PDUFA IV Information Technology Plan

Preface to the PDUFA IV IT Plan Update – March 31, 2011

This update completes the May 2010 Abbreviated PDUFA IV IT Plan Update. All sections reflect the current FDA strategy and program status for PDUFA IV. FDA does not anticipate any major revisions to the Plan through the end of PDUFA IV (September 2012).

FDA is soliciting comments from the public for this PDUFA IV IT Plan update. The Comment Period is forty-five (45) days from the **Start Date (TBD)** to **Closing Date (TBD)**.

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, in many cases, a fee. In addition, companies that are subject to fees 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/ForIndustry/UserFees/PrescriptionDrugUserFee/default htm.

The PDUFA III reauthorization 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/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/UCM085361) and the implementation of the Electronic Submissions Gateway (ESG) (http://www fda.gov/ForIndustry/ElectronicSubmissionsGateway/default.htm). 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/ForIndustry/DataStandards/StructuredProductLabeling/default.htm).

The PDUFA program has enabled the 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 the May 2008 PDUFA IV Information Technology Plan, the 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." In May 2010, FDA updated the IT Plan on a number of initiatives. This is the third version of the IT Plan within the PDUFA IV timeframe.

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/AboutFDA/ReportsManualsForms/Reports/UserFeeReports/PerformanceReports/PDUFA/ucm209456.htm). This plan also provides a future-state vision for the FDA standards and technical infrastructure which supports 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;
- 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 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.

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 in a predictable, standard format; 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 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 Strategic Action Plan in the Fall of 2007, (http://www fda.gov/AboutFDA/ReportsManualsForms/Reports/StrategicActionPlan/default.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.

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

Secure information management is a critical element of FDA's strategic goals to address challenges of new legislative mandates, fully electronic submission, and industry shifts to multi-site worldwide operations. The FDA IT strategy considers both short and long-term initiatives to provide the mechanisms that establish an appropriate environment for identifying data assets, facilitating data interoperability, and employing repeatable processes for technology upgrade and development efforts. This requires modern, secure, and high availability IT infrastructure. FDA has planned the development of a large-scale Information Technology (IT) Modernization Program that encompasses data management, data warehousing, scientific computing, IT infrastructure, and IT security, and is designed to improve the FDA's ability to promote and protect the public

health. The IT Modernization Program efforts span the FDA enterprise and include development and implementation of computing infrastructure standards. 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 IV commitment letter, the FDA through the PDUFA Review Board (PRB), 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 increase overall efficiency and enhance 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 investments, and the overall architecture to produce the initial enterprise architecture. The enterprise architecture will serve as a living document to be updated as on-going analysis is performed of the technology to support the funded investments that are managed to achieve the Agency's strategic priorities inclusive of the IT goals defined in the PDUFA IV Commitment Letter. The strategic vision supporting the development of the Agency's target architecture is defined in Section 5.2.

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.

The Agency continues to evaluate opportunities for improving the governance model. To ensure that the implemented IT governance model was meeting the needs of the Agency, an independent assessment of the BiB was completed in April 2010. The assessment identified the need for greater emphasis on governance, separation of management and governance, increased transparency, and formalized and enforced governance processes. The recommendations from the assessment are being implemented but the direction remains consistent - to focus on the entire Agency IT portfolio, and to establish common governance processes – both to prioritize new projects and operate efficiently around the current portfolio.

In May 2010, FDA's Principal Deputy Commissioner and Acting Bioinformatics Board (BiB) Chair, after reviewing the proposed governance structure and plan with FDA's Senior Leadership and with the Science Board IT Subcommittee, approved the replacement of the Bioinformatics Board with the new recommended Informatics Governance Board (IGB) governance and organization structure. An interim governance board (also known as iIGB) has been established, consisting of executive representatives from each of the Centers and Office of the Commissioner, to execute governance while the new structure is implemented. The iIGB recommends IT portfolio decisions to FDA's senior leadership for ratification.

The Office of Information Management (OIM) officially began operating as a single entity, centralizing information technology resources for the Agency, on October 1, 2008. Activities are ongoing to improve operating processes and to identify and establish appropriate workforce skills and staffing levels required to operate efficiently in this enterprise environment.

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 Enterprise Architecture

FDA's Enterprise Architecture (EA) 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 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 EA will also provide stakeholders with a view into the complex relationships that exist among these different perspectives. For example, the 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 EA will:

- **Improve Program Performance**: The overarching benefit of the 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 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 EA reduces system development and operation and maintenance costs by eliminating duplicative investments, promoting sharing of common services, and establishing Agency-wide standards.

