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

PDUFA V
Information Technology/ Informatics Assessment

FY 2014

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1.0 Executive Summary

On July 9, 2012, the Food and Drug Administration Safety and Innovation Act (FDASIA) of 2012 was signed into law. This new law includes the reauthorization of the Prescription Drug User Fee Act (PDUFA) that provides FDA with the necessary resources to maintain a predictable and efficient review process for human drug and biologic products. The fifth authorization of PDUFA ensures that FDA will continue to make significant progress toward achieving certain performance and procedural goals as agreed to under the prescription drug user fee program, which among other aims includes the long-term Information Technologies (IT) objective of achieving a fully automated standards-based IT environment.

In order to achieve these objectives, FDA developed a five-year IT plan for PDUFA that was published on FDA's Web site in Q4 of FY 2014. The salient milestones in the IT plan are organized around five, core goals intended to improve the exchange, review, and management of human drug and biologic applications throughout the product life cycle. These include:

1. Supporting Regulatory Operations—describing the approach to strengthening the Electronic Submissions Gateway (ESG) 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.

On an annual basis, between FY 2013 and FY 2017, FDA plans to conduct an assessment for measuring its progress against these IT goals. FDA will provide a summary of its findings in the IT Assessment report, which will be posted on the FDA website no later than 120 days after the end of the fiscal year.

Purpose

This document provides an IT assessment for reporting FDA's progress in achieving targeted IT goals in the 2014 fiscal year (FY). It also identifies future milestones FDA intends to accomplish during the FY 2015 through FY 2017 time frame.

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.

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.

2.0 Goal 1: Supporting Regulatory Operations

Activity in FY 2014 involved continuing the Agency's efforts in providing reliable access to the FDA Electronic Submissions Gateway (ESG). The FDA ESG, an Agency-wide solution that enables the secure transmittal and receipt of electronic regulatory submissions, has been operational since May 2006.

The electronic submission process encompasses the following: the receipt, acknowledgment of receipt, and routing of the submission to appropriate FDA Centers/Offices for review and processing.

Objective	
1. Ensure the ESG is stable and can meet current demand and projected future increases in submission loads.	
FY 2014 Milestone	**Accomplishments**
Conduct analysis on the long-term operation and governance needs of the ESG consistent with the needs of the FDA and its broad stakeholder community to ensure continued viability.	FDA conducted an internal agency analysis to identify the governance and operational needs of the ESG. Specific steps taken in FY 2014 to address these needs included: • Established an ESG Program Governance Board (PGB), which has executive oversight requirements of the ESG. The PGB provides a new model for the ESG governance to improve decision-making and accountability. • Obtained representation of all FDA Centers and FDA's Office of Information Management on the PGB. • Established an integrated project team focusing on the development, modernization, enhancement, and operations and maintenance of the ESG. • Designed a new architecture that will feature enhancements to support higher submission volumes and increase in system availability for the user community. • Added new hardware and software for testing new configurations.

Future Milestones
To meet projected demand of increases in the number and size of electronic submissions, the following measures are expected to begin in FY 2015: • Enhance the functional capabilities of the ESG (receipt and routing of submissions) to increase the effectiveness and efficiency of the electronic submission process. • Increase ESG availability to meet the higher concentration of submissions per hour over the next 5 years.

3.0 Goal 2: Electronic Regulatory Submissions

PDUFA V calls for a consistent approach to the creation and review of regulatory submissions. Efforts to meet this goal in FY 2014 involved developing draft guidance to improve consistency of submission processing, ensure access to documents and data, and facilitate evaluation of information contained in submissions. FDA also continued to update technical specifications and IT-related guidance documents in support of an electronic environment.

Objectives	
1. Enhance electronic Common Technical Document (eCTD) formation to provide additional capabilities. 2. Require submissions in a standardized format.	
FY 2014 Milestones	**Accomplishments**
Publish the revised draft guidance for industry on Providing Regulatory Submissions in Electronic Format Using the eCTD Specifications.	• Published the revised eCTD draft guidance document in Q4 of FY 2014.
Future Milestones	
Two major milestones for meeting the Electronic Regulatory Submissions objectives are expected to be completed no later than FY 2015. • First, implement the eCTD M1 update to include enhanced promotional submission capabilities. • Second, finalize the eCTD guidance document detailing submission requirements in the eCTD format. FY 2015 will also mark advancements the eCTD v4.0 project. Key project benchmarks include: • Reaching ICH Step 2. • Releasing the eCTD v4.0 implementation package and the US regional implementation guide for public comment.	

