OPERATIONS MANAGER
Position Announcement

Collaborative Strategies, Inc. is excited to be conducting a search on behalf of Sundance Clinical Research. This organization serves the community of St. Louis by advancing drug development. Sundance works to bring awareness to the importance of participating in clinical research studies. Their state-of-the-art, dedicated, multi-specialty research facility works to test new treatments during the multi-phase research and development process. These medical treatments are not generally available and are provided to patients at no cost.

If you are looking for an organization where you can really make a difference in the world of health care and have a big impact on the organization, then this is the place for you! The dedicated team at Sundance all works together to get the job done and no job is too small for anyone – even the president! But the leader of this company needs help managing the day-to-day operations, which is why they are looking for an Operations Manager to join their team.

The Operations Manager will manage all aspects of the operations and clinical research program of the site, ensuring compliance, reporting on studies and maintaining the site.

Reporting to the President, the Operations Manager will:

LEAD OPERATIONS OF CLINICAL STUDIES: Responsible for the overall administration and coordination of activities for clinical research studies and programs. Promptly complete and submit feasibility questionnaires. Meticulously oversee how the research plan is executed. Troubleshoot and resolve any issues that arise during the course of a study.

OVERSEE CLINICAL RESEARCH STUDY PROTOCOLS: Implement protocol standards developed by the pharma company and approved by the Food & Drug Administration (FDA) and provide feedback. Determine, implement and document enrollment procedures, data management, essential documents management, trial monitoring and operational project management. Supervise the lab coordinator shipping clinical specimens in a secure manner as required by the protocol. Oversee the regulatory coordinator's file maintenance for every study and tracking of participation in training conducted by the pharma company. Perform quality reviews to ensure adequate execution of protocols and site training, as needed.

MANAGE RECRUITMENT OF STUDY PARTICIPANTS: Develop a recruitment plan for each study to include sponsor-provided advertising funds, methods of recruitment, rate of recruitment and development of recruitment scripts, etc. Ensure study participant enrollment and recruitment goals are met or exceeded. Evaluate site's website and Facebook page on a regular basis for

updates, post new study information and link to the site's CTMS system to enable interested subject contact.

MANAGE DATA AND REPORTING: Generate reports on patient enrollment and tracking on a regular basis and as needed, and implement actions to correct inadequacies in reaching the site's enrollment goals. Ensure accurate, confidential and complete compilation of data through oversight of the Quality Assurance (QA) function. Conduct data analysis and reporting. Ensure maintenance of source documents and subject files in accordance with policies and procedures.

MANAGE THE SITE: Conduct site meetings and communicate information to keep staff informed. Maintain and manage the inventory of needed equipment, supplies and outsourced services with acceptable suppliers in a cost-effective manner. Ensure the site is maintained in an attractive, safe and efficient manner. Perform human resources duties including ensuring compliance with human resources policies, posting positions on Indeed or other recruitment tool, screening and scheduling applicants, assisting with offers to applicants, onboarding of new staff, monitoring overtime and paid time off and acting as a liaison between staff and payroll. Draft new policies for the employee handbook as needed and review collaborate with the President to finalize and roll out to staff.

ENSURE COMPLIANCE: Monitor and ensure site compliance with company, government and industry regulations, policies and procedures, quality assurance guidelines and all federal, state and local laws. Ensure compliance and maintain study-related documentation requirements, including regulatory documents. Audit operations to ensure compliance with protocol and applicable regulations. Prepare for and coordinate all aspects of regulatory agency site visits, including required paperwork.

FOSTER RELATIONSHIPS: Establish and maintain positive relationships with external clinical/contract research organizations and clinical study site. Build strong relationships with various persons involved in studies, including but not limited to: patients, relatives/friends of patients, doctors, pharmaceutical sponsors and all levels of the company. Serve as a contact for principal investigators and sub-investigators as needed an in the absence of the President.

MANAGE A HIGH PERFORMING TEAM: Recruit, onboard/train, supervise and evaluate the performance of assigned staff. Establish objectives and define results required for direct reports in support of the strategic business goals. Coach, inspire and enable staff to effectively perform and work with other departments.

QUALIFICATIONS

- Bachelor's degree in business, a clinical area or related field. Clinical knowledge preferred.

- Minimum of five years of experience in business operations management and ensuring ends goals are met. Experience managing operations of clinical research studies a plus.
- Minimum of two years of experience managing staff, including attracting, training, establishing performance expectations and retaining top talent.
- Familiarity with government compliance of clinical research studies.
- Marketing experience including social media, Google analytics and/or website administration.
- Experience analyzing and implementing new technology.

OTHER SKILLS AND ABILITIES

- High ethical standards and professional integrity.
- Strong communications skills, including verbal and written communication skills. Keeps supervisor and others informed as appropriate.
- Collaborative nature and able to quickly build trust.
- Excellent interpersonal skills that garner cooperation from others.
- Innovative mindset.
- Process-oriented; develops and updates processes to maximize efficiency and maintain quality.
- Ability to quickly analyze situations and develop strong solutions.
- Outstanding critical thinking and analytical skills.
- Organized and able to multi-task well.
- Solid understanding of technology.
- Strong negotiation skills.

READY TO APPLY?

If you are interested, qualified and ready to take the next step, apply on-line at getcollaborative.com/careers. All inquiries and resume submissions will be treated as strictly confidential. Please do not contact Sundance Clinical Research directly.

Collaborative Strategies, Inc. is a St. Louis-based consulting firm with a dedicated search practice and has been connecting talent with opportunity since 1994. We take pride in matching talented leaders seeking mission-critical endeavors with entrepreneurial organizations. For more information, visit us at getcollaborative.com. To view our job board, visit getcollaborative.com/careers.

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