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 2015

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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 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 website in quarter (Q) 4 of fiscal year (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 FY15. It also identifies future milestones FDA intends to accomplish during the FY 2016 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 2015 involved continuing the Agency's efforts in providing reliable access to the FDA 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 2015 Milestone	**Accomplishments**
Implement the recommendations arising from the ESG analysis, as appropriate.	• Initiated Phase 1 of an ESG project in May 2015, which will meet critical user needs to support a significant increase in submission loads, and increase system availability and processing capabilities. • The ESG Program Governance Board (PGB) completed its first year, and has initiated a review of all documents and processes to increase communication and effectiveness. • The ESG PGB met with Pharmaceutical Research and Manufacturers of America (PhRMA)/Biotechnology Industry Organization (BIO) and Industry members in September 2015, to discuss industry needs and requirements. • Implemented automated Help Desk Ticket software into production in August 2015, which will improve efficiency by automating manual help

	desk processes.

Future Milestones
• Completion of Phase 1 of an ESG project to enhance the functional capabilities of the ESG (receipt and routing of submissions) to increase the effectiveness and efficiency of the electronic submission process. • Initiation of Phase 2 an ESG project to increase ESG availability to meet the projected increase in submission volume. • Implementation of new Help Desk software to provide ability to publish an electronic form for ticket submissions and to allow Industry users to track the status of tickets. • Review of the Industry-facing website to identify and implement changes that will make the website more intuitive and user-friendly. • Completion of the review of the account set-up process to achieve greater efficiencies.

3.0 Goal 2: Electronic Regulatory Submissions

Efforts to reach an all electronic environment involved finalizing the electronic Common Technical Document (eCTD) guidance and updating the FDA eCTD Module 1 (M1) specifications in FY 2015. These accomplishments helped to improve consistency of submission processing, ensure access to documents and data, and facilitate evaluation of information contained in submissions. FDA also continued participation and collaboration with International Conference on Harmonisation (ICH) to develop the eCTD v4.0 technical specifications.

Objectives	
1. Enhance electronic Common Technical Document (eCTD) formation to provide additional capabilities. 2. Require submissions in a standardized format.	
FY 2015 Milestones	**Accomplishments**
Implement major Module 1 release.	• FDA implemented the Module 1 (M1) update and started accepting submissions using the new M1 Specifications (v2.3) in June 2015.
ICH Step 2 adoption of eCTD v4.0	• ICH Step 2 signoff was achieved in January 2015.
ICH (eCTD v4.0) Public Comment Period	• Posted both ICH and FDA eCTD v4.0 Implementation Guides and related technical information for public comment. The comment period ended in May 2015. • ICH M8 group reviewed the public comments at the ICH June 2015

	meeting, and are in the process of updating the ICH eCTD v4.0 implementation package. • Reviewed public comments on the FDA regional M1 Implementation Guide in July/August 2015, and are in the process of updating the FDA eCTD v4.0 implementation package.
Publish the revised draft and final guidance for Industry on Providing Regulatory Submissions in Electronic Format Using the eCTD Specifications.	• The final eCTD guidance was posted on May 5, 2015. • Worked on the eCTD Technical Conformance Guidance and updates to related specifications (e.g., transmission) to be in alignment with final eCTD requirement guidance. The document was published in October 2015. • The eCTD web page was updated and includes a link to the eCTD Submission Standards spreadsheet.

Future Milestones
• Achieve ICH Step 4 adoption of eCTD v4.0 which is a major milestone for meeting Electronic Regulatory Submissions objectives. • Review comments and publish an update to the eCTD Technical Conformance Guidance.

4.0 Goal 3: Data Standards

FDA participates in 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 products 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 2015 Milestones	Accomplishments
Publish final guidance requiring regulatory submissions in electronic format — Submissions Under Section 745A(a).	• Published Final Guidance on December 17, 2014.
Publish final guidance requiring regulatory submissions in electronic format — Standardized Study Data.	• Published Final Guidance on December 17, 2014.
FDA Data Standards Catalog	• Posted Version 4.0 in December 2014 and subsequent updates.
Study Data Technical Conformance Guide	• Posted Version 1.0 in December 2014 and subsequent updates.
Therapeutic Area (TA) Data Standards Initiative Project Plan	• Annual updates published. • Updated the Therapeutic Area (TA) (Disease/Domain) Data Standards Prioritization List in July 2015.
Require electronic submissions using E2B (R3) for vaccines.	• Implemented electronic reporting to the Vaccine Adverse Event Reporting System (VAERS) in June 2015. • Published final guidance in August 2015.
Require electronic submissions using E2B (R3) for drugs and biologics.	• Continued progress toward finalizing regional technical specifications for drugs and biologics.
ISO/HL7 balloting of Identification of Medicinal Products (IDMP) implementation guides	• Completed Draft Technical Specifications Ballots in August 2015. • Completed Committee Information Ballot for substance annexes in October 2015.
Assess standardization needs and uses for drug quality data areas supporting CMC, product, and facility requirements; implement the recommendations arising from the analysis, as appropriate.	• Completed assessment of CMC data standardization in the following areas: drug substance specification, batch analysis, and product and substance stability.

	• Identified common data elements, definitions, and harmonized data models.

Future Milestones

- Finalize E2B (R3) regional technical specifications for drug and biologics.
- Initiate an E2B (R3) pilot for CBER-regulated biologics.
- Confirm FY16 SDO approach and timelines for finalizing all IDMP technical specifications and updates to published standards.
- Issue guidance for premarket manufacturing establishment information.
- Initiate work in HL7 to support structured CMC submissions.
- Initiate discussions concerning a limited pilot and use of adopted standards to support electronic submission of biologics component (e.g., animal, biologics, or chemical) information for CBER-regulated products.
- Publish version updates of the Study Data StandardsTechnical Conformance Guide.
- Publish version updates of the Therapeutic Area Standards Initiative Project Plan.

