CASE STUDY

Caidya Leads Phase II Atopic Dermatitis Study

Supporting treatment progress in moderate to severe cases

Situation

A **biotechnology** company partnered with Caidya to manage a **Phase II** clinical trial assessing the safety, pharmacokinetics (PK), dose exploration, and preliminary efficacy of an investigational therapy in patients with moderate to severe **Atopic Dermatitis**.

The study represented a key step in the early development of a novel treatment for this chronic and often debilitating condition.

Given the protocol complexity and therapeutic challenges, Caidya provided strategic and operational leadership to ensure **study execution**, **regulatory compliance**, and high-quality **data delivery**.

Challenge

The study encountered several challenges, including COVID-19 restrictions, enrollment difficulties, and the mandatory use of a placebo control group. These factors introduced operational complexity and required adaptive strategies to maintain timelines and participant engagement.

- Despite **pandemic restrictions**, the team worked diligently to streamline the Site Start-Up (SSU) process. Remote coordination and flexible site support helped maintain momentum during a period of widespread disruption.
- **COVID-19 policies and site-level variability** impacted the SSU timeline, leading to delays in site activation and requiring additional oversight to align start-up activities across regions.
- The use of a placebo control group introduced **additional enrollment challenges.** Participants were informed of a 75% chance of receiving the active treatment, which impacted recruitment dynamics. To mitigate this and prioritize participant safety, a **remedial treatment option** was offered to those who received placebo following study completion.

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Solution

To enhance patient recruitment, the sponsor team took a proactive and tailored approach by engaging directly with site staff, particularly focusing on Principal Investigators (PIs) and key Sub-Investigators (Sub-Is). These discussions were designed to identify challenges, collect feedback, and create customized strategies for each site.

The following actions supported successful recruitment:

- **Early site engagement**: Sponsor reps met with PIs and Sub-Is to align on recruitment strategies and potential challenges.
- **Site-specific plans**: Investigator input shaped tailored recruitment approaches based on local capabilities.
- **Leveraged internal networks**: Investigators recruited from their own departments to boost efficiency.
- **Therapeutic motivation**: The IMP's promising outlook encouraged investigator support.
- **Patient incentives**: A modest, EC-approved allowance helped improve compliance and retention.
- **Ongoing communication**: Weekly WeChat updates kept investigators informed and motivated.
- **Strategic site selection**: Included sites in tier 3 and 4 cities to broaden the recruitment pool.

18% Increase in subject enrollment beyond original targets.

Outcome

Caidya exceeded expectations by completing enrollment **six weeks ahead of schedule**, enrolling **18% more subjects than planned**. In parallel, the team achieved **full inspection readiness** and successfully passed a CFDI inspection, demonstrating operational excellence and regulatory compliance.

This case study highlights the **resilience and adaptability** of the Caidya team in navigating significant challenges — including evolving sponsor requirements and disruptions caused by the COVID-19 pandemic.

Through a combination of **strategic communication**, **agile problem-solving**, and **rigorous quality oversight**, the team effectively mitigated risks and maintained study momentum.

Caidya's commitment to continuous improvement not only ensured successful trial execution, but also drove meaningful enhancements in **project management discipline** and **operational efficiency** across the portfolio.

- **Enrollment finished 6 weeks early**
- **Recruitment 18% above target**
- **Passed CFDI inspection successfully**

Caidya's proactive approach and agile project management enabled the team to overcome pandemic-related disruptions and shifting sponsor demands. This commitment to quality and adaptability resulted in accelerated enrollment, enhanced operational efficiency, and successful regulatory inspection outcomes.