San Diego, California, USA
619-788-8022
Silva@hyequalityconsulting.com
hyequalityconsulting.com

Core Values

- Collaborative
- Timely
- Strategic
- Driven

Database Experience

- Medidata RAVE®
- DATATRAK™
- Medrio
- TrialKit (formerly ClinStudio)
- IBM Merge
- Veeva Vault CDMS
- DataFax® and iDataFax®
- SynCapture™ (Synteract's proprietary EDC platform)

Silva Stoughton

Data Management Consultant

Introduction

Senior level clinical research professional with over 20 years of preclinical and clinical research experience. Extensive knowledge and experience in various data management systems and therapeutic areas. Able to lead all levels of data management activities, delivering quality, accuracy, and timeliness with professional service. Educated, experienced, and committed to Clinical Data Management and the advancement of clinical research.

Indication Experience

Advanced or Metastatic Solid Tumors, Relapsed and/or Refractory Multiple Myeloma, Recurrent High-Grade Glioma, Diabetic Foot Ulcers, Mountain Cedar pollen allergic sensitivity, Non-Small Cell Lung Cancer, Ocular Inflammation and Pain Following Cataract Surgery, Migraine, Basal Cell Nevus Syndrome, Molluscum Contagiosum, Relapsed or Refractory Acute Myeloid Leukemia, Retinitis Pigmentosa, Study Drug Bioavailability in healthy subjects.

Education

- Master of Science, Health Sciences
  Clinical Research Administration (Summa Cum Laude)
  Trident University International, Cypress, CA - Dec. 2013
- Associate of Science, Animal Health Technology
  Mesa College, San Diego, CA - June 2002
- Bachelor of Science, Biology
  San Diego State University, San Diego, CA - June 2000

Certification/Licensure

- Society of Clinical Data Management
  Certified Clinical Data Manager - Nov. 2016 - Present
- Graduate Certificate in Clinical Research Administration
  Trident University International, Cypress, CA - April 2009

Employment History

Owner/Clinical Data Management Consultant **January 2024 - Present**
Hye Quality Clinical Data Consulting Inc., San Diego, CA, USA

Services offered:

- Provide Data Management Oversight of CRO and accompanying vendors
- Partner / collaborate with sponsor for data management related activities
- Study lead data manager, leading data management staff and reporting to company leadership

Data Management Consultant **June 2021 - Present**
Insight Clinical Consulting, San Marcos, CA, USA

- Data Management Oversight, including budget review and tracking, adherence to contracts and timelines, oversight of data management support staff.
- Function as the interim or contract Head of Data Management, reporting to company leadership
- Present data management status updates in leadership team meetings
- Development of data management related Standard Operating Procedures
- Participation in protocol development and review
- Data Management Capabilities:
    - Author, review and approve Data Management documents such as: Data Management Plans, CRF Completion Guidelines, Data Transfer Agreements, Data Review Plans, User Acceptance Testing Plans
    - CDMS Implementation: protocol review, eCRF specifications, entry screen QC, edit check development, facilitation of database UAT, lab normal administration
    - Identify needed database updates for complex mid-study protocol amendments; create specification documents for needed updates; perform user acceptance testing of database modifications
    - Collaborate with data management programmers to develop custom data listings to be used for cross functional team review, in accordance with safety and protocol endpoints.
    - Develop data review plans to identify data abnormalities and outliers to ensure data quality and accuracy; including managing study team data review and query adjudication processes.
    - Manage external vendor data transfers and perform reconciliation
    - Maintain laboratory reference ranges and reconcile with the CRF lab data
    - Generate regular metrics reports and data listings for team review
    - Ensure proper execution of interim analyses within scope of the deliverable. Coordinate with the study team to achieve data cleanliness and meet timelines
    - Achieve successful database lock in accordance with data management and project related plans
    - Oversight of in-house and out-sourced data management activities
    - eTMF maintenance

Senior Clinical Data Manager — **March 2018 - June 2021**
Clinical Data Manager II — **September 2016 - March 2018**
Clinical Data Manager — **July 2013 - September 2016**
Senior Clinical Data Coordinator — **July 2008 - July 2013**
Synteract Inc., San Marcos, CA, USA

