

## Shaheer Shafiq

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### WORK EXPERIENCE

#### **Assistant Manager Data Operations**

Metrics Research Pvt Ltd

*(October 2023 - Present)*

- Planned and managed data management activities for multiple clinical trials simultaneously.
- Led the development and implementation of data management plans.
- Ensured the accuracy, completeness, and integrity of clinical trial data.
- Oversaw data collection, entry, validation, and storage processes.
- Developed and maintained standard operating procedures (SOPs) for data management.
- Designed case report forms (CRFs), cleaned data, generated CRF instructions, and managed data transfer agreements (DTA).
- Enhanced EDC tool functionality and security, coordinated with developers for advanced feature development, customized system settings, and ensured data protection.
- Developed data backup and recovery strategies, conducted regular tests, and ensured data integrity at project completion.
- Collaborated in data extraction, transformation, and loading (ETL) processes; supported report and dashboard creation for data-driven insights.
- Conducted data accuracy audits, compliance checks with study protocols, and implemented quality assurance processes.
- Managed updates and enhancements for all systems, troubleshooting issues, and executing system improvements.
- Delivered training on EDC, LMS, and CTMS systems, and provided ongoing technical support and troubleshooting.
- Maintained compliance with HIPAA, GDPR, and other regulations; implemented data governance and standard operating procedures.
- Actively worked with the clinical operations team in the execution and completion of medical writing projects, including writing manuscripts, systematic reviews, and meta-analyses.
- Engaged with external stakeholders as a BD person and sought partnerships with different companies to find new tools for data acquisition.
- Managed Learning Management System including course creation, user access control, and content updates; collaborated with trainers for effective utilization.
- Led the setup and oversight of the Clinical Trial Management System, ensuring data accuracy, protocol compliance, and efficient EDC integration.
- I have also been engaged in writing and implementing different SOPs for the company.
- Involved in data management procedures like data collection, data base set up, data cleaning, analysis and statistical analysis.

#### **Clinical Project Manager**

Hekma Inc. CA. USA

*(June 2023 - October 2023)*

- Assisted in the design and development of clinical research software solutions, including electronic data capture and clinical trials management systems, collaborating closely with developers to meet specific research needs.
- Engaged in data mining and data mapping for health-tech software products, contributing to the training of AI models to enhance product functionality and user experience.
- Skilled in grant writing, successfully securing funding for various health-tech initiatives and clinical research projects.

- Played a key role in clinical business development, identifying new opportunities, and fostering strategic partnerships to drive growth and innovation.
- Led clinical project management, efficiently coordinating resources, timelines, and teams to ensure project success and adherence to clinical standards.
- Ensured strict compliance with Good Clinical Practice (GCP) and HIPAA regulations, maintaining high standards of data privacy and ethical conduct in all clinical research activities.

## **Project Manager Level II (Sr.CRA)**

OIRRC Inc. CA. USA

*(October 2021 - June 2023)*

- Assisted project managers in the design, execution, and monitoring of Phase 1, 2, and 3 clinical trials at Ocular Imaging Research and Reading Centre, CA, USA, ensuring adherence to trial protocols and timelines.
- Actively participated in trial-specific and organizational training, ensuring all activities were conducted in compliance with Good Clinical Practice (GCP) and organizational policies and Standard Operating Procedures (SOPs).
- Collaborated with project managers and clinical science teams in data management tasks, including source data verification and comprehensive data analysis.
- Supported the clinical science team in the development of trial protocols, Informed Consent Forms (ICFs), Case Report Forms (CRFs), and other essential study support materials.
- Facilitated global site management activities encompassing site feasibility assessments, site initiation, activation, and training of trial teams, thereby enhancing trial efficiency and site performance.
- Built **eSource/eCRF** from protocols/SOA: visit schedules, **branching logic**, **edit checks**, ranges; authored CRF completion guidance.
- **CTMS setup** end-to-end: study/site creation, calendars, **CTMS-only visit schedules**, task lists, document checklists, alerts.
- Ran **post-build QC & UAT** for eSource/CTMS workflows; handled lock/unlock, versioning, and amendment rollouts.

