STATKING

Clinical Services

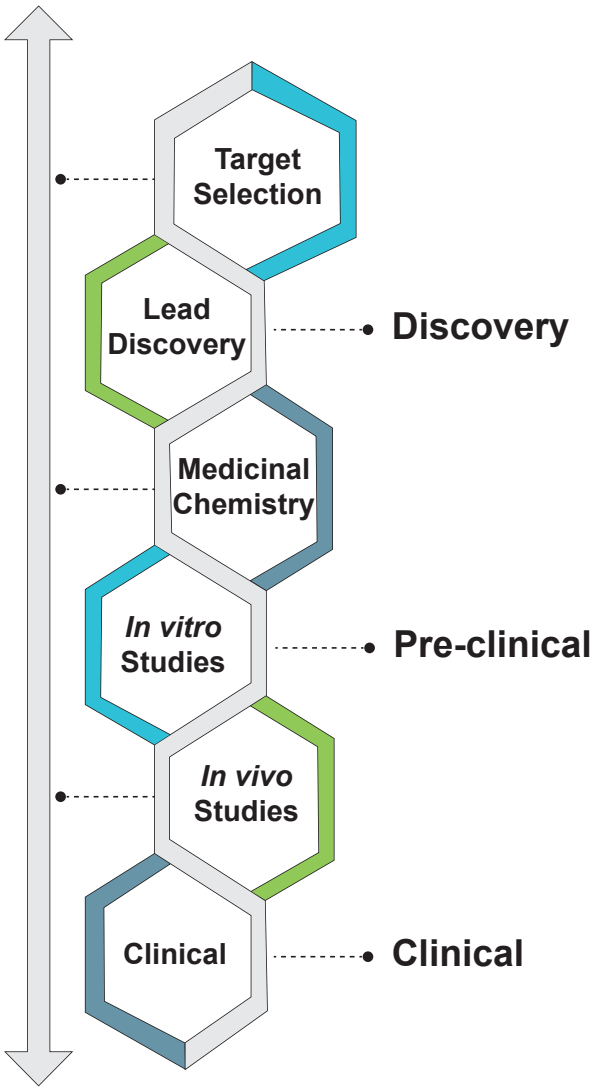
A GENESIS DRUG DISCOVERY & DEVELOPMENT COMPANY

OVERVIEW OF SERVICES

Genesis Drug Discovery & Development (GD³) is is a fully integrated CRO providing services to support drug discovery programs of our clients from target discovery through IND filing and managing Phase I-IV clinical trials. GD3 portfolio includes services for HTS and assay development, synthetic organic and medicinal chemistry, DMPK/in-vivo pharmacology and safety pharmacology, toxicology as well as clinical trial services for the regulatory approval of novel drug and medical device products.

GD³ Genesis
Drug Discovery & Development

- **Chemistry**
  - Venenum Biodesign Chemistry
  - NEDP New England Discovery Partners
  - BioBlocks
  - Organochem — Accelerate Your Business
- **Biology/ Bioanalytical**
  - ias integrated analytical SOLUTIONS
  - Venenum Biodesign Biology
  - Pharmoptima
  - Ingenio Diagnostics
- **Disease Modeling**
  - Invivotek
  - nexus pharma
- **Preclinical-Toxicology**
  - Comparative Biosciences Inc.
- **Clinical**
  - STATKING Clinical Services
  - JSS RESPONSIVE RELIABLE RESULTS



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STATKING Clinical Services

STATKING Clinical Services is proud of its over 30-year history of service to pharmaceutical and medical device industry clients. Since the company's founding in 1989, the company has evolved from providing statistical consulting and data analysis services on various household products to a full-service Contract Research Organization (CRO) serving the pharmaceutical and medical device industries.

The company's consistent growth over this period has been due to its ability to expand its services offering to meet the needs of STATKING's target market, emerging and mid-size pharmaceutical and medical device companies. The addition of clinical trial management services, clinical study monitoring services, medical coding software, electronic data capture services, medical writing, medical monitoring, and safety reporting services all provided solutions to problems and accelerated development timelines of STATKING's client companies.

Today, the company employs a staff of product development specialists heavily involved in all phases of the client's development program, including protocol development and study management tasks. STATKING's highly experienced team of professionals has been instrumental in achieving regulatory approval for many new medical devices, drugs, and biologics. At STATKING, our team is committed to providing services that meet or exceed all Federal Guidelines and Regulations for Good Clinical Practice.

Services

STATKING is a contract research organization (CRO) specializing in clinical trial services for the regulatory approval of novel drug and medical device products.

