CASE STUDY

Driving Clinical Development of T-Cell Engagers in China

Integrated execution across multiple studies enabled by strong KOL engagement and streamlined study start-up

Situation

Caidya partnered with a U.S. based biotech company to enable and **accelerate clinical development in China** across Investigator-Initiated Trials (IITs) and IND studies in autoimmune disease.

The engagement began in November 2024 with feasibility activities, including principal investigator (PI) identification, site assessments, and in-country engagement with key investigators supported by Caidya's established **KOL network**. Following a successful feasibility phase, the client expanded into China and, in February 2025, confirmed an **ambitious development plan** covering three IITs and three IND studies.

From the outset, the program was designed for **accelerated timelines**, **parallel study execution**, and high operational complexity across regulatory, start-up, and clinical delivery activities.

Challenge

The client operated with exceptionally high expectations for **speed**, **quality**, **and responsiveness** across all study activities, requiring consistent execution under compressed timelines and complex operational conditions.

Key challenges included the need to accelerate critical start-up activities such as **GCP set-up**, **Ethics Committee review**, **contract negotiation**, and **HGRAC approvals**, all within established site-level processes in China that inherently require careful coordination and alignment.

In parallel, the program demanded **rapid patient enrollment** across multiple sites, frequent protocol amendments, and agile decision-making to maintain study momentum across parallel trials.

Additional complexity was introduced by IIT studies involving non-marketed products, which reduced site availability and created significant feasibility constraints at the outset.

The client also expected near **real-time communication**, rapid turnaround on decisions, and highly experienced operational oversight capable of managing multiple concurrent studies without compromising quality, compliance, or operational control.

Driving Clinical Development in China

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Solution

Caidya deployed a dedicated, fully integrated study team spanning project management, clinical trial management, and site monitoring, ensuring **continuity and clear accountability** across all studies.

A high-frequency communication model was established, with daily interaction between CRAs, site coordinators, and investigators to enable **rapid issue resolution** and maintain study momentum. To prevent delays, client decisions and approvals were consistently processed and communicated back to sites within **24–48 hours**.

To manage site contracting complexity, Caidya took a **pragmatic**, **partnership-driven approach**—working closely with both sites and the sponsor to align expectations early and maintain timelines while respecting local requirements.

Enrollment was supported through close collaboration between CRAs and site CRCs, including structured screening of patient pools and real-time tracking of eligible subjects. This was further enhanced by engaging **multiple recruitment vendors** per study to broaden patient outreach and accelerate enrollment.

Caidya also leveraged its strong **KOL network in China** to support early site selection and investigator engagement, ensuring access to experienced sites and enabling faster activation across multiple programs.

100% Milestones met or exceeded

Outcome

Within six months, all three IIT studies were successfully initiated, meeting or exceeding **aggressive timelines** defined at study outset. In parallel, all three IND submissions were successfully delivered to the **National Medical Products Administration** (NMPA).

The program achieved activation across **seven IIT sites with 30 patients enrolled**, **and 37 IND sites with 24 patients enrolled** across studies. Strong execution performance led to immediate expansion of the partnership, including the award of four additional IITs and one additional IND study.

Beyond China, the collaboration extended into **global development activities**, including initiation of Phase II MRCT programs, further expanding the client's clinical portfolio.

Overall, the partnership enabled **accelerated multi-indication development**, improved operational efficiency versus traditional development models, and established a scalable framework for future global clinical expansion.

- **6 studies delivered in 6 months**
- **37 IND sites and 7 IIT sites activated**
- **Partnership expanded from 6 to 11 trials**

Rapidly enabling clinical development in China through accelerated study start-up, strong KOL engagement, and seamless multi-study execution