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 2015 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 as totals for FY 2015. The time span is October 2014 through September 2015.

In summary, there were a total of 189,458 NDA, BLA, and IND submissions to CDER and CBER in FY 2015. Sponsor submissions to CDER accounted for 94%, while sponsor submissions to CBER accounted for 6%. Most sponsor submissions (61%) were received through the ESG), however 22% of submissions were received in paper. Overall, 78% of all electronic submissions were sent in standardized eCTD format. Less than 1% of all electronic submissions were rejected in FY 2015 with the largest problem type (40%) being the receipt of duplicate sequences.

FY 2015 Total Number and Percent of Submissions Categorized by Type of Submission, Method of Transmission, and Electronic Format

Table 1.0 – Number and Percent of Submissions by Type of Submission

	BLA	IND	NDA	Total
CDER	10,325 (6%)	110,795 (62%)	57,001 (32%)	178,121 (94%)
CBER	5,803 (51%)	5,523 (49%)	11 (0%)	11,337 (6%)
Total	16,128 (9%)	116,318 (61%)	57,012 (30%)	**189,458**

Figure 1.0 – Total Number and Percent of CDER Submissions by Type

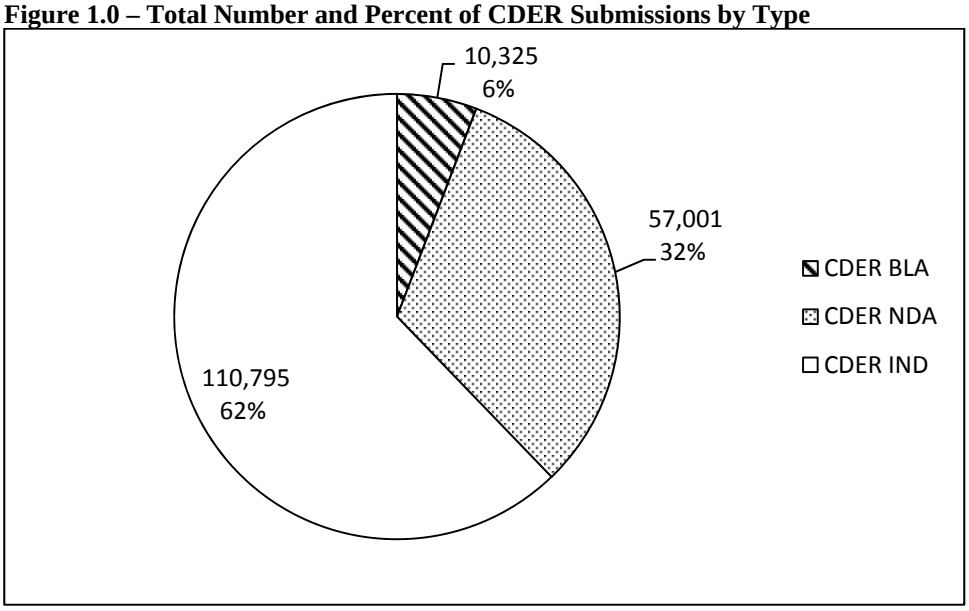


Figure 1.1 – Total Number and Percent of CBER Submissions by Type

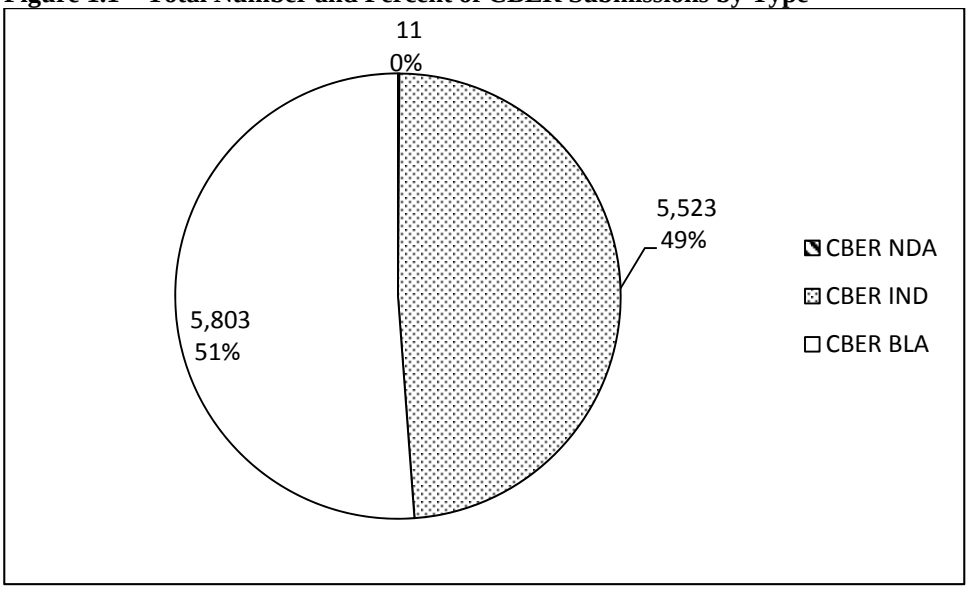


Table 2.0 – Number and Percent of Submissions by Method of Transmission

	ESG	Paper	Other Methods	Total
CDER	108,393 (61%)	39,012 (22%)	30,716 (17%)	178,121 (94%)
CBER	7,334 (65%)	1,841 (16%)	2,162 (19%)	11,337 (6%)
Total	115,727 (61%)	40,853 (22%)	32,878 (17%)	**189,458**

