Lumanity's IND Readiness Assessment

Accelerating your path to a confident and compliant IND submission

Bringing a new therapy to the clinic begins with a high-stakes milestone: the successful submission of an Investigational New Drug (IND) application. At Lumanity, we help biopharma companies navigate this complex and highly regulated process with confidence. Our IND Readiness Assessment is a strategic, end-to-end solution designed to identify gaps, mitigate regulatory risks, and ensure submission excellence, ultimately accelerating your development and program timelines.

The challenge: Complexity, scrutiny, and the high cost of delay

Submitting an IND to the FDA requires robust, well-documented data across preclinical, CMC, and clinical domains. Yet many sponsors, particularly emerging or resource-constrained teams, face challenges such as:

- Incomplete or non-GLP-compliant preclinical data
- Gaps in manufacturing or quality documentation
- Misaligned protocols lacking key components
- Non-compliance with regulatory formatting and submissions standards

A gap in any of these areas can lead to regulatory holds, information requests, or other delays, jeopardizing investor confidence, clinical timelines, and competitive advantage.

Why Lumanity?

Specialized Expertise
Our team combines deep regulatory insight with hands-on experience across therapeutic areas and modalities, from novel biologics to repurposed small molecules.

Tailored, Fit-for-Purpose Approach
Whether you're a biotech startup or an established global pharmaceutical company, we adapt our process to meet your specific needs, development stage, and target indication.

Operational Efficiency
Early identification of deficiencies helps avoid downstream rework, minimize delays, and protect your development investment.

Stakeholder Confidence
An IND readiness assessment provides clear visibility into program risks and opportunities, instilling confidence among investors, partners, and internal teams.

Value inflection points in an asset's lifecycle

- Understanding the unmet need & defining the path to value
- Defining & delivering the optimal development strategy & evidence generation plan
- Configuring the optimal go-to-market engagement strategy & model
- Engaging, measuring & refining for sustained market success

Our solution: A structured, strategic approach to IND readiness

Lumanity's IND Readiness Assessment helps sponsors prepare a compliant, complete, and compelling IND submission. We provide a thorough cross-functional, proactive evaluation, focused on the following:

01 Comprehensive Gap Analysis

We conduct an in-depth review of all IND components, including:

- **Preclinical:** Evaluation of toxicology, pharmacology, and safety studies for completeness and compliance with GLP standards, as applicable.
- **Chemistry, Manufacturing, and Controls (CMC):** Assessment of drug substance and drug product documentation, manufacturing processes, stability data, and quality controls.
- **Clinical:** Review of proposed protocols for scientific integrity, regulatory alignment, and feasibility.
- **Regulatory:** Audit of submission formatting, module completeness, and alignment with FDA's regulatory expectations.

02 Strategic Road Mapping and Timeline Optimization

We develop a tailored roadmap for IND preparation, aligning timelines with regulatory milestones. This prioritizes tasks, such as completing additional studies or refining protocols, to meet FDA expectations. This strategic approach ensures efficient use of resources and keeps the project on track.

03 Regulatory Expertise and Submission Excellence

FDA requirements are dynamic and often vary by therapeutic area or drug type. Our regulatory experts provide precise guidance on what's required, what's optional, and what's likely to raise red flags. We bring deep knowledge of agency guidelines to ensure your IND is submission-ready and successful.

Delivering value beyond submission

Our IND Readiness Assessment is more than a checklist. It is a strategic alignment tool that sets the foundation for long-term development success, ensuring your IND supports not just FDA clearance, but a cohesive and efficient clinical development plan, ultimately leading to approval. Partnering with Lumanity is a strategic investment in speed, quality, and regulatory confidence, bringing you one step closer to delivering innovative therapies to patients.

The Lumanity difference

Strategy Consulting offers seamless, integrated asset development by uniting deep cross-functional expertise – spanning clinical to market access – with a powerful understanding of future market dynamics and competitive landscapes.

Contact us

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