Clinical Research Associate – Oncoloy Experience a MUST

- **About us**

Advanced Accelerator Applications (AAA) is an International pharmaceutical company and a leader in molecular nuclear medicine. We have an established pipeline of innovative products, double-digit annual revenue growth for the past 10 years and unique entrepreneurial culture with approachable, hands-on management that partners with employees and empowers them to contribute to the success of the business.

Our team of over 500 people is based across 13 countries in Europe and North America.

As a valued team member, you will enjoy a competitive compensation package, excellent benefits, 401K match, flexible working hours and very generous PTO.

Due to continuous growth, we are looking for a **Clinical Research Associate** (CRA) to join our NJ office. This is an exciting newly created position working on an International clinical development team on some high-profile projects.

The selected candidate will contribute to the management and oversight of clinical trials.

He/She will work closely with all R&D members as well as Project Management, Regulatory Affairs and Pharmacovigilance teams to coordinate and ensure the successful completion of the clinical activities within the agreed timelines and budget, and in compliance with the required quality, Good Clinical Practice and ICH Guidelines. Overall, He/She will coordinate activities related to clinical studies, monitor and document progress, and escalate issues to upper management. Act as liaison between site personnel and the sponsor.

Key Responsibilities:

- Contribute in the design of clinical trials, and review trial documents including but not limited to study protocols and amendments, patient information and informed consent forms, study manuals, monitoring plan, progress reports, clinical trials reports.
- Perform a comprehensive checklist of study requirements.
- Conduct pre-study visits and draft pre-study evaluation reports.
- Conduct site feasibility checks, designs and implement training to site's personnel and assess the trial site and applicable personnel on an ongoing basis.
- Conduct site-initiation visits and writes initiation visit reports.
- Perform monitoring in the field.
- Communicate with investigators and their staff, and ensure compliance with protocols, regulatory requirements, and good clinical practices.
- Perform on-site data verification, data integrity and monitor CRF completion and queries.

- Assist site personnel with internal audits or regulatory inspections, if applicable.
- Track site performance applying metrics standards and write follow-up visit reports.
- Draft an appropriate intervention plan for the avoidance of redundant errors and deviations.
- Verify the receipt, handling, accounting, storage conditions, and availability of IMP and other study materials in collaboration with the assigned resources.
- Verify the integrity of investigator files, ensuring the availability of clinical and non-clinical materials, maintain the required documentation in the Trial Master File according to the company standards and applicable guidelines, and check for consistency with the contents of sponsor files.
- Ensure compliance with the procedures to apply in the event of serious adverse events.
- Jointly review with investigators the obligations inherent at the end of the study and writes closure visit reports.
- Contribute with the project plan and monitor related budgets and resources allocation in collaboration with the clinical study managers.
- Perform ongoing follow-up with the in-house clinical project team.
- Prepare/review clinical documentation and ensure on time availability of critical documents and progress reports.
- Anticipate, recognize and resolve issues proactively with the project team.
- Travel up to 80%

Professional skills & experience:

- BSc degree in life sciences.
- Minimum 4 years of CRA experience in a pharmaceutical company or a CRO with on-site monitoring activities, preferably in oncology or nuclear medicine.
- Comprehensive and practical knowledge of the principle of clinical trial conduct in accordance with ICH/GCP and other clinical trials-related regulations or guidelines.
- Thorough knowledge of clinical development processes and conduct of clinical studies.
- Awareness of global regulatory and pharmacovigilance environments.
- Experience in coordinating collaboration with investigative centers, clinical staff and CROs.
- Experience in EC & CAs submission preparation.
- Professional proficiency in both spoken and written English.
- Experience in EDC & CTMS is a plus.
- Experience in site selection is a plus.
- Experience in contracts negotiation is a plus.

Personal skills & abilities

- Excellent communication skills.
- Strong organizational and time management skills.

- Quality oriented with attention to details.
- Highly proactive, self-motivated, professional and dedicated.
- Excellent computer skills.
- Ability to drive and willingness to travel for study monitoring and auditing.

- **Submission of your application:**

Please send your application in via email to recruitment-US@adacap.com. Your application shall include all the information you consider relevant, and at a minimum, a motivation letter, your personal data, education, employment history and details on your current position and salary as well as your salary expectations for this position.

Please note that we will only reply to candidates that we wish to bring to interview stage.

For further information on the company, please visit our web site www.adacap.com