KIMBERLY (SPENCER) ROESCH

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Eko Clinical Data Management
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Core Professional Values

Committed Accountable Organized Communicative Meticulous

Introduction

Dedicated clinical data management professional with 15+ years comprehensive experience in the biotech industry working on Phase I-IV and Non-Interventional Trials. Provides exceptional quality, strong leadership, and timely and concise communication on behalf of sponsor companies and CROs. Proven history of exemplary relationships with study sponsors, resulting in repeat requests to work on consecutive trials. Highly experienced in data review, vendor management, CRO oversight, and document/specification preparation. Expertise in the design, testing, management, cleaning, and locking of clinical study databases. Comprehensive understanding of CDISC/CDASH industry standards, Good Documentation Practices, and Good Clinical Data Management Practices.

Indication Experience

Nerve Function Restoration; Diabetes; Cushing's Syndrome; Polymyalgia Rheumatica; Oncology; Solid Tumor Malignancies; Breast Augmentation; Covid-19; Non-Hodgkin's Lymphoma; Psoriatic Arthritis; Scar Development, Evolution, and Resolution; Ventricular Dysfunction; Rheumatoid Arthritis; Opioid Dependency; Joint Osteoarthritis; Lymphoma; Sjögren's Syndrome; Epilepsy

Pain efficacy studies in patients undergoing Ventral Hernia Repair, Total Knee Arthroplasty, Bunionectomy, Complete Abdominoplasty, Wisdom Tooth Extraction, Post-Operative Narcotic Therapy

Clinical Data Management Database Experience

- Medidata RAVE
- Single Interface
- Viedoc
- Zelta
- Medrio
- Oracle Inform
- Veeva
- Axiom Real-Time Metrics
- DATATRAK
- TrialMaster
- DataLabs
- ClinSpark
- DataFax
- TrialKit

Employment History

Clinical Data Management Consultant — *Bethesda, MD* — *Solaxa Inc.*
Apr 2026 – present

- Manage out-sourced data management activities for ongoing clinical trials.
- Provide CRO Oversight.
- Oversight of eCRF and edit check specifications.
- Data maintenance, including but not limited to: query applications/resolutions, data/SAS listing reviews oversight.
- Oversight of study plan developments: Data Management Plans, Data Review Plans, and eCRF Completion Guidelines.
- Vendor Management.
- Oversight of reconciliations: external data and SAE reconciliations.

Clinical Data Management Consultant — *Portland, OR* — *Sparrow Pharmaceuticals*
Feb 2023 – July 2026

- Manage in-house and out-sourced data management activities for ongoing clinical trials.
- Provide CRO Oversight.
- Oversight of database developments, eCRF and edit check specifications.
- Data maintenance, including but not limited to query applications/resolutions, data/SAS listing reviews, and data cleaning strategies & development.
- Oversight of study plan developments: Data Management Plans, UAT Plans, Protocol Deviation Plans,
- Data Review Plans, and eCRF Completion Guidelines.
- Vendor Management.
- Oversight of reconciliations: external data and SAE reconciliations.

Clinical Data Management Consultant — *San Marcos, California* — *Zogenix Inc and Mirati Therapeutics on behalf of Insight Clinical Consulting*
Feb 2021 – Feb 2023

- Data review (hands-on and oversight): UAT Testing, Cross-Function Team Reviews, Data Cleaning.
- Provide CRO Oversight.
- Support database builds.
- Create and/or review data management documentation, including but not limited to: data management plans, data quality review plans, CRF completion guidelines, annotated CRFs, and edit check specifications.
- Support CRF development in accordance with CDASH standards.
- Support successful database development and execute database UAT.
- Develop and implement the data correction process, discrepancy resolution, data control activities, and data validation.
- Review and clean data in support of accurate data reporting.
- Manage in-house and out-sourced data management activities for ongoing clinical trials.
- Develop Controlled Documents, Work Instructions, and Templates.
- Clean and lock data in support of interim analyses and submissions.
- Proactively manage timelines and projections.
- Communicate with cross functional groups throughout the project lifecycle.
- Proactively participate in appropriate sponsor/project team meetings.

Clinical Data Manager *Pasadena, California* *Lotus Clinical Research*
Oct 2015 – Feb 2021

- Build and maintain data standards for clinical trials.
- Assist with study start up, including protocol review, case form design, database design, data specifications, data transfer specifications, and review of data management and handling plans.
- Develop and implement the data correction process, discrepancy resolution, data control activities, and data validation.
- Support clinical trial studies from preparation through closeout, including regulatory submissions by standardizing data management.
- Ensure documentation and management of clinical study data is in accordance with regulations.
- Proactively coordinate and perform start-up, processing and finalization activities as detailed in Lotus SOPs.
- Proactively manage timelines and projections.
- Proactively manage project quality through supervision and Quality Control of team members' work.
- Participate in reviewing and responding to QA audit reports.
- Proactively participate in appropriate sponsor/project team meetings.
- Lead and/or participate in User Acceptance Testing for projects.
- Actively participate in departmental and organizational meetings and initiatives.
- Assist with development and documentation of department procedures.
- Participate in the review of cross functional department procedures.
- Train and mentor team members in accordance with established departmental procedures.
- Proactively coordinate and perform start-up, processing and finalization activities as detailed in Lotus SOPs.
- Create study documentation and obtain signatures via DocuSign.
- Communicate with cross functional groups throughout the project lifecycle.
- Monitor project scope and alert team to any risk areas.
- Maintain key vendor relationships such as EDC System Vendor, Statistical Group etc.

Clinical Data Coordinator *Carlsbad, California* *Synteract, Inc.*
Aug 2010 – Oct 2015

- Design case report forms for data collection.
- Develop data management plan and QA program.
- Define, validate, and document logical edit checks for data quality control.
- Respond to inquiries and provide guidance to data entry personnel to ensure accuracy of data.
- Ensure completion of a comprehensive data review.
- Verify data entry, process edit checks and data clarifications.
- Communicate with the study Sponsor as needed regarding data/database issues. Respond to any
- requests or needs of the Sponsor during the course of their study.
- Understand the sequence of running programs to ensure up-to-date data and to troubleshoot problems.
- Produce reports, listings and others as required.
- Create patient profiles to check all critical data points.
- Ensure medical coding is performed in a timely manner, as directed by the Data Management Plan.
- Receive electronic data and prepare it for use by Programming/Stats. Interact with vendors to resolve discrepancies.
- Ensure that all study documentation is complete, accurate and reviewed by the appropriate personnel.
- Conduct and document the database closeout.
- Provide training and guidance to other data management personnel.