POROUS

Cortical Bone Microstructure Analysis

CLINICAL TRIAL MANAGER

Mission & Company Introduction:

Porous GmbH was founded in 2021 with the goal of inventing a product that will revolutionize osteoporosis diagnostics worldwide using intelligent algorithms and harmless ultrasound.

Osteoporosis accounts for more days in the hospital than breast cancer, heart attack, diabetes, and other diseases. Due to this fact, the cost that osteoporosis imposes on healthcare budgets is staggering. In 2010, European Union countries spent €37 billion (US$40 billion), while in 2015, the United States spent US$20 billion, a staggering total annual cost of US$60 billion and growing.

Current measurement methods cannot detect the onset of osteoporosis but rather approximate the bone-loss associated relative fracture risk, typically at advanced stages of the disease progression. Early detection is vital because the highest fracture incidence is not seen in people diagnosed to have osteoporosis but in those diagnosed to be healthy or osteopenic (losing bone mass), rendering osteoporosis one of the most underdiagnosed diseases in the western world. Early detection technology to overcome this clinical need was not available, until today.

The Porous solution uses quantitative ultrasound (QUS) technology with patented intelligent algorithms being able to measure the cortical bone quality to a microscopic pore level without radiation hazards. The intelligent algorithms overcome the limitations of ultrasound imaging in the bone where waves are scattered, making it impossible to analyze the cortical bone (micro) structure. This unique technology can measure for the first time not only the cortical thickness, but also the microscopic pores and pore-size distribution in human cortical bone of the peripheral skeleton.

Due to the use of ultrasound systems (mobile by design), this solution can be used anywhere in- or outside the hospital, e.g., primary care, elderly homes, or even pharmacies. It creates the ability to use the technology for prevention (screening); being able to diagnose patients already at the onset of osteoporosis.

In the near future, Porous will move to a brand-new location at the Potsdam Science Park, which can be reached from Berlin in about 30 minutes by public transportation. Due to Covid, mobile working will be deeply integrated into the company culture. You will be one of the first team members which will give you the opportunity to move a lot yourself and you can take away a lot for yourself. We embrace innovation, curiosity and flexibility.

With this position we expect you to:

In today's ever-advancing medical field, clinical trials serve an essential purpose to determine if a type of medical treatment, device, or medication is safe and effective. To ensure the smooth operation and effectiveness of clinical trials, qualified professionals are essential. As clinical trial manager you are responsible for directing the process of clinical trials by employing effective organizational strategies and reviewing the results using rigorous clinical procedures. He or she often interacts with clinical staff, reviews the progress of trials, and makes the necessary modifications to the structure and processes based on results or feedback. In all activities, a clinical trial manager must respect confidentiality and privacy and abide by safety standards.

Your role and responsibilities:

The primary responsibility the clinical trial manager is managing new and ongoing clinical trials. He or she is in charge of preparing protocols and case forms and finalizing monitoring and data management options. He or she is responsible for the development of recruitment methods to increase patient randomization into the trial, approval for trials from an ethics committee, delivery of materials for clinical trials, and coordinating the trial to make sure it runs smoothly. The clinical trial manager also trains, directs, and manages other professionals, such as clinical trial investigators, clinical trial nurses, and other clinical trial associates. He or she must make sure all individuals are up to date on all aspects of a clinical trial. The clinical trial manager also spends a great deal of time communicating with other professionals via phone, email, and face-to-face meetings to make sure the whole clinical trial team is consistently aware of any relevant information and issues.

- The overall efficient day-to-day management of the trial.
- Recruitment, retention, training, appraisal and supervision of trial team members.
- Establishment of procedures to ensure adherence to trial protocols and administrative requirements.
- Ensuring the timely recruitment of trial participants with secure randomisation processes and subsequent efficient and effective data management.
- Monitoring trial progress to ensure compliance with and adherence to the project plan and to identify, evaluate and rectify problems.
- Management of the trial budget(s) and maintenance of the accounts.
- Act as the point of contact for all external and internal agencies.
- Co-ordinate the preparation and publication of data, reports and information, ensuring that they meet legislative, contractual and ethical requirements.
- Understand the requirements of the various controlling bodies, agencies and frameworks, guiding the project in conforming to those requirements and co-ordinating any necessary audit processes.
- Liaison with the Trials Steering Committee and Data Monitoring and Ethics Committee with a particular view on compliance with Research Governance, Good Clinical Practice, Data Protection and Ethical Requirements.
- Provision of regular and ad hoc information, both written and verbal, to all the trial participants and sponsors, to include reports, updates, guidance, preformed commitments and possibly a newsletter.
- Work with the Chief Investigator to ensure that the trial is meeting its targets, is producing meaningful output and to predict and plan any changes that warrant requests to changes in protocol, funding or time.
- Ensure the inclusion of consumer group representatives at the appropriate levels and times.
- Planning and supporting the meetings and work of the various groups and bodies associated with the trial.
- Creation and maintenance of all trial files, including the trial master file, and oversight of site files.
- Assurance that personal and confidential information is restricted to those entitled to know.

Your skills:

As clinical trial manager you must have the ability to work independently as well as communicate well with other professionals. He or she must have strong written and verbal communication abilities and highly effective interpersonal skills. He or she must also have the confidence to direct training sessions or present protocols, research findings, and trial results. Excellent organization and ability to focus on detail are also essential as all paperwork must be filed systematically and submitted to the appropriate individual or organization. As clinical trial manager you must also possess effective leadership abilities including excellent communication and presentation skills.

Porous offers:

- An international high end MedTech start-up environment where your work makes the difference for Osteoporosis patients.
- A gross monthly salary depending on your experience, knowledge of the field, etc.
- 25 Holidays
- And more….the perks of a start-up!

Interested?

If you are interested, please contact Jonas Massmann by sending you resume and introduction letter to jonas@porous.care