DIA 2018
GLOBAL ANNUAL MEETING
BOSTON | JUNE 24-28

FDA Electronic Submissions Update

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Agenda

- Important Submission Deadlines
- Submission Metrics
- Top 3 Rejections and How to Avoid Them
- Validation Resources
- Application Lifecycle Management
- Frequently Asked Questions

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Important Submission Deadlines

eCTD Guidance became binding

- May 5, 2017: NDA, BLA, and ANDA must be in eCTD format
- May 5, 2018: Commercial IND and Master Files must be in eCTD format

Important Submission Deadlines

eCTD Submissions

- Must use Fillable Forms (e.g., 356H and 1571)
- Must use Gateway for submissions 10GB or less
- Must use correct lifecycle operators
  - Use the “Replace” lifecycle operator when updating content

Important Submission Deadlines

eCTD Submission

- Exemptions are outlined in the guidance
- Submissions that do not adhere to the requirements stated in the eCTD Guidance will **not be filed or received**
- Please see the eCTD website www.fda.gov/ectd for further information

Important Submission Deadlines

Study Data Submission Deadlines

- Studies that start after December 17, 2016 must be in standardized format for NDA, BLA and ANDA submissions
- For IND submissions, the date is December 17, 2017

See the following resources for more information

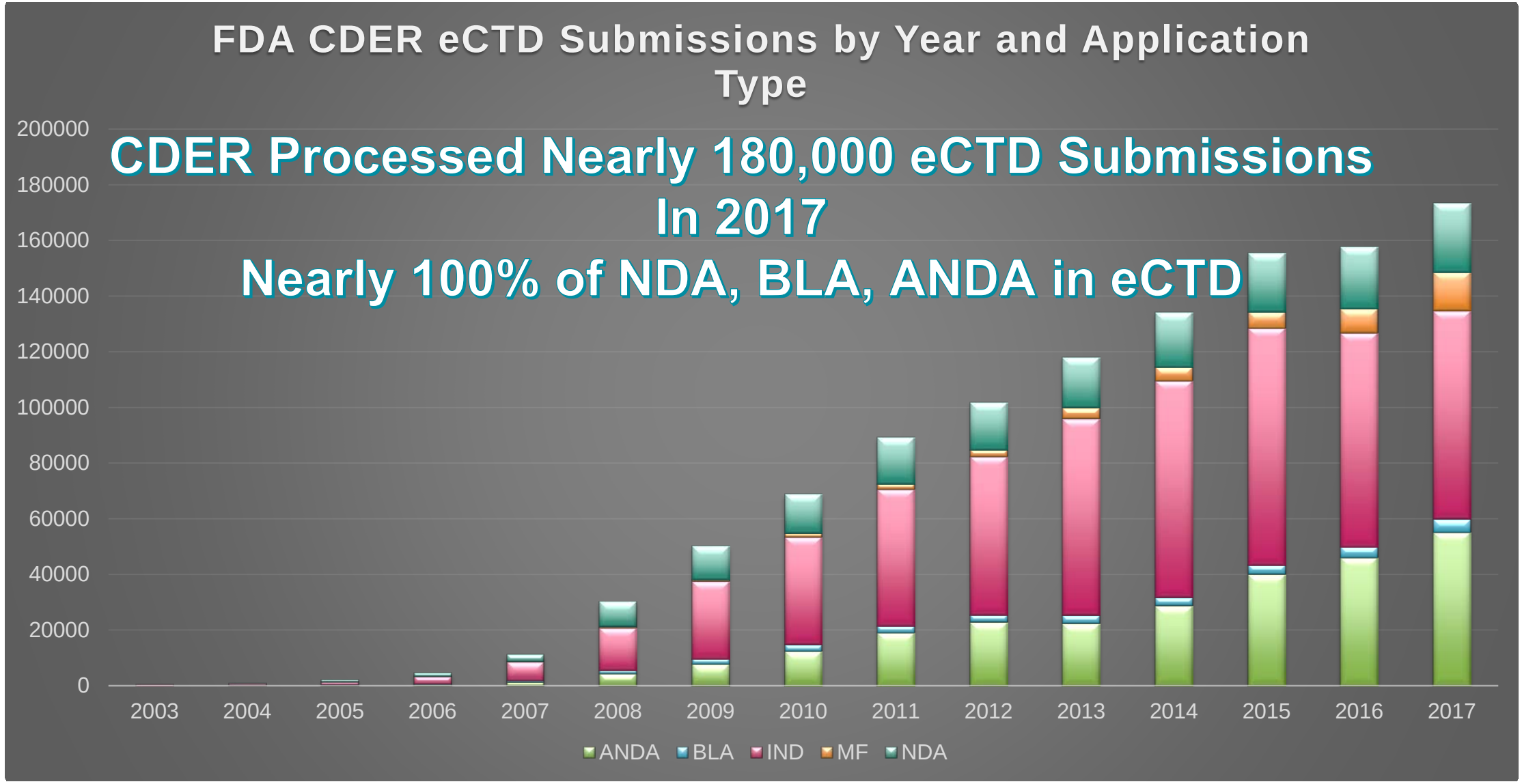
Study Data Standards Resources page

Technical Rejection Criteria for Study Data

The Study Data Guidance

Have Questions? Contact eData@fda.hhs.gov

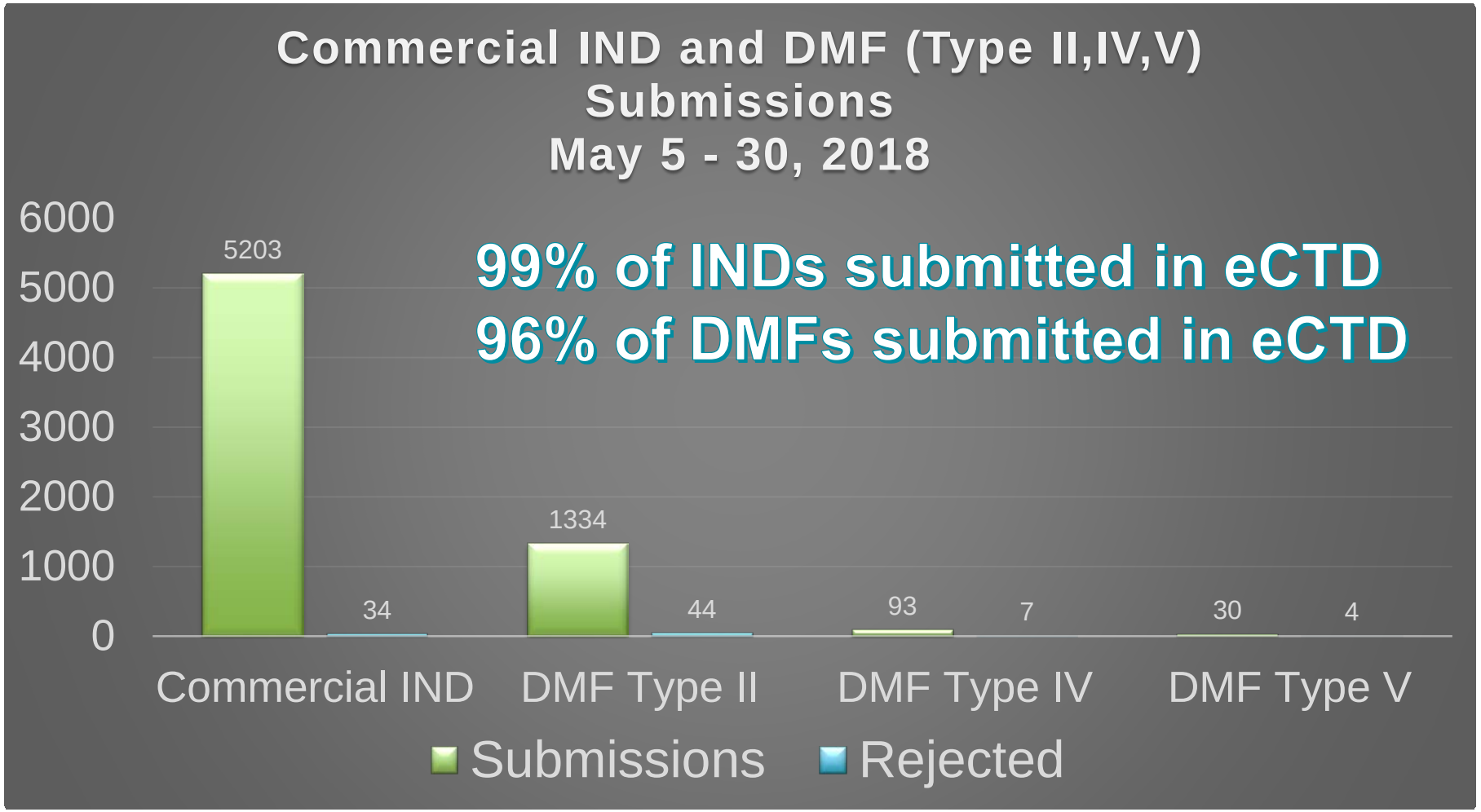
Submission Metrics



Excludes Promotional and Advertising Submissions

eCTD Submission Metrics – Cont.

