

## OBJECTIVE

To obtain a role in clinical data management, overseeing clinical trials for a CRO or sponsor company.

## CONTACT

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## PROFESSIONAL VALUES

- Committed
- Accountable
- Organized
- Communicative
- Meticulous

## EDC EXPERIENCE

- Medidata RAVE
- Viedoc
- Zelta
- Veeva
- Medrio
- Oracle

## SKILLS

- Database Builds/UAT
- Development of:
  - eCRF/Edit Check Specifications
  - eCRF Completion Guidelines
  - Study Plans
- CRO/Vendor Oversight
- Data Reconciliations
- Bid Defense Support
- Protocol Review
- Development of Data Cleaning Strategies
- SAE Reconciliation

# Kimberly Roesch

## CLINICAL DATA MANAGEMENT CONSULTANT

Dedicated professional with 15+ years comprehensive experience in the biotech industry working on Phase I-IV clinical 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.

## EXPERIENCE

### CLINICAL DATA MANAGEMENT CONSULTANT SPARROW PHARMACEUTICALS

Feb 2023 - Present

Managed in-house and out-sourced data management activities for ongoing clinical trials. Provided CRO oversight including database developments, eCRF/edit check specifications, and study plans. Managed multiple study vendors and reconciliations.

### CLINICAL DATA MANAGEMENT CONSULTANT INSIGHT CLINICAL CONSULTING

Feb 2021 – Feb 2023

Provided CRO and data review oversight. Supported database builds and data migration. Created data management documents. Reviewed and cleaned data in support of accurate data reporting. Developed SOPs, work instructions, and templates.

### CLINICAL DATA MANAGER LOTUS CLINICAL RESEARCH

Oct 2015 – Feb 2021

Built and maintained data standards for clinical trials. Assisted 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. Developed and implemented the data correction process, discrepancy resolution, data control activities, and data validation. Supported clinical trial studies from preparation through closeout, including regulatory submissions.

### CLINICAL DATA COORDINATOR SYNERACT, INC.

Jun 2010 – Oct 2015

Directed the design of study CRFs and an efficient, logical database using CRO and/or sponsor standards and specifications. Reviewed and provided feedback on coding, external data reconciliations, and data entry. Provided training and guidance to other data management personnel. Produced reports, metrics, and listings to study team members.