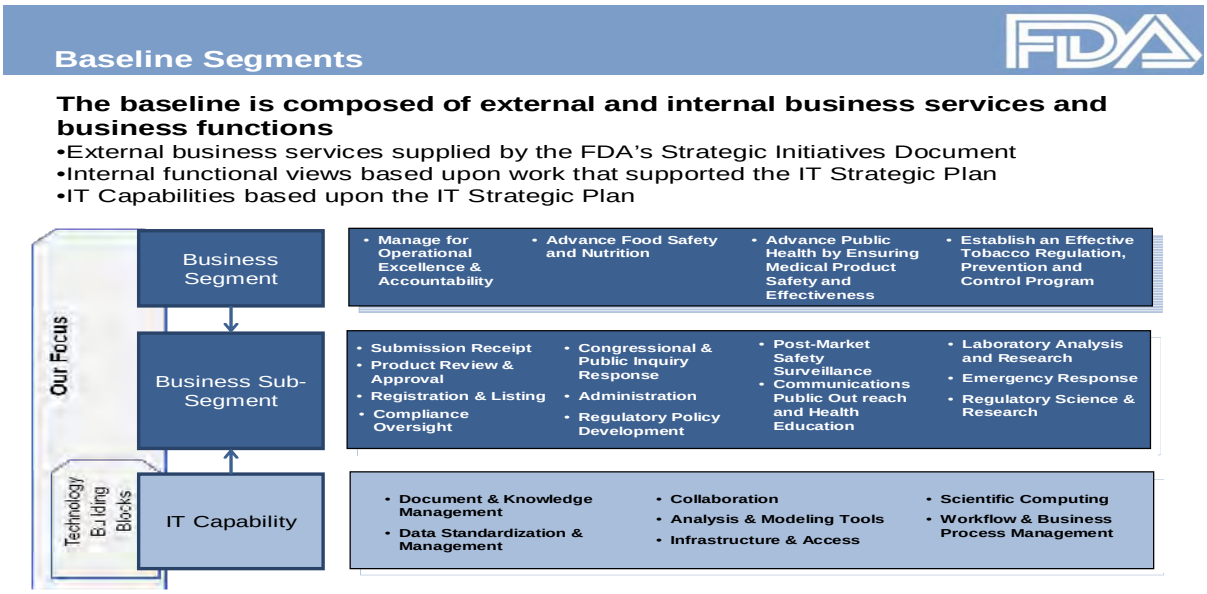
- **Accelerate System Implementation:** The EA equips the Agency's system developers and architects with an inventory of component-based services from which to choose that provide well defined functionality, thus maximizing reuse and portability of previously developed processes, components, code, etc.

- **Simplify Investment Decisions:** The 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 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 as depicted in the following diagram:

Figure 1: FDA Enterprise Architecture Baseline Segments framework



The interim Informatics Governance Board (iIGB) will be leveraged to rank and prioritize the segments which will provide a roadmap to assign appropriate resources to complete the segment analysis and customized reporting effort.

Figure 1 presents the segment framework. The business segment row depicts high-level segments based on the agency's Strategic Priority Plan and IT Strategic Plan. The business sub-segment row depicts mid-level segments based on the agency's Business Process Hierarchy. Lastly, the IT capability row depicts low-level segments based on the agency's IT Capabilities document. Segment architecture uses a business-oriented framework from which a specific methodology will be employed to drill down to the lowest details, slicing the whole of the agency architecture into manageable segments, in order to identify, assess and provide recommendation for improvement of business services and business functions based on the technology developed by projects that support the investment portfolio's achievement of agency strategic priorities. This methodical approach to slicing the agency's architecture into manageable, understandable segments will be an iterative, repeatable process to complete each segment until the entire agency architecture has been analyzed, assessed, documented and presented to the stakeholder community.

Segment architecture is mandated by the Office of Management and Budget (OMB) and is a business-driven and mission-oriented analysis of the agency's business functions and leverages integrated linkages with strategic planning, business, technology, performance management and budget.

Segments are a business view into the agency's portfolio investments eventually producing customized reports that can demonstrate the following outcomes, at a minimum: monitor and track effectiveness of budget expense from a business point of view, including the identification of additional funding needs and/or potential duplication of services; map Center/Office IT spending directly to business benefit/value; track value within the life-cycle phase of investment (development, modernization and enhancement vs. operations and maintenance); measure gaps in IT capabilities and how they are being (or could be) filled; areas of heavy or light investments to balance distribution of resources; and, provide a visual 'terrain' map or line-of-sight into the health of the agency's projects that comprise investments for educated decision making.

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.

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 one way 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 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 the 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/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default htm. The link to the CBER Guidance Agenda is: http://www fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default 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 publicly available, consensus-based data standards for regulatory submissions wherever possible. For the purposes of this plan, data standards are 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 timelines.

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 processes in accredited standards development organizations in place of government unique standards unless such standards are either inconsistent with law or otherwise impractical.[1]

- 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, 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 product review and other regulatory functions. The projects with near-term benefits should align with the Centers' 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

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

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 receive regulatory submissions in the expected form, the Centers need to align related regulatory guidance to industry, conduct outreach and training on standards and tools for 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, software tools are developed and tested with end-user input, and end-users are trained in the adoption and use of data standards and review tools. 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.[2] The discussion that follows applies equally to exchange, format and terminology standards, unless otherwise noted. These elements will be incorporated into the Data Standards Management Lifecycle, currently being developed at CDER and CBER to support the Centers' 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 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[3]:

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 user community during subsequent phases.

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 a 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 stakeholders, such as the healthcare community, Clinical Data Interchange Standards Consortium (CDISC), International Conference on Harmonization (ICH), other government agencies, and international regulatory

[2] 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.

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

bodies to bring their business requirements to HL7 to ensure interoperability among health information exchange standards.

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) and in collaborating with SDO's processes to ensure proposed standards meet scientific and regulatory needs.

