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

MMRF OVERVIEW:

A pioneer in precision medicine, the Multiple Myeloma Research Foundation (MMRF) seeks to find a cure for all multiple myeloma patients by relentlessly pursuing innovations that accelerate the development of precision treatments for cancer. Founded in 1998 by Kathy Giusti, a multiple myeloma patient, and her twin sister Karen Andrews as a 501(c)(3) nonprofit organization, the MMRF has created the business model around cancer—from data to analytics to the clinic. The MMRF identifies barriers and then finds the solutions to overcome them, bringing in the best partners and aligning incentives in the industry to drive better outcomes for patients. Since its inception, the organization has collected thousands of samples and tissues, opened nearly 100 trials, helped bring 13 FDA-approved therapies to market, and built CoMMpass, the single largest genomic dataset for any cancer. Today, the MMRF is building on its legacy in genomics and is expanding into immune oncology, as the combination of these two fields will be critical to making precision medicine possible for all patients. The MMRF has raised nearly $500 million and directs nearly 90% of the total funds to research and related programs. To learn more, visit www.themmrf.org

The mission of the MMRF has always been to provide a cure for each and every patient. We know that multiple myeloma is different in every patient. Our goal is to generate and collect as much patient data as possible and make it available to researchers worldwide, to speed new discoveries and propel new clinical options for myeloma patients into the clinic as quickly as possible.

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 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.
- Report on all aspects of the study progress to MMRC/F management
- 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 amendments
- 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 5+ years of pharmaceutical, biotech, academic, or CRO related/oncology clinical trial operations experience
- Ability to manage complex protocols within a matrix environment.
- Experience in working with and overseeing Contract Research Organizations (CROs) and other external vendors is required.
- 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.