We provide expertise:

- Clinical Trial Management
- Biostatistics
- Clinical Data Management
- Statistical Programming
- Safety Database & Reporting
- Medical Writing
- Clinical Study Monitoring
- Medical Monitoring
- Clinical Project Management
- Management Data Monitoring Committee (DMC) & Data Safety Monitoring Board Management (DSMB)
- Clinical Event Committee (CEC) Management
- Full Phase I Services
- Statistical Consulting

We provide expertise in the following therapeutic areas:

- Oncology
- Central Nervous System (CNS)
- Diagnostics and Radiopharmaceuticals
- Cardiology
- Women's Health
- Orthopedics
- Gastrointestinal (GI)
- Respiratory/COVID-19
- Orphan Drug/Rare Disease Development
- This is not a comprehensive list. Call for details.

Clinical Trial Management

STATKING clinical trial managers provide independent, objective leadership. Their broad-based medical expertise offers scientific credibility for your trial. Their depth of knowledge allows your clinical trial to move forward smoothly and within the timelines.

STATKING trial managers have the following capabilities:

- Organization and Management of Sponsor Team Meetings
- Protocol Development
- Institutional Review Board (IRB) Submissions
- Trial Master File Administration and Updating
- Site Contracting and Payment
- Site ID and Recruitment
- Other Service Provider Contracting and Payment
- Planning and Conduct of Investigator Meetings
- Organization and Execution of Investigator Meeting
- Site Management
- Site Auditing
- Study Supply (Lab and other) Management
- Drug Supply Management

Biostatistics

STATKING's biostatisticians have the education and industry experience necessary to execute a data analysis strategy for your studies. Count on STATKING biostatisticians to provide the following services:

- Statistical Analysis Plans
- Randomization/Blinding Plans
- Interim Analyses/Interim Analysis Plans
- Efficacy and Safety Data Analyses
- Data Analyses/Meta-Analyses for INDs, IDEs, NDAs, 510Ks, PMAs, ANDAs and BLAs
- Stand Alone Statistical Reports
- Clinical Study Reports
- Meta-Analyses of Literature Studies
- Publications Support
- Prepare for and Attend FDA Meetings

Clinical Data Management

The clinical data management staff at STATKING is dedicated to creating a SAS® database for your study that contains the highest quality data. Our team of professionals has refined their processes to reduce your most valued data management metric, time to database lock. You can trust STATKING data management professionals to perform the following services for your studies involving electronic data capture (EDC) using Anju Software TriMaster® EDC Software:

- Source Document Development
- Database Design and Creation
- Development of Data Entry Screens
- Data Management Plan Creation
- Query Generation and Resolution
- Autoencoding Adverse Events
- Autoencoding Concomitant Medications
- Creation of CDISC SDTM and ADaM Datasets

STATKING provides the following clinical data management services for your paper-based trials:

- Development of Case Report Forms (CRFs)
- Printing/Assembly/Distribution of CRFs
- Data Management Plan Creation
- Data Entry Screen Design and Creation
- Database Design and Creation
- Double Data Entry
- Electronic Logic Check Programming
- Data Quality Assurance Checks
- Autoencoding Adverse Events
- Autoencoding Concomitant Medications
- Query Generation and Resolution
- Creation of CDISC Study Data Tabulation Model (SDTM) Datasets