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 standards 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 Study Data Tabulation Model (SDTM) and Analysis Data Model (ADaM) implementation guides and to provide additional data specification documents to ensure that Centers' data requirements are clear and consistently communicated. CDER and CBER will continue refining, improving, and expanding the use of CDISC standards for regulatory submissions for the process of human drug review in the near-term, e.g., 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 processes described below with stakeholders 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 clearly defined business processes for accepting, validating and reviewing standardized data, including sharing lessons learned with stakeholders.
- 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 data standards, which include overseeing implementation of CDER business processes which will iteratively define, adopt, and enforce data standards. Similarly, CBER's data standards program will provide consistent oversight of the Center's data standards activities.

An important measure of success is how well a 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 (UNII), 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)
  - Communication strategy and stakeholder engagement

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 and when (i.e. ensuring alignment with Agency strategic goals) the FDA is moving towards an automated standards-based IT environment. The FDA is continuing to implement its strategy for a fully 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.

6.1 Pre-Market Activities

In this section we will discuss the efforts currently underway to improve CDER and CBER Pre-Market IT capabilities.

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	The RPS Release 2 (R2) passed the HL7 Draft Standard for Trial Use (DSTU) ballot in January 2010. FDA participated in the RPS DSTU	RPS Release 3 DSTU ballot – September 2011. In preparation for the RPS R3 DSTU testing, the RPS R2 DSTU

Project Name and Description	Current Status	Strategy / Milestones
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.	process as members of the HL7 RPS R2 DSTU subgroup. The R2 DSTU scope was US based eCTD submissions with the objective to test the functionality of the RPS message and to provide feedback to the RPS R3 project. During 2010 the RPS R2 DSTU subgroup developed a number of US based eCTD test scenarios and created the test RPS messages. The subgroup completed two phases of testing and presented recommendations to the RPS R3 workgroup on RPS requirements, model changes, and message development. The RPS R2 DSTU activities were completed in January 2011. In coordination with the RPS R2 activities, FDA is participating in the RPS Release 3 (R3) project. The RPS R3 will incorporate additional ICH requirements, for the next major version of the eCTD, and ICH regional requirements. The requirements phase for the R3 DSTU has been completed and the workgroup is now preparing for the September 2011 HL7 ballot. Information on the HL7 RPS project activities can be found at http://wiki hl7.org/index.php?title=Regulated_Product_Submissions and includes the documentation of the RPS R2 test scenarios, controlled vocabulary, and RPS R2 test exchange messages.	subgroup will be integrated into the RPS R3 activities. The RPS R3 DSTU subgroup is leveraging the work done during the RPS R2 DSTU and will expand the group to include additional ICH testing and ICH regional participation. The plan is to develop a set of test scenarios by the September 2011 ballot that will allow the technical team to create the RPS messages for testing. In addition, ICH will be developing the draft implementation guide for human pharmaceuticals that will include regional Module 1 implementation guides. RPS HL7 Normative ballot – September 2012. 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 4th quarter 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 electronic submissions for the following Operating Divisions (OPDIVs): AERS, CDER, CBER, CDRH, CVM, OC, CTP, and CFSAN. Many of the listed OPDIVs have developed and implemented a fully automated electronic submission process. The electronic submission process	The FDA ESG is currently is the process of migrating to the FDA's ITC21 facility in Ashburn, Virginia. The schedule dictating the migration process and the current target date for the cutover to the ITC21 facility is under revision. An announcement to our Industry Partners will be sent out delineating the schedule change via email.	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. Currently, the FDA does not plan upon expanding the ESG functionality in this area in 2011. Depending on the progress garnered as well as the uptake by interested parties, the FDA could expand the ESG to additional areas of interest during FY 2011.

Project Name and Description	Current Status	Strategy / Milestones
encompasses the receipt, acknowledgment of receipt and any processing errors (to the sender), routing, notification (to a receiving Center or Office), and providing access to the review team of the electronic submission.		
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 completed requirements gathering to resolve validator issues encountered during the implementation of the upgraded validator in 2009. This process has also identified changes required to the FDA viewing tool. The requirements included revised eCTD Validation Criteria and the draft validation criteria were published on the "eCTD Validation Specifications" webpage (http://www fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm163181.htm) on December 10, 2010. CDER and CBER completed the internal 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.	The FDA is currently testing the vendor software and plans to implement the software in June 2011. The software includes the updated validation criteria, the revised validation criteria will also be implemented in June 2011. The FDA plans to implement the revised US eCTD Module 1 in 2011. FDA will make a formal announcement on the Module 1 revisions and will provide a mechanism for public feedback. The Module 1 implementation will include a development timeframe to allow vendors to modify their software. The implementation will also include a phase-in period when both current Module 1 and the revised Module 1 will be accepted. The FDA's target for accepting the updated Module 1 with eCTD submissions is the end of 2011.
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. DARRTS Release 3.1 was deployed in September 2010. 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 implement tracking to support

