# Occlutech

# Clinical Research Associate

Occlutech is the leader in developing innovative products for the treatment of structural heart disease. The Company manufactures, develops, sells and markets Class III medical devices for the transcatheter repair of structural heart defects, including a range of specialized devices for patients with atrial fibrillation or heart failure, in over 90 markets around the world. Occlutech operates facilities in Germany, Turkey and Sweden. For additional information please visit our website at www.occlutech.com.

**Position:** Clinical Research Associate (CRA)

**Location:** Istanbul, Turkey

The CRA will assist in the conduct of clinical trial activities such as supporting in submission process, ensuring appropriate documentation and preparing relevant trial specific documents and communication with trial sites.

A young and motivated team will welcome you to meet the challenges of clinical research. After an introduction period, you will have freedom for self-organization to fulfill your tasks. We also offer opportunities for further professional development.

## Your work will focus on

- Plan, prepare and manage all monitoring related activities, performance of monitoring of trial/registry sites
- Conduct clinical trials, clinical studies and registries according to all applicable regulations, to commonly accepted practices, and to Occlutech's internal guidelines, i.e.
    - Prepare Essential documents according to ISO 14155, MDR
    - Care for submission-approvals by Competent Authorities and favorable opinions by responsible Ethics Committees
    - Plan and track the course of the studies and update tracking lists
    - Liaise with study investigators and site staff on a regular basis
- Oversee and lead subcontractors such as, but not limited to, data management, local monitors
- If required, assist in Study audits
- Mainline of communication between investigators/site staff and Occlutech
- Provide regular updates to CRM on trial status, plans and bottlenecks
- Contribute to Occlutech QM system (e.g. preparing SOPs)
- Perform other related duties and responsibilities, on occasion, as assigned
- Flexibility and openness to providing assistance in non-specific daily work tasks when and wherever needed

**Occlutech Ltd.**
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## We are looking for a candidate, who has

- A minimum of 3 years experience in the field of clinical research
- Knowledge of relevant government regulations, standards and guidelines
- Knowledge on Medical Device Regulation (MDR)
- Strong analytical and problem-solving skills & excellent interpersonal and communication skills & team player.
- Proven track record of working in a dynamic, international environment
- Proficient user of computer applications, software's for the execution of daily project operations
- Experience in using on Clinical trial management system (CTMS) or equivalent
- Ability to travel when it is needed
- Excellent written and spoken English.
- Excellent written and verbal communication skills are required. Demonstrated proficiency with ICH, and GCP,ISO is required

## If you are

- a team player who likes challenges
- a confident user of standard office software
- excellent in communication, organization and time management
- open to international travel

Then we can offer you an interesting job in a team of people who like to work together and always focus on helping our customers to save and improve patient's lives with innovative and highest quality products.

## Are you interested?

We look forward to receiving your application (cover letter, CV, references - all documents in one pdf file), your salary expectation and the earliest possible date for start of work to tugce.erdogan@occlutech.com

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