



## **Expedited IND Pilot Program Application: Instructions for Sponsors Submitting to CDER and CBER**

Sponsors should submit an Expedited IND Pilot Program Application on behalf of themselves, and their prospective QRI, as a pre-submission using ESG. FDA will evaluate the application as a single package across the two entities. Application forms can be found on the Expedited IND Pilot Program webpage.

The sections below outline the differences to guide you when submitting applications to each center.

### **Timeline of Pilot Program Selection:**

1. **September 15:** FDA launches Expedited IND Pilot Program and opens window for sponsors to submit applications.
2. **\*October 30:** Deadline for sponsors to submit Expedited IND Pilot Program applications.
3. **\*December 18:** FDA will notify applicants of Expedited IND Pilot Program participant selections.

**\*Note:** Timelines may vary depending on the number of submissions received.

### **Application Submission Instructions:**

1. **Request a Pre-Submission Tracking Number:** Before submitting an application to participate in the pilot via the ESG Gateway, sponsors should first request a Pre-Submission Tracking Number

#### **Instructions for Requesting a Pre-Submission Tracking Number in CBER:**

Prior to submitting the Expedited IND Pilot Program Application via eCTD, sponsors should contact [Cberrib@fda.hhs.gov](mailto:Cberrib@fda.hhs.gov) to request a pre-submission (pre-IND) tracking number per SOPP 8117:

<https://www.fda.gov/media/93416/download>

For information on electronic submissions in CBER, refer to:

<https://www.fda.gov/vaccines-blood-biologics/development-approval-process-cber/regulatory-submissions-electronic-format-cber-regulated-products>.



The DTD 3.3 eCTD backbone should reflect the following:

- application-type = “fdaat4” (This is the code for “IND”)
- submission-type = “fdast1” (This is the code for “Original Application”)
- submission-sub-type = “fdasst2” (This is the code for “Presubmission”)

### **Instructions for Requesting a Pre-Submission Tracking Number in CDER:**

To obtain a Pre-Submission file number (e.g., “pre-IND number”), navigate to this CDER webpage ([Request a Pre-Assigned Application number](#)) on FDA.gov and follow the instructions.

## **2. Submit the Expedited IND Pilot Application Via the FDA ESG Gateway:**

After obtaining a Pre-Submission Tracking Number, Sponsors should submit the Expedited IND Pilot Program Application forms through [FDA’s ESG Gateway](#). Please label the application as “**Pre-submission [add assigned number]: Expedited IND Pilot Program Application**” in the Cover Letter. The application forms should be submitted in eCTD Module 1.12.1 – Pre-IND Correspondence.

The Expedited IND Pilot Program Application submission should contain the following forms, which can be found on the Expedited IND Pilot Program Website:

1. Sponsor Pilot Program Application, filled out by the sponsor,
2. Prospective Qualified Research Institution Pilot Program Application, including QRI expert CVs, filled out by QRI

For non-exempt submission types (including commercial INDs), all eCTD submissions of 10 GB or less must be submitted via the Electronic Submissions Gateway Next Generation (ESG NextGen). Please consult the [ESG NextGen page](#) for general information about using the gateway, including how to set up an account.

Sponsors who have additional questions about submitting an Expedited IND Pilot Program Application or the status of their request should email [ExpeditedINDPilot@fda.hhs.gov](mailto:ExpeditedINDPilot@fda.hhs.gov).