

Navigating the FDA: YOUR GUIDE TO IND **APPLICATIONS**



Every year, the FDA handles a staggering 1,500 Investigational New Drug (IND) applications, a critical step in bringing pharmaceutical innovations to market. The IND review process is pivotal, ensuring the safety of study subjects and the integrity of clinical trials. To successfully navigate this complex landscape, understanding the FDA's priorities, common stumbling blocks, and the benefits of pre-IND meetings is essential.

2 Primary IND Categories:







FDA priorities: Animal Pharmacology and Toxicology Studies

- Manufacturing Information
- Clinical Information Including Protocols





Insufficient nonclinical data

Insufficient safety, pharmacodynamic, and/or pharmacokinetic information

Inadequate information around manufacturing

processes, control measures, and

product characterization Weak trial design

Inadequate regulatory documentation

potential issues Provide insights into preparation process

meetings⁷:

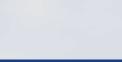
Pre-IND

 Streamlines the process Minimizes risk of

clinical holds

Proactively prevent

- Provides regulatory insights





Guidance tailored to the specific drug

regulatory affairs

Consultants

provide:

Expertise in

characteristics Streamlining of the IND

post-submission

- preparation process Prevention of regulatory delays, rejections, or
- amendments Increased likelihood of successful IND submission

- **Syner-G provides:**

Teams of skilled and practiced experts

Deep experience in every stage of the IND process

Capabilities around managing the entire product pathway

 Up to date knowledge of the constantly changing healthcare landscape

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encouraged%20but%20optional.

- 1 https://pubmed.ncbi.nlm.nih.gov/26911627/#:~:text=Background%3A%20 The %20 Food %20 and %20 Drug, applications %20 (INDs) %20 per %20 year.
- 2 https://www.fda.gov/media/92604/download 3 https://www.fda.gov/drugs/cder-small-business-industry-assistance-sbia/ research-investigational-new-drug-applications-what-you-need-know#:~: text=The%20key%20difference%20between%20the,are%20highly%20
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small-business-and-industry-assistance-frequently-asked-questions-pre-