

Contact

www.linkedin.com/in/nikta-karimi-ms-dba-88781569 (LinkedIn)

Top Skills

Healthcare
Research
Clinical Research

Languages

English (Full Professional)
Farsi (Native or Bilingual)
Kurdish (Native or Bilingual)

Nikta Karimi, MS, DBA

Principal Clinical Data Manager Consultant at Moderna
Boston, Massachusetts, United States

Summary

Clinical Data Manager and Research Database Administrator with deep experience in leading and managing data management teams and activities (eCRF specifications, edit check specifications, UAT, custom report specifications) for assigned EDC studies. Particular strength in managing vendors, ensuring deliverables are timely and of high quality; participated in multiple vendor audits assuring compliance with regulations and sponsor requirements. Strong budget/cost management skills and experience in contracting. Experience with multiple CDMs such as EDC, Clintrak, Oracle Clinical and Medidata RAVE.

Experience

Moderna

Principal Clinical Data Manager Consultant

July 2020 - Present (3 years)

Cambridge, Massachusetts, United States

Imaging Endpoints

Principal Clinical Data Manager

July 2019 - July 2020 (1 year 1 month)

Waltham Massachusetts

Execute as Lead CDM and oversee data management project deliverables for all imaging studies in clinical trials in accordance with project scope of work and within sponsor specified timelines including but not limited to:

- o Data Management Plan
- o Data Validation Plan
- o Data Transfer Specification
- o Analysis Report (IEAP), Analysis and Final Study Reports, as applicable
- Provide and oversee the data management input into the following as necessary/applicable:
 - o Image Review Charters
 - o Central Reader Rules (and other reader training material)
 - o Central reading/image analysis platform design/specifications

- o Analysis Report (IEAP), Analysis, and Final Study Reports, as applicable
- o Study Protocols
- o Clinical Case Report Forms
- Provide and oversee the training to Data Management staff to ensure the development and maintenance of staff competence on data management including but not limited to:
 - o Project-specific Image Review charter/Reader Rules
 - o Image analysis platform
 - o Protocol-specific assessment criteria
 - o Creation of Data Management Documents
 - o Project Management of Data Management tasks and deliverable
 - o Monitor/evaluate data to ensure compliance with protocol, IRC, and Data Management documents.

Abiomed

Clinical Data Manager and Research Database Administrator

April 2013 - July 2019 (6 years 4 months)

Danvers, MA

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Genzyme Inc.

Lead Data Manager

April 2012 - April 2013 (1 year 1 month)

Cambridge, MA

Manage databases and provide reporting with a high degree of confidentiality for Federal and State Funded drug assistance programs/grants. Extensive data reporting, oversight of technical consultants. Experience overseeing 3-5 direct reports, providing training and mentorship and reviewing grant proposals. Delegate data based on self-evident corrections

Spectrum Pharmaceutical

Manager Clinical Data Management

April 2011 - April 2012 (1 year 1 month)

Irvine, CA

Education

National University

· (2007 - 2010)

University of California, San Diego

Bachelor's Degree, Biochemistry and Molecular Biology · (1996 - 1999)