Electronic Submissions Update

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Topics

• Deadlines for Required eCTD Submission
• Submission Metrics & Milestones
• Under Discussion 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

• Paper and non-eCTD submissions will no longer be accepted
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 subject to rejection

• Please see the eCTD web page www.fda.gov/ectd for further information
Submission Metrics & Milestones

• **Highest month ever:** 14,700 ESG submissions to CDER in December 2015

• >1600 ‘new Module 1’ submissions (using 2.3 specifications) as of February 1, 2015

• 88% of **study data** submitted in support of NEW NDAs

• 75% of **study data** submitted to NDA submissions are in standardized SDTM format (FYQ1-Q2 partial)

• Study data from 500 applications have been loaded into Portes, a system that provides access to study data for tools such as JMP, JMP Clinical, NIMS and CDER’s Jump Start program
Submission Metrics & Milestones

• PORTES in Production
  – a system that provides access to study data for tools such as JMP, JMP Clinical, NIMS and CDER’s Jump Start program

• Study data from 500 applications have been loaded into Portes
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

- NDA
- IND
- ANDA

Fiscal Year

Percent
Under Discussion for FY2016-17

• More information added to 2nd (Center) Gateway Acknowledgement

• Addition of a 3rd Gateway Acknowledgement

• 1st Update to Technical Conformance Guide

• Update to Transmission Specification

• Rejection criteria for study data

• Planning for eCTD v4.0 implementation
Thank You

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