

Biometrics

Biometrics are the backbone of the drug development process, and our global Biometrics group understands how to use the power of data-driven decision making to deliver high-quality services from development through to market launch and beyond. By employing tested technologies and approaches, we support clients' projects with a time-tested operational model, while providing insightful access to study data, metrics, and industry-standard delivery models.

Executive Summary

The biometrics landscape is changing, and the need for expert design, analytics, risk-management and data coordination is more critical than ever. Our patient-centered team understands the importance of high-quality data with optimal statistical design, ongoing risk management/mitigation and rapid database build, closure and lock, and appropriate study analysis and reporting across the product development process. We also provide biostatistical consulting services at the start of your drug development process, ensuring the right statistical input to the clinical development strategy.

Our data collection and analysis solutions start with the key endpoints in mind. Working backward, we employ our end-to-end connected health technology platform to enable innovative data collection from a variety of sources, including directly from patient-connected devices. Our integrated data review strategy is differentiating as our holistic review model removes the fragmented approach, incorporates risk management, and facilitates the reduced monitoring model. We build an optimal strategy with the patient always at the center, determining the best path to collect data for study endpoints that are most patient-friendly. By involving the Biometrics team early, we not only contribute to optimal strategy but help create it with executive representation in numerous industry groups such as CDISC, SCDM, and PSI.

Commitment to Patients

We bring treatments to patients by focusing first and foremost on their needs. Our approach starts at the finish line to offer the best data and strategy solutions based on what your patients need. Instead of changing patient lives for the sake of our research, we integrate research into their lives using convenient methods through means they already have available, including apps, wearables, and telemedicine. At PRA, we think about the clinical trial aspect of data collection, so patients don't have to. We commit to getting involved early, providing innovative thinking, and making research as natural as breathing for patients.





“At PRA we live by the philosophy of “start with the end in mind”. We understand that quality needs to be built into the planning stages, through cross functional strategic planning, followed by ongoing risk mitigation and efficient processes to ensure data integrity and regulatory compliance.”

ANGELA MCPARTLANE

Vice President, Global Biostatistics and Programming

Key Features

PRA's Biometrics team consists of four key support areas:

- Global Data Operations, which includes Global Data Standards and Clinical System Management, ensures analysis-ready clinical data while adhering to the highest standards of data integrity and regulatory compliance. This team helps to ensure that standards are compliant with CDISC and regulatory requirements, and oversees the full clinical system lifecycle.
- Biostatistical Consulting Services (Portfolio-Level Strategy) provides client consultation in the best practices for Clinical Development Plan and Protocol Development, Submission Documents, Regulatory Interactions, and Publications. This sets the foundation for successful study-level execution by our Biostatistics and Programming team.
- Biostatistics and Programming (Study-Level Execution) support study design, analysis and reporting while adhering to the highest standards of data integrity and regulatory compliance. This group also includes the Data Monitoring Committee (DMC) team who provide independent DMC set-up and reporting services.
- The Biometrics Delivery Office provides governance and support to the Biometrics Operational team. We have dedicated project management professionals specialized in the technical aspects of biometrics delivery needs, who also support client and departmental training programs.

This comprehensive model benefits clients by:

- Supporting clients at a relationship level, functional manager level, and oversight level through our Account Groups Heads (AGHs), who ensure interconnected oversight across clients.
- Providing strategic statistical consultancy to the overall clinical development plan.
- Delivering global standards, processes, and integrated systems.
- Producing consistent, reliable, and high-quality service for biometrics delivery.
- Allocating team members based on relevant time zones and therapeutic expertise.
- Providing cost-effective solutions for both small- and large-scale studies.

Expertise & Experience

PRA Biometrics has over 1,000 staff members worldwide with an average of 19 years of industry experience. We offer a variety of biometrics solutions, including full service, stand-alone, embedded, and hybrid models. We have participated in over 450 projects using electronic data capture (EDC) in the last five years, involving more than 300,000 patients. With 70+ designers and developers, we are well versed in Rave and other systems, including PRA's PRISM EDC.

Our knowledge of Rave and other EDCs, their role in biometrics data collection, and analytical processes have allowed us to build a significant number of optimized databases. We are experts in CDASH, SDTM, ADaM, Define.xml, and Controlled Terminology, and are active participants in shaping biometrics practices as leaders in industry organizations.

In addition, we have set-up and reported DMCs across multiple therapeutic areas and have established relationships with DMC KoLs.

Next Steps

For more information about the data collection and analysis solutions we can offer your project or study, email us at BiometricsBDSupport@prahealthsciences.com.