

Submitting Research INDs and subsequent amendments via CDER NextGen Portal

The CDER NextGen Portal has now been expanded to accept Research IND¹ submissions! This includes all **non-emergency** expanded access INDs and amendments.

Sponsors of [Research INDs](#) can now submit an original IND and subsequent amendments online via the [CDER NextGen Portal](#).

What are the benefits of submitting via the Portal?

- **Efficiency:** Eliminate the time and hassle of printing and mailing paper or physical media (e.g. CDs, thumb drives, etc.). Simply submit online.
- **Timeliness:** No more waiting days for your submission to be delivered by physical mail, now your electronic submission can be delivered immediately.
- **Ease of Use:** Requesting via the Portal is easy, and all information regarding your requests is stored in one place.
- **Automated confirmation:** You can log in, initiate a request and receive an automated confirmation of your transaction.
- **Historical record:** Requestor can view all transactions at any time.

How to Gain Access

- **New Users**
To register for an account with the CDER NextGen Portal, navigate to <https://edm.fda.gov> and follow the signup instructions.
- **Existing Portal Users**
Research IND tab was added to your account automatically – click on it when you are ready to submit a request.

What File Types Are Accepted

- **CDER Currently accepts the following file types as part of an original IND or amendment:** PDF, SAS, MS Word, Text, MS Excel, MP4, XPT and Simcyp Simulator

Need Support?

In order to get assistance on registering for the CDER NextGen Portal, please reference the [user guides and FAQ's](#). For additional support, please contact CDER Platform Support at edmsupport@fda.hhs.gov.

¹ This is for INDs which are exempted from the eCTD Guidance: See *Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications Guidance for Industry* (<https://www.fda.gov/ectd>)