

# Biotechnology Hypertension Trials

## How Caidya's Agility and Expertise Supported Client's Complex Phase II and III Trials

### Situation

A fast-moving biotechnology sponsor initiated a series of complex **Phase II and Phase III clinical trials** targeting **uncontrolled and resistant hypertension**.

These global studies involved many investigative sites and patients spread across numerous complex regulatory environments.

The sponsor **transitioned the program from a previous CRO** due to unmet expectations regarding flexibility and data handling, and needed a new partner that could deliver with speed, adaptability, and operational precision.

### Challenge

This program presented several challenges driven by the **studies' complexities, fast-moving timelines**, and evolving sponsor needs. Success required adaptability, close coordination, and continuous process refinement.

**•Complex Study Design:**

The trials involved at-home data collection, wearable devices, and extensive lab data—demanding advanced coordination and data handling.

**•High Screen Failure Rate:**

Elevated screen fail rates slowed enrollment and created operational backlogs.

**•Evolving Data & Protocols:**

Frequent protocol amendments owing to data findings required ongoing batch cleaning and process adjustments.

**•Fast-Paced Sponsor Environment:**

The sponsor's rapid pace including their IPO during our collaboration required quick decisions, real-time issue resolution, and high flexibility from the team.

**•Tailored Communication:**

Early feedback pointed to the need for in-person meetings and regular leadership interactions to build trust and a partnership mindset.

*“Working on this project has been a great opportunity to apply our scientific and operational expertise to advance a promising therapy for cardiorenal conditions.”*

Veljko Kopjar, Sr Dir Clinical Development





### Solution

In response to the studies complexity and global scale, a collaborative, **cross-functional support structure** was activated, involving clinical research associates, trial management, project managers, and executive leadership. The CRO team provided a **"white glove" service**, focusing on responsiveness and proactive management, especially during protocol amendments and operational shifts.

Risk mitigation strategies were implemented early, including planning around holidays, **ensuring resource consistency across the program**, and quickly escalating issues for resolution. The Governance Committee comprised of senior leadership from the Sponsor and CRO facilitated **rapid decision-making**.

Data management teams established a workflow for **continuous data cleaning**, ensuring accuracy while keeping pace with the sponsor's fast timelines.

A fit-for-purpose delivery model was implemented for each trial while recognizing and maximizing cross-study efficiencies.



### Outcome

Despite high complexity, the clinical databases for two of the trials **were locked ahead of schedule**. This early delivery was crucial for the sponsor, enabling data release before a major cardiovascular conference. The remaining two trials, including an open-label extension study, are still open.

The CRO's performance on the first trial demonstrated **flexibility, rapid execution, and alignment** with the sponsor's goals leading to the CRO being awarded the entire program.

The relationship evolved over the trials leading to commercial benefits for the sponsor **including volume-based discounts**.

This case showcased the CRO's ability to **adapt to demanding biotech clients**, manage complex trial dynamics, and deliver **high-quality results under pressure**, highlighting the importance of executive engagement, proactive risk management, and a client-focused approach.



Last Patient In achieved ahead of schedule on both key trials



Databases locked early



Cross-functional involvement

### Success in Phase II & III Trials

Caidya's successful delivery of this program has strengthened our position as the go-to CRO for emerging biotech clients active in the cardiovascular, metabolic and renal therapeutic areas