



U.S. Food And Drug Administration
Center for Drug Evaluation and Research and
Center for Biologics Evaluation and Research

PDUFA V
Information Technology/Informatics Plan
FY 2013 – FY 2017

September 2014

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1.0 Introduction

This 5-year plan describes how the Food and Drug Administration (FDA) proposes to meet the information technology (IT) goals of the Prescription Drug User Fee Act Reauthorization (PDUFA V) Performance Goals fiscal year¹ (FY) 2013 through FY 2017. The plan includes FDA's proposed approach for enhancing business processes, data quality and consistency, supporting technologies, and IT operations. Industry can use this information to adequately plan for, resource, and implement the necessary IT changes to enable efficient and consistent adoption of the data standardization, IT, and informatics changes described in the PDUFA V Performance Goals Sections XII and XIV.²

The plan considers assumptions, available resources, and statutory requirements of the Food and Drug Administration Safety and Innovation Act (FDASIA)³, signed into law on July 9, 2012. Section 1136 of FDASIA, which added section 745A to the Federal Food Drug and Cosmetic Act (FD&C Act), gives FDA the authority to require the electronic submission of certain information and data in standardized formats. Section 1136 applies to certain Investigational New Drug applications (INDs), Biologics License Applications (BLAs), and New Drug Applications (NDAs) as well as Abbreviated New Drug Applications (ANDAs). In addition, global collaborative initiatives, such as the International Conference on Harmonization (ICH), affect this plan.

Further, the plan relies on the development and acceptance of regulatory standards. Changes in those standards could result in changes to the plan; therefore, FDA intends to publish periodic draft revisions to the PDUFA V IT plan to communicate minor updates and corrections. FDA intends to publish an annual assessment plan for measuring its progress on meeting milestones mapped directly to the PDUFA V IT goals. The assessment plan will also report key performance measures associated with these goals.

Background

Reauthorized on July 9, 2012, as part of FDASIA, PDUFA V is designed to speed the delivery of safe and effective prescription drugs to the public. FDASIA also includes provisions that increase FDA's authorities and responsibilities to address issues such as drug shortages, drug supply chain, drug safety, drug security, and drug innovation. PDUFA authorizes FDA to collect user fees from industry that will provide funding to expand and modernize FDA's prescription drug regulatory process.

PDUFA V continues to provide FDA with a consistent source of funding to help maintain a predictable and efficient review process for human drugs and biologics. In return for additional resources, FDA agreed to certain review performance goals, such as

¹ Fiscal Year is 1 October through 30 September.

² <http://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm270412.pdf>.

³ <http://www.gpo.gov/fdsys/pkg/BILLS-112s3187enr/pdf/BILLS-112s3187enr.pdf>.

completing reviews of NDAs and BLAs and taking regulatory actions on them within predictable time frames.

Vision

FDA is committed to achieving an automated standards-based information technology environment for the exchange, review, and management of information supporting the regulation of biological and human drug products. Our long-term vision is to share and leverage information that meets the increasing complexity and expected growth of the user fee program. The PDUFA V IT plan depicts FDA's IT strategic direction to enhance flexibility and interoperability across information systems, reducing redundancies and inefficiencies and improving access to accurate, timely, and consistent information.

To achieve this vision, IT investments must be aligned with business objectives and address all aspects related to discrete structural components within business, data, application, technical, security, and performance. The plan for optimally allocating resources towards this realization includes developing and implementing a comprehensive suite of strategic capabilities aimed at modernizing FDA's regulatory, surveillance, compliance, and enforcement oversight of drugs and biological products. In practice, IT is a key enabler that helps FDA meet its user fee goals.

Overview of the 5-Year Plan

FDA has governance processes in place to ensure the alignment of IT investments with the PDUFA commitments. These processes define decision-making authorities and assign accountability for executing decisions. Within FDA, the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) are accountable for meeting the PDUFA commitments and for allocating resources to support PDUFA. Each Center has an Information Technology Investment Review Board (ITIRB) that recommends and prioritizes IT investment decisions. Through this process, each Center's ITIRB selects, evaluates, and controls the proposed IT investments.

As part of the overall governance process, the ITIRBs monitor performance and risks associated with each investment and work closely with stakeholders to ensure these investments support PDUFA objectives, including reuse of common business processes, shared best practices, and employment of common authoritative data sources. FDA's User Fee Board reviews the total PDUFA allocation to ensure alignment with Agency PDUFA goals. The alignment between the Center ITIRBs and FDA's User Fee Board ensures good stewardship.

