



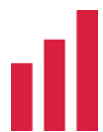
RAPS'
**Regulatory
Convergence**

17-20 September 2016
San Jose, CA

Electronic Submissions Update

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Electronic Submission Support Team
Office of Business Informatics, CDER
September 20, 2016





FDA DISCLAIMER



The views and opinions presented here represent those of the speaker and should not be considered to represent advice or guidance on behalf of the U.S. Food and Drug Administration.



TOPICS COVERED

1. Important Submission Deadlines
2. Submission Metrics
3. CDER Gateway Third Acknowledgement
4. Study Data Standards Resources
5. Lessons Learned When Implementing eCTD
 - Rejections
 - Submission Errors with new M1
 - Helpful Tips
6. Coming Soon



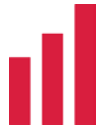
DEADLINES FOR REQUIRED ECTD SUBMISSION

- **May 5, 2017:** NDA, BLA, ANDA and DMFs must be in eCTD format
- **May 5, 2018:** Commercial INDs must be in eCTD format
- Do not send Paper and/or non-eCTD submissions after these deadlines!



DEADLINES FOR REQUIRED ECTD SUBMISSION

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



WHAT ELSE?

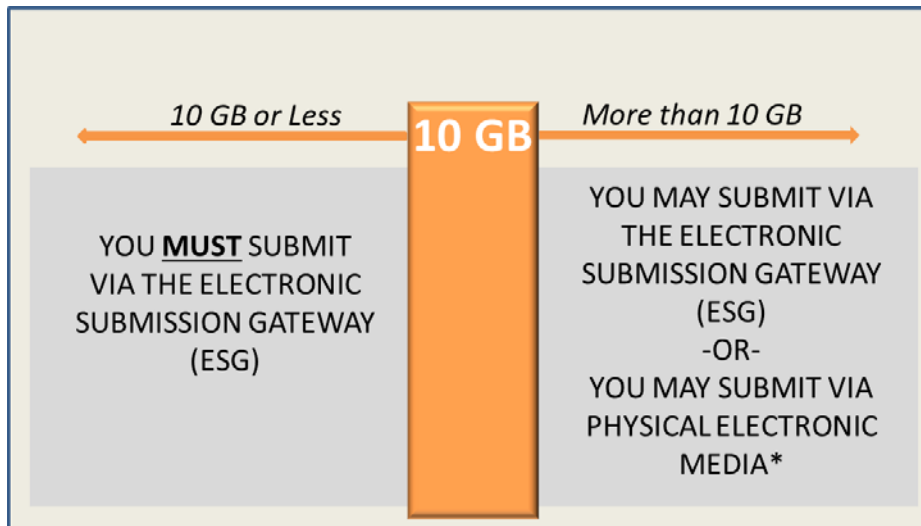
- ✓ Must use Fillable Forms & Electronic Signatures within those forms
- ✓ Must use correct Lifecycle operators
 - ✓ Do not send the same study data over and over



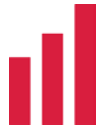
WHAT ELSE?



- ✓ Must use Gateway for submissions 10GB and smaller – no more CD/DVDs
 - ✓ Submissions larger than 10GB may come via the Gateway or USB drive

