



SEPTEMBER 22TH 2016

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1. [FDA Small Business RED! Conference](#) – Sept. 27/28 - Silver Spring, MD – in-person or online attendance.
2. TBA: CDER SBIA LIVE webinar - [Study Data Standards in eCTD: What You Need to Know about the New Technical Rejection Criteria](#) – Oct. 12th at 1 PM EST

FDA Requires Use of eCTD Format and Standardized Study Data in Future Regulatory Submissions

FDA now requires that certain regulatory submissions conform to the electronic Common Technical Document (eCTD) format. In addition, study data will have to be submitted in standardized format for certain studies.

The eCTD has been the standard format for submitting applications, amendments, supplements, and reports to the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) since 2008.

Electronic submission makes it easier for FDA to review data, approve new drugs, and monitor drugs after they go on the market. The eCTD format also simplifies the process for submitters, because the CTD format is used by drug regulatory agencies in many countries. Starting in 2017, eCTD will be required for applications submitted to CDER and CBER.

Deadlines: Beginning May 5, 2017, submitters MUST use eCTD for:

- New Drug Applications (NDAs), Abbreviated New Drug Applications (ANDAs), Biologics License Applications (BLAs), and all subsequent submissions to these types of applications, including amendments, supplements, and reports, *even if* the original submission was filed before the requirements went into effect.
- Master files, such as Drug Master Files (DMFs), which are considered to be submissions to an IND, NDA, ANDA, or BLA.
- Combination products (if CDER or CBER is designated as the lead center).

Beginning May 5, 2018, submitters MUST use eCTD for commercial IND submissions. Non-commercial IND submissions (including investigator-sponsored INDs and expanded access INDs) are exempt.

After these deadlines, paper submissions or electronic submissions that are NOT in eCTD format will NOT be filed or received unless exempt from the requirement. There are no waivers to the eCTD format.

Electronic submissions must include [FDA fillable forms](#) (e.g., 1571, 356h) and electronic signatures to enable automated processing of the submission. Fillable forms are fillable on the computer, which makes it easier to process them electronically. Non-fillable forms and scanned images of FDA forms will NOT be accepted.

How to Submit in eCTD Format: Resources to help you prepare and submit applications in eCTD format to CDER include:

* [eCTD Basics and Getting Started](#) * [Electronic Submissions Gateway](#) * [Submit a Sample eCTD or Standardized Data Sample](#) * [Request a CDER Pre-assigned Application Number](#) * [Study Data Standards Resources](#) *



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Details are provided in the [Guidance for Industry, Providing Regulatory Submissions in Electronic Format - Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications](#).

The [eCTD website](#) contains relevant guidances and eCTD technical specifications, along with a step-by-step guide to setting up an Electronic Submissions Gateway account and an [eCTD web-based learning course](#). You may contact esub@fda.hhs.gov (CDER) or esubprep@fda.hhs.gov (CBER) for additional eCTD related questions.

Study Data Standards provide a consistent general framework for organizing study data, including templates for datasets, standard names for variables, and standard ways of doing calculations with common variables. Data standards facilitate application reviews and bring uniformity to assessments of drug safety and efficacy. Standardized data at all levels of the drug lifecycle will enable researchers to better capture data and answer new questions about medicines and health.

The FDA Data Standards Catalog (located on the [Study Data Standards Resources](#) page) is a spreadsheet that provides a listing of supported and/or required standards, their uses, the date FDA will begin (or has begun) to support a particular standard, and the date support ends (or will end), the date the requirement to use a particular standard will begin (or has begun) and the date such requirement ends (or will end), and other pertinent information.

In addition, FDA has a [Study Data Technical Conformance Guide](#), which provides specifications, recommendations, and general considerations on how to submit standardized study data using FDA-supported data standards located in the FDA Data Standards Catalog. It is intended to complement and promote interactions between sponsors and FDA review divisions. Sponsors and applicants must submit study data electronically for both clinical and nonclinical studies.

Deadlines: Sponsors submitting studies to CDER or CBER that start *after December 17, 2016* must use the data standards listed in the FDA Data Standards Catalog for:

- NDAs, ANDAs, BLAs
- All subsequent submissions to these types of applications, including amendments, supplements, and reports, even if the original submission was filed before the requirements went into effect.

The requirement for commercial INDs (for products that are intended to be distributed commercially) starts after *December 17, 2017*. Data from studies starting before December 17, 2016, need not be converted to comply with the standards. Non-commercial IND submissions (including investigator-sponsored INDs and expanded access INDs) are exempt.

The FDA may [refuse to file NDAs and BLAs, or refuse to receive ANDAs](#) if an electronic submission that contains study data does not conform to the required standards specified in the FDA Data Standards Catalog.

FDA's [Study Data Standards Resources webpage](#) contains FDA's most recent versions of FDA's Data Standards Catalog, guidance documents, and technical specifications. Exemptions are discussed in FDA's [Guidance for Industry, Providing Regulatory Submissions in Electronic Format - Standardized Study Data](#). Please contact cdcr-edata@fda.hhs.gov (CDER) or cber.cdsc@fda.hhs.gov (CBER) for additional information.

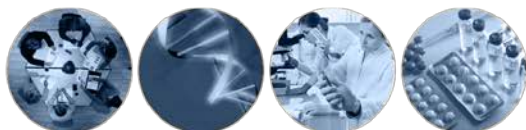
We strongly encourage sponsors to plan for the implementation of the eCTD standard format now, and to consider the use of data standards for the submission of applications as early as possible in the product development lifecycle, so that data standards are accounted for in the design, conduct, and analysis of studies.

Cheers,
Renu Lal, Pharm.D.

CDER Small Business and Industry Assistance

Issues of this newsletter are archived at <http://www.fda.gov/cdersbiachronicles>

This communication is consistent with 21CFR10.85(k) and constitutes an informal communication that represents our best judgment at this time but does not constitute an advisory opinion, does not necessarily represent the formal position of the FDA, and does not bind or otherwise obligate or commit the agency to the views expressed.



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