Curriculum Vitae

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1. CAREER HIGHLIGHTS

- About 9.5 years of experience in healthcare & clinical research industry (BA/BE studies, Phase I study and PK & PD in patient as well as healthy), have coordinated more than 75 BA/BE studies in healthy as well as in patients and have faced various sponsor audits and regulatory inspections.

- Currently part of core team involved in establishing a Phase I and Proof of Concept research unit

- Regulatory Inspections Faced – EU, 3 USFDA, 2 ANVISA, DCGI, UAE

2. PROFESSIONAL EXPERIENCE

I. Medanta Duke Research Institute (Academic Research Organization), Medanta, The medcity, Gurgaon,

Clinical Research Nurse (Phase I and Proof of Concept studies) Mar 2012 – Till date

Responsibilities

- Prepare for site selection visits
- Assist in developing treatment protocols and methods
- Determine potential patient care issues and devise plans for care
- Coordinate activities of study sites to ensure protocol, regulatory and standard operation procedures and Good Clinical Practice compliance
- Set up and organize study essential documents files, Create or review study-specific source documents (i.e.; medical records, case report forms) and other study- related materials.
- Assist in the consenting process
- Record physical assessments and vital signs and phlebotomy
- Administer the investigational compounds or therapies

- Assist in screening potential subjects for the study
- Prepare for each study subject visit to ensure that all the appropriate study procedures are done
- Assist the investigator with study subject's visits
- Ensure that all necessary data are gathered and recorded in the appropriate source documents (i.e.; patient charts) and the case report forms
- Review case report form entries for completeness, correctness and logical sense
- Review of the source documents and case report forms for adverse events
- Work with sponsor monitors (CRAs) during monitoring visits
- Maintain study test IP accountability
- Manage payments to study subjects, per protocol
- Complete study closeout activities at the end of the study

II. Jubilant Clinsys Limited

Senior Research Nurse (Mar 2010 – Mar 2012)

Roles & Responsibilities:

- Responsible for preparation for relevant standard operating procedures as per the current technicalities with respect to ICH GCP guidelines and other regulatory requirements
- Recruitment and Registration and Screening of volunteers and ensuring that the registration and screening related activities and documents are done as per the SOP.
- Assist in consent process and maintain screening log
- Preparation of the selected and failure volunteer list with in consultation with medical officer as per acceptance range
- Cannulation and blood sampling as per current SOPs and protocol requirements
- Study drug administration as per current SOPs and protocol requirements
- Drugs (unit dose) dispensing and verifying as per current SOPs and protocol requirements
- Ensuring the ICU readiness prior to each clinical study
- To ensure the availability and to maintain inventory of various medicines in the department in consultation of principal Investigator/ Manager/ Head-CPU to handle medical adverse events occurs with study subjects
- Responsible for the monitoring, recording and reporting of adverse event of volunteers/subjects at all time
- To ensure proper functioning of various departmental instruments required for medical examination and handling of medical emergency
- Ensuring the handle of biomedical waste as per current SOP
- Ensuring that the all staff vaccinated for hepatitis B, involved in various activities of the study.
- Responsible for the archive of the document as per current SOPs and company policy
- Assist principal Investigator/ Manager/ Head-CPU during audit process (QA audit, Any regulatory/Sponsor audit etc) at all times
- QC of the all study related data (Member of Internal QC Dept)
- Ensuring that the contract staff involved in various activities of the study is properly trained for the respective SOPs/ protocol.
- Search the literature and guidelines

III. Fortis Clinical Research Ltd.

Senior Research Nurse (Sep 2009-Mar 2010)

