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Clinical Affairs Program Manager Belgium

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Company: Chronos Consulting

Location: Belgium

Category: computer-and-mathematical

Job Description

Our client is a global medical device company, a pioneer of the MR-guided focused ultrasound technology which is a game-changing innovation. They are looking for a Clinical Affairs Program Manager Europe. The role is % remote with up to 40% travel and based in Europe.

As part of the global clinical affairs team, you will be responsible for developing strategies for a successful execution of roadmap clinical trials that demonstrate medical product safety and efficacy. Additional responsibilities include management of clinical trials approvals with local IRBs and/or Competent Authorities.

Required Skills and Experience:

1) BS, BA, BSN or RN or higher degree in the Life Sciences or related disciplines

2) Minimum 3+ years in clinical management position in biopharmaceutical or device industry, Clinical Research Organization. Biopharmaceutical experience would provide a strong advantage

3) Additional 4+ years direct experience in clinical trial management

4) Solid track record in successfully executing Phase I – III clinical trials

5) Demonstrated expert knowledge and comprehensive understanding of applicable GCP, ICH, ISO guidelines. Additional FDA and or Health Canada experience would provide a strong advantage but will not be required.

6) Strong, hands-on manager with experience in managing Core Labs, data management, biostatistics, and medical safety reporting

7) Knowledge of electronic data capture systems and web-based clinical trial management tools

8) Excellent interpersonal, written / verbal communication, computer & organizational skills, strong program management and financial skills

9) Excellent command of the English language; both written and verbal. Additional language beside native language is a significant advantage

10) Collaborative team player with strong abilities to operate independently

11) Willing & able to travel domestically and internationally, as required (up to 40%)

Responsibilities:

Collaborate with Company Stakeholders to execute company objectives into successful clinical trials, investigator-sponsored studies, etc.

Overall responsibility for design of clinical trials including protocol development, clinical trial discussions with EU Competent Authorities, and development of timeline and budget

Manage the process of screening/qualifying, selecting, and contracting with investigators, sites and vendors required for conduct of clinical trials

Direct/Manage necessary clinical trial approvals from IRBs/ECs, and ensure studies are on track for site initiation, patient recruitment and enrollment; take corrective actions where necessary to address issues

Develops budget for all clinical projects and adhere to company financial goals

Ensure clinical results are interpreted and documented clearly and concisely for regulatory submissions and publications

Develop, maintain and expand collaborations with Company Stakeholders, clinical investigators and researchers, and key opinion leaders to optimize the clinical development programs

Participate in the development of SOPs and work instructions to assure internal files and clinical study files (patient; site; country) conform to Good Clinical Practice regulations and standards

Ensure adherence to protocols and compliance with regulatory (FDA/ICH/ISO/GCP) guidelines as well as SOP procedures

Identify clinical training needs and develop training materials for in-house and clinical site use

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