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 2016

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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 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 FY16. It also identifies future milestones FDA intends to accomplish during the 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 2016 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 2016 Milestone	**Accomplishments**
Implement the recommendations arising from the ESG analysis, as appropriate.	• ESG increased the server capacity by 100% in October 2015 to ensure the ability to handle continued increases in submission volume. • Infrastructure provisioning and software license procurement for all environments to support Phase I was completed January 2016. • The Pre-Production and Production implementation of Phase I began on 6/1/2015. Phase I implementation included updating hardware from Solaris to Linux and software for Center Inbox processing from Activator to Cross File Transfer (CFT) providing faster processing time and submission receipt generation by 79%. Phase I was completed April 2016. • The 2nd Generation ESG Modernization Phase II is proceeding as scheduled with an anticipated release date of Q3 FY16.

	Phase II will provide a number of benefits to the FDA and Industry users, including: 1. increased system availability so users can always submit files and access historical submissions; 2. the elimination of system downtime for planned outages; 3. an enhanced ESG User Interface for web-based users that eases navigation, and supports multi-file upload. • The ESG PGB completed their second year and have continued the review of all documents and processes to increase communication and effectiveness. • The ESG Program Governance Board (PGB) is continuing to a review the industry-facing website to be more intuitive and user-friendly. • ESG PGB continues to review of the account set-up process to achieve efficiencies. • ESG PGB updated its external communications plan for greater consistency and clarity.

Future Milestones

To meet projected demand of increases in the number and size of electronic submissions, the following measures are expected to continue in FY 2017:

- Enhance the functional capabilities of the ESG (receipt and routing of submissions) to increase the effectiveness and efficiency of the electronic submission process.
- Enhance the functional capabilities to capture metrics on submission and acknowledgment processing and provide a proactive view of submission status.
- Increase ESG availability to meet the higher concentration of submissions per hour over the next 5 years.

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 Council on Harmonisation (ICH) to develop the eCTD v4.0 technical specifications.

<table>
<tr><th colspan="2">Objectives</th></tr>
<tr><td colspan="2">1. Enhance electronic Common Technical Document (eCTD) formation to provide additional capabilities.
2. Require submissions in a standardized format.</td></tr>
<tr><th>FY 2016 Milestones</th><th>Accomplishments</th></tr>
<tr><td>ICH Step 4 adoption of eCTD v4.0</td><td>• ICH M8 achieved Step 4 sign-off on the eCTD v4.0 Implementation Package during the ICH 2015 December meeting.
• ICH posted the ICH eCTD v4.0 Implementation Package on April 4, 2016.
• FDA posted the FDA eCTD v4.0 Module 1 Implementation Package on March 31, 2016.</td></tr>
<tr><td>Publish the revised draft and final guidance for industry on Providing Regulatory Submissions in Electronic Format Using the eCTD Specifications.</td><td>• The final eCTD guidance was posted on May 5, 2015.
o The FDA published the eCTD Technical Conformance Guidance on October 5, 2015.
o The FDA published the updated Transmission Specifications on March 4, 2016.</td></tr>
<tr><th colspan="2">Future Milestones</th></tr>
<tr><td colspan="2">• Starting on May 5, 2017 NDA, BLA, ANDA and Master Files must be submitted in the eCTD format. For additional information on the guidance, including any exemptions, please refer to the Final Guidance for Industry: Providing Regulatory Submissions in Electronic Format – eCTD Specifications.</td></tr>
</table>

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 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 Pharmaceutical Quality/ Chemistry Manufacturing Controls (PQ/CMC), product, and facility requirements.	
FY 2016 Milestones	**Accomplishments**
Publish Study Data Technical Conformance Guide.	• Posted Version 3.1 to Study Data Standards webpage. (http://www.fda.gov/forindustry/datastandards/studydatastandards/default.htm)
Therapeutic Area (TA) Data Standards Initiative Project.	• The FDA published the Therapeutic Area Standards Initiative Project Plan (Version 3.0) on October 2015. (http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm287408.htm)
Require electronic submissions using E2B (R3) for vaccines.	• Production eVAERS Release 1 System was implemented on June 5, 2016. • Several pharmaceutical companies have gone live with electronic ICSR reporting before the expiration of their waiver period.
Require electronic submissions using E2B (R3) for drugs and biologics.	• CDER published the regional requirements document in June 2016.

Issue final guidance for premarket manufacturing establishment information	• Draft guidance is in Agency-level clearance.
Assess standardization needs and uses for drug quality data areas supporting Pharmaceutical Quality/Chemistry, Manufacturing, and Controls (CMC), product, and facility requirements; implement the recommendations arising from the analysis, as appropriate.	• CDER scheduled to publish a Federal Register Notice announcing availability of data elements and terminologies for public comment in FY Q2 2017.
Future Milestones	
• Issue draft guidance for premarket manufacturing establishment information. • Issue Federal Register Notice of the availability of data elements supporting CMC. • Require NDA, certain BLA, and ANDA submissions of data in standardized formats December 17, 2016. (Milestone 1.6). • Issue Federal Notice on availability of CMC data elements and terminologies.	

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 2016 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 2016. The time span is October 2015 through September 2016.