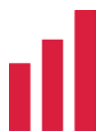


*See Transmission Specification for additional details

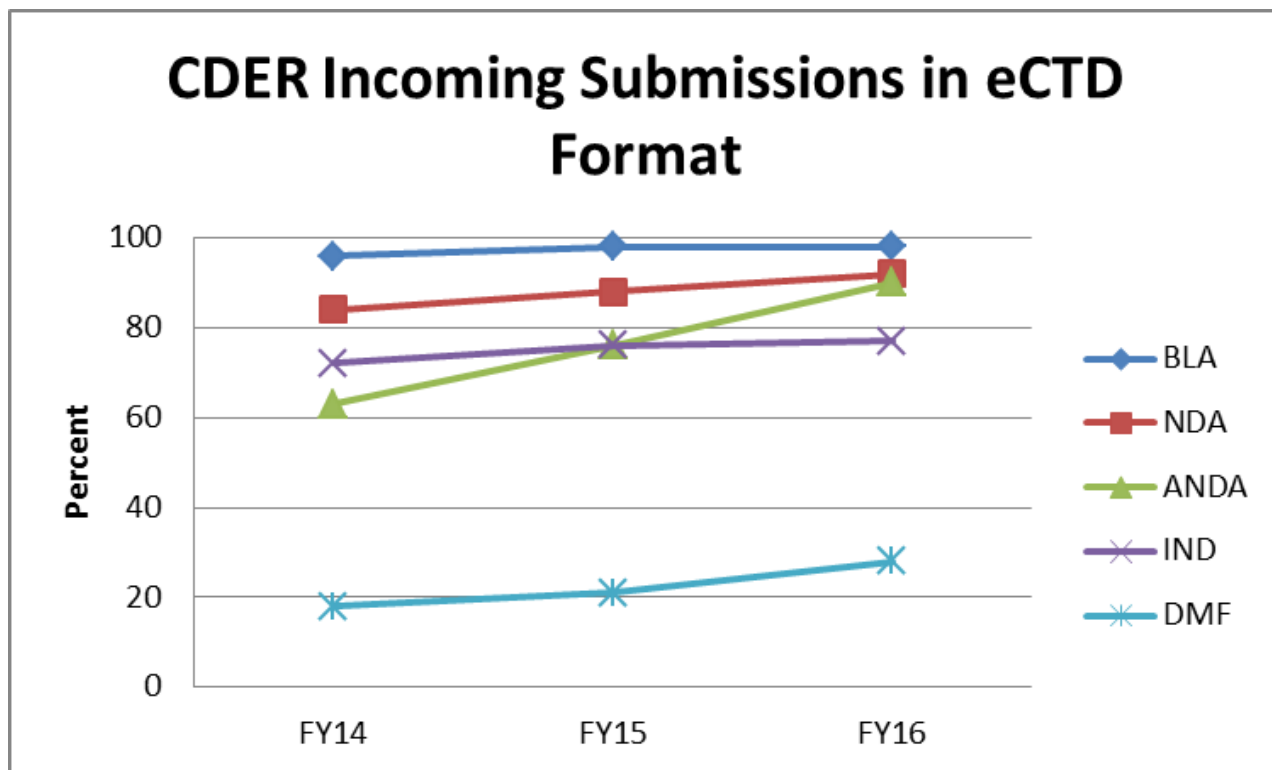


DEADLINES FOR STANDARDIZED STUDY DATA

- 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



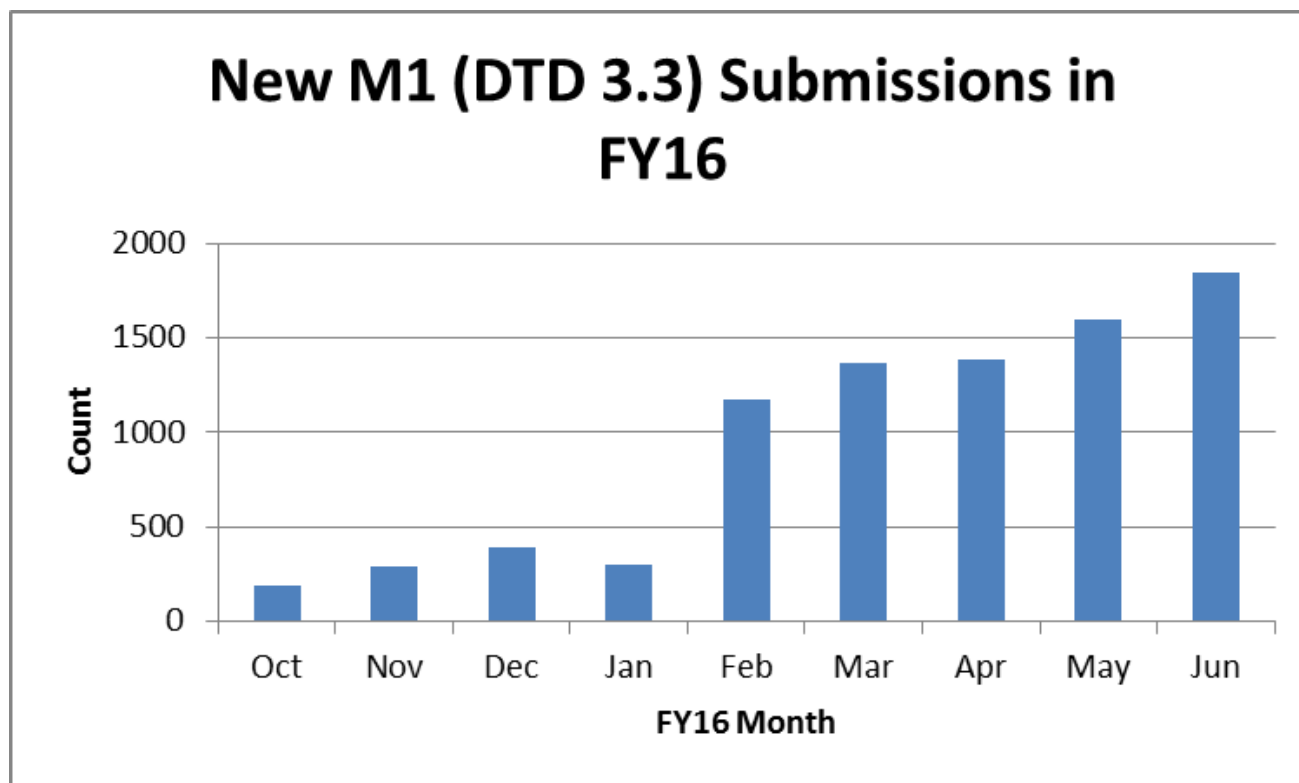
SUBMISSION METRICS & MILESTONES



EXCLUDES PROMOTIONAL ADVERTISING & LABELING SUBMISSIONS



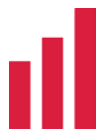
SUBMISSION METRICS & MILESTONES





CDER GATEWAY THIRD ACKNOWLEDGEMENT


- Began May 31, 2016
- Applies only to NDA, ANDA, BLA, IND or DMF submissions
- Sent to you when your submission has successfully completed validation and processing, and is available to the assigned review division



NEW: CDER GATEWAY THIRD ACKNOWLEDGEMENT



*****TEST PURPOSE ONLY*****



Your submission was successfully processed into the CDER Electronic Document Room, and is available to the assigned review division.

Application Type/Number: IND123456
eCTD Sequence Number: 0001
CoreID: ci144192717707454973@fdai08620_in2

Your official receipt date is calculated in accordance with the following final Guidance for Industry:
<http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072385.pdf>

Contact Information:
For technical assistance only: eSUB@fda.hhs.gov
For all other questions regarding your submission, contact your review division.

Thank you,
Electronic Document Room
Center for Drug Evaluation and Research
U.S. Food and Drug Administration

CDER GATEWAY THIRD ACKNOWLEDGEMENT

- This is in addition to the ESG Message Delivery Notification acknowledgement (first acknowledgement) and the Official Center acknowledgement (second acknowledgement)
- May be delayed if your submission fails validation and needs manual processing (e.g., Mismatch between your form and your eCTD XML)



