ERGOMED
Clinical Research

De-risk development before you submit.

Strategic, integrated expertise for pre-IND and IND, so you can make the right decisions early and accelerate a successful development path.



EARLY STRATEGY, BUILT IN
Pre-IND and IND are included with qualified full-service trials, aligning strategy with trial execution.

ONE INTEGRATED TEAM
A multidisciplinary team that complements yours, without disparate consultants to coordinate.

STRATEGY THROUGH EXECUTION
We carry programs from development strategy into trial delivery, so advice holds in the clinic.

BOLDER SCIENCE • SMARTER DEVELOPMENT • GREATER IMPACT

110+	55+	10+	2,000+	160+	~30
In-house physicians	Regulatory professionals	Ex-regulators & assessors	Studies completed	Countries served	Years in clinical development

IND clearance is a milestone. Our goal is bigger.

Build a development program that is scientifically sound, operationally feasible, and positioned for meaningful patient impact.

1. **Pre-IND strategy**
   Define the regulatory path and evidence plan.
2. **Regulatory engagement**
   Ask the right questions and get actionable FDA feedback.
3. **IND package**
   Build a coherent submission for efficient review.
4. **Executable first study**
   Design a protocol that works for regulators, sites, and patients.
5. **Evidence-driven development**
   Make each study inform the next decision.

De-risk the path before you submit.

Surface the issues that can create avoidable delay before they reach FDA.

- ☐ **Dose and exposure**
  Support dose, escalation, and exposure with PK/PD evidence.
- ☐ **Development and study design**
  Design for the next development decision, not just this IND.
- ☐ **CMC readiness**
  Align formulation and comparability with the clinical timeline.
- ☐ **Patient, investigator, and site reality**
  Build around a recruitable population and a protocol that sites can execute.

ERGOMED Clinical Research

CONNECTED EXPERTISE

One team. One strategy.

Clinical Development and Medical

Development strategy

Target population

Endpoints

Clinical Pharmacology and PK/PD

Dose selection

Exposure–response

Model-informed development

Nonclinical and Translational Science

Pharmacology

Toxicology

Translation to first-in-human

CMC and Quality

Formulation

Manufacturing and comparability

Clinical-stage CMC

Regulatory Strategy and Medical Communications

Pre-IND strategy

FDA interactions

Regulatory responses

Biostatistics and Quantitative Sciences

Model-based design

Simulations

Adaptive approaches

BALANCED STRATEGY

Designed to clear. Built to run.

Balance regulatory expectations, scientific rigor, and practical execution from the start.

REGULATORY ACCEPTABILITY	PRACTICAL EXECUTION	PROGRAM REALITY
FDA expectations	Investigator and site input	Development timeline
Scientific rationale	Patient burden	Budget
Protocol optimization	Recruitment feasibility	

Modeling and simulation can evaluate alternative scenarios before key decisions are locked into the protocol.

THE OUTCOME

Built for real-world success.

01 Regulatory-ready

02 Executable in the clinic

03 Continuity of Judgment

The same medical, safety, regulatory and development experts who help you secure IND clearance can continue to support your program through study execution, DSMBs, safety management, aggregate reporting and global development.

Planning to advance an asset from preclinical to clinical? Talk to us early.

Plan early. De-risk development. Move forward with confidence.

Contact us today →

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