- Database development activities including protocol review, CRF development, database design, IRT integration, Edit Check specification, ePRO/eCOA integration, Targeted SDV implementation, medical coding and CRF Completion Guidelines
- Responsible for development of Data Management Plan specific to each project
- On-board and mentor new data management personnel on EDC systems throughout the course of a study from database build to database close
- Train data management personnel how to train end users in EDC systems (site staff, CRAs, sponsor, etc.)
- Review and author work instructions to assist internal and external users when using EDC platforms
- Responsible for all aspects of clinical database development, maintenance and closure for multiple complex projects
- Present software demonstrations and/or study specific CRF instructions at sponsor meetings and capabilities presentations
- Provide EDC system training to sites, CRAs and sponsors
- Data Management lead for rescue studies that required creative thinking and sharp problem solving skills to quickly satisfy the needs of the client and the studies
- Collaborate with the secondary data managers and data management support personnel on studies to ensure quality, timeliness and efficiency
- Define and validate logical edit checks for data quality control
- Provide CRF and database training to study team
- Maintain and clean study database by verifying data entry and processing edit checks and query resolutions
- Produce SAS reports and listings, as requested by study sponsor
- Receive external electronic data, reconcile external data with CRF data and work with vendor to resolve discrepancies
- Maintain laboratory reference ranges and reconcile with CRF laboratory data
- Work with sites and CRAs to resolve all data discrepancies, prior to database lock
- Create patient profiles to check all critical data points
- Ensure that all study documentation is complete and accurate
- Develop specifications and quality control of Medidata Imaging Module
- Communicate with cross functional groups and stakeholders throughout the project lifecycle
- Data Management training presentations at Investigator Meetings
- Patriciate in Business Development presentations and bid development, serving as a subject matter expert
- Create agendas and communication materials for study team meetings and training.
- Attend all study-related meetings
- Plan and lead Data Review meetings prior to interim analyses and database lock

Preclinical Drug Development Associate **March 2008 - June 2008**
Acadia Pharmaceuticals, San Diego, CA, USA

- Organize and review preclinical study documents for quality assurance and maintenance of contract files
- Perform quality control of preclinical study reports and clinical trials Investigator's Brochure
- Manage preclinical Common Technical Document data entry for NDA submission
- Understand the drug development process with knowledge of preclinical safety and clinical trial studies with working knowledge of GLP, GCP, FDA and ICH regulations

Research Associate III, In Vivo Pharmacology **January 2004 - February 2008**
TargeGen, Inc., San Diego, CA, USA

- Design and implement in vivo models in support of early phase drug discovery.
    - Therapeutic areas of study: oncology, rheumatoid arthritis, hind limb edema, ocular, pulmonary, cardiovascular, asthma, toxicology, and pharmacokinetic studies
- Document study results and utilize graphing software to analyze and interpret results for future study planning and optimization of model design
- In-vitro assays
- Microscopic tissue analysis
- Collaborate with other internal research teams for full study write up
- Present data at team and company meetings
- Utilize computer software such as Microsoft Word, Excel, PowerPoint, and graphing software

Research Associate **June 2002 - Jan 2004**
Androclus Therapeutics, San Diego, CA, USA

- Design and perform in vivo models in support of early phase drug discovery.
    - Therapeutic areas of study: rheumatoid arthritis, experimental autoimmune encephalomyelitis and inflammatory bowel disease
- Perform in vitro assays to include cell isolation from animal tissue, cellular staining, tissue culture, flow cytometry and immunological assays

Publications

Hydrolysis of a novel topically delivered AMD pro-drug TG100801 in ocular tissues and plasma. Author Block: Steven Hu, Shiyin Yee, Adrienne Racanelli-Layton, Juliet Chin, Silva Stoughton, Ahmed Kousba, Jann Key, Jana Yu, Arek Tabak, Luis Dellamary, and Rich Soll, TargeGen, Inc. 9380 Judicial Drive, San Diego, CA 92121. (2007)

Discovery of [7-(2,6-dichlorophenyl)-5-methylbenzo[1,2,4]triazin-3-yl]-[4-(2-pyrrolidin-1-ylethoxy) phenyl] amine – a potent, orally active src kinase inhibitor with anti-tumor activity in preclinical assays. Glenn Noronha, Kathy Barrett, Antonio Boccia, Tessa Brodhag, Jianguo Cao, Chun P. Chow, Elena Dneprovskaia, John Doukas, Richard Fine, Xianchang Gong, Colleen Gritzen, Hong Gu, Ehab Hanna, John D. Hood, Steven Hu, Xinshan Kang, Jann Key, Boris Klebansky, Ahmed Kousba, Ge Li, Dan Lohse, Chi Ching Mak, Andrew McPherson, Moorthy S.S. Palanki, Ved P. Pathak, Joel Renick, Feng Shi, Richard Soll, Ute Splittgerber, Silva Stoughton, Suhan Tang, Shiyin Yee, Binqi Zeng, Ningning Zhao, Hong Zhu. Organic & Medicinal Chemistry Letters. 2007. 17(3): 602-608.

Discovery and preliminary structure--activity relationship studies of novel benzotriazine based compounds as Src inhibitors. Author Block: Glenn Noronha, Kathy Barrett, Antonio Boccia, Tessa Brodhag, Jianguo Cao, Chun P. Chow, Elena Dneprovskaia, John Doukas, Richard Fine, Xianchang Gong, Colleen Gritzen, Hong Gu, Ehab Hanna, John D. Hood, Steven Hu, Xinshan Kang, Jann Key, Boris Klebansky, Ahmed Kousba, Ge Li, Dan Lohse, Chi Ching Mak, Andrew McPherson, Moorthy S.S. Palanki, Ved P. Pathak, Joel Renick, Feng Shi, Richard Soll, Ute Splittgerber, Silva Stoughton, Suhan Tang, Shiyin Yee, Binqi Zeng, Ningning Zhao, Hong Zhu. Organic & Medicinal Chemistry Letters. Nov 1, 2006. 16(21): 5546-5550.

References

Available upon request