barcelonaβeta
BRAIN RESEARCH CENTER

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Clinical Operations Manager – BBRC

About the employer

The BarcelonaBeta Brain Research Center (BBRC) is a new research center, constituted by the Pasqual Maragall Foundation. The goal of BBRC is to become an internationally recognized centre of excellence in our understanding of age-related cognitive disability in order to provide practical solutions to the global challenges posed by the world's aging population. Our goal will be achieved by championing primary and secondary prevention programs for Alzheimer's disease and other related neurodegenerative disorders, the study and promotion of healthy aging, and the research of the basic physiological mechanisms of cognitive functions affected by healthy or pathological aging such as memory, learning and decision-making, among others. The vision of BBRC is to provide the society with distinct and innovative solutions for age-related cognitive disability by leveraging these complementary research programs in order to attain a multidisciplinary comprehension of the aging process and the pathophysiology of neurodegeneration.

Pasqual Maragall Foundation, Pompeu Fabra University and "la Caixa" on are permanent members of the BBRC Board. International competitive recruitment, state-of-the-art scientific facilities, effective management and continuous high-standard peer-review evaluation are the BBRC core proceedings to ensure achieving world-class research results. BBRC is affiliated and located in the Campus Ciutadella of the Barcelona Pompeu Fabra University, the building contains excellent technical facilities, including a research-dedicated 3T MR scanner, Clinical Trials facilities, EEG and Eye Tracker labs.

BBRC is also part of the Barcelona Biomedical Research Park (PRBB), a large research facility that hosts other seven different research institutions related to biomedical research, including the Center for Genomic Regulation (CRG), the Hospital del Mar Medical Research Institute (IMIM), the Department of Experimental and Health Sciences of the Pompeu Fabra University (CEXS-UPF), the Institute of Evolutionary Biology (IBE CSIC-UPF), the Barcelona Institute of Global Health (ISGlobal) and the Barcelona site of the European Molecular Biology Laboratory (EMBL), among others, in a multidisciplinary, collaborative and stimulating international environment in close contact with a clinical setting, thus conducive to translational research.

For more information see: www.fpmaragall.org and www.barcelonabeta.org

Registre de Fundacions Privades de la Generalitat de Catalunya N. 2765 30/05/2013 NIF/VAT: G65895401

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About the job

BBRC is looking for a full-time position Clinical Operations Manager (COM) to lead the BBRC Clinical Research Office. The COM will coordinate and lead the team responsible of the development and execution of clinical studies and trials performed at BBRC. The candidate will have to work with the highest research standards, in accordance to requirements of legal authorities (EC, AEMPS, EMA, FDA, etc.), following the IHC Good Clinical Practice (GCP), studies protocols, internal guidelines and when applicable SOPs of pharmaceutical companies and CROs.

The candidate will be in charge of a team of approximately 20-25 persons, composed of BBRC contracted professionals (Study Coordinators, Medical Advisors, CTAs, Study Nurses, Neuropsychologists, Participant's helpdesk) and external specialists (neurologists, anaesthetists, etc.). As a reference, BBRC has approximately 10 to 12 studies ongoing and performs more than 4.000 clinical research visits per year.

The candidate will have experience conducting clinical research in an academic research environment and will also have knowledge of procedures involved in clinical trial for the industry.

The candidate will report to the Scientific Resources Manager.

Main Responsibilities:

Project management:

- Control the Clinical Research Management System (example Global Study Tracker: GST).
- Supervise the start-up, execution and follow-up of clinical studies and assure the studies are performed with high quality standards and within the expected timings and budgets.
- Lead and supervise the team assigned to each clinical study and the related professionals (BBRC team, external providers, CRA, Auditors, etc.) in order to control and resolve any possible issues.
- Prepare and distribute studies status reports (recruitment, timing, costs. etc.)
- Act as the contact person with Regulatory Authorities, CROS, pharmaceutical companies, suppliers, providers, subcontracted institutions and others stakeholders.
- Guarantee the inclusion of the participants agreed for the different studies with BBRC, Pharma's o CROS and control the specific selection strategy needed for each study.

