

Vacancy: Clinical study manager

As a clinical study manager at MRIguidance, a UMC Utrecht spin-off company, you will be responsible for the regulatory strategy and the setup, management and follow up of clinical studies, which are of utmost importance for the validation and certification of our product portfolio to facilitate market entry.

What you tell at birthdays about your job

“The company I work for prevents cancer in patients that need to undergo a bone scan. We create solutions that help doctors to better diagnose and cure their patients. I make sure that our products are tested on patients in hospitals around the world and that it is safe and effective.”

What you actually will be doing

At MRIguidance, the performance of clinical validation studies is a crucial part towards CE and FDA certification and clinical introduction of our products. Your task will be the planning, management and administration of these clinical research and validation studies. Utilizing existing templates and standard operating procedures in line with ISO 14155 and the MDR as a guide, you will help in setting up, implementing and monitoring these studies. You actively contribute in shaping the clinical regulatory strategy within the company. You will facilitate communication and interaction with participating medical centers, medical ethical and legal organisations in Europe and the USA. An important part of your work is ensuring the study is properly documented. You keep track of the planning and timelines. As MRIguidance is a small but growing company, we stimulate personal growth and development such that your skills and capabilities grow with the needs of the company. You will be part of the clinical team and will be supported by the current CSM and the QA officer of MRIguidance and report to the CSO.

Your responsibilities:

- Projectmanagement;
- Study administration;
- Design, write and review ethics/IRB approvals and regulatory submissions;
- Design, write and review study documents (clinical investigation plans and reports);
- Define the clinical regulatory strategy
- Manage contacts with doctors and researchers from participating medical centers, both in the Netherlands and abroad;
- Monitor and stimulate patient inclusion.

Qualifications

Minimum qualifications:

- Life Science or technical graduate (University level or equivalent);
- Knowledge of GCP, METC, CCMO;
- Knowledge of ISO standard 14155;
- Knowledge of the MDD/MDR;
- Experience with writing and reading study protocols;
- Good administrative and organisation skills;
- Fluency in Dutch and English;
- Good working knowledge of Microsoft Office tools;
- Able to work in teams but also independently;
- Ambitious and eager to learn.

Preferred qualifications:

- Knowledge of statistics and/or epidemiology
- Knowledge of the USA FDA process
- Experience with multi-center and international clinical studies
- Ability to communicate and collaborate effectively with imaging researchers and clinical specialists;
- The desire to work in a dynamic environment of a start-up company.

About MRGuidance BV

During their research MR physicist Peter Seevinck and medical image scientist Marijn van Stralen identified great unused potential for MRI-based medical imaging technologies. Together with entrepreneur Roel Raatgever, they have founded UMC Utrecht spin-off company MRGuidance in 2016. The team of MRGuidance actively collaborates with hospitals in the Netherlands and abroad to acquire unique patient data sets and clinically validate and commercialize BoneMRI, the world's first imaging technique that visualises all human tissues from one imaging exam, without the use of harmful radiation. MRGuidance's BoneMRI software will improve diagnosis and is used for surgical planning and guidance. In July 2020, MRGuidance was selected as Europe's best-in-class innovation in healthcare by the European Institute of Innovation & Technology.

Our offer

This is what we offer you:

- A market conform salary.
- A unique opportunity to, at an early stage, become part of a med-tech start-up with vast growth potential.
- Work that has a positive impact on people's health and life.
- Work in a team of smart and ambitious people.
- Work with international partners.
- Work in a startup environment where you both get freedom and responsibility.
- Work at our beautiful office at Gildstraat 91a in Utrecht.

Additional information

We believe diversity is beneficial for the creativity and a good atmosphere in our company. However, Dutch regulation makes it very complicated for smaller companies to help people from outside the EU with a work visa. Therefore, all people are welcome to apply, as long as we do not have to arrange a work visa.

For more information about this position please contact Roel Raatgever by email (info@mriguidance.com) or simply give us a call (+31 (0)85 4000 810). To apply, please send a motivation letter and your CV. Application closes 24 Nov, 2020.

Acquisition regarding this vacancy is not appreciated.

