Position: **Clinical Trials Administrator**

Appointing organization: **Tata Translational Cancer Research Centre (TTCRC)**

Last Date of Application :15th February 2019

The Tata Medical Center and the Tata Translational Cancer Research Centre

The Tata Medical Center (TMC) is a multispecialty institution for tertiary cancer care. At TMC, clinical and research activities are integrated to provide state-of-the-art care for patients with cancer. This integration is enabled by the Tata Translational Cancer Research Centre (TTCRC), the research arm of TMC. At TTCRC, a multidisciplinary team of clinicians, scientists, academics and industry professionals collaborate to develop a systems medicine approach in cancer research. This approach is focussed on developing innovative, indigenous, cost-effective and equitable strategies to improve cancer diagnosis; develop treatments that match disease characteristics and adapt to treatment response; and, identify prognostic and predictive disease biomarkers. These strategies are multi-dimensional and involve an iterative pathway that include clinical studies, high-throughput laboratory investigations, computational strategies to integrate, analyse and model data, hypothesis- based pre-clinical studies and translation of findings to clinical practice.

The Post

We have a dedicated clinical trials unit, staffed by 3 data managers with statistical support. Trials are conducted using an electronic clinical trial management system (CTMS). TTCRC is the nodal centre for an academic multicenter clinical trial in childhood acute lymphoblastic leukaemia. This study is funded by ICMR and NCG. Annual target recruitment is around 1000 patients. The post holder has the chief responsibility of managing all aspects of the trial.

Data collection and handling are supported by Tata Consultancy Services. TTCRC innovates in data acquisition and analyses. The post holder will be required to support the research team working in this area.

You will work with Investigators to develop new trials and grant applications in a variety of therapeutic areas and then work closely with the Clinical Trial Coordinators to ensure that projects are set up and delivered on time, within budget and in accordance with the protocol and relevant regulations, including reporting to regulatory and monitoring committees. You will also work with trial teams and database engineers to identify problems and help formulate and implement strategies to resolve them; develop and implement systems for effective trial management; review staff resources for your portfolio of trials to make sure resource is being used in the most efficient way and contribute to the publication and presentation of the research. We expect you to understand GCP and have excellent interpersonal skills, effective communication skills (both oral and written), experience of supervising and mentoring staff, strong team working skills and an innovative approach to challenges. The post is core funded by TTCRC.

The post reports to the Associate Director of Operations, TTCRC.

Role and responsibilities

The duties of the Clinical Trial Administrator will be as follows :

(a) **Day-to-day operational management**

(i) Management of active clinical trials
(ii) Supervision of data managers
(iii) Liaison with the principal investigators
(iv) Protocol development and generation of allied information documents
(v) Quality management procedures (standards of procedure, quality assurance and quality control processes) and include verification of data entry and output
(vi) Information management including review of CTMS requirements and software needs
(vii) Participating in innovation, in areas such as data acquisition, good clinical practice, and resource management
(viii) Interactions with research organisations and industry to share experience, exchange knowledge and explore collaboration
(ix) Maintain budget and prepare budget and expense statements

(b) Training and Meetings

(i) Training and evaluation of staff within the CTU
(ii) Training and support for staff at other trial centres
(iii) Development of online training modules for staff involved in clinical trials
(iv) Organising courses on clinical trials for intramural and extramural faculty
(v) Organise and present at national meetings
(vi) Maintain regular educational sessions with CTU staff

(c) **Reporting**

(i) Prepare regular reports as required by funding bodies , IRB's and data safety monitoring committees
(ii) Respond to queries raised by regulatory authorities
(iii) Prepare analytical reports as required by the principal investigator

(d) **Additional duties**

(i) Prepare clinical trial data for presentations and publications

The Clinical Trials Administrator is a senior member of the TTCRC management team and may also require to take on additional administrative roles to facilitate interactions within the centre.

Minimum required qualifications/experience

(a) Master's Degree
(b) Data handling and statistics
(c) Clinical Trials Experience

(d) Working with and managing teams

Desirable qualities, skills and opportunities

(a) PhD or MD
(b) An energetic, enthusiastic individual capable of independent research
(c) A team player
(a) A vision for the future and a commitment to building a resource that will benefit patients with cancer in India

Appointment and reporting

Appointment to the position will be for an initial three (3) years, and the first year will be considered probationary. Progression through the second and third years will be based on annual appraisals of performance. The successful applicant will be managed by Associate Director for Operations and report to the Director.

Enquiries

(a) For further details on TMC and TTCRC, visit www.tmckolkata.com
(b) Submission of applications by post or by e-mail to:
Mr Suvasish Mukherjee; Head, Human Resources; Tata Medical Center; 14 Major Arterial Road (East-West); Newtown, Rajarhat; Kolkata 700 160
e-mail: suvashish.mukherjee@tmckolkata.com
(c) For informal enquiries,
Professor Shekhar Krishnan (sukanya.guha@tmckolkata.com)

Knowledge/ aptitude, skills, etc.	Requirements	Essential / desirable	Information from
1. Disposition / Attitude / Work habits	a. Flexible b. Self-motivated c. Hardworking d. Willing to learn new skills e. Works as part of a team f. Receptive to new ideas g. Capable of independent work, to an agreed plan h. Good time management i. Organised, able to prioritise responsibilities	a. Essential b. Essential c. Essential d. Essential e. Essential f. Essential g. Essential h. Essential i. Essential	Application form CV Profile Interview References
2. Education / Qualifications	Masters/PhD/MD	Essential	Interview Application form CV
3. Experience	a. Experience in Clinical Trials	a. Essential	Application form CV Interview References
4. Skills and ability	a. GCP b. Management of people and resources c. Able to communicate effectively to peers, clinicians and senior colleagues d. Willing to shoulder responsibility and provide support to colleagues e. Focused on maintaining high technical and quality standards f. Ability to handle information technology and data g. Readiness to explore and develop new strategies in clinical trials h. Meticulous in documentation and preparation of reports i. Able to work & contribute as part of a collaborative research group	a. Essential b. Essential c. Essential d. Essential e. Essential f. Essential g. Essential h. Essential i. Essential	Application form CV Interview References

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