CDER and the CBER have collaborated with the Office of Information Management (OIM) and other components of the Office of the Commissioner (OC) to develop this FDA PDUFA IV Information Technology Plan. Together, these offices will address a key objective of PDUFA IV: applying technology to the FDA regulatory review process in the most efficient and effective way possible to ensure reviewers have the information and tools that will allow them to make more informed and timely decisions.

The main purpose of this document is to provide an update on the data standards process and to communicate the progress and strategic changes for key initiatives that illustrate accomplishment of near-term objectives and describe FDA's strategy in meeting the long-term goal of a fully electronic submission and review environment. The FDA is not soliciting comments from the public for this PDUFA IV IT Plan update. The FDA plans to provide another update later this year and will solicit comments before publishing a final version of this later update of the PDUFA IV IT Plan.

3.0 Vision

The FDA is committed to achieve the long-term goal of an automated standards-based information technology environment for the exchange, review, and management of information supporting the process for the review of human drug applications throughout the product lifecycle. The FDA vision is a fully electronic submission and review environment of all regulatory documents and data; and the elimination of future paper-based submissions. While FDA does not expect to completely achieve this vision during the PDUFA IV timeframe, meeting the PDUFA IV Information Technology commitments will allow the Agency and regulated stakeholders to make tremendous progress towards implementing the vision.

4.0 Goals and Objectives

This section presents the strategic goals and objectives of the various governing layers within which FDA operates. First, it presents the goals, objectives, and strategic planning progress of the Department of Health and Human Services. FDA Agency level goals and objectives, under the leadership of the FDA Commissioner, are then presented. Next, specific information management/information technology goals and objectives for the FDA are presented. It is important to understand how the PDUFA Program, and in particular, the PDUFA Information Technology Goals are linked to the HHS and FDA strategic goals. Accomplishment of these goals will be critical to the success of the Agency and Departmental goals.

4.1 Department Goals

The Department of Health and Human Services published its Strategic Plan for FY 2007 – 2012. Complete details can be found at the following link: http://www.hhs.gov/strategic_plan/. FDA directly supports 3 of the 4 HHS strategic goals:

Goal 1: Improve the safety, quality, affordability and accessibility of health care, including behavioral health care and long-term care.

Goal 2: Prevent and control disease, injury, illness and disability across the lifespan, and protect the public from infectious, occupational, environmental and terrorist threats.

Goal 4: Advance scientific and biomedical research and development related to health and human services.

4.2 FDA Strategic Goals and Objectives

The FDA published its most Strategic Action Plan in the Fall of 2007, (http://www.fda.gov/ope/stratplan07/stratplan07.htm). FDA's strategic goals and objectives address the entire life cycle of FDA-regulated products. Information management is an important theme that cuts across numerous goals and objectives.

Goal 1: Strengthen FDA for Today and Tomorrow

- Strengthen the scientific foundation of FDA's regulatory mission.
- Cultivate a culture that promotes transparency, effective teamwork, and mutual respect, and ensures integrity and accountability in regulatory decision making.
- Enhance partnerships and communications.
- Strengthen FDA's base of operations. (Includes action items to improve FDA's information management infrastructure.)

Goal 2: Improve Patient and Consumer Safety

- Strengthen the science that supports product safety.
- Improve information systems for problem detection and public communication about product safety.
- Provide patients and consumers with better access to clear and timely risk-benefit information for medical products.
- Provide consumers with clear and timely information to protect them from food-borne illness and promote better nutrition.

Goal 3: Increase Access to New Medical and Food Products

- Increase the number of safe and effective new medical products available to patients.
- Improve the medical product review process to increase the predictability and transparency of decisions using the best available science.
- Increase access to safe and nutritious new food products.

Goal 4: Improve the Quality and Safety of Manufactured Products and the Supply Chain.

- Prevent safety problems by modernizing science-based standards and tools to ensure high-quality manufacturing, processing, and distribution.
- Detect safety problems earlier and better target interventions to prevent harm to consumers.
- Respond more quickly and effectively to emerging safety problems, through better information, better coordination and better communication.

4.2.1 Information Management/Information Technology Goals

The Office of Information management has realigned operations to support the Agency goals and objectives more effectively and efficiently. The IT strategy considers both short- and long-term initiatives to provide the mechanisms to establish an appropriate environment that facilitates data interoperability and identifying data assets. A planned infrastructure will incorporate standards at many levels, including application development, terminology, content exchange and content where appropriate. The underlying standards will be promoted from a central organization to ensure all Centers are reusing code effectively as well as managing master data elements and data sources in a similar fashion.

5.0 PDUFA IV IT Strategy

The PDUFA IV IT strategy is one component of the overall FDA IM strategy. In order to accomplish the goals in the PDUFA commitment letter, the FDA through the PDUFA Review Board, has developed the PDUFA IV IT Strategy, which incorporates efforts that are currently underway to improve general IT processes and practices, alongside efforts that have been developed specifically to satisfy PDUFA-driven goals. These efforts increased overall efficiency and enhanced the FDA's ability to further the Agency mission.

The FDA is committed to achieve the long-term goal of an automated standards-based IT environment for the exchange, review, and management of information supporting the process for the review of human drug applications and continued risk and benefit assessment throughout the product life cycle. To realize this goal, the Agency's strategy is to evaluate current business processes, IT Applications, and the overall IT architecture to define a target enterprise architecture that will achieve the IT goals defined in the PDUFA IV Commitment Letter. This target enterprise architecture will be drafted to provide a timeline including key project milestones.

5.1 Business Modernization and Transformation

The FDA has embarked on a business modernization and transformation effort to improve how the Agency achieves its mission. This work included development of a business process framework that describes work processes at a high level, using general language and concepts that demonstrate the commonality of core mission functions among all of the FDA product centers and other programs and organizational units. In addition, analyses of business processes were completed to assess the importance of: business process vs. capability to perform, and importance vs. IT system capability.

5.1.1 Business Process Improvement

While considering the role of information technology and automation, the FDA's general approach to business process improvement is to:

- identify a target area for improvement
- establish performance goals
- model the business processes using the Agency-wide standard methodology; and
- identify opportunities for improvement through analysis and collaborative problem-solving

This approach includes active involvement of senior management and operational business owners who understand and champion business process improvement initiatives that improve the effectiveness and efficiency of the FDA. An important component of these activities will be a continuing focus on the quality management aspects of FDA operations.

5.2 Target Architecture

The Target Enterprise Architecture (EA) for the FDA will provide a business-driven plan that describes the desired end-state for the FDA's business architecture, data architecture, applications architecture, technical architecture, security architecture, and standards profile. The primary purpose of the Target EA is to effectively plan a course for achieving the FDA's strategic vision and goals. It is one element in a broader set of interrelated activities that collectively enable the FDA managers and staff to define a vision, develop strategies and plans for achieving the vision, make resource decisions, implement strategies and evaluate performance.

By defining the end-state from several distinctive perspectives (e.g. business, data, etc.), the Target EA will also provide stakeholders with a view into the complex relationships that exist among these different perspectives. For example, the Target EA will provide insight into how a particular need translates into a set of target FDA business processes, and how those business processes will be supported by a common set of technologies.

The FDA has numerous information systems, executes overlapping business and information processes, and relies on a number of technologies that are expensive to maintain. To reduce costs and streamline operations, the FDA is migrating toward a more service-oriented and component-based approach to architecture. This approach, consistent with government and industry best practice, will enable the FDA to "build once, use often." In other words, by separating out the functionality or capabilities of a business process or application into discrete pieces, components can be shared and reused across the enterprise. As a result of this approach, the FDA Target EA will:

- Improve Program Performance – The overarching benefit of the Target EA is that it provides opportunities to improve the efficiency and effectiveness of the FDA's programs. It ensures that data is optimized in support of the business, and applications and technology solutions are driven by business needs. It also allows FDA to more readily share services/data across organizational and functional lines.

- Improve Interoperability – The Target EA establishes enterprise-wide standards that promote platform and vendor independence, enabling greater interoperability across disparate applications, both internal and external.

- Improve Utilization of Resources – The Target EA reduces system development and operation and maintenance costs by eliminating duplicative investments, promoting sharing of common services, and establishing Agency-wide standards.

- Accelerate System Implementation – The Target EA equips the Agency's system developers and architects with an inventory of component-based services from which to choose that provide well defined functionality, thus maximizing reuse and portability of previously developed processes, components, code, etc.

- Simplify Investment Decisions – The Target EA provides a view from strategy to business function to technology, allowing decision-makers to be able to more quickly assess the relative value of initiatives, and to identify duplicative and misaligned initiatives.

- Reduce IT Diversity and Complexity – The Target EA simplifies the FDA's IT environment by promoting standards and the sharing and reuse of common technologies.

The FDA EA program intends to accomplish this by addressing the EA in segments: Post-Market, Pre-Market, Product Quality, Scientific, and Administrative. The corporate governance structure of the FDA Bioinformatics Board and the subordinate Business Review Boards will be leveraged to architect these segments.

The Agency's approach to target architecture development will follow OMB's "Analyze-Architect-Implement" model. Under the "Analyze" phase, the Agency is executing three parallel initiatives to analyze and assess current regulatory business processes and the IT systems that support them. These enterprise initiatives are:

1. Business Modernization / Transformation (BMT) – This initiative is described above in Section 5.1.
2. IT Assessment – The FDA completed an IT Application Assessment to identify potential Agency-wide applications. This initiative used a set of agreed upon criteria to assess existing IT Applications. It was sponsored through the Agency's Office of the CIO and assesses the IT applications from two perspectives, business value and technical viability. The outcome of the assessment was recommendations and supporting analysis that identify systems to be enhanced to satisfy common business needs, systems to be expanded and/or maintained to satisfy special purposes, and systems to be retired from the Agency's IT portfolio. The primary focus of the assessment was the Agency's pre-market activities.
3. Electronic Platform (e-platform) – On December 18, 2006, the FDA held a Part 15 hearing requesting public comment on transitioning to an all-electronic submissions environment and an electronic

platform (http://www.fda.gov/ohrms/dockets/dockets/06n0464/06n0464.htm). The FDA requested the public to comment on the following issues related to an all-electronic environment.

i. The feasibility issues related to the electronic submission of pre-market submissions and other regulatory information; and

ii. The issues related to the concept and feasibility of an electronic platform that would facilitate the exchange of clinical research information and other regulatory product information, the role of a public/private partnership helping the creation and assessment of such an electronic platform, and the management of the platform after its creation by a private entity with the relevant technological expertise.

The table below provides an update on the e-platform activities and two ongoing efforts that have a potential to become components of an e-platform.

