



Powered by Experience

THE EMB ADVANTAGE

- ▶ **Accessible team** that functions as a seamless partner.
- ▶ **CDISC** data standards expertise and active CDISC team representation.
- ▶ **Zero turnover** since forming in 2000.
- ▶ Majority **senior-level** associates who are directly involved on all projects.
- ▶ Frequent, direct **FDA interaction**.
- ▶ Extensive **clinical development and submission** experience.
- ▶ Supported numerous **DMC/DSMBs**.
- ▶ Worked with **5 of the top 20 pharma**.
- ▶ **Overflow** support for pharma and CROs.

Contact Us



Brenda Bishop
Director, Business Development
bbishop@EMBstats.com
913.322.6557
www.EMBstats.com

Please see other side for more information →

Data Management

- ▶ Certified Clinical Data Managers (CCDM)
- ▶ 25+ years average experience
- ▶ EDC or paper support

EMB Data Management Services:

- ✓ Protocol to CRF design
- ✓ Database design
- ✓ CDISC compliance (CDASH/SDTM)
- ✓ Data Management Plan (DMP)
- ✓ Data edit checks
- ✓ Coding (MedDRA and WHO Drug)
- ✓ External data import/transfers
- ✓ Database audit plan
- ✓ Data reconciliation
- ✓ Independent user acceptance testing (UAT)
- ✓ Custom reports

SAS Programming

- ▶ Statistics or math majors (PhD, MS, BS)
- ▶ 21+ years average experience
- ▶ Beginning-to-end perspective

EMB SAS Programming Services:

- ✓ SDTM specifications/programming
- ✓ ADaM specifications/programming
- ✓ Define.xml (or .pdf) generation
- ✓ CDISC validation and compliance
- ✓ Safety lab conversions/standardization
- ✓ TLF generation (appendix or in-text)
- ✓ ISS/ISE data integration (US and global)
- ✓ Data surveillance
- ✓ Adjudication support
- ✓ Patient profiles
- ✓ Custom software development

Statistical Analysis

- ▶ Doctorate- and master's-level senior staff
- ▶ 23+ years average experience
- ▶ Insightful and astute leadership

EMB Statistical Analysis Services:

- ✓ Power/Sample size estimation
- ✓ Protocol development
- ✓ Randomization (static or adaptive)
- ✓ Statistical Analysis Plan + mock TLFs
- ✓ Analysis (interim, final, meta, exploratory)
- ✓ PK/PD analysis and reporting
- ✓ Statistical writing (CSR, publications)
- ✓ ISS/ISE support for global submissions
- ✓ DMC/DSMB support (blinded or unblinded)
- ✓ IVRS/IWRS validation
- ✓ US/EU/Canada/Japan submission defense

Therapeutic Areas

Cardiology/Vascular Diseases	Genetic Disease	Nephrology/Urology	Plastic Surgery
Dentistry	Gynecology	Neurology	Psychiatry/Psychology
Dermatology	Hematology	Nutrition and Weight Loss	Pulmonary/Respiratory Diseases
Diagnostics	Hepatology	Oncology	Rheumatology
Endocrinology	Immunology/Infectious Diseases	Ophthalmology	Sleep
Gastroenterology	Musculoskeletal System	Otolaryngology	Surgical Interventions
		Pediatrics/Neonatology	Vaccines



Gold member