

JOB DESCRIPTION

POSITION TITLE: *Clinical Project Manager*

REPORTS TO: *Director of Operations*

EXEMPT/NON-EXEMPT: Exempt

POSITION OVERVIEW:

The Clinical Project Manager (CPM) manages day-to-day operational and tactical aspects of multiple large-scale projects simultaneously, including those of high-volumes of data, increased risk, and complexity. The CPM has overall responsibility and accountability to successfully execute projects as defined by the governing contract and protocol, and working closely with the Director of Operations to facilitate decisions necessary for timely delivery of high-quality work products.

DUTIES AND RESPONSIBILITIES:

- Project Support for Trials and Studies
 - Internal Support and Delivery
 - Leads planning and communication with cross-functional teams to ensure proper and timely execution of clinical projects, assigning individual responsibilities (as needed), identifying appropriate resources needed, and developing the project plan and schedule to ensure timely completion of project deliverables
 - Manage the project teams and ensure the project tasks are in line with the project goals
 - Apply effective communication and reporting strategies to meet objectives
 - Produce project-specific reports, and participate in the design of new reports
 - Monitor and track compliance to current, cumulative contractual scope of work
 - Follows a structured and practical method for managing change and scope to account for complex and often emergent client needs
 - Serves as a key participant on the team and in the production of client deliverables
 - Accountable for QC/QA and review procedures to ensure profitable and successful execution of agreements as measured by internal goals and customer satisfaction
 - Effectively communicates relevant project information to superiors and peers within the organization
 - Provide a structured and practical method of managing project risks
 - Accountable for billing support and documentation of project deliverables
 - Sponsor & Client (External Support)
 - Leads and manages all aspects of the clinical project and accountable for adherence to the contract and timelines
 - Executes project initiation activities including management of schedule, cost, resources, milestones and key deliverables
 - Develop and finalize the image transfer protocol for each project
 - Oversee an approve project specific materials
 - Primary point of contact for all operational issues relating to study conduct

- Maintain continual and clear communication to set expectations, target delivery dates and milestones for client deliverables and project activities in support of sponsor deadlines and regulatory submissions
- Manages and reports on the progress and status of the project
- Continually seek and capitalize upon opportunities to increase customer satisfaction and deepen client relationships
- Anticipates client needs and proposes business solutions
- Possesses a knowledge base of each client's business, origination and objectives
- Tactfully communicate sensitive information
- Site & Clinical Investigator (External Support)
 - Monitor and oversee site initiation activities, and maintain documentation of process
 - Schedule and deliver site training (via web or in person), as needed
 - Ensure required materials and/or equipment is available for delivery to sites
 - Support sites for image acquisition and/or image transfer, as needed
 - Oversight and management of discrepant data handling, including the submission of queries to site/sponsor/CRO for resolution and documentation
- General
 - Manages projects with quick turn processing and reporting (i.e. eligibility studies)
 - Reviews high-level deliverables and trends for projects across multiple studies to identify areas for organizational improvement and project-specific corrective actions
 - Work across organization to share lessons learned and best practices
 - Lend expertise/assistance to internal teams
 - Assists in evaluation and redesign of organizational offerings
 - Manages/Leads Clinical Project Management Initiatives
 - Manages and provides Production overview training and orientation to internal (non-Production) staff, as designated Provide oversight and mentorship to Associate Clinical Project Manager(s)
 - Assists in determining new, creative ways to employ teams on projects and distribute responsibilities
 - Recognizes areas for internal improvement and develops plans for implementation
 - Lead preparation for regulatory and project / sponsor audits, and provide support during onsite visits
 - Understand the Medical Metrics Quality Policy and support the achievement of the organization's quality objectives and take corrective action when necessary to mitigate organizational risk
 - Comply with company policies and procedures, ISO 9001, and Current Good Clinical Practices (cGCP's) relative to job tasks
 - Ensures compliance with HR policies and procedure

EDUCATION & EXPERIENCE:

- Bachelor's degree in research, medical, or science-related discipline or comparable work history
- Minimum of 2 years project/study/trial management experience, including large scale, complex, cross functional projects
- Minimum of 3 years clinical research experience

SKILLS REQUIRED:

- Strong project management and best practices
- Demonstrated excellence in both written and oral communication skills
- Strong customer service skills
- Strong leadership skills
- Strong analytical skills
- Self-motivated and directed
- Experience working in a team oriented, collaborative environment
- Ability to communicate technical information in a business-friendly manner at all levels of the organization
- Ability to manage multiple concurrent tasks, determine relative importance of each, and set working priorities for self and team
- Ability to plan, facilitate, and conduct meetings
- Negotiating skills within a context of conflicting interests
- High aptitude for learning new tools and skills quickly
- Ability to influence without direct authority
- Experience with standard tools, including but not limited to Microsoft Office (Word, Excel, PowerPoint, etc.), to deliver assigned projects
- Working knowledge of clinical trials of all phases, both device and pharmaceutical

PLUSES:

- Global project/study/trial management experience preferred
- Working knowledge of conventional clinical imaging modalities (XR, CT, MR, and others)
- Prior experience at an imaging core lab, contract research organization (CRO), regulatory agency, device manufacturer, or pharmaceutical / biotech company
- Knowledge and understanding of the FDA 510(k) / PMA regulatory pathways

COMPANY & COMPENSATION:

- Medical Metrics Inc. (MMI) is a fast-growing, independent imaging core laboratory and medical imaging solutions company based in Houston, TX. MMI provides image analysis and consulting services to medical device, biologics, and pharmaceutical companies in support of their clinical trials and product R&D.
- Competitive salary, commensurate with experience and qualifications
- Excellent benefits package including medical, dental, and life insurance, 401(k) plan, and paid vacation and holidays

For further information, please contact:

Michal Houston, MS
Director of Operations
mhouston@medicalmetrics.com

Sara Minton, MA
Sr. Manager, HR & Administration
sminton@medicalmetrics.com