Figure 2.0 – CDER Submissions by Method of Transmission

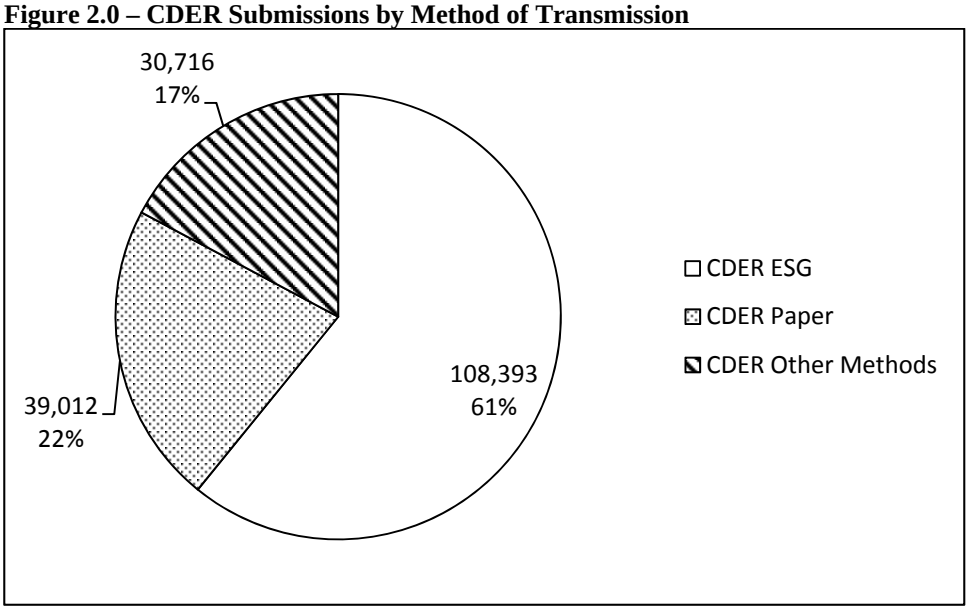


Figure 2.1 – CBER Submissions by Method of Transmission

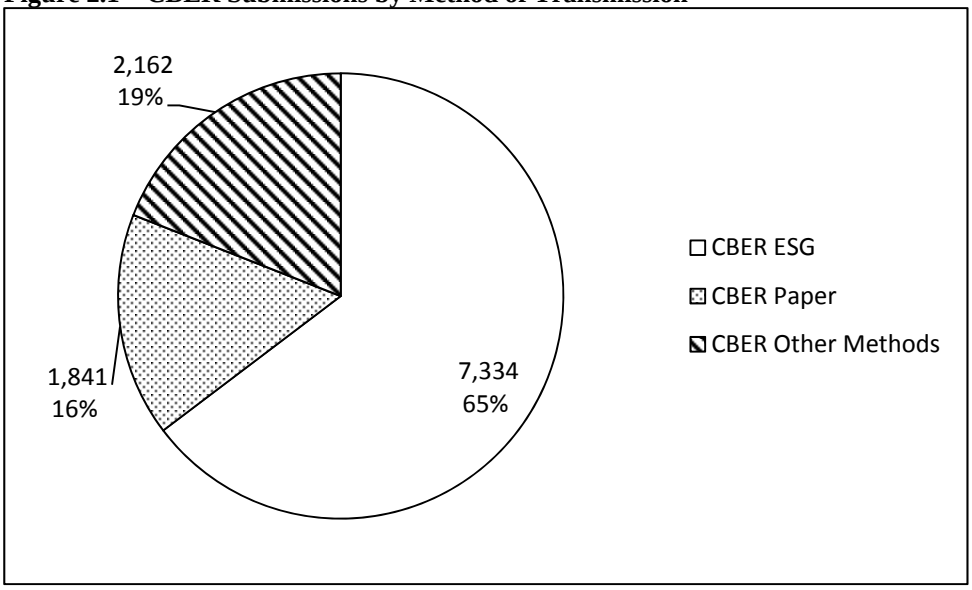


Table 3.0 – Number and Percent of Submissions by Electronic Format

	eCTD	Non-standard Electronic	Total
CDER	108,364 (78%)	30,745 (22%)	139,109 (94%)
CBER	6,911 (73%)	2,585 (27%)	9,496 (6%)
Total	115,275 (78%)	33,330 (22%)	**148,605**

