



saransh inc.

Saransh Inc

Your Partner for Success in Drug Development



Saransh Inc provides unique yet comprehensive services tailored to optimize success in your drug development cycle. We have a track record with the pharmaceutical and biotechnology industries for providing high-value services in clinical data management, biostatistics, SAS programming, medical writing and regulatory affairs.

We focus on providing strategic value addition for startup to mid-size clinical project teams. Our diverse integrated delivery models allow us to recommend the model that segues most smoothly into your internal workflow. In the competitive and demanding world of drug development, you can count on Saransh Inc to be:

Reliable: Strict adherence to regulatory guidelines and principles forms the foundation of our regulatory-driven, cost-effective services

Efficient: Your timelines and budgets are internalized by our dedicated project management team

Innovative: We leverage our technical expertise to design data analysis and management systems that work for you through the drug discovery process

Nimble: We have an insider's perspective on the fluid nature of drug development, and are experienced in handling mid-cycle adaptations

BioStatistics and SAS Programming

Accurate Analyses...Robust Programming...Extensive Experience



Saransh Inc biostatisticians and SAS programmers are committed to studying your data meticulously, developing optimal programming models and reporting your findings accurately. Project managers with extensive experience in all phases of clinical trials, and in multiple therapeutic areas, ensure that your project stays its course. Our specialization in end-to-end bioanalyses and reporting of preclinical and clinical data, coupled with our flexible and customizable delivery models, greatly augment your chances of success.

Saransh Inc biostatisticians and SAP programmers work with your internal team to optimize workflow. We leverage innovative technology to build you delivery models that reflect easy incorporation of data, accurate data interpretation, rigorously scrutinized datasets and comprehensible, compliant reports.

Our biostatistics and SAP programming teams:

- Develop intuitive and innovative statistical analysis plans
- Design and build optimal reporting metrics
- Analyze and interpret your pharmacokinetic/pharmacodynamic data
- Provide both interim and final statistical analysis and reporting
- Prepare reliable and accurate CRT and analysis datasets that comply fully with CDISC data models
- Author detailed integrated analyses for ISS/ISE submission to the FDA
- Recommend efficient design methodologies and recommend sample sizes that ensure randomization
- Provide broad-based consultancy for study design, protocol development and CRF design

Clinical Data Management

From Data Mining to Database Lock



The Saransh Inc data management team fully understands the role of a robust database in the success of your development cycle. Although we recommend end-to-end electronic data gathering, we can work with your paper based or electronic data to create database structures that lends themselves to high-quality data capture, analysis and reporting. Our data management team excels at Oracle Clinical, ClinTrial, iReview, EDC tools such as DKDE, and other industry-standard database-managing software. Working closely with your internals team, we strive to deliver on-schedule database lock. Robust database design and reusability has always been a cornerstone of our data management practice.

For top-notch data management, the Saransh Inc team will:

- Design, develop, install and configure databases customized to your needs
- Execute validation and derivation design enabling smooth, rapid regulatory reviews
- Author efficient database programming for fluid data integration between current and legacy databases
- Perform data migration, transformation and warehousing using innovative off-the-shelf or customized solutions
- Smooth workflow with user-friendly electronic data capture systems that manage broad data sourcing
- Set up reliable and accurate thesaurus and dictionary coding that maintain global and project specific standards
- Provide double key data entry for conversion of paper-based data to electronic data
- Create modules with versatile CRF design and CRF annotation which improve quality of data collected and increase efficiency of data analysis
- Perform accurate and extensive data extraction to build broad, robust, reusable databases

Medical Writing

Documents that Succinctly Speak for You



Thorough and concise documents are integral to smoother submissions and reduced cycle times. Saransh Inc' medical writing expertise spans the drug development cycle. We organize and prepare your reports and documents in accordance with regulatory guidelines and requirements. From comprehensive protocols, interim and final clinical study documents to regulatory reports, our writers work in close cooperation with both programming and project management teams.

For clean, error-free reporting that enables speedy submission and smooth approval, our medical writers:

- Document study protocol
- Write and format clinical study and integrated statistical reports
- Compile ISS/ISE packages
- Collate references from abstracts, manuscripts and journal articles
- Prepare presentations for marketing and regulatory support

Regulatory Submissions Guidelines are Paramount



We understand that regulatory compliance can make or break a development cycle. From initiation to delivery, we have earned client confidence by provide total programming support for your regulatory process, minimizing the chances for oversight or error. Our team works closely with your regulatory affairs department to ensure that all FDA (CDER) guidelines are adhered to, even within aggressive timeframes.

Our study models are created with compliance in mind. We prepare integrated summaries and regulatory submissions that undergo rigorous internal scrutiny to ensure that your study design withstands regulatory review. To this end, our services include:

- Data mapping of current/legacy Databases to CDISC SDTM (SDS v3.1)
- Annotation of the CRF using the transformed CDISC SDTM variables
- Development of data definition files and CRT tabulations for eSub/eCTD (Define.pdf, define.xml)
- Generation of SAS transport files for NDA submission
- Creation of integrated Clinical Data Repositories (for Safety and Efficacy)
- Development and validation services to comply with the FDA's CFR Part 11 guidance for electronic submissions

Training

Multiplying the Benefit



Saransh Inc training programs are tailored to bring the benefits of our skills and experience within our clients' reach. Our training modules are designed to encompass the business, clinical and technical aspects of clinical trials. Our certified training programs, delivered by trained professionals, are designed to be modular, keeping in mind the schedule and other internal constraints of your workforce.

Training modules are delivered in stepwise progression. Core modules cover the essentials of statistical analyses and system analysis planning. Participants receive a thorough grounding in designing and building efficient data management structures and models. Ancillary modules covering regulatory requirements, documentation guidelines and validation checking refresh the skills of your internal team and ensure a smoother workflow with external teams such as ours.

Our training programs hone and polish your internal skills in:

- Data analysis, SAS and statistical methodologies
- Conceptualizing and developing flexible, reusable, statistical analysis models and systems
- Devising robust, efficient data management systems
- Authoring documentation and collateral
- Performing quick validation checks
- Maintaining a focus on GCP/GLP guidelines and requirements

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