

Biometrics Rescue Study

Integrating data from 50+ studies for ISS/ISE in an NDA



Situation

A biotechnology company approached Caidya to help with ISS/ISE for NDA submission. The sponsor pulled the work from another CRO who was experiencing quality issues, as well as challenges getting resources assigned with ISS/ISE experience.



Challenge

There were different coding dictionaries, laboratory units, and visit structures in place from various studies. There were also multiple database structures (over 50 studies involved). Urgent needs were consistently coming from the sponsor since the timelines were delayed. Caidya needed to identify stakeholders as well as main-point of contact before moving forward.



Solution

The Caidya Biometrics team helped ensure all adverse events and concomitant medications were re-coded, converted all lab results to System International (SI) and created a new unique visit structure.

The team built exhaustive database structure for **50+ studies** and fully integrated a query ready database of SDTM and ADaM datasets. Following *Caidya's Transition Blueprint* for rescue studies, the team focused on key areas that help ensure success:

Seamless Transition: Our project manager and Biometrics team prepared detailed study plans and checklists and instituted a solid team model that facilitated seamless cooperation and consistent processes across the programs.

Meticulous Execution: Our team organized a kickoff meeting to train all personnel in roles, responsibilities, procedures, and systems management. To further ensure stellar execution, we conducted accountability checks to ensure quality and progress were meeting Caidya's standards.

Smooth Integration: The Caidya Biometrics and project manager supervised overall programming and completed checklists and reported on progress to the main sponsor contact.



Outcome

Caidya successfully integrated all new studies within **five (5)** working days. We put into place consistent dictionary, units, and visit structure for ISS/ISE reporting and submission to NDA.

The Caidya team immediately actioned the sponsor's and requests from FDA within **two (2)** business days.

The result was an on-time and high-quality submission.

Because the biotech company was so pleased with the outcome and our team's performance, they have awarded additional new work to Caidya.

Speed, Quality and Consistency