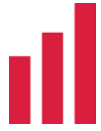
CDER GATEWAY THIRD ACKNOWLEDGEMENT

- Note: A rejection is also a third acknowledgement, and separate from this acknowledgement



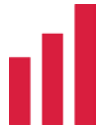
NEW: STUDY DATA STANDARDS RESOURCES

- What's New
 - Studies that start after **December 17, 2016** must be in standardized format for NDA, BLA and ANDA submissions
 - Study Data Technical Conformance Guide v3.1
<http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards/default.htm>
- Validation Codes
Coming soon. Will be posted on www.fda.gov/ectd
- When
CDER will start using the new validation criteria - TBD



LESSONS LEARNED WHEN IMPLEMENTING ECTD

- Rejections
- Common Submission Errors (new M1)
- Helpful Tips



REJECTIONS

Most common reasons for rejections

- **Duplicate Submissions**
 - You send the same submission sequence more than once
- **Submitted to Wrong Center**
 - Selecting wrong center when using gateway (e.g., CDER instead of CBER)
- **Mismatched Application/Sequence Type**
 - Specifying NDA in us-regional.xml while indicating BLA in 356h Form
- **Invalid File Type**
 - Submitting file types such as zip and exe
- **Not in Standard eCTD Format**
 - Missing key files such as us-regional.xml and index.xml



COMMON SUBMISSION ERRORS WITH NEW M1

Top 3 Errors Specific to New M1 (DTD v3.3)

1. Choosing a Submission Type and Submission Subtype that starts a new Regulatory Activity but providing a Submission-ID different to the Sequence Number
2. Choosing a Submission Subtype of Amendment and specifying an incorrect Submission-ID
3. Transitioning from paper to eCTD and choosing a submission type of original application and submission subtype of amendment.



HELPFUL TIPS: DOUBLE CHECK YOUR PDFS

Make sure...