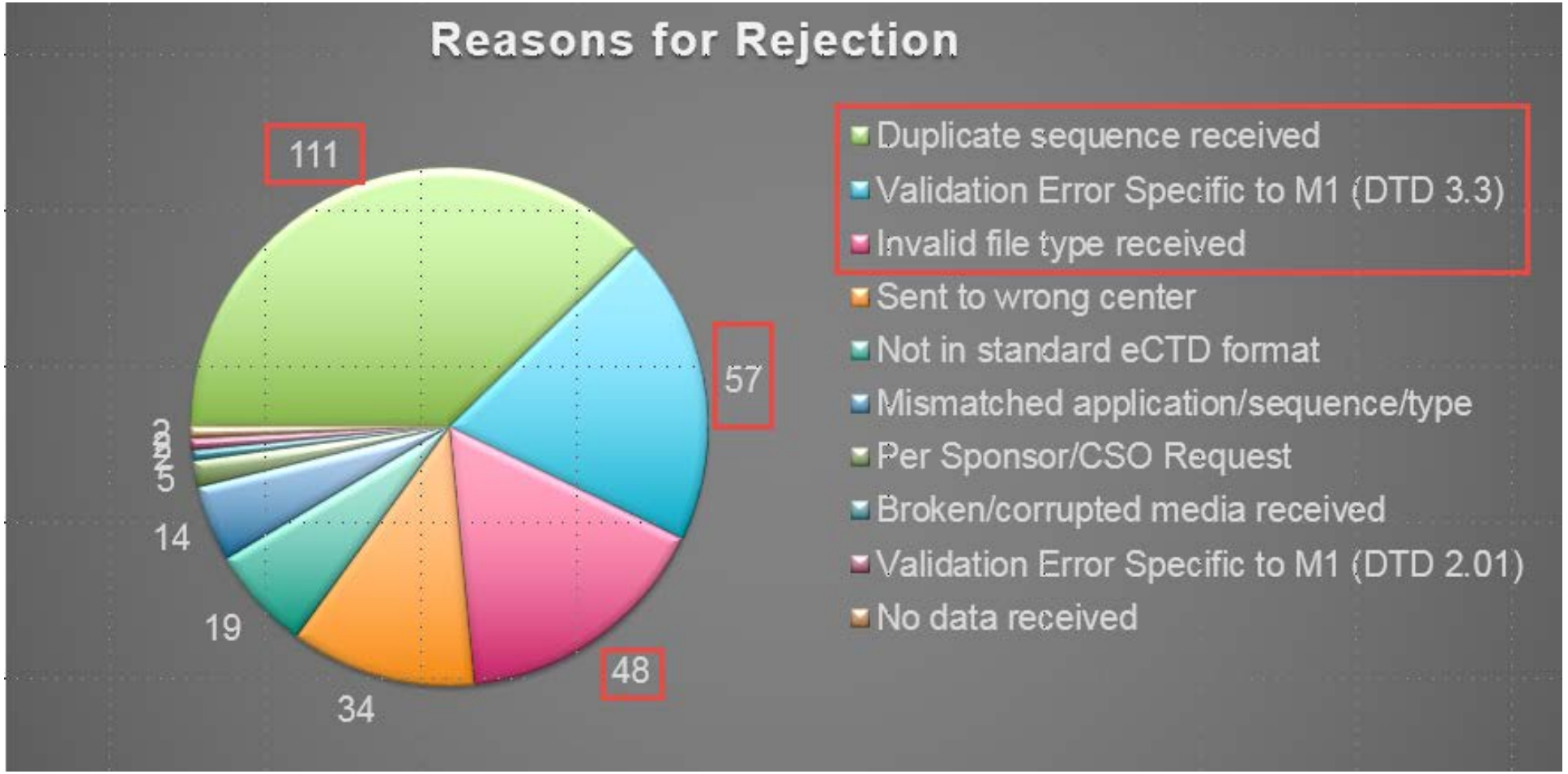
- May 5, 2018: Commercial IND and Master Files (Type II, IV and V) must be in eCTD format



