

Clinical Study Manager

Full-time · On-site · Minneapolis, Minnesota, U.S.

At TRiCares, we are dedicated to providing innovative, minimally invasive treatment solutions for patients suffering from failing tricuspid valves. As a growing MedTech company based in Munich, we are looking for a proactive and skilled Clinical Study Manager to join our dynamic team and support us in our mission to improve patient care.

This is a unique opportunity to join a growing medical device company, where you will be part of a passionate and international team working towards transforming the landscape of cardiovascular treatment through innovative technology.

The Clinical Study Manager will lead the day-to-day execution of a global pivotal IDE clinical study, working closely with sites, CROs, vendors, and internal teams to keep the trial on track. This role is responsible for enrolment, study timelines, data quality, and ensuring the study is inspection-ready from start-up through closeout.

Key Responsibilities:

- Manage all operational aspects of the study from site selection through database lock, PMA submission and closeout.
- Lead study team meetings and coordinate cross functional activities across clinical, data management, safety, biostatistics, regulatory, and quality teams.
- Oversee study start-up activities, including site activation, contracts, IRB approvals, and site training.
- Monitor enrolment and site performance, identify risks early, and implement plans to keep recruitment on track.
- Manage CROs and vendors, ensuring deliverables, timelines, and budgets are met.
- Review monitoring reports, track study issues, and ensure corrective actions are completed.
- Maintain TMF quality and inspection readiness throughout the study.
- Track study budgets, site payments, and vendor invoices, escalating potential budget concerns as needed.
- Coordinate protocol amendments, including site communications, re-consenting activities, and regulatory submissions.
- Support database lock, study closeout, investigational product reconciliation, and final site payments.

Qualifications and Experience:

- Bachelor's degree in Life Sciences, Nursing, or a related field.
- 7+ years of clinical research experience, including management of medical device studies.
- Experience managing IDE and/or pivotal clinical trials.
- Strong understanding of FDA regulations, GCP, and ISO 14155.
- Experience working with CROs, investigators, and cross-functional teams.
- Strong project management, communication, and organizational skills.

Preferred:

- Cardiovascular, structural heart, or Class III medical device experience.
- Experience supporting PMA submissions.
- Startup or fast-growth medical device company experience.
- ACRP or SOCRA certification.

What We Offer:

- A dynamic and forward-thinking work environment, shaping the future of transcatheter heart valve therapy
- The opportunity to work in a truly international team, with talented and driven colleagues from around the globe
- A strong company culture rooted in collaboration, innovation, and purpose
- Excellent opportunities for personal and professional development in a fast-growing MedTech company
- A competitive compensation and benefits package tailored to your experience and contribution
- Regular team events and offsites to connect, celebrate successes, and foster team spirit
- An inclusive and respectful workplace where diversity is not only welcomed but valued

Ready to make a difference?

We look forward to receiving your application. Join us on our journey to transform patient care – one heartbeat at a time.

Apply now at: hr@tricares.de.