FY 2016 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	12,880 (7%)	104,389 (60%)	58,331 (33%)	175,600 (93%)
CBER	7,488 (56%)	5,920 (44%)	13 (0%)	13,421 (7%)
Total	20,368 (11%)	110,309 (58%)	58,344 (31%)	**189,021**

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

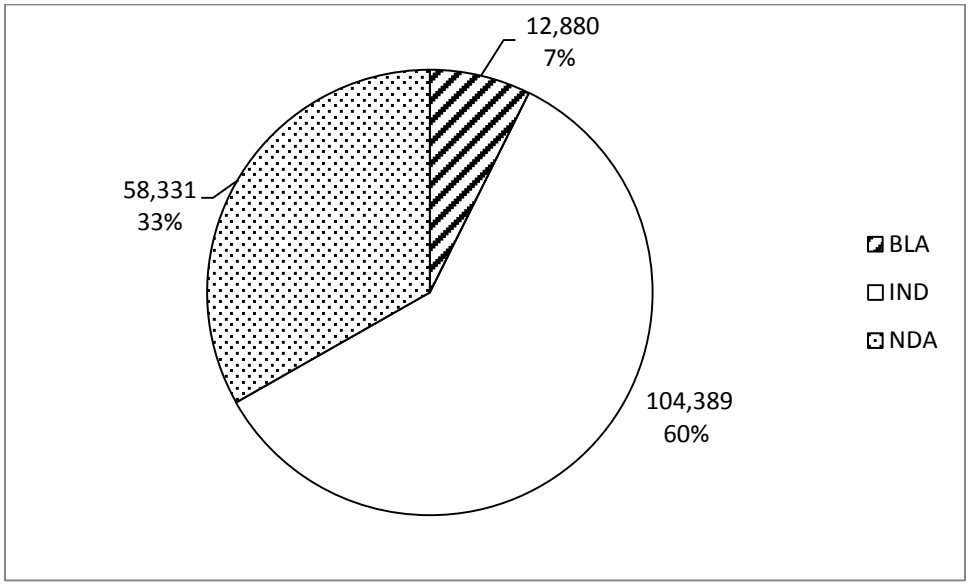


Figure 1.1 – Total Number and Percent of CBER Submissions by Type

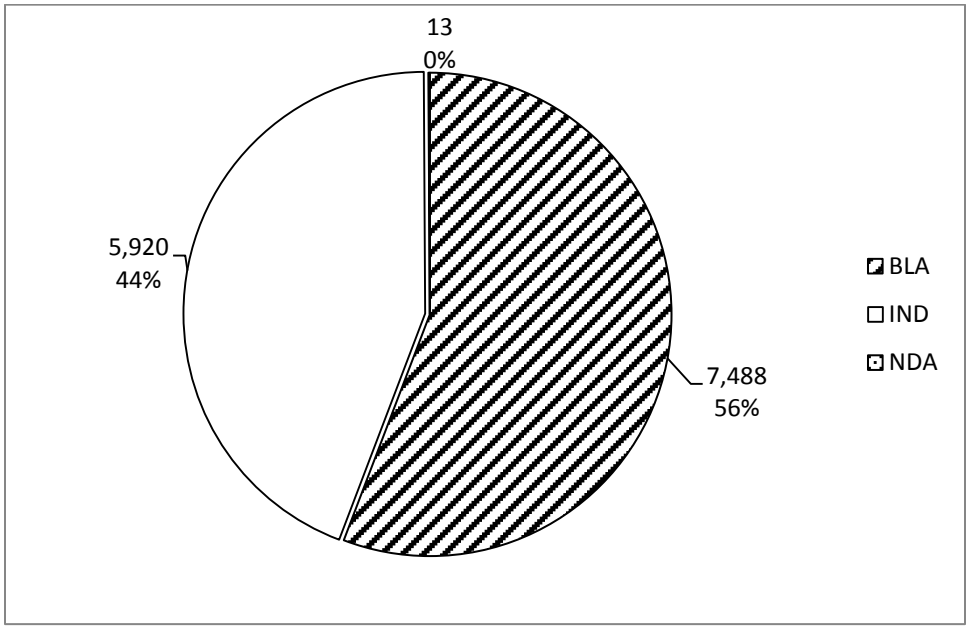
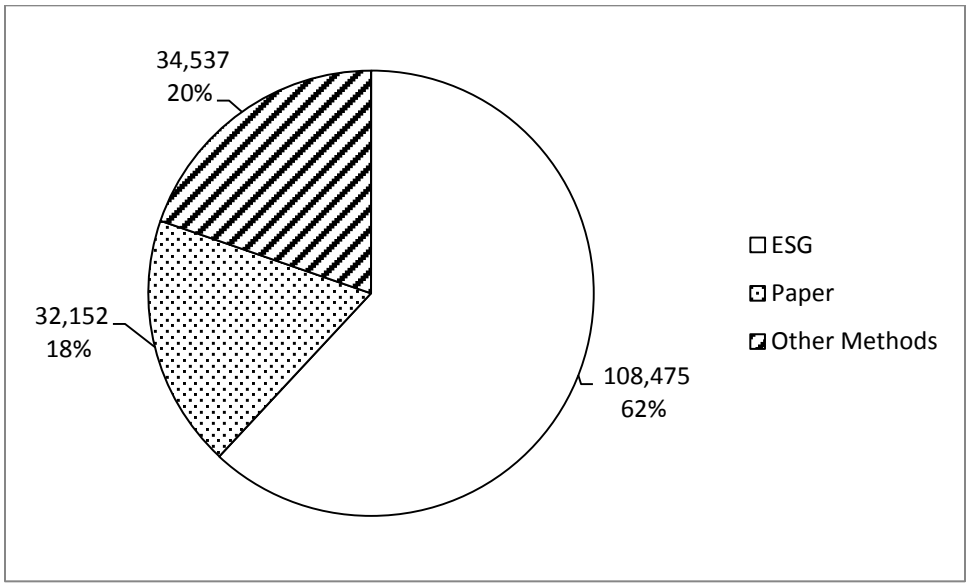