Figure 3.0 – CDER Electronic Format Submissions by Format Type

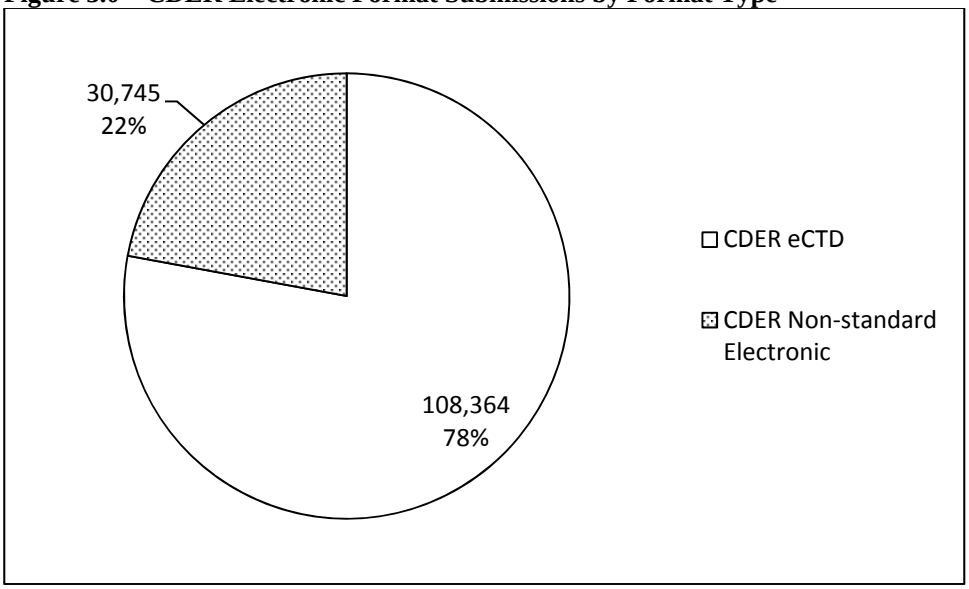
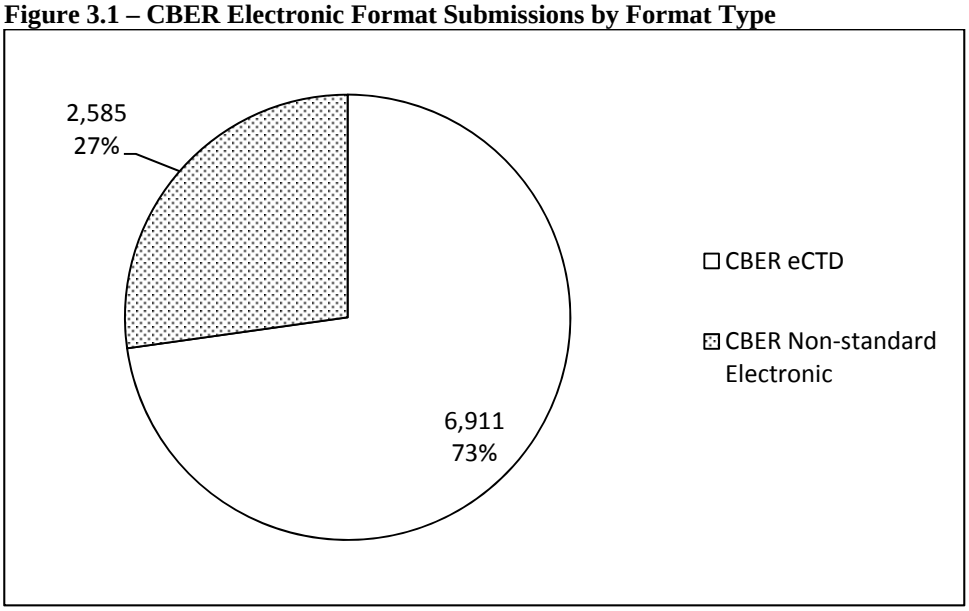


Figure 3.1 – CBER Electronic Format Submissions by Format Type



FY 2015 Total Number and Percent of Submissions Received in Valid Electronic Format in Compliance with FDA Standards – eCTD

Table 4.0 – Number and Percent of Submissions in Valid Electronic Format

	BLA	IND	NDA	Total
CDER	3,266 (3%)	84,595 (78%)	20,503 (19%)	108,364 (94%)
CBER	3,577 (52%)	3,328 (48%)	6 (0%)	6,911 (6%)
Total	6,843 (6%)	87,923 (76%)	20,509 (18%)	**115,275**

