Title: **Clinical Research Officer** Department: **Clinical Operations**

Position Summary:

This position will be responsible for oversight of activities related to outcome assessment of clinical trials and ensuring that the study is conducted in accordance with the study protocol, standard operating procedures, good clinical practice, and applicable guidelines It will involve coordination between investigators, project conduct team, data management team and monitoring team; tracking the progress of the project with updates; safety reporting within the prescribed timelines; monitoring deliverables; and ensuring adherence to regulatory requirements.

Responsibilities:

- Oversight and coordination of outcome assessment in clinical trials.
- Oversight of monitoring of patients till discharge
- Safety reporting for adverse events in patients
- Preparing the SAEs reports to be shared with all stakeholders promptly.
- Review and verify completed CRFs promptly before they are transmitted to the data management team for entry. Timely resolution of queries in data collected.
- Supervising the study processes to ensure compliance with SOPs, protocols, and national regulations.
- Supervision of process of assessing clinical support during emergency
- Ensuring timely follow-up visits of all patients till the end of the study; liaising with the project manager for this activity
- Coordinating the smooth flow of data from collection to data entry in the electronic platform
- Reviewing data queries, protocol deviations, and loss to follow up for hospital site performance.
- Responsible for equipment related to newborn assessments at the site.
- Liaise with the QM team to ensure the quality of study data is good.
- Training of research assistants and field workers for newborn data collection, outcome assessments, follow-ups, CRF completion
- Any other work assigned by PI

Minimum Qualifications & Experience:

- **BAMS/ PharmD/**BDS/BHMS/ BPT or equivalent degree from a recognized University with at least two years of post-qualification work experience after completing an internship, preferably in Critical Care, Oncology, **or Emergency Medicine.**
- Conversant with **Good Clinical Practice**
- Computer skills, including proficiency in the use of Microsoft Office applications.
- Ability to build effective project teams, motivate others, delegate, drive, and timely/ quality decision-making.
- Good organizational behaviours and problem-solving skills
- Effective time management skills and ability to manage competing priorities.

Title: **Clinical Research Nurse** Department: **Clinical Operations**

Position Summary:

This position will be responsible for the delivery of direct and indirect care for research studies undertaken in the clinical research sites, in accordance with the Site standard operating procedures, the clinical trial protocol, Food and Drug Administration, Good Clinical Practice, International Conference on Harmonisation Good Clinical Practice Guidelines and the Clinical Trials Directive, New Drugs & Clinical Trial Rule,2019. This position participates in the effective running of research studies on a day-to-day basis, maintaining the confidentiality, safety, and well-being of study participants and utilizing skill knowledge, and judgment to provide a high standard of care while always maintaining dignity and respect.

Responsibilities:

- Ensure patient safety and well-being in various settings by working collaboratively within a multidisciplinary team.
- Identify and promptly report potential or actual adverse events to a senior nurse and physician.
- Perform all types of drug administration for which they have been competency assessed per the study protocol and within the appropriate guidelines for administering medicines.
- To be competent in performing and supervising other multidisciplinary team members in core clinical skills, utilizing clinical knowledge to identify potential clinical abnormalities and recognizing and reporting any deviation from the parameters as stated in the study protocol.
- To perform clinical procedures as per SOP/protocol including but not limited to;
    - Recording of 12 lead ECG
    - Continuous Cardiac Monitoring
    - Blood sampling both direct Venepuncture and via cannula
    - Recording of vital signs in accordance with the study protocol
    - Pulse Oximetry
- Collect accurate, high-quality data in accordance with Good Clinical Practice and resolve queries promptly so as not to delay the time to study completion.
- May screen participants for inclusion into the study based on predetermined criteria.

Minimum Qualifications & Experience:

- **GNM / B.Sc. in Nursing** or equivalent degree from a recognized University with at least two years of post-qualification work experience after completing an internship, preferably in **Critical Care, Oncology, or Emergency Medicine.**
- Conversant with **Good Clinical Practice**
- Computer skills, including proficiency in the use of Microsoft Office applications.
- Ability to build effective project teams, motivate others, delegate, drive, and timely/ quality decision-making.
- Good organizational behaviors and problem-solving skills
- Effective time management skills and ability to manage competing priorities.

Title: **Senior Clinical Research Coordinator** Department: **Clinical Operations**

Position Summary:

This position will be responsible for planning, implementing, and coordinating clinical research studies. Need to work closely with principal investigators, study participants, and other healthcare professionals to ensure the successful execution of research protocols following regulatory requirements and ethical standards.

Responsibilities:

- Coordinate and manage all **Oncology Biosimilar clinical research studies** from initiation to closeout.
- Screen, recruit, and enrol eligible participants according to study protocols.
- Obtain informed consent and ensure compliance with regulatory guidelines and institutional policies.
- Schedule study visits, perform assessments, and collect study data accurately and on time.
- Communicate effectively with study participants, principal investigators, Ethics Committee, Sponsors, and other study team members.

Minimum Qualifications & Experience:

- **B. pharm** *(Min. 2-3 Yrs. Experience in Oncology Biosimilar Studies)* or **M. Pharm** in Pharmacology *(Min.1 Yr. Experience in Oncology Biosimilar Studies)* degree from a recognized University
- Conversant with **ICH-Good Clinical Practice, ICMR Guidelines,2017, New Drugs & Clinical Trial Rule,2019**
- Must have faced at least one sponsor QA Audit or Regulatory Inspection
- Computer skills, including proficiency in the use of Microsoft Office applications.
- Ability to build effective project teams, motivate others, delegate, drive, and timely/ quality decision-making.
- Good organizational behaviours and problem-solving skills
- Effective time management skills and ability to manage competing priorities.