E-Platform Initiatives

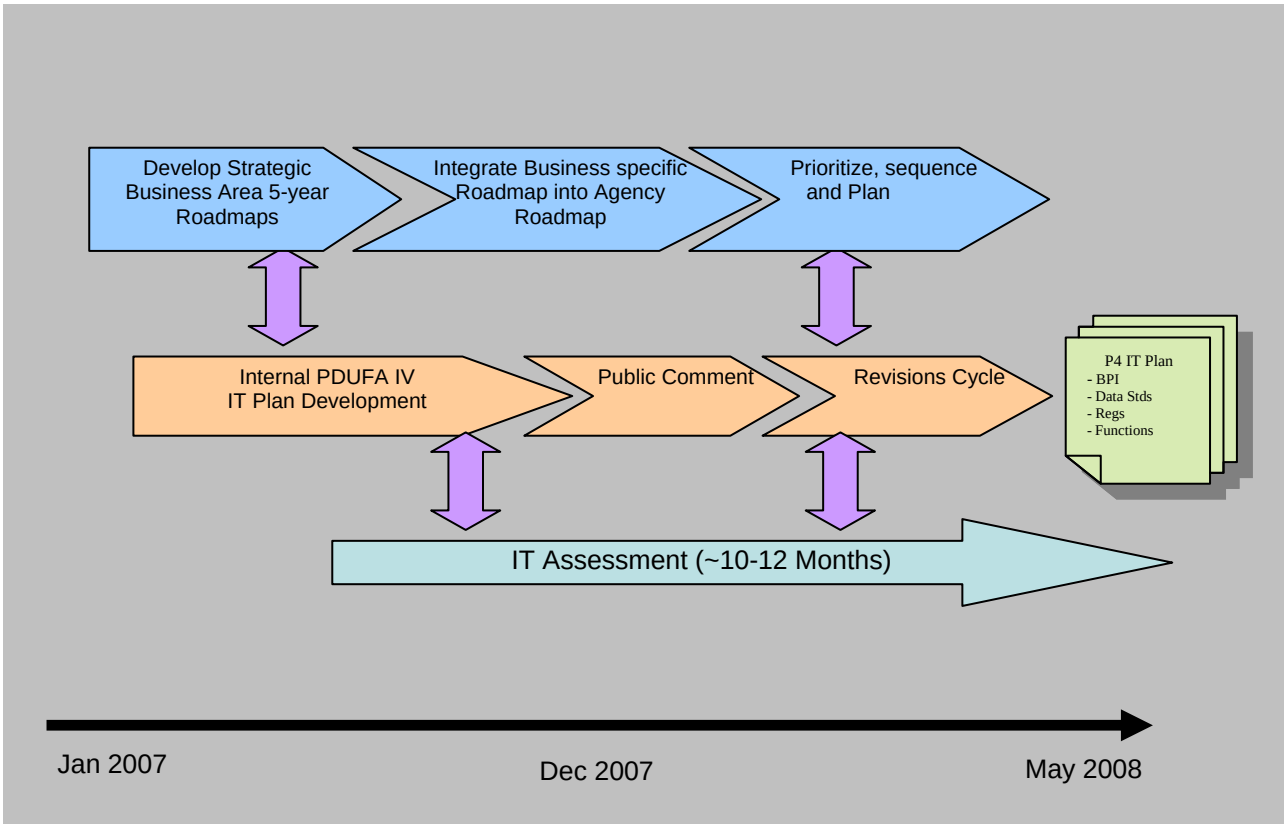
Dates listed are in calendar year format. Milestone timelines are approximate and will evolve over the PDUFA IV timeframe as will Center implementation.

Project Name and Description	Current Status	Strategy / Milestones
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.)	FDA completed an examination of the available information through literature review and stakeholder interviews to identify and characterize the needs of an e-Platform from both the perspectives of FDA, as well as industry and other stakeholders. The results of the review were summarized in a report entitled *Business Model for Partnerships to Develop and Implement an Electronic Data Exchange Project*. The FDA is currently reviewing the report's recommendations.	
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.	This project was placed on hold as CRIX International was unable to deliver the FIREBIRD application.	This project is on hold, the FDA will discuss options within the Agency and with NCI
The Collaboration Portal will provide a web-based collaboration platform where applicants and the	CDER and CBER Review Management is currently re-evaluating this initiative	FDA will provide update in the next publication of the IT Plan.

Project Name and Description	Current Status	Strategy / Milestones
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. This project is no longer active, the strategy on implementing modular labeling review will be evaluated in 2010.		

As these enterprise initiatives progress, the FDA governance process (e.g., Bioinformatics Board, PDUFA Review Board, Business Review Boards, etc.) will evaluate the aggregate recommendations and collaborate with the FDA Chief Information Officer (CIO) to define the enterprise target architecture. This Plan reflects what is known today and be updated periodically to reflect the priorities and direction of the FDA governance bodies. The following diagram graphically depicts the plan's dependencies on two of these initiatives.

Figure 2 depicts PDUFA IV planning and analysis and how it is coordinated with planning activities across the Agency



Once the enterprise target architecture is defined and business has prioritized and sequenced the Agency's priorities, the OIM will design the IT solutions that will implement the business needs within the target architecture. As the enterprise architecture matures, the FDA will focus on the development of common IT solutions that support multiple process areas (e.g., Application Submissions, Review Workflow/Tracking, Electronic Document Repositories, etc.). FDA recognizes that specific business needs exist that may not be satisfied through common software and will develop IT solutions that support these specific needs.

The Agency will leverage the outcome from the IT Assessment and other business process modeling efforts to determine which solutions can be built upon with new or additional functionality, maintained as an ongoing IT investment (steady state) or retired from service. Once this assessment has taken place, the Agency will refine the PDUFA IV IT Plan to reflect greater detail.

5.3 Guidance, Policy and Regulation

During the PDUFA III timeframe from fiscal years 2002 through 2007, the FDA developed regulations and published guidance to improve the consistency of electronic submission of regulatory documents and data. During this timeframe, there was a significant increase in the number of submissions sent to the Agency electronically. The increase in the number of electronic submissions received by the FDA can be directly attributed to the PDUFA III strategy to implement the Electronic Common Document (eCTD) submission format, the implementation of the FDA Electronic Submissions Gateway (ESG), and the implementation of the Electronic Labeling Rule (ELR) and the Physicians Labeling Rule (PLR). The development and publishing of guidance to industry and regulation changes were critical to the success of these initiatives.

During PDUFA IV, the FDA will continue to work with Industry to increase the number of submissions sent to the Agency electronically. The FDA will develop regulations and guidance to improve the consistency of data

organization, to improve submission processing, to improve access to documents and data, and to improve the evaluation of submission information. The FDA will continue the work that has already begun to establish an electronic architecture for enhanced information management. This directly supports the FDA strategy for implementing an all-electronic environment.

Format and data standards are integral to the receipt of electronic submissions. The FDA will continue to work with our stakeholders to coordinate the implementation of standards through public meetings, pilot testing, external training and tutorial sessions. As standards are approved through the various standard organizations and adopted internally, the FDA will update our guidance and modify our regulations to utilize the new standards.

This section describes the FDA's strategy for managing all policy throughout its life cycle. All important FDA policy is documented in the form of (1) regulation, (2) guidance, or (3) Manual of Policies and Procedures (MaPP) and Standard Operating Procedure and Policy (SOPP).

Regulation, Rule

A Regulation or Rule is a policy that is legally binding and enforceable. It is promulgated under the procedures set forth in the Administrative Procedure Act (5 U.S.C. 551), usually with notice and comment rulemaking.

The Unified Agenda of Federal Regulatory and Deregulatory Actions, (also know as the semi-annual regulatory agenda) is published in the spring and fall of each year. Since 1978, Federal agencies have been required by Executive Orders to publish agendas of regulatory and deregulatory activities. The Regulatory Plan, which is published as part of the fall edition of the Agenda, identifies regulatory priorities and contains additional detail about the most important significant regulatory actions that agencies expect to take in the coming year. More information can be found at the following link: http://www.fda.gov/oc/industry/unifiedagenda/agenda.html.

The FDA is working on the following proposed rules pertaining to electronic submissions:

- Electronic Registration and Drug Listing Rule
- Submission of Standardized Electronic Study Data Evaluating Human Drugs and Biologics[1]

Guidance

A Guidance document is a nonbinding recommendation or guidance that is intended primarily to assist industry or other regulated entities. A Guidance document refers to any written communication that describes or explains an Agency or Center policy on a regulatory issue (See 20 CFR 10.115(b)). The term guidance generally refers to guidance for regulated entities (e.g., the pharmaceutical industry). In some instances, Centers have developed reviewer guidance or guidance for industry and reviewers. Guidance documents do not include (1) FDA reports; (2) general information documents provided to consumers; (3) documents relating solely to internal FDA procedures (e.g., where there is no external interaction); (4) speeches, journal articles, editorials, press materials or media interviews; (5) warning letters; (6) memoranda of understanding; or (7) other communications or actions taken by individuals at the FDA directed to individual persons or firms.

Guidance documents must be developed according to good guidance practices. The Food and Drug Administration Modernization Act of 1997 (FDAMA) amends the Federal Food, Drug, and Cosmetic Act by incorporating aspects of good guidance practices, including the provision for public participation in the development of significant guidance documents and the opportunity for public comment upon issuance of all guidance. In response to FDAMA, the FDA codified its policies and procedures for the development and issuance of guidance documents in 21 CFR 10.115 in September 2000.

Guidance documents provide assistance to the regulated industry and the FDA by clarifying requirements imposed by Congress or promulgated by the FDA and by explaining how industry and the FDA may comply with those statutory and regulatory requirements. Guidance documents are prepared to establish clarity and consistency in the FDA policies, regulatory activities, and inspection and enforcement procedures. Guidance documents provide industry with specific details that often are not included in the relevant statutes and regulations, and are intended to assist the pharmaceutical industry in carrying out its obligations under laws and regulations on subjects such as the processing, content, evaluation, and approval of drug and biologic product

[1] Anticipated publication date December 2010

applications and the design, production, manufacturing, and testing of regulated products. These documents also provide specific review and enforcement approaches to help ensure that the FDA's employees implement the FDA's mandate in an effective, fair, and consistent manner. Guidance documents do not establish legally enforceable rights or responsibilities and, as such, are not binding on the Agency or the public. Rather, they explain how the Agency believes the statutes and regulations apply to regulated activities and reflect the FDA's current thinking on the subject addressed in the document.

The Agency recognizes the importance of maintaining a transparent guidance development process. Therefore, the Agency has implemented various practices intended to obtain input at the earliest stages of guidance document development and abide by good guidance practice (GGP) regulation (21 CFR 10.115).

- The Agency is required to annually publish in the Federal Register an Agency guidance agenda with the goal of soliciting comment on Agency intentions to develop guidance.
- CDER and CBER maintain Guidance Agendas on their Internet sites listing the Guidance documents they intend to issue in the current year. This enables the public to see what the Centers are working on. The link to the CDER Guidance Agenda is http://www.fda.gov/cder/guidance/ and the link to the CBER Guidance Agenda is http://www.fda.gov/cber/guidelines.htm.
- The Agency may solicit or accept early input on the need for a new or revised guidance, or assistance in the development of a particular guidance document, from individual governmental and/or nongovernmental groups (e.g., National Institutes of Health, consumer groups, trade associations, patient groups, public interest groups).
- The Agency may participate in meetings with these various parties to obtain each party's views on priorities for developing guidance documents.
- The Agency may hold meetings and workshops to obtain input from interested parties on the development or revision of guidance documents on a particular subject area.
- The Agency may hold a public workshop to discuss a draft and/or present a draft to an advisory committee when there are highly controversial or unusually complex new scientific issues.
- The Agency may issue a notice in the Federal Register soliciting public input before developing draft guidance.

