NOVACYT
GROUP

# VACANCY

**Job title**: Clinical Performance Manager
**Location**: Stratford-Upon-Avon
**Contract:** Fixed Term Contract – until end of December 2021

We are Novacyt, a rapidly growing diagnostics group specialising in infectious diseases. We have a number of successful brands and serve a large global customer base, from hospitals to large corporates.

Primerdesign, part of the Novacyt Group, is a leading provider of RT PCR solutions. We have thousands of happy customers based across the globe and have a real ambition to drive our business forward and achieve even more. We have delivered exceptional products to combat formidable challenges. We developed the world's first swine flu detection kit, played an important part in uncovering the UK's horse meat scandal and are currently producing high-performing detection kits to support the fight against COVID-19.

We're now looking for a Clinical Performance Manager to join our team on a fixed term contract until the end of December 2021 working 37.5 hours per week.

**Job Summary**

The Clinical Performance Manager will be expected to build on the success for Novacyt in response to COVID-19 and additional assays for infectious diseases and support clinical validation of the products. This individual will be responsible for supporting the external Clinical Performance Studies, coordinate studies and reports.

**Main duties and responsibilities**

- Leads clinical operations including: Design, initiation, coordination of clinical studies to support regulatory submissions, as well as post-market clinical trials. In case of CRO managed studies: leads CRO evaluation and selection process, and provides ongoing CRO oversight. Accountable for all project timelines and deliverables
- Coordinate to make sure that the team has the resources (e.g. equipment, staff, training etc.) to properly perform validation and clinical performance tasks
- Evaluates and communicates the probability and impact of risks, develops quality and risk management plans, and ensures integration into the overall management of the project to ensure delivery consistent with the project plan
- Leads preparation and provides input into materials for Investigator Meetings, Initiation Visits, Training Meetings, and similar study related activities
- Coordinates and holds responsibility for ensuring that all data pertaining to study status is compiled and reported monthly as appropriate
- Works collaboratively with Medical Writers for the writing and editing of manuscripts, protocols, IDE submissions, CSRs, outlines, tables, and figures for clinical publications
- Responsible for ensuring that staff are consistently driving and partnering with the project teams to ensure transparency and partnership structure that assures the appropriate updates are provided, that performance is to their expectations, and that there is clear understanding of expectations as a project team member from the function to ensure the success of a matrix management structure
- Exhibits active mentorship of study team to build talent across the department
- Exhibits active leadership in project teams
- Assists in updating corporate Standard Operating Procedures (SOPs) to support adherence to company policies and procedures concerning Clinical Affairs, in coordination with Global Clinical Affairs team members
- Support in providing the information to prepare and finalize reports to stakeholders such as research and development managers and company executives

- Work closely with QA/RA in ensuring that projects are run to relevant quality standards (including the CE-IVD and FDA standards) for medical devices and in-vitro diagnostic equipment
- Ideally, excellent team leadership skills to work with a friendly team; excellent relationship building skills to work with both new and existing KOLs / Investigators and have good experience in the development of in vitro diagnostics
- Manage and organize work on product validation in accordance with regulatory directives
- Provide specialized technical training to other members of the team
- Have a deep understanding of the products in development to work as a bridge between internal analytical validation and clinical performance studies

**Qualifications and experience required**

**Essential:**

- PhD or equivalent in Biology/Molecular biology or biomedical sciences
- A minimum of five to seven years' of progressively responsible experience in clinical research within a medical device, pharmaceutical, biotechnology, CRO, and/or healthcare setting required. A minimum of one year of on-site monitoring experience or related equivalent experience required. International study management experience is preferred
- High level of molecular biology (PCR/qPCR) technical competence
- Demonstrated analytical, negotiation, meeting management, cross-functional team and leadership skills at a management level are required
- Demonstrated ability to effectively interact with and collaborate at all levels in the organization, including effective interfaces at the senior management level
- Ability to work in a logical and organised manner, with excellent attention to detail
- Excellent verbal and written communication and good organisational skills
- Ability to multitask and work in a very fast paced, dynamic environment

**Desirable:**

- Previous laboratory experience
- Category 2 lab experience is desirable, full training will be given

It's an exciting time to join our team as we are making huge leaps in the fight against COVID-19 and have recently been awarded a Breakthrough of the Year award at the European Mediscience Awards 2020.
We are the best in the world at what we do. If you are looking to learn, grow and succeed as part of a passionate team who are eager to make a difference, we want to hear from you.

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| Hours of Work | 37.5 hours per week |
| For further information or to apply for this vacancy please e-mail recruitment@novacyt.com | |