Associate Manager/Manager, Clinical Operations

Title: Associate Manager/Manager, Clinical Operations
Reports to: Vice President, Clinical Research
Department: Clinical
Location: Norwalk, CT/Remote

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 $500 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: The Manager, Clinical Operations will provide management and oversight of clinical trials conducted through the Multiple Myeloma Research Consortium (MMRC). The Manager, Clinical Operations will be responsible for all aspects of study conduct and CRO oversight and the primary point of contact for clinical study project management, communications, and decisions for the clinical INDs being held by the MMRC. Experience and knowledge of end-to-end management of clinical trial conduct, knowledge of the pharmaceutical industry and an understanding of clinical drug development, clinical trials operations and regulatory components is essential.

Essential Functions:

- Manage all clinical aspects of MMRC clinical trials, including responsibility for oversight of study execution, develop and manage comprehensive study timelines

and metrics; management/oversight of external vendor deliverables reports and budgets.

- Partner with MMRC sites to ensure appropriate study management of investigator-initiated clinical trials conduct and close out activities
- Partner with MMRF finance to reconcile clinical trial invoices and payments due per budget and contractual designations
- Report on all aspects of the study progress to MMRC/F management (VP Clinical Research)
- Provide study-specific training and leadership to clinical research staff, including CRO, sites and other contract personnel.
- Oversees the following groups across the trial program: clinical supplies, DM, outsourcing and vendor alliance management.
- Prepare and present project reports as required. Plans, executes, and leads study-specific meetings as needed (e.g., Study Management Meetings, site calls etc.).
- Study budget management and oversight of vendor and site payments. Liaise with MMRF's finance group on budget expense projections and payment reconciliation. Review and approve clinical invoices against approved budgets.
- Ability to identify and manage or escalate risks.
- Review and sign off on monitoring reports, ensure study issues and action items are addressed and closeout appropriately and in compliance with study management plans.
- Daily interaction with study CRO project manager, the MMRC medical monitor and other members of the cross-functional study team.
- Prepares and/or reviews study-related documents (e.g., Study Operations Plan, Monitoring Plan, Pharmacy Manual, Informed Consent, Laboratory Manual, CRF Completion Guidelines, study tools/worksheets and other study-specific documents or manuals).
- Tracking of all CDA, MSA, Agreements and other legal documentation as required for new and
  returning sponsors, vendors and suppliers
- Ensures audit-ready condition of clinical trial documentation including central clinical files
- Write and review study protocols, informed consents and associated amendments
- Write and prepare regulatory documents for submission to IRB and FDA (IND documents, safety reports, etc)
- Process regulatory documents submissions to IRB and FDA
- Write and review statements of work (SOW) for clinical trial services vendors
- Develop and manage clinical trial budgets and associated amendments
- Review and process clinical trials invoices
- Ensures SAEs /SUSARs are managed and reported according to the study safety plan
- 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

Qualifications:

- Bachelor's Degree (BA, BS) in scientific or health care discipline preferred
- Minimum of 10 years of pharmaceutical, biotech, academic site, or CRO related/oncology clinical trial operations management experience
- Ability to manage complex protocols within a matrix environment.
- Experience in working with and overseeing Contract Research Organizations (CROs) and other external vendors.
- 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.
- 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
- 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.

The MMRF does not sponsor/facilitate any type of work authorization for this role. All applicants must currently have original valid unrestricted authorization to accept new employment in any role in the U.S. with any employer. There is also no future employer-provided sponsorship for this role to obtain or extend authorization to work in the U.S.