M/F CLINICAL PROJECT MANAGER
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- **About us**

Advanced Accelerator Applications (AAA) is a radiopharmaceutical company founded in 2002 to develop innovative diagnostic and therapeutic products. AAA main focus is in the field of molecular imaging and targeted, individualized therapy for the management of patients with serious conditions ("Personalized Medicine"). The company has a strong pipeline and has maintained continuous double-digit growth in sales for the last 10 years of commercial operations. AAA is headquartered in St Genis Pouilly, France, and currently has 18 production and R&D facilities able to manufacture both diagnostics and therapeutic MNM products, and over 440 employees in 13 countries (France, Italy, UK, Germany, Switzerland, Spain, Poland, Portugal, The Netherlands, Belgium, Israel, U.S. and Canada). AAA is listed on the Nasdaq Global Select Market under the ticker "AAAP".

AAA has also a broad pipeline of products in development. The company's lead product, Lutathera®, is an advanced Phase III theragnostic oncology product developed to treat gastroenteropancreatic neuroendocrine tumors. Another AAA product in development is the radiopharmaceutical Gallium-68 Dotatate which received orphan drug status designation by both FDA and EMA, in early 2014, as a diagnostic agent for the management of GEP-NETs. Also, Phase I/II studies have been initiated with Annexin V-128, a diagnostic 99mTc tracer for apoptosis and necrosis.

AAA is looking for a **Clinical Project Manager** and a Senior Clinical Project Manager to be based in Saint Genis Pouilly, France. This position will report to the Head of Clinical Development.

- **Role**

The selected candidate will be in charge of the overall operational management and oversight of clinical trials. He/She will work closely with all R&D members as well as Regulatory Affairs, Medical 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 and Good Clinical Practice and ICH Guidelines.

- **Key tasks**
  - Coordinate activities of clinical development project, monitor and document progresses and escalate issues to management.
  - Collaborate in the design, review and approval of clinical trials and trial documents including but not limited to study protocols and amendments, investigator brochures, patient information and informed consent forms, case report forms, study manuals (e.g. monitoring plan), study tools, progress reports, final clinical trials reports, presentations.

- Prepare/ review clinical documentation and ensure on time availability of critical documents and progress reports.
- Prepare project plan and monitor related budgets and resources allocation.
- Be accountable for the deliverables of clinical trial projects within the agreed timelines and budget.
- Ensure that the scope of work, planning, expectations and establish timelines are unequivocally understood by all project team members and stakeholders.
- Anticipate, recognize and resolve issues proactively with the project team
- Organize, either directly or through selected CRO, site selection and contracting, including negotiation of budgets through completion of contract.
- Ensure that the agreed vendors and study sites activities are aligned to the established planning, timelines and budget. Validate the invoices from vendors and study sites (PI grants, subject reimbursement).
- Develop / maintain related processes, policies and SOPs.
- Ensure the appropriate communication among all functions within the company and with external vendors.
- Coordinate clinical documentation and submissions to IRB/ERBs and Regulatory Agencies within appropriate project timelines, in collaboration with selected CRO and the AAA Regulatory department.
- Ensure that the required documentation is maintained in the Trial Master File according to company standards and is available in a timely manner when required.
- Management of investigational medicinal product supplies in collaboration with the assigned resources.

- **Professional skills & experience**
  - Thorough knowledge of Project Management and Clinical Development processes.
  - Advanced scientific degree with emphasis on clinical development.
  - Comprehensive and practical knowledge of the principles of clinical trial conduct in accordance with ICH/GCP and other clinical trials-related regulations/guidelines.
  - Minimum 2 years clinical development experience in a clinical research environment including leading clinical staff.
  - Experience in oncology clinical development is a plus.
  - Experience in leading collaboration with investigative centers, KOLs and CROs
  - Professional proficiency in both spoken and written English
- **Personal skills & abilities**
  - Strong organizational and time management skills
  - Highly proactive, self-motivated, professional and dedicated
  - Flexibility and ability to prioritize and manage multiple tasks in a challenging environment

- Ability to influence and convince key stakeholders in completing clinical studies on time and within budget
- Excellent English written and oral communication skills; other languages an asset
- Proficient PC skills: Word, Excel, PowerPoint, email. Experience of e-CRF, IVRS, databases and project management tools an asset
- Quality oriented with attention to details
- Accept to travel as required

- **Submission of your application:**

Please send your application in English via email to recrutement@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