Associate Manager, Clinical Operations

Title: Associate Manager, Clinical Operations
Reports to: Associate Director, Clinical Operations
Department: Clinical/Research
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: Working closely with the clinical and translational research teams, the Associate Manager, Clinical Operations will provide project management support and oversight of assigned translational and clinical research projects such as clinical trials and observational studies involving human subjects, site-based biospecimen, clinical site operations and data collection.

Essential Functions:

- Oversee and support the management of clinical and translational research projects such as clinical trials and observational studies involving human subjects, biospecimen collection and analysis, clinical site operations, including contract research organization (CRO) and other research vendor engagement.

- Partner with study team to develop and drive timelines for clinical and translational studies.
- Develop and partner with study team to manage and adhere to research study project plans, timelines, Gantt charts, metrics, presentations, etc.
- Report on study progress to MMRF clinical operations and translational research leadership.
- Prepare and present project reports as required.
- Plan, execute, and lead study-specific meetings as required, both internal and external (investigator/site-based).
- Interface with key departments to discuss status of current studies at The MMRF, as well as strategies for any potential challenges, including but not limit to staffing, vendor or site issues.
- Provide support for the development of study budgets, vendor, and site payments.
- Prepare and/or review study-related documents as appropriate (e.g., Protocol, Study Operations Plan, Monitoring Plan, Informed Consent, Laboratory Manual, CRF Completion Guidelines, study tools/worksheets and other study-specific documents or manuals, and other relevant study documents)
- Review and provide input on study data forms.
- Prepare and facilitate IRB submissions to central IRB.
- Engage with biorepository laboratories to manage shipment, storage and tracking of samples, results, etc.
- Ensure audit-ready condition of study documentation including central research files, (i.e., trial master file (TMF)) and general research documents.
- Support and contribute to the writing and review of study protocols, informed consents and associated amendments.
- Provide support for the development of statements of work (SOW) for research vendors.
- Other duties as assigned by manager.

Qualifications:

- Bachelor's Degree (BA, BS) in scientific or health care discipline preferred
- Minimum of 5 years of pharmaceutical, biotech, academic research site, or CRO related.
- Laboratory experience (molecular, biology, chemistry, genetics) experience preferable.
- Oncology research experience required
- Experience with creating and submitting study documents to IRB
- Ability to manage complex research protocols within a matrix environment
- Experience in working with Contract Research Organizations (CROs) or other external vendors
- Excellent working knowledge ICH GCP Guidelines
- Excellent team player; willingness and ability to fill functional gaps in a small organization
- Effective oral, written, and interpersonal communication skills
- Flexible, adaptable to change
- Computer literacy required (MS word, MS excel, MS PowerPoint and MS Project)
- Strong project management skills
- Strong organizational skills
- Comfortable multi-tasking in a fast-paced small company environment and able to adjust workload based upon changing priorities
- Ability to travel as necessary (up to 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.