PDUFA V IT/Informatics Goals

This 5-year plan discusses objectives and related key milestones for achieving the following PDUFA V IT goals:

1. Supporting Regulatory Operations—describing the approach to strengthening the Electronic Submissions Gateway to support the long-term exchange and review of drug and biologics applications.
2. Electronic Regulatory Submissions—providing a consistent approach to the creation and review of regulatory submissions.
3. Data Standards—defining and implementing standards supporting drug efficacy, drug safety, manufacturing, product identification, and other areas.
4. Metrics and Measures—tracking progress and assessing implementation of goals.
5. Communications and Technical Interactions—disseminating information to stakeholders to help improve the program.

FDA maintains many systems that support the User Fee Program. The milestones in this plan depict when the program objectives, under the PDUFA Reauthorization Performance Goals and Procedures FY 2013 through FY 2017, are anticipated to be accomplished. However, many of these key milestones have dependencies that can affect the schedule, such as international guidelines, implementation timelines, and availability of resources.

2.0 Goal 1: Supporting Regulatory Operations

FDA plans to strengthen the Electronic Submissions Gateway (ESG) to support the long-term exchange and review of drug and biologics applications. The ESG has been critical to the success of FDA's electronic submission initiatives. Originally implemented in May 2006, the ESG has grown to support more than 1.4 million submissions a year. ESG initially supported CDER, CBER, and the Center for Devices and Radiological Health (CDRH), but has since expanded to support seven centers and the Office of the Commissioner. In addition, FDA has been working with Health Canada through the Regulatory Cooperation Council (RCC) to enable Health Canada to use the ESG to receive regulatory submissions.

To ensure that the ESG is stable and can meet current demand and projected future increases in submission loads, FDA intends to analyze current ESG operations. This analysis will look at:

- Current program structure of the ESG
- Current ESG capacity and planning capabilities
- Effectiveness of the current ESG Communication plan
- Adequacy of contingency planning and continuity of operations
- Long-term viability of the current technology and security provisions

The results of this analysis could lead to program changes that may become part of a future assessment of the PDUFA IT plan.

Table 1 shows the regulatory operations milestones for the objective.

Table 1: Supporting Regulatory Operations FY 2013 – FY 2017 Milestones

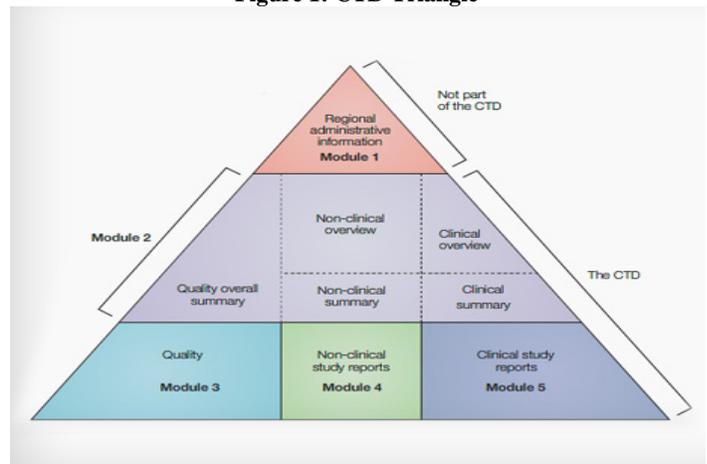
Objective	Milestones	FY13				FY14				FY15				FY16				FY17						
		Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4			
Objective 1: Ensure the ESG is stable and can meet current demand and projected future increases in submission loads.	Milestone 1.1: Conduct analysis on the long-term operation and governance needs of the ESG consistent with the needs of FDA and its broad stakeholder community to ensure continued viability.	▶				▶																		
	Milestone 1.2: Implement the recommendations arising from the ESG analysis, as appropriate.									▶				▶										

3.0 Goal 2: Electronic Regulatory Submissions

FDASIA calls for a consistent approach to the creation and review of regulatory submissions. FDA ensures that the standardized format follows international guidelines. Since 2003, FDA has accepted electronic submissions using ICH’s electronic Common Technical Document (eCTD) format.