Top 3 Rejections and How to Avoid Them

Top 3 Rejections and How to Avoid Them

A closer look at the 3 most common rejections for eCTD
NDA, BLA, IND, MF, ANDA (sample size: 15,765)



Top 3 Rejections and How to Avoid Them

- 1. Duplicate Sequence Number Received

Issue	Resolution
Submitting revised content under same sequence number (e.g. trying to swap out a sequence)	Content should be updated by submitting changes in the next available sequence
Transfer of application but new owner is not aware of sequence numbers used	Recommend obtaining full sequence history from prior owner
Re-using a sequence number if submission has been withdrawn	Even if a submission is withdrawn, FDA continues to keep the sequence

Top 3 Rejections and How to Avoid Them

- 2. Most Common M1 (DTD 3.3) Mistake

Issue

Validation Code 2022: You have used a submission-sub-type which is not allowed for the submission-type and/or type of application.
Ex: **Original Application/Correspondence**

Resolution

See list of valid **Submission Type** and **Sub-Type** combinations.

Resource: eCTD Backbone Files Specifications for Module 1, Table 2: Submission Types and Descriptions of Use

Table 2: Submission Types and Descriptions of Use

Submission Type	Submission Sub-Type	Supplement Effective Date Type (if applicable and *submission-sub-type* = "application")	Valid For Application Types
Original Application	Presubmission Application Amendment Resubmission		IND, NDA, ANDA, BLA, DMF, EUA
Efficacy Supplement	Presubmission		NDA, BLA
	Application	Prior Approval Supplement (PAS)	
	Amendment Resubmission		
Chemistry Manufacturing Controls Supplement	Presubmission		NDA, ANDA, BLA
	Application	Prior Approval Supplement (PAS), Changes Being Effected (CBE-0), or Changes Being Effected 30 (CBE-30)	
	Amendment Resubmission		
Annual Report	Report Amendment		IND, NDA, ANDA, BLA, DMF
Product Correspondence	Correspondence Amendment		IND, NDA, ANDA, BLA, DMF

Top 3 Rejections and How to Avoid Them

- 3. Invalid File Types
  - .exe, .zip, and others single file submissions are not allowed

Validation Resources

Specification documents are posted on www.fda.gov/ectd in the *eCTD Submission Standards*

Validation Documents Include:

- eCTD Validation Specifications
- Technical Rejection for Study Data Criteria

Lifecycle Management

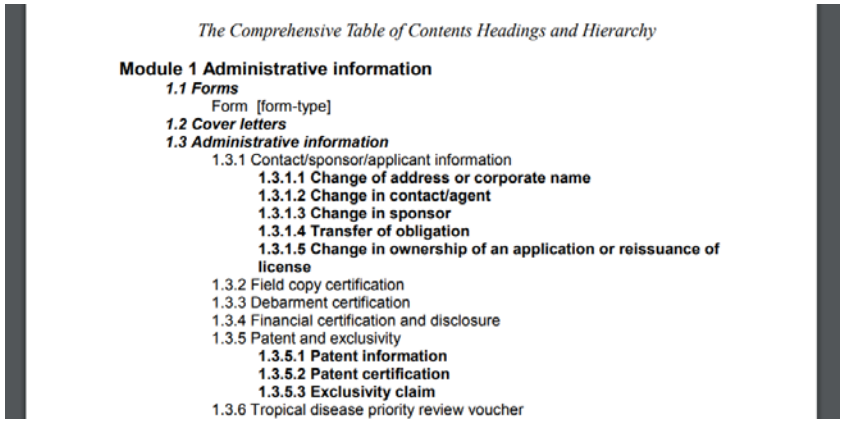
- Submission Type/Subtype
  - Tells FDA the regulatory activity of your submission (e.g. Original, Supplement, Annual Report) and to which regulatory activity amendments belong
- Sequences
  - Recommend starting with 0001
  - Part of the record (FDA does not delete them)
  - Can be cross referenced
- Use eCTD Lifecycle Operator
  - Replace
  - Delete

Frequently Asked Questions

Frequently Asked Questions

Where do I place my content?

