Randa K. Aladdin

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Employment History

FORTREA (Formerly Labcorp)

Sr. Clinical Research Associate I – Jan 2023 – Present

- Responsibilities for all aspects of study site monitoring including routine monitoring and close out of clinical sites, maintenance of study file, conduct of pre-study and initiation visits; liaise with vendors; and other duties, as assigned
- Ensure the study staff who will conduct the protocol have received the proper materials and instructions to safely enter patients into the study.
- Ensure the protection of study patients by verifying that informed consent procedures and protocols requirements are adhered to according to the applicable regulatory requirements.
- Ensure the integrity of the data submitted on CRFs or other data collection tools.
- Ensure resources of the Sponsor and organization are spent wisely by performing the required monitoring tasks in an efficient manner, according to SOPs and established guidelines, including managing travel expenses in an economical fashion according to travel policy.
- Travel, including air travel, is required and essential function of the job.
- Serve as lead, *unblinded,* monitor for a protocol or project, and may assist in establishing monitoring plans and trip report review as assigned.
- Undertake feasibility work AS requested.
- Recruitment of potential investigators, preparation of EC submissions, notifications to regulatory authorities, translation of study-related documentation, organization of meetings and other tasks.
- Ensure audit readiness at the site level.
- Assist with training and mentoring of new employees.
- Track and follow-up on SAE reporting.

LABCORP (Formerly Covance)

Clinical Research Associate II – Jan 2022 – Jan 2023

- Responsible for all aspects of study site monitoring including routine monitoring (both onsite and remote) and close out of clinical sites, maintenance of study file, conduct of pre-study and initiation visits; liaise with vendors; and other duties, as assigned.

- Ensured study staff can conduct the protocol and received the proper materials and instructions to safely manage patients in the study.
- Ensured the protection of study patients by verifying protocols requirements are adhered to according to the applicable regulatory requirements.
- Ensured the integrity of the data submitted on Case Report Forms (CRFs) or other data collection tools by careful source document review/source data review.
- Ensured resources of the Sponsor and organization are spent wisely by performing the required monitoring tasks in an efficient manner in accordance with the SOP(s).
- Managing travel expenses in an economical fashion according to travel policy.
- Served as lead, *unblinded,* monitor for a protocol or project.
- SDV and SDR data.
- Assisted in establishing site monitoring plans, reviewed trip reports, etc. as assigned.
- Undertook feasibility work when requested.
- Recruitment of potential investigators, preparation of EC submissions, notifications to regulatory authorities, translation of study-related documentation, organization of meetings and other tasks as instructed by the supervisor.
- Ensured audit readiness at the site level.
- Assisted with training/mentoring of new employees.
- Tracked and followed-up on SAE reporting, process production of reports, and narratives.

ICON (Formerly PRA Health Sciences)
Clinical Research Associate I – Mar 2021 – Jan 2022

- Reviewed and verified the accuracy of oncology clinical trials onsite and remotely.
- Provided site status updates to team members and trial management.
- Assessed IP accountability, dispensation, and compliance at the investigative sites.
- Facilitated audits and participated in audit resolution.
- Performed SDVs and query resolution.
- Assessed the qualification of potential investigative sites, initiated and closed clinical trials at investigative sites, and instructed site personnel on the proper conduct of clinical trials.
- Ensured required training is completed and documented.

- Implemented and monitored clinical trials to ensure sponsor and investigator obligations are met and in compliance with applicable local regulatory requirements and ICH/GCP.
- Escalated site and trial related issues per ICON/PRA Health Sciences SOPs.
- Updated applicable trackers.
- Worked closely with clinical teams to facilitate the timely resolution of trial/clinical issues.
- Verified SAE reporting according to trail specification and ICH/GCP guidelines.
- Ensured the study staff who will conduct the protocol have received the proper materials and instructions to safely enter patients into the study.
- Ensured the integrity of the data submitted on CRFs or other data collection tools.
- Served as lead, *unblinded,* monitor for a protocol or project, and may assist in establishing monitoring plans and trip report review as assigned.
- Ensured audit readiness at the site level.

