Caidya™

Rescue Study: Data Management

Caidya builds seven databases and standards within seven months for biotech company

Situation

A biotechnology company approached Caidya's Data Management (DM) team to provide comprehensive support for building seven databases within a challenging seven-month timeline.

The sponsor had previously faced operational and portfolio management issues with other CROs, resulting in inefficiencies and lack of return on investment.

The company sought a more reliable and effective solution, turning to Caidya to address these challenges and deliver a streamlined, high-quality database build process.

Challenge

To get the programs on track, Caidya's DM team focused on building trust with the sponsor while swiftly transitioning into a collaborative partner relationship.

Understanding the urgency, Caidya took on the challenge of building multiple databases concurrently, all while simultaneously developing the necessary standards and libraries for the project.

This required a high level of coordination and precision across teams to ensure all components were aligned and moving forward seamlessly.

Execution was key to the success of the project, and the Caidya team was determined to not only meet deadlines but to also elevate the quality of the deliverables.

The approach had to be faster, more efficient, and of a higher quality than previous efforts, ensuring the sponsor received a significant improvement in both process and output.

7 databases in 7 months

Personalized execution

Flexible, adaptable "one team" approach

Solution

The Caidya Global Clinical Analytics team identified Data Management team members to ensure consistency across the studies.

We created a comprehensive transition plan comprised of timelines, role definitions, and transition checklists at the project and site level. The thorough attention to detail we put into the planning and training set the stage for exemplary results.

Specifically, we ensured a:

- **Seamless transition**

  The PM and DM lead prepared detailed study plans and checklists, fostering smooth cooperation and consistent processes across database builds.

- **Meticulous global execution**

  The DM team organized kick-off meetings to train staff on roles, responsibilities, and systems. We also applied best practices and efficiencies, creating a startup timeline template and standards alongside early builds.

- **Smooth integration of Caidya processes**

  Our "one team" approach prevented quality issues. The DM team completed detailed checklists and metrics reporting for the sponsor, working closely with the main contact to drive performance and build trust.

Outcome

Caidya successfully developed seven databases within seven months, with eCRF design and screen programming completed in just six weeks.

The project included approximately five arms, expansive visit schedules, over 150 customized functions, and more than 100 unique eCRFs, all tailored to the sponsor's requirements.

Efficiencies gained from shortened timelines led to significant cost savings for the sponsor. **By optimizing processes, we were able to deliver high-quality results ahead of schedule, adding value to the project.**

The biotech company was highly satisfied with the transition and our team's performance, leading to a long-term, successful partnership that continues to thrive today.

+150 **Customized functions completed**

Database Lock

Study	Mar	Apr	May	Jun	Jul	Aug	Sept	Oct
Study 3	■							
Study 1		■						
Study 2				■				
Study 6						■		
Study 4							■	
Study 5							■	
Study 7								■

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