Electronic Submissions Update

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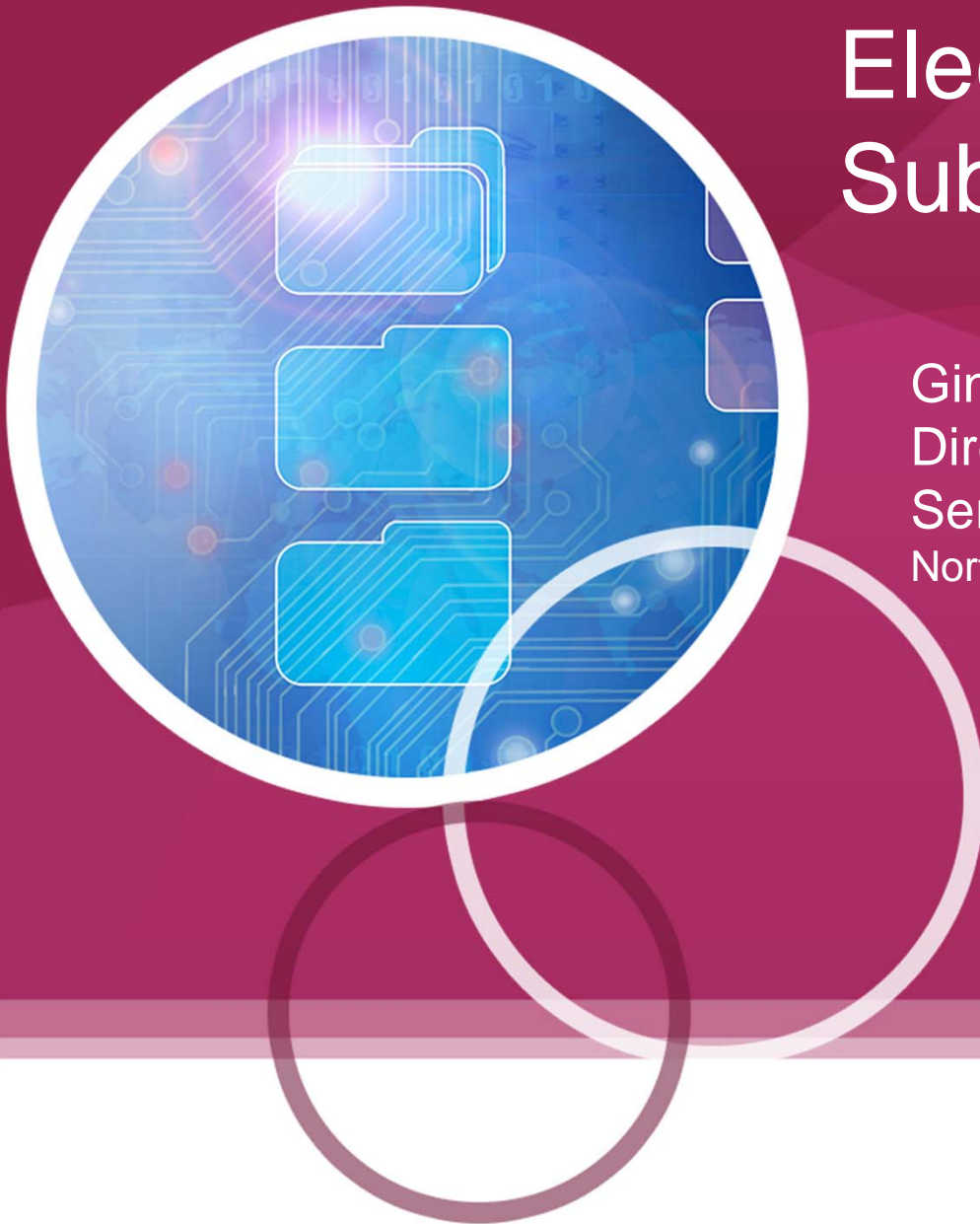
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Topics