Table 2.0 – Number and Percent of Submissions by Method of Transmission

	ESG	Paper	Other Methods	Total
CDER	108,475 (62%)	32,152 (18%)	34,537 (20%)	175,164 (93%)
CBER	9,542 (71%)	1,257 (9%)	2,622 (20%)	13,421 (7%)
Total	118,017 (62%)	33, 409 (18%)	37,159 (20%)	**188,585**

Figure 2.0 – CDER Submissions by Method of Transmission



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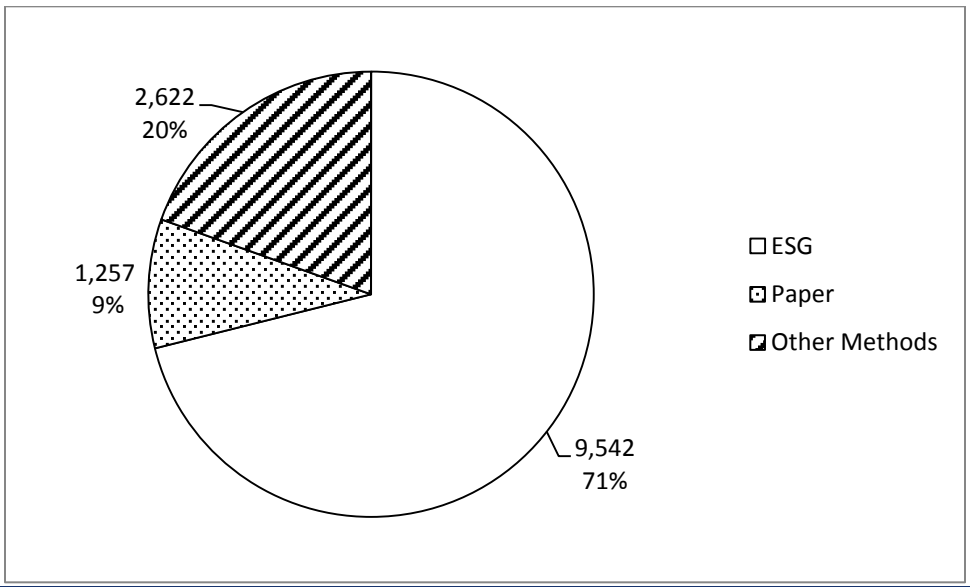


Table 3.0 – Number and Percent of Submissions by Electronic Format

	eCTD	Non-standard Electronic	Total
CDER	108,322 (76%)	34,627 (24%)	143,016 (92%)
CBER	9,039 (74%)	3,125(26%)	12,164 (8%)
Total	117,361 (76%)	37,752 (24%)	**155,180**