Figure 4.0 – CDER Valid Electronic Format Submissions by Submission Type

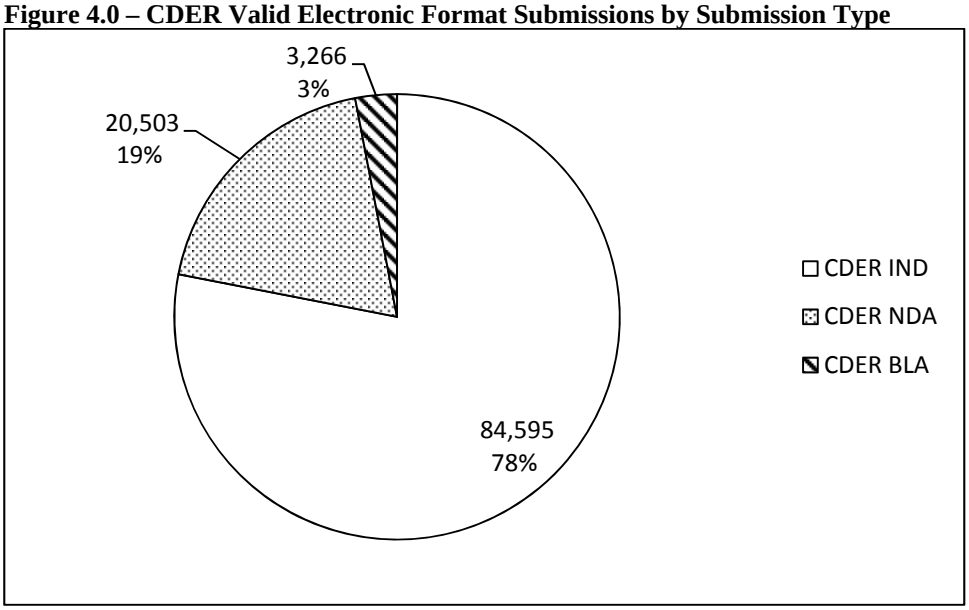
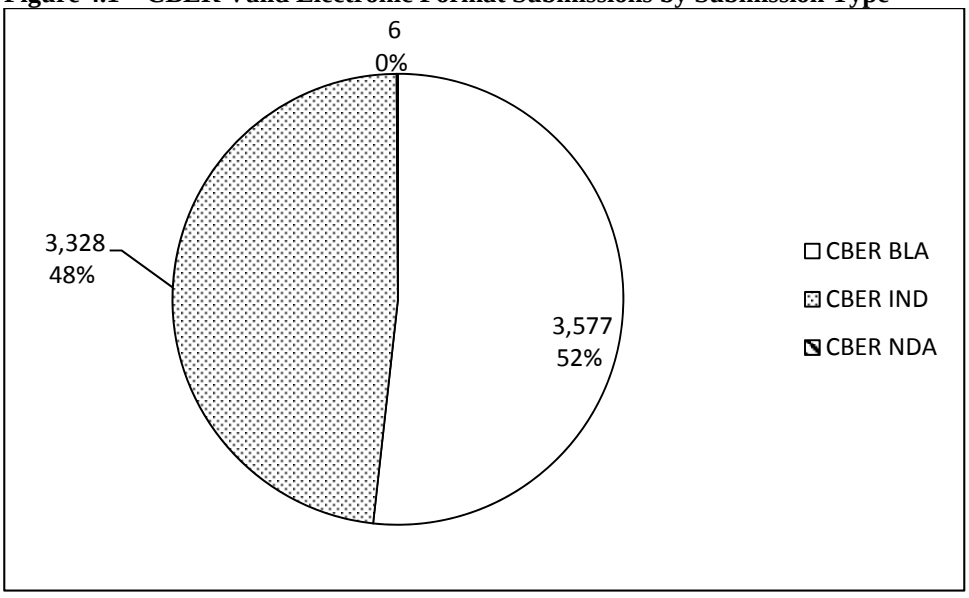


Figure 4.1 – CBER Valid Electronic Format Submissions by Submission Type



FY 2015 Total Number and Percent of Submissions Received through the Secure Electronic Single Point of Entry – ESG

Table 5.0 – Number and Percent of Submissions through ESG

	BLA	IND	NDA	Total
CDER	3,245 (3%)	84,502 (78%)	20,646 (19%)	108,393 (94%)
CBER	3,852 (53%)	3,476 (47%)	6 (0%)	7,334 (6%)
Total	7,097 (6%)	87,978 (76%)	20,652 (18%)	**115,727**

Figure 5.0 – CDER ESG Submissions by Submission Type

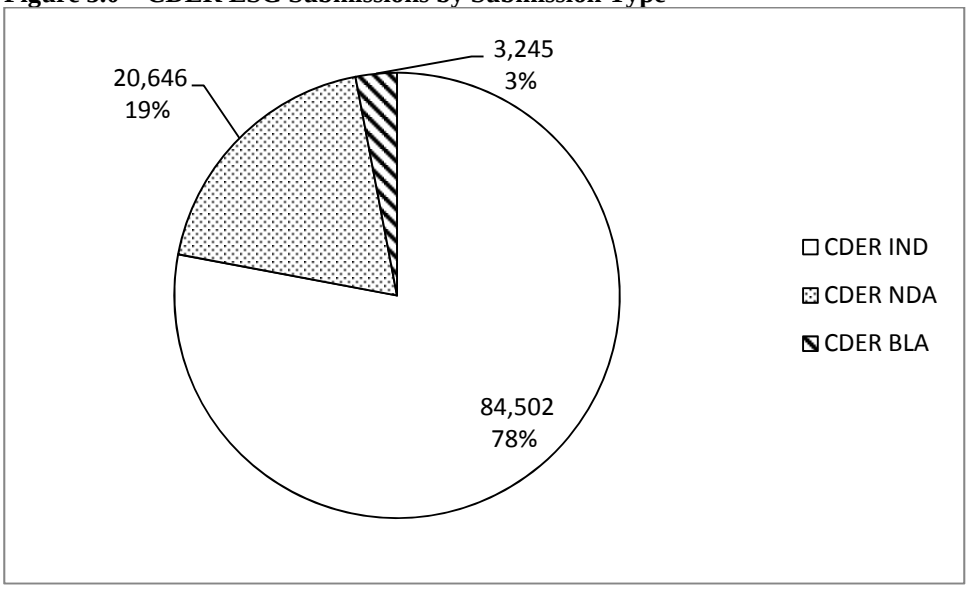
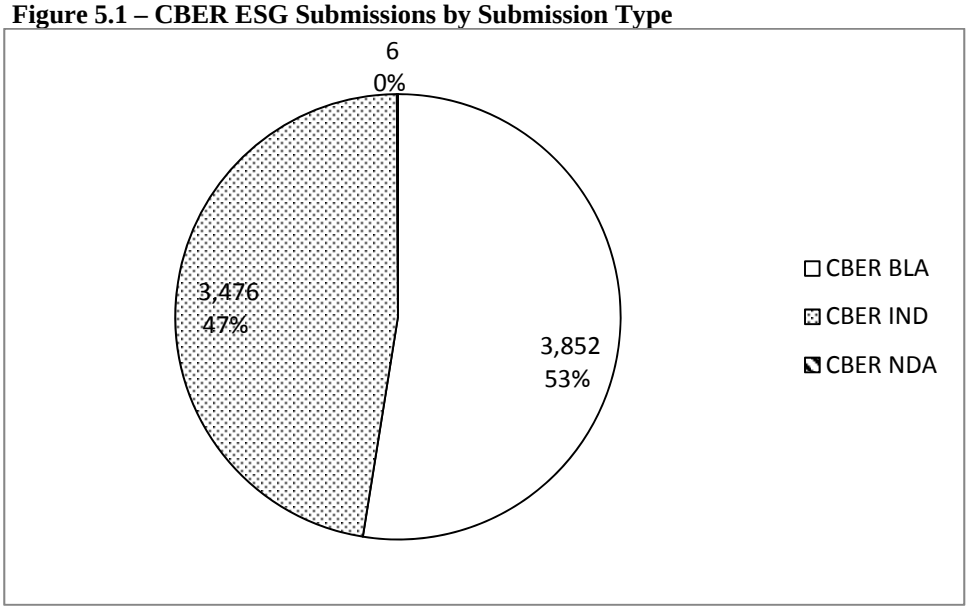


