**SOWMYA**

[**SOWMYA.363265@2freemail.com**](mailto:SOWMYA.363265@2freemail.com)

**OBJECTIVE:**

To involve in clinical research including drug testing, which will continuously challenge my critical thinking and technical skills, in order to allow me to make meaningful contributions to research and drug discovery.

**CLINICAL RESEARCH EXPERIENCE:**

***10-2013 – Present*** – Involved in monitoring activities, Meenakshi Mission Hospital and Research Centre, Madurai.

***05- 2012 – 10-2013*** - Clinical Research Coordinator, Meenakshi Mission Hospital and Research

Centre, Madurai.

**ROLES AND RESPONSIBILITIES:**

* Coordinate clinical trials for Oncology diseases with Oncologists and major pharmaceutical companies.
* Coordinate and perform all duties and procedures associated with the research studies under the responsibility of Principal Investigator
* Familiarity with all study protocols, informed consents, study visit schedules, and regulatory documents.
* Assist with study participant recruitment.
* Prepare study participants for clinical research visits and telephone them to remind them of upcoming visits.
* Maintenance and updating of study enrollment logs and participant contact lists.
* Maintain inventory of all supplies needed for clinical trials including study drugs and devices, lab kits, and medical supplies.
* Manage multiple studies simultaneously, average of 5 at a time
* Maintain source documents for patients for each visit and ensure the completion of the same after each visit.
* Completion of Case report form entry, Electronic data capture entry.
* Resolve Data clarification forms and queries raised by data management.
* Maintenance and updating Master drug accountability logs and Individual subject drug dispensing log.
* Maintenance and updating Site Master File.
* Work directly with CRA assisting Feasibility, Initiation, Monitoring and Close-out visits.
* Call IVRS and IWRS (Interactive Voice/Web Response System)for patient randomization and visits.
* Call IXRS for IP dispensing.
* Documentation of Adverse events and Concomitant medications.
* Labeling and Shipment of samples.
* Report serious adverse events on timeline as per new regulation guidelines to DCGI, Sponsor and Institutional Ethics Committee.
* Facilitate Institutional Ethics Committee submission including new study documents, amendments, CIOMS.

***11-2011 – 04-2012***- Clinical Research Associate Trainee, Consortium Clinical Research Pvt.Ltd,

Coimbatore.

**ROLES AND RESPONSIBILITIES:**

* Identifying and assessing the suitability of facilities to be used as the clinical trial site.
* Identifying/selecting an investigator who will be responsible for the conduct of the trial at the trial site.
* Liaising with doctors/consultants or investigators on conducting the trial.
* Verifying that data entered on to the CRFs is consistent with patient clinical notes, known as source data/document verification (SDV).
* Archiving study documentation and correspondence.
* Maintenance and updating Trial Master File.
* Raising queries through data clarification forms.

**CLINICAL RESEARCH TRAINING:**

**Received training for all clinical trials mentioned above at Meenakshi Mission Hospital and research Centre,Madurai.**

**Consortium Clinical Research Pvt.Ltd.,Coimbatore** (Nov,2011).

**Project**:Training on Protocol Details,SAE reporting and Timelines for reporting,Pharmacovigilance, Schedule Y, ICH guidelines and Good Clinical Practice sessions.

**ConsortiumClinical Research Pvt.Ltd., Coimbatore**(2012)

**Project**:Training on Ocular Hyper Tension, Open Angle Glaucoma Study Protocol and Study specific Documentation.

**TRAINING COURSES:**

* Completed Certified E-learning course in RAVE EDC and RAVE 5.6 EDC Essentials
* Completed Certified E-learning course in ORACLE
* Completed Certified E-Learning course in InForm.
* Completed training in introduction to ALMAC IXRS/IVRS.

**OTHER EXPERIENCES**

* Monitored data of Clinical Research Coordinators.
* Involved in Institutional Ethics Committee Auditing.

**EDUCATION:**

***2007 - 2011*** – B.Tech – Industrial Biotechnology.

SASTRA University, Tanjore.

***2011 – 2013*** - PG Diploma in Clinical Trial Management and Regulatory Affairs,

Consortium Clinical Research Pvt.Ltd, Coimbatore.

**LANGUAGES KNOWN:**

Speak - English & Tamil

Read - English & Tamil & Hindi

Write - English & Tamil & Hindi

**DECLERATION:**

I do hereby declare that all the details furnished above are true to the best of my knowledge and belief.

**PROJECT DETAILS**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Start date** | **TrialName** | **Phase** | **No.ofPatients** | **Status** | **Role** |
| 2009 | Breast Cancer | III | 06 | Ongoing | CRC |
| 2010 | Head and Neck | III | 03 | Ongoing | CRC |
| 2010 | Acute VTE | III | 34 | Ongoing | CRC |
| 2010 | VTE | Observational  study | 10 | Completed | CRC |
| 2012 | Head and Neck | II | 07 | Ongoing | CRC |
| 2012 | NHL | III | 09 | Ongoing | CRC |
| 2012 | Metastatic Breastor  Colorectal Cancer | BA/BE | 08 | Ongoing | CRC |
| 2012 | GBM/Anaplastic  Astrocytoma | BA/BE | 02 | Ongoing | CRC |
| 2012 | Solid Tumor | I | 02 | Ongoing | CRC |
| 2012 | Breast Cancer | III | 06 | Ongoing | CRC |
| 2013 | GBM/Anaplastic  Astrocytoma | BA/BE | 03 | Ongoing | CRC |
| 2013 | Neulasta breast cancer | III | 04 | Ongoing | CRC |
| 2013 | Metastatic Breast Cancer | III | 02 | Ongoing | CRC |
| 2013 | Metastatic Colorectal  Cancer | III | 05 | Ongoing | CRC |