Figure 3.0 – CDER Electronic Format Submissions by Format Type

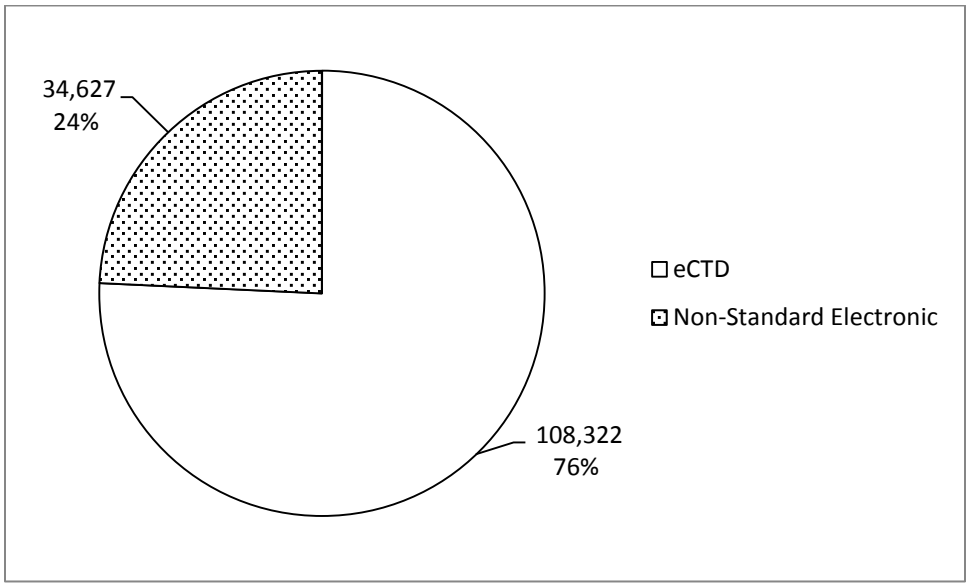
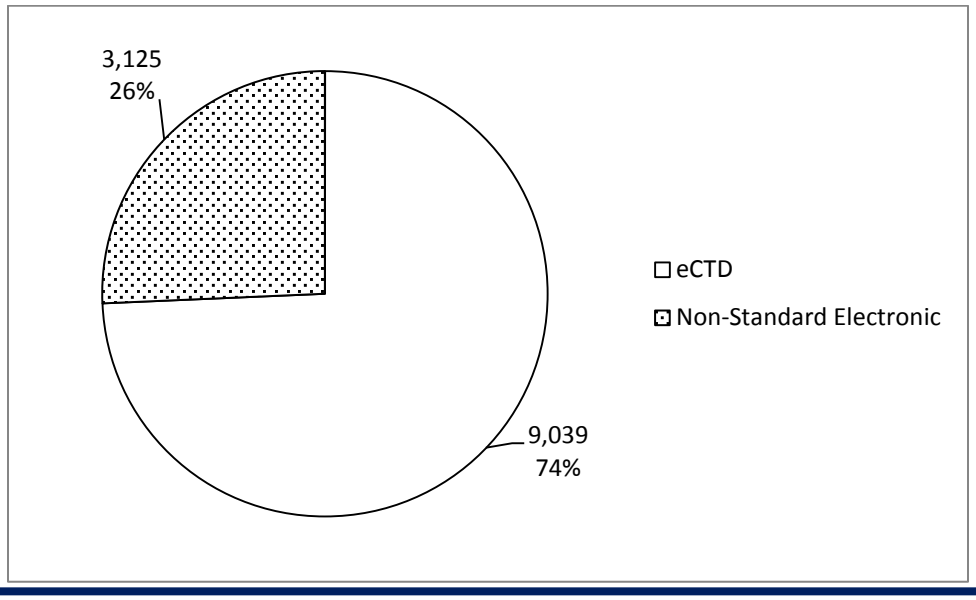


Figure 3.1 – CBER Electronic Format Submissions by Format Type



FY 2016 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	4,161 (4%)	79,953 (74%)	24,209 (22%)	108,323 (92%)
CBER	4,859 (54%)	4,170 (46%)	10 (0%)	9,039 (8%)
Total	9,020 (8%)	84,123 (72%)	24,219 (20%)	**117,362**

Figure 4.0 – CDER Valid Electronic Format Submissions by Submission Type

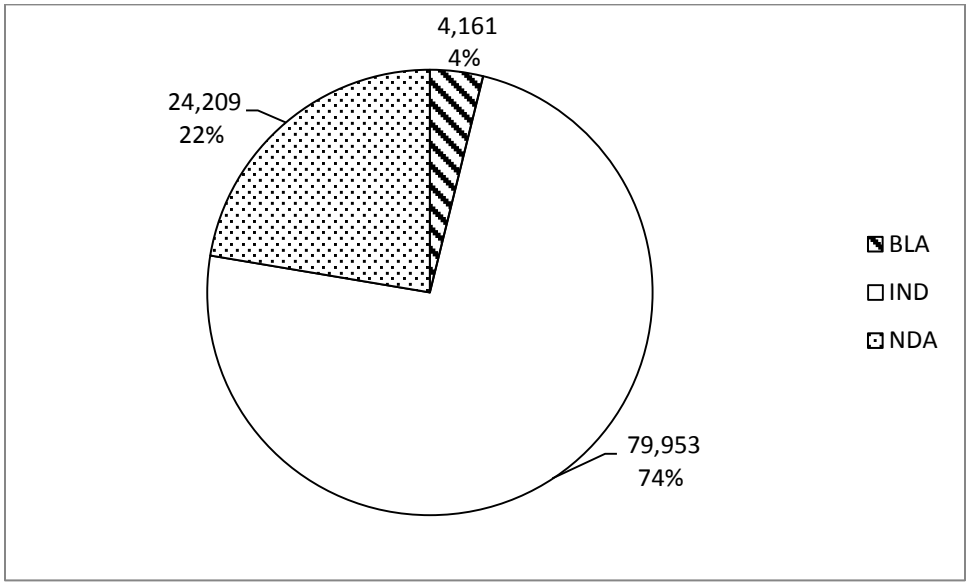
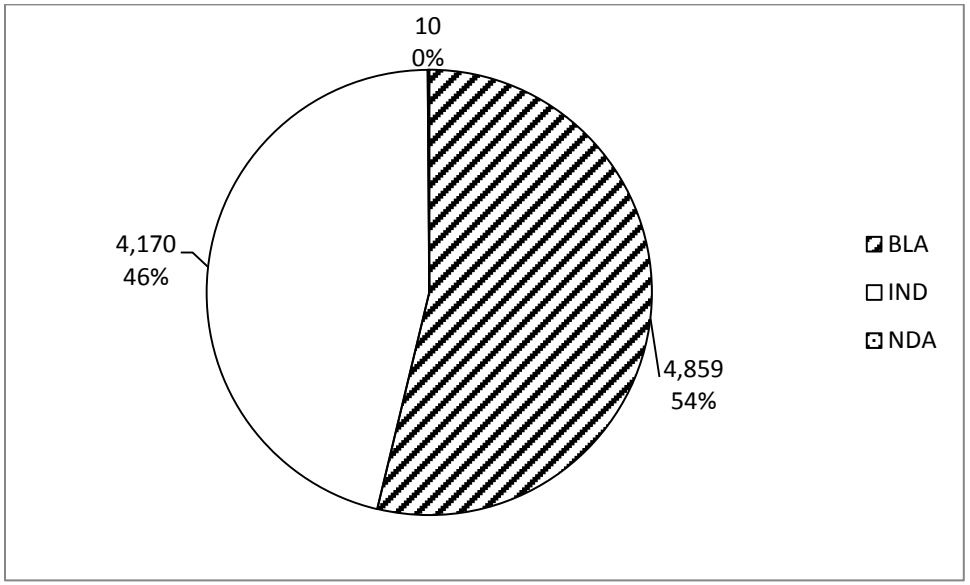


