SENIOR CLINICAL TRIAL ASSISTANT

(OPERATIONS DEPT.)

MEDSIR is a private company founded by scientific experts in Barcelona, Spain in 2012. We are dedicated to the design and management of strategic clinical trials in oncology, from study conception to the publication of study results. Together, we create the best strategies that are both clinically relevant and scientifically meaningful. We strive to improve our knowledge of this complex disease and the vast array of available treatments in a fast-innovative way.

We are looking for a **Senior Clinical Trial Assistant (CTA) / Senior Regulatory Affairs** in our Operations Department. The position's main objective will be to fully carry out international MEDSIR-sponsored clinical trials in the pre-established time frames. We offer a professional career development within a growing company.

DESCRIPTION: As a **Senior Clinical Trial Assistant (CTA),** in our Operations Department. CTA will report to Project Operations Director. The Senior Clinical Trial Assistant (CTA) main goal is to provide administrative and logistics support within the Clinical Operations team in the successful execution of clinical trials from protocol concept to clinical trial report, complying with international Good Clinical Practice (GCP) guidelines/regulations and Standard Operating Procedures (SOPs). This position undertakes a variety of the daily activities of the Operations Department, focus on reports and operational documents. We offer a professional career development within a growing company.

Senior Clinical Trial Assistant (CTA)

Include key duties as follows:

- Coordinate the preparation, collection, distribution and tracking of study documents such as confidential disclosure agreements (CDA), Financial Disclosures, contracts, newsletters, etc
- Set-up, update and maintain clinical trial-related trackers such as regulatory documents, trial master file, start- up progress, screening/enrollment, study invoices/payments, project budgets and others as necessary;
- Prepare, maintain, and archive trial master files;
- Perform trials master file quality controls to ensure completeness and audit-readiness;
- Request, manage, distribute and track study supplies (Regulatory Binders, Study Reference Manuals & ancillary supplies);
- Distribute recruitment and other research subject-facing trial materials;
- Support on oversight of budgets and payments from customers/providers
- Support on the preparation and follow-up of audit/inspection readiness;
- Assist with IRB/EC and regulatory submissions and annual reports;
- Assist with regulatory submissions of Clinical Trials to EU and EEUU (highly valued)
- Coordinate, provide set up, and attend project meetings including internal team, CRO /vendor meetings, support presentations, etc.;
- Regularly review documents to ensure adherence to Clinical Operations and/or project specific quality requirements (e.g. SOPs, work practices, training guides) as applicable;

- Assist with identifying and implementing best practices and continuous improvement plans within the company;
- Perform quality checks on submission documents and site essential documents;
- Prepare and approve informed consent forms;
- Review pertinent regulations to develop proactive solutions to start-up issues and challenges

Experience

- Experience of leading the coordinating of preparation of high-quality submissions to regulatory agencies for clinical trial within project timelines.
- Experience in the Pharmaceutical industry in Regulatory Affairs or Drug Development.
- Understanding of, and ability to determine relevance of, governmental regulatory processes and regulations as pertains to investigational drug regulation.
- Project management experience and ability to work independently, supervisory experience would be an asset although not essential.
- Excellent communication skills, organization and planning skills and attention to detail.
- Must be able to communicate effectively in the English language.

SKILLS AND QUALIFICATION

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- High education degree in a related field.
- Based in the EU.
- Fluent in English, both oral and written.
- Strong interpersonal, communication, facilitation and presentation skills.
- Strong analytical and problem-solving skills.
- Ability to work independently and with minimal supervision.
- Demonstrated ability to work in a small team setting.
- Good computer skills, proficient with MS Office (Word y Excel) applications.
- Good database management
- Ability to communicate effectively in both official languages is an asset.

Benefits/what we can offer:

- Flexible work-life balance: we are focused in performance and everybody has different ways to achieve it. We make our best so that our colleagues feel comfortable in their work environment.
- Growing together: We are an early stage company with a multidisciplinary team. We offer the opportunity to people to grow together with the company.
- Equal Employment Opportunity: We proudly pursue a diverse workforce and we don't make any hiring or employment decisions that could be discriminatory in any way.
- Workplace: Torre Glòries. Planta 27 in Barcelona, 360º beautiful views of the city and Mediterranean Sea.
- We work with MAC computer (Apple)

Required languages:
Fluent in English, knowledge of other EU languages would be highly valued.

Minimum professional experience required:
3-4 years of experience of the following areas: Regulatory Affairs, Regulatory Clinical Trial Submission (Knowledge of Oncology Clinical Trials would be highly valued)

Industry
Pharmaceuticals, Research, Health Care and Hospitals.

Employment Type: Fulltime.
Flexible time schedule, and with the opportunity to work homebased some days of the week.

Salary: (according to the experience and references)

Company location: Torre Glòries. Planta 27. Barcelona.