Begin with the End in Mind: Investigational New Drug (IND) Services

IND Support

The IND application is the primary means through which the FDA allows the testing of new drugs and biologics in humans. The path to a successful IND can be long and resource intensive. The first key to success is understanding the IND process and how to best support your clinical program. Clinical Pharmacology Modeling and Simulation (CPMS) provides expert advice and strategy for preclinical and clinical pharmacology and pharmacokinetics (PK), including authorship of these sections in briefing packages, IND modules, clinical protocols and investigator brochures. We offer subject matter expert representation at Pre-IND meetings to address agency questions and concerns to begin clinical development.

Our scientists understand what it takes to enable a successful IND. We have the expertise to develop novel small molecule, biologic and cell and gene therapy products. Through gap analysis, translational DMPK and clinical pharmacology services, CPMS supports the interpretation of data and transition from preclinical to clinical development. Our Model-Informed Drug Development capabilities support selection of starting clinical doses in healthy volunteers or patients. We have former FDA reviewers on staff who can provide essential "behind the curtain" insights into your program. If you need help with your preclinical program, clinical study design, or IND submission, CPMS has a team of experts with many years of experience to help you succeed.

Services

- DMPK, Clinical Pharmacology and PK/PD Expertise
- GAP Analysis and Expert Advice
- Clinical Pharmacology Plans
- Translational PK/PD Modeling
- Human Dose Predictions
- Clinical Study Design and Protocol Development
- Authorship for IND Documents
- FDA Meeting Attendance

In response to an IND written by Allucent:

"This IND was written quite well and is a pleasure to read. Most interesting and novel".

-FDA Medical Reviewer

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