Biometrics Partnership

Experience

Built on a foundation of biometrics, Rho has positioned itself as an industry leader providing right-sized biometrics services and support for more than 39 years. With over 100 biometrics personnel, across data management, biostatistics, data standards, and statistical programming, we have the capacity and depth to provide consistency throughout your development program, from product development through marketing application, advisory committee, and approval.

Flexibility & Scalability

We recognize there is more than one solution and understand the complexities unique to each study. Instead of the typical one-size-fits-all approach to clinical trials found at large CROs, we work with you to develop a biometric support model that fits your development program. With your end goal top of mind, we provide a customized solution with unparalleled access to biometrics tools and insights that only a CRO like Rho can provide.

Partnering with Rho provides a customizable support model to fit your development program.

That is what drives us. Experience, Rho.

Biometrics Partnership

Support Models

Project Based	Full Time Equivalent	Consulting
• Services aligned with a project/program • RFP for each project • Contracted on a unit basis • Full service or stand-alone	• Functional services across multiple projects • Rho personnel 100% dedicated to client • Contracted on an FTE basis	• Consulting services for any biometric needs • Contracted on a time and materials basis

Our Services for End-to-End Biometrics Support:

- Study design and protocol development (including ICH E9(R1) estimand language)
- Representation at Regulatory Agency Meetings
- Database development, maintenance and close out
- Third-party vendor data set-up, integration, and reconciliation
- Development of study-level statistical analysis plans (SAP) and integrated summary of safety and efficacy (ISS/ISE) SAPs
- CDISC deliverables (SDTM, ADaM, submission packages)
- SAS programming and validation of tables, listings, and figures
- Clinical data gap analysis, dataset remediation, and legacy dataset conversions
- Dataset integration (ISS/ISE) and marketing application support
- Consultation

39+
years of expertise in biometrics

100%
technical acceptance rate with FDA

95%
of our biometrics clients have expanded their partnership with Rho

Rho Experts

Heather Kopetskie
Senior Director, Biostatistics
Heather Kopetskie, Senior Director of Biostatistics, has worked at Rho for more than 19 years. Ms. Kopetskie provides leadership and oversight for the biostatistics department and utilizes her experience to guide sponsors on the design and analysis of clinical trials. Her experience spans many therapeutic areas with an emphasis on solid organ and cell transplantation along with rare disease (orphan) products. Ms. Kopetskie has supported both federally funded projects and biotech/pharmaceutical companies. She has served as the biostatistical functional lead for the Immune Tolerance Network (ITN) Statistical and Data Coordinating Center and the Clinical Trials in Organ Transplantation (CTOT) Statistical and Clinical Coordinating Center overseeing more than 30 studies in the areas of allergy, immunology, and transplantation.

Amanda Parsons
Senior Director, Clinical Data Management
Amanda Parsons brings over 25 years of biostatistics and data management Contract Research Organization (CRO) experience to her role as Senior Director, Clinical Data Management. Ms. Parsons has worked with biotech, pharmaceutical and medical device companies to meet the biometric needs of their studies and programs. She has experience in all phases of clinical trials, as well as integrated summaries of safety and efficacy (ISS/ISE) for New Drug Application (NDA) submissions. She has engaged in the definition and implementation of standards including the adoption of CDISC, onboarded new electronic data capture systems, managed third party and data vendors, and created and maintained departmental standard operating procedures, processes, and training.

Ben Vaughn
Chief Strategist, Biostatistics & Protocol Design
A proven leader in the industry for more than 20 years, Ben Vaughn serves as Rho's Chief Strategist for Biostatistics and Protocol Design. In this role, he utilizes his extensive expertise to guide sponsors through marketing applications, regulatory interactions, and the design and analysis of analgesia trials. Mr. Vaughn has supported over 75 pain trials, over 30 marketing applications, and 6 FDA advisory committee meetings (both back room and bullpen) over the course of his career. He has represented sponsors in more than 50 Type A/B/C meetings with FDA.

"We were impressed with Rho because:

- Rho was able to use their experience and insights to help us address the complexity of our clinical trial in our analysis plan. They did this by closely partnering with us and working through all of the details of the protocol, SAP, and clinical trial operational execution to ensure that we were approaching the analysis in a sound and defensible manner.
- They stepped into a program that was struggling mid-stream and were able to quickly assess the issues and help us drive to a locked database and top-line results in a very short period of time.
- We had easy and quick access to Rho's Senior Leadership for consulting when we were making important strategic decisions."

Don Cilla, Pharm.D., M.B.A.
President & CEO, Appili Therapeutics Inc

Learn how our customized Biometrics services can benefit your clinical development program and marketing application.

Contact Us

rhoworld.com/biometrics

Rho®

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