Comments will be accepted at any time pertaining to all final guidance documents. Comments on guidance documents in use should be submitted to the Division of Dockets Management or to the relevant division. Guidance documents will be revised in response to such comments, as appropriate.

Policy, Procedure
Policies and procedures primarily intended to provide direction to reviewers or other staff within the Centers on how they are to do their work will be issued in a MaPP or SOPP. Instructions and templates for the proper development, formatting, processing, routing, and use of policy documents are published and utilized for each of the Centers. These instructions and templates provide consistency in the policies and procedures that are published, and decrease the time to develop, review and implement the policies and procedures in the Centers.

5.4 Data Standards

The FDA recognizes the importance of, and is committed to using open-consensus based data standards for regulatory submissions wherever possible. For the purposes of this discussion, data standards can be divided into three broad categories: exchange standards, format standards and terminology standards. Exchange standards provide a consistent way to exchange information between organizations and computer systems. Exchange standards help ensure that the sending and the receiving system both understand unambiguously what information is being exchanged. The FDA Data Standards Council leads these efforts. Format standards describe the structure, content, naming conventions and variable formats for any given data domain. Terminology standards provide a consistent way to describe concepts, controlled vocabularies to improve communications and enhance analytical capabilities. Efforts at CDER and CBER, described below, are focused on format and terminology standards.

This section describes the FDA’s strategy for managing data standards within FDA throughout their life-cycle, as well as efforts currently underway within CDER and CBER to establish comprehensive data standards programs.

The objectives of the Centers' comprehensive data standards programs are to ensure development of data standards for all key data needed to make regulatory decisions, and to ensure successful implementation of the standards with respect to business processes, policy/procedures, and timeline.

The important principles in standards management at the FDA are described below. From the FDA's perspective, standards should:

- Use voluntary consensus based standards (VCS) development process in accredited standards development organizations in place of government unique standards unless such standards are either inconsistent with applicable laws and procedures.[2]

- Align with existing health information technology initiatives, laws, regulations, and mandates (e.g. executive orders) and

- Coordinate with other standards currently in use.

In addition to these principles, which apply to the standards at the FDA, a general approach has been identified for the management of data standards within CDER and CBER. With an increasing volume of submissions, CDER and CBER must transition to standardized electronic regulatory submissions in order to meet strict regulatory deadlines. In order to adhere to the Centers' data standards management programs, projects and activities should adhere to the following three guiding principles:

1. Projects should be focused on addressing end-user requirements. This "reviewer-centered" approach should work from requirements to specifications to implementation, to produce the most useful standards to support modern regulatory work.

2. Data standards projects and activities should be focused on concrete near-term improvements that benefit pre-market drug review and other regulatory functions. The projects with near-term benefits should align with the center's long-range informatics goals.

3. Data standards-related decisions and standards-related processes should be clear, predictable, and widely communicated in a timely manner to all stakeholders. Moreover, the timeline associated with data standards adoption should be made clear to both internal and external stakeholders, such that these organizations can prepare to adopt these data standards.

A holistic approach to developing data standards to facilitate effective, efficient, and forward-looking regulatory decision making will consist of four objectives:

- **Ensure that useful, publicly available data standards exist.** An early and necessary step toward that objective involves developing an inventory of data elements required for drug regulatory decision making, and building on this inventory to establish data standards for all data needed to make regulatory decisions. FDA reviewers must have the opportunity to review the candidate terminology and related implementation guides in order to ensure that the proposed standards meet their scientific and regulatory requirements.

- **Ensure that there is a well defined standards adoption process in place.** A well defined standards adoption process must consider the impact of adoption on CDER and CBER core business processes and the associated regulatory burden. The process must clearly address the goal of adopting a given standard, the changes necessary to the business and review processes, the tools required to integrate the standard, an implementation schedule that is sensitive to the abilities of the stakeholders to successfully implement the standard (while still maintaining forward momentum) and a well-defined, comprehensive, communication plan that addresses outreach and education.

- **Ensure that regulatory data is submitted according to those standards.** To ensure that CDER and CBER receives regulatory submissions in the expected form, the center needs to align related

[2] Office of Management and Budget (OMB) Circular A-119

regulatory guidance to industry, conduct outreach and training on standards and tools for our reviewers, and provide compliance checklists for both reviewers and sponsors.

- **Ensure that regulatory review processes can fully-leverage the standardized data.** To fully utilize standardized data, reviewers need to be able to load, access, and manipulate electronic submissions. This requires planning to ensure the needed server infrastructure is in place, and software tools are developed and tested with end-user input. It also requires that regulatory business processes be reviewed for potential enhancement with expanded access to better-quality data and new analytic tools.

The FDA recognizes that not all of the principles can be met in all cases. The FDA will strive to adhere to as many principles as possible when selecting a standard for implementation.[3] The discussion that follows applies equally to both exchange and terminology standards, unless otherwise noted. These elements will be incorporated into the Data Standards Management Lifecycle, currently being developed at CDER to support its comprehensive data standards program. Because a data standard, like information systems, needs to be well-designed, tested, implemented and updated as user needs change, a "life cycle" management approach informed by existing processes will be adopted to meet CDER and CBER's data standards management needs. For example, the US Department of Health and Human Services (HHS) Enterprise Performance Lifecycle (EPLC) offers a framework for rigorous application of project management and best practices to information technology governance.

The life-cycle of a data standard can be divided into the following steps[4]:

1. Needs Assessment and Requirements Gathering
2. Development, User Acceptance Testing, and Adoption
3. Implementation and Maintenance

Needs Assessment and Requirements Gathering

An FDA business component identifies the need for a standard and identifies a business sponsor to represent the business community during subsequent phases.

The Data Standards Council works with the business sponsor including representatives from CDER and CBER to create a working group of the FDA subject matter experts to gather business requirements.

The end-product or deliverable at the conclusion of this phase is a document that describes the business needs or defines the business processes that the standard is intended to support (e.g., scenarios, use cases, or storyboards) in sufficient detail to begin standards development and adoption.

Development, User Acceptance Testing, and Adoption

FDA first attempts to identify an existing standard that will meet the business need. Priority is given to standards that adhere to the principles described previously. If a standard is not already available, then FDA begins development activity. FDA identifies and works with a well-recognized standards development organization (SDO), when appropriate to develop and adopt the standard. Priority is given to voluntary, consensus based standards recognized by the American National Standards Institute (ANSI) such as the International Organization for Standardization (ISO), Health Level Seven (HL7) and National Council for Prescription Drug Programs (NCPDP).

For new health information exchange standards, the FDA works within HL7. The FDA also encourages other business experts, such as CDISC, ICH, other government agencies, and international regulatory bodies to bring their business requirements to HL7 to ensure interoperability among health information exchange standards.

[3] An example of a standard adopted for use within FDA, which is not a VCS, is the portable document format (PDF v. 1.4) standard for electronic documents. Although a proprietary standard, it is in widespread use and no comparable VCS existed that met the business requirements at the time of adoption.

[4] Note that steps 2 and 3 overlap. Implementation and Maintenance usually occur concurrently.

For format and terminology standards, the FDA uses existing standards and terminologies whenever possible (rather than create new terminologies). Priority is given to standards that adhere to the principles described previously. The FDA recognizes its role in maintaining certain terminologies (e.g., Unique Ingredient Identifier).

User Acceptance Testing and Adoption represent phases critical to the ultimate success and value of a developed standard. FDA is currently developing a more comprehensive data standards lifecycle management template to structure and help support this process.

FDA works with its end-user community and the appropriate SDO or terminology standards maintenance organization to update the standard as needed. Examples of this work, required to maximize the effectiveness of standards, include the need for FDA reviewers to work with CDISC to remove ambiguity in published SDTM and ADaM implementation guides and to provide additional data specification documents to ensure that Center's data requirements are clear. CDER and CBER will continue refining, improving, and expanding the use of CDISC standards for regulatory submissions for the process of human drug review through FY 2013 and beyond.

Implementation and Maintenance

In general, the implementation of standards can be difficult due to the vast number of stakeholders using or planning to use a standard. Therefore, there is a great deal of uncertainty about specific timelines.

The FDA is committed to working throughout the standards development and implementation process describe below with the business community to bring important improvements in information management that provide significant performance benefits and improve public health and safety.

Implementation of data standards should improve the quality of submitted data, and enable reviewers to access the data more quickly and consistently to conduct more thorough and timely reviews. Establishing a basic set of clear processes to support data standards development and implementation that engages all key stakeholders is a priority for CDER and CBER.

In order to begin a center-wide process that is clear, predictable, and aggressive in advancing the availability and utility of data standards and standardized data submissions, the Centers need to establish procedures and baseline capabilities. These include the following:

• Develop and initiate a process for prioritization of data standards development activities.

• Develop documentation, guidance, and training materials prior to the roll-out of any data standard.

• Develop and implement a communications strategy to support roll-out of the center data standards program.

• Establish a clear process for data standards development that engages all key stakeholders

To be effective, data standards development and implementation requires sustained organizational attention and senior leadership. Establishment of the CDER Data Standards Program Board arose out of the identified need for Center-level planning and coordination of its data standards activities. The purpose of the CDER Data Standards Program Board is to provide consistent oversight of CDER data standards activities, critical factors to the successful implementation of a data standard, which includes overseeing implementation of CDER business processes which will iteratively define, adopt, and enforce data standards.

An important measure of success is how well the standard is implemented according to a well-described, well-designed, publicly available implementation plan, and maintained to support functionality.

Another important measure of a successful standard is the extent to which the standard improves existing business processes. This measure depends on the existence of business performance metrics and data before and after standards implementation. These assessments are important as a move towards an overall quality systems approach to assure continuous business process improvements.

