Mary Long

Principal Project Manager

Profile

- Experienced Administrative Leader with demonstrated success in leading and administering oncology clinical trials.
- Accomplished in leading and developing teams, Food & Drug Administration regulations, ICH/GCP, clinical trial design, regulatory processes, and global clinical development process.
- Adept at identifying and leveraging synergistic opportunities, including healthcare and technology.
- Proven ability to execute clinical research and development; budget and timelines, including identification of project risks & development of contingency plans.
- Instrumental in conducting clinical trials in accordance with global regulations, good clinical practice and internal standard operating procedures.

Skills

Program / Project Mgmt	Clinical Protocol Dev	Employee Engagement	Clinical Data Mgmt
Excellent Communication	QA Compliance	Operations Mgmt	Strategic Planning
Strategic Analysis	Organizational Skills	Competitive Intelligence	Exec Level Leadership
Software Proficiency			

Experience

eClinical Solutions, LLC, Mansfield, MA
Manager, Project Management October 2017 – Present

- Provides leadership and assigns projects to Project Management staff, monitors progress, assesses resource needs and makes appropriate individual assignment decisions
- Develop and implement project management initiatives and metrics to deliver sustainable results and reliable measurements for project performance
- Ensures that all projects are proceeding according to timelines, meeting targets and expectations, and adhering to established key performance indicators (KPIs) by establishing a project status tracking program
- Develop and lead execution of training and knowledge transfer opportunities for project management team
- Train, mentor and monitor project manager to ensure delivery of quality projects
- Develops and implements project and change management standards and best practices and drives adoption into teams
- Ensure project progress by measuring the variance in scope, schedule, cost and quality from the respective baselines
- Analyze challenges, problems, and process breakdowns to ensure that lessons are learned, and improvements are made
- Collaborates with management in the evaluation of project management personnel, which includes work allocation, training, and problem resolution; makes recommendations for improvements
- Ensure compliance with eClinical Solutions/industry quality standards, regulations guidelines and procedures
- Lead projects as Principal Project Manager when needed

Principal Project Manager January 2017 – October 2017

- Demonstrate project leadership capabilities with an ability to manage multiple projects and programs
- Manage oversight of clinical development milestones to ensure key Data Management and Statistical Programming deliverables are complete and timelines are met
- Manage data management activities in support of clinical studies, including eCRF development, user acceptance testing, data maintenance, data review, data coding, cleaning, analysis and reporting
- Manage oversight of a QC process for review of clinical trial specific documents
- Establish and facilitate meetings throughout the process cycle
- Manage project timelines and budgets with oversight
- Manage communications with internal and external key stakeholders clearly and effectively
- Prepare and manage SharePoint workspaces for the documents and process

ECOG-ACRIN Medical Research Foundation, Boston, MA

Senior Director January 2016 – December 2016

Execute operational activities for all phases of clinical research with direct & indirect management of operational project leaders. Instigate team which strategically sets the vision, priorities and work across the development operations at large. Direct medical undertakings such as study life cycle management, publication planning, literature reviews and advisory boards. Develop, track, and manage clinical study planning and implementation within pre-specific program plan and timelines.

- Solely in charge of interconnecting management of multiple departments; data management, protocol development, grants and contracts management, industry interactions, GCP compliance, member services, publications, QA program, information systems, supply chain management, with related projects concentrating on tactical business and organizational objectives. Direct report +6; indirect +30.
- Premediate and organize all clinical trial activities while managing the interfaces with legal, clinical science, regulatory, biostatistics, vendors including CRO's, industry partners, the National Cancer Institute and the FDA. Maintain continuous alignment of program scope with business goals, and deliver suggestions to modify the program to boost overall business performance. Trial activity includes over 30 active trials and over 50 trials in follow-up.
- Arrange project meetings in multiple cross-functional development activities in partnership with cross-functional colleagues, such as RAVE clinical database build and electronic case report form (eCRF) development, supply chain planning, clinical education, finance & regulatory submissions. Ensure accuracy and timeliness of service provider and site payments.
- Manage and coordinate Data Safety Monitoring Board (DSMB) functions.
- Responsible for the creation, maintenance and ongoing compliance and efficient conduct of program area Standard Operating Procedures.

Frontier Science Technology & Research Foundation, Boston, MA 1992 - 2015

Director of Administrative Programs 2006 - 2015

Led the operations team on six pivotal FDA registration trials which resulted in changes to the standard of care for patients (E3200, E4599, E1496, E1A00, E4494 and E2100) and ensured appropriate balance between tactical & strategic demands.

- Proficiently managed IIS timelines and grants from initial scientific letters of intent through study closure, and in addition built credibility, established rapport, and maintained communication with stakeholders at multiple levels.
- Developed and managed project metrics; adapted and implemented quality improvement plans and cost–effective ways