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# *Accelerate* Your IND Approval

Navigate FDA Headwinds with Confidence & Get to Clinic Faster

**Are you walking the tightrope of an Investigational New Drug (IND) application?**

In today's fast-evolving regulatory landscape, a strong IND submission isn't just important – it's essential. With the FDA shifting toward modernization and real-world data/ evidence (RWD/RWE), and early-phase funding tighter than ever, every decision matters. A weak IND isn't just a delay; it's a costly misstep that jeopardizes your entire clinical future.

## Your Strategic Pathway to First-in-Human Trials

**Introducing the Pre-IND Accelerator**

Designed for early-stage biotechs, this curated package simplifies the complex. We combine deep data intelligence, cross-functional SME expertise, and a tailored strategic roadmap to help you submit a high-quality IND right the first time.

With the Pre-IND Accelerator, you will:

### Craft Gold-Standard IND Strategy

Use data-driven insights and market landscape clarity to build an approval-ready IND package that justifies your early-phase investments.

### Accelerate Regulatory Progress

Reduce costly FDA queries and eliminate unnecessary delays, accelerating your path into the clinic.

### Design a Precision Clinical Plan

Develop a first-in-human protocol and clinical roadmap built for success from day one.

### Mitigate Risk & Maximize Confidence

Gain multi-angle insights, reduce iterations, and secure a clearer, more predictable path to patient trials.

TRANSFORMING THE WAY
YOU SEE THE WORLD

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### Access Expert SME Guidance

Gain strategic advice and actionable intelligence from our industry specialists who know how to navigate FDA headwinds and de-risk development.

# Expanded Capabilities to Power Your IND Success

Strengthen your IND strategy with targeted tools and expert-driven insights:

### Protocol Smart Design

Accelerate protocol development with AI-powered recommendations for inclusion/exclusion criteria, endpoints, and study design.

### TrialTrove + SiteTrove

Access comprehensive global trial and site data to identify high-performing investigators and optimize site selection.

### Real-World Data (RWD)

Validate your assumptions and support diversity goals with real-world evidence aligned to FDA expectations.

### SME Strategy Hours

Get flexible, expert-led support for protocol planning, feasibility or CRO discussions tailored to your needs.

## Accelerate IND Success with Strategic Precision

From discovery to IND, we help you move forward faster with clarity and confidence.

**Schedule your free Pre-IND Accelerator consultation today**

CONTACT US

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