

**WORK INSTRUCTIONS:
ELECTRONIC SUBMISSIONS FOR NON-ECTD RESEARCH INDS**

Version Number: v.1.0

16 August 2022



TABLE OF CONTENTS

WORK INSTRUCTIONS: ELECTRONIC SUBMISSIONS FOR NON-ECTD	
RESEARCH INDS	I
TABLE OF CONTENTS	2
ABBREVIATIONS.....	3
INTRODUCTION	4
1 REQUEST PRE-ASSIGNED APPLICATION NUMBER.....	5
2 PREPARATION OF DOCUMENTS WITH STUDY TEAM	5
3 PREPARATION OF FOLDERS FOR EIND SUBMISSIONS.....	5
3.1 Action Item for EIND Submission through ESG.....	6
4 ESG DOCUMENTATION OF FINAL MERGED PDF WITH STUDY TEAM.....	6
APPENDIX 1. RESOURCES.....	7



ABBREVIATIONS

ANDA Abbreviated New Drug Application

BLA Biologics License Application

CBER Center for Biologics Evaluation and Research

CDER Center for Drug Evaluation and Research

CTD Common Technical Document

eCTD Electronic Common Technical Document

EIND Noncommercial (Research) IND in non-eCTD format submitted electronically

eSub Electronic Submission

ESG Electronic Submissions Gateway

FDA Food and Drug Administration

IND Investigational New Drug Application

LMS Learning Management System

NDA New Drug Application

PDF Portable Document Format



INTRODUCTION

Regulatory submissions can be submitted to the United States Food and Drug Administration (FDA) via the Electronic Submissions Gateway (ESG), which enables the secure submission of pre-market and post-market regulatory information for review. The FDA ESG is the central transmission point for sending information electronically to the proper FDA Center or Office.

Certain types of regulatory submissions are required to be submitted electronically using the electronic common technical document (eCTD) format, including NDAs, ANDAs, certain BLAs, commercial INDs, and master files. eCTD submissions are optional but encouraged by the Agency for certain other types of submissions, including noncommercial INDs, such as investigator-sponsored INDs and expanded access INDs. While eCTD is encouraged, it is not required for noncommercial (research) INDs to be submitted electronically through the ESG (EINDs).

INDs previously submitted on paper can be transitioned to electronic submissions through the ESG, but it is recommended to notify the applicable FDA regulatory project manager of the change in submission procedures. If a sponsor-investigator later leaves the institution and no longer has the capabilities to submit their IND through the ESG, their noncommercial EIND submissions can be submitted again on paper.

To define procedures for preparing and submitting EINDs through the FDA ESG in non-eCTD format, these work instructions have been developed.

1 REQUEST PRE-ASSIGNED APPLICATION NUMBER

If submitting an initial application to CDER, the investigator-sponsor must request a pre-assigned application number if one has not already been assigned. CDER will issue pre-assigned application numbers for non-eCTD submissions number within 4 weeks of the target receipt date, but initial applications for CDER can be submitted through the ESG without an assigned number.

Requests for CDER are made via the NextGen Portal with a turnaround time of 1-3 days. New users must register an account by going to <https://edm.fda.gov> and following the instructions provided. Alternatively, requests can be made via email at cderappnumrequest@fda.hhs.gov.

Requests for CDER can only be made via email. If requesting a pre-assigned application number from CDER, send an email to cberrims@fda.hhs.gov and include the sponsor name and address, primary point of contact name and phone number, the biologic product name, indication, FDA review division (if known), and the anticipated submission date. CDER will only issue a number within 4 weeks of the target receipt date.

Additional details for requesting a pre-assigned application number through the CDER NextGen Portal can be found in Appendix 3 of the eCTD Submissions Work Instructions.

2 PREPARATION OF DOCUMENTS WITH STUDY TEAM

The study team should work on the preparation of regulatory documents to ensure they are in the proper format, preferably with navigation aids (e.g. bookmarks and cross-references). Please see the tip sheets and other guidance documents for assistance.

3 PREPARATION OF FOLDERS FOR EIND SUBMISSIONS

It is advised that the study team should create a folder for each serial submission within the corresponding IND folder. Please see the example below:

S:\Projects by PI\Last Name, First Name\IND 123456\Serial 0123

The following sub-folders should be created within each serial folder for an EIND submission:

1. “Docs for EIND” – The study team will place the merged PDF for the submission (if applicable) and the fillable version of the Form FDA 1571 (or Form FDA 3926, if applicable) into this folder for the RDS. When the study team is creating the merged PDF, they should review the ESG Submission Tipsheet for instructions, including how the document should be named.
2. Receipts:
 - CDER submissions will receive the following 3 Acknowledgment files:
 1. “Receipt for [file name].tar.gz.txt”



Appendix 1. RESOURCES

Table 1: Resources for EIND Submissions

Title	Purpose	Link or Location
FDA Portable Document Format (PDF) Specifications	Describes specifications for creating documents in PDF for submission to CDER or CBER	https://www.fda.gov/downloads/Drugs/UCM163565.pdf