Biometrics

The difference is in the data.™

Committed quality standards, a shared sense of urgency, and a focused dedication to your success

Driven by quality, the experts at MMS approach every biometrics deliverable as a top priority, no matter how big or small the project may be. From the onset, MMS colleagues work with a sense of urgency and leadership – meaning they perform efficiently and provide proactive guidance. Setting clear expectations and having open communication across functional areas enables a seamless workflow for shared deliverables. And, you can expect in-depth, thoughtful conversations with team members, knowing that they are thought leaders, invited speakers, and change makers in industry groups across the globe.

Scalable with process strength and know-how to quickly ramp up and provide global support from the largest submission to a trial-level project

Capable **and Flexible** with the experience to transform the most challenging sponsor data into successful submissions

Innovative and able to draw upon decades of experience to create processes, standards, and methods to solve the most complex problems for sponsors

DATA MANAGEMENT

- Electronic Data Capture (EDC) including selection of best-fit systems
- eCRF design, including expedited database builds, and creation of completion guidelines
- Full data handling, data validation planning, and complex data integrations
- Efficient reviews of data, including validation checks, listings, and query management
- Preparation of data discrepancy trending reports
- Application of Risk-Based Monitoring (RBM) strategies
- Independent database Quality Gate checks/QC
- Creation and maintenance of sponsor data collection standards libraries
- Development of GCP compliant procedures, work practices, and sponsor-specific templates
- Establish detailed data sharing plans

STATISTICAL PROGRAMMING & BIOSTATISTICS

- Provide CDISC and legacy standards expertise, annotated CRFs, SDTM, and ADaM specifications
- SDTM and ADaM dataset development, conformance, and traceability
- Specifications for metadata and eSub Define-XML 2.0 applications and Define.pdf
- PHUSE format reviewer's guides
- Planned & ad-hoc TLGs
- Data anonymization programming + proprietary technology
- Data pooling and integrated data analyses
- Input into the Protocol, Clinical Development Plans, & CSRs
- Development and review of SAP/ISAP for submission documents
- Sample size calculations and development of randomization and materials schedules
- DMSB support, Advisory Committees, and IND reporting
- Rapid responses to regulatory agencies (FDA, EMEA, PMDA)

We love what we do and are committed to making a difference!

MMS is an award-winning, data-focused CRO that supports the pharmaceutical, biotech, and medical device industries with a proven, scientific approach to complex trial data and regulatory submission challenges. Industry experts across 4 continents are available to support your programs 24x7 with a 97 percent sponsor satisfaction rating. With strong science, strength of process, and a sense of urgency, MMS is redefining the CRO experience.