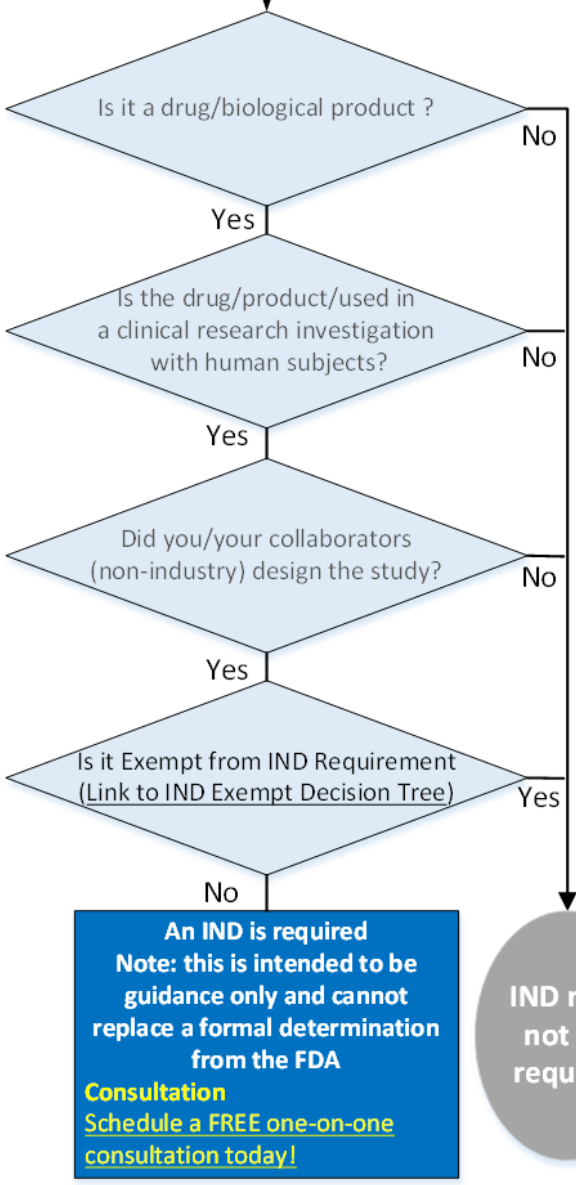
Investigational New Drug (IND) Application Quick Guidance

Do I Need an IND?



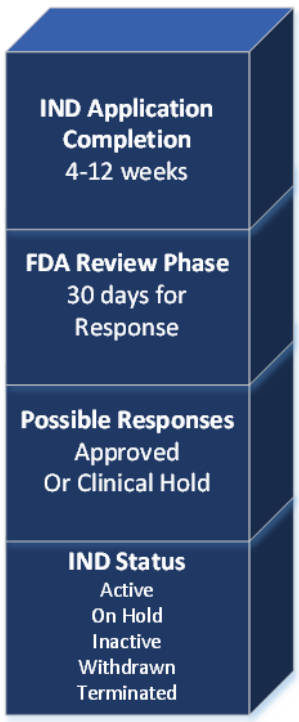
UTSouthwestern Medical Center

An Investigational New Drug (IND) is a request for authorization from the Food and Drug Administration (FDA) to administer an investigational drug or biological product to humans