Project Name and Description	Current Status	Strategy / Milestones
		Biomarker/Qualification business processes, improve support for FDAAA Title VIII requirements as well as other improvements. Release 3.2 is scheduled for deployment in Q3 2011. This release will include: - Harmonized Annual Reports - Subsume EDR Maintenance Screens and modify EDR/ASR Functionality - ADMIS/MACMIS Replacement and RMS/BLA References or BLA Shell - Integration to display labels - View Application History Filter. Future releases will include: - Tracked Safety Issue (TSI) Safety Updates - Drug Development Tools - Create Application Redesign / Emergency Use Authorization (EUA) - Pharmacologic Drug Class Search (UNII Codes). Release 4.0 will include CDER BLAs.
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.	- All OIM-managed applications have been migrated to CHDC - New Standard Operating Procedures are in place to support new data center operations - White Oak Data Center (WODC), the Development and Test facility, received Authority To Operate (ATO) in April, 2010 - Development and Test migrations to WODC are in progress - Development environment is configured and first application installed - 1st production application live in Contractor Hosted Data Center (CHDC) – May 2010.	- The Extranet is scheduled to migrate in Q1 CY2011 - Center-managed application migrations are in progress and scheduled to migrate in Q1 CY2011 - WODC-destined Development, Test, and Production application migrations are scheduled to complete by 03/31/2011 - All applications moved out of the old datacenter in Park Lawn - 03/31/2011.

Project Name and Description	Current Status	Strategy / Milestones
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 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).	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 2008) - Current state and to-be business process models were defined (April 2009) - Requirements document and requirements traceability matrix (October 2009) - Common taxonomy and metadata elements (March 2010). The most recent deliverables in Q2 FY2010 are the final documents for the current contract.	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, 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. The set of work products delivered as a result of this effort are ready to be used by the FDA for efforts related to building a new EDR and/or enhancing an existing EDR environment. They enable new projects to avoid rework and get a jump start on their EDR development efforts. Leveraging as much of the common components (e.g., classification, vocabulary) as possible allows projects and their stakeholders to be more efficient in developing, maintaining, and using EDRs. The common classification system and vocabulary that can be applied to these EDRs increases the ability to understand where to look and find documents in a more efficient manner. In the long term, the common classification system and vocabulary offers an opportunity to reduce redundancy (e.g., gathering the same basic set of requirements again) and related costs and complexities associated with sustaining multiple electronic document rooms.

Project Name and Description	Current Status	Strategy / Milestones
The Facts@FDA program is part of the broader US effort to achieve electronic prescribing and other e-health information technology initiatives: e-List, CP, and SRSID		
Electronic Listing – eLIST is the production system for managing Structured Product Labeling (SPL) files. The SPL files are used for product labeling, listing and indexing as well as for establishment registration.	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. eLIST manages SPL files for product labeling for approved drugs regulated by CDER and CBER.	Continue updates to validation procedures, develop procedures for including indexing files, begin pilots for managing SPL files for other FDA regulated products.
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.	As part of the ISO Identification of Medicinal Products (IDMP) effort substance and specified substance models have been developed to define all types of material regardless origin or complexity. The specified substance allows the capture of more detailed information on a give substance. This could include specifications, manufacturing and analytical data. UNIIs are now listed in The United States Pharmacopeia (USP) Dictionary, Martindale, and Wikipedia and the Merck Index will list them in their next edition. Integration of the SRS with SPL has been accomplished on a development server. The Substance model has been tested in ICH and an XForm was developed in collaboration with the European Medicines Agency (EMA).	Migrate the SRS system to a platform within the ICT21 framework – Q1 CY2011. Release a new SRS search interface which will allow molecular structure-based and name based searching of NDAs, INDs and Products for substances as well as links to internal and external resources – Q2 CY2011. Complete development of a data and messaging model and implementation guide for specified substance that is compliant with the ISO 11238 standard – Q3 CY2011. Deploy new SRSID system for substances to production environment – Q2 CY2012. Begin a pilot study with industry and/or other regulatory agencies that allows the direct submission of HL7/XML messages for substances and specified substances – Q3 CY2012. Deploy registration system for specified substances – Q2 CY2013. Deploy new search interface that allows searching and display of substance and specified substance data – Q3 CY2013.

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		

Project Name and Description	Current Status	Strategy / Milestones
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). - 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 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) has developed tools (XForms and stylesheets) that can be used to create and display data that conform to the Study Data Standards. Special purpose XForms that can be used to easily create FDA 1572 forms and patient narratives have been completed. 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. Contract awarded for HL7 Message Exchange Service.	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. FY2012 - Complete DSTU testing of Study Participation and Study Design standards - Have draft of CDA R3 for use as Subject Data Standard. FY2013 - Complete pilot testing of HL7 Study Data Standards - Ballot Study Design and Study Participation standards as H& normative standards.
BRIDG Model - The Biomedical Research Integrated Domain Group, BRIDG Model, is a domain analysis model representing protocol-driven biomedical/clinical research. The BRIDG Model is a collaborative effort of stakeholders from the Clinical Data Interchange Standards Consortium (CDISC), the HL7 Regulated Clinical Research Information Management Work	FDA reviewed the BRIDG model in the HL7 May 2010 ballot cycle and provided comments. 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),	FDA continues to have a representative on the Board of Directors and will continue to provide input on efforts to harmonize FDA standards with the BRIDG.

