Preparing the Initial IND Application Submission

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The IND Sponsor-Investigator compiles information in three broad areas:

1. **Nonclinical Components - Animal Pharmacology and Toxicology Studies:** Preclinical data used to assess whether the product is reasonably safe for studies in humans. For studies of marketed drugs in new indications, this section might contain data from animal models supporting the utility of the drug in the new indication.

2. **Chemistry, Manufacturing, and Controls (CMC):** The composition, stability, and controls used for manufacturing the drug substance and the drug product.

    - For marketed drugs, the FDA already has this information on file in the manufacturer's Drug Master File (DMF). For unmarketed drugs, the Investigator-Sponsor can request a Letter of Authorization (LOA) from the manufacturer to cross-reference the Drug Master File or existing IND if there is one. Although it is not required, the LOA is recommended.

    - For legally marketed drugs, the information in the product label or package insert might suffice for the manufacturing information.

3. **Clinical Components:** A detailed clinical study protocol, summary of previous human experience with the investigational drug, and Investigator Brochure (IB) are required sections of an IND application. The IB is primarily needed for multi-center studies and is a summary of information needed by participating investigators to assess the safety of the investigational product. For approved medications, a copy of the Prescribing Information may be used in place of an IB.

The IND Sponsor-Investigator prepares the IND using the IND Application Template format. The initial IND submission should be accompanied by a cover letter, an IND Application Form - FDA 1571 (see instructions) and a ClinicalTrials.Gov Certification of Compliance - FDA 3674.

The IND Sponsor-Investigator must also submit a Statement of Investigator - FDA Form FDA 1572 (see instructions). This form is a formal contract with FDA to adhere to Informed Consent, IRB review, and general IND regulations.

Need assistance or have regulatory questions? Please contact ResearchGo.

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