Figure 4.1 – CBER Valid Electronic Format Submissions by Submission Type



FY 2016 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	4,155 (4%)	80,006 (74%)	24,315 (22%)	108,476 (92%)
CBER	5,244 (55%)	4,288 (45%)	10 (0%)	9,542 (8%)
Total	9,399 (8%)	84,294 (71%)	24,325 (21%)	**118,018**

Figure 5.0 – CDER ESG Submissions by Submission Type

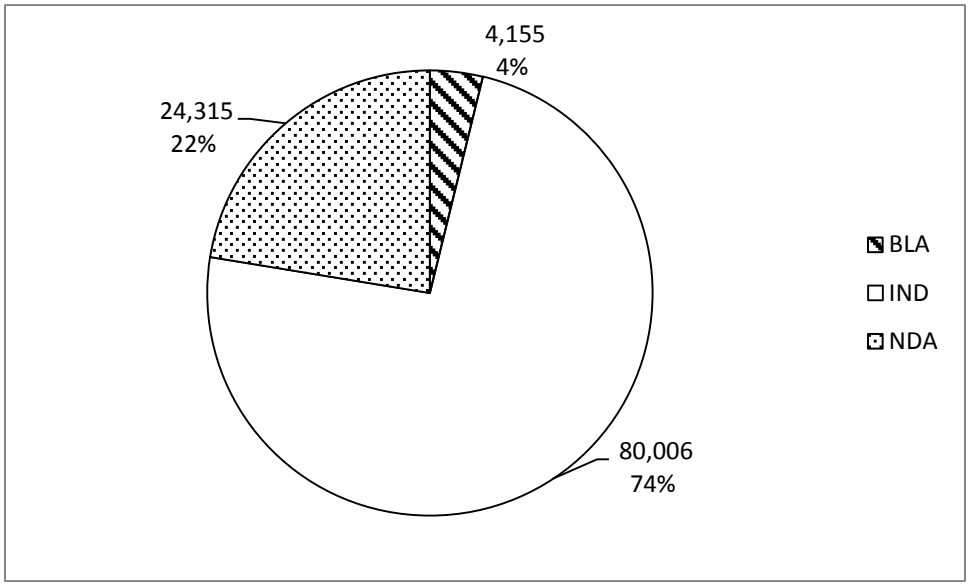
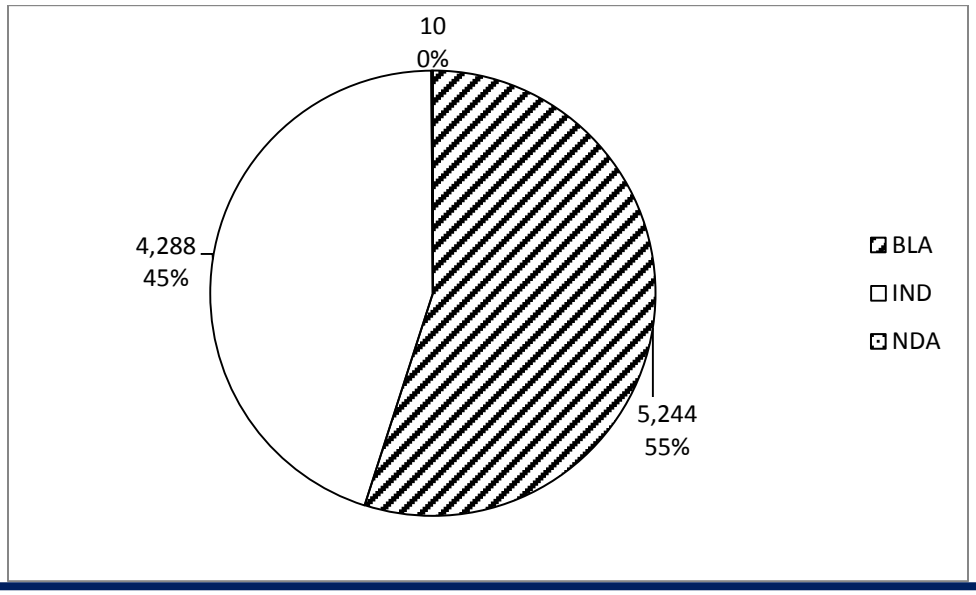