Statistical Programming

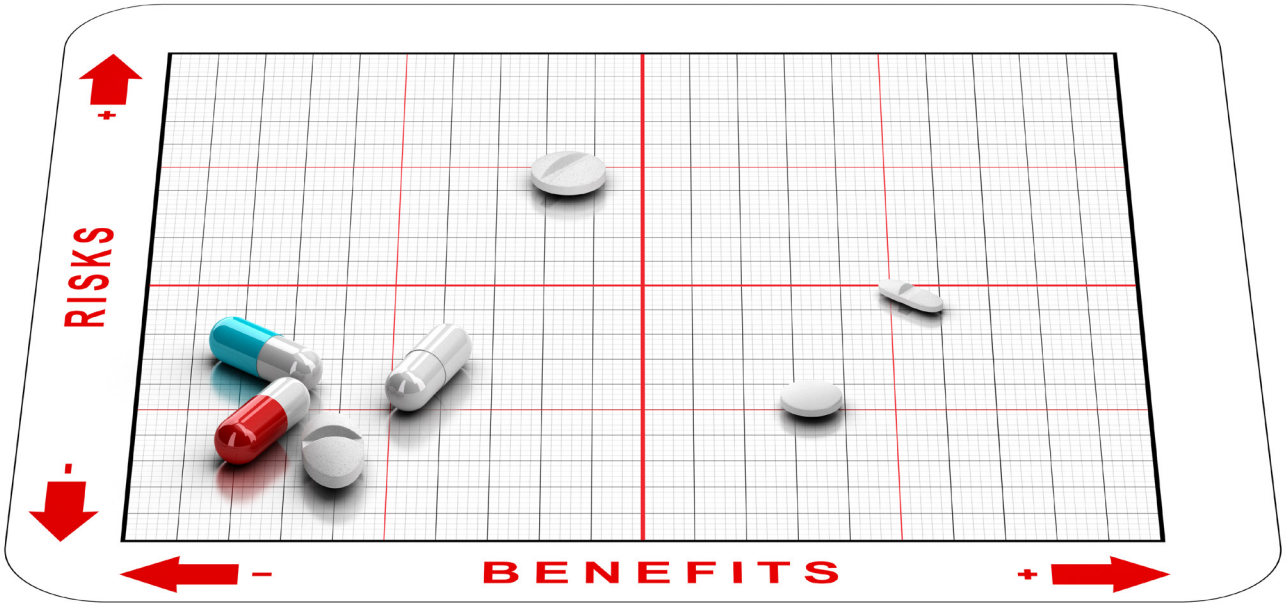
Having written hundreds of thousands of lines of validated SAS® code to analyze and display client's data, STATKING's statistical programmers are ready to produce tables, listings, and graphs for your studies. STATKING programmers are adept at creating data displays that are concise and easily reviewed by regulatory authorities. STATKING programmers provide the following services exclusively with SAS® software:

- SAS® Programming for Efficacy Tables, Listings and Graphs
- SAS® Programming for Safety Tables, Listings, and Graphs
- Electronic Document Integration
- SAS® Programming for Integrated Safety and Efficacy Summaries
- Investigational New Drug (IND) Safety Report Programming
- Interim Analysis Programming
- SAS® Programming Support for DMC/DSMB Tables, Listings, and Graphs

Safety Database & Reporting

STATKING medical personnel will work with your staff to provide the following drug safety reporting services:

- Safety Database Creation and Data Entry of Safety Data
- Serious Adverse Event (SAE) Narrative Writing
- SAE Follow Up with Study Sites
- Preparation of Med Watch 3500A/CIOMS forms
- Preparation of Periodic Safety Update Reports (PSURs)
- Electronic Submissions of SAEs to FDA



Medical Writing

STATKING medical writers work to integrate your trial's medical and statistical results into an electronic document that meets the client needs and regulatory requirements. The medical writer produces documents that the clients and the regulatory agencies find easy to review. STATKING medical writers provide the following services:

- Protocol Development
- Clinical Study Report Writing
- Writing Periodic Safety Update Reports
- Publications Support
- Integrated Summary of Efficacy (ISE) and Integrated Summary of Safety (ISS) Document Generation
- Writing:
    - o Clinical Development Plans
    - o Investigator Brochures
    - o Literature Reviews
    - o Clinical Evaluation Reports
- Electronic Document Control
- Document Management Services
- Writing Modules 2 and 5 of New Drug Application (NDA) and Biologics License Application (BLA) Submissions

STATKING document specialists prepare documents for publication or integration into larger submission documents. They convert components of the document into PDF format that includes pagination, bookmarking, and hyperlinking within the PDF document.

Clinical Study Monitoring

STATKING manages a network of internal and contract clinical research associates (CRAs) with experience in a broad range of therapeutic areas. Our CRAs understand your study and the importance of a professional relationship with investigators, site coordinators, and site personnel. STATKING CRAs obtain the highest quality data for your study by performing the following services:

- Site and Lab Pre-Study Qualification Visits
- Clinical Study Monitoring Plans
- Creation of Regulatory Binders
- Site Initiation Monitoring Visits
- Interim Monitoring Visits
- Drug/Device Accountability
- Close-out Monitoring Visits
- Clinical Study Monitoring Reports

Medical Monitoring

STATKING medical monitors provide the critical components of the safety monitoring plan for your study including input on medical coding, annual safety reporting to the regulatory agencies and review of safety-related documents.

