

How to Submit Nonclinical Data as Part of the CDER Pilot Program
(Electronic Nonclinical Study Data Submission; Notice of Pilot Project
[Docket No. 2007N-0343]

Background:

This pilot project aims to test, in a regulatory setting, the electronic submission of nonclinical study data using the Standard for Exchange of Nonclinical Data (SEND).

Pilot participants will provide the same nonclinical study data in both PDF and SEND formats to an existing IND.

Instructions

STUDY REPORTS:

Submit archival PDF study reports, along with pertinent regulatory documents in eCTD format using any of the standard submission methods.

SEND DATASETS:

1. Submit the test SEND datasets and any accompanying materials to the Test Gateway (see: http://www.fda.gov/esg/userguide/WebHelp_10_2007/WebHelp_10_2007.htm). Note that SEND datasets do not have to be submitted using the eCTD format. Please make sure that when choosing the options in WebTrader you use the same options when submitting your regulatory submission.

e.g. Choose CDER as Center and eCTD as type of submission

2. Place the SEND datasets in a folder that follows the following nomenclature [A666666] where A = application type (I =IND or N=NDA) and 666666 refers to 6-digit application number) See examples below.

Folder name for sample IND submission will be [I012345]

Folder name for sample NDA submission will be [N098765]

Note that if your application number has less than 6 digits, you should add a 0 (zero) at the beginning of the number.

3. Immediately email the following addresses:

- (1) esub@fda.hhs.gov
- (2) gary.gensinger@fda.hhs.gov
- (3) john.omalley@fda.hhs.gov
- (4) paul.brown@fda.hhs.gov
- (5) edward.bearden@fda.hhs.gov

Also, include the Core-ID of the test submission from the Official Center Acknowledgement (i.e., receipt) in the body of the e-mail. See example below and <http://www.fda.gov/esg/ESG/faq.htm>):

MessageId: 666168.1122063776231.JavaMail.rmyneni@mnhu
CoreId: 1122063551533.777@appserver7
DateTime Receipt Generated: 4:25:17,7-22-2005

Notes:

- The PDF must comply with all applicable regulations, including those in part 11 (21 CFR part 11)¹. FDA intends to exercise additional enforcement discretion with regard to part 11 requirements as applied to data submitted in SEND format under this pilot.
- The SAS transport files (version 5) should be based on the SEND format.
- PDF version will continue to be the version used for archival purposes during the pilot.
- Both data formats (i.e., PDF and SEND) will be used by FDA for pilot evaluation purposes.

Please contact CDER's Electronic Submission Help Desk (esub@fda.hhs.gov) with questions relating to eCTD submissions and FDA's Electronic Submissions.

¹ See "Guidance for Industry; Part 11, Electronic Records; Electronic Signatures-Scope and Application," August, 2003; <http://www.fda.gov/Cder/guidance/5667fnl.htm>