Specific Activities associated with Standards Development:

- Interaction with standards development and standards maintenance organizations

- Exchange standards development
  - Data standards requirements gathering / use case development
  - Modeling requirements and use cases (e.g., modeling to HL7 Reference Information Model)
  - Testing model against requirements and use cases to include development of visualization tools (e.g., stylesheets, XForm) documentation and coordination assistance
  - Balloting (e.g., ballot preparation, presentation and reconciliation)
  - Accreditation
  - Conformance specifications (implementation guide)
- Terminology standards development
- Format standards development
- Standards maintenance (e.g. Unique Ingredient Identifier, NCI Enterprise Vocabulary Services, ongoing evaluation and updating)
- Training and implementation support
  - Support for training or other related IT development activities associated with standards adoption and implementation (e.g. data type specification, message instance examples or data standards harmonization)

Drivers of Data Standards Development

- Business-driven requirements
- Clear policy mandate
- Business and IT impact analyses
- Development or enhancement of an IT system to use the standard
- Business process re-engineering

6.0 Programs

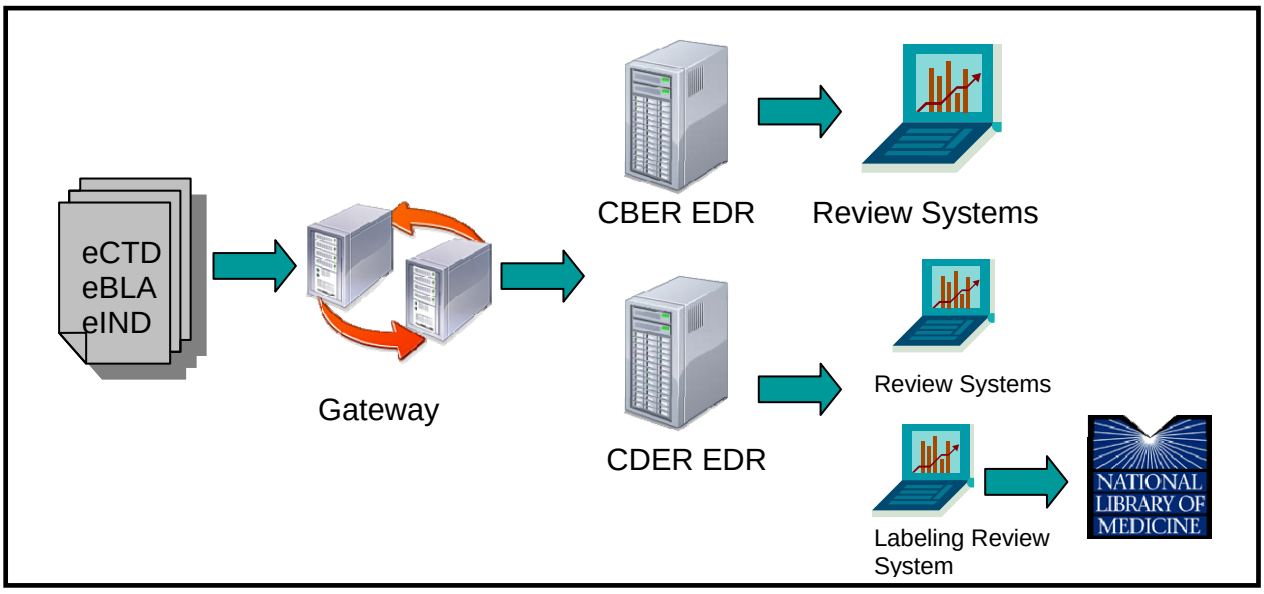
This section is divided into two sub-sections; Pre-Market Activities and Post Market Activities. The purpose of this section is to describe the current IT environment at a high-level and to show the FDA's current vision for the PDUFA IV target environment. As stated in previous sections, there are a number of ongoing planning activities that may impact how (e.g. the role of the e-Platform) and when (i.e. ensuring alignment with Agency strategic goals) the FDA is moving towards an automated standards-based IT environment. Although the FDA is continuing to address the strategy to fully implement the standards-based environment, the FDA has made a number of important strategic decisions in moving towards this vision and the initiatives described below reflect those decisions and the direction of the PDUFA Program. The division of this section into Pre-Market and Post-Market has been done for readability purposes, the FDA's plans and governance structure has been setup to ensure that information is shared throughout the product life-cycle. Examples of this are the FDA Electronic Submissions Gateway and the FDA Common EDR initiatives, these are described in the Pre-Market section but the scope of these efforts includes all regulatory documents.

6.1 Pre-Market Activities

In the past, most Centers in the FDA have developed and implemented software developed by their Center IT organizations. During the PDUFA III timeframe the FDA implemented the FDA Electronic Submissions

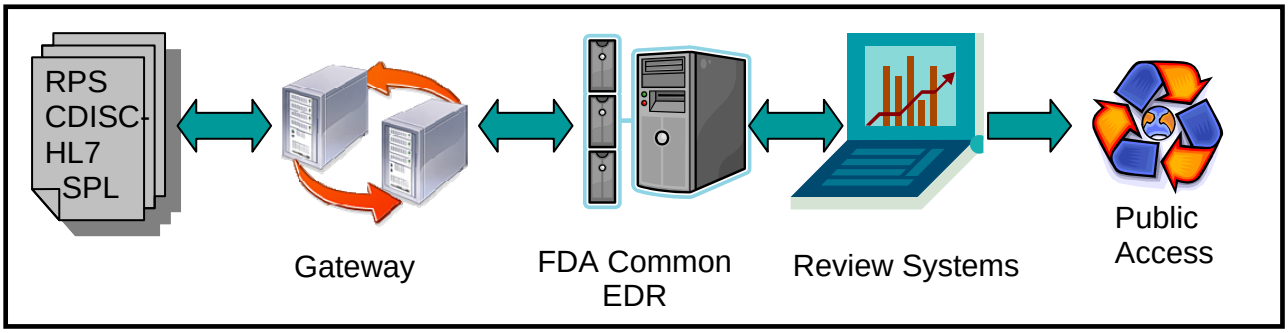
Gateway across the Agency and implemented the eCTD Review System, but both CBER and CDER continue to have separate systems to track and report on PDUFA goals and timelines. Many times there are separate systems to track PDUFA goals (e.g. meeting request). The diagram below represents the current environment at a high-level without providing the details on all the current systems supporting CBER and CDER.

Figure 7: E Submission Tracking and Archiving Premarket Current State



The Pre-Market target diagram represents FDA's current approach in developing and implementing an automated standards-based IT environment that will support the Agency's strategic goals and enable the FDA to meet the PDUFA IT Goals.

Figure 8: E Submission Tracking and Archiving Premarket Target State based on Standards Based Submissions



The table below describes the various initiatives and activities that are being performed or planned to move towards the target IT environment. The table describes the project, gives some background on the current status, discusses the FDA strategy and milestones for the project, and provides information on the PDUFA IT Goals that the project supports.

Dates listed are in calendar year format. Milestone timelines are approximate and will evolve over the PDUFA IV timeframe as will Center implementation.

Project Name and Description	Current Status	Strategy / Milestones
Regulated Product Submission, RPS, is a Health Level Seven (HL7) exchange standard to facilitate the processing and review of regulated product submissions. The next major version of the eCTD will be transitioned to the RPS standard and will include two-way communication. Two-way communication will handle the current electronic submission process (sponsor to FDA) and will handle FDA to sponsor communication using the RPS exchange standard. Additional enhancements include; additional submission metadata to facilitate submission processing; the ability to handle grouped supplements; and the ability to correct/modify attributes. The FDA plans on using the RPS standard to meet the PDUFA goal to cross-reference to previously submitted electronic materials and to standardize the two-way communication between the sponsor and the FDA.	The RPS Release 2 (R2) passed the HL7 Draft Standard for Trial Use (DSTU) ballot in January 2010. The DSTU phase of the project will enable FDA and regulated industry to test the RPS functionality to ensure that its meets eCTD submission requirements and the PDUFA IV requirements. FDA is participating in the RPS DSTU process through a HL7 RPS DSTU subgroup. The DSTU subgroup plans to use the first half of 2010 to prepare for DSTU testing and to use the second half of 2010 to conduct internal and industry testing. The DSTU objective is to test the functionality of the RPS message and will not include all the necessary processing modifications required to fully implement two-way communication. This will be done during the next phase of the project. In coordination with the RPS R2 activities, FDA is participating in the RPS Release 3 (R3) project. The RPS R3 will incorporate the core ICH requirements, for the next major version of the eCTD, and ICH regional requirements. Additional information on the HL7 RPS project can be found at http://wiki.hl7.org/index.php?title=Regulated_Product_Submissions	Perform RPS R2 DSTU testing and provide feedback to the RPS R3 project. June 2010 – Complete development of test cases and controlled vocabulary. September 2010 – Complete testing and; provide feedback and recommendations on updates to the RPS exchange standard. RPS Release 3 DSTU ballot – May 2011. After passage of the RPS R3 DSTU ballot FDA will participate in the RPS testing and prepare for implementation of the eCTD based on the RPS exchange message. Implementation activities include; updating ICH specifications; updating FDA guidance; documenting and finalizing RPS controlled vocabulary; and performing system development and enhancements. FDA's current target for accepting eCTD RPS based messages is mid-2013.
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. CBER, CDER, CDRH, AERS and CVM 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	As part of the Extranet Database Separation Project the ESG recently received four new database servers – two productions and two pre-production. This infrastructure configuration change will lead to greater system uptime for the ESG as a result of removing dependencies on shared hardware. The ESG and the FDA Industry Systems (FIS) Extranet has just completed the standing of a test and development area complete with network head. The new network head will be shared with the present pre-production environment. The	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 2010. Depending on the progress garnered as well as the uptake by interested parties, the FDA could expand the ESG in several areas during 2010.

Project Name and Description	Current Status	Strategy / Milestones
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.	production environment now utilizes a separate network head.	Begin limited testing in support of the use of the SPL standard version 4 for registration and listing.
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.	FDA is nearing completion of requirements gathering to resolve validator issues encountered during the implementation of the upgraded validator. This process has also identified changes required to the FDA viewing tool. We are working in close cooperation with the vendor and anticipate that final requirements will be completed by May 1, 2010 at which time work will commence on the development of testing and implementation plans. Following the delivery of requirements we anticipate that FDA's vendor will provide estimates as to the availability for the next version of their product. A work stream has been initiated with CDER and CBER to begin the process of modifying Module 1 of the eCTD. These changes are intended to promote further automation of FDA's submission receipt process, provide support for submissions related to the submission of advertising and promotional materials, provide specific locations for materials not currently included in Module 1 such as the 3674, and general improvements to enhance the usability of Module 1.	Following the availability of the next version of FDA's review tool, FDA will finalize it implementation and testing plans and move aggressively to implement this new version. Additionally, FDA will be revising it's eCTD Validation Criteria to align with the validation criteria implemented in this new version. FDA will also look to clarify existing documentation to remove any ambiguities which may exist in the current documentation. Since a release date has not been established by the vendor, FDA cannot provide an estimated implementation date at this time. FDA does anticipate that the vendor will make available a beta version of the validation and review tool that FDA could utilize for testing of the RPS2 message. The availability of a beta version will help FDA further refine its plans for the implementation of the production version of the tool. The vendor has indicated that they anticipate that they can provide this in late Q310.
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.	Release 3.0 implemented in July 2009 resulting in the retirement of 17 legacy systems. Several minor releases have been implemented to address data migration and functional issues. Requirements for Release 3.1 have been developed and delivered to the developers. Requirements solicitation is underway for Release 3.2 to include the migration of DDMAC submissions into DARRTS and the subsequent retirement of 2 additional legacy systems.	DARRTS continues to develop using an iterative process. Release 3 development will continue as CDER continues planning for Release 4.0 to include the development and migration requirements for implementing CDER's BLAs. Anticipated future DARRTS 3 releases are expected to include functionality designed to enhance FDA operations by further automating the submission receipt process through enhancements to Module 1 of the eCTD, to