Project Name and Description	Current Status	Strategy / Milestones
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.	and LabViewer).	
The Janus data warehouse for study data is being developed by the National Cancer Institute (NCI) with the FDA participating through its Interagency Oncology Task Force activities. The NCI and the FDA are collaborating to implement a common, standards-based electronic infrastructure for the submission, review, and analysis of regulatory data.	Contract for Janus Operational Pilot (Phase 3) for Patient Centered Outcomes Research (PCOR) was awarded Q3 CY 2010. Request for subcontractor proposal (RFP) for the Janus Operational Pilot (Phase 3) to be released Q4 CY 2010. Contract for Janus Phase 3A was awarded Q1 CY 2010 and will end	Subcontractor award for Janus Operational Pilot (Phase 3) is expected Q1 CY 2011. Complete requirements analysis and use cases, including functional and technical requirements for the Janus/Clinical Trial Repository (CTR) database; develop test cases and test plans and finalize overall architecture design – FY2011.

Project Name and Description	Current Status	Strategy / Milestones
	on Q4 CY 2010. This contract includes system and software requirements and design. Developed version 1 XForms and Style sheets as testing tools for the CDISC HL7 Study Data standards designed to exchange study data into Janus.	Iteratively develop Janus/CTR logical and physical database designs and overall system and software design. Integrate with NCI Enterprise Services and begin to test incremental loading and testing of legacy converted data – FY2012 Janus/CTR database operational for Patient Centered Outcomes Research (PCOR)/comparative effectiveness research; deployment in staging environment initially for PCOR use – FY2013.
Standard for Exchange of Nonclinical Data (SEND) Pilot – CDER, in collaboration with NCTR is conducting a pilot project to test, in a regulatory setting, the electronic submission of nonclinical study data using the CDISC Standard for Exchange of Nonclinical Data (SEND). The purpose of this pilot is to test the ability of a new electronic data format to support nonclinical review activity. The pilot also will involve a collaboration of FDA, pilot participants, and the CDISC SEND team to update and create a new draft SEND implementation guide that will harmonize SEND with SDTM. FDA anticipates that a successful pilot will enable CDER to routinely accept nonclinical study data electronically in SEND format, instead of paper or portable document format (PDF), in investigational new drug applications (INDs), new drug applications (NDAs), and biologics licensing applications (BLAs).	SEND pilot (Phase II) is ongoing in CDER. SEND team updated the SEND Implementation Guide (SENDIG) to v3.0 Draft B and the SEND Controlled Terminology to v3.0 Draft B – Q4 CY2010. Center for Veterinary Medicine (CVM) conducted the first meeting with pilot participants during Q1CY2010. This pilot project was instituted to test the electronic submission of margin of safety and non-clinical toxicology study data using SEND (Fed. Reg. Vol. 74(236)) Q4 2009. Participants committed to submit a range of studies that will meet CVM's needs to evaluate SEND.	SEND pilot (Phase II) is expected to be extended beyond the original 3 years (in accordance with the FR notice). This extension will be considered in Q1 CY2011. Training is planned in FY2011 for CDER reviewers and CVM pilot reviewers for both the SEND standard and the reviewing tool. Release production SENDIG 3.0 for initial studies (general toxicology and carcinogenicity studies) – 2011. Extend SEND pilot to develop and test the standard for representing additional types of studies (e.g. reprotoxicity studies) – 2011. Provide assessment to standard development organization of SEND improvements and maintenance needed for standard optimization based upon Agency experience – 2012. Update SEND production guide to incorporate additional studies - 2013.
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	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.

Project Name and Description	Current Status	Strategy / Milestones
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.		
CDISC CDASH (Clinical Data Acquisition Standards Harmonization) - The project goal is to develop a set of "content standards" (element name, definition, and related metadata) for a basic set of global data collection fields (also known as CRF, or Case Report Form, variables) that will support clinical research studies. The initial scope of the project is the development of 16 CRF content 'safety data/domains'; Adverse Events, (Prior and) Concomitant Medications, Comments, Demographics, Disposition/End of Study, Drug Accountability, ECG, Exposure, Inclusion and Exclusion Criteria, Lab, Medical History, Physical Examination, Protocol Violations, Subject Characteristics, Substance Use, and Vital Signs. These safety domains are common to all therapeutic areas. The initial scope is not the physical layout of the CRF or terminology; terminology is incorporated through collaboration with the CDISC Terminology Team. Basic data collection fields identified by CDASH project work streams are mapped into the Study Data Tabulated Model (SDTM) and are compliant with the SDTM Implementation Guide (SDTM IG). FDA's role in this effort is to ensure	- 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 - Completion of draft CDASH V 1.1. for both the internal CDISC review and the open public review - Finalized the responses to the public review comments - Publication of CDASH V 1.1.	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. - Publish Version 1.1 of the CDASH Implementation Guide – Q1 CY2011 - Release Initial Device Standard – Q2 CY2011 - Publication of E2B- Serious Adverse Event Elements – Q3 CY2011 - Release of Version 1.0 of User Guide with Machine-Readable Metadata – Q4 CY2011.

Project Name and Description	Current Status	Strategy / Milestones
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.	eStability Release 2 as Normative Standard passed ballot in May 2010. Schematron (business rules) procurement announcement made in August 2010. eStability, Release 2 Implementation Guide passed normative ballot in October 2010.	- Secure funding for the development of JMP script JSL Code that allow for statistical evaluation from the eStability XML Code. - Develop eStability Validation Procedures document. - CDER is currently evaluating next steps for the future implementation of the eStability standard.
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.	- Data Specifications point to ADaM as an option for submitting analysis files for review - ADaM released model for analysis of adverse events among a number of other implementation guides - "CDISC ADaM Validation Checks" published.	- Public review of the "The ADaM Basic data Structure for Time-to-Event Analyses" – Q1 CY2011. - Release final version of the Analysis Data Structure for Adverse Events – Q2 CY2011. - Release final versions of Metadata Document and Data Structure for Time-to-Event Analysis – Q3 CY2011. - Release of General Examples Document – Q4 CY2011. - Q1 Draft of Analysis Data Structure for Multiple Endpoints – Q1 CY2012.

