CDER Small Business and Industry Assistance (SBIA)
CHRONICLES

JUNE 25TH, 2019

Research Investigational New Drug Applications – What You Need to Know

Listen to our Audio Podcast

Featuring:
Paul Phillips
Team Leader
Program Development, Implementation, & Management Team
CDER Office of New Drugs

Resources:

1. Providing Regulatory Submissions in Electronic Format
2. Investigator-Initiated IND webpage
3. IND Applications for Clinical Investigations: Regulatory & Administrative Components
4. FDA Forms
5. Information for Sponsor-Investigators Submitting INDs

Upcoming Events:

1. Complex Generic Drug Product Workshop – Sept. 25-26 – College Park, MD (Live webcast available)

2. Clinical Investigator Training Course (CITC) – Nov. 12-14 – College Park, MD

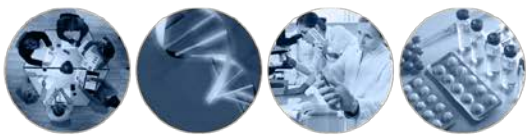
FDA recently released an update to clarify when 'Research' vs. 'Commercial' should be selected on FDA Form 1571, and thus when electronic common technical document (eCTD) requirements apply for an investigational new drug (IND) application.

A commercial IND is one for which the sponsor (usually a corporate entity) intends to commercialize the product by eventually submitting a marketing application. In this case, the sponsor should select "Commercial IND" on FDA Form 1571 Field 6B. FDA may also designate an IND as commercial if it is clear that the sponsor intends for the product to be commercialized at a later date.

In comparison, a research IND (also called a non-commercial IND) is one for which the sponsor (generally an individual investigator, academic institution or non-profit entity) does not intend to later commercialize the product. These studies are strictly for research, are usually shorter in duration and may result in publications in peer-reviewed journals.

IND Application. Commercial and research INDs are both expected to contain the following as described *HERE*:

- Cover Letter
- FDA Forms:
  - 1571 – Investigational New Drug Application
  - 1572 – Statement of Investigator
  - 3674 - Certification of Compliance with Requirements of ClinicalTrials.gov Data Bank
- Table of Contents
- Introductory Statement and General Investigational Plan
- Investigator Brochure
- Clinical Components
  - Protocol
  - Summary of Previous Human Experience with the Investigational Drug
- Nonclinical Components
  - Animal Pharmacology and Toxicology (PT)
- Chemistry, Manufacturing and Controls (CMC)
- Other information as necessary



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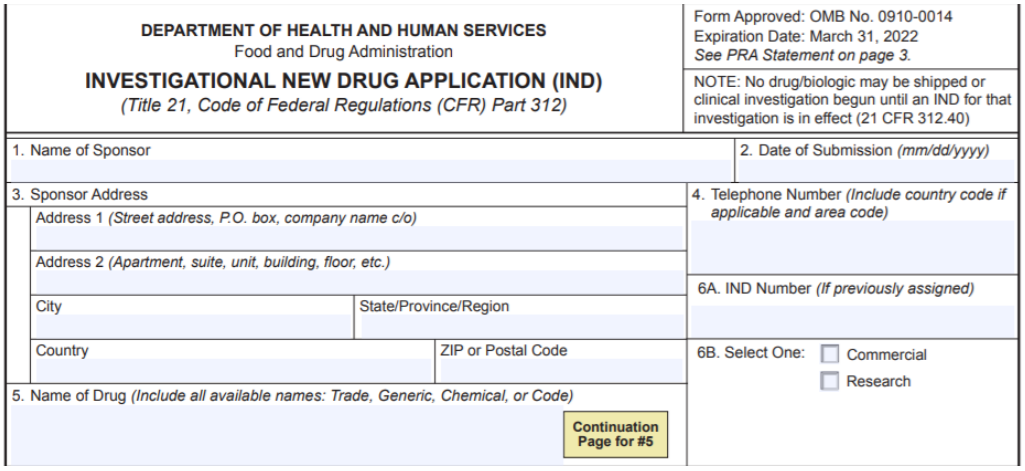
*Often investigator-sponsored research INDs will address the requirements for nonclinical and CMC information by providing a Letter of Authorization (LOA) from the commercial manufacturer. The LOA allows FDA to reference the nonclinical and CMC information in the commercial manufacturer's IND on behalf of the sponsor-investigator, to fulfill the requirements.

The key difference between the submission of commercial vs. research INDs is that commercial INDs must be submitted in electronic format, whereas electronic submission standards for research INDs are highly encouraged but optional.

When a sponsor of a research IND submits either a Phase 2 or Phase 3 protocol, the IND will normally then be considered "commercial" and eCTD requirements would become applicable. In this case, the sponsor should select "Commercial" on FDA Form 1571 Field 6B: IND Type. However, if the product under investigation is not intended to be commercialized at a later date (i.e., the intent of the Phase 2 or Phase 3 protocol is still solely for research), the sponsor should submit a justification explaining their rationale in the cover letter, along with the protocol, and the sponsor should select "Research" on FDA Form 1571. If the FDA agrees, the IND will remain a "Research" IND and the eCTD requirements will not apply. *Note that in all cases, expanded access INDs and protocols should be marked as "Research" on the Form 1571 and are exempt from eCTD requirements.*

Research INDs in paper format should be mailed to the Central Document Room. Sponsors submitting in paper are expected to send their applications in triplicate (one original and two copies). FDA will notify the sponsor of the date it receives the application through an IND acknowledgment letter.



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

INVESTIGATIONAL NEW DRUG APPLICATION (IND)
(Title 21, Code of Federal Regulations (CFR) Part 312)

Form Approved: OMB No. 0910-0014
Expiration Date: March 31, 2022
See PRA Statement on page 3.

NOTE: No drug/biologic may be shipped or clinical investigation begun until an IND for that investigation is in effect (21 CFR 312.40)

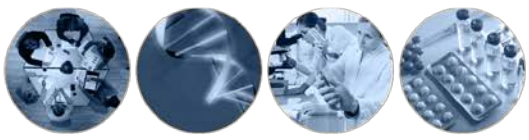
1. Name of Sponsor
2. Date of Submission *(mm/dd/yyyy)*
3. Sponsor Address
Address 1 *(Street address, P.O. box, company name c/o)*
Address 2 *(Apartment, suite, unit, building, floor, etc.)*
City
State/Province/Region
Country
ZIP or Postal Code
4. Telephone Number *(Include country code if applicable and area code)*
6A. IND Number *(If previously assigned)*
6B. Select One: Commercial Research
5. Name of Drug *(Include all available names: Trade, Generic, Chemical, or Code)*
Continuation Page for #5

The IND application goes into effect 30 days after FDA receives the application, unless FDA notifies the sponsor that the investigations described in the application are subject to a clinical hold, or on earlier notification by FDA that the clinical investigations in the IND may begin. Once an IND application is in effect, a drug manufacturer may ship the investigational new drug to the investigator(s) named in the application. An investigator may not administer an investigational new drug to human subjects until the IND application goes into effect.

Additional information on submission of research INDs is located on our Investigator-Initiated Investigational New Drug (IND) Applications webpage.

Cheers,
Renu Lal, Pharm.D.
CDER Small Business and Industry Assistance

Issues of this newsletter are archived at http://www.fda.gov/cdersbiachronicles



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