Associate Study Manager, Clinical Operations

Title: Associate Study Manager, Clinical Operations
Reports to: Associate Director, Clinical Operations
Department: Clinical
Location: Norwalk, CT/Remote (hybrid)

MMRF OVERVIEW:

The Multiple Myeloma Research Foundation (MMRF) is the largest nonprofit in the world solely focused on accelerating a cure for each and every multiple myeloma patient. We drive the development and delivery of next-generation therapies, leverage data to identify optimal and more personalized treatment approaches, and empower myeloma patients and the broader community with information and resources to extend their lives. Central to our mission is our commitment to advancing health equity so that all myeloma patients can benefit from the scientific and clinical advances we pursue. Since our inception, the MMRF has committed over $600 million+ for research, opened nearly 100 clinical trials, and helped bring 15+ FDA-approved therapies to market, which have tripled the life expectancy of myeloma patients. To learn more, visit www.themmrf.org.

MMRF Core Values:

At the MMRF our core values define both who we are and how we work together as an organization. We believe in investing in our team and building a culture that will help us pursue our highest level mission to accelerate a cure for each and every multiple myeloma patient. Our five core values are expressed below:

1. **Prioritize Patients** - Patients are at the center of everything we do. Every decision we make is grounded in the needs and best interests of the patients we serve.
2. **Drive Innovation** - We are committed to pursuing big, bold ideas. Taking risks, trying new approaches, and challenging the status quo are necessary to speed new discoveries.
3. **Deliver Solutions** - Taking on complicated challenges is what sets us apart. To deliver results, we must be decisive, take action, and act with urgency on behalf of the myeloma community.
4. **Do It Together** - We know that together, we are stronger. We work cross-functionally with the entire community to achieve our mission and are invested in the success of others.
5. **Build Trust** - We build trust-based relationships. We advocate for each and every myeloma patient by committing to diversity, equity, and inclusion and treating others with respect.

Position Overview: Reporting to the Associate Director, Clinical Operations, the Associate Study Manager is responsible for leading the operational planning and execution of translational research studies, overseeing all aspects of a study from initiation through to completion, ensuring compliance with regulatory standards (FDA, GCP), and collaborating with cross-functional teams to deliver high-quality data on time and within budget. The Associate Study Manager will provide high level management and oversight of translational research studies conducted through the Multiple Myeloma Research Consortium (MMRC), including the Translational Research Umbrella studies (TRU). The Associate Study Manager will be responsible for all aspects of study conduct, accountable for ensuring that timelines and milestones are met, and for will serve as the primary point of contact, under the direction of the Associate Director. Experience and knowledge of end-to-end management of clinical and translational research conduct, knowledge of academic and hospital study site operations, the pharmaceutical and biotech industry, and regulatory

requirements is essential.

Essential Functions:

- Manage all aspects of the study, including responsibility for oversight of study execution, develop and manage comprehensive study timelines and metrics; management/oversight of external vendor deliverables reports and budgets.
- Study design and planning: Actively participate in protocol development, feasibility assessments, site selection, and budget planning for assigned studies. Write and review study protocols, informed consent forms, and amendments, as appropriate.
- Manage and report on study budget, working closely with finance and accounting.
- Manage/track study budget progress, expenses, vendor, pharma/biotech partner invoices, and study site payments.
- Prepare study reports and disseminate, present, and inform on all aspects of the study progress to MMRF leadership and cross functional teams.
- Prepare and present project reports as required.
- Plans, executes, and leads study-specific meetings as needed (e.g., Study Management Meetings, site calls etc.).
- Risk management: Proactively identify potential risks associated with the study and implement mitigation strategies.
- Develop and facilitate requests for proposals (RFP) for all study vendors, including and others, as appropriate, under the direction of the Associate Director, Clinical Operations.
- Conduct critical analysis of areas of risk; identify, manage or escalate risks as appropriate.
- Ensure that study issues and action items are addressed, closeout appropriately and in compliance with study management plans.
- Prepares and/or reviews and takes accountability for the accuracy of study-related documents.
- Accountable for study-specific legal agreements and other legal documentation as required for vendors, pharma partners, sites, etc.
- Ensures audit-ready condition of study records and documentation, both electronic and paper.
- Develops internal processes for improved efficiencies associated with study management
- Develops, reviews and is responsible for the maintenance of study-specific standard operating procedures (SOPs)
- Prepare and submit regulatory documents to central IRB. Manage all study IRB and other regulatory documents.
- Other duties as assigned by manager.

Qualifications:

- Bachelor's Degree (BA, BS) required, in scientific or health care discipline required; master's degree preferred
- Minimum of 5 years of pharmaceutical, biotech, academic, or CRO related/oncology clinical study operations experience
- Ability to manage complex protocols within a matrix environment.

- Must have extensive experience in clinical research and strong leadership skills to manage study teams and external vendors effectively
- Experience in working with and overseeing Contract Research Organizations (CROs) and/or other external vendors is required
- Laboratory research experience preferable
- Must have experience working in Medidata Rave, including eCRF and database management; experience in query creation and resolution
- Demonstrated ability to drive clinical trial activities: i.e. experience in all aspects of study start-up and conduct, regulatory obligations, adverse event reporting, budgeting.
- Experience reviewing and writing study protocols, informed consent forms, etc.
- Experience with study budgets, processing study site payments, and study account management.
- Experience preparing and submitting regulatory documents to IRBs.
- Excellent working knowledge GCP, FDA and ICH Guidelines. Ensures the assigned clinical trials are executed in compliance with FDA and ICH GCP guidelines/regulations and SOPs
- Comfortable multi-tasking in a fast-paced small company environment and able to adjust workload based upon changing priorities
- Excellent team player; willingness and ability to fill functional gaps in a small organization
- Effective oral, written and interpersonal communication skills
- Computer literacy required (MS word, MS excel, MS PowerPoint and MS Project)
- Hematology Oncology therapeutic experience strongly preferred
- Strong leadership skills and leader communication skills
- Strong organizational skills
- Ability to travel as necessary (approximately 10%)

EEO Statement

The Multiple Myeloma Research Foundation (MMRF) is an equal opportunity employer and does not discriminate against any candidate based on race, religious creed, color, national origin, ancestry, physical disability, mental disability, medical condition, genetic information, marital status, sex, gender, gender identity, gender expression, age, military and veteran status, sexual orientation, or any other factor protected by federal, state, or local law.