**LINDA**

**LINDA.331542@2freemail.com**

**CLINICA DATA MANAGEMENT / RESEARCH / HEALTHCARE**

**PROFESSIONAL SUMMARY**: An assiduousand competent professional with about 8.5 - 9 years of qualitative and rich exposure across Clinical Research &Operations,ClinicalData Management. Comprehensive knowledge, progressive, technically competent with capabilities to synergize technical & social needs for Health Improvement. Ingrained confidence, adaptability, maturity & tact emanating from versatile experience in the industry, resulting into ability to handle multifarious functions for all kind of managerial activities in a high pressure environment. Hands on experience structuring of effective quality control measures to improve the overall quality performance of data processing activities in the process. Acknowledged for being resourceful, adaptable & self-directed with the ability to meet even the most challenging goals due to outstanding troubleshooting, analytical, and problem solving skills. Proven expertise in study coordination for Epidemiology and Pediatric Research Studies.

Holding a **Registered Pharmacist License(RPh)**from Mumbai,India and also possess excellent knowledge of Clinical Trial Studies

**PROFESSIONAL SKILLS**

* Clinical Trial & Operations
* Research Coordination
* Clinical Data Management
* Drug and Study Research
* Clinical Project Management
* Planning/ Designing
* Bio Availability Studies (Phase I)
* Clinical Trials (Phase II & III)
* Report Management
* Service Level Adherence
* Literature Search & Review
* SOP Development

**PROFESSIONAL EXPERIENCE**

**DASMAN DIABETES INSTITUTE, KUWAIT NOV 2010-SEP 2016**

**Research Assistant**

**Key Highlights –**

* Conducting Literature Search and Reviews on for various articles that support research purposes in addition to also responsible for designing of the Standard operating procedures (SOPs)
* Enrolling and Consenting patients/participants for Research and Clinical Trial Studies while authenticating study data by routine data collection, verification and quality control
* Ensuring compliance of study activities with Scientific Regulatory Engagement principles and standards in all activities at area level & ensure that all medical governance is managed proactively & with urgency.
* Assisting the PI (Principal Investigator) in development and management of manuscripts and publications
* Responsible for managing and developing clinical research data and trial protocol studies in addition to also integrating the work activities in specific area considering strategic and operational decisions
* Significantly contributing in making technological advances and new developments while recording important breakthrough information and making overall enhancements to medicine
* **Major Projects Handled –**
	+ Pediatric Research Studies.
	+ Clinical Trials on Type 2 diabetic patients (Adults / Children)
	+ Epidemiology of Childhood and Adolescence Diabetes, Metabolic Syndrome and Obesity
	+ A Population based study of Diabetes & Obesity in Kuwait (Adult population)
* **Key Achievements –**
	+ **Co Author for the Publication:** ‘Ketoacidosis at first presentation of type 1 diabetes mellitus among children a study from Kuwait.’ Scientific Reports. 2016 Jun 22; 6:27519. doi: 10.1038/srep27519
	+ Managed the activities as **Study Coordinator** for a Clinical Trial that is being conducted by Quintiles [CRO] /AstraZeneca
	+ **Completion of successful training:** Harvard Medical School on Research field activities

**PRA INTERNATIONAL PVT LTD,INDIA OCT 2009 – JUN 2010**

**Clinical Research Associate – In house [IHCRA]**

**Key Highlights –**

* Performed essential document collection, review, maintenance and close out activities of the study also tracked the samethrough eTMF[Electronic Trial Master file] and in CTMS [Clinical Trial Management Systems] to ensure study files are accurate and complete
* Provided extensive support to CRA and CTM in order to manage investigator sites, ensure compliance and coordinate clinical monitoring activities also submitted Newsletters and Safety letters in co-ordination with the global safety team
* Constantly monitored day-to-day operations at micro level, maintained daily checklists and executed the tasks assigned in accordance with organizational standards
* Proficiently improved the operational systems, processes and policies in support of organizations mission, specifically, supported better management reporting, information flow and management, business process and organizational planning
* Created & sustained a dynamic environment that fosters development opportunities and motivated performance among team members also possessed therapeutic expertise in Oncology Clinical Trial Studies
* **Key Achievements –**
	+ Successfully managed 15-20 Investigational sites to ensure compliance with the trial protocol, ICH-GCP and all other applicable regulations
	+ Responsible for Ethics Committee [EC] and Regulatory (Clinical Trial Application) submissions for India
	+ Trained and worked for Pfizer projects

**ACE BIOMED PVT LTD,INDIA AUG 2006 – APR 2008**

**Research Pharmacist /Clinical Research Associate**

**Key Highlights –**

* Responsible for the Pharmacy area and conduction of important activities like procurement of the investigational drugs, dispensing and labelling of the drug in compliance with GCP guidelines along with dosing study participants
* Conducted literature searches for various drug moieties for Bioavailability / Bioequivalence studies
* Managed clinical researches and established labs as applicable by providing study training, study materials, facilitating enrolments, ensuring high quality data collection identifying & resolving issues
* Assisted in development of Study Protocol and Final Report in adherence to the protocol, SOPs and regulatory guidelines for Phase –I Studies [BA/BE]
* Defined business mission and performance standards across all functional areas and periodically reviewed performance with deft application of concurrent management audit procedures
* Processed blood samples by centrifuging, separation and storage of plasma blood samples while recorded these activities in their respective documents
* Experienced in oral route and nasal route of drug administration while identified various methods in Standard Operating Procedures (SOP) in accordance with the updated regulatory guidelines
* Managing search data storage and analysis for characterization of isolated cells, ensuring adherence to standard protocols
* **Key Achievements –**
	+ Dosing Study Participants (10-15) per study and responsible for monitoring the overall Clinical Study Operations also gained therapeutic expertise in Psychiatry and Hypertension

**GEBBES INFOTECH,INDIA AUG 2005 – JUL 2006**

**Medical Coder**

**Key Highlights –**

* Analysed the codes allocated for a particular procedure conducted and symptom of a disease in a clinical medical report while performed a cross check for various medical reports and raising queries for the same
* Finalized the medical report for submission purpose and well versed with medical dictionary and terminologies besides worked with CPT and ICD codes

**EDUCATION**

* **Post Graduate Diploma inClinical Research (Patency & Regulatory Affairs),** Pharmaceuticals Experts Association, 2006
* **Bachelors of Pharmaceutical Sciences,** Mumbai University, 2005

**IT SKILLS**

* **Electronic Trial Master File Systems [eTMF]**
* **Clinical Trial Management Systems [CTMS]**
* **Research Electronic Data Capture System [RED Cap]**
* Working knowledge of **MS Office, MS Outlook**

**CONTINUOUS PROFESSIONAL DEVELOPMENT/WORKSHOPS**

* Attended International Conference on**Women in Science and Technology in the Developing World,** May 2016
* **‘Introduction to Clinical and Clinical Trial Practice’,**by Dr Allison Messom MICR, The Institute of Clinical Research UK, Oct 2015
* **‘The Research Project Management Workshop’,** Mar 2014
* **‘Fundamentals: Integrated Laboratory Safety and Management Workshop’,** Mar 2013
* **‘Protecting Human Research Participants’,** The National Institutes of Health (NIH) Office of Extramural, Oct 2012

**Visa Status:**Visit Visa; **Nationality:** Indian /Female; **DOB**:28TH March 1982

**Languages Known:**English, Hindi,Marathi,Konkani

**References:** Available on request