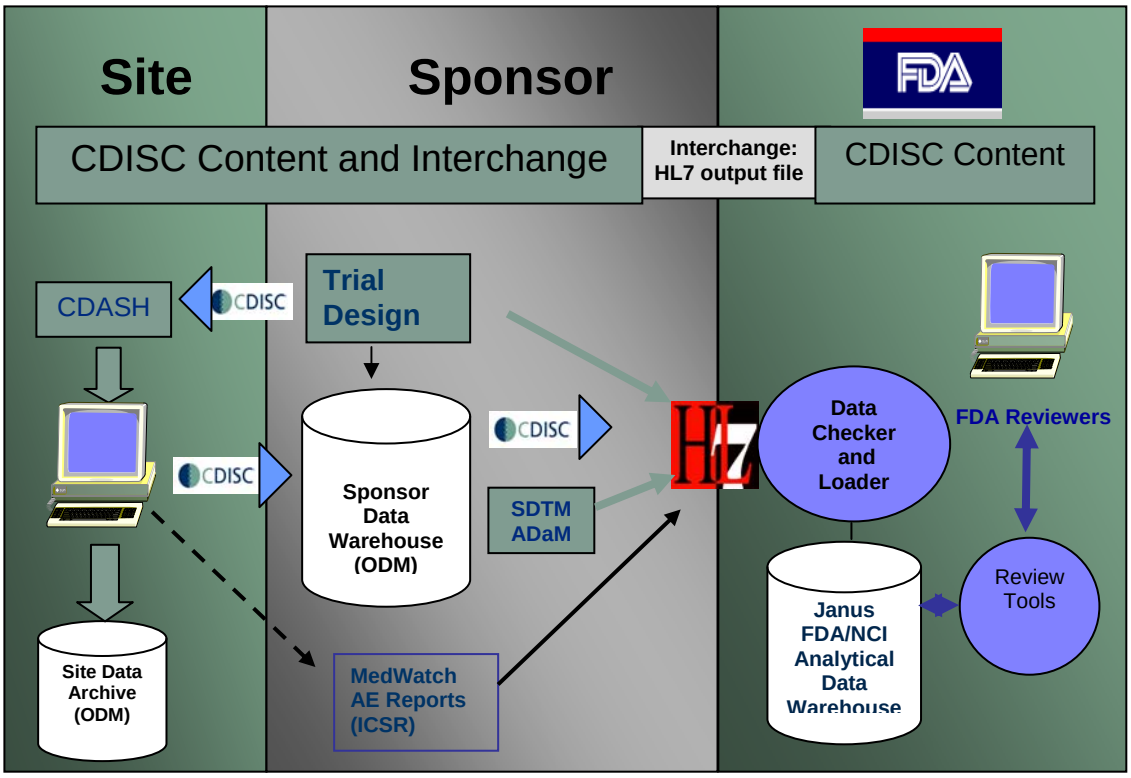
Project Name and Description	Current Status	Strategy / Milestones
		implement tracking to support Biomarker/Qualification business processes, improve support for FDAAA Title VIII requirements as well as other improvements. DARRTS Release 3.1 is currently scheduled for 3Q10. Due to the ongoing work under the ICT21 initiative there may be issues which impact the 3.1 and later releases.
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.	Production data center received Authority To Operate (ATO) on 10-15-2009 Development environment is configured and first application installed WODC Management environment configuration underway Security monitoring of WODC being configured	1st production application live in Contractor Hosted Data Center (CHDC) - 6-1-2010 Authority to Operate (ATO) for the White Oak Data Center - 5/31/2010 All OIM managed applications live in CHDC - 10/29/2010 All OIM managed applications (except VMS based) moved out of the old datacenter in Park Lawn - 12/31/2010
FDA's Common Electronic Document Room (cEDR) initiative is intended to establish one common, Agency-wide, standards-based EDR as a single platform repository for all FDA-regulated product documents. Having a single platform repository 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 reviewers and others to perform their jobs. In addition, having an Agency-wide EDR offers the opportunity to reduce redundancy and related costs	Since the project initiated in September 2008, a significant number of requirements definition has been completed based on input from all the Centers, ORA, select OC offices, and the Record Managers. This includes: • Current state taxonomy and metadata of each of the existing Agency EDRs was documented (November 5, 2008). • Current state and to-be business process models were defined (April 15, 2009). • Requirements document and requirements traceability	Initial plans following the requirements phase and the alternatives analysis phase of the project were to proceed with procurement activities and to deliver the cEDR initial operating capability (i.e., an operational, production system) followed by the migration of existing EDRs/documents. The FDA recently completed an enterprise IT portfolio assessment to evaluate the overall progress, approach, and risks of each project. The resulting recommendations focus on leveraging the FDA's limited resources. Specifically,

Project Name and Description	Current Status	Strategy / Milestones
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).	matrix (October 7, 2009). The most recent deliverables in FYQ2 2010 are the final documents for the current contract.	Documentum was selected as the EDR tool of choice, based on FDA's current use of the tool. With completion of the most recent deliverables, the project will not proceed further in FY 2010 and will be reevaluated in the near future.
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		
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.	The eLIST system has been in production since July 2008. Since June 2009, in addition to labeling being processed, eLIST is used to process all establishment registrations and drug listings submissions.	Continue updates to validation procedures and evaluation for use with other FDA regulated products.
CP (Collaboration Portal) – Please refer to the e-Platform Initiatives in Section 5.2		
Substance Registration System – The overall purpose of the 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. The SRS is currently being used to define and identify substances in regulated products and is used to identify substances in SPL submissions.	A simplified substance model has been developed to define all types of material regardless origin or complexity. This model forms the basis of the proposed ISO IDMP standards. UNII's are now listed on NLM's Chemid website.	Collaborate with outside substance databases. Structure-based searching SRS for FDA reviewers. Public search function for substances in the public domain.

Figure 9 below describes the FDA's direction in moving towards XML exchange messages based on the HL7 Reference Information Model to submit clinical study data to the FDA. A similar diagram is envisioned for preclinical data. It should be noted that FDA does not determine which data standards are used at the study site or by the sponsor prior to a regulatory submission. The diagram below represents our current thinking of the

standards activity in these domains. As stated in the Guidance, Policy and Regulation, Section 5.5, the FDA is currently working on a proposed rule that would require the electronic submission of clinical data to the FDA.

Figure 9: PDUFA Vision for Clinical Data Flow



Central to this vision is the creation of an enterprise data infrastructure within FDA to improve the management of all structured scientific data, including standardized clinical study data. The Janus initiative will improve FDA management of structured scientific data through the creation of a standards-based infrastructure that supports the exchange and management of structured scientific data about the products that the FDA regulates. More specifically, implementation of the Janus initiative will enable the FDA to:

- Establish an enterprise-wide data architecture and standards that facilitate the integration of structured scientific data from a wide variety of internal and external sources to create large-scale data-sharing infrastructures;
- Develop the standards-based scientific data exchange networks that are needed to ensure the quality, safety, and efficacy of medical and consumer products as defined by FDA's regulatory mandate;
- Create structured scientific data repositories that support the acquisition, validation, integration, and extraction of data from the increasingly large and complex datasets received by the Agency; and
- Make use of enhanced analytical, mathematical, visualization, and other computational tools and techniques that enable reviewers to search, model, and analyze data to conduct better safety and efficacy analyses.

The ultimate goal of this initiative is to support and improve the regulatory review process through which the FDA can convert scientific data into useful scientific knowledge to inform its regulatory decisions.

Dates listed are in calendar year format. Milestone timelines are approximate and will evolve over the PDUFA IV timeframe as will Center implementation.

Project Name and Description	Current Status	Strategy / Milestones

Project Name and Description	Current Status	Strategy / Milestones
Clinical/Preclinical Data Standards & Initiatives – The FDA receives massive amounts of clinical research data in extremely disparate formats using a variety of proprietary standards. This makes it extremely difficult, if not impossible, to do cross-study and application reviews. The FDA has been working towards a standardized approach to capture, receive, and analyze clinical study data. The standardization of clinical data is vital to the FDA strategic initiatives to integrate pre-marketing clinical trial data and post-marketing safety data to improve public health and patient safety. The goal of these efforts are to; • Enhance FDA regulatory decision making and address complex public health questions through improved data management through; – Standardize data - exchange and terminology standards to facilitate data aggregation, analysis, data mining and signal detection – Improved access to aggregate data – User friendly tools for review The foundation for the standardized clinical content is the Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTM). The SDTM will also include nonclinical requirements based on the Standard for Exchange of Nonclinical Data (SEND) models that is being harmonized with the SDTM. SDTM version 3.1.2 submissions are accepted by FDA. FDA and CDISC are in the process of forming a communications team that will ensure SDTM meets FDA's scientific requirements.		
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.	The Study Data Standards have passed ballot as DSTUs. FDA's Data Standards Council (DSC) is actively developing tools (xforms and stylesheets) that can be used to create and display data that conform to the Study Data Standards. The DSC is developing via a CRADA software that can be used to create and display Study Design data that conform to the HL7 Study Design standard. Initial testing of the Study Data Standard has been completed, and has resulted in the successful conversion of CDISC SDTM data to Study Data Standard data, and this Study Data Standard data has been successfully loaded into a RIM database, and a JANUS database.	FDA's DSC will: Continue to collaborate with CDISC and FDA stakeholders to develop a comprehensive testing plan for the Study Data Standards. Work with CDISC and FDA stakeholders to develop a long term strategy for transitioning to HL7 Study Data Standards. Design and develop tools that can be used to implement the Study Data Standards in CDER and CBER. Work with CDER and CBER to determine a reasonable implementation strategy and timeline for CDER and CBER.
BRIDG Model - The Biomedical Research Integrated Domain Group, BRIDG Model, is a domain analysis model representing protocol-driven	FDA will review the BRIDG model currently in the HL7 May 2010 ballot cycle and will provide comments.	FDA continues to have a representative on the Board of Directors and will continue to provide input on efforts to

Project Name and Description	Current Status	Strategy / Milestones
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 Work group (RCRIM WG), 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. The goal of the BRIDG Model is to produce a shared view of the dynamic and static semantics for the domain of 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, subject characteristic, or device on a human, animal, or other subject or substance plus all associated regulatory artifacts required for or derived from this effort, including data specifically associated with post-marketing adverse event reporting. 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.	Harmonization status with NCI projects: (May-June 2010) NCI's Clinical Participant Registry (C3PR) project is in progress NCI projects (Patient Study Calendar (PSC**),** caBIG® Adverse Event Reporting System (caAERS), and LabViewer).	harmonize FDA standards with the BRIDG.
The JANUS data warehouse for study data is being developed by the National Cancer Institute (NCI) with the FDA participating through	Implementation of an operational pilot (Phase 2) in CY2008 through Q3 CY2009 (for intermittent processing of SDTM submissions).	The system implementation stage of the JANUS operational pilot (phase 3) is scheduled to begin on the Q2 CY2010. This phase includes

Project Name and Description	Current Status	Strategy / Milestones
its Interagency Oncology Task Force activities. The NCI and the FDA are collaborating to implement a common, standards-based electronic infrastructure for the submission, review, and analysis of regulatory data.	Included development of a data validation and import facility, loading of validated SDTM datasets into the JANUS repository, and creation of analytical views that could be accessed with reviewer analytical and visualization tools, such as WebSDM and JReview. Planning for operational pilot (Phase 3) completed Q4 CY2009. Proposed extensions to JANUS logical data model (JANUS 1.0) based on stakeholder input. Process managed by JANUS Change Control Board (CCB), with representation from NCI, FDA, CDISC, and industry CY2007-2009). Published FR notice announcing JANUS Phase 3 Pilot Q2 CY 2008 to engage interested stakeholders in future JANUS development. CDER JANUS CONOPS (Concept of Operations) and implementation plan began Q3 CY2009.	update to the JANUS physical database design (JANUS 2.0 database design), automating the process of validation and data loading, and security enhancements. The system deployment stage of the JANUS operational pilot (phase 3) is scheduled for CY 2011. This includes the installation package and guide, user support and software product documentation. Currently, the standard for the submission of human study data for JANUS is the Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTM). FDA will continue to partner with NCI's Enterprise Vocabulary Services (EVS) for controlled terminology and vocabulary issues.
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	CDISC SEND is an implementation of SDTM for animal studies. SEND pilot (Phase II) is ongoing in CDER The SEND Implementation Guide (SENDIG) v3.0 Draft A and the SEND Controlled Terminology for v3.0 Draft A were released Q3 2009 (http://www.cdisc.org/). CVM announced a pilot project to test the electronic submission of margin of safety and non-clinical toxicology study data using SEND (Fed Reg Vol 74(236)) Q4 2009.	

