

Data Management, Sized to Your Program

Worldwide Flex functional service provider solutions for clinical data management

Clinical decisions are only as reliable as the underlying data; poor data quality can compromise study conclusions and patient safety.

Database design shapes what your clinical team can see week to week. Coding and reconciliation choices shape what reaches a regulator. The pace of data cleaning shapes when your program reaches its next decision point.

Worldwide Flex builds data management engagements around your needs. That can start with one or two experienced clinical data managers and grow into a full data management function operating across a program of studies. Our teams work inside your systems and SOPs, inside ours, or in a combination that suits how your organization runs.

Worldwide Flex sits within Worldwide Clinical Trials, so a data management engagement includes access to the therapeutic depth, biostatistics and programming capability, and global infrastructure sponsors need from a full-service CRO.

**275+**

Data management
team members

**20+**

Years of Data Management
project experience

**5**

Delivery regions
across North America,
Europe, and India



Demand moves with the study timeline.

Data management workload rises and falls around the study build, first patient in, interim analyses, and database lock. Functional outsourcing lets you match capacity to those points in the timeline.



The database is a long-lived asset.

A stable team carries study knowledge, platform conventions, and edit-check logic from one milestone to the next. Continuity in the data management team influences quality of the submission package.



Your operating model is the starting point.

Some sponsors want teams working in their own SOPs, and under their own oversight. Others want an established operating model handed to them. Worldwide Flex supports both and supports combinations of the two.

Key Services for Your Program's Success

We look at data management across the full study lifecycle, from the first eCRF specification through archival, so that the data you collect is ready for the decisions you need to make.

Service	Questions We Help You Answer	What This Entails
 Study Build & Database Design	How quickly can the database be ready?	- eCRF design, database development, and validation across multiple platforms - EDC custom function development - Edit check specification - User acceptance testing - URL management, site setup, and access - Certified EDC programmers on the in-house team
 Data Review & Cleaning	How do we keep the data current and decision ready? Who is reviewing, and against what standard?	- Data review and cleaning - Managing data currency and accuracy - Medical coding - Safety data reconciliation
 External & Laboratory Data	How do data from vendors and labs come together?	- Vendor data transfer specifications and agreements - Vendor data reconciliation - Local and central laboratory management
 Documentation & Study Support	What documentation supports the database through inspection?	- Development and support of data management driven documentation - Documentation aligned to the systems and SOPs in use on the study
 Lock, Submission, & Close-Out	What happens as the study closes? What does the submission package need?	- Database lock and regulatory submission files - Study archival support and close-out

Working Alongside Biostatistics and Statistical Programming

Data management and biostatistics sit in the same Worldwide Flex organization and work from a shared set of conventions. Sponsors who begin with data management can extend into statistical programming, biostatistics, or a combined biometrics team as the program develops.

- Direct communication between data management and biostatistics teams inside Worldwide
- Internal standards-based toolkit for SDTM mapping in SAS and R
- Standard TFL packages alongside custom TLF development
- In-house PK team, Phoenix certified
- India-based statistical programming team for cost-managed delivery

Experience Behind the Team



Team Experience

An average of 10 years of experience across the biometrics team, with half the team at 15+ years



Study Type

Experience across all phases, post-market studies, and medical device studies



Transitions

Extensive study rescue and transition experience



Resourcing

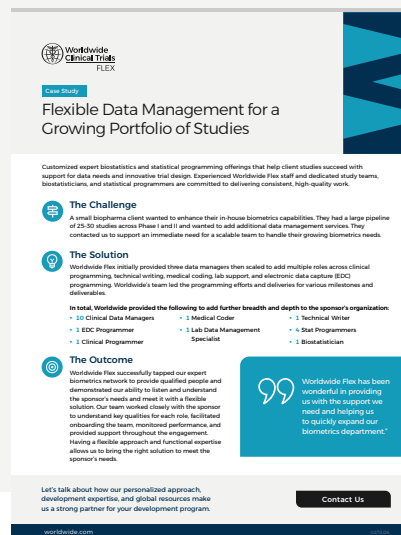
More than 20 years in the resourcing space, with an average contractor bringing 10 or more years of experience across therapeutic areas

Proof in Practice

A Growing Phase I/II Portfolio

A small biopharma sponsor with 25 to 30 studies across Phase I-II wanted to add data management capacity to their in-house biometrics group. Worldwide Flex started with three data managers and grew the team to ten clinical data managers supported by EDC and clinical programmers, a medical coder, laboratory data management specialist, technical writer, four statistical programmers, and a biostatistician.

Read the full case study: Flexible Data Management for a Growing Portfolio of Studies →



Ways to Work Together

The right structure depends on how your organization runs today. We start by understanding that, then design the engagement around it.

 Client-Managed	Our data management teams work in your systems and under your SOPs, managed by your organization. You keep direct operational control.
 CRO-Managed	Teams operate on Worldwide SOPs and Worldwide systems, with Worldwide holding day-to-day delivery accountability. This suits sponsors who want a fast start without provisioning systems and access.
 Blended	A combination of the two, designed around the needs of the program. Worldwide Flex can also own the defined functions alongside a full-service engagement.

Meet Our Data Management Leads

Our data management leadership brings deep platform experience and long-standing sponsor relationships to every engagement.



Melanie Dyer



Kim Harle



Nidheesh Sreedharan



Shannon Villiers



Kathryn LaTendresse



Lori Reis



Move Forward Confidently with Worldwide Clinical Trials

Worldwide Flex is the functional service provider offering within Worldwide Clinical Trials. We design data management solutions that scale with your portfolio, staffed by people chosen for technical depth and for how well they will work alongside your team. Our clients have direct access to the decision makers who stay close to the day-to-day work.

To talk about how a data management team could support your program, contact us today.