Clinical Development Physician (Oncology)

About us

Advanced Accelerator Applications (NASDAQ:AAAP) is an innovative radiopharmaceutical company developing, producing and commercializing molecular nuclear medicine theragnostics. AAA's theragnostic platform is based on radiolabeling a targeting molecule with either gallium Ga 68 for diagnostic use, or lutetium Lu 177 for therapy. AAA's first theragnostic pairing for neuroendocrine tumors includes diagnostic drugs NETSPOT® in the US and SomaKit TOC® in Europe; and therapeutic USAN: lutetium Lu 177 dotatate/INN: lutetium (177Lu) oxodotreotide (Lutathera®), which is approved for use in Europe and currently under review with the FDA. Additional theragnostics in development target gastrointestinal stromal tumors (GIST), and prostate and breast cancer. AAA is also an established leader in molecular nuclear diagnostic radiopharmaceuticals for PET and SPECT, mainly used in clinical oncology, cardiology and neurology. Headquartered in Saint-Genis-Pouilly, France, AAA currently has 20 production and R&D facilities, and more than 600 employees in 13 countries (France, Italy, the UK, Germany, Switzerland, Spain, Poland, Portugal, The Netherlands, Belgium, Israel, the US and Canada). AAA reported sales of €109.3 million in 2016 (+23% vs. 2015) and €69.2 million in 1H17 (+27% vs. 1H16).

We are currently recruiting for a **Clinical Development Physician (Oncology)** to join our Clinical Development team.

Core Responsibilities:

- Works within a Global Clinical Development Team with responsibilities across geographies within the assigned clinical trial program
- Supports the clinical development strategy for one or more indications including successful regulatory submission
- Designs and optimizes Clinical trial design
- Leads the Clinical Development Team, including interactions with discovery, safety, marketing, regulatory, research and other functions
- Designs and assists in authoring protocols and protocol amendments
- Oversees and is responsible for the quality, coordination and timeliness of protocol development
- Conducts medical review and interpretation of efficacy and safety data from clinical trials
- Responsible for the quality, coordination, medical accuracy and timeliness of clinical study reports
- Works with Head of Clinical and other team members to prepare abstracts, manuscripts and presentations for external meetings as well as author clinical sections of regulatory documents (IB, IND sections)
- Assists senior management to oversee quality, coordination and timeliness of clinical sections of INDs, Investigator Brochures, CTAs, ISS's, ISE's, and clinical expert reports

- Presents and discusses data and findings at relevant team, governance, KOL and regulatory meetings
- Participates, as required, as a clinical representative on Project Teams
- Establishes and maintains working relationship with Study investigators, key opinion leaders, academicians, and Senior managers and department heads across the corporation
- Ensures adherence to GCP/ICH and AAA SOP standards
- Maintains clinical and scientific awareness in area of expertise
- Guides day to day work of one or more Clinical Development Managers
- Implements lifecycle requirements and plans for designated indications

Key Requirements

- Minimum M.D. with a specialized knowledge in Solid Tumor Therapeutic or Disease Area (sub specialty, certification a plus)
- Minimum 6 years in Clinical Medicine with at least 4 in the pharmaceutical industry
- Understanding of drug development process
- Proven ability to work with and develop key opinion/thought leader
- Knowledge of Good Clinical Practices (GCP), FDA regulations and guidelines, and applicable international regulatory requirements
- Experience in designing Clinical trial strategies to obtain regulatory approval
- Ability to provide scientific and clinical expertise to a clinical development program and evaluate scientific and clinical strategies for a product
- Ability to develop and evaluate strategies for the clinical development of a designated indication and to critically evaluate outside expert advice
- Experience leading strategic planning for an indication or disease state
- Experience in Clinical project planning
- Experience working on global and complex Clinical trials
- Experience working effectively in a team/matrix environment
- Leadership Competencies
    - Drive Innovation
    - Shape Strategy
    - Promote Open Communication, Foster Teamwork
    - Create Global Mindset
    - Demonstrate Adaptability, Foster Risk Taking

Competencies /Skills

- Ability to use scientific and clinical knowledge to conceptualize study designs
- Ability to anticipate and resolve problems
- Excellent interpersonal skills and ability to communicate effectively with people in different regions and
- functions

- Sound organizational skills
- Strong scientific/technical skills
- Strong interpersonal capabilities and ability to build networks
- Proven leadership skills
- Proven verbal communication and technical writing skills
- Ability to present clearly in scientific and clinical settings
- Ability to lead cross-functional teams and be a true team player
- Possesses sense of urgency and initiative
- Project management skills and focus on delivery of results

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.