RAPS' Regulatory Convergence

17–20 September 2016
San Jose, CA

Electronic Submissions Update

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Office of Business Informatics, CDER
September 20, 2016

40 YEARS
RAPS REGULATORY AFFAIRS PROFESSIONALS SOCIETY
Driving Regulatory Excellence™

RAPS

FDA DISCLAIMER

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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

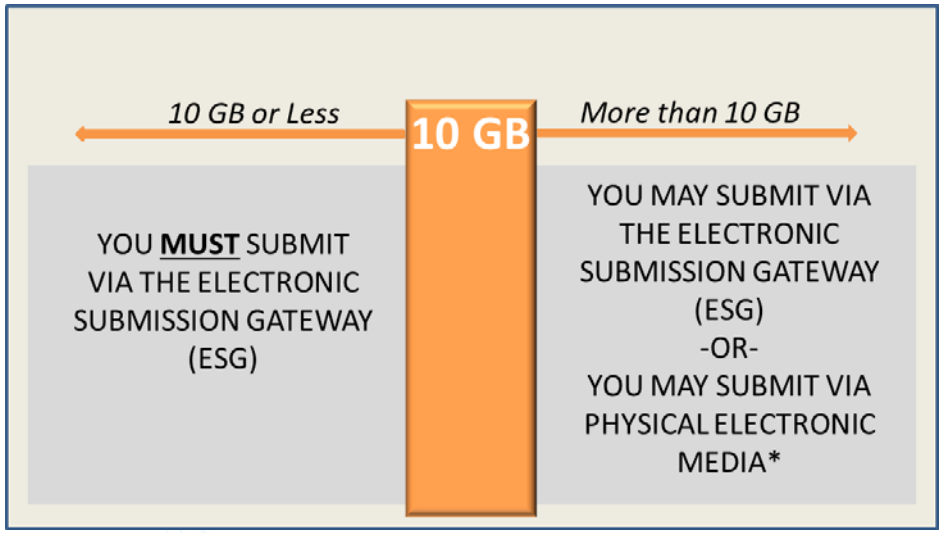
- Exemptions are outlined in the guidance
- Submissions that do not adhere to the requirements stated in the eCTD Guidance will be **not be filed or received**
- Please see the eCTD web page www.fda.gov/ectd for further information

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



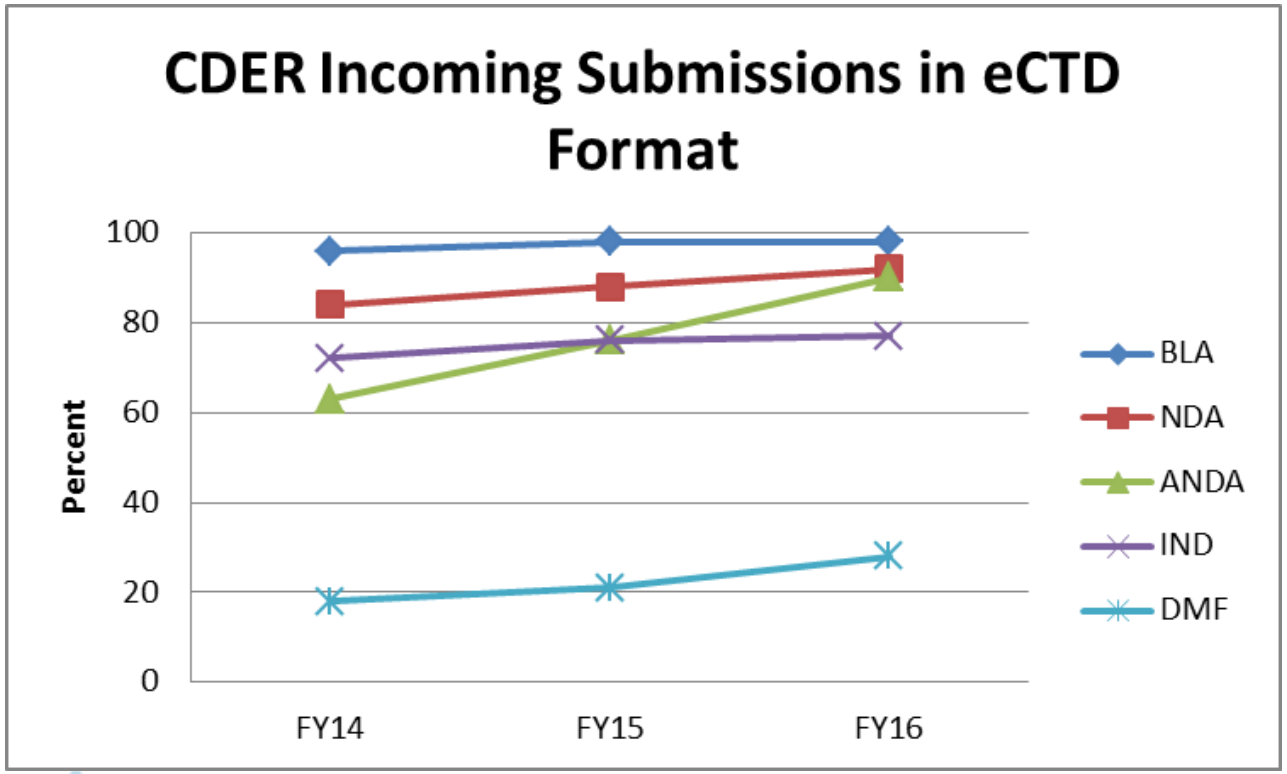
*See Transmission Specification for additional details