Roles & Responsibilities

- Responsible for preparation for relevant standard operating procedures as per the current technicalities with respect to ICH GCP guidelines and other regulatory requirements
- Registration and Screening of volunteers and ensuring that the registration and screening related activities and documents are done as per the SOP.
- Perform the alcohol breath test of the volunteers/subject during screening and study as per current SOPs and protocol requirements
- Oral presentation (ICD) of the screening and Study procedure to the volunteers
- To Maintain the screening LOG
- Cannulation and blood sampling as per current SOPs and protocol requirements
- Study drug administration as per current SOPs and protocol requirements
- To assist medical officer/investigator/co-investigator in subject admission /selection process for the study
- Ensuring the ICU readiness prior to each clinical study
- Responsible for the preparation of emergency medicine check list prior to each clinical study
- Responsible for the monitoring, recording and reporting of adverse event of volunteers/subjects at all time
- Assisting medical officers during management of adverse event
- Ensuring the handle of biomedical waste as per current SOP
- To do quality check of all screening source record and study source record
- Liaisoning with contract staffs (Doctors, Nursing staffs, Phlebotomist)
- Arrangement of staffs duties as per study activity
- Assist principal Investigator/ Manager/ Head-CPU during audit process (QA audit, Any regulatory/Sponsor audit etc) at all times
- QC of the all study related data (Member of Internal QC Dept)
- Ensuring that the contract staff involved in various activities of the study is properly trained for the respective SOPs/ protocol.
- CRF transcription and resolution of DATA Mgt query (H1N1 vaccine trial).

IV. Paras Spring Meadows Hospital

Staff Nurse (May-2009 - Sep 2009)

Roles & Responsibilities

- Assisting of medical emergency in Casualty
- Cannulation and blood sampling
- Maintain inventory of Emergency medicine
- To ensure proper functioning of departmental instruments required for medical examination and handling of medical emergency
- Performing all nursing duties
- Ensuring the handle of biomedical waste as per institution policy

V. Jubilant Clinsys Limited

Senior Research Nurse (Apr 2005 – Mar 2009)

Roles & Responsibilities:

- Responsible for preparation for relevant standard operating procedures as per the current technicalities with respect to ICH GCP guidelines and other regulatory requirements
- Recruiting, Registration and Screening of volunteers
- Perform the alcohol breath test of the volunteers/subject during screening and study as per current SOPs and protocol requirements
- Informed consent and screening, maintain the screening log
- Preparation of the selected and failure volunteer list with in consultation with medical officer as per acceptance range
- Counseling of the failure volunteers
- Cannulation and blood sampling as per current SOPs and protocol requirements
- Study drug administration as per current SOPs and protocol requirements
- Drugs (unit dose) dispensing and verifying as per current SOPs and protocol requirements
- Ensuring the ICU readiness prior to each clinical study
- Responsible for the monitoring, recording and reporting of adverse event of volunteers/subjects at all time
- Assisting medical officers during management of adverse event
- Ensuring the handle of biomedical waste as per current SOP
- To do quality check of all screening source record and study source record
- Liaisoning with Vendors (Contract hospital etc)
- Liaisoning with contract staffs (Doctors, Nursing staffs, Phlebotomist)
- Ensuring that the all staff vaccinated for hepatitis B, involved in various activities of the study.
- Arrangement of staffs duties as per study activity
- Responsible for the archive of the document as per current SOPs and company policy
- Assist principal Investigator/ Manager/ Head-CPU during audit process (QA audit, Any regulatory/Sponsor audit etc) at all times
- QC of the all study related data (Member of Internal QC Dept)
- Ensuring that the contract staff involved in various activities of the study is properly trained for the respective SOPs/ protocol.
- Ensure that the performance check, operation and calibration of the equipments are done as per the SOPs, calibration and maintenance schedules and to verify timely updating of the logbooks.

