

# PREPARING FOR YOUR FIRST IND FAQs

## WHAT IS AN IND?

An Investigational New Drug (IND) application is a request for authorization from the FDA to administer an investigational drug to humans. It is required before clinical trials can begin.



## WHO MUST SUBMIT AN IND APPLICATION?

Any sponsor (individual, company, or institution) intending to conduct a clinical trial involving a new drug or biological product that is not approved for marketing in the U.S.

## WHAT ARE THE KEY COMPONENTS OF AN IND?

- **Preclinical Data:** Evidence from lab and animal studies demonstrating drug safety and biological activity.
- **Manufacturing Information:** Details on drug composition, manufacturing, stability, and quality controls.
- **Clinical Protocols:** Plans for the clinical study, including objectives, design, methods, analysis, and safety.
- **Investigator Information:** Qualifications of the clinical investigators conducting the study.



## WHAT ARE THE CRITICAL STEPS IN PREPARING AN IND?

- Step 1: Conduct laboratory and animal tests for preliminary efficacy, toxicity, and pharmacokinetic data.
- Step 2: Outline the clinical trial design, including the phases (I, II, III), patient population, endpoints, and safety measures.
- Step 3: Ensure the drug product is manufactured under Good Manufacturing Practice (GMP) standards.
- Step 4: Assemble all necessary documents in proper formats.
- Step 5: Engage with the FDA through pre-IND meetings to discuss study designs and any potential issues.
- Step 6: Submit the application electronically using the FDA's Electronic Submissions Gateway (ESG). Include all necessary forms & documents.



## WHAT HAPPENS AFTER THE IND SUBMISSION?

The FDA has 30 days to review the IND. They may issue a "safe to proceed" letter, or they may place the trial on hold if there are concerns.

## WHAT ARE COMMON PITFALLS TO AVOID WHEN PREPARING AN IND?



- **Incomplete or Inadequate Preclinical Data:** Ensure all required safety and efficacy studies are completed and well-documented.
- **Poorly Defined Clinical Protocols:** Clinical study protocols should be detailed and clear to avoid confusion and delays.
- **Non-compliance with Regulatory Guidelines:** Strictly adhere to FDA guidelines and requirements to prevent application rejections.

## HOW CAN YOU ENSURE A SUCCESSFUL IND?

- **Engage Early with Experts:** Consider consulting with regulatory experts and experienced professionals who can guide you through the process.
- **Utilize FDA Resources:** Take advantage of FDA guidance documents, webinars, and pre-IND meetings.
- **Quality Control:** Maintain high standards in the preparation activities to ensure accuracy and completeness.



Contact **WAYS** to ensure no trauma or drama for your first IND!