- Providing Medical Expertise for Trial
- Answering Questions Pertaining to Patient Safety
- Reviewing Safety Related Documents
- Writing Safety Monitoring Plans
- Writing Annual Safety Reports
- Writing Annual Safety Report Updates
- Reconciliation of Clinical and Safety Databases

Clinical Trials Management

STATKING has a dedicated team approach to servicing your clinical study. STATKING clinical trial managers lead the team of professionals assigned to your project. They will move your project forward by communicating with all the project shareholders. STATKING clinical trial managers ensure processes follow FDA guidelines and internal SOPs. All STATKING clinical trial managers have medical training and backgrounds in clinical research. They utilize this expertise to provide insight to the client on decisions needed during the execution of a clinical trial. STATKING clinical trial managers service our clients by providing the following deliverables:

- Project Plans
- Project Progress Reports
- Meeting Minutes
- Project Timelines

DMC/DSMB Management

STATKING personnel will manage this critical component of your study that FDA and other regulatory bodies often require. Data Monitoring Committee (DMC) and Data and Safety Monitoring Board (DSMB) management services include:

- Contracting and Payment of DMC/DSMB Members
- Writing DMC/DSMB Charter
- Organization and Execution of DMC/DSMB Meetings
- Programming of Tables, Listings, and Graphs (TLG)s for Presentation at DMC/DSMB Meeting
- Preparation of Summary Documents for DMC/DSMB Review
- Archival of All DMC/DSMB Documentation

CEC Management

The FDA and other regulatory bodies require adjudication of adverse events for many medical device and drug studies. Clinical Event Committee (CEC) management services include:

- Contracting and Payment of CEC Members
- Writing CEC Charter
- Organization and Execution of CEC Meetings
- Tracking of Adverse Events to be Adjudicated
- Preparation of Summary Documents for CEC Review
- Creation of CEC Database
- Archival of All CEC Documentation

Full Phase 1 Services

STATKING provides full Phase I Study support services for pharmacokinetic (PK)-related clinical studies. Through partnerships with Genesis Drug Discovery and Development (GD^3) member companies and key service providers, STATKING now offers pharmaceutical clients the option of full Phase I study support. Full Phase I study support services include:

STATKING Services

- Protocol Development
- Randomization
- Biostatistics
- PK Modeling
- Clinical Study Monitoring
- Clinical Data Management (EDC & paper CRF's)
- CRF Design and Implementation
- Safety Reporting
- Medical Writing
- Project Management

Study Site Partner Services

- IRB Approval
- Pharmacy Support
- Patient Enrollment
- Study Execution
- Medical Monitoring
- Protocol Design
- ECG Services

Laboratory Services

- Clinical Laboratory Services
- Assay Laboratory Services

Statistical Consulting

- Sample Size/Power Calculations
- Experimental Design Consulting including Adaptive Designs
- Write Statistical Sections of Protocols
- Strategic Planning for Clinical Research Plans
- Consulting on Statistically Related Regulatory Issues
- Write Statistical Sections of Regulatory Submission Documents
- Write Interim Analysis Plans
- Service on Data Monitoring Committees and Data Safety Monitoring Boards
- Completion of FDA Pivotal IDE Description Forms
- Bayesian and Frequentist Data Analyses of Medical Device Trials
- Statistical Programming of TLGs for DMCs and DSMBs
- Stability Study Data Analysis and Reporting
- Sampling Plans for Validation Studies and Manufacturing Applications
- Development of Statistical Models for Diagnostic Devices
- Randomization Tasks

Company Management

Sarah Landenwitsch, MSPH
Managing Member

As Vice President & Managing Member, Sarah works with SCS directors to determine company priorities and coordinate Corporate Core Services Divisions, including Information Technology, Human Resources, and other GD3 member companies. Sarah joined SCS in 2008 and since that time has held various positions of increasing responsibility, including Data Manager, Statistical Programmer, Section Head for Statistical Programming, and Director of Statistical Programming and Data Management. Her specific areas of expertise are biostatistics, SAS programming, CDISC standards and EDC software programming. She is an accomplished SAS programmer who has written SOPs governing auditable SAS programming processes. She received her MS in Public Health in Biostatistics at the University of South Carolina in Columbia, South Carolina.

Tawanna Childs, MS
Director of Statistical Programming and Data Management

As Director of Data Management and Statistical Programming, Tawanna manages a team of Programmers and Data Managers, in accordance with SCS's Policies and procedures. Ms. Childs acts as a liaison between the team and clients to assist in the completion of projects. She identifies the training needs of individuals and assists with training in compliance with GCP and industry standards. Ms. Childs also creates test analysis datasets that are according to ADaM specifications. Tables, listings and figures are created according to a Statistical Analysis Plan as well as working with Statisticians to ensure correct methodologies are used in the analysis. She reviews the Data Transfer Agreement to ensure that external data received is correct and accurate. She also reviews Statistical Analysis Plans and Requirement Documents.

STATKING

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