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Clinical Study Lead (maternity leave)

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Company: Oxford Global Resources

Location: United Kingdom

Category: other-general

Oxford Global Resources is hiring a Clinical Study Lead (IVD experience is a must) for temporary maternity leave. As a Clinical Study Lead/Trial Manager you will be responsible for the development and execution of all study associated documentation including protocols, investigator brochure, informed consent, contracts, and reports, in compliance with relevant regulations, guidelines and SOPs.The Trial Lead is responsible for creating and implementing study-specific clinical monitoring tools and documents; responsible for managing and tracking of clinical studies and budget, ensuring study completion in a timely manner within budget, escalating potential issues, setting up internal and external communications for correction, trouble shooting, and prevention planning.Also: Accountable for ensuring study site preparation, equipment, and training are compliant to the clinical protocol and organization’s SOPs.Responsible for clinical study data entry and audit; adherence to all regulations including patient privacy per organizational policies.Coordinating and supervising clinical monitoring team.Providing Clinical Research Associates with project-specific training and having regular meetings with them.Arranging and overseeing site visits. Accountable for managing site auditing or QC visits where necessary to address or improve quality.Accountable for study close out procedures on study binders, datasets and study supplies working with CTAs, CRAs and Data / Statistic stakeholders for close-out documents and reviews.Authors clinical study reports and study related submission documents to regulatory authorities, IRBs and local agencies in line with their requirements. Accountable for supplementing data or documents for any queries from authorities during submission procedures. Support CA function input for studies during audits e.g. BIMO,

Pharma partner, FDA.Education: Bachelor’s degree in, life sciences, biomedical engineering or nursing5-8 years working experience with in vitro diagnostic devices company. Minimum 3 years working experience in Clinical Affairs/Operations is preferred, but experience in product development, quality and regulatory will be considered as part of overall professional experience. Working experience in clinical study management including good clinical practice is preferred . YesWorking knowledge of Regulatory requirements e.g. FDA CFR, ICH GCP, ISO14155, IVDR. Proficient with Microsoft Office Word and Excel. Understanding of Electronic Data Capture (eDC), eTMF and CTMS or similar clinical operations systems. Proficient English oral and written communication.

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