Electronic Submissions Update

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TOPICS COVERED

1. Important Submission Deadlines

2. Submission Metrics and Recent Milestones

3. Plans for FY2016-17
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](http://www.fda.gov/ectd) for further information
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

✓ Must use Fillable Forms & Electronic Signatures within those forms

✓ Must use correct Lifecycle operators
  ✓ Do not send the same study data over and over
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
# Number and Percent of Submissions by Delivery Description and Application Type

<table>
<thead>
<tr>
<th>FY2016</th>
<th>ANDA</th>
<th>BLA</th>
<th>IND</th>
<th>MF</th>
<th>NDA</th>
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<tbody>
<tr>
<td>#</td>
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<td>#</td>
<td>%</td>
<td>#</td>
<td>%</td>
</tr>
<tr>
<td>Electronic Only</td>
<td>356</td>
<td>1.0%</td>
<td>8</td>
<td>0.3%</td>
<td>832</td>
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<tr>
<td>Gateway</td>
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<td>2,650</td>
<td>97.8%</td>
<td>60,810</td>
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<tr>
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<td>8</td>
<td>0.3%</td>
<td>2,125</td>
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<tr>
<td>Paper Only</td>
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<td>5.5%</td>
<td>43</td>
<td>1.6%</td>
<td>15,249</td>
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<tr>
<td>Grand Total</td>
<td>37,065</td>
<td>100.0%</td>
<td>2,709</td>
<td>100.0%</td>
<td>79,016</td>
</tr>
</tbody>
</table>

**EXCLUDES PROMOTIONAL ADVERTISING & LABELING SUBMISSIONS**
SUBMISSION METRICS & MILESTONES

CDER New Original Submissions in eCTD Format FY2015

- NDA
- ANDA
- BLA
- IND Commercial
SUBMISSION METRICS & MILESTONES

CDER Incoming Submissions in eCTD Format
STUDY DATA METRICS & MILESTONES

As of FY2016, 2\textsuperscript{nd} Quarter:

- 88\% of \textbf{study data} submitted in support of NEW NDAs are coming in standardized format

- 75\% of \textbf{study data} submitted within all NDA submissions are coming in standardized format
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
CTD Sequence Number: 0001

Your official receipt date is calculated in accordance with the following final Guidance for Industry:

Contact Information:
For technical assistance only: eSUB@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: AUTO REJECTIONS

• Duplicate Submissions
  • You send the same submission sequence more than once

• Single File Submissions
  • Not allowed

• Empty Submissions
  • You send nothing inside your folders
COMING SOON…

• More information added to 2\textsuperscript{nd} (Center) Gateway Acknowledgement

• 1\textsuperscript{st} Update to Technical Conformance Guide

• Updates to validation criteria
  • Rejection criteria for study data & more

• Planning for eCTD v4.0 implementation
WE ARE IN THE EXHIBIT HALL

ARE YOU READY FOR eCTD?

The Electronic Common Technical Document (eCTD) format will soon be required for submissions to the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER).

Start dates for mandatory eCTD submissions:
- May 8, 2017: NDAs, ANDAs, BLAs, and master files
- May 8, 2018: Commercial INDs

Standardized electronic submissions support FDA’s review of the safety and effectiveness of medical products for regulatory decisions.

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. With eCTD, reviewers can focus more on the scientific review rather than spending precious time navigating large amounts of less-structured data.

Don’t forget

Requirements for study data standards are also coming soon. If you are beginning a study after December 17, 2016, make sure you understand FDA’s new mandatory data standards for most CDER/CBER submissions.

Learn more at [www.fda.gov/ForIndustry/DataStandards/StudyDataStandards or Booth 1426](http://www.fda.gov/ForIndustry/DataStandards/StudyDataStandards or Booth 1426).

Learn more about the eCTD requirements and how to submit electronically at [www.fda.gov/ectd or Booth 1426](http://www.fda.gov/ectd or Booth 1426).
Thank You

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www.fda.gov/ectd