- You have a TOC, bookmarks and links in your PDF files
- Documents are legible and viewable
- Avoid scanning (if you find that you have to scan then correct any pages that needs to be rotated and perform OCR)
- Reviewers have the ability to copy and paste text, tables and figures
- Blue text are reserved for links

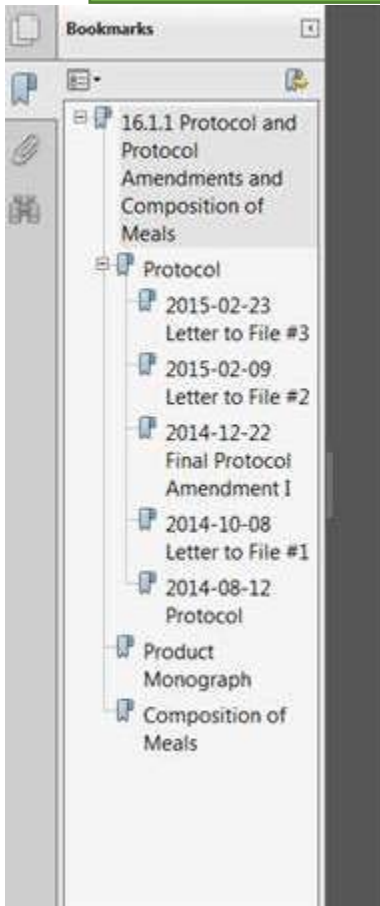


HELPFUL TIPS: PDF TABLE OF CONTENTS AND BOOKMARKS

- Table of Contents and Bookmarks should match
- For documents **5 pages or longer**
- Up to **4 levels deep** in hierarchy

HELPFUL TIPS: TABLE OF CONTENTS AND BOOKMARKS

BAD – Bookmarks and TOC do not match. TOC does not contain hyperlinks

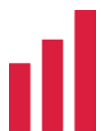


Bookmarks

- 16.1.1 Protocol and Protocol Amendments and Composition of Meals
 - Protocol
 - 2015-02-23 Letter to File #3
 - 2015-02-09 Letter to File #2
 - 2014-12-22 Final Protocol Amendment I
 - 2014-10-08 Letter to File #1
 - 2014-08-12 Protocol
 - Product Monograph
 - Composition of Meals

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HELPFUL TIPS: TABLE OF CONTENTS AND BOOKMARKS



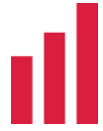
GOOD!

Bookmarks

- And Consent
- 6.0 Investigators And Study Administrative Structure
- 6.1 Facilities
- 7.0 Introduction
- 8.0 Study Objectives
- 9.0 Investigational Plan
 - 9.1 Overall Study Design And Plan-Description
 - 9.2 Discussion Of Study Design, Including The Choice Of
 - 9.3 Selection Of Study Population
 - 9.3.1 Inclusion Criteria

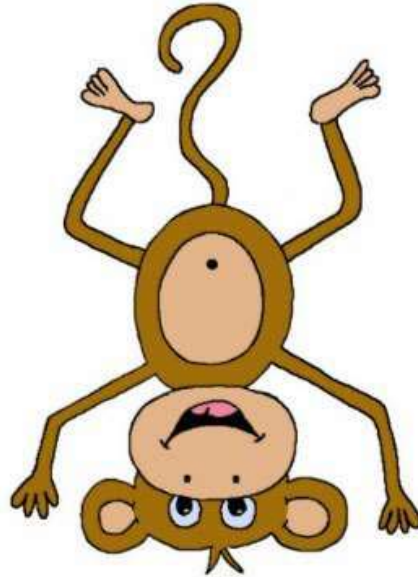
INTEGR

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HELPFUL TIPS: ORIENTATION

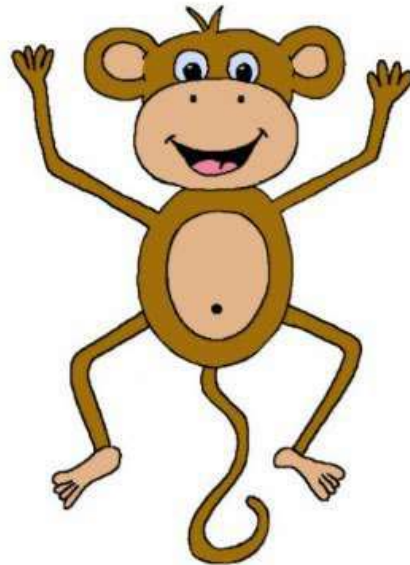
Any documents provided in the submission should be in the correct orientation





HELPFUL TIPS: ORIENTATION

Any documents provided in the submission should be in the correct orientation





COMING SOON...

1st Update to eCTD Technical Conformance Guide

Updates to validation criteria

- Rejection criteria for study data & more



REFERENCES

- eCTD Web Page:

<http://www.fda.gov/ectd>

- Electronic Submissions Gateway:

<http://www.fda.gov/esg>

- Electronic Submissions Presentations:

<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/ucm229642.htm>

- Questions about submitting electronically to CDER: ESUB@fda.hhs.gov

Thank You

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www.fda.gov/ectd