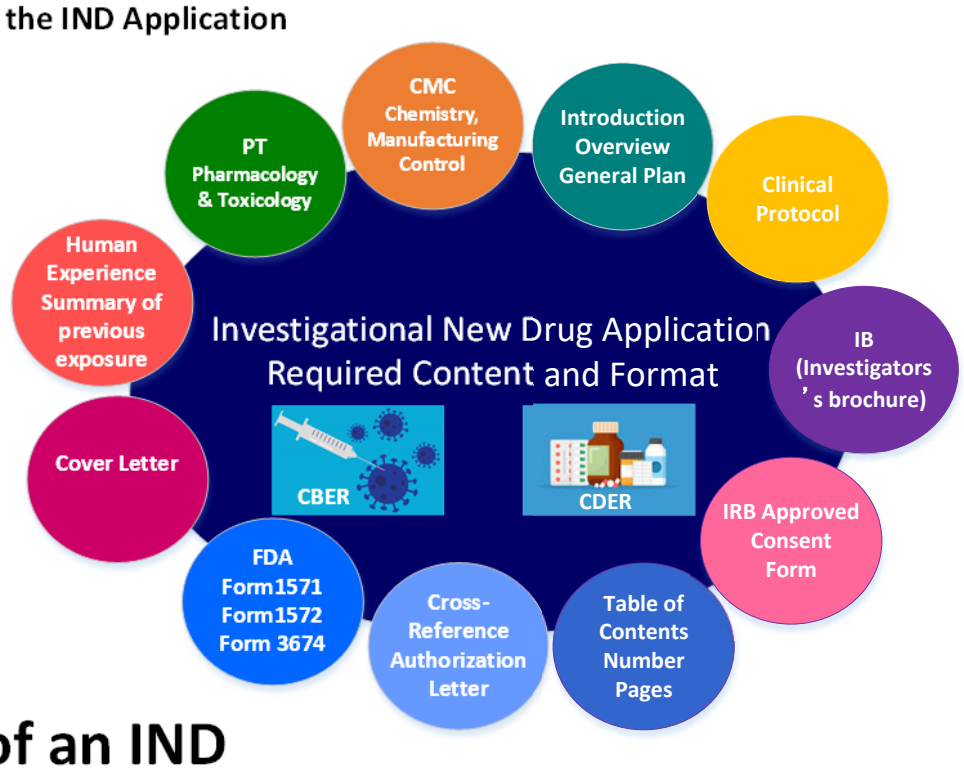
Product	Agency Center	Regulatory Pathways	Ways to Submit
Drug E.g., prescription/non-prescription drugs, toothpaste, antiperspirants, shampoos, sunscreens	**CDER** (Center for Drug Evaluation and Research)	**IND** • Investigator IND • Emergency Use IND • Treatment IND	**CDER NextGen Portal*** CBERDCC_eMailSub@fda.hhs.gov
Biologic E.g., blood products vaccines, allergenic, gene/cellular therapy, tissue products	**CBER** (Center for Biologics Evaluation and Research)	**IND** • Investigator IND • Emergency Use IND • Treatment IND	CBERDCC_eMailSub@fda.hhs.gov

* 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)