Figure 5.1 – CBER ESG Submissions by Submission Type



FY 2015 Total Number and Percent of Submissions Received by Other Methods*

Table 6.0 – Number and Percent of Submissions by Other Methods

	BLA	IND	NDA	Total
CDER	5,189 (17%)	3,551 (12%)	21,976 (71%)	30,716 (93%)
CBER	833 (39%)	1,327 (61%)	2 (0%)	2,162 (7%)
Total	6,022 (18%)	4,878 (15%)	21,978 (67%)	**32,878**

Figure 6.0 – CDER Submissions by Other Methods by Submission Type

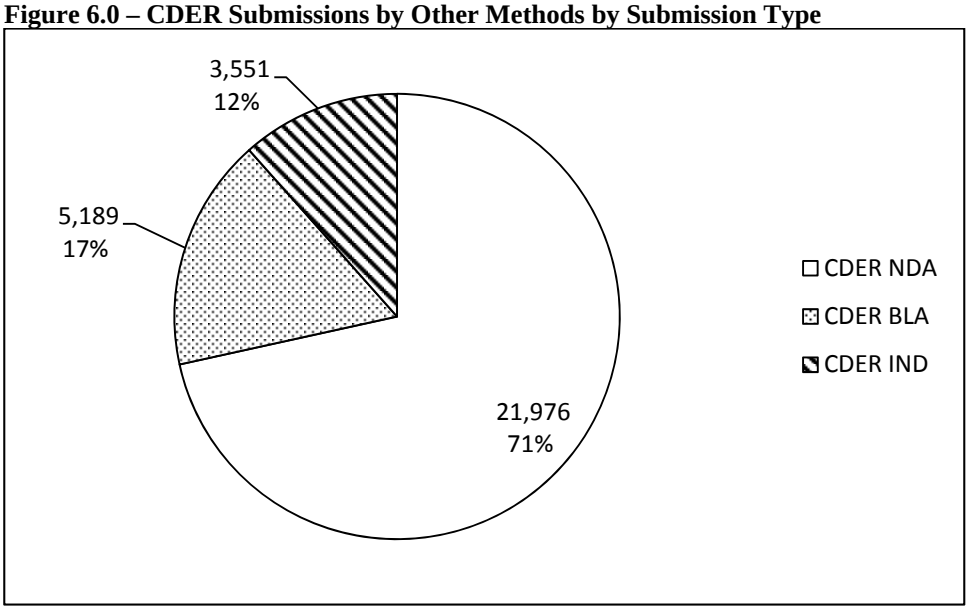
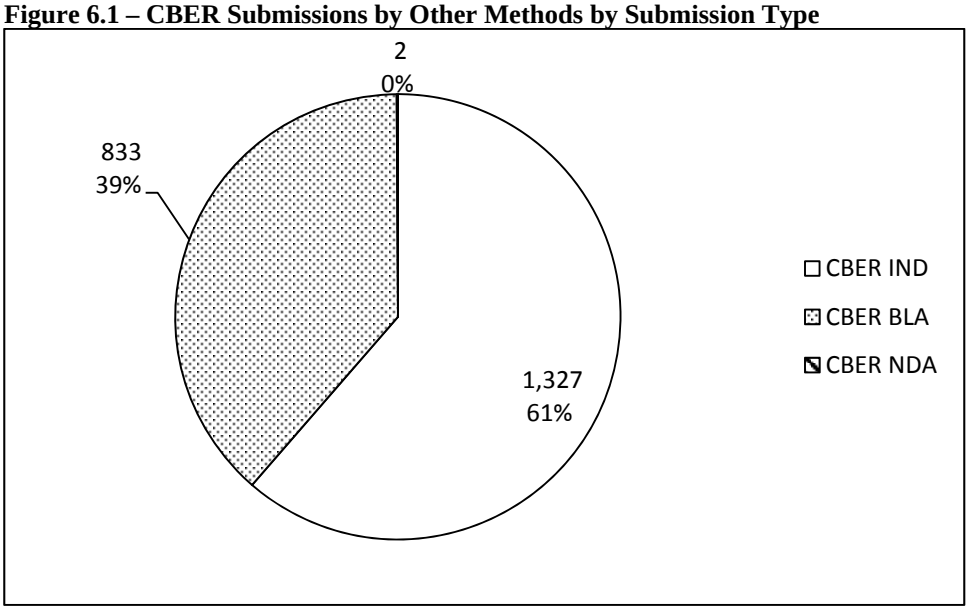


Figure 6.1 – CBER Submissions by Other Methods by Submission Type



*Physical media (e.g., hard drive, CD, DVD, USB)