DEADLINES FOR STANDARDIZED STUDY DATA

- Studies that start after December 17, 2016 must be in standardized format for NDA, BLA and ANDA submissions

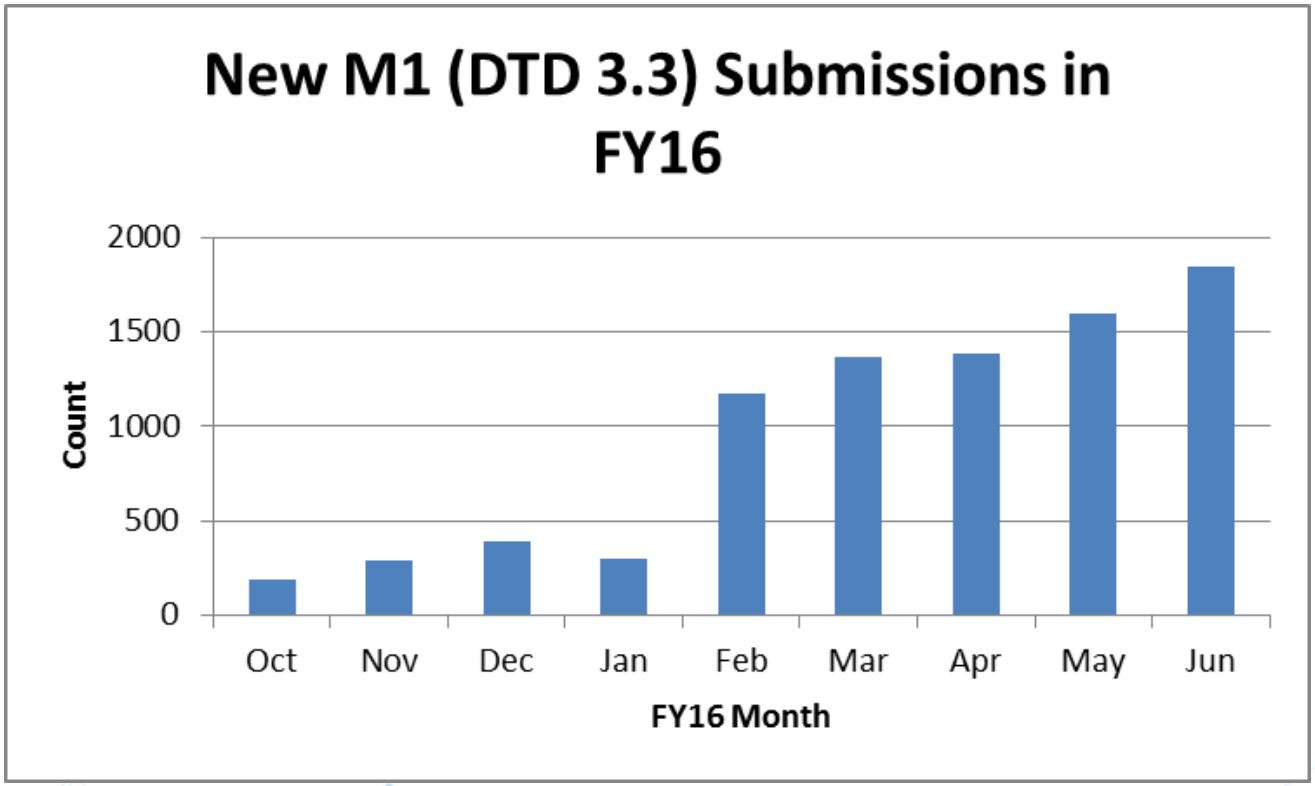
- For IND submissions, the date is December 17, 2017