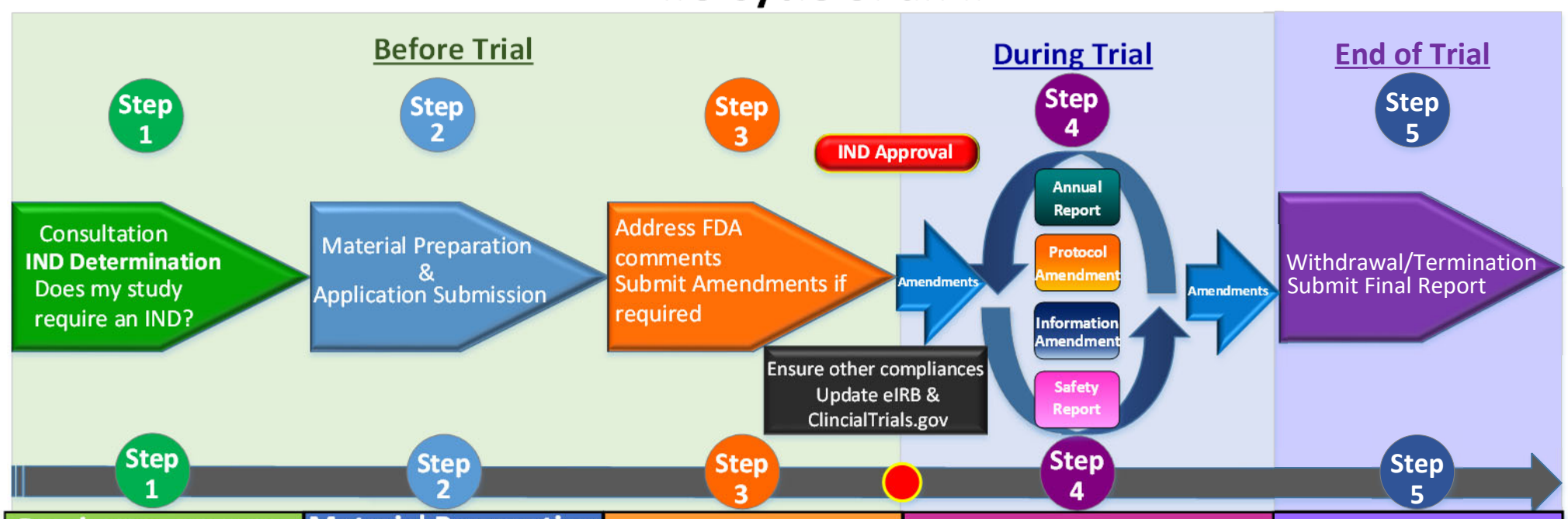
At a GLANCE



Sponsor-investigator (an individual who initiate and conducts a clinical investigation) must include following information in the IND Application



Life Cycle of an IND



Step 1: Book one-on-one Consultation

Assigned SI-Support staff help with:
1. Determination of regulatory passway based on the product classification
- Types of drug and agent
- Types of IND
  - -Research Intent
  - -Commercial intent
2. Create an CDER NextGen Portal Account if required
3. Determination of the division based on the indication studies in the IND
4. Initial IND application preparation by providing Templates
IND Submission Guidance
5. Preparation of other parallel requirements
- IRB submission
- ClincialTrials.gov registration

Step 2: Material Preparation & Submission

1. Prepare IND contents using
  - Initial application template
  - Cover Letter template
2. Once completed, contact SI office for review
3. Submit initial IND applications to FDA either:
  - via CDER NextGen Portal for research IND involving small molecule drug
  - via emailing CBERDCC_eMailSub@fda.hhs.gov for research IND involving biologics, antibody, gene therapy agent
* Send IND to the correct FDA division. Choose the division based on the indication studies in the IND. Descriptions of specific indications can be found
CDER Offices & Divisions
CBER Key Staff Directory

Step 3: FDA Review IND

Once IND application is submitted, FDA issues IND Acknowledgement Letter which includes review division, IND#, division contact, official FDA date of receipt)
Within 30 Calendar days: FDA will issue
- IND Approval (Study May Proceed)
- IND Clinical Hold (Must response within 30 days)
Address FDA comments, submit protocol amendment if required

* Sponsor investigator (SI) may proceed with a clinical investigation once SI has been notified by FDA that the investigation may proceed or after 30 days if the IND is not placed on Clinical Hold.

Step 4: Maintenance

Once IND is approved, update IND status in IRB study & ClincialTrials.gov record accordingly

Submit required IND reports

- **Annual Report**
- **Protocol* & Information** Amendments**

Amendment Types	Example
Protocol Amendments* **New protocols**	Same drug & indication For example, study transitioning to Phase 2
Protocol Amendments* **Change in a protocol**	Changes that significantly affect safety of subjects, the scope of the investigation, scientific quality of the study
Protocol Amendments* **New investigator**	
Information Amendments**	Any amendment outside of protocol. For example new toxicology, chemistry, technical information

- **Safety Reports**

Type of AE	Example
Unexpected fatal or life-threatening adverse drug experience	Within 7 calendar days of sponsor’s initial receipt of information
Serious & unexpected adverse drug experience	Within 15 calendar days
New animal findings that suggest significant risk to human subjects	Within 15 calendar days
Follow-up Reports	As relevant information is available (no later than 15 calendar days after notification)

Step 5: Closing IND

Withdraw IND
-If the development of the investigational product has been abandoned for any reason
Terminate IND
- based on safety issues or deficiencies in the IND or in the conduct of the investigation
- If FDA concludes continuation of the investigation presents an immediate and substantial danger to the health of individuals
* FDA may inactivate IND if no subjects enrolled for 2 years or clinical hold for ≥1 year

Submit Final Report within 30 working days of termination/ completion of the study
-When all subjects have reached the end of follow-up