Syner·G

Understanding the Stakes of IND Submissions: Why Timely Approvals Matter

- **An estimated 800-1200 INDs are submitted annually, with approximately 20-30% facing delays, requiring additional data, or facing rejection.**
- **The journey from pre-clinical testing to approval in the U.S. typically takes 12 years for new drugs and 7 years for medical devices.**
- **Developing a new drug can cost up to $1 billion, highlighting the huge financial investment involved.**

Top 5 Reasons for IND Delays or Rejections:

Insufficient or Incomplete Data
Missing preclinical results or safety profiles hinder approval.

Regulatory Non-Compliance
Issues with GLP, GMP, or application formatting cause setbacks.

Manufacturing & Quality Control Gaps
Lack of detailed manufacturing, quality, and stability information.

Safety and Risk Concerns
Toxicity or adverse preclinical findings halt progress until additional data is provided.

Incomplete Applications
Lack of clarity or incomplete documentation prolongs review or causes rejection.

The Cost of Delay:

Each month of IND delay can cost hundreds of thousands to millions in R&D expenses.

Phase 1 trial delays range from $2M to $5M per month; overall trial costs can reach $20M to $50M+.

Market opportunities are lost, with delays potentially costing $1M to $10M+ per month in missed revenue.

Most importantly, each month of delay affects hundreds of thousands of patients still in need of a critical therapy.

Partner with Syner-G to make sure your IND submissions are thorough, compliant, and timely—helping you avoid costly delays. We're committed to helping our biopharma partners accelerate breakthroughs, minimize risks, and deliver critical therapies to patients more quickly and safely.