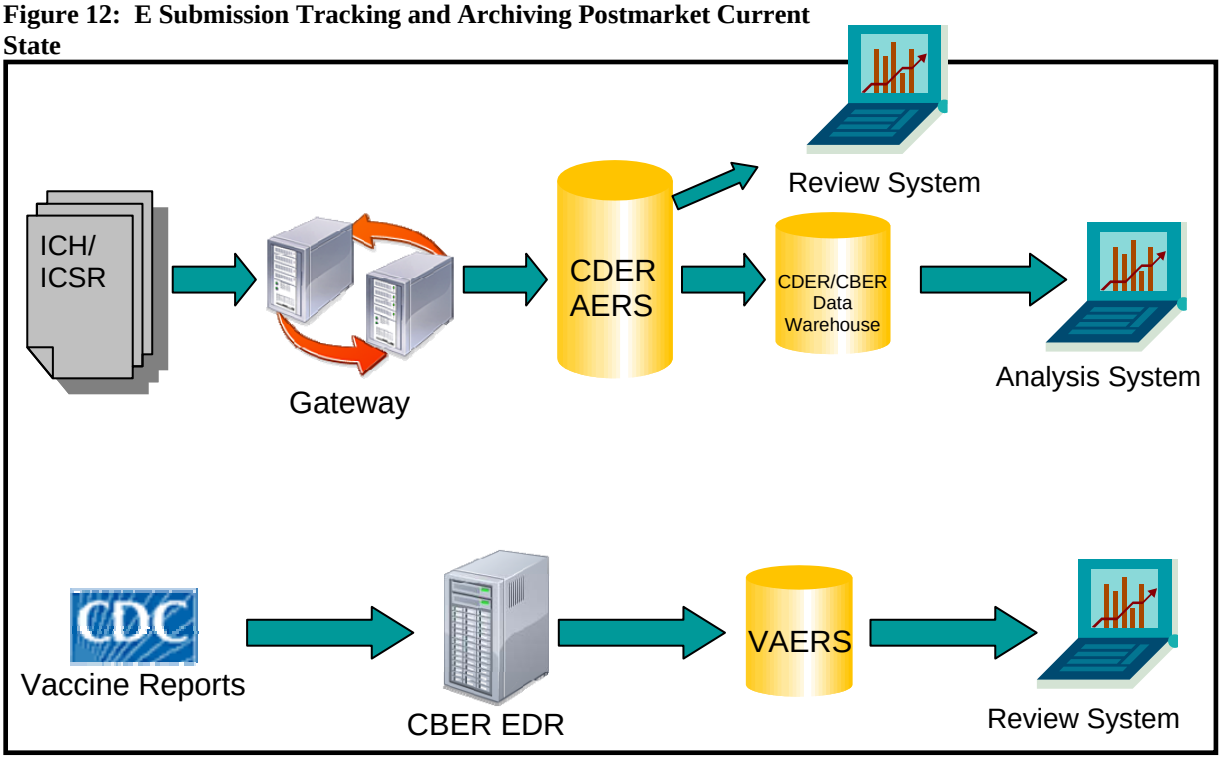
Project Name and Description	Current Status	Strategy / Milestones
applications (NDAs), and biologics licensing applications (BLAs).		
Electronic Case Report Form eCRF Pilot - The purpose of the eCRF pilot project is to obtain experience with the CDISC Operational Data Model (ODM) based CRFs. Based on 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.	FDA discontinued its originally planned CDISC ODM pilot to focus agency-level efforts on longer-term standards development work	While the FDA DSC pursues continued longer-term development of HL7 study data standards, as a near-term strategy to support drug review, CDER and CBER are re-evaluating the benefits of pilot testing an ODM based eCRF.
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.	Set of "content standards" for a basic set of global data collection fields to support clinical research studies CDISC published Version 1.0 CDASH on Oct 2008 (available on CDISC website) CDISC collected feedback from early implementers Developed and tested clinical endpoints/efficacy terminology The public review period for CDASH V. 1.1 and the CDASH User Guide V 1.0 is planned to commence on April 8th. Visit cdisc.org to download and review these draft documents.	The next steps on the CDASH horizon include working as part of the CDISC Share project to ensure that the SDTM and CDASH are semantically in line and working with the SDS team (the team that produced and maintains the SDTM) to identify the basic device related collection fields. In addition to maintaining the CDASH standard and User Guide as well as developing updated training materials and courses.

Project Name and Description	Current Status	Strategy / Milestones
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.		
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.	Release 2 Implementation Guide passed ballot in January 2009 and Release 2 published a DSTU with 9 month test period in April 2009 Stability Style sheet procurement announcement made in August 2009 Started work on Input Tool in August 2009.	Ballot eStability Release 2 as Normative Standard in May 2010. Secure funding for the development of Schematron (business rules).
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.	Our Data Specifications point to ADaM as an option for submitting analysis files for review – Q1 2010.	ADaM is pointing to release model for analysis of adverse events among a number of other implementation guides – Q2 2010.

6.2 Post-Market Activities

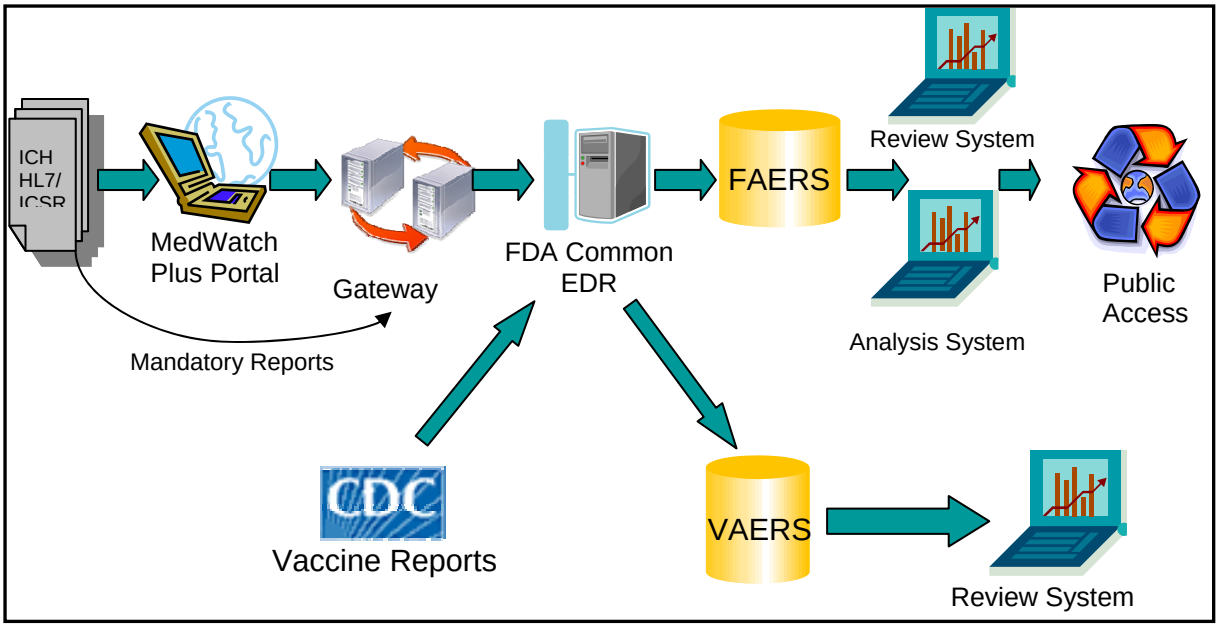
As outlined in the Pre-Market Activities section, most Centers in the FDA have developed and implemented software developed by their Center IT organization to track and analyze spontaneous post-market safety reports. The CDER Adverse Event Reporting System (AERS) has been the exception to this rule. Although the drug safety reports are submitted to and processed by CDER, both CBER and CDER use the same AERS application to view the ICSR and the same data warehouse to perform analysis on the safety reports. Within the PDUFA program there is a separate reporting mechanism for the submission of vaccine adverse reports; this process is handled by the Center for Disease Control (CDC) with the information transferred to CBER for analysis.

Figure 12: E Submission Tracking and Archiving Postmarket Current State



The Post-Market target diagram represents FDA's future approach in developing and implementing an automated standards-based IT environment that will support the Agency's strategic goals and enable the FDA to meet the PDUFA drug safety IT Goals. As described below the FDA is taking an Agency approach in capturing, tracking, and analyzing drug safety reports through the MedWatch Plus initiative.

Figure 13: E Submission Tracking and Archiving Postmarket Target State



Dates listed are in calendar year format. Milestone timelines are approximate and will evolve over the PDUFA IV timeframe as will Center implementation.