FY 2015 Total Number and Percent of Submissions Received in Paper

Table 7.0 – Number and Percent of Submissions by Paper

	BLA	IND	NDA	Total
CDER	1,891 (5%)	22,742 (58%)	14,379 (37%)	39,012 (95%)
CBER	1,118 (61%)	720 (39%)	3 (0%)	1,841 (5%)
Total	3,009 (7%)	23,462 (57%)	14,382 (35%)	**40,853**

Figure 7.0 – CDER Paper Submissions by Submission Type

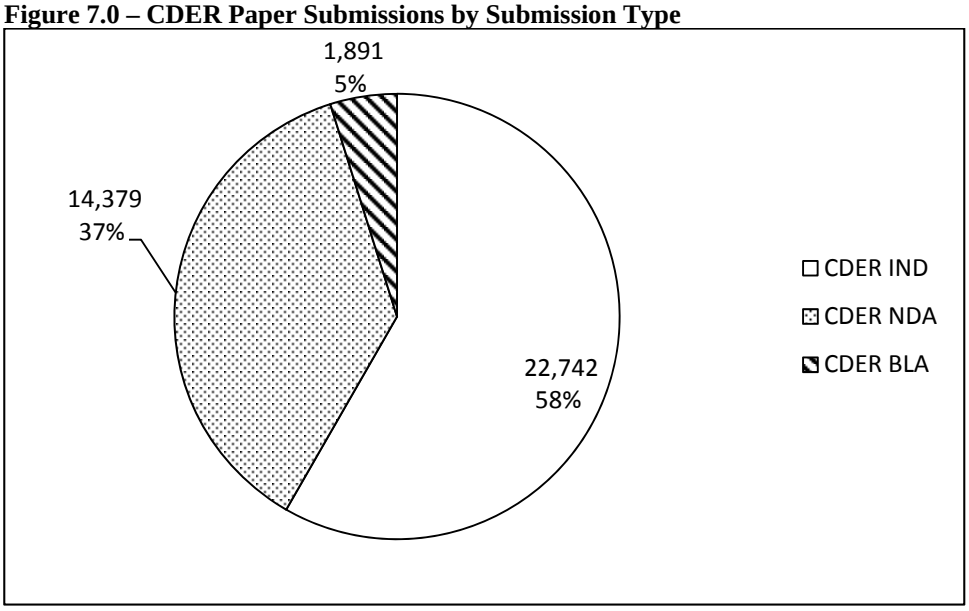
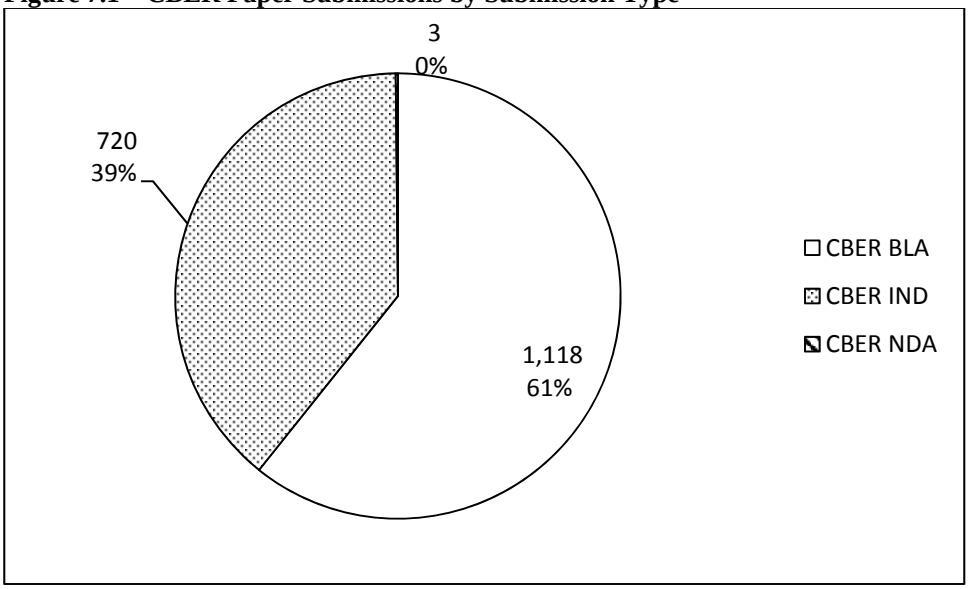


Figure 7.1 – CBER Paper Submissions by Submission Type



FY 2015 Total Number and Percent of Submission Received in Non-Standardized Electronic Format

Table 8.0 – Number and Percent of Submissions in Non-Standardized Electronic Format

	BLA	IND	NDA	Total
CDER	5,168 (17%)	3,458 (11%)	22,119 (72%)	30,745 (92%)
CBER	1,108 (43%)	1,475 (57%)	2 (0%)	2,585 (8%)
Total	6,276 (19%)	4,933 (15%)	22,121 (66%)	**33,330**

Figure 8.0 – CDER Non-Standardized Electronic Format Submissions by Submission Type