The eCTD⁴ derives from the ICH Common Technical Document (CTD) and allows for the electronic submission of the CTD from applicant to regulator. The eCTD contains an electronic table of contents also referred to as a backbone that manages all the metadata for an application. This backbone is broken down into five modules. Documents are placed appropriately into modules, which

Figure 1: CTD Triangle



⁴ <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm153574.htm>.

are graphically presented in Figure 1: CTD Triangle.⁵

- **Module 1** references regional information such as forms, cover letters, labeling, and investigational brochures.
- **Module 2** references summaries such as quality, clinical, and non-clinical summaries.
- **Module 3** references quality information.
- **Module 4** references non-clinical information.
- **Module 5** references clinical information.

Module 1 is region specific. Modules 2, 3, 4, and 5 are harmonized. The current harmonized version of the eCTD is 3.2.2.

FDA intends to require submissions in a standardized electronic format. Section XII of the PDUFA V Performance Goals describes the process FDA intends to follow to require submissions using the eCTD format. FDA agreed to publish draft guidance by December 31, 2012, and agreed to publish final eCTD guidance “no later than 12 months from the close of the comment period on the draft guidance.” The phase-in period for the NDA and BLA submissions is 24 months after publication of the final guidance. ANDA applications also follow the 24-month phase-in period under the GDUFA program.⁶ The phase-in period for commercial INDs is 36 months.

FDA published the “Draft Revision of Guidance for Industry on Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications” on January 3, 2013, and the comment period closed on March 4, 2013. The guidance specifies eCTD version 3.2.2 as the required harmonized format. After review of the public comments and internal discussions, FDA has decided to issue a second draft for public comment, which will affect the schedule for publishing of the final guidance. FDA published the updated [draft guidance](#) in July 2014 and intends to publish the final guidance by the fourth quarter of FY 2015. Per the requirements of FDASIA 1136, FDA intends to require submissions in eCTD format no sooner than 24 months after publication of the final eCTD guidance.

FDA has two initiatives to provide additional capabilities to the eCTD standard: the update of our U.S. regional Module 1 (M1) and development of the eCTD version 4 (v4.0). These initiatives enhance our electronic submission process and expand the eCTD capabilities. FDA published draft M1 specifications in October 2011 and published updated M1 specifications in August 2012. FDA continues work on the implementation of the updated M1 and plans to implement the updated M1 specifications by the end of the second quarter of FY 2015. The specification is posted on the [eCTD](#)

⁵ <http://www.ich.org/products/ctd.html>.

⁶ This requirement also applies to Master Files that are submitted for incorporation by reference into an NDA, BLA, or ANDA.

[M1](#).⁷ The updated M1 functionality includes updates to support the submission of Promotional Labeling in eCTD format through the ESG, the organization of submission types and submission numbering, functionality for grouped submissions, and additional headings and metadata to improve submission processing and review.

ICH also continues work on eCTD v4.0, the next major version of the eCTD, which uses the Health Level Seven International (HL7) Regulated Product Submission (RPS) standard. After RPS Release 2 becomes a normative HL7 standard, RPS will be submitted to the International Organization for Standardization (ISO) for approval.

ICH published the “ICH eCTD v4.0 DRAFT Implementation Guide v1.0” and conducted tests during the first half of 2013. The project documentation on the [ICH eCTD v4.0 Step 2 for testing page](#)⁸ includes a link to the U.S. regional eCTD v4.0 Web page. The next major eCTD v4.0 milestone is the HL7 RPS Normative re-ballot in September 2014. ICH continues testing and updating the ICH and regional implementation guides with a Step 4, adoption of the eCTD v4.0, in November 2015. The ICH timeline determines when FDA can start receiving eCTD v4.0 submissions, estimated to begin in 2017. The eCTD v4.0 enhancements include:

