**Professional Profile**

I have more than 5.5 years’ experience in international clinical research and am currently working at INC Research as CRA-III. I am working in INC Research (Erstwhile Kendle) since January 2009.I have monitored global multinational studies on indication such as Oncology phase III, Burn Injuries phase IV, Ophthalmology phase III, Oncology phase III, DVT phase III and Adult Asthma phase III during tenure as CRA at INC Research (Erstwhile Kendle) and currently working on Rheumatoid Arthritis phase IIb study

I joined INC Research(Erstwhile Kendle) as Trainee CRA and was responsible for handling in-house site management activities, creating site files and initiation packets for global Asthma study. I am trained and experienced in ICH-GCP regulations and have good understanding of local regulatory regulation.

Before joining INC Research, I was associated with a multispecialty hospital as a Clinical

Research Coordinator for 1.4 years and worked there on various global trials with the indications

like Deep Vein Thrombosis in Total Knee Replacement and Total Hip Replacement, Severe

Sepsis, Diabetes Mellitus Type II, Pain management in Osteoarthritis and Back Pain Patients.

**Career Summary**

**November- 2012– Present,  INC Research(Erstwhile Kendle Inc.) as a CRA- III**

* Maintains timely and effective communication among team members and site staff. Routinely anticipates/identifies potential issues and implements corrective actions independently .Keeps project leadership apprised of team issues, seeking guidance as needed. Demonstrates effective conflict resolution.
* Assures compliance with local regulations, Code of Federal Regulations (CFR)/ International Conference of Harmonization (ICH) and GCP guidelines, and Company and Sponsor SOPs. Maintains current regulatory documentation according to Essential Regulatory Document Guidelines and Trial Master File (TMF) Plan. Participates in TMF and on-site audits as requested. Responds to less complex findings without oversight and may require guidance to respond to more complex/serious findings. May be responsible for submission of regulatory packages to ethics committees and/or competent authorities.
* Responsible for site management and site staff performance including: monitors all types of clinical trials; participates in all types of site visits; assures compliance with all protocol requirements; assures effective patient identification and recruitment plan is in place; assures timely reporting of Adverse Events (AEs)/Serious Adverse Events (SAEs) and protocol violations; ensures proper storage, dispensation, and accountability of all Investigational Product(s) and trial-related materials; regularly reviews the status of the contents of the site regulatory binder; exhibits effective time management skills; may perform training visits with less experienced CRAs; and may perform assessment of less experienced CRAs during the sign-off visits. Working as Lead CRA and assist LCRA activities e.g. tool development, study plans, and team training.
* Performs source data verification according to contractual requirements. Assures timely completion and submission of Case Report Forms according to Clinical Monitoring Plan and/or Data Management Plan. Assures timely and accurate completion of Data Clarification Forms. Proficient with multiple data capture systems/methodologies in course of monitoring. Performs clinical data listings reviews as needed.
* Completes and submits reports according to SOP/Works Instructions (WI) or Sponsor requirements requiring minimal revisions. Maintains awareness of key study performance indicators for own sites, e.g. Telephone Communications Reports, patient enrollment, and SAEs. Updates study and patient status information and serves as Clinical Trial Management System resource for Project Manager (PM)/Lead CRA. Tracks Investigator payments/milestones. Documents and tracks the resolution of alloutstanding site-specific protocol-related issues from visit to visit.
* Prepares for and attends Investigator meetings. May attend Customer and Business Development meetings. May present materials, as requested. Assists with the preparation of study start-up materials and tools, as requested. Attends clinical monitoring staff meetings, project team meetings, clinical committees, and clinical training sessions according to the project communication, monitoring and/or training plans.

**May- 2011– October 2012,  INC Research(Erstwhile Kendle Inc.) as a CRA- II**

* Performs clinical trial initiation, monitoring and close out activities while adhering to all applicable regulatory and Standard Operating Procedures (SOPs) and Project Specific Operating Procedures (PSOPs).
* Develops and implements innovative approaches for site selection, and pre-study activities to identify and evaluate potential investigators
* Completes site evaluation and reports to Lead CRA / Project Leader as appropriate.
* Currently working as Lead CRA and managing the study team with high ability and providing the result to sponsor with adhered timeline.
* Complete review of submission of documents to the Ethics Committees
* Collects, reviews and tracks regulatory documents when required.
* Manage and track investigator grants with study sites when required
* Development of study specific monitoring plan, annotated CRFs, monitoring conventions, tracking forms, and other study related documents.
* Completes pre-study visits with study site staff.
* Completes initiation visits with study staff through training, reviewing regulatory requirements, collecting outstanding documents, reviewing patient screening/randomization procedures, reviewing SAE reporting requirements, and reviewing drug storage and accountability procedures.
* Develops patient enrollment strategies with the project team and study sites.
* Completes monitoring visits to ensure the integrity of clinical data and appropriate follow up procedures, including source document verification and SAE reporting in accordance with the project plan.
* Maintains tracking records for assigned sites such as tracking of status and source document review per patient.
* Conducts and assists with Project specific administrative activities as a member of the project team.
* Participates in feasibility activities and reports outcome to appropriate manager.
* Continues to increases knowledge of drug development process, therapeutic areas, Good Clinical Practices, and any applicable local regulatory requirements.
* Providing clinical and technical support for CRA I and administrative staff as a mentor.  
    
