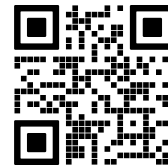


Powered by Experience

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



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Please see other side for more information →

Data Management

- ▶ **Certified Clinical Data Managers (CCDM)**
- ▶ **29+ years average experience**
- ▶ **Electronic data capture 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
- ✓ Data visualization and analytics
- ✓ Custom reports

SAS Programming

- ▶ **Statistics or math majors (Ph.D., M.S., B.S.)**
- ▶ **24+ years average experience**
- ▶ **Beginning-to-end perspective**

EMB SAS Programming Services:

- ✓ SDTM specifications/programming
- ✓ ADaM specifications/programming
- ✓ Define.xml and reviewers guides
- ✓ 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

Statistical Analysis

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

EMB Statistical Analysis Services:

- ✓ Early study planning
- ✓ 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 (protocol, CSR, publications)
- ✓ ISS/ISE support for global submissions
- ✓ DMC/DSMB support (blinded or unblinded)
- ✓ IRT validation
- ✓ US/EU/Canada/Japan submission defense

Therapeutic Areas

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



Gold member