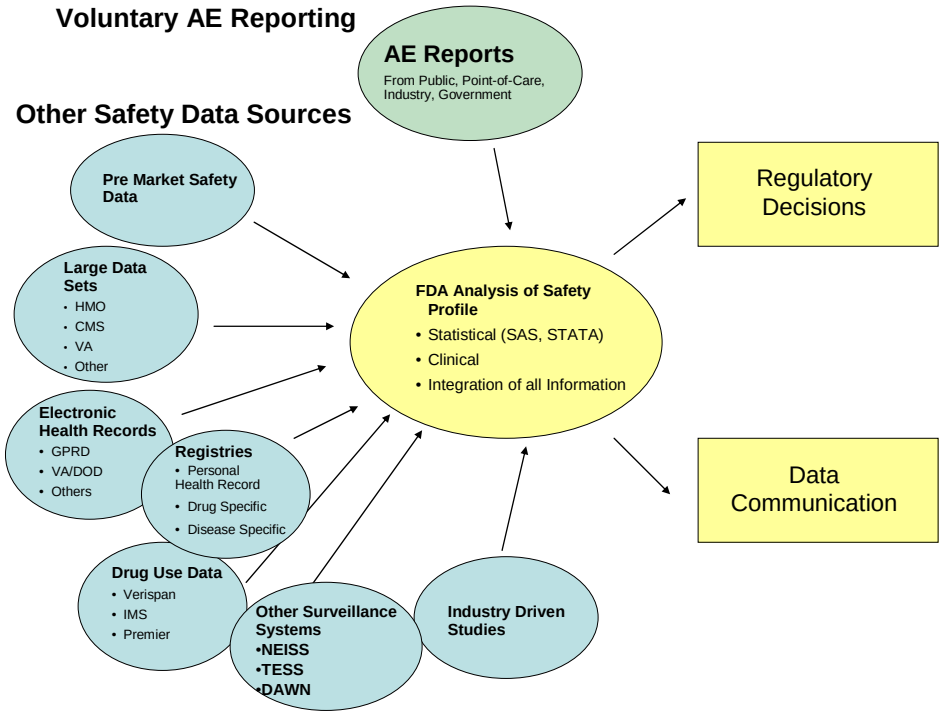
Project Name and Description	Current Status	Strategy / Milestones
The MedWatch Plus initiative will enable the FDA to improve the timeliness, accuracy, and usability of its product safety surveillance data by significantly reducing delays and errors associated with manual data entry and coding of paper 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. The goal of the FDA Adverse Event Reporting System (FAERS) is to provide the best available, efficient, supportable technology to enhance the analysis of adverse events, product/consumer complaints, and product problem reports from regulated industry, consumers, and healthcare professionals. The purpose of this system is to improve the FDA's post-market product	Delivered final Proof of Concept on March 23, 2010.	Product Dictionary Requirements Document – June 2010 Prototype training: May 2010 Approve and Prioritize gap Requirements for Rel. 1 July 2010 Prototype Release 0.1 June 2010 Prototype Release 0.2 September 2010 Prototype Release 0.3 - TBD FAERS Release 1.0 - CBER and CDER TBD

Project Name and Description	Current Status	Strategy / Milestones
safety surveillance capabilities by providing enhanced individual and aggregate safety report handling and analysis.		
The HL7 Individual Case Safety Report (ICSR) captures information needed to support reporting of adverse events, product problems and consumer complaints associated with the use of FDA regulated products.	Completed proof of concept testing to convert legacy E2B(M) ICSRs into HL7 ICSRs and make data available for review using the Pragmatic RIM database and AE Sentinel module tool Completed Phase I proof of concept testing to create HL7 ICSR messages based upon revised ICH E2B(R3) content using XFORMs	Conduct ICH E2B and VAERS Phase II pilot testing 2 - 3 Quarter 2010 ICSR Final DIS ballot publication 4th Quarter 2010 Conduct proof of concept testing to convert legacy VAERS data into HL7 ICSR using the Pragmatic RIM database and AE Sentinel module Conduct end-to-end proof of concept testing for triggered AE reporting using electronic health record systems and HL7 ICSR
Sentinel System - The Sentinel System will enable FDA to query multiple, existing data sources, such as electronic health record systems and medical claims databases, for information about medical products. The system will enable FDA to query data sources at remote locations, consistent with strong privacy and security safeguards. Data sources will continue to be maintained by their owners.	The Agency believes that funding for this ambitious postmarket program is more appropriate within the context of the PDUFA drug safety program, rather than the PDUFA IT plan. Therefore, the Sentinel System will be removed from the PDUFA IT plan and discussions for inclusion in the PDUFA drug safety program are underway.	

The modernized post-market safety related IT systems will ensure the best collection, evaluation, and management of the vast quantity of safety data that may be received by the FDA as noted below in figure 14. Improvement in the infrastructure will support access to and the analyses of externally linked databases, as well as enhancement of the FDA's AERS and safety signal detection and management tools. The MedWatch Plus initiative will result in a common FDA portal for electronic receipt of adverse event reports from the public and will provide direct electronic transfer of these reports to the database and data analysis tools.

In addition to the enhancement and modernization of the drug safety systems, the FDA will be expanding CBER's and CDER's acquisition/access and analyses of externally-linked databases for purposes of targeted, or active, post-marketing surveillance. The figure on the next page includes both passive surveillance data sources, and active surveillance data sources that FDA will use to ensure drug safety.

Figure 14: Sources of both Passive and Active Surveillance Data for FDA Drug Safety Activities



7.0 Appendices

7.1 PDUFA IV Metrics

The PDUFA IV Information Technology Performance Goals Metrics and Measures subsection (Section XIV, D) states, 'FDA will measure progress toward achievement of the objectives defined in PDUFA IT Goal A.' One of the measures the FDA has agreed to track and report on is spending on common IT systems, item 3 under the Metrics and Measures subsection. It states 'Annual spending on maintenance of legacy IT systems and IT systems that are common across the organizational divisions participating in the process for the review of human drug applications.' The FDA will report on the progress towards a common PDUFA IT environment by reporting on the percentage of funding used for Common IT Systems and Legacy IT Systems. Each of these categories is defined below.

> **Common IT Systems** – Development & maintenance spending on software applications, tools, and other products that both CDER and CBER use or plan to use to receive, track, and review PDUFA submissions. In addition, enterprise architecture activities and IT infrastructure consolidation activities are incorporated into this category of spending.
>
> **Legacy IT Systems** – Development & maintenance spending on software applications that are used by a single Center and that overlaps with software functionality performed by another Center. These systems are not part of the target enterprise architecture.

The FDA will report on progress towards a fully electronic submission process by reporting on NDA, BLA, and IND submissions that are totally electronic and submitted through the FDA Electronic Submissions Gateway. The FDA will provide overall progress towards this objective including information based on the type of submissions. In addition, electronic standards based submissions will be reported that fail to comply with FDA electronic submission standards across categories of failure or problem type.

7.2 PDUFA Information Management/IT Goals and Objectives

INFORMATION TECHNOLOGY GOALS (Section XIV)

A. Objectives

1. FDA is committed to achieve the long-term goal of an automated standards-based information technology (IT) environment for the exchange, review, and management of information supporting the process for the review of human drug applications throughout the product life cycle. Towards this goal, FDA will work toward the accomplishment of the following objectives by the end of FY 12:

a) Develop and periodically update an IT plan, as defined in Sections B) and C) below, covering a rolling five-year planning horizon.

b) Develop, implement, and maintain new information systems consistently across all organizational divisions participating in the process for the review of human drug applications, and in compliance with the IT plan, the FDA's program-wide governance process, the FDA's target enterprise architecture, and with HHS enterprise architecture standards. The consistency of development, implementation, and maintenance of new information systems will be determined by the FDA based on considerations of program efficiency and effectiveness. Emphasis will be placed on the consistency of interactions with regulated parties and other external stakeholders.

c) Update technical specifications and IT-related guidance documents as necessary to reflect consistent program-wide implementation of new information systems supporting electronic information exchange between FDA and regulated parties and other external stakeholders.

d) Extend the capability of the secure electronic single point of entry to include two-way transmission of regulatory correspondence.

e) Establish an automated standards-based regulatory submission and review environment for INDs, NDAs, and BLAs, and their supplements, that enables the following functions over the life cycle of the product:

(1) Electronic IND, NDA, and BLA submissions received by FDA can be archived to enable retrieval through standardized automated links;

(2) Electronic IND, NDA, and BLA submissions can include cross-references to previously submitted electronic materials through standardized automated links; and

(3) Archived electronic IND, NDA, and BLA submissions can be retrieved through standardized automated links.

f) Establish a system for electronic exchange and management of human drug labeling information in a modular manner (e.g., at the label section level) that is based on FDA standards and that enables revision tracking.

g) Establish standards-based information systems to support how FDA obtains and analyzes post-market drug safety data and manages emerging drug safety signals, as described in Section VIII addressing the enhancement and modernization of the FDA drug safety system.

B. Communications and Technical Interactions

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.

4. The FDA and industry stakeholders will meet on a quarterly basis to discuss ongoing implementation of the IT plan, status of IT metrics as available, and potential impacts that future activities may have on stakeholders. These meetings will also be used to discuss potential FDA revisions to the IT plan based on operational experience.

C. Standards and IT Plan

The IT plan referenced in PDUFA IT Goal B will provide a vision for FDA standards and technical infrastructure supporting the process for the review of human drug applications and will address the following:

1. A description of the scope and approach for an evaluation and design of the target enterprise architecture necessary to achieve the objectives defined in PDUFA IT Goal A.

2. The business processes targeted for automation to achieve business-driven objectives.

3. Which electronic data standards, including the associated Standards Development Organization, are being considered for adoption or development. (Note: The FDA's process for adopting or developing standards includes the consideration of existing open consensus standards prior to the development of new standards. FDA participates in international Standards Development Organizations and supports global harmonization of data standards through open structured processes.)

4. Implementation of information systems that are based on the electronic data standards.

5. Training for system users, stakeholder adoption, and communications for transitioning to new or reengineered information systems supporting the process for the review of human drug applications.

6. A description of FDA's processes for

a) evaluating business processes for electronic information exchange between FDA and regulated parties or external stakeholders;

b) evaluating, adopting or developing electronic data standards for information exchange between FDA and regulated parties or external stakeholders; and

c) developing, piloting, and deploying information systems that use those standards in supporting the process for the review of human drug applications.

D. Metrics and Measures

FDA will measure progress toward achievement of the objectives defined in PDUFA IT Goal A. Measures will include:

1. The number and percentage of IND, NDA, and BLA submissions received in valid electronic format in compliance with FDA standards, categorized by types of submissions. Increasing the number and percentage of IND, NDA, and BLA submissions received in valid electronic format is a goal that is supported by the FDA and industry stakeholders. Achievement of this goal requires the cooperation of regulated industry. To support the assessment of this goal, the following information will be tracked and reported at least annually:

a) Total number of submissions categorized by type of submission;

b) Total number of submissions in valid electronic format in compliance with FDA standards

c) Total number of submissions received through the secure electronic single point of entry versus other methods; and

d) Total number of submissions received substantially on paper.

2. Total number of standards-based electronic submissions that fail to comply with FDA electronic submission standards, along with a distribution of these submission failures across categories of failure or problem type.

3. Annual spending on maintenance of legacy IT systems and IT systems that are common across the organizational divisions participating in the process for the review of human drug applications.

4. Other measures and milestones to be identified in the IT plan addressed under Sections B and C above.

Drug Safety Goals (Section VIII)

A. Development of 5-year plan, and Communications and Technical Interactions

1. The FDA will develop and periodically update a 5-year plan describing activities that will lead to enhancing and modernizing FDA's drug safety activities/system. The activities described in the 5-year plan will include:

c) Expanding CBER/CDER's database acquisition and use for the purposes of targeted post-marketing surveillance and epidemiology;

e) Improving post-market IT systems (e.g., AERS 2, safety tracking system, and opportunities for linked data management).

B. Conduct and support activities designed to modernize the process of pharmacovigilance

3. Expanding Database Resources: A critical part of the transformation of the drug safety program is maximizing the usefulness of tools used for adverse event signal detection and risk assessment. To achieve this end, data other than spontaneous reports, including population-based epidemiological data and other types of observational data resources will be used and evaluated. Access to these types of data will expand the FDA's capability to carry out targeted post-marketing surveillance, look at class effects of drugs, and potentially carry out signal detection using data resources other than reports from AERS system. PDUFA funds will be used to obtain access to additional databases and program staffing with epidemiologists and programmers who are able to use these new resources.

