Worldwide Clinical Trials FLEX

Biostatistics & Statistical Programming, Sized to Your Study

Functional service provider and resourcing solutions for biostatistics, statistical programming, and PK analysis

A late-stage oncology biotech selected Worldwide Clinical Trials to manage its Phase I/II European trial evaluating a promising acute myeloid leukemia (AML) therapy. The award was driven by the sponsor's positive experience partnering with Worldwide on a previous solid tumor study. Following the success of the Phase I/II program, the sponsor expanded the relationship and non-competitively awarded Worldwide the registrational global Phase II/III trial.

250 Biostatistics and statistical programming team members

10–15 Years average industry experience across the department

5 Delivery regions across North America, U.K., Europe, and India

Statistical thinking should start early

Sample size, design, and endpoint definition decisions made before first patient in determine what the analysis can support later. Bringing biostatistics in at the protocol stage protects the program downstream.

Continuity carries the submission

A stable team holds the analysis conventions, derivation logic, and study history from SAP through database lock and into the submission package. This avoids handoffs, where quality is often lost.

Your operating model is the starting point

Some sponsors want resources provided to them to work within their own systems, macros, and SOPs, under their own oversight. Others want an established operating model without the burden of operational oversight. Worldwide Flex supports both, and combinations of the two.

Ways to Work Together

Client-Managed	CRO-Managed	Blended
Highly qualified resources are a part of your internal team, working in your systems, macros, and SOPs. You keep direct operational control of deliverables and timelines.	Worldwide Flex teams operate on Worldwide SOPs and systems, with Worldwide holding day-to-day delivery accountability.	Worldwide Flex can deliver defined tasks or functions while also providing qualified resources embedded within your organization, creating a tailored model that flexes with your workload, systems, and oversight needs.

Key Services for Your Program's Success

We look at biostatistics and statistical programming across the full study lifecycle, from protocol design through submission support.

Service	Questions We Help You Answer	What This Entails
Design & Planning	Is the design addressing the question we need answered?	• Protocol development, sample size estimation, and statistical methodology review • Adaptive, enrichment, group sequential, and Bayesian designs • Randomization list specification, generation, and verification; QTL support
Analysis Planning & Outputs	What will the analysis show, and when can we see it?	• SAP and TFL mock shell development, with independent statistician review • Interim analyses, from sample size re-estimation to full interim reports • Topline tables within 5 working days of lock; full draft TFL sets in ~2 weeks
Programming & Standards	Will the datasets stand up to regulatory review?	• SDTM and ADaM production, specifications, and define.XML • Reviewer guides (SDRG, ADRG), annotated CRFs, and dual programming of all variables • Ongoing CDISC compliance checks via Pinnacle 21 Enterprise
Submission & Committee Support	What does the filing package need, and who supports it?	• ISS and ISE packages; BIMO datasets and TFL programming • Independent and unblinded statistician support for DSMBs, DMCs, and SRCs • CSR support, legacy data integration, and manuscript/ publication support

What Sets the Team Apart

- Direct communication between biostatistics, programming, and data management
- Internal standards-based toolkit for SDTM mapping in SAS and R
- In-house PK team, Phoenix WinNonlin-certified
- India and Serbia based statistical programming teams for ex-US delivery models
- Access to a network of highly experienced biometrics professionals available through our biometrics resourcing team

Experience Behind the Team

Study Type & Breadth

All phases, post-market, and medical device studies across autoimmune, cardiometabolic, immune-mediated inflammatory diseases, CNS, oncology, and rare diseases

Transitions

Extensive study rescue and transition experience

One Programmer to 130+ FTEs at a Large Pharmaceutical Company

A large biopharmaceutical company needed a single full-time statistical programmer, scaling to seven FTEs in year one, with all studies staying on the client's systems, SOPs, and macros. Worldwide Flex built an internal SAS platform mirroring the client environment, so deliverables ran natively on their systems, governed by tiered executive, operations, and functional oversight with KPI reporting and defined escalation pathways. Within two years the engagement expanded into data management and biostatistics by 30+ FTEs; over 11 years it grew past 130 FTEs across programming, application development, and biometrics IT — absorbing surges of 20+ FTEs in a single month at a 93% staff retention rate.

Read the full case study: Providing Biometric Services to a Large Pharmaceutical Company

Meet the Team



Jennifer Ly, EG

Vice President,
Biostatistics & Programming

- 25+ years in global clinical development with expertise in clinical trial design, statistical strategy, regulatory submissions, and cross-functional leadership across all phases; has overseen a global team of 200+ staff.
- Led process improvement initiatives generating $1.8M in first-year savings and drove AI-enabled workflow modernization that doubled annual efficiency gains; member of the Worldwide Flex Leadership Team.



Limna Salim

Senior Director,
Head of India Office

- 15+ years in clinical research spanning Phase I–III, post-marketing studies, and ISS/ISE submissions, with therapeutic expertise across oncology, neurology, rare diseases, immunology, vaccine, and device trials.
- Proficient in CDISC standards (SDTM/ADaM) and SAS programming; SAS Global Certified Base and Advanced Programmer with a B.Tech in Electronics & Communication.



Robin White

Senior Director,
Head of Internal Medicine

- Nearly four decades in clinical research spanning biostatistics, statistics, statistical programming, biostatistical leadership, and regulatory submission support across Phase II–IV, including NDA submissions and complex multi-protocol programs.
- Therapeutic expertise in cardiovascular disease, neurology/psychiatry, oncology, and infectious diseases; published in journals such as Circulation; holds an M.S. in Biostatistics from UNC Chapel Hill.



Brian Hetzell

Senior Director,
Biostatistics & Programming

- Over 20 years in biostatistics and clinical research, with trial experience spanning the full development spectrum from preclinical and healthy volunteer studies through Phase I–IV and pilot feasibility trials.
- Provides executive oversight of all biostatistical and statistical programming activities across multiple clinical research programs, with extensive experience managing NDA submissions and complex, multi-protocol programs across pharmaceutical and medical device studies, including federal research with the NIH.



Lidia King

Senior Director, Biostatistics & Statistical Programming, Head of Oncology

- 30+ years in biostatistics, statistical programming, and epidemiology across Phase I–IV and real-world evidence, with therapeutic expertise spanning oncology, hematology, neurology, infectious disease, pediatrics, pulmonology, virology, and vaccine trials; regulatory experience includes NDA/BLA packages, ISS/ISE, and DMC reporting.
- Lead Biostatistician for the bluebird bio program that achieved FDA approval as Abecma, the first CAR T therapy for multiple myeloma; built and managed a high-performing biometrics team across geographies; holds a PhD in Epidemiology & Statistics from the Medical University of South Carolina.

Worldwide
Clinical Trials

Move Forward Confidently with Worldwide

Worldwide Flex is the functional service provider offering within Worldwide Clinical Trials. We design biostatistics and programming solutions that scale with your portfolio.

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