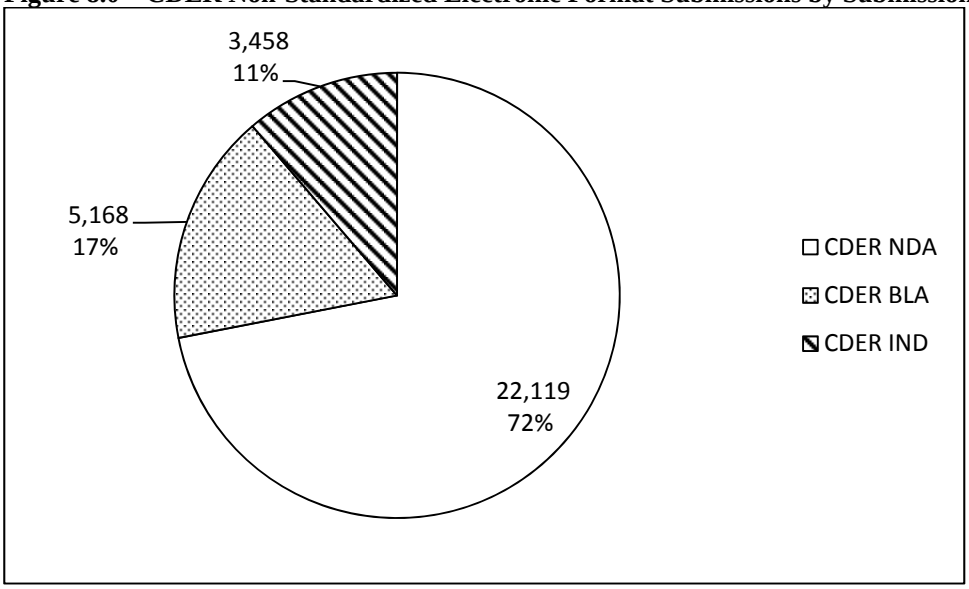
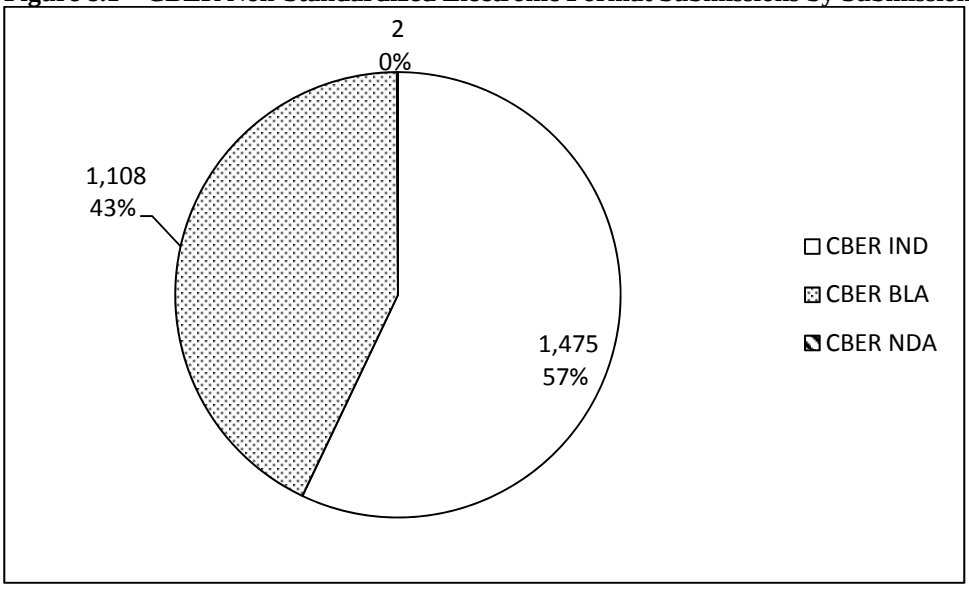


Figure 8.1 – CBER Non-Standardized Electronic Format Submissions by Submission Type



FY 2015 Total Number and Percent of Standards-Based Electronic Submission Failures (Rejections)

Table 9.0 – Number and Percent of Submission Failures (Rejections)

Problem Type	BLA	IND	NDA	Total
Duplicate Sequence Received	10 (2%)	354 (74%)	115 (24%)	479 (40%)
Sent to Wrong Center	32 (19%)	117 (69%)	20 (12%)	169 (14%)
Mismatched Application/Sequence/Type	8 (7%)	52 (46%)	54 (47%)	114 (10%)
Invalid File Type	7 (6%)	41 (38%)	60 (56%)	108 (9%)
Not in Standard eCTD Format	2 (2%)	70 (74%)	23 (24%)	95 (8%)
Duplicate Content Received	33 (39%)	51 (61%)	0 (0%)	84 (7%)
Sent in Error	8 (14%)	33 (59%)	15 (27%)	56 (5%)
No Data Received	7 (16%)	18 (40%)	20 (44%)	45 (4%)
Broken / Corrupted Media	2 (7%)	10 (37%)	15 (56%)	27 (2%)
Invalid Application/Sequence	3 (33%)	4 (44%)	2 (22%)	9 (1%)
Multiple Application / Sequence / US-Regional.xml	1 (50%)	0 (0%)	1 (50%)	2 (0%)
eCTD High Validation Error	0 (0%)	1 (100%)	0 (0%)	1 (0%)
Total	113 (10%)	751 (63%)	325 (27%)	**1,189**

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 2015 Milestones	**Accomplishments**
Annually, publish the PDUFA V IT Assessment and post on FDA website within three months after the close of each fiscal year.	• Published the FY 2015 PDUFA V IT/ Informatics Assessment to the FDA Web site by December 31, 2015. The FY 2015 Assessment includes FY 2015 metrics based on Industry recommendation.
Conduct quarterly meetings with Industry stakeholders.	• Conducted quarterly meetings with Industry in December 2014, March, June, and September 2015. Quarterly meeting 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.
Future Milestones	
• Publish the FY 2016 PDUFA IT/Informatics Assessment within three months after the close of FY 2016. • Continue engaging Industry stakeholders, fostering productive meetings on a quarterly basis and throughout FY 2016.	