M/F HEAD OF BIOMETRICS AND STATISTICS

- **About us**

Advanced Accelerator Applications (AAA) is an innovative radiopharmaceutical company that develops, produces and commercializes Molecular Nuclear Medicine (MNM) products. AAA's lead therapeutic product candidate, Lutathera®, is a novel MNM compound that AAA is currently developing for the treatment of neuroendocrine tumors, a significant unmet medical need. Founded in 2002, AAA has its headquarters in Saint-Genis-Pouilly, France. AAA currently has 22 production and R&D facilities able to manufacture both diagnostics and therapeutic MNM products, and has over 490 employees in 13 countries (France, Italy, UK, Germany, Switzerland, Spain, Poland, Portugal, The Netherlands, Belgium, Israel, U.S. and Canada). AAA reported sales of €88.6 million in 2015 (+27% vs. 2014) and sales of €81.3 million for the first 9 months of 2016 (+23% vs. 9 months 2015). AAA is listed on the Nasdaq Global Select Market under the ticker "AAAP".

AAA has a broad pipeline of products in development. In addition to the company lead product, Lutathera®, and its Gallium-68 Dotatate product NetSpot recently approved by the FDA, Phase II studies have been initiated with Annexin V-128, a diagnostic 99mTc tracer for apoptosis and necrosis, and the company has other imaging and therapeutic radiopharmaceutical products in development.

AAA is recruiting a **Head of Biometrics and Statistics** based in Geneva, Switzerland. This position will report to the Global Head of Research & Development.

- **Role**

The selected candidate will play a critical role in the preclinical and clinical development programs, and regulatory submissions, providing expertise and guidance in activities related to statistical analysis and data management in compliance with best practices and regulatory guidelines. He/She will supervise biostatisticians, statistical programmers and data managers.

- **Key tasks**
  - Provide strategic and operational expertise for data interpretation and reporting from early through late stage product development programs.
  - Mentor and provide statistical guidance to data managers and statisticians.
  - Active member of protocol development core team providing input in design, outcome measures, endpoint assessment, sample size and power calculations.
  - Ensure databases are appropriately cleaned, QC'd and locked.
  - Supervise the preparation and review of statistical analysis plans for preclinical and clinical studies, statistics sections of protocols and integrated summary documents.
  - Lead qualification, routine and for-cause audits of CRO and vendors to assess effectiveness of related GCP and GLP compliance with biometrics standards.
  - Anticipate, recognize and resolve issues proactively with the project teams.

- Ensure the appropriate communication among all functions within the company and with external vendors.

- **Professional skills & experience**
  - Higher degree in biostatistics, PhD preferred, with a minimum of 10 years of pharmaceutical experience.
  - Comprehensive knowledge of US and EU guidelines on data submission format and statistical analysis requirements.
  - Working knowledge of database and software packages for statistical analysis, e.g. SAS, and statistical programming languages.
  - Demonstrated working experience with CDISC and requirements for database submission and statistical analysis.
  - Experience in implementing and interpreting meta-analyses and data modeling with prior involvement in preparing ISS/ISE.
  - Documented interactions with regulatory authorities, including the FDA and EMA, with successful NDA/MAA submission/approval(s) as a significant contributor.
  - Highly developed management and communication skills, with experience in working in a matrix organisation.

- **Personal skills & abilities**
  - Strong organizational and time management skills.
  - Quality oriented with attention to details.
  - Highly proactive, self-motivated, professional and dedicated.
  - Able to thrive in a small group setting, with high energy hands-on attitude.
  - Ability to influence and convince key stakeholders in completing pharmaceutical development on time and within budget.
  - Professional proficiency in both spoken and written English; other languages an asset.
  - Proficient PC skills: Word, Excel, PowerPoint, email.
  - 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