6.2 Post-Market Activities

In this section we will discuss the efforts currently underway to improve CDER and CBER Post-Market IT capabilities.

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
FDA Adverse Event Reporting System - The FDA is responsible for monitoring the safety of FDA regulated products in order to protect and promote public health. Analysis of adverse event and safety report information is critical to achieving this goal, and the MedWatch Plus program is necessary to facilitate the proper gathering and analysis of this safety reporting information. The FDA needs to modernize its aging systems, improve its analytic capabilities, and make it easier for the public to submit adverse event and safety reports to the FDA. FDA is shifting to a more outcome-focused operating model and has developed a FAERS schedule that will provide operational releases in 6 month intervals to establish a regular cadence of delivering outcomes. Operational benefits for 6 month intervals will create efficiencies for safety evaluators by lowering time spent on queries for widely dispensed product classes (with multiple subclasses), facilitate quicker responses to public health threats for urgent situations like product recalls, and expedite drug quality reporting by eliminating duplicate entry and harmonizing medical coding. Specific examples include: FAERS initial release will provide expedited query capabilities for a group of safety evaluators and reduce evaluator time significantly, thereby increasing overall efficiency. Specifically, the initial release will focus on lipid lowering drug class/products and 15-day reports. Other products and drug classes will be addressed in subsequent releases.	- Delivered Prototype Training to CDER, CBER, and Data Entry in May 2010. - Delivered final FAERS Boundary Document and successfully passed the Initiation Stage Gate Review held on July 15, 2010. - Completed evaluation feedback from CDER and Data Entry based on Prototype Training in August 2010. - Completed Product Dictionary Requirements document in September 2010. - Development contractors started on-boarding process in September 2010. - Business analyst finalized requirements gathering with all stakeholders in October 2010. - Approval of Product Dictionary Requirements Document – October 2010. - Prioritized release .5 requirements with Stakeholder in November 2010. - Determined Requirements by Release categorization (best effort) in November 2010. - Delivered final FAERS Improvement Plan to OMB and HHS – Version 5b delivered on November 29, 2010. - Completed Project Charter and Staffing Management Plan for FAERS in November 2010. - Completed Concept stage gate in November 2010. - Finalize and signed off on business requirements for baseline activities.	At the request of OMB, FAERS was mandated to change key deliverables and major milestones for drugs, biologics and devices – see milestone chart for additional details; however, a summary is provided below: - 10/1/10 – 4/30/11: Proof of Concept Evaluation for Alternatives Analysis - 11/1/10 – 4/30/11: Rel 1.0 for Drugs/Biologics to focus on lipid lowering drug class queries and 15 day reporting - 5/1/11 -9/30/11: Rel 2.0 for Drugs/Biologics to retire legacy AERS and vastly improve product identification, user identifiable dashboards and alerts. This release will be the system of record for adverse event reporting - 5/1/11 – 9/30/11: Rel 3.0 for Devices to improve safety signal detection and evaluation - 10/1/11 – 3/31/12: Rel 4.0 for Drugs/Biologics for interactive data manipulation and analysis - 10/1/11 – 3/30/12: Rel 5.0 for Devices to build on release 1 functionality to detect and evaluate signals - 4/1/12 – 9/30/12: Rel. 6.0 for Drugs/Biologics to retire legacy AEPP, human cell tissues AE analysis - 4/1/12 – 9/30/12 Rel 7.0 for Devices to retire legacy MAUDE, enhance queries to reduce workload and time - 10/1/12 – 3/30/13: Rel 8.0 for Devices to support patches and minor enhancements.

Project Name and Description	Current Status	Strategy / Milestones
The second release will provide a much-enhanced product dictionary for FAERS which will improve product identification in adverse event reports. Release 2.0 will be fully implemented in September 2011 and will be documented as the system of record for adverse event reporting. As functionality from different legacy systems is subsumed into FAERS and the old systems retired, overall operations and maintenance costs will reduce over time. Examples of legacy systems to be retired, in addition to AERS, include CDER's Drug Quality Reporting System (DQRS) (planned for release in 2012) and CBER's Adverse Event Product Problem (AEPP) system (planned for release in 2012). Overall cost savings for eliminating legacy systems is estimated at over $850,000. FAERS for CDRH is still being evaluated and analyzed for use of the Oracle adverse event reporting tool. If the tool is selected, the noted timeline will provide additional details.		
The Individual Case Safety Report (ICSR) is a data exchange standard based on the Health Level Seven (HL7) Version 3 Reference Information Model (RIM) used to facilitate the processing and review of adverse event (AE), product quality problems and consumer complaints associated with the use of FDA regulated products. It supports the revision of the International Conference on Harmonization's (ICH) electronic AE reporting standard ICH E2B. The ICSR is compliant with a data architecture based on the RIM allowing the files to be processed using existing infrastructure and the information to be integrated with related data.	Completed Phase I vaccine and Phase II ICH proof of concept testing for human drugs and biologics. Successful SDO Joint Initiative Draft International Standard (DIS) ballot. Contract award for HL7 Message Exchange Service and AE Sentinel Module software. Contract award for HL7 ICSR consulting services. Complete SDO ballot reconciliation in October 2010. Finalized FDA ICSR Vocabulary Concept Domains in December 2010.	- Ballot draft FDA HL7 ICSR Implementation Guide – Q1 CY2011. - Provide ICSR Final DIS ballot publication - Q2 CY2011. - Finalize ICSR vaccine AE Sentinel requirements December 2011. - Conduct proof of concept testing to convert legacy Vaccine Adverse Event Reporting System (VAERS) data into HL7 ICSR using the Pragmatic RIM database and AE Sentinel module March 2011. - Begin FDA review demonstrations of AE Sentinel Module software May 2011. - Begin Conduct end-to-end proof of concept pilot testing for Electronic Health Record (EHR) triggered AE reporting based upon using electronic health record systems and HL7 ICSR July 2011.