Figure 5.1 – CBER ESG Submissions by Submission Type



FY 2016 Total Number and Percent of Submissions Received by Other Methods[1]

Table 6.0 – Number and Percent of Submissions by Other Methods

	BLA	IND	NDA	Total
CDER	6,775 (19%)	4,069 (12%)	24,058 (69%)	34,902 (93%)
CBER	1,161 (44%)	1,460 (56%)	1 (0%)	2,622 (7%)
Total	7,936 (21%)	5,529 (15%)	24,059 (64%)	**37,524**

Figure 6.0 – CDER Submissions by Other Methods by Submission Type

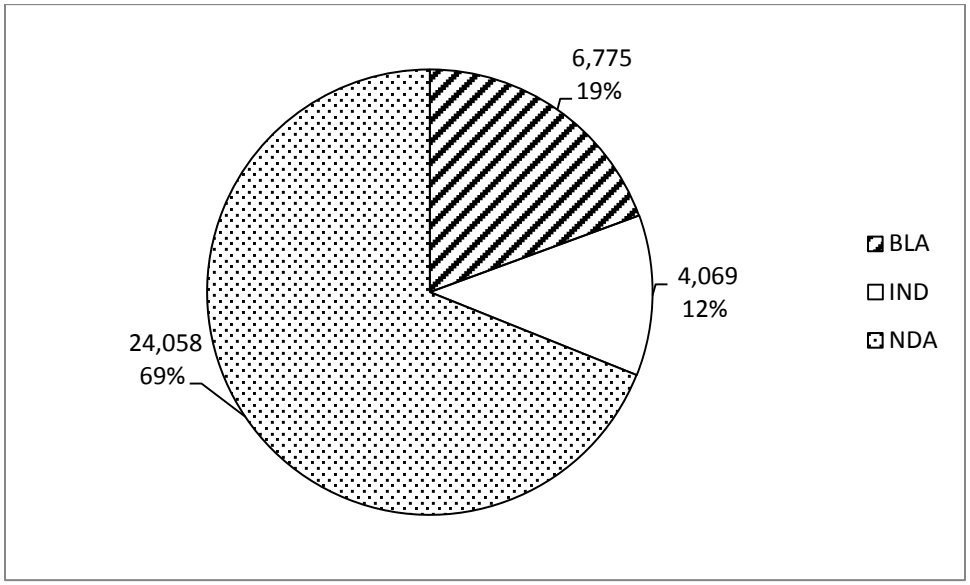
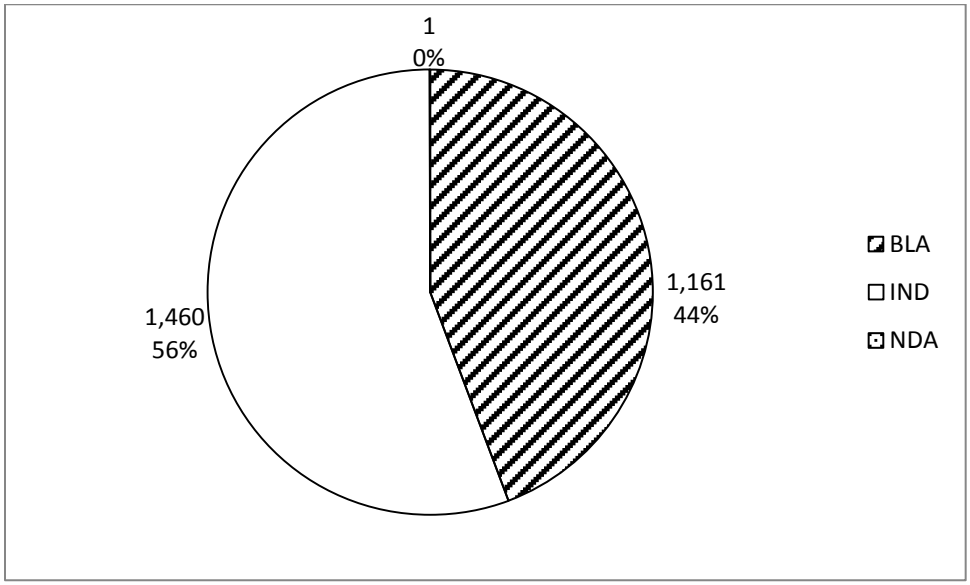


Figure 6.1 – CBER Submissions by Other Methods by Submission Type



[1]Physical media (e.g., hard drive, CD, DVD, USB)

FY 2016 Total Number and Percent of Submissions Received in Paper

Table 7.0 – Number and Percent of Submissions by Paper

	BLA	IND	NDA	Total
CDER	1,950 (6%)	20,311 (63%)	9,958 (31%)	32,219 (96%)
CBER	1,083 (86%)	172 (14%)	2 (0%)	1,257 (4%)
Total	3,033 (9%)	20,483 (61%)	9,960 (30%)	**33,476**