- **Message is managed through the use of controlled vocabularies:** In developing eCTD v3.2 the rigid structure of the CTD was applied. The technology behind eCTD v3.2 makes it impossible to simply add a new heading. eCTD v4.0 is built on controlled vocabulary lists. To add a new heading only requires adding a new entry into the vocabulary lists.
- **Complete standard:** All regional administrative needs have been incorporated into eCTD v4.0, eliminating the need for a separate Module 1. All content differences with respect to Module 1 are handled by the controlled vocabularies.
- **Simple reuse of previously submitted files:** In eCTD v4.0, each file is assigned a unique identification number. To reuse that file, only a reference to that unique identification number is needed.
- **Enhanced lifecycle control:** In eCTD v4.0, this core capability will be extended to support one-to-one, one-to-many, and many-to-one situations.
- **Enhanced control of dossier:** eCTD v3.2 requires that certain data (e.g., manufacturer) accompany documents in the dossier. These values change over time or may contain mistakes when they are submitted, e.g., the manufacturer’s name changes or is misspelled. eCTD v4.0 provides the ability to correct this information.
- **Enhanced identification of information contained with a submission:** It is often very important to identify certain content (e.g., datasets) for further processing. eCTD v4.0 provides the capability to tag files based on the purpose. Regulatory authorities receiving these messages can use this information to properly process incoming submissions.

⁷ <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm253101.htm>.

⁸ <http://estri.ich.org/new-eCTD/index.htm>.

- **Support for two-way communication:** Currently, eCTD 3.2 supports only one-way communication from industry to regulatory authorities. eCTD v4.0 enables the exchange of FDA correspondence using the standardized electronic format.

Table 2 shows the electronic regulatory submissions milestones for each objective.

Table 2: Electronic Regulatory Submissions FY 2013 – FY 2017 Milestones

Objectives	Milestones	FY13				FY14				FY15				FY16				FY17					
		Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4		
Objective 1: Enhance eCTD formation to provide additional capabilities.	Milestone 1.1: Implement major Module 1 release.											▼											
	Milestone 1.2: Implement eCTD version 4.0.																		▼	▶	▶	▶	▶
	Milestone 1.2.1: ICH Step 2 adoption of eCTD v4.0.											▼											
	Milestone 1.2.2: ICH Public Comment Period.												▼	▶	▶								
	Milestone 1.2.3: ICH Step 4 adoption of eCTD v4.0.																						▼
Objective 2: Require submissions in a standardized format.	Milestone 2.1: Publish the revised draft and final guidance for industry on Providing Regulatory Submissions in Electronic Format Using the eCTD Specifications.												▼	▶	▶	▶							
	Milestone 2.2: Require NDA, BLA, and ANDA submissions in eCTD format.																						▼

4.0 Goal 3: Data Standards

FDA follows an open, consensus-based process to develop and maintain data standards. Open, consensus-based data standards are necessary to integrate, analyze, report, and share regulatory information. FDA’s standards development and maintenance program aligns with three principles:

1. Ensure the use of high-quality data standards through the use of voluntary, consensus-based standards development processes in accredited standards development organizations (SDO) in place of government-unique standards unless such standards are inconsistent with law or otherwise impractical.

2. Reduce the burden of regulation through alignment with existing health IT initiatives, laws, regulations, and mandates such as Executive Orders.
3. Ensure the efficiency of data standards through the adoption or adaptation of other standards currently in use, when feasible.

FDA's new Data Standards Advisory Board will provide the overarching Agency framework for the management of data standards throughout their lifecycle, including policies, procedures, accountabilities, and decision-making. At the center level, both CDER and CBER have well-defined data standards governance structures that ensure cross-center collaboration, communication, and alignment with respect to data standards development, implementation, and policy.

FDA collaborates with stakeholders (e.g., regulated industry, SDOs, academia, and medical-clinical societies, as well as other government agencies and FDA's review divisions) to develop new and refine existing data standards. The PDUFA V Goals Letter states that FDA will perform an assessment of the impact of electronic submissions and data standards on the efficiency and other performance attributes of the human drug review process beginning in FY2015. FDA is committed to the consistent use of data standards in regulatory submissions and plans to develop a set of metrics to assess their impact on the efficiency of the review process. Further, FDA will develop a mechanism for the tracking and reporting of the number of submissions that comply and fail to comply with FDA-supported standards.

FDA has promoted and encouraged the submission of data in standard, electronic formats and to enable those data to be used efficiently and effectively in the process of reviewing drug marketing applications, safety reports, and other regulatory functions requiring data. Section 745A(a)(1) of the FD&C Act, passed in 2012 as part of section 1136 of FDASIA, granted explicit authorization to FDA to implement the statutory electronic submission requirements by specifying the format for such submissions in guidance. In February 2014, FDA published two draft guidances focused on electronic submission requirements and standardized study data. The first guidance entitled "Providing Regulatory Submissions in Electronic Format — Submissions under Section 745A(a) of the Federal Food, Drug, and Cosmetic Act" provides the implementation framework for the specification, in individual guidances, of the electronic requirements for certain submissions. The second guidance entitled "Providing Regulatory Submissions in Electronic Format — Standardized Study Data" specifies the formats for electronic submissions of study data contained in submissions under NDAs, ANDAs, and certain BLAs and INDs.

