

Streamlined Pre-IND Strategy

Streamlined FDA Pre-IND submission through cross-functional regulatory strategy in Phase 1 cell therapy development.



Situation

A small, innovation-driven biotech company was advancing a **first-in-class biologic therapy** composed of **umbilical cord-derived mesenchymal stem cells** for the treatment of **acute alcoholic hepatitis**, a complex indication with significant unmet medical need.

As an early-stage organization developing a novel cell-based therapy, the sponsor needed to navigate **regulatory complexity** while establishing an efficient path into clinical development.

To support this, the sponsor engaged Caidya to provide **Pre-IND and IND-enabling** support for a Phase 1 program in the United States, including regulatory strategy, protocol design, and submission readiness delivered through a cross-functional team.



Challenge

The primary challenge was **timeline volatility driven by external dependencies**, a common but critical risk in early-phase clinical development.

Shortly after project initiation, delays in nonclinical testing and third-party vendor deliverables began to impact key milestones.

These delays created a cascading impact across the development timeline, slowing progress against the original development plan.

At the same time, the initial regulatory strategy included a planned **FDA interaction prior to the Pre-IND meeting**. This approach became misaligned with the sponsor's need to accelerate clinical development timelines.

Maintaining this approach would have added both time and cost, compounding delays already outside the sponsor's control.

For a small biotech with limited resources, these challenges threatened program momentum and budget efficiency.

The situation required not only careful management of evolving timelines, but also a **proactive reassessment of the regulatory pathway** to identify opportunities to streamline development without compromising scientific or regulatory rigor.

“Thank you all for your tremendous support. We are excited to work with you and eagerly look forward to making this project a success. Thank you!”

Senior VP of R&D





Solution

Caidya deployed a fully **integrated cross-functional team**, including Regulatory Strategy & Development (RSD), CMC, Medical, Medical Writing, and Biostatistics, to realign the program and maintain forward progress.

Working in close collaboration with the sponsor, Caidya:

- Conducted a cross-functional gap assessment across regulatory, nonclinical, and CMC documentation
- Provided regulatory consulting and project management to align evolving timelines and priorities
- Supported nonclinical strategy refinement to address delays and maintain submission readiness
- Led development of the protocol synopsis and study design
- Integrated medical and biostatistics input throughout
- Authored and managed the Pre-IND Meeting Request and Briefing Package, serving as the primary FDA liaison

Caidya guided a **strategic regulatory pivot**, skipping the initial FDA interaction and proceeding directly to the Pre-IND meeting, streamlining the pathway while preserving scientific and regulatory integrity.

\$30K in development cost savings

Cross-functional regulatory strategy enabled a streamlined Pre-IND pathway in a Phase 1 cell therapy program despite upstream development delays.



Outcome

Despite early delays, the program successfully completed a Pre-IND meeting with the FDA in December 2025, supported by a high-quality, submission-ready package.

The revised strategy delivered measurable impact:

- **3–5 months saved** on the overall development timeline
- Approximately **\$30,000 in cost savings**
- Maintained program momentum despite external setbacks

This engagement reinforced a key principle in early-phase development: proactive strategic adaptation can mitigate development delays.

By reassessing the regulatory pathway in real time and aligning execution with evolving conditions, Caidya enabled the sponsor to **accelerate progress while optimizing both time and cost**, a key advantage in rare and innovative therapeutic development.



Resolved delays via regulatory realignment



Optimized FDA engagement strategy



Delivered 3–5 months timeline reduction