4.0 Goal 3: Data Standards

FDA coordinates the development of data standards by working with Standards Development Organizations (SDOs), industry, other government agencies and other stakeholders,

subsequently implementing these standards internally through the Centers. FDA supports an open, consensus-based process for the development, implementation and maintenance of data standards. Open, consensus-based data standards are necessary to integrate, analyze, report, and share regulatory information.

Objectives	
1. Require the electronic submission of data in standardized formats. 2. Implement ICH E2B (R3). 3. Issue regional guidance and specifications to describe the electronic submissions process and requirements applicable for its regulatory processes. 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. 5. Issue guidance for pre-market manufacturing establishment information. 6. Assess standardization needs and uses for drug quality data areas supporting Chemistry Manufacturing Controls (CMC), product, and facility requirements.	
FY 2014 Milestones	**Accomplishments**
Post therapeutic area standards Initiative Project Plan, version 2.0 for public comment.	• Posted Initiative Project Plan (version 2.0) therapeutic area standards to FDA Web site in Q3 of FY 2014.
Publish draft guidance to Industry providing regulatory submissions in electronic format—Standardized Study Data.	• Published draft guidance in Q2 of FY 2014.
Publish draft guidance to Industry providing regulatory submissions in electronic format – Submissions Under 745A(a) of the Federal Food, Cosmetic and Drug Act.	• Published draft guidance in Q2 of FY 2014.
Posted version 1.0 of the technical specification document entitled Study Data Technical Conformance Guide.	• Posted version 1.0 in Q2 of FY 2014.
Conduct E2B (R3) pilot testing.	• Conducted Electronic Vaccine Adverse Event Reporting System (eVAERS) pilot kick-off with Industry in Q3 of FY 2014. • Began iteration 1 testing in Q4 of FY 2014.
Publish draft guidance requiring electronic submission of post-market ICSRs to VAERS.	• Published VAERS draft guidance and associated technical specifications in Q4 of FY 2014. • Conducted technical review of VAERS draft guidance comments. FDA is currently revising technical specifications based on review and discussion with pilot participants.
Publish draft guidance requiring electronic submission of post-market Lot Distribution Report to CBER.	• Published Electronic Lot Distribution Data Reporting (eLDD) draft guidance

	in Q4 of FY 2014.
Issue draft guidance for pre-market manufacturing establishment information.	• Completed technical interdependences for this item; however, final CDER review and release of guidance document is still outstanding. • Publication is expected in Q3 of FY 2015.
Begin to implement the recommendations arising from the CMC analysis, as appropriate.	• Initiated the CMC data standardization project; Established Technical Advisor Group (TAG) to provide subject matter expertise and governance oversight. • Completed preliminary planning, through an incremental approach the FDA determined initial CMC data elements and identified standardization options.
Future Milestones	
• Complete remaining IDMP implementation guides Q4 of FY 2015. • Publish final guidance to Industry providing regulatory submissions in electronic format—Standardized Study Data. • Publish final guidance to Industry providing regulatory submissions in electronic format – Submissions Under 745A(a) of the Federal Food, Cosmetic and Drug Act. • Post version 2.0 of the technical specification document entitled Study Data Technical Conformance Guide. • Develop, implement and publish a standard process for the testing and acceptance of data standards, including therapeutic area standards. • Conduct FDA Adverse Event Reporting System (FAERS) E2B (R3) pilot testing after the regional requirements for Drugs and Therapeutic Biologics are published. • Publish draft FAERS Technical Regional Requirements for E2B (R3). • Development and implementation of proposed CMC datasets are scheduled to start in late 2014 and will continuing into FY 2015.	

5.0 Goal 4: Metrics and Measures

Increasing the number and percentage of investigational new drug (IND) applications, new drug applications (NDA), and biologics license applications (BLA) submissions received in valid electronic format is a goal that is supported by FDA and industry stakeholders. To support the assessment of this goal, this section provides the FY 2014 submissions by type of prescription drug application submitted to either the Center for Biologics Evaluation and Research (CBER) or the Center for Drug Evaluation and Research (CDER). The following types of submissions reported include: BLAs, INDs, and NDAs. The frequency data for submissions are reported by quarters (Q) and as totals for FY 2014. The time span by quarter is: Q1 – October through December 2013, Q2 – January through March 2014, Q3 – April through June 2014, and Q4 – July through September 2014.