The IT plan addresses targeted data standards that include therapeutic areas, which facilitate clinical research and the regulatory review of medical products. FDA is actively participating with external stakeholders to support the development of these therapeutic area standards as specified in PDUFA V. FDA published Therapeutic Area

Objective(s)	Milestones	FY13				FY14				FY15				FY16				FY17				
		Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	
	Milestone 1.3: Publish final Data Standards Catalog.																					
	Milestone 1.4: Publish final Study Data Technical Conformance Guide.																					
	Milestone 1.5: Publish therapeutic area standards Initiative Project plan, v2.0, for public comment.																					
	Milestone 1.6: Require NDA, certain BLA, and ANDA submissions of data in standardized formats.																					

4.2 Individual Case Safety Report Submission Standards

FDA collaborates with external SDOs to develop, test, and implement electronic data exchange standards for pharmacovigilance reporting between ICH regulators and industry. The ICH E2B (R2) Individual Case Safety Report (ICSR) standard has been updated to use the new International Standards Organization/Health Level Seven (ISO/HL7) 27953 International Standard. ISO/HL7 27953 is a multi-part international standard developed to support adverse event, product problem, and consumer complaint reporting for all FDA-regulated products. ISO/HL7 27953 is an HL7 version 3 data exchange standard, which ICH has adopted for the next major release of ICH E2B (R2). ICH completed its E2B (R3) Step 4 Implementation Guide in July 2013, and FDA will continue its efforts to pilot test and phase implementation of ICH E2B (R3) for electronic drug, biologics, and vaccine adverse event reporting.

ICSR provides a consistent format for receipt and analysis of drug and biologics safety information and facilitates the use of consistent tools and processes for pharmacovigilance activities. The worldwide exchange of standardized safety information involves a high volume of data and a large number of potential participants. Therefore, drug safety relies on the efficient exchange of formatted safety reports that can be automatically generated and processed. Key business process improvement goals include reducing the costs associated with manual data entry and coding of paper-based adverse event reports, increasing the timely access and review of safety reports, and using harmonized analysis tools and controlled vocabulary for drugs, biologics, and vaccines.

FDA has accepted ICSRs since the late 1990s using ICH E2B specifications. Subsequently, ICH E2B (R3) evolved through the ICH standards development process and the Implementation Guide, published in July 2013. FDA intends to implement ICH E2B (R3) in a phased manner. FDA works with industry to conduct pilot testing of E2B

(R3) formatted ICSRs to identify any technical issues that may require additional guidance.

FDA intends to continue accepting safety reports in E2B (R2) format until FDA publishes regional guidance for E2B (R3). The timeline for this implementation is tentatively 2 years for drugs and biologics. CBER intends to implement the acceptance of Individual Case Safety Reports (ICSRs) pertaining to vaccines by 2015.

FDA intends to issue regional guidance and specifications to describe the electronic submissions process and requirements applicable for its regulatory processes. This guidance helps facilitate pilot projects for regional requirements needed to implement the standard in the United States. CBER has already begun this pilot for vaccines. FDA anticipates a FDA Adverse Event Reporting System (FAERS) pilot will extend to 2015.

FDA intends to publish clarifications for FDA regional requirements in a regional E2B (R3) implementation guide and technical specifications. These documents, in conjunction with the ICH E2B (R3) Implementation Guide, provide information needed to implement electronic submission of E2B (R3) formatted ICSRs. FDA also intends to apply feedback from the ICH Implementation Working Group to address ICH E2B (R3) implementation questions emerging from regulatory agencies and pharmaceutical manufacturers.

Table 4 shows the ICSR standards milestones for each objective.

