CASE STUDY

Cardiovascular Phase IV Registry

Remote monitoring and proactive site engagement ensured success across 12 countries and 28 sites

Situation

One of Caidya's sponsors engaged us to manage a **Phase IV**, prospective, multicenter medical **device registry**. The study spanned 12 countries and involved 28 sites, many of which were research-naïve.

With long enrollment timelines and the observational nature of a registry, site engagement and study prioritization were limited. Additionally, **the Clinical Events Committee** (CEC) process was only agreed upon and implemented after the study had started, requiring mid-study operational adjustments.

Caidya was responsible for **full study oversight**, including project management, monitoring, regulatory submissions, data management, and safety reporting.

Challenge

The study faced several challenges, primarily due to a large number of research-naïve sites. These sites struggled with **study protocols**, **patient recruitment**, and regulatory compliance, requiring extensive support.

The long duration of the Phase IV registry further led to **decreased site engagement** and focus over time. Additionally, the Clinical Events Committee (CEC) process was only established after the study began, creating delays in event adjudication and complicating operational management.

These challenges demanded a **flexible and hands-on approach** to ensure consistent progress across all sites.

Solution

Caidya implemented a proactive operational strategy to maintain site engagement and manage the study effectively despite its challenges:

•**Remote Site Support:** CRAs maintained consistent remote communication with sites, enabling quick resolution of issues and sustained oversight, especially for research-naïve locations.

•**Strong COM Involvement:** Country Operations Managers were highly engaged, providing additional structure and guidance across countries and acting as key liaisons between the sites and project leadership.

•**Ongoing Communication:** Regular newsletters were developed and distributed to keep sites informed and aligned on study expectations, timelines, and updates.

•**Rapid CEC Process Integration:** Once the CEC process was established post-study start, Caidya immediately began managing event preparation and submission to keep adjudications on track.

•**Centralized Oversight Tools:** PMs and COMs maintained detailed issue logs and action trackers to monitor pending protocol deviations, unresolved contacts, and site-specific items, easing the burden on CRAs and ensuring nothing fell through the cracks.

Outcome

Caidya's strategic and collaborative approach yielded strong operational performance across the registry:

•**Effective Issue Resolution:** The regular remote contact between CRAs and sites enabled near real-time resolution of operational issues. Remote visits and phone calls were leveraged to maintain study momentum without the need for frequent on-site presence.

•**CEC Deliverables on Track:** Despite the late start of the adjudication process, Caidya consistently delivered CEC event submissions on time, ensuring efficient preparation, documentation, and routing without backlog or delay.

•**Remote Monitoring Consistency:** Monthly remote contacts were established with each site, documented as remote visits, and tracked using internal tools, with minimal delays or missed engagements.

•**Sustained Site Engagement:** Through continuous communication, site newsletters, and dedicated oversight by CRAs and COMs, even the less experienced sites remained engaged throughout the 26-month enrollment period.

12 Countries involved

On-time CEC event adjudication

Consistent site engagement during the study

Flexible monitoring model

Callout

Caidya successfully navigated a complex Phase IV medical device registry across 12 countries and 28 sites by leveraging strong remote monitoring, proactive communication, and agile operations—ensuring consistent site performance, timely adjudication, and zero missed visits despite initial site inexperience.