- Resources
  - The Comprehensive Table of Contents Headings and Hierarchy
  - M4 Organization of the Common Technical Document for the Registration of Pharmaceuticals for Human Use Guidance for Industry
  - FDA Regulatory Project Manager



The Comprehensive Table of Contents Headings and Hierarchy

Module 1 Administrative information
- ***1.1 Forms***
  - Form [form-type]
- ***1.2 Cover letters***
- ***1.3 Administrative information***
  - 1.3.1 Contact/sponsor/applicant information
    - **1.3.1.1 Change of address or corporate name**
    - **1.3.1.2 Change in contact/agent**
    - **1.3.1.3 Change in sponsor**
    - **1.3.1.4 Transfer of obligation**
    - **1.3.1.5 Change in ownership of an application or reissuance of license**
  - 1.3.2 Field copy certification
  - 1.3.3 Debarment certification
  - 1.3.4 Financial certification and disclosure
  - 1.3.5 Patent and exclusivity
    - **1.3.5.1 Patent information**
    - **1.3.5.2 Patent certification**
    - **1.3.5.3 Exclusivity claim**
  - 1.3.6 Tropical disease priority review voucher

Frequently Asked Questions

- Can I submit a xyz file format?
  - When creating content, follow the Specifications for File Format Types Using eCTD Specifications for guidance on file formats FDA expects under the different CTD headings
- Questions related to PDF files (e.g. hyperlinks, bookmarks, font, etc)
  - Follow FDA's PDF Specifications and communicate to vendors the need to follow these specifications

Frequently Asked Questions

- How do I get started with eCTD?
- How do request an application number?
- How do I get a gateway account?

These questions and more are answered on the eCTD website:

Electronic Common Technical Document (eCTD)

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The eCTD is the standard format for submitting applications, amendments, supplements, and reports to FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER).

Important Dates

After the dates listed below, eCTD requirements for submissions to CDER and CBER will go into effect and submissions that do not use eCTD will not be filed or received.

- **May 5, 2017:** New Drug Applications (NDAs), Abbreviated NDAs (ANDAs), and Biologics License Applications (BLAs), must be submitted using eCTD format.
- **May 5, 2018:** Commercial Investigational New Drug Applications (INDs) and Master Files must be submitted using eCTD format.
- Please refer to the eCTD Guidance for the complete details to meet the eCTD requirement.

Quick Links

- eCTD Guidance (PDF -11 KB)
- eCTD Submission Standards (PDF - 91KB)
- FDA Data Standards Catalog
- eCTD Technical Conformance Guide (PDF - 303KB)
- Drug Master Files (DMFs)
- Technical Rejection Criteria for Study Data (PDF - 921 KB)
- eCTD Submission Types and Sub-Types (PDF - 630 KB) **NEW**

Notices

- FDA Extends Compliance Date for DMF Type III in eCTD Format **NEW**
- Third Acknowledgement for Successful eCTD Submissions (May 2016)
- Past Notices

Visit our Submit Using eCTD page to learn how to submit an application using eCTD and obtain an ESG account.
To view all eCTD Submission Resources, visit our eCTD Resources page.

Submit Using eCTD

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When submissions arrive in eCTD format, reviewers can easily find and access the information they need to review, whether it was part of the original submission or added later by the product sponsor.

Electronic submissions make it easier for FDA to review data, approve new drugs, and monitor drugs after they go on the market. Using eCTD also simplifies the process for submitters, because it is the same format used by drug regulatory agencies in other countries.
If you are new to eCTD, follow these steps to get started:

Learn about eCTD
Review the Electronic Submission Resources
Submit Fillable Forms and Compliant PDFs
Request an Application Number
Register for an Electronic Submissions Gateway Account
Send a Sample Submission to FDA
Submit Via the Electronic Submission Gateway

1. **Learn About eCTD**
   - **NEW** eCTD Submission Requirements: What You Need to Know fact sheet (PDF - 224KB)
   - Recent eCTD presentations by FDA staff
   - CDER Small Business and Industry Assistance (CDER SBIA) Webinar - Electronic Submission Requirements for ANDAs: Are You Ready? – November 21, 2016

Tip: Build and maintain a knowledge base by staying informed about existing, new, and updated eCTD-related tools and information.

Thank You

Jonathan Resnick

Electronic Submission Support Team

Office of Business Informatics, CDER

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