Table 4: ICSR Standards FY 2013 – FY 2017 Milestones

Objectives	Milestones	FY13				FY14				FY15				FY16				FY17			
		Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4
Objective 1: Implement ICH E2B (R3).	Milestone 1.1: Conduct E2B (R3) pilot testing.					▼	▶														
	Milestone 1.2: Require electronic submissions using E2B (R3) for vaccines.									▼	▶	▶	▶	▶	▶	▶	▶	▶	▶	▶	▶
	Milestone 1.3: Require electronic submissions using E2B (R3) for drugs and biologics.											▼	▶	▶	▶	▶	▶	▶	▶	▶	▶
	Milestone 1.4: Publish FDA Regional E2B (R3) implementation guidance Technical Specification.			▼																	

Objectives	Milestones	FY13				FY14				FY15				FY16				FY17			
		Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4
Objective 2: Issue regional guidance and specifications to describe the electronic submissions process and requirements applicable for its regulatory processes.	Milestone 2.1: Publish draft guidance requiring electronic submission of postmarket ICSRs to VAERS. ¹³																				
	Milestone 2.2: Publish draft guidance requiring electronic submission of postmarket Lot Distribution Report to CBER.																				

4.3 Identification of Medicinal Products

FDA is working with the European Union (EU) to implement the ISO Identification of Medicinal Products (IDMP) standards that define, characterize, and identify each regulated Medicinal Product for human use from approval through postmarketing. FDA and the EU are collaborating with ISO to create and ballot a set of IDMP implementation guides balloting within ISO and HL7 and for public comment. The remaining IDMP implementation guides will be released starting in December 2014.

Following the finalization of the IDMP implementation guides in ISO and HL7, FDA plans to publish draft guidance on the use of the standards in regulatory submissions.

Table 5 shows the IDMP milestone for the objective.

¹³ Vaccine Adverse Event Reporting System (VAERS).

Table 5: IDMP FY 2013 – FY 2017 Milestones

Objective	Milestone	FY13				FY14				FY15				FY16				FY17			
		Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4
Objective 1: Implement International Organization for Standardization (ISO) Identification of Medicinal Products (IDMP) standards with reliable and robust repositories and processes to support efficient, consistent, and timely decision-making in the regulation of medicinal product throughout the product development lifecycle.	Milestone 1.1: Successful ISO/HL7 balloting of IDMP implementation guides.																				

4.4 Drug Quality and Facilities

FDA plans to issue draft guidance by the end of FY 2014 for the premarket submission of manufacturing establishment information using Structured Product Labeling (SPL) standards. In addition, FDA is assessing standardization needs and uses for drug quality data areas supporting Chemistry, Manufacturing, and Controls (CMC), product, and facility requirements. This assessment is likely to lead to other projects that may require additional guidance or standards development. Moreover, the assessment may support other efforts outlined in this plan, such as IDMP implementation. FDA plans to solicit public input on standardization in these areas through *Federal Register* notices and public meetings.

Table 6 shows the drug quality and facilities milestones for each objective.

Table 6: Drug Quality and Facilities FY 2013 – FY 2017 Milestones

Objectives	Milestones	FY13				FY14				FY15				FY16				FY17			
		Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4
Objective 1: Issue guidance for premarket manufacturing establishment information.	Milestone 1.1: Issue draft guidance for premarket manufacturing establishment information.																				

Objectives	Milestones	FY13				FY14				FY15				FY16				FY17			
		Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4
	Milestone 1.2: Issue final guidance for premarket manufacturing establishment information.																				
Objective 2: Assess standardization needs and uses for drug quality data areas supporting Chemistry, Manufacturing, and Controls (CMC), product, and facility requirements.	Milestone 2.1: Implement the recommendations arising from the analysis, as appropriate.																				

5.0 Goal 4: Metrics and Measures

FDA will track and report its progress towards achievement of targeted metrics and measures as established in Section XIV.A of the PDUFA Goals Letter. FDA will report these performance metrics in the annual PDUFA Performance Report, prepared by FDA’s Office of Planning.

In addition, PDUFA requires FDA to report annually on the financial aspects of its implementation. Through this process, FDA will report its financial metrics in the PDUFA Financial Reports submitted to Congress each fiscal year on the PDUFA program’s activities, collections, and spending.

Table 7 shows the metrics and measures milestones for the objective.