  Mar- 2009 – April 2011,  Kendle International Inc. as a CRA- I
* Perform clinical trial initiation, monitoring and closeout activities while adhering to all applicable regulatory, Standard Operating Procedures (SOPs) and Project Specific Operating Procedures (PSOPs).
* Assists with study start-up activities.
* Assists in site selection, and pre-study activities to identify and evaluate potential investigators.
* Assists in site evaluation and reports to Lead CRA / Project Leader as appropriate.
* Assist with the development of study specific monitoring plan, annotated CRFs, monitoring conventions, tracking forms, and other study related documents.
* Assists with the preparation and coordination of investigator meetings and attends meeting.
* Completes pre-study visits with study site staff.
* Provide status updates of pre-study and initiation activities to Lead CRA / Project Leader.
* Completes initiation visits with study staff through training, reviewing regulatory requirements, collecting outstanding documents, reviewing patient screening/randomization procedures, reviewing SAE reporting requirements, and reviewing drug storage and accountability procedures.
* Ensures proper storage, dispensation, and accountability of all Investigational Product(s) and trial-related materials.
* Completes monitoring visits to ensure the integrity of clinical data and appropriate follow up procedures, including source document verification and SAE reporting in accordance with the project plan.
* Manages study site activities and provides ongoing updates of site status to Lead CRA / Project Leader.
* Completes in-house monitoring activities as appropriate, such as updating in-house site files, and completing visit reports.
* Maintains tracking records for assigned sites such as tracking of status and source document review per patient.
* Completes study site closeout visits.
* Responsible for representation of Kendle in a professional manner.
* If appropriate, maintains home-office set-up to include computer, fax/copier printer, appropriate filing system, adequate telephone lines, and voice mail system when applicable
* If appropriate, maintain appropriate lines of communication and use of mail and delivery services
* Other duties and assignments as requested for the overall performance of Clinical & Data Monitoring .

**Jan- 2009 – Feb 2009,  Kendle International Inc. as a Trainee CRA**

* Assists the Project Leader and/or Lead CRA in the conduct of all in-house project activities, and providing administrative support to the clinical project team. Responsibilities typically include preparation, collection, tracking and analysis of data and/or documentation the produce high quality reports. Performs basic in-house & on-site activities.
* Handles project correspondence
* Compose complex or confidential correspondence
* Track site level information
* creates site files and prepares site initiation packets.
* Participating in project specific training and project team meetings as required.
* Gather information, searches files & records and make personal contacts to obtain specific information in order to prepare detailed reports for project and company needs.

**Oct 2007 to Dec- 2008 ,  Shalby Hospitals Ltd. as a Clinical Research Coordinator**

* Coordination with pharmaceutical companies / CRO monitors
* Assist in administering informed consent with patient.
* Assisting Principle Investigator in Subject recruitment by helping in advertisement to achieve the recruitment in given timeline.
* Patient care by proper follow-up with the central as well as local lab to get the lab reports on time.
* Management and reporting of AE/SAE to EC
* Completing Paper CRF and forward to Data management.
* Attended Study close visit . The activities performed during study close out visit were reconciliation of investigational product, tracking of investigator’s payment, completing the filing of Investigators site file, archival of study documents, tracking of airway bill for blood samples sent to central laboratory.
* Communication with Ethics Committee for getting approval for the new study and also arranging minutes of meeting for Ethics Members.
* Complete Data Clarification Forms and send it to Sponsor / CRO.
* Co-ordinate PSV, SIV, monitoring as well as audit visits at site.
* Maintain study related logs- screening, enrollment, drug administration ,temperature, phone contact logs/forms.
* Ensure adequate and appropriate use of IVRS.
* Maintain clinical Trial supplies and arrange adequate supplies.
* Maintain adequate supplies of investigational product/test article.

**Therapeutic Experience**

* Endocrinology

Type 1 Diabetes Mellitus, Phase IV

* Infectious Diseases

Severe Sepsis, Phase II

* Respiratory

Adult Asthma, Phase III

* Oncology

Sarcoma Cancer, Phase III

Cancer Pain, Phase III

DVT in Cancer patient, Phase III

* Skeletal Diseases

Hip Replacement Surgery, Phase III

Knee Replacement Surgery, Phase III

Deep Vein Thrombosis, Phase III

* Ophthalmology

Age Macular Degeneration, Phase III

* Dermatology

Burn Injuries, Phase IV

* Immunology

Rheumatoid Arthritis, Phase IIb

**Formal Qualifications**  
  
 Masters in Biochemistry from T. John College, Bangalore, Bangalore University  
  
 Bachelor in Microbiology from R G Shah Science College, Ahmedabad, Gujarat University

**Certification in Clinical Research**

Good Clinical Practice

Informed Consent Process

Monitoring Responsibility

Adverse event Reporting

Study Documentation

Pharmacogenetic Research

From ***Bristol Myers Squib Pharmaceutical Company***

Certification in Basics in Clinical Data Management from Xcellon Institute, Ahmedabad.

**Achievement**

Received Superstar Award from CEO in current organization for an outstanding work during Global Trial.

**Personal Details**  
Date of Birth: 14/Aug/1985    Languages: English, Hindi & Gujarati  
  
Nationality: Indian    

Interests & Activities

Currently include:  Travelling, Cricket, Reading and Watching News

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References will be Available on Request

**(Devesh R. Verma)**