

Case Study

# Delivering Critical Milestones Through a Strategic DM Transition

After encountering challenges with a clinical trial's data management and biostatistics, Worldwide Flex swiftly resolved the biotech sponsor's quality and performance issues with their previous service provider. Through rapidly deploying solutions, comprehensively transitioning systems, and implementing robust data quality controls, Worldwide Flex transformed a struggling data management environment into a well-functioning operation. The team achieved critical milestones and established a strong collaborative partnership. This case study outlines the challenges, the strategic approach, and the measurable improvements delivered.



## The Challenge

A biotech sponsor faced persistent difficulties with the existing academic CRO (ACRO) data management processes, including lapses in data quality and delays in cleanup activities. The sponsor made the strategic decision to transition data management and biostatistics responsibilities to Worldwide Flex.



## The Solution

Worldwide Flex initiated a rapid and comprehensive rescue of the study's DM and biostatistics functions. The process included:

- Collaborating with both the sponsor and ACRO to transition all essential systems and materials
- Assuming responsibility for the EDC platform, IBM Clinical Development (now known as Zelta), including programming and administrative rights
- Quickly establishing user administration and ensuring access controls were accurately implemented

During the transition, Worldwide Flex discovered that the EDC database lacked programmed edit checks and that little data cleaning had occurred. This discovery underscored the urgency and importance of the transition, as the study's data integrity was at risk.

Worldwide Flex worked closely with the sponsor to identify, design, and implement necessary data quality measures:

- Developed and programmed comprehensive edit checks for the EDC database.
- Collaborated with the sponsor to create and deploy manual data review checks.
- Initiated systematic data cleaning activities, rapidly improving the quality and reliability of the study database.

In addition, Worldwide Flex maintained ongoing communication and partnership with the sponsor, ensuring seamless support for user access, regular data cleaning, and timely delivery of statistical outputs and reports.



## The Outcome

As a result of Worldwide Flex's intervention:

- 1 The integrity and cleanliness of the study's data improved significantly.
- 2 A successful interim database lock was achieved within the first year after transition.
- 3 The working relationship between Worldwide Flex and the sponsor flourished, with open channels of communication and timely support for evolving needs.
- 4 Ongoing activities are on track as the study approaches its final database lock in the coming year.

Looking to outsource one or multiple functions to support your clinical development program? Worldwide Flex functional service provider (FSP) offerings help to achieve high-quality, cost-effective results in many areas. Contact us today to learn more about our FSP solutions and see how you can start fast and scale seamlessly.

Contact Us

### About Worldwide Clinical Trials

Worldwide Clinical Trials (Worldwide) is a global CRO serving development-driven biopharmaceutical companies, with more than 4,400 professionals operating across more than 70 countries. The company delivers therapeutically dedicated expertise in neuroscience, oncology, rare disease, and internal medicine, with comprehensive support across every development phase - from early-stage and first-in-human studies through Phase III registration trials.

The company's flexible service model - spanning full-service trial management to functional service partnerships through Worldwide Flex - is powered by a people first, partnership driven outsourcing approach that strengthens collaboration, enhances data transparency, and supports more informed decision making. This provides sponsors with tailored, adaptable solutions that keep pace with the evolving demands of clinical research.

Learn more at [www.worldwide.com](http://www.worldwide.com)