MULTIPLE MYELOMA Research Foundation

Clinical Trials Manager Job Description

Title: Clinical Trials Manager
Reports to: VP of Research
Department: Research
Location: Norwalk, CT

Position Overview: The Clinical Trials Manager is responsible for assisting to drive Multiple Myeloma Research Foundation (MMRF) and Multiple Myeloma Research Consortium (MMRC) clinical studies forward in an expeditious manner from protocol concept through trial execution. Works closely with MMRC investigators and site coordinators (MMPMs) to ensure that the overall day-to-day project management, support and communications among the MMRF and MMRC clinical trials (Phase I-II), network sites and industry/CRO partners are running according to specified start up and enrollment benchmarks. Capable of assuming full project, site and/or monitoring management of Phase I/Phase II clinical trials on an as needed basis. Individual MUST have previous Phase I/II clinical trial experience in oncology/hematology.

Essential Functions

Specific Clinical Trial Operational Responsibilities:

- Assists with the development of overall clinical trial budgets for protocol concept and full protocol submissions. Provides guidance to MMRC site-personnel to develop patient and site management budgets.
- For IIT protocols works with pharma partners to define appropriate milestone payments to MMRC if MMRC is responsible for payments to the sites.
- Assists the team in the preparation and review of protocols and other study documentation.
- In study start-up for IITs sets up meetings with sites (and pharma partners where appropriate) to monitor progress towards SIV.
- Submits invoices to Finance Department for lead and sub-site payments and notifies Finance Department to invoice Pharma when milestones are met according to the terms of the contract.
- Obtains appropriate signatures for Participation Agreements from sub-sites when MMRF/C multi-party clinical trial agreements are being used.
- Oversees project, site and/or monitoring management on specified trials when MMRF/C Norwalk is the sponsor of the trial.
- When working with a CRO as a sub-contractor:
    - Manages and oversees CRO and third party vendor activities to ensure the SOW associated with the contract is being delivered.
    - Serves as the point person with the CRO Project Leader to keep the management of CRO and MMRC informed with updates of study progress and potential issues to ensure alignment with senior MMRF management on any program adjustments.
    - Works with CRO to ensure appropriate Project Plans are established and implemented to fully outline the processes by which the program will be implemented and managed including: communication plan, monitoring plan, data management plan, eCRF/EDC completion guidelines, and the overall data flow plan to delineate the overall flow of data among vendors to combined data platforms.
    - Works with CRO Project Leader to develop and implement a data quality strategy by which key variables are prospectively tracked for adherence with "real time" follow-up by CRO to optimize the end quality of the trial outcomes.

- Serves as trouble-shooter on behalf of the MMRF/C and CRO to review the program as a whole, identify areas of potential risk and prospectively define mitigation steps to optimize study quality and ensure the program is being appropriately resourced.

- **General Operational Responsibilities and Communication:**
  - Regularly updates MMRC site-specific process maps describing each member institution's internal submission processes including: internal regulatory procedures, budget procedures and associated timing for clinical trial start up.
  - Establishes, updates, tracks and maintains study specific trial management tools/systems, and status reports (ie. Monthly Clinical Operations report) as required.
  - Provides ongoing education and training for the Multiple Myeloma Project Manager (MMPM) at each of the MMRC sites via site visits, monthly MMPM teleconference meetings, and follows up on action items as appropriate.
  - Assists with the MMPM Annual Summit.
  - Communicates effectively with team members and management to relay protocol/study issues and implements necessary actions in response to those issues.

Qualifications

- Minimum degree requirements of a Bachelor's Degree (BA,BS) with science/research concentration or RN or BSN or Pharmacy degree.
- 5 – 10 years of relevant clinical research experience with strong Phase I/II clinical trials experience in oncology, preferably at pharma or Biotech Company or CRO.
- Previous experience in oncology required.
- Strong experience and knowledge within clinical trial and drug development organizations.
- Strong communication and organizational skills including Microsoft Office with particular focus on Excel and PowerPoint.
- Strong ability to build and maintain relationship with investigators at MMRC member sites and with pharma/biotech companies for business relations.
- 10% domestic travel required.

Interested applicants please send your cover letter and resume to hr@themmrf.org

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Multiple Myeloma Research Foundation (MMRF)
383 Main Avenue
5th Floor
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http://www.themmrf.org/
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This is a non-profit organization.