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 Center 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.
>
> **Center 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.

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
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)	✓		✓	✓	✓	✓							✓		✓
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															
FDA Adverse Event Reporting System (FAERS)	✓	✓				✓							✓		✓

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 Governance Boards 5-year Goals, Priorities and Current Projects

As discussed in Section 5.1, the core recommendation from the FDA's IT governance assessment was to focus on the Agency IT portfolio's efficient and effective operations. To that end, the post-market safety, product quality and compliance, administrative services, and pre-market review business review boards (BRBs) have been decommissioned as they have served their purpose in identifying strategic direction for the different functional areas. All of the goals and priorities previously defined by the BRBs have been considered and incorporated as appropriate into the draft FDA IT Strategic Plan.

Many stakeholders remain engaged through advisory boards, governance boards (e.g., IGB or Center/Office ITIRBs), or as subject matter experts. Ownership of the major projects associated with the BiB and BRBs was transitioned to the primary stakeholder Center or Office for project execution. For example, the FDA Adverse Event Reporting System (FAERS) project is managed by CDER with engagement and subject matter expert input from stakeholder Centers (i.e., CBER, CDRH, CDER). The Scientific Computing/Computational Sciences BRB was re-chartered as the Scientific Computing Board (SCB), and serves as an advocate for users of scientific computing and an advisor to the interim Informatics Governance Board (iIGB) and Office of the Chief Scientist (OCS). They currently have three key areas of focus including: strategic planning, advocacy, and tactical operations improvements. This group remains engaged with the Information and Computer Technologies for the 21st Century (ICT21) initiative with iIGB governance oversight.

The shift in priority to operational efficiency places a focus on effective project execution to enable FDA to deliver smaller increments of functionality faster. For example, the FAERS project is deploying operational functionality in six (6) month increments to achieve immediate, incremental business value. In addition to project execution, having a governance structure in place that ensures oversight at the appropriate levels, with aggregation and awareness at the Agency level, helps to ensure Agency resources are allocated effectively.

Post-Market Safety

Primary Focus:

- Strengthen capability to rapidly identify, assess and mitigate safety problems
- Develop electronic receipt capabilities (i.e. improve receipt of spontaneous reporting, create a usable receipt interface, adopt, develop, and implement data standards HL7 ICSR & SPL)
- Enhance exploratory data analysis (i.e., strengthen signal detection & management of spontaneous reports)
- 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 and eliminate paper submissions).

Major Project:

- MedWatch Plus - FDA Adverse Event Reporting System.

Product Quality and Compliance

Primary Focus:

- Assure product quality and compliance through timely access to and better use of accurate FDA-related entity information across the Agency
- Implement a harmonized authoritative source 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 authoritative source access to Comprehensive Entity Information
- Enhance Automation of Import Screening Processes.

Major Project:

- Harmonized Inventory of FDA-related entities, including registration and listing. Initial focus of the project is on drug registration and listing.

Pre Market Review

Primary Focus:

- Implement a standards-based end-to-end fully electronic receipt, review, dissemination and archival environment
- Create or Adopt Standardized Structure and Formats for Data and Documents
- Adopt HL7 Regulatory Product Submission (RPS) Standard for FDA Regulated Products
- Improve and Automate Electronic Receipt Functions
- Improve Search Tools and Capabilities
- Improve Automation of Workflow
- Improve Document Management.

Major Project:

- Regulated Product Submission (RPS).