PHARMARON

Senior Research Nurse – Jul 2019 – Jan 2022

- Managed protocols and site staff in the clinical research department in this Clinical Research Organization (CRO).
- Adhered to GCP in implementing research activities in the execution of clinical trials and ensured protocol guidelines are met.
- Independently managed inpatient research studies.
- Collaborated with the PI, PM, and CRC to prepare for study execution, data collection, etc.
- Managed onsite, inpatient, clinical research and provided leadership to the clinical team in addition to screening, inpatient, outpatient follow-up, and pharmacy.
- Provided protocol training for clinical site staff as needed and guidance to temporary staff members to ensure consistent implementation of protocol procedures.
- Administered informed consent and discuses study details with participants in accordance with ICH/FDA guidelines to ensure understanding and adherence.
- Performed study-related tasks and procedures not limiting to administering study medication, phlebotomy/IV catheters, urine/stool collections, EKG, vitals, and other study related tasks.
- Monitored and documented AEs/SAEs and respond to study medications and treatments.

- Mentored site staff on the clinical and administrative research teams, aiding in the professional growth of Nurses, Research Associates, and Technicians.
- Responded in a timely manner to queried related clinical research data from the subject binder, ISF, and other sources of data related to the study management.
- Demonstrated the knowledge and application of all privacy and safety standards as they relate to job responsibilities, human research subjects, staff, and the general clinical operations.

HOLY CROSS HOSPITAL
Clinical Research Nurse – Oct 2017 – Jan 2022

- Supported clinical research nurses for several oncology clinical trials that includes but not limited to Breast, OBGYN, Lung, Brain, and Multiple Myeloma conducted within the hospital facility, local physicians' offices, and at Maryland Oncology/Hematology.
- Documented in Medidata and other approved databases.
- Maintained an electronic/paper regulatory binder.
- Uploaded documents on an electronic hospital-based IRB system.
- Data mined medical charts to document medical history on (e)CRFs.
- KSA for this position includes knowledge of medical terminology, project related medical procedures (i.e. blood draws/IV placement) and oncology.
- Provided protocol training for clinical site staff as needed and guidance to temporary staff members to ensure consistent implementation of protocol procedures.
- Administered informed consent and discuses study details with participants in accordance with ICH/FDA guidelines to ensure understanding and adherence.
- Monitored and documented AEs/SAEs and respond to study medications and treatments.
- Responded in a timely manner to queried related clinical research data from the subject binder, ISF, and other sources of data related to the study management.
- Demonstrated the knowledge and application of all privacy and safety standards as they relate to job responsibilities, human research subjects, staff, and clinical operations.

HENRY M. JACKSON FOUNDATION (Department of Defense, Defense Health Agency)
Clinical Research Nurse Project Manager – May 2014 – May 2019

- Project manager for a post-licensing study (Smallpox) conducted by Sanofi Pasteur/Emergent BioSolutions.
- Data mined the EMR to collect data for the CRFs.

- Maintained an electronic regulatory binder.
- Liaison for the adjudication committee.
- Adhered to GCP in implementing research activities in the execution of clinical trials and ensured protocol guidelines are met.
- Monitored and documented AEs/SAEs and response to study medications and treatments.
- Responded in a timely manner to clinical research data queried from the subject binder and ISF.
- Demonstrated the knowledge and application of all privacy and safety standards as they relate to job responsibilities, human research subjects, staff, and clinical operations.

Therapeutic Experience

- **Allergy/Asthma**: Allergic Reaction Anaphylaxis - <Phase IIb
- **Infectious**: Disease Bacterial Infection C. Difficile (Bac) – Phase III
- **Psychiatry**: Psychoses Schizophrenia – Phase I
- **Nephrology**: Renal Disease, End Stage – Phase II
- **Dermatology**: Dermatitis and Eczema Atopic Dermatitis – Phase I
- **Infectious Disease**: Viral Infection Coronavirus Disease (COVID-19) – Phase III
- **Infectious Disease**: Viral Infection Human Immunodeficiency Virus (HIV) – Phase III
- **Infectious Disease**: Vaccines Pneumococcal MMRV Vaccines – Phase III
- **Oncology**: Genitourinary Cancer Ovarian – Phase III
- **Oncology**: Lung Cancer NSCLC (Non-Small Cell Lung Cancer) – Phase III
- **Oncology**: Skin Cancer Melanoma – Phase II
- **Oncology**: Gastrointestinal Cancer Hepatocellular Carcinoma -
- **Oncology**: Genitourinary Cancer Bladder -
- **Oncology**: Lung Cancer NSCLC (Non-Small Cell Lung Cancer) -
- **Oncology**: Genitourinary Cancer Prostate – Phase III
- **Oncology**: Breast Cancer, Breast – Phase III
- **Oncology**: Genitourinary Cancer Ovarian – Phase III
- **Neurology**: Sleep, EEG Analysis – Phase II
- **Neurology**: Sleep, EEG Analysis – Phase III
- **Neurology:** Physical Sciences, Movement Activity (Actigraph Watch) – Phase II
- **Neurology:** Physical Sciences, Movement Activity (Actigraph Watch) – Phase III
- **Toxicology**: Environmental, Phloxine B Toxicity – Phase II
- **Toxicology:** Environmental, Phloxine B Toxicity – Phase III