Table 7: Metrics and Measures FY 2013 – FY 2017 Milestones

Objective	Milestones	FY13				FY14				FY15				FY16				FY17			
		Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4
Objective 1: Track and report progress towards	Milestone 1.1: Publish the PDUFA V IT Metrics on FDA’s Web site.	▼				▼				▼				▼				▼			

Objective	Milestones	FY13				FY14				FY15				FY16				FY17			
		Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4
achievement of targeted metrics and measures, on an annual basis, as defined in Section XIV of the PDUFA Reauthorization Performance Goals and Procedures.	Milestone:1.2: Report number and significance of IT technical specifications or e-submission guidance implemented requiring industry to change submission content that are not forecasted accurately in the 5-year plan or those whose content has not been available to industry at least 2 months prior to required implementation.	▼				▼				▼				▼				▼			
	Milestone 1.3: Publish the financial metrics in the PDUFA Financial Reports submitted to Congress each fiscal year on PDUFA program activities, collections, and spending.	▼				▼				▼				▼				▼			

6.0 Goal 5: Communications and Technical Interactions

FDA develops, updates, and publishes a 5-year PDUFA IT plan for business process improvement. To support improvements and to track these planning efforts, FDA will improve its processes for communicating timely, accurate, and consistent IT information. These processes include facilitating as well as participating in meetings and discussions to foster early and continued interactions between FDA and industry. As part of this process, FDA takes a collaborative approach to strengthening communications and sharing information technology data standards goals under PDUFA. FDA pursues opportunities for improving stakeholder collaboration through approaches aimed at reporting progress towards meeting these goals. The dissemination strategy also provides and obtains data from industry and other stakeholders that present important action-oriented information.

FDA uses a multi-tiered approach to improve communications and distribute IT and data standards information to industry at regular intervals. FDA improves communications between FDA and industry stakeholders to promote effective relationships. Among these activities, FDA employs both formal and informal written correspondence, electronic media, and person-to-person communications. The media used to distribute information include FDA’s Web site, face-to-face meetings, electronic mail, and media communications techniques. FDA meets with industry stakeholders to discuss ongoing implementation efforts, outcome measures, and potential revisions to the PDUFA IT plan.

As part of the overall communications and technical interactions approach, FDA develops and posts on its Web site the 5-year PDUFA IT plan and, as appropriate, will provide updates to the plan. The IT plan frames FDA’s approach for prioritizing IT-enabled business process change and identifies key business process improvements expected from each IT investment associated with PDUFA. Each year for the next 5 years, FDA will assess progress against targeted goals and performance metrics. FDA intends to report its performance in meeting these metrics in an annual summary report published on FDA’s Web site.

A key component of the communications plan involves publishing program guidance and providing formal notifications to industry. FDA develops and disseminates guidance and policy to achieve IT goals and objectives of the PDUFA IT plan. FDA continually publishes written communications that describe Agency and Center policy for industry to help improve decision-making and planning. FDA also solicits feedback for facilitating two-way communication across a wide range of industry stakeholders. Additionally, FDA performs monitoring, reporting and evaluation, which includes providing effective and relevant reporting of funds as they align to meet IT and data standardization goals under PDUFA.

FDA intends to meet quarterly with stakeholders to discuss prospective implementation of the PDUFA IT plan. Fundamental to these efforts, FDA establishes a collaborative process to identify opportunities for continual quality improvement, to make modifications to the IT plan when appropriate, and to assess potential impacts among FDA and stakeholders. Through this process, FDA encourages dialogue, particularly on the development of the PDUFA IT plan and requisite impacts.

Table 8 shows the metrics and measures milestones for each objective.

Table 8: Communications and Technical Interactions FY 2013 – FY 2017 Milestones

Objectives	Milestones	FY13				FY14				FY15				FY16				FY17				
		Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	
Objective 1: Distribute IT/Informatics and data standards information to industry at regular intervals.	Milestone 1.1: Publish the draft IT plan on FDA’s Web site and publish a notice of availability in the <i>Federal Register</i> with a 60-day public comment period.				▼																	
	Milestone 1.2: Finalize the IT plan and publish to FDA’s Web site.								▼													

Objectives	Milestones	FY13				FY14				FY15				FY16				FY17				
		Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	Q 1	Q 2	Q 3	Q 4	
	Milestone 1.3: Periodically update and publish the IT plan, as determined by FDA.																					
	Milestone 1.4: Publish the PDUFA V IT Assessment on FDA’s Web site.	▼				▼					▼										▼	
Objective 2: Collaboratively identify opportunities for continual quality improvement, to make modifications to the IT/Informatics plan when appropriate, and to assess potential impacts among FDA and stakeholders.	Milestone 2.1: Conduct quarterly meetings with industry stakeholders.	▼	▶																			▼

7.0 Next Steps

The next steps for this plan involve conducting assessments, collecting feedback from stakeholders, and issuing guidance. These steps depend on FDA interaction and agreement with international SDO’s decisions, stakeholder involvement, and agency resources. To this end, FDA remains committed to working with industry to successfully implement and address implementation challenges for collaboratively meeting the PDUFA V IT goals.

