KIMBERLY (SPENCER) ROESCH

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Eko Clinical Data Management
www.ekocdm.com

Core Professional Values

Committed Accountable Organized Communicative Meticulous

Introduction

Dedicated clinical data management professional with 12+ 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. 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

Advanced Cancers; 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®
- Medrio
- Oracle Inform
- Veeva
- Axiom Real-Time Metrics
- DATATRAK™
- TrialMaster®
- DataLabs
- SynCapture™
- DataFax® and iDataFax®
- TrialKit

Education

- Aug 2006 – May 2007
  Studies in Elementary Education at Flagler College, St. Augustine, FL USA
- Sep 2008 – Jun 2009
  Studies in Social Work at Harrisburg Area Community College, Lancaster, PA USA

Employment History

Owner/Clinical Data Management Consultant *San Diego, California* *Eko Clinical Data Management*
Sep 2022 – present

- Database development, eCRF and edit check specifications
- Data maintenance, including but not limited to: query applications/resolutions, data/SAS listing reviews, metric reporting, and data cleaning strategies & development
- Study plan developments: Data Management Plans, UAT Plans, Protocol Deviation Plans, Data Review Plans, and eCRF Completion Guidelines.
- Vendor Management.
- Reconciliations: External data and SAE reconciliations.
- Data Review Oversight: UAT Testing, Cross-Function Team Reviews, CRO Oversight

Clinical Data Management Consultant *San Marcos, California* *Insight Clinical Consulting*
Feb 2021 – present

- 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.
- Proactively coordinate and perform start-up, processing and finalization activities as detailed in Insight SOPs.
- Communicate with cross functional groups throughout the project lifecycle.
- Proactively manage project quality though supervision and Quality Control of team members' work.
- 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 though 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.*
May 2012 – Oct 2015

- Assists in the designing or directing of the design of a Case Report Form for data collection.
- Assists in the development of a data management plan and QA program, which will be approved by the
- sponsor.
- Assists in the design, or directs the design of, an efficient logical database using Synteract standards or the Sponsor's specifications, which can be exported efficiently into SAS.
- Defines, validates, and documents logical edit checks for data quality control.
- Responds to inquiries and provides guidance to Data Entry personnel to ensure accuracy of data.
- Ensures completion of a comprehensive data review.
- Verifies data entry, processes edit checks, resolutions and data clarifications.
- Communicates with the study Sponsor as needed regarding data/database issues. Responds to any
- requests or needs of the Sponsor during the course of the study.
- Understands the sequence of running programs to ensure up-to-date data and to troubleshoot problems.
- Produces reports, listings and others as required during the course of the study.
- Exports data from the clinical database to update the SAS database.
- Creates, or directs the creation of, patient profiles to check all critical data points.
- Ensures medical coding is performed in a timely manner, as directed by the Data Management Plan.
- Receives electronic data and prepares it for use by Programming/Stats. Interacts with vendors to resolve discrepancies.
- Ensures that all study documentation is complete, accurate and reviewed by the appropriate personnel.
- Ensures that the DM Study Binder is kept up-to-date.
- Conducts and documents the database closeout, reviews patient profile findings, provides 10% QC results
- to the study sponsor and Synteract executive personnel.
- Provides training and guidance to other Data Management personnel.

Clinical Data Management Assistant *Carlsbad, California* *Synteract, Inc.*
July 2011 – May 2012

- Assists in the designing or directing of the design of a Case Report Form for data collection.
- Assists in the development of a data management plan and QA program, which will be approved by the
- sponsor.
- Assists in the design, or directs the design of, an efficient logical database using Synteract standards or the Sponsor's specifications, which can be exported efficiently into SAS.

- Defines, validates, and documents logical edit checks for data quality control.
- Responds to inquiries and provides guidance to Data Entry personnel to ensure accuracy of data.
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- Provides training and guidance to other Data Management personnel.

Clinical Data Processor *Carlsbad, California* *Synteract, Inc.*
Jun 2010 – Jul 2011

- Accurate entry of clinical data or codes exactly as written on the Case Report Form or the Case Report Form image.
- Follow an assigned list of Data Conventions which detail the protocol of the entry/query process for a particular clinical study.
- Visual verification of clinical data: flag and make note of any illegible, misspelled or incorrectly entered data.
- Assist the Clinical Data Manager in the QC of data by reviewing patient profiles.
- Assist the department with copying, stamping and filing.
- Assess unreadable documents in the DataFax Router and route them to the appropriate study id number and/or personal fax view.
- Conducts and documents the database closeout, reviews patient profile findings, provides 10% QC results to the study sponsor and Synteract executive personnel.
- Provides training and guidance to other Data Management personnel.