- **C14**: High Dose, First In Human – Phase 0-I
- **C14**: Low Dose, First In Human – Phase 0-I

Systems Experience

- InForm: Ten (10) Years of Experience
- Almac: Seven (7) Years of Experience
- EndPoint: Twelve (12) Years of Experience
- Signant Health: Three (3) Years of Experience
- Florence: Ten (10) Years of Experience
- CTMS: Ten (10) Years of Experience
- Veeva Vault: Five (5) Years of Experience
- Vestigo: Five (5) Years of Experience
- Concur: Five (5) Years of Experience
- Oracle/Peoplesoft: Ten (10) Years of Experience
- NIH System (RedCap): Five (5) Years of Experience
- Medidata: Fifteen (15) Years of Experience
- Amazon Workspace: One (1) Year of Experience

Language Capabilities

- English – ILR 5 Native

Education

- BSN, University of Maryland, Baltimore, Maryland, United States of America
- ASN, Howard Community College, Columbia, Maryland, United States of America
- BS in Biology, University of Maryland, College Park, Maryland, United States of America
- BS in Psychology, University of Maryland, College Park, Maryland, United States of America
- Registered Nurse (RN/BSN), Maryland Board of Nursing (Compact License)
- Registered Nurse (RN/BSN), District of Columbia Board of Nursing

PUBLICATIONS

- Rayburn JR., Aladdin RK. Developmental toxicity of copper, chromium, and aluminum using the shrimp embryo teratogenesis assay: Palaemonid with artificial seawater. Bull Environ Contam Toxicol. 2003 Sep; 71(3):481-8. PMID: 14567573 [PubMed – indexed for MEDLINE].

Abstracts

- R. Aladdin, H. Sing, M. Thomas, J. Williams, D. Redmond, D. Thorne, T. Balkin, N. Wesensten, L. Bowlin, L. Rowland, A. Welsh, D. Johnson, R. Cephus, S. Hall & G. Belenky. Objective Analysis of Sleep Electroencephalographic Signals. Abstract accepted for the 14th Congress of the European Sleep Research Society, Sep, 1998. Madrid, Spain.

Presentations

- Aladdin, R. Rayburn, J., Blair, B., and Meade, M. Phloxine B's toxicity on Xenopus laevis using FETAX.

- Accepted for the Association of Southeastern Biologist, April 2002. Boone, NC and the 8th Annual Symposium, April 2002. Jacksonville, AL.

- Aladdin, R., Rayburn, J., Blair, B., and Meade, M. Toxicity of Phloxine B on the developing embryos of Xenopus laevis. Abstract accepted for the Association of Southeastern Biologist, April, 2001. New Orleans, LA.

- Aladdin, R. and Rayburn, J. Aluminum's toxicity on shrimp and frog embryos. Abstract accepted for the Association of Southeastern Biologist, April 2000. Chattanooga, TN and College of Arts and Sciences 6th Annual Symposium, April 2000. Jacksonville, AL.

- Aladdin, R., Rayburn, J., Blair B., and Meade, M. The development toxicity of Phloxine B with and without exposure to light using FETAX. Abstract accepted for the Society of Environmental Toxicology and Chemistry, November 2000. Pensacola, FL.

- Aladdin, R., Rayburn, J., Blair, B., and Meade, M. the photoactivation of Phloxine B's developmental toxicity to Xenopus laevis embryos using the frog embryo teratogenesis assay – Xenopus. Abstract accepted for the Society of Environmental Toxicology and Chemistry, November 2001. Baltimore, MD.