

Functional Biometrics Solutions

We know that FSP means different things to different people. Designing bespoke biometrics models is our differentiator. We listen to your challenges,

requirements, and preferences, then customize our biometrics solutions based on those needs.

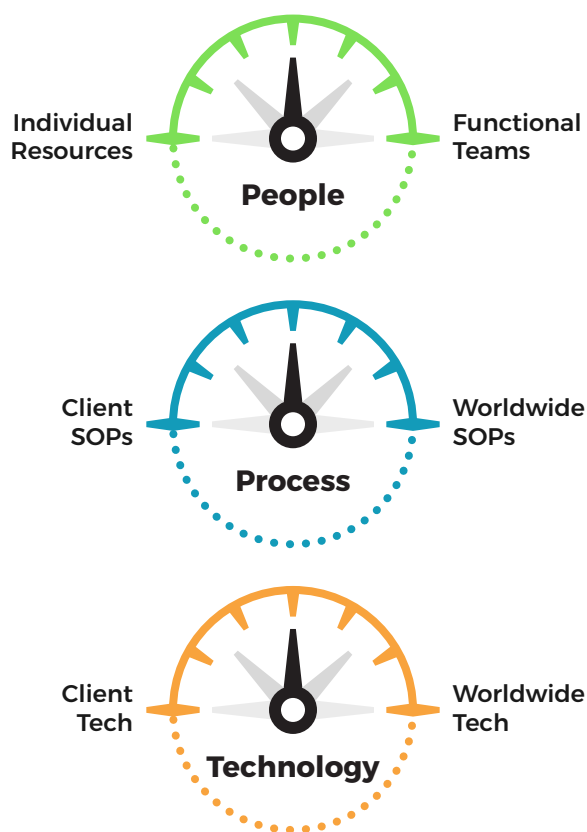
We are a dedicated partner that listens to you, then provides the people, processes, and technology solutions to meet your needs. Worldwide Flex is here to help solve your biometrics problems.

The Worldwide Flex approach to biometrics provides active participation from the start to finish of your project.

At Worldwide Flex we:

- Focus on quality to build a solid foundation
- Work cohesively with your teams and across functions
- Assign a functional lead to each project
- Require senior leader review of all deliverables
- Ensure study data integrity – from database development to database lock and beyond
- Provide executive oversight for each engagement

Most outsourcing partners can provide a project biometrics team. We deliver biometrics by tapping into our pool of talent – which includes a database of 7,000+ known subject matter experts (SMEs) – and pulling experts to support from a single resource, from a program of studies, or full functional outsourcing.



“Worldwide Flex properly identified the resource we needed, aligned with our very short turnaround, and was available to support us.”

Worldwide Flex Customer

Our solutions range from concept design through database build to regulatory reporting and beyond. With expertise in medical devices, vaccines, and medicinal products across multiple therapeutic areas, Worldwide Flex works with all types of clients, across all phases of development to support information for decision making.

We work with a variety of electronic data capture (EDC) systems and have skilled people working across many platforms. Since we are program-agnostic, we recommend options based on the situation, work with your specific systems, or work together to design a unique technology solution for your needs.

Our forward-thinking use of multiple programming languages means that we have capabilities in SAS for statistical programming or program in R, Python, and other open source languages. Programming is provided on a project basis or Worldwide Flex places SMEs with your team.

Worldwide Flex is also able to provide medical writing and scientific authoring services to help you achieve high-quality results for regulatory, safety, medical, and scientific communications, including health economics and outcomes research (HEOR).

Our offerings incorporate robust and flexible processes, job aids, and guidance that our teams leverage to deliver across therapeutic areas and all phases with one global set of standard operating procedures (SOPs) unless there is a requirement to follow your SOPs.

Other features we offer:

- Dynamic visualization capacities to use for ongoing management of a study, such as dosing decisions, monitoring safety of patients, highlight trends / signals in the data
- Pharmacokinetic (PK) analyses for new or ongoing studies
- Partnerships between statisticians and programmers to work closely with experienced medical writers utilizing AI technology

Worldwide Flex Biometrics Services



Data Management

- Vendor - Data Transfer Agreements
- Vendor Reconciliation
- Data Review / Cleaning
- Managing Data Currency & Accuracy
- eCRF Design, Database Development & Validation Across Multiple Platforms
- Medical Coding & Data Reconciliation
- Local / Central Lab Management
- Database Lock & Regulatory Submission Files
- EDC Development & Programming
- Edit Check Specification
- User Acceptance Testing
- Development / Support of Data Management-Driven Documentation



Biostatistics & Programming

- Adaptive Designs
- Bayesian Methodology
- Statistical Consultancy
- Manuscript & Publication Support
- Trial Design
- Randomization
- SAP & TLF Shell Development
- IB / DSUR / SRC Development
- DSMBs / DMCs / Interim Analysis
- CSR Support
- CDISC Compliant Datasets Documentation
- Legacy Data Integration



Additional Services

- Regulatory Submissions
- Grant Applications