Scientific Computing / Computational Science

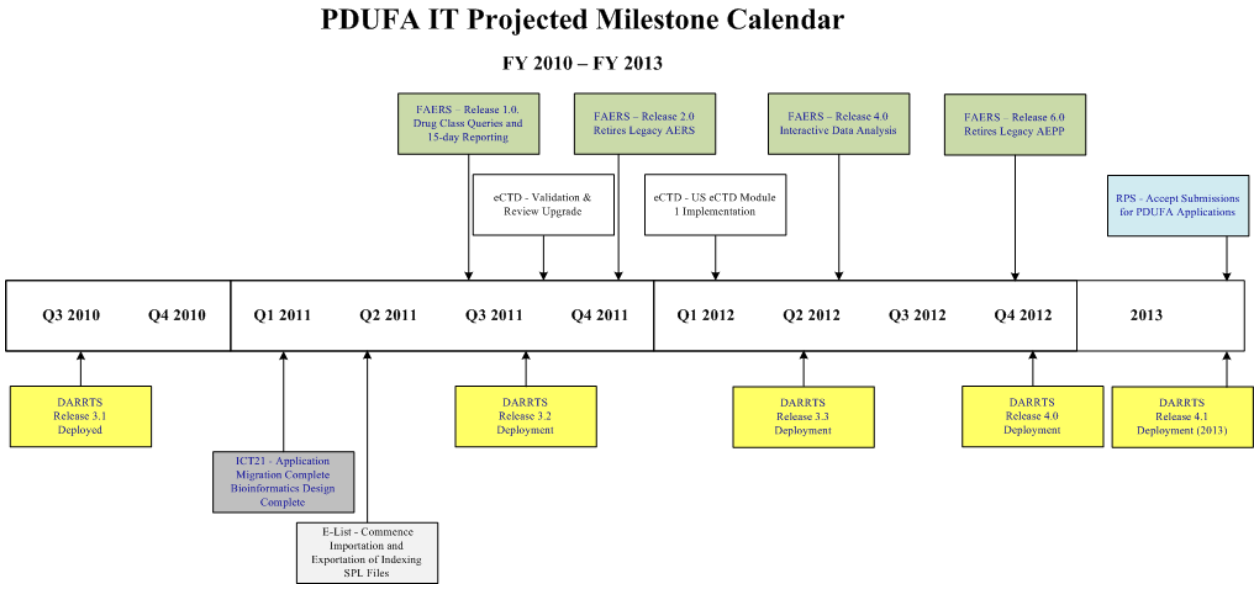
The Scientific Computing Board (SCB) addresses both review and laboratory information management scientific needs of the FDA. This includes automated laboratory management including improving field and center laboratories. Workgroups are formed to address the Agency needs in the following areas:

- Procedural and collaboration
- Networks and data storage
- Data and knowledge management
- 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 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
ADMIS	Advertising Management Information System
AERS	Adverse Events Reporting System
ANSI	American Nation al Standards Institute
BiB	Bioinformatics Board
BLA	Biologic License Application
BMT	Business Modernization / Transformation
BRBs	Business Review Boards
BRIDG	Biomedical Research Integrated Domain Group
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
CDRH	Center for Devices and Radiological Health
CFSAN	Center for Food Safety and Applied Nutrition
CHDC	Contractor Hosted Data Center
CIO	Chief Information Officer
CRADA	Cooperative Research and Development Agreement
CTP	Center for Tobacco Products
CVM	Center for Veterinary Medicine
CY	Calendar Year
DARRTS	Document Archiving Reporting And Regulatory Tracking System
DDMAC	Division of Drug Marketing, Advertising and Communications
DHHS	Department of Health and Human Services
DSC	Data Standards Council
DSTU	Draft Standard for Trial Use
DT	Developmental Test
EA	Enterprise Architecture
eCRF	electronic Case Report Form
eCTD	electronic Common Technical Document
EDSR	Electronic Document Submission and Review
EHR	Electronic Health Record
ELR	Electronic Labeling Rule
EMA	European Medicines Agency
EPLC	Enterprise Performance Life Cycle
ESG	Electronic Submissions Gateway
EVS	Enterprise Vocabulary Services
FAERS	FDA Adverse Event Reporting System
FASTAR	FDA Advanced Submission Tracking and Review Framework
FDA	Food and Drug Administration
FDAAA	Food and Drug Administration Amendments Act of 2007
FHA	Federal Health Architecture
FDAMA	FDA Modernization Act
FTE	Full Time Equivalent
FY	Fiscal Year
GGP	Good Guidance Practice
HL7	Health Level Seven
ICH	International Conference on Harmonization
ICSR	Individual Case Safety Report
ICT21	Information and Computer Technologies for the 21st Century

IDMP	Identification of Medicinal Products
IGB	Informatics Governance Board
iIGB	interim Informatics Governance Board
IM	Information Management
IND	Investigational New Drug Application
ISO	International Standards Organization
IT	Information Technology
ITIRB	Information Technology Investment Review Board
MACMIS	Marketing, Advertising and Communication Management Information System
MaPP	Manual of Policies and Procedures
NCI	National Cancer Institute
NCPDP	National Council for Prescription Drug Programs
NDA	New Drug Application
OC	Office of the Commissioner
OCIO	Office of the Chief Information Officer
OCS	Office of the Chief Scientist
ODM	Operational Data Model
OIM	Office of Information Management
OMB	Office of Management and Budget
OPDIV	Operating Division
OPL	Office of Planning
ORA	Office of Regulatory Affairs
OT	Operational Test
PDUFA	Prescription Drug User Fee Act
PLR	Physicians Labeling Rule
PRB	PDUFA Review Board
RMS	Regulatory Management System
RPS	Regulated Product Submission
SCB	Scientific Computing Board
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
SRS	Substance Registration System
UNII	Unique Ingredient Identifiers
USP	United States Pharmacopeia
VAERS	Vaccine Adverse Event Reporting System
VCS	Voluntary Consensus Standard
WODC	White Oak Data Center