- Updating the training schedules and maintaining the training records of all the study personnel.
- Search the literature and guidelines

VI. Cadila Pharmaceutical Ltd., Dholka, Ahemdabad

Clinical Nurse (Mar-2004-Apr- 2005)

Roles & Responsibilities:

- Drafting/ preparation of relevant Standard Operative Procedures as per the current technicalities with respect to ICH GCP guidelines and other regulatory requirements.
- Screening and recruitment of study subjects
- Explain of Subject about screening, study & study drugs
- Preparation of final report of selected subject
- Responsible for assisting (ECG & vital sign measurement) medical officer during medical examination.
- Arrange pre-study meeting
- Admission of the volunteers for study (Check-in procedure)
- Cannulation & blood sampling as per current SOPs and protocol requirements
- Ensuring unit dose dispensing is done as per defined SOP & GCP guidelines
- Study drug administration as per current SOPs and protocol requirements
- Intimate involvement and active participation in the study as research nurse & study custodian
- Responsible for the monitoring, recording and reporting of adverse event of volunteers at all times
- Assisting medical officers during management of adverse events
- Providing first aid
- Liaisoning with Contract hospital
- Preparation and documentation of Case Record Forms, Trial master file, screening record and other related documents
- Maintain Control Form utilization records which issued by QA
- Maintain store

3. EDUCATION

General Nursing Midwife (GNM), with 80 % marks, Sambhram Institute of Nursing, KGF, Bangalore, Karnataka, August 2002.

Bachelor of Arts (BA) with Second class from Maharishi Dayanand Saraswati University Ajmer (Rajasthan), 1999.

4. CERTIFICATIONS / PROFESSIONAL TRAININGS

- Trained on Mortara Telemetry system by Mortara Inc. product management team
- Have been awarded Employee of the month while working in Jubilant Clinsys Limited
- Participated in the training education programmes of Cadila pharmaceuticals in conducting bioavailability and bioequivalence studies as per Good Clinical Practices
- “Workshop on GCP “ by ACADEMY OF CLINICAL EXCELLENCE BOMBAY 2005
- “Workshop on GCP “ by CATALYST CLINICAL SERVICES DELHI 2006
- Training program on ***AIDS COUNSELING by PROJECT CONCRN INTERNATIONAL DELHI***
- Training program on ***BLS (BASIC LIFE SUPPORT) by AMERICAN HEART ASSOCIATION*** (Indian Institute of Emergency Medical Services, Trivandrum).
- Training program on ***ACLS (Advanced cardiac life support) by AMERICAN HEART ASSOCIATION*** (Indian Institute of Emergency Medical Services, Trivandrum)
- Training program on AIDS COUNSELING by PROJECT CONCRN INTERNATIONAL DELHI 31 May to 02June, 2007
- Participated in the training education programmes of the PHASE I UNIT / STUDY MONITORING
- Participated in the training education programmes OF THE SELECTION OF A PHASE I UNIT
- Participated in the training education programmes of GOOD DOCUMENTATION PRACTICE
- Participated in the training education programmes of SAFETY AND LIVE FIRE DEMONSTRATION
- Participated in the training education programmes of GOOD LABORATORY PRACTICE
- Participated in the training education programmes of ICH-GCP GUIDELINES
- Participated in the training education programmes of DOCUMENTATION DURING CLINICAL STUDY
- Participated in the training education programmes of GMP
- Participated in the training education programmes of INVESTIGATION PRODUCT
- Participated in the training education programmes of OVER VIEW OF A CLINICAL DATA MANAGEMENT
- Training in the INFORMED CONSENT DOCUMENT
- Symposium: “Polytraumacon conference 2006” Sponsor by Fortis hospital (Ranbaxy group)

5. PROFESSIONAL REGISTRATION / AFFILIATION

- Life Member of the Karnataka state nursing council (Registration No. 45489)
- Member of the Rajasthan state nursing council (Registration No. 19488 Part I A)

- Member of Health care provider, issued by “American heart association” from 14 sep 2005 to 13 2007
- Member of Health care provider (Advanced cardiac life support), issued by “American heart association” from 10 Apr 2007 to 09 Apr 2009

Dose preparation and administration experience

- Tablets/capsules, Chewable Tablets, Oral Disintegrating tablet, Suspension, **Injectable drug (Propofol injection & Rabeprazole)**, **Rectal route drug administration** (Mesalamine rectal suspension), 4 FDC Dosing (**15** tablets/subject dosed), **Vaccine** (H1N1)

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(Sign & Date)