Senior Clinical Co-ordinator and Senior Research Associate (CRA)

Job Summary (Purpose / Scope)

EnGeneIC is an innovative clinical stage, biotechnology company, based in Sydney Australia and New York, USA that has developed a first-in class targeted cyto-Immunotherapy nanocell platform technology for the treatment of cancer. The company is conducting Phase IIa clinical trials in Australia and will soon commence in USA.

Recently our nanocell (EDV™, EnGeneIC Dream Vector) has also been committed to a COVID vaccine trial in Australia and EnGeneIC is building up its clinical team. We are seeking a Senior Clinical Co-ordinator and a Research Associate (SCRA)/CRA I-II to join our clinical team. This is a unique chance to join a world-class team and participate in the development of a new and exciting second generation SARS-CoV2 vaccine for immune-compromised patients.

After probation of 6 months, these are full time, permanent positions. The roles are office based in Lane Cove West, Sydney. Study sites are located throughout Australia.

The roles will report directly to EnGeneIC's joint CEO's but will work closely with members of the Clinical Operations Team. Critical to the role is a clinically orientated, methodical and organised approach with an ability to act as a liaison between the clinical research sites and EnGeneIC. Both will play a key role in assuring high quality research data and ensuring effective information provision and communication between EnGeneIC and study site personnel.

Responsibilities and Accountabilities:

Qualifications and Experience:

- Bachelor's degree preferably in clinical or life sciences or a similar discipline or equivalent relevant clinical experience.
- A minimum of 6 years' (or 3 years in the case of the CRA) independent monitoring experience within commercial clinical research including analysis of potential patient recruitment, consent documents, e-Case Report Forms etc.
- Understanding and demonstrated proficiency in ICH GCP guidelines, local regulatory environment governing clinical research and ethics submission and approval processes.
- Australian permanent resident/citizen residing in New South Wales, with the ability to travel interstate (or potentially overseas) for site monitoring.
- Valid driver's license.
- Computer literacy in Microsoft Office, experience in e-DC systems and the ability to learn appropriate software.
- Therapeutic area knowledge and experience in oncology and Phase I/II trials is preferred
- Knowledge of adverse event coding.

- Excellent interpersonal verbal and written communication skills.
- Exceptional organizational capability with strong time management skills with the ability to work autonomously with minimal supervision.
- Strong solutions focused and problem-solving skills with attention to detail.
- Demonstrated ability to be a team player.

Key Responsibilities:

Monitoring & Logistics:

- Primary responsibilities will include taking the lead on all aspects of study monitoring responsibilities from study start-up to close out, ensuring trials are conducted in accordance with the protocol, standard operating procedures (SOPs), ICH-GCP, local laws and all applicable regulatory requirements.
- Maintain / tracking of e-DC user management including but not limited to, compiling master user lists and activating/deactivating user accounts.
- Monitor patient safety, ensure timely reporting of adverse event (AE) and serious adverse event (SAE) reports in order to comply with regulatory and local requirements.
- Comply with Australian legislation, organisational standard operating procedures and regulatory frameworks relating to patient privacy and confidentiality.
- Experience with US FDA IND applications would be an advantage.
- Assist with training for team members, and investigative site staff.

Communication:

- Act as the real time point of communication between EnGeneIC and investigational sites and escalate serious issues to the EnGeneIC CEO's and/or Clinical Trial Coordinator as appropriate.

Maintenance of regulatory documentation:

- Assist with the preparation, review and submission of relevant regulatory documents to the appropriate Regulatory Authorities and HRECs as required.

Anna Donato

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