



## TIPSHEET:

### Submitting non-eCTD Research INDs through the ESG

Once you have your WebTrader Account set-up and your submission is ready, follow these steps (Note – One merged PDF or multiple files will work):

1. A folder structure containing an “m1” folder (stands for Module 1) is required for a successful submission via CDER, but not CBER. For CBER, a PDF alone can be submitted. For consistency, our office always uses this folder structure for CDER and CBER.
  - a. Create a folder on the desktop, we recommend naming it “IND\_ *application number*” (e.g. IND\_123456)\*
  - b. Next, create a subfolder within the IND folder named “m1”.
  - c. Copy the document(s) you would like to submit into the “m1” folder on the desktop.
2. We recommend including a fillable copy of the Form FDA 1571, either with a digital signature, or with no signature, but containing identical information included on the signed version of the Form FDA 1571 (e.g. handwritten signatures or using an e-signature process that removes the fillable properties such as Adobe Sign). This is not required, but the submission will be processed more efficiently.
3. Log onto <https://esg.fda.gov/login> and select the light blue button with a paper airplane on it, this button will be labeled “Send Document” if the list is expanded.
4. Select the appropriate content in the drop down menus according to the information included in the calendar appointment.
  - a. \*Center: (e.g., CDER or CBER)
  - b. \*Submission Type: (CDER only choose EIND, for CBER only choose: EIND or Pre-IND)
5. Click “+Add Documents” and go to your desktop.
6. Select the folder created in step #1. The folder should highlight in bold and grayed out if correctly selected. Then hit the blue “Select” button at the bottom of the window.
  - a. Note: Cursor should have arrow icon  to select the folder, instead of hand . The hand will open the folder instead of selecting it.
7. Type in your certificate password, double-check that all information appears correct, and hit the blue “Send” button.
8. Click on the envelope button on the left. This button will be labeled “Sent Items” if the menu is expanded.
9. Select the application that was submitted, download all ESG documentation received, and save it for your records.



- a. Note: There should be 3 pieces of documentation for CDER submissions, and only 2 pieces of documentation for CBER submissions for non-eCTD applications.
  - i. CDER submissions will receive the following 3 Acknowledgement files:
    1. "Receipt for IND\_XXXXX\_SXXXXX.tar.gz.txt"
    2. "cixxxxxxxxxxxxxx.xxxxxxxxx@fdsuvxxxxx\_tex.txt"
    3. "cixxxxxxxxxxxxxx.xxxxxxxxx@fdsuvxxxxx\_tex.pdf"
  - ii. CBER submissions will receive the following 2 Acknowledgement files:
    1. "Receipt for IND\_XXXXX\_SXXXXX.tar.gz.txt"
    2. "cixxxxxxxxxxxxxx.xxxxxxxxx@fdsuvxxxxx\_tex.txt"

\*If submitting an initial application to CDER, you must request a pre-assigned application number if one has not already been assigned. CBER will issue pre-assigned application numbers for non-eCTD submissions, but initial applications for CBER can be submitted through the ESG without an assigned number (we recommend always requesting pre-assigned application numbers if possible). CDER and CBER will provide the number within two business days of the request (often sooner).

Requests for CDER can be made via the NextGen Portal. 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](mailto:cderappnumrequest@fda.hhs.gov). Requests for CBER can only be made via email at [CBERRIMS@fda.hhs.gov](mailto:CBERRIMS@fda.hhs.gov). If requesting via email for either CDER or CBER, provide the following information:

**Subject:** Request for a Pre-Assigned <insert Application Type> Number

**Application information:**

Name of Applicant

Address line 1

Address line 2

Name of U.S. Contact

Phone number

Fax number

Email address

**Drug Information:**



Drug Name:

Trade Name:

Dosage Form:

Indication:

**Review Division:**

**Type of IND: Research (not Commercial)**

**Submission Format: EIND**

**Anticipated date of submission:** (CBER will only issue a number within 4 weeks of the target receipt date)