

Seamless Transition, Measurable Results

How Worldwide Flex Stabilized a Biotech Sponsor's Data Management and Biostatistics Functions

A biotech ran a study with an academic CRO (ACRO) managing data and biostatistics. The sponsor faced repeated issues with data quality and clean-up cadence in that arrangement. The sponsor then transitioned data management and biostatistics responsibilities to Worldwide Flex.



Challenge

The sponsor needed a partner who could quickly take over data management and biostatistics while protecting study data integrity. After the transition began, Worldwide Flex discovered that the EDC database lacked programmed edit checks and had undergone little data cleaning. This discovery added a foundational data quality build to the standard transition workstream and required immediate action to safeguard study data integrity.



Solution

Worldwide Flex executed a rapid rescue of the data management and biostatistics functions, working with the sponsor and outgoing ACRO to stand up the new operating model.

Specific actions we took included:

- Coordinating with the sponsor and ACRO to transfer essential systems and study materials
- Taking over the EDC platform assuming both programming and administrative rights
- Establishing user administration and confirmed access controls were correctly applied
- Designing and programming edit checks for the EDC database
- Working with the sponsor to build and deploy manual data review checks
- Initiating systematic data cleaning activities, which improved database quality
- Maintaining continuous communication with the sponsor to support user access, ongoing data cleaning, and the timely delivery of statistical outputs and reports

Other Differentiators:

We combined a clean mid-study transition with the build-out of foundational data management infrastructure, including edit checks and manual review checks, that were missing from the original setup. In addition, we took on full programming and administrative ownership of the EDC platform to ensure that the new data were captured appropriately. We demonstrated our clear ability to rescue a study mid-flight, stabilize data quality, and deliver against database lock milestones.



Results

Data integrity and cleanliness improved after the transition to Worldwide Flex, and together we achieved an interim database lock within the first year. The sponsor and Worldwide Flex built a strong working relationship with open communication and timely support for the changes in study needs as the program advanced. As a result, the final database lock activities remained on track for the coming year.

Let's talk about how our personalized approach, therapeutic expertise, and global resources make us a strong partner for your drug development program.

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