Figure 7.0 – CDER Paper Submissions by Submission Type

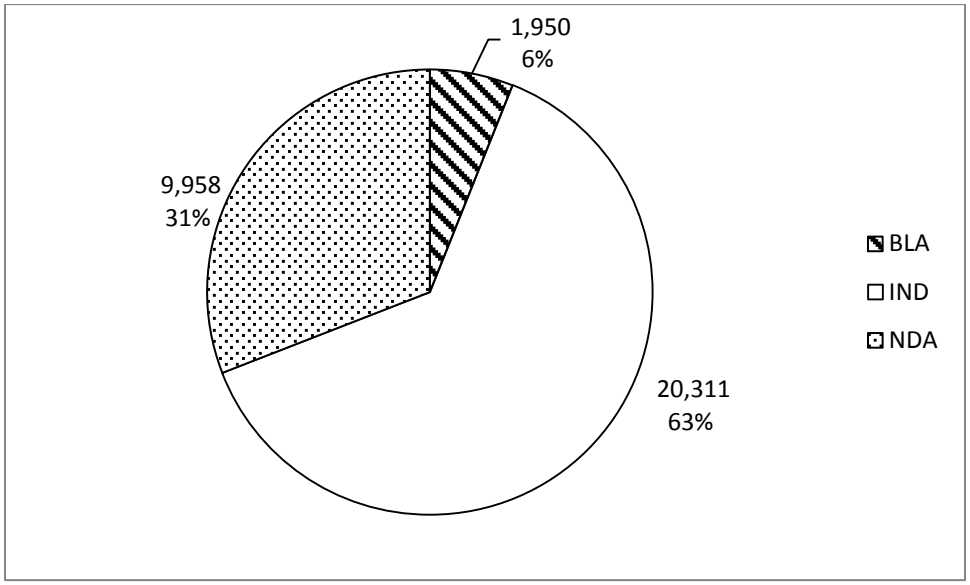
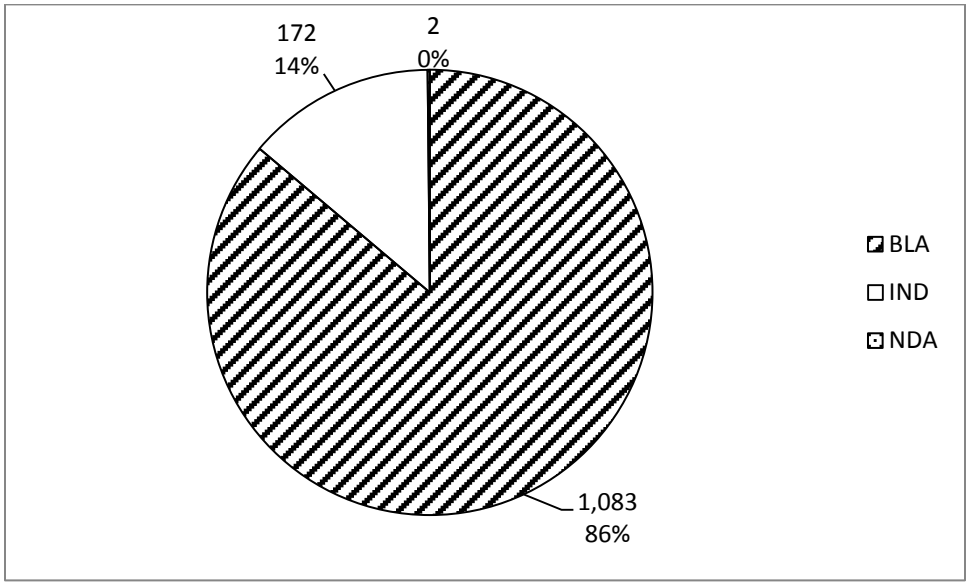


Figure 7.1 – CBER Paper Submissions by Submission Type



FY 2016 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	6,769 (19%)	4,125 (12%)	24,165 (69%)	35,059 (97%)
CBER	1,546 (49%)	1,578 (51%)	1 (0%)	3,125 (9%)
Total	8,315 (22%)	5,703 (15%)	24,166 (63%)	**38,184**

