Spaulding Clinical

Data Management and Biometrics

Biostatistics & Statistical Programming

- **Protocol Contribution**
  - Sample Size Calculation
- **Randomization Plan Creation**
- **SAP**
  - TLF Mocks
  - Complete Analysis
- **Creation of SDTM Compliant Datasets**
- **ADaM & TLF Creation**
- **Data Review Meeting**
  - Clinical, DM, Biostatistics, PK
- **eSUB Support**
  - SDTM aCRF
  - Define.xml
  - Reviewer's Guide

DATA MANAGEMENT AND BIOMETRICS FOR PHASES I–III

As regulatory requirements and the information they require become more complex, accurate, precise, and actionable data are more critical than ever. Spaulding Clinical has been 100% committed for almost 15 years to providing flawless data deliverables in a timely and fully integrated manner for Phase I through III clinical trials.

Our platform captures all forms of structured and unstructured data, giving you the flexibility and freedom to configure your data in a manner that best suits your study. With real-time results you can quickly and cost-effectively adjust reporting parameters as needed.

Absolute Precision From Data Management Experts

Spaulding Clinical uses a CDISC ODM certified eSource system, which supports clients in Phase I through III studies. The web-based, electronic data capture, data management, and eSource system supports real-time data entry and data viewing. Sponsors and monitors can review data immediately, preventing errors or breach of private health information (PHI).

Spaulding Clinical Data Management Advantages

- Accessible on any Chromium-based web browser (Google Chrome recommended)
- Real-time data entry and data viewing
- Eliminates most data entry and potential for transcription errors
- Integrated Pharmacy, Lab, and ECG Core Lab
- Supports multisite studies and decentralized trials
- Custom dashboards for following studies from remote locations
- CFR 21 Part 11 compliance through full audit trail
- ECG analysis and expert reports provided by world-renowned cardiologists
- Build time of 4-6 weeks vs. industry average 12 weeks

SPAULDING CLINICAL
First in Phase I

262-334-6020 | **spauldingclinical.com**

BIOMETRICS: ACCURACY BY DESIGN

Accurate reporting of clinical trial data starts with correct database design, data collection, and data analysis. Spaulding Clinical's biostatisticians, data managers, and other experts use industry-leading tools to efficiently manage the most complex projects and produce accurate data deliverables.

Data is exported and analyzed directly with Spaulding's SAS programming/services, resulting in time and cost savings.

Data Management

- **Project Management**
- **DMP & CRF Design**
- **EDC Database Design**
  - CDASH Compliant
- **External Data Management**
  - Labs, ECGs, PK
- **Data Validation**
- **Medical Coding**
- **Study Management & QC**

Spaulding Statistical Programming Quick Facts

- Each study assigned a dedicated biostatistician to contribute to the protocol
- All experts highly experienced in CDISC standards
- Analysis datasets developed to ADaM standards
- Fully annotated version of the Pinnacle21 (aka OpenCDISC) report outlining any discrepancies from the standard
- Statistical analysis plan (SAP) created that outlines the exact analysis needed for your study
- Design includes mock table, listing, and figures (TLFs) to match the shells outlined in the SAP

The Spaulding Difference

Spaulding Clinical delivers high-quality data faster than anyone in the industry. Our eSource system was designed by Spaulding Clinical to decrease the number of errors that occur in traditional data capture and management platforms. We support that high level of accuracy with expert biostatistical programming. Our experienced biostatisticians assist through all phases of your project, from sample size calculation to DMPK to electronic submission (eSub) to the FDA.

Taking You to the Next Milestone by Delivering Quality Data, Fast.

THINK SPAULDING FIRST

ABOUT SPAULDING CLINICAL RESEARCH

Founded in 2007, Spaulding Clinical is a full-service, state-of-the-art paperless Phase I clinical pharmacology unit. Our facility, originally a hospital, features fully integrated bedside electronic data capture and sets the standard for patient care. We specialize in IND-enabling clinical pharmacology studies, cardiovascular safety, and clinical proof of concept. We provide expertise on study design, offering in-house medical writing, clinical data management, biostatistics, project management, clinical laboratory, and PK/PD analysis. For high-quality data to inform your decisions, Think Spaulding First. To learn more, visit **spauldingclinical.com**.

SPAULDING CLINICAL
First in Phase I