Table 1: FY 2014 Total Number of Submissions Categorized by Type of Submission

Type	Q1	Q2	Q3	Q4	Total
CBER BLA	2,017	1,741	1,809	1,783	**7,350**
CBER IND	1,447	1,330	1,397	2,713	**6,887**
CBER NDA	11	3	13	2	**29**
CDER BLA	2,354	1,987	2,266	2,420	**9,027**
CDER IND	24,183	23,230	24,388	24,819	**96,620**
CDER NDA	5,858	5,752	6,016	5,703	**23,329**
Total	**35,870**	**34,043**	**35,889**	**37,440**	**143,242**

Table 2 A: FY 2014 Total Number of Submissions Received in Valid Electronic Format in Compliance with FDA Standards – eCTD

Type	Q1	Q2	Q3	Q4	Total
CBER BLA	780	795	993	898	**3,466**
CBER IND	787	757	767	883	**3,194**
CBER NDA	2	0	3	0	**5**
CDER BLA	1,015	777	931	1,193	**3,916**
CDER IND	16,443	15,960	17,150	17,848	**67,401**
CDER NDA	4,822	4,742	5,049	4,864	**19,477**
Total	**23,849**	**23,031**	**24,893**	**25,686**	**97,459**

Table 2 B: FY 2014 Percentage of Submissions Received in Valid Electronic Format in Compliance with FDA Standards – eCTD

Type	Q1	Q2	Q3	Q4
CBER BLA	38.7%	45.7%	54.9%	50.4%
CBER IND	54.4%	56.9%	54.9%	32.5%
CBER NDA	18.2%	0.0%	23.1%	0.0%
CDER BLA	43.1%	39.1%	41.1%	49.3%
CDER IND	68.0%	68.7%	70.3%	71.9%
CDER NDA	82.3%	82.4%	83.9%	85.3%

Table 3 A: FY 2014 Total Number of Submissions Received through the Secure Electronic Single Point of Entry – ESG

Type	Q1	Q2	Q3	Q4	Total
CBER BLA	961	931	1,086	1,022	**4,000**
CBER IND	825	797	805	919	**3,346**
CBER NDA	6	1	6	2	**15**
CDER BLA	257	116	421	384	**1,178**
CDER IND	16,351	15,892	17,084	17,787	**67,114**
CDER NDA	4,988	4,833	5,167	4,951	**19,939**
Total	**23,388**	**22,570**	**24,569**	**25,065**	**95,592**

Table 3 B: FY 2014 Percentage of Submissions Received through the Secure Electronic Single Point of Entry – ESG

Type	Q1	Q2	Q3	Q4
CBER BLA	47.6%	53.5%	60.0%	57.3%
CBER IND	57.0%	59.9%	57.6%	33.9%
CBER NDA	54.5%	33.3%	46.2%	100.0%
CDER BLA	10.9%	5.8%	18.6%	15.9%
CDER IND	67.6%	68.4%	70.1%	71.7%
CDER NDA	85.1%	84.0%	85.9%	86.8%

Table 4 A: FY 2014 Total Number of Submissions Received in Physical Media

Type	Q1	Q2	Q3	Q4	Total
CBER BLA	320	210	181	272	**983**
CBER IND	289	286	291	958	**1,824**
CBER NDA	5	1	3	0	**9**
CDER BLA	1,791	1,527	1,484	1,709	**6,511**
CDER IND	272	239	295	317	**1,123**
CDER NDA	101	114	88	92	**395**
Total	**2,778**	**2,377**	**2,342**	**3,348**	**10,845**

Table 4 B: FY 2014 Percentage of Submissions Received in Physical Media

Type	Q1	Q2	Q3	Q4
CBER BLA	15.9%	12.1%	10.0%	15.3%
CBER IND	20.0%	21.5%	20.8%	35.3%
CBER NDA	45.5%	33.3%	23.1%	0.0%
CDER BLA	76.1%	76.8%	65.5%	70.6%
CDER IND	1.1%	1.0%	1.2%	1.3%
CDER NDA	1.7%	2.0%	1.5%	1.6%

Table 5 A: FY 2014 Total Number of Submissions Received on Paper

Type	Q1	Q2	Q3	Q4	Total
CBER BLA	736	600	542	489	**2,367**
CBER IND	333	247	301	836	**1,717**
CBER NDA	0	1	4	0	**5**
CDER BLA	306	344	361	327	**1,338**
CDER IND	7,560	7,099	7,009	6,715	**28,383**
CDER NDA	769	805	761	660	**2,995**
Total	**9,704**	**9,096**	**8,978**	**9,027**	**36,805**