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: ci1441927177074.54973@fdsul08620_te2

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

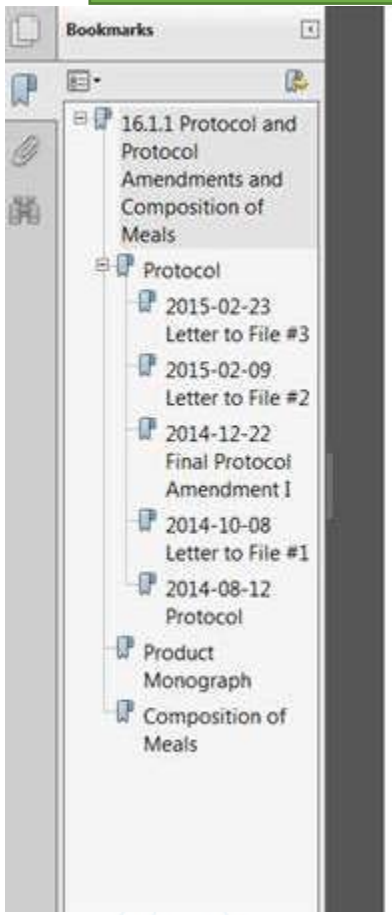
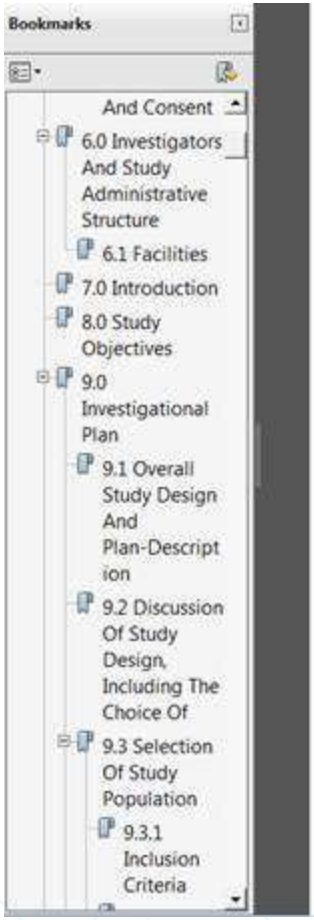


TABLE OF CONTENTS

HELPFUL TIPS: TABLE OF CONTENTS AND BOOKMARKS

GOOD!



HELPFUL TIPS: ORIENTATION

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

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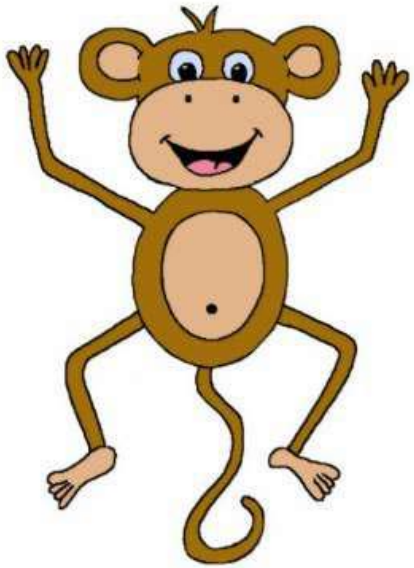

COMING SOON…

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