Clinical studies: Observational studies and clinical trials

- Establish the project flowchart, assuring the correct and most efficient assignment of human, technological and economic resources and their corresponding cost.
- Develop strategic initiatives to improve the efficiency of the Clinical Operations Office.
- Assure the correct execution of clinical research operations (BBRC own studies, European research or clinical trials), developing all the project phases in accordance with guidelines and logistic needs, including material, essential documents, costs of operations, and activities planning (initiation, execution and closure) of clinical projects.

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- Review protocols (from the BBRC Research Management Office, CROs, etc.) and coordinate the adequate submission to Ethic Committee and Regulatory Agencies for their approval.
- Guarantee the integrity of Trial Master File (TMF) of each clinical research study.

Safety and quality

- Control the creation, implementation, follow-up and maintenance of internal processes and guidelines of the Clinical Operations Office.
- Assure adherence to GCPs, internal guidelines and legislation requests.
- Interact with Regulatory departments of CROS and pharmaceutical companies.
- Maintain the standards of quality at any steps of clinical projects.
- Guarantee preparation and assure the correct realization of audits and inspections. Coordinate the resolution of findings.
- Control safety procedures for study participants following the highest standards requested in clinical research.

Costs Coordination and Budgeting

- Elaboration Clinical Operations Budgets and costs tracking (Visits/Studies costs, Investigator fees, office infrastructure budgeting and costs control, etc.).
- Contact person for BBRC clinical research fees negotiations with Industry, CROs and providers.
- Control the process of conciliation of derivative bills of the payments of the clinical assays.

Team Management

- Attract and retain the talent, reducing the rotation and increasing the sentiment of belonging.
- Promote maximum motivation and efficiency among the professionals (individual interviews, constructive feed-back, training selection, etc.).
- Distribute and control the tasks and dedications of professionals.

Required qualifications:

Qualifications and professional experience

- University degree in science or health science-related disciplines
- 5 years' experience in clinical trials, Clinical Research in Hospitals, CROs o Pharma-industry
- Proved experience in team management
- Training or Master in Clinical Research Management
- Fluent in Catalan and Spanish
- English required (Proficiency Level-written and spoken).
- Advanced level in Word Office suite.

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Personal skills

- Effective Oral and Written quality communication skills.
- Strong organizational skills: ability to plan objectives and strategies, which allow team members to perform optimally. Must be able to put systems in place that maintain order and guide team members toward the institution objectives.
- Should demonstrate integrity values and must possess effective interpersonal skills, be respectful and able to empower team members.
- Demonstrated ability in decision-making process, solving problems and reach objectives.
- Ability to think independently and work collaboratively (empathic and focused team-worker).
- Interest in joining a non-profit organization with a mission of high social impact.

We offer

- Full-time position.
- Salary will be in accordance with qualifications and experience.

We offer work in a highly stimulating team, and BBRC offers and promotes a diverse and inclusive environment. In the foundation we also care about developing your professional career so you will participate in internal and specific training for your job, promotion opportunities and development of your professional career. We evaluate the potential of our team in order to develop those skills necessary to achieve a high level of professional performance.

Application process:

To apply, please submit a single PDF file containing the following:
1) Cover letter describing research interests and relevant background;
2) CV
3) The names of up to three individuals who could provide reference letters. All files or inquiries should be submitted electronically to: rh@barcelonabeta.org

Subject: Clinical Operations Manager

Deadline: 14 Feb th 2020

We inform you that your personal data will be part of a file which Pasqual Maragall Foundation and Barcelonaβeta Brain Research Center is responsible for, in order to manage the job offer you have requested. Once the process is complete, the data processed will be erased.

You have the right to exercise the rights of access, rectification, cancellation and opposition recognized in Regulation (EU) 2016/679 (General Data Protection Regulation), to be addressed to the Pasqual Maragall Foundation and Barcelonaβeta Brain Research Center: Wellington Street 30, 08005 Barcelona.