Appendix A: PDUFA V IT/Informatics Goals and Objectives

The table below summarizes the PDUFA V IT/Informatics goals and FDA objectives described throughout this document.

PDUFA V IT/Informatics Goals	Objectives
<p>Goal 1: Supporting Regulatory Operations—describing the approach to strengthening the Electronic Submissions Gateway to support the long-term exchange and review of drug and biologics applications.</p>	<p>Objective 1.1: Ensure the ESG is stable and can meet current demand and projected future increases in submission loads.</p>
<p>Goal 2: Electronic Regulatory Submissions—providing a consistent approach to the creation and review of regulatory submissions.</p>	<p>Objective 2.1: Enhance eCTD formation to provide additional capabilities.</p> <p>Objective 2.2: Require submissions in a standardized format.</p>
<p>Goal 3: Data Standards—defining and implementing standards supporting drug efficacy, drug safety, manufacturing, product identification, and other areas.</p>	<p>Objective 3.1: Require the electronic submission of data in standardized formats.</p> <p>Objective 3.2: Implement ICH E2B (R3).</p> <p>Objective 3.3: Issue regional guidance and specifications to describe the electronic submissions process and requirements applicable for its regulatory processes.</p> <p>Objective 3.4: Implement International Organization for Standardization (ISO) Identification of Medicinal Products (IDMP) standards with reliable and robust repositories and processes to support efficient, consistent, and timely decision-making in the regulation of medicinal product throughout the product development lifecycle.</p> <p>Objective 3.5: Issue guidance for premarket manufacturing establishment information.</p> <p>Objective 3.6: Assess standardization needs and uses for drug quality data areas supporting CMC, product, and facility</p>

PDUFA V IT/Informatics Goals	Objectives
<p>Goal 4: Metrics and Measures—tracking progress and assessing implementation of goals.</p>	<p>requirements.</p> <p>Objective 4.1: Track and report progress towards achievement of targeted metrics and measures, on an annual basis, as defined in Section XIV of the PDUFA V Reauthorization Performance Goals and Procedures.</p>
<p>Goal 5: Communications and Technical Interactions—disseminating information to stakeholders to help improve the program.</p>	<p>Objective 5.1: Distribute IT and data standards information to industry at regular intervals.</p> <p>Objective 5.2: Collaboratively identify opportunities for continual quality improvement, to make modifications to the IT plan when appropriate, and to assess potential impacts among FDA and stakeholders.</p>

Appendix B: References

The documents listed below were referenced in the development of the PDUFA V IT/Informatics plan FY 2013 – FY 2017.

- The Food and Drug Administration Safety Innovation Act (FDASIA)
<http://www.gpo.gov/fdsys/pkg/BILLS-112s3187enr/pdf/BILLS-112s3187enr.pdf>.
- PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2013 through 2017
<http://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm270412.pdf>.
- HHS Strategic Plan and Secretary's Strategic Initiatives FY 2014 - 2018
<http://www.hhs.gov/strategic-plan/priorities.html>.
- FDA Strategic Priorities 2011 - 2015
Responding to the Public Health Challenges of the 21st Century
<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM252092.pdf>.
- FDA Information Management and Office of Information Management Strategic Plan FY 2012 - FY 2016
<http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Reports/UCM325437.pdf>.
- Center for Biologics Evaluation and Research Strategic Plan FY 2012 - FY 2016
Innovative Technology Advancing the Public Health
<http://www.fda.gov/downloads/aboutfda/centersoffices/officeofmedicalproductsandtoxicology/cber/ucm266867.pdf>.
- FDA Center for Drug Evaluation and Research Strategic Plan 2013 - 2017
<http://www.fda.gov/downloads/aboutfda/centersoffices/officeofmedicalproductsandtoxicology/cder/ucm376545.pdf>.