## **Research Assistant**

National University of Sciences & Technology

*(September 2020 - October 2021)*

- Developed and characterized liposomes using techniques such as Scanning Electron Microscopy (SEM), Fourier-Transform Infrared Spectroscopy (FTIR), Zeta Potential Analysis, and X-Ray Diffraction (XRD).
- Conducted cell culturing and in vitro testing assays, including MTT assays, to evaluate cellular responses and interactions.
- Performed in vivo testing on rats and mice, adhering to ethical standards and protocols for animal research.
- Conducted biochemical and histopathological analyses to assess tissue and organ responses to treatments.
- Engaged in sequence data retrieval, sequence alignments, protein modeling, and refining, applying advanced bioinformatics tools and methods.
- Performed DNA/RNA extraction, Polymerase Chain Reaction (PCR), Gel Electrophoresis, and concentration assessment using Nanodrop.
- Wrote scientific abstracts and conducted lab demonstrations for undergraduate students, fostering their understanding of complex scientific concepts and techniques.

## **EDUCATION**

**MS Industrial Biotechnology**

Islamabad, Pakistan

National University of Sciences & Technology

(September 2019 – May 2022)

### **BS Biochemistry**

*PMAS-Arid Agriculture University  
(October 2015 – July 2019)*

Rawalpindi, Pakistan

## **TRAINING & CERTIFICATIONS**

- OIRRC CRO Standard Operating Procedures  
*Ocular Imaging research and reading center, CA, USA.*
- NIDA-GCP  
*The National Institute of Health*
- Certified Clinical Research Professional (CCRP)  
*Metrics Research Pvt Ltd – Kriger research group international*
- Getting Started with SAS Programming  
*SAS – Coursera*
- AWS Cloud Technical Essentials  
*AWS- Coursera*
- E6 (R3)  
*Metrics Research Pvt Ltd*
- Privacy Law and HIPAA  
*University of Pennsylvania - Coursera*

## **Publications**

### **Published**

- Shafiq, S., Abduh, M. S., Iqbal, F., Kousar, K., Anjum, S., & Ahmad, T. (2024). A novel approach to insulin delivery via oral route: Milk fat globule membrane derived liposomes as a delivery vehicle. *Saudi Journal of Biological Sciences*, 103945. <https://doi.org/10.1016/j.sjbs.2024.103945> (IF: 4.4)
- Kousar, K., Shafiq, S., Sherazi, S. T., Iqbal, F., Shareef, U., Kakar, S., & Ahmad, T. (2024). In silico ADMET profiling of Docetaxel and development of camel milk derived liposomes nanocarriers for sustained release of Docetaxel in triple negative breast cancer. *Scientific Reports*, 14(1), 912. <https://doi.org/10.1038/s41598-023-50878-8> (IF: 4.9)
- Riaz, R., Shafiq, S., Fatima, M., Siddique, M. A., Shah, S., & Abbas, S. R. (2024). Contrast efficacy of novel phase convertible nanodroplets for safe CEUS imaging. *Saudi Journal of Biological Sciences*. <https://doi.org/10.1016/j.sjbs.2024.103945> (IF:4.4)

## **Conference Presentations**

- Riaz, R., Shafiq, S., Fatima, M., Siddique, M., Shah, S., & Abbas, S. R. (2023, March 26). In vivo safety evaluation and contrast enhancement of novel elastomer-based phase convertible nanobubbles as echocardiographic contrast agents. Paper presented at ACS Spring 2023 Crossroads of Chemistry, Indianapolis, IN and hybrid. Retrieved from <https://acs.digitellinc.com/speakers/view/341229>

The information in the above CV is true to the best of my knowledge.

Signature: \_\_\_\_\_ Date: \_\_\_\_\_

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