IND Submission Types and Process

IND contents and the processing FDA offices vary depending on whether the application will involve:

- Small molecule drug, biologics, antibody-based drug, or gene therapy agent
- Contents in electronic **C**ommon **T**echnical **D**ocument (**eCTD**) format
- An investigator-initiated study conforming to Research IND, Research Pilot IND without commercial intent, or emergency use Expanded Access Trial for single patient/ limited population
- A pilot/ first-in-human study including a novel, investigational agent with application contents partly or fully conforming to an eCTD format but the IND not prepared for Electronic Submission Gateway (ESG) route
- Application documents prepared in eCTD format for ESG submission (IND with expressed commercial intent; commercial organization formally designated as Sponsor)

INDs Involving Small Molecule Drug

- Investigator Initiated Research INDs, Research Pilot INDs, and INDs involving novel agents for a pilot/ first-in-human study will be submitted via **CDER NextGen Portal**
  - Contents* will be prepared in multiple documents per the CDER NextGen suggested list
- Emergency use Expanded Access Single patient or Limited Population INDs will also be submitted via **CDER NextGen Portal**
  - Contents will be prepared in multiple documents which will include, but not limited to, Emergency Use Treatment Plan, Clinical Protocol, Informed Consent Document, Investigator CV, and formal document(s) explaining drug procurement, storage, and utilization, and recommended FDA forms

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* *If the contents are partly or fully in eCTD format, the different eCTD module items need to be re-distributed within the closely matching slots and sections of the* **CDER NextGen Portal**; *the other submission option for the fully eCTD formatted application is via ESG*.

INDs Involving Biologics, Antibody-based, or Gene Therapy Drug Agent

- Investigator Initiated Research INDs and Research Pilot INDs will be submitted via **CBERDCC_eMailSub@fda.hhs.gov**
  - Contents will be provided in multiple documents per the FDA guidance for Investigator Initiated Research INDs
- INDs involving novel agents for a pilot/ first-in-human study with contents partly or fully in eCTD format will be submitted via **CBERDCC_eMailSub@fda.hhs.gov**
- Emergency use Expanded Access Single patient or Limited Population INDs will also be submitted via **CBERDCC_eMailSub@fda.hhs.gov**
  - Contents will be prepared in multiple documents which will include, but not limited to, Emergency Use Treatment Plan, Clinical Protocol, Informed Consent Document, Investigator CV, and formal document(s) explaining drug procurement, storage, and utilization, and recommended FDA forms

INDs Involving Novel, Investigational agents

- If the Investigational Agent is a small molecule drug agent, **CDER NextGen Portal** is the submission pathway
  - Contents* will be provided in multiple documents, which can be assorted into administrative, nonclinical, CMC, and clinical areas. They need not be necessarily in eCTD format; recommended FDA forms along with the Investigator CV, key reports (nonclinical, CMC) are included as additional documents
- If the Investigational Agent is a biologics, antibody-based, gene therapy agent, then INDs will be submitted via email (previously accepted as paper submission) to **CBERDCC_eMailSub@fda.hhs.gov**
  - Contents** will be provided in multiple documents, which can be assorted into administrative, nonclinical, CMC, and clinical areas. They need not be necessarily in eCTD format; recommended FDA forms along with the Investigator CV, key reports (nonclinical, CMC) are included as additional documents

If the contents of IND are in eCTD format, the different eCTD module items need to be re-distributed within the closely matching slots and sections of the **CDER NextGen Portal and submitted via this Portal; **Contents in eCTD format can be submitted via CBERDCC_eMailSub@fda.hhs.gov; the other submission option is ESG.*