Table 5 B: FY 2014 Percentage of Submissions Received on Paper

Type	Q1	Q2	Q3	Q4
CBER BLA	36.5%	34.5%	30.0%	27.4%
CBER IND	23.0%	18.6%	21.5%	30.8%
CBER NDA	0.0%	33.3%	30.8%	0.0%
CDER BLA	13.0%	17.3%	15.9%	13.5%
CDER IND	31.3%	30.6%	28.7%	27.1%
CDER NDA	13.1%	14.0%	12.6%	11.6%

Table 6 A: FY 2014 Total Number of Submission Received in Non-Standardized Electronic Format

Type	Q1	Q2	Q3	Q4	Total
CBER BLA	501	346	274	396	**1,517**
CBER IND	327	326	329	994	**1,976**
CBER NDA	9	2	6	2	**19**
CDER BLA	1,033	866	974	900	**3,773**
CDER IND	180	171	229	256	**836**
CDER NDA	267	205	206	179	**857**
Total	**2,317**	**1,916**	**2,018**	**2,727**	**8,978**

Table 6 B: FY 2014 Percentage of Submissions Received in Non-Standardized Electronic Format

Type	Q1	Q2	Q3	Q4
CBER BLA	24.8%	19.9%	15.1%	22%
CBER IND	22.6%	24.5%	23.6%	37%
CBER NDA	81.8%	66.7%	46.2%	100%
CDER BLA	43.9%	43.6%	43.0%	37%
CDER IND	0.7%	0.7%	0.9%	1%
CDER NDA	4.6%	3.6%	3.4%	3%

Table 7: FY 2014 Total Number of Standards-Based Electronic Submission Failures (Rejection)

Problem Type	BLA	IND	NDA	Total
Broken / Corrupted Media Device	1	9	17	**27**
Duplicate Content Received	24	26	5	**55**
Duplicate Sequence Received	21	606	172	**799**
GS Validate High Error	0	1	0	**1**
Invalid Application or Sequence	0	5	2	**7**
Invalid File Type Received	3	39	32	**74**
Mismatched Application, Sequence, or Type	2	77	48	**127**
Multiple Application / Sequence / US-Regional.xml	1	0	1	**2**
No Data Received	2	23	14	**39**

Problem Type	BLA	IND	NDA	Total
Not in Standard eCTD Format	4	76	19	**99**
Per CSO / Sponsor Request	1	12	6	**19**
Sent to Wrong Center	35	128	36	**199**
Total	**94**	**1,002**	**352**	**1,448**

6.0 Goal 5: Communications & Technical Interactions

FDA uses a multi-tiered approach to improve communications and distribute IT and data standards information to Industry at regular intervals. The aim of improved communications is to promote effective relationships between FDA and Industry stakeholders. Among these activities, FDA employs both formal and informal written correspondence, electronic media, and person-to-person communications.

Objectives	
1. Distribute IT/Informatics and data standards information to industry at regular intervals. 2. Collaboratively identify opportunities for continual quality improvements to make modifications to the IT/Informatics Plan when appropriate and to assess potential impacts between FDA and Industry stakeholders.	
FY 2014 Milestones	**Accomplishments**
Finalize the IT/Informatics Plan and publish to FDA website.	• Published a draft five-year IT/Informatics plan in Q1 FY 2014 with a 60 day comment period that ended on February 24, 2014. • Published final PDUFA V IT/Informatics Plan to the FDA Web site in Q4 FY 2014. The final plan incorporates Industry feedback to the PDUFA V IT/Informatics draft plan.
Annually, publish the PDUFA V IT Assessment and post on FDA website within 3 months after the close of each fiscal year.	• Published the FY 2014 PDUFA V IT/ Informatics Assessment to the FDA Web site on December 31, 2014. The FY 2014 Assessment included FY 2014 metrics based on Industry recommendation.
Conduct quarterly meetings with industry stakeholders.	• Conducted quarterly meetings with industry on the following dates: December 16, 2013, March 10, July 24, and September 8, 2014. Quarterly meetings participants discussed prospective implementation of the IT plan, progress toward the long term goal, potential impacts that future activities may have on FDA or stakeholders, and

	potential revisions to the IT plan. • Established a new User Fee IT/ Informatics email box in FY 2014 as a tool to enhance ongoing communications and technical interactions between FDA and industry stakeholders.
Future Milestones	
• Publish the FY 2015 PDUFA IT/Informatics Assessment within three months after the close of FY 2015. • Continue engaging industry stakeholders fostering productive meetings on a quarterly basis and throughout FY 2015.	