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

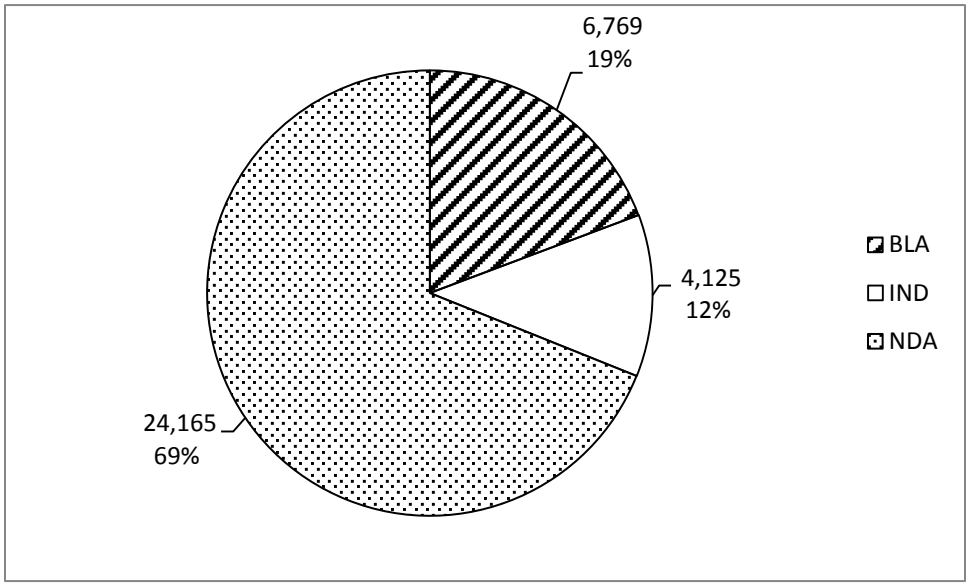
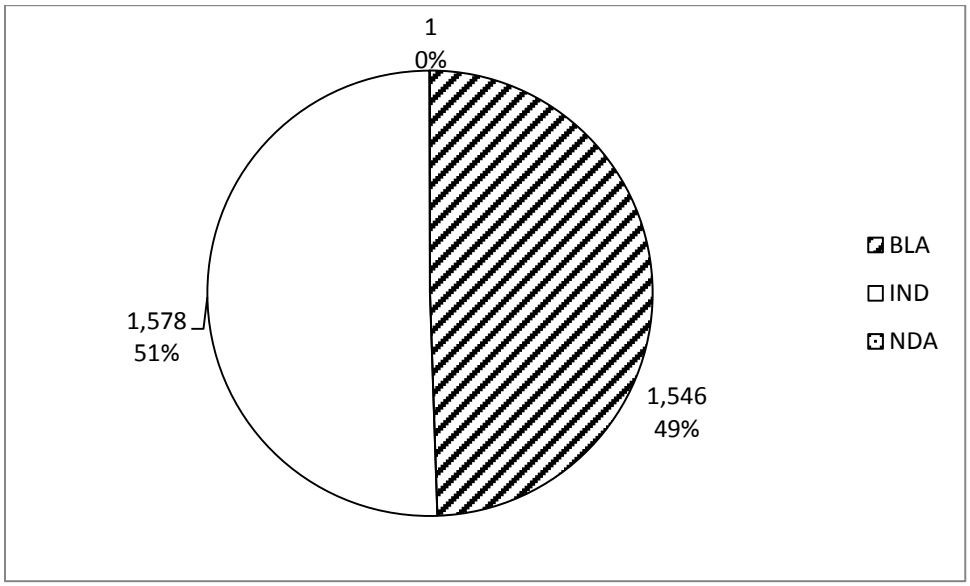


Figure 8.1 – CBER Non-Standardized Electronic Format Submissions by Submission Type



FY 2016 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	15 (3%)	375 (72%)	134 (26%)	524 (38%)
Sent to Wrong Center	30 (18%)	125 (74%)	15 (9%)	170 (12%)
Duplicate Content Received	98 (62%)	55 (35%)	5 (3%)	158 (11%)
eCTD High Validation Error	20 (13%)	65 (42%)	71 (46%)	156 (11%)
Mismatched Application/Sequence/Type	2 (2%)	70 (64%)	37 (34%)	109 (8%)
Invalid File Type	6 (7%)	42 (47%)	42 (47%)	90 (6%)
Not in Standard eCTD Format	2 (3%)	35 (52%)	30 (45%)	67 (5%)
No Data Received	4 (8%)	35 (66%)	14 (26%)	53 (4%)
Sent In Error	1 (3%)	19 (66%)	9 (31%)	29 (2%)
Broken / Corrupted Media	5 (20%)	6 (24%)	14 (56%)	25 (2%)
Multiple Application / Sequence / US-Regional.xml	0 (0%)	5 (71%)	2 (29%)	7 (1%)
Invalid Application/Sequence	0 (0%)	4 (67%)	2 (33%)	6 (0%)
Total	183 (13%)	836 (60%)	375 (27%)	1394

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.

<table>
<tr><th colspan="2">Objectives</th></tr>
<tr><td colspan="2">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.</td></tr>
<tr><th>FY 2016 Milestones</th><th>Accomplishments</th></tr>
<tr><td>Annually, publish the PDUFA V IT Assessment and post on FDA website within 3 months after the close of each fiscal year.</td><td>• Published the FY 2016 PDUFA V IT/ Informatics Assessment to the FDA Web site on November 30, 2016. The FY 2016 Assessment included FY 2016 metrics based on Industry recommendation.</td></tr>
<tr><td>Conduct quarterly meetings with industry stakeholders.</td><td>• Conducted quarterly meetings with industry on the following dates: December 16, 2015, March 7, June 7, and September 13, 2016. 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.</td></tr>
<tr><th colspan="2">Future Milestones</th></tr>
<tr><td colspan="2">• Publish the FY 2017 PDUFA IT/Informatics Assessment within three months after the close of FY 2017.
• Continue engaging industry stakeholders fostering productive meetings on a quarterly basis and throughout FY 2017.</td></tr>
</table>