

# Empowering a Biotech Startup

## Caidya's Agility and Expertise Driving Growth in Oncology



### Situation

Caidya began working with a **biotech startup led by experienced industry professionals**. The company had recently acquired a promising oncology drug from a large pharmaceutical firm.

The drug, which **targets specific exon mutations in a rare gastric cancer, showed strong preclinical results** but wasn't aligned with the larger company's strategy, leading to its independent development, by a biotech startup.

Initially planned as part of a combination therapy, early clinical data revealed the drug's **exceptional efficacy as a monotherapy**. This prompted a shift in clinical strategy, accelerated timelines, and the **need for an experienced, flexible CRO** to support the evolving clinical development plan (CPD).



### Challenge

The project presented several challenges that tested Caidya's flexibility and expertise:

- **Clinical Strategy Shift**

Strong monotherapy results led to a pivot away from combination therapy, requiring study rapid adaptation to new regulatory and operational demands as well as a significant expansion of the ongoing study.

- **Contingency-Based Award**

The Phase II study was awarded to Caidya following positive results from an interim analysis. This study required a quick start to maintain the momentum of the clinical development pathway. The team was positioned and ready to commence work on the project, which had to be planned efficiently with a seamless transition to the next step.

- **Expanding Global Reach**

The Phase III trial required a larger, global site footprint. While the sponsor had strong KOL and advocacy group ties, Caidya expanded the network and added more countries to meet broader recruitment goals.





## Solution

Caidya's approach was built on three pillars: trusted relationships, operational agility, and scientific excellence.

- **Trusted Relationships**

Partnership & Continuity: **strong, existing relationships** with the biotech's leadership, including team members, enabled seamless communication and trust. Executive involvement and face-to-face engagement further strengthened the partnership.

Positioning for Impact: the team helped **shape a compelling story for investor and partner communications**, focusing on the drug's promise, rare tumor type, rapid recruitment, and strength of the collaboration. A blinded testimonial is in progress to support future promotion.

- **Operational Agility**

Flexibility & Execution: the team adapted quickly to the shift toward monotherapy and **supported planning for Phase III**. Despite delays tied to the acquiring company's vendor policies, Caidya remained engaged and operationally prepared.

Cross-Functional Alignment: Caidya worked with the sponsor to establish dual contract pathways—separating operational execution from quality oversight—to align with the acquiring company's processes without disrupting delivery.

- **Scientific Excellence**

Strategic Recruitment: Caidya built on the sponsor's KOL network and added global investigator sites, especially for Phase III. Collaboration with a leading patient advocacy group for GIST also boosted recruitment and engagement.



## Outcome

This collaboration became a standout case study in Caidya's ability to manage complex oncology programs in dynamic, fast-evolving environments.

- **Clinical & Financial Growth**

The Phase I study saw a significant increase in direct costs, while the Phase III study expanded notably in both scope and budget.

- **Scientific Validation**

A Phase I cohort is now testing the drug as a first-line therapy—a rare and confident move that highlights its strong potential.

- **Reputation & Positioning**

Caidya proved its strength in rare oncology, adaptability through change, and ability to maintain delivery across organizational transitions—positioning the team for continued work with the acquiring sponsor.

- **Relationship & Recognition**

The project reinforced Caidya's role as a trusted, high-performing partner. A blinded testimonial and case study are in development to support future BD and investor outreach.



Growth in Phase I and III



Drug tested as a first-line therapy in Phase I



Quickly adapted to strategic and operational changes

Caidya's ability to navigate complex oncology trials, even during transitions, solidified its reputation as a trusted partner in high-stakes environments.