D. Other Activities

FDA will establish the following standards-based information systems to support how FDA obtains and analyzes post-market drug safety data and manages emerging drug safety information:

1. Enhanced adverse event reporting system and surveillance tools;
2. IT infrastructure to support access and analyses of externally-linked databases; and
3. Workflow tracking system.

7.3 PDUFA IV Goals Mapped to FDA Initiatives

(On next page)

	PDUFA IV Information Technology Goals (Section XIV)												Drug Safety Goals (Section VIII)		
FDA Initiatives	**A 1. b Implement new systems consistently across divisions**	**A.1.c Update Tech Specifications as needed**	**A.1.d Extend single entry to two way transmission**	**A.1.e Electronic IND, NDA and BLA with automated links**	**A.1.f Human drug labeling modular system/exchange**	**A.1.g Standards based postmarket systems**							**D 1. Enhanced adverse event reporting system and surveillance tools**	**D 2. IT infrastructure to support access and analyses of externally-linked databases**	**D 3. Workflow tracking system**
E-Platform Initiatives															
Firebird	✓	✓													
Collaboration Portal	✓	✓			✓										
Pre-market Initiatives															
Regulated Product Submission (RPS)	✓	✓	✓	✓											
Electronic Submissions Gateway (ESG)	✓	✓	✓	✓											
eCTD Review System	✓	✓	✓	✓											
Workflow Tracking and Information Management System (DARRTS)	✓			✓											✓
Information and Computer Technologies for the 21st Century (ICT21)	✓		✓	✓	✓	✓							✓		✓
Common Electronic Document Room (EDR)	✓			✓		✓									✓
Electronic Labeling Review System	✓	✓		✓	✓										✓
Electronic Listing	✓	✓		✓											✓
Substance Registration System	✓			✓	✓										✓
Clinical/Preclinical Data Standards and Initiatives															
CDISC – HL7 Project	✓	✓				✓								✓	
BRIDG Model	✓	✓				✓								✓	
Janus Data Warehouse	✓	✓	✓			✓							✓	✓	
Standard for Exchange of Nonclinical Data (SEND)Pilot	✓	✓													
Electronic Case Report Form (eCRF) Pilot	✓	✓				✓								✓	
Clinical Data Acquisition Standards Harmonization (CDISC CDASH)	✓	✓				✓								✓	
Product Stability Data Standard	✓	✓		✓	✓										
CDISC ADaM Analysis Data Model	✓	✓				✓								✓	
Post-market Initiatives															
MedWatch Plus	✓	✓				✓							✓		✓
Sentinel System						✓							✓	✓	✓

Note: Goals section 'B. Communications and Technical Interactions' and 'D. Metrics and Measures' are not included on the goals listed above. Both goals are discussed in the plan and do not directly map to programs.

7.4 Business Review Boards 5-year Goals, Priorities and Current Projects

Post-Market Safety

5-year goal:

Strengthen capability to rapidly identify, assess and mitigate safety problems

Priorities:

- Develop electronic receipt capabilities (i.e. improve receipt of spontaneous reporting, create a usable receipt interface, adopt, develop & implement data standards HL7 ICSR & SPL)
- Enhance exploratory data analysis (i.e., strengthen signal detection & management of spontaneous reports)
- Harmonize terminologies (i.e. create or adopt common terminology reference sources, implement terminology standards for all FDA product)
- Improve knowledge base systems (i.e. Increase capacity to archive and search data & information, implement MedWatch plus – FAERS)
- Create supporting rule making (i.e. modify & update regulatory documentation (rules & guidance) to reduce / eliminate paper submissions)

Major Project(s):

- MedWatch plus, including MedWatch plus portal project and FDA Adverse Event Reporting System (FAERS)

Product Quality and Compliance

5-year goal:

Assure product quality and compliance through timely access to and better use of accurate FDA-related entity information across the Agency (entities are firms, facilities, points of contact, products, components/ingredients)

Priorities:

- Implement Harmonized Business Processes and Systems for Identification and Tracking of FDA-Related Firms and Facilities across the Agency
- Implement Harmonized Business Processes and Systems for Identification and Tracking of FDA-Regulated Products and Components/Ingredients across the Agency
- Provide Single Portal Access to Comprehensive Entity Information
- Harmonize FDA and Customs and Border Protection (CBP) Processes in order to Ensure Import Data Quality and Completeness
- Enhance Automation of Import Screening Processes

Major Project(s):

- Harmonized Inventory of FDA-related entities, including registration and listing.

Pre Market Review

5-year goal:

Implement a standards-based end-to-end fully electronic receipt, review, dissemination and archival environment

Priorities:

- Create or Adopt Standardized Structure and Formats for Data and Documents
- Adopt HL7 Regulatory Product Submission (RPS) Standard for all FDA Regulated Products
- Improve and Automate Electronic Receipt Functions
- Improve Search Tools and Capabilities
- Improve Automation of Workflow
- Improve Document Management

Major Project(s):

- Common Electronic Document Room (EDR) and Regulated Product Submission (RPS)

Administrative Services

Priorities:

- Human resources
- Payroll
- Budget formulation and planning
- Tracking systems
- Travel

They are now in the process of identifying priority initiatives.

Scientific Computing / Computational Science

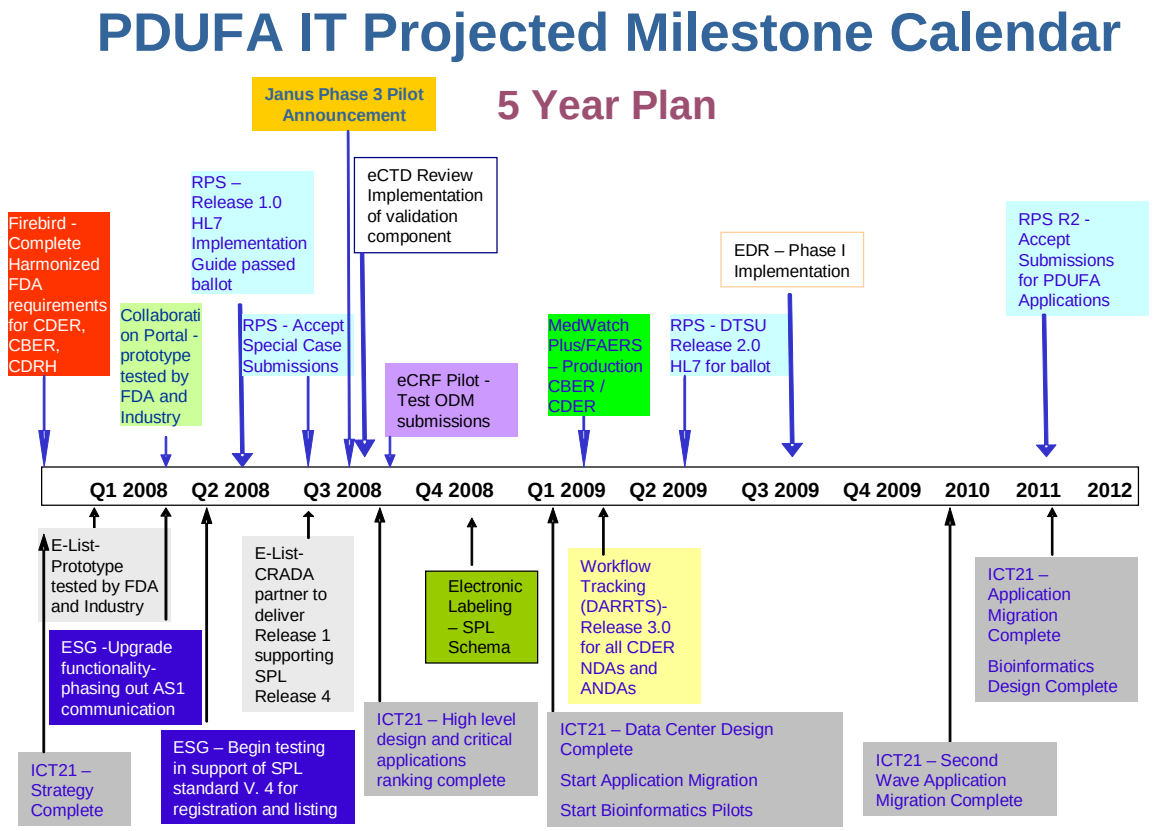
The Scientific Computing / Computational Science BRB addresses both review and laboratory information management scientific needs of the FDA. This includes automated laboratory management including improving field and center laboratories. Workgroups are formed to address the Agency needs in the following areas:

- Procedural and collaboration
- Networks and data storage
- Data and knowledge management, and
- Advanced analytics

Major Project:

- Information and Computer Technologies for the 21st Center (ICT21) to support bioinformatics including scientific computing platforms, high speed scientific networking, scientific data storage, scientific computing analytics; and Janus for structured scientific data management.

7.5 Summary Schedule



7.6 Acronym List

(ICH, VICH, GHTF)	Global regulatory standards groups
ADaM	Analysis Data Model
AERS	Adverse Events Reporting System
ANSI	American Nation al Standards Institute
BiB	Bioinformatics Board
BMT	Business Modernization / Transformation
BRBs	Business Review Boards
CBER	Center for Biologics Evaluation and Research
CDASH	Clinical Data Acquisition Standards Harmonization
CDC	Center for Disease Control
CDER	Center for Drug Evaluation and Research
CDISC	Clinical Data Interchange Standards Consortium
CIO	Chief Information Officer
CRADA	Cooperative Research and Development Agreement
DDMAC	
DHHS	Department of Health and Human Services
DSC	Data Standards Council
DT	Developmental Test
EA	Enterprise Architecture
eCTD	electronic Common Technical Document
EDSR	Electronic Document Submission and Review

ELR	Electronic Labeling Rule
EPLC7	Enterprise Performance Life Cycle
ESG	Electronic Submissions Gateway
EVS	Enterprise Vocabulary Services
FASTAR	FDA Advanced Submission Tracking and Review Framework
FDA	Food and Drug Administration
FHA	Federal Health Architecture
FMAMA	FDA Modernization Act
FTE	Full Time Equivalent
GGP	Good Guidance Practice
HL7	Health Level Seven
ICSR	Individual Case Safety Report
IM	Information Management
ISO	International Standards Organization
IT	Information Technology
MaPP	Manual of Policies and Procedures
NCI	National Cancer Institute
NCPDP	National Council for Prescription Drug Programs
OC	Office of the Commissioner
OCIO	Office of the Chief Information Officer
ODM	Operational Data Model
OIM	Office of Information Management
OMB	Office of Management and Budget
OPL	Office of Planning
ORA	Office of Regulatory Affairs
OT	Operational Test
PDUFA	Prescription Drug User Fee Act
PLR	Physicians Labeling Rule
SDLC	System Development Lifecycle
SDO	Standards Development Organization
SDTM	Study Data Tabulation Model
SEND	Standard for Exchange of Nonclinical Data
SIT	System Integration Test
SOPP	Standard Operating Procedures and Policies
SPL	Structured Product Labeling
SQT	System Qualification Tests
UNII	Unique Ingredient Identifiers
VCS	Voluntary Consensus Standard