- 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 <u>will no longer</u> 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
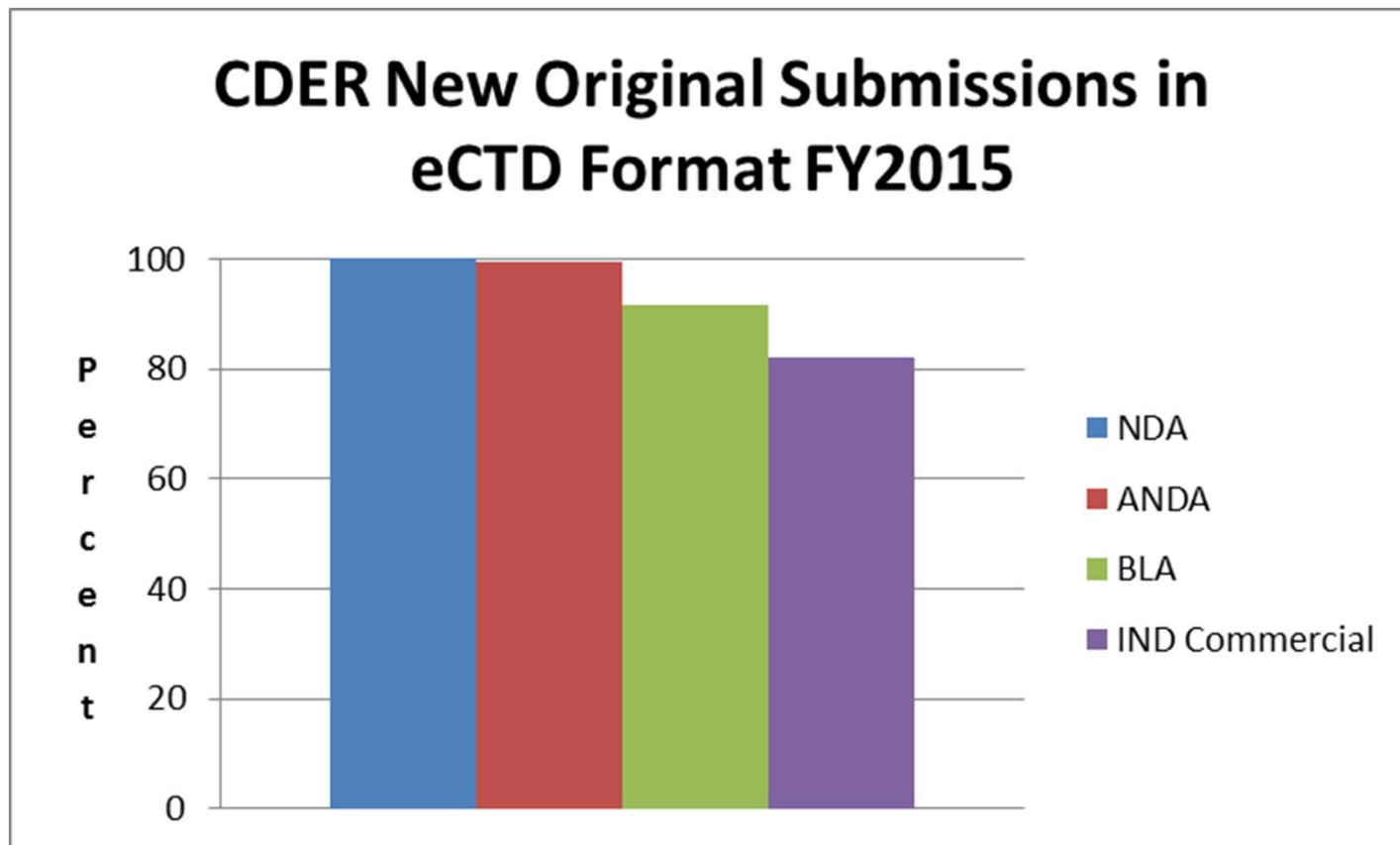
Submission Metrics & Milestones

- 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

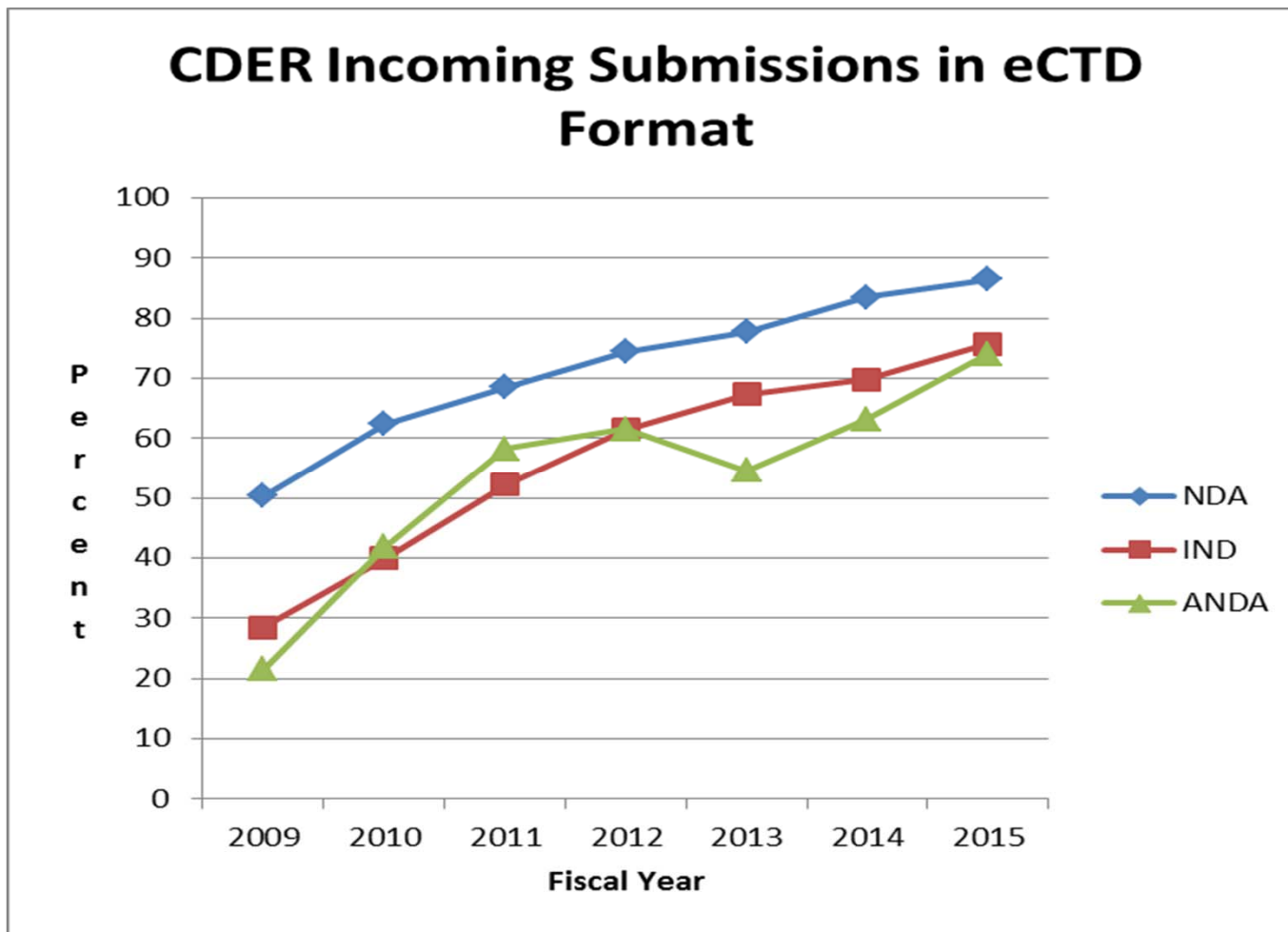- Study data from 500 applications have been loaded into Portes

Submission Metrics & Milestones

Submission Metrics & Milestones

CDER Incoming Submissions in eCTD Format

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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