

## Vacancy: **Clinical study manager** (+/- 32 hours per week)

As a clinical study manager at MRIguidance, a UMC Utrecht spin-off company, you will be responsible for the setup, administration, management, follow up and monitoring 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 prevents cancer in patients that need to undergo a bone scan. We create software solutions that help doctors to better diagnose and cure their patients. I am responsible for the clinical studies that proof that our software is safe and actually benefits the patients”.

### What you actually will be doing

At MRIguidance, the performance of clinical validation studies is a crucial part towards CE-marking and clinical introduction of our product. Your task will be the planning, setup, management and follow up of these clinical research and validation studies. You will be involved in the design, writing and statistical considerations of the research protocols. Utilizing existing templates and standard operating procedures in line with ISO 14155 as a guide, you will be responsible for implementing, administering and monitoring these studies. You will facilitate communication and interaction with participating medical centers, medical ethical and legal organisations and the notified body and are responsible for the organisation of the documentation. 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 work in close cooperation with the Quality Assurance officer of MRIguidance and report to the CSO.

### Your responsibilities:

- Projectmanagement;
- Study administration;
- Design and write METC and non-WMO protocols for IRB approval;
- Design and write clinical investigation plans and clinical evaluation reports;
- Doing literature studies;
- 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).
- Affinity with clinical scientific research.
- Experienced in reading scientific papers.
- Experience with writing and interpreting METC protocols.
- Good administrative and organisation skills.
- Fluency in Dutch and English.
- Able to work in teams but also independently.
- Ambition and capability to grow towards senior level.

**Preferred qualifications:**

- Knowledge of statistics and/or epidemiology.
- Knowledge of METC and CCMO.
- Knowledge of ISO standard 14155.
- BROK certification.
- 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 Roel Raatgever, former director of Europe's no.6 academic business incubator UtrechtInc, they have founded UMC Utrecht spin-off company MRGuidance. The team of MRGuidance actively collaborates with hospitals in the Netherlands and abroad to acquire unique patient data sets and clinically validate the results of the deep learning developments. MRGuidance is a fast growing company of which you will become colleague no. 10. The enthusiastic team works in a inspiring work environment in Utrecht together with other young companies. We work hard, but there's always room to play hard.

**Our offer****This is what we offer you:**

- A market conform salary.
- A unique opportunity to, already at an early stage, become part of a med-tech start-up with vast growth potential.
- The possibility to get a stake in the company.
- 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 Maliesingel 29 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 ([roel@mriguidance.com](mailto:roel@mriguidance.com)) or simply give us a call (+31 624 674 383). To apply, please send a motivation letter and your CV. Application closes February 17th, 2019.

*Acquisition regarding this vacancy is not appreciated.*

