Role: Marie Curie ESR Fellowship in clinical evaluation of tumour biomarkers and clinical investigation of the diagnostic system

Grade: 32,000 Euro approx. (gross yearly salary) + mobility and family allowance

Report to: Dr Cristina Morelli, Prof C Oliver Hanemann, and Dr Raffaella Vergura

Direct responsibility for: Development and implementation of a clinical validation plan for tumour biomarkers encompassing retrospective clinical studies and prospective clinical trial on brain tumour patients and healthy control subjects. Clinical evaluation of safety and suitability of diagnostic systems.

Role Summary:

Under the guidance of the supervisory team, the main role of the Early Stage Researcher(ESR) is to develop and implement the comprehensive clinical validation plan for the new diagnostic systems. This implies both clinical validation of biomarkers, using the diagnostic devices and assuring a minimal clinical dataset. Based on the needs of the research project's partners, ESR will develop/harmonize the standard procedures for suitable samples collection, identify existing accessible biobanks, identify suitable clinical study sites/institutions for the conduct of clinical protocols, implement and follow up the clinical trials working closely with relevant clinical, academic and industrial collaborators in the AiPBAND consortium, and spending periods of placement at partner organisations across Europe and in China.

Key Accountabilities:

- To define the specificities of samples needed by other members of the consortium.
- To develop Standard Operating Procedures (SOPs) for the samples collection and distribution.
- To identify hospitals/research institutions suitable for providing adequate samples
- To develop in collaboration with other partners a virtual bio-bank for the member of the consortium.
- To identify and evaluate statistical models to assess clinical data related to the candidate biomarkers identified by other member of the consortium .

- To actively contribute with the support of the supervisory team to the development of the clinical validation plan for the diagnostic biomarkers.
- To develop the clinical protocols for the retrospective and prospective trials.
- To collaborate with other member of the consortium for the development of the clinical data database.
- To develop with the support of the supervisory team the Case Report Form (CRF) to be used for clinical data collection.
- To develop and finalise any study documents required for the clinical trials.
- To carry out any regulatory steps required for study approval and conduction.
- To set up clinical trials at investigational sites and follow up operational activities at sites.
- To actively participate in the network training programmes and secondments and constantly update interdisciplinary and intersectoral knowledge.
- To contribute to the achievement of the research and training objectives in conjunction with supervisory team, ESRs and other members of the consortium.
- To plan and manage own research activities in conjunction with the supervisory team and more senior colleagues within the network.
- To use own initiatives to identify areas for development of the research and to create solutions by collecting, analysing, interpreting research data and reporting on key findings.
- To help coordinate and contribute to relevant meetings, visits, conferences and to facilitate knowledge exchange.
- To deal with problems and issues which may affect the achievement of the research objectives, and to find solutions to meet delivery deadlines.
- To follow the appropriate financial and regulatory policies ensuring necessary regulations and standards are adhered to.
- To be familiar with research ethics requirements, principles of the good clinical practice and applicable regulations for clinical trials and clinical investigations with medical device.
- To ensure all activities undertaken are in compliance with MTA SOPs.

Measures of Success:

- Successful delivery of key priorities and objectives agreed.
- Successful delivery of key research and training objectives specified in the AiPBAND project proposal.
- Successful provisioning of needed samples to the member of the consortium
- Development of a clear and realistic validation plan for diagnostic biomarkers.
- Successful development of a clinical data database suitable for other member of the consortium.
- Successful set-up and follow up of clinical trials.
- Publication of high-quality journal and conference papers.

Knowledge, Education & Training; Experience – see Person Specification below.

PERSON SPECIFICATION

POST: RF	ESSENTIAL CRITERIA	DESIRABLE CRITERIA
1. Qualifications/ Education	Bachelor of pharmaceutical or medical science	Master's degree in relevant discipline, MD
2. Experience/ Knowledge	Two or more of the following areas: (a) Oncology (b) Research projects involving human subjects (c) Biostatistics (d) Clinical research	Experience/knowledge of some of the following: - medical practice - clinical research at investigational sites - project management - regulatory activities linked to clinical research
3. Skills	(a) Strong interpersonal skills (b) Excellent problem solving attitude (c) Ability to work in team (d) Excellent communication skills • (e) Excellent verbal and written communication skills in English (f) Ability to motivate collaborators	Ability to liaise with wide board of referents (scientists, neurologists, regulatory authorities..)
4. Personal Qualities/ Attributes	• Ability to work as part of an interdisciplinary team as well as independently. • Ability to meet deadlines. • Ability to prioritise based on actual needs • Flexible. • Ability to show initiative. • Organised. • Very good inter-personal skills. • Ability to present work clearly, both verbally and in written form.	
5. Other	Willingness and ability to act as a catalyst for collaboration between the consortium and the investigational sites.	