



Strategic Solutions Division Biometric Services

Our embedded model allows us to develop custom solutions for our biometrics clients.

Data Management | Data Analytics | Programming | Biostatistics

PRA Health Sciences is a global CRO with nearly 17,000 employees around the world. We support biotech and small to large pharmaceutical companies around the globe with our more than 70 offices in USA, Canada, Europe, Asia, Latin America, Africa, and the Middle East. Our comprehensive Phase I-IV biopharmaceutical drug development services help support our clients' growing needs.

We created the Embedded Solutions model to implant the ultimate in accessible expertise and efficiency for our strategic partners. Currently, under this model, we have 6000+ employees embedded with our strategic partners all around the world.

Our biometric services support our pharmaceutical partners globally, with approximately 500 resources across North America, Latin America, Europe, and Asia Pacific. PRA's embedded biometric services include data management, data analytics (encompassing business intelligence/informatics), programming, and biostatistics. Each of these are tailored to fit the needs of our partners, allowing us to implement our embedded model for as little as one resource to as many as hundreds of resources.

In our flexible, customizable embedded model, we can:



Utilize either client's or PRA hardware, software, and support structure



Assemble teams at client-specified locations or at PRA locations



Tailor resource oversight to program requirements, ranging from administrative oversight to full functional management





Data Management (DM):

PRA provides expert dedicated data management support in all key DM related activities, including:

- Project management and delivery of all DM related deliverables
- Oversight and management of eCRF, EDC design, and SDTM related deliverables
- Review and approval of all data management plans and documentation
- Oversight of DM CRO vendor delivery
- Data review/validation, SAE reconciliation, query processing
- eCRF design, EDC database build programming, and SDTM deliverable oversight
- ePRO set-up, coordination, and updates
- IXRS set-up, coordination, and updates
- Data coding
- Lab data management, review, and validation including specialty lab data
- UAT of EDC database, edit checks, custom functions, SAS listings, etc

Data Analytics:

PRA provides expert dedicated data analytics/business intelligence support, including:

- Programming visualizations for business intelligence requirements based on user requirement specifications (for example, metric reporting, data review at function or trial level, and predictive tools)
- Providing data-modelling/ warehousing and Master Data Management support.

Programming:

Our programmers are experts in their field and can assist our clients at every step in the process of submitting their trials to a regulatory agency. These services include:

- Data Monitoring Committee/Data Safety Monitoring Board Support
- CDISC submission-ready Study Data Tabulation Model (SDTM) datasets and/or Analysis Data Model (ADaM) datasets
- Statistical analyses of clinical studies including tables, listings, and figures
- Case Report Tabulation (CRT) documentation

Oversight of CRO programming work/Vendors

Biostatistics:

We assign a dedicated biostatistician to each client to provide statistical services from phase I to phase IV of clinical development. These services include:

- Study design and protocol development
- Statistical analysis plan - Individual Studies and Integrated Summaries
- Statistical analyses of clinical studies
- Clinical study report writing
- Data Monitoring Committee
- Statistical Submission documents
- Health Authority Interaction

Besides these statistical services rendered by dedicated biostatisticians, we can provide short-term and long-term statistical consulting to clients depending on their needs throughout clinical development.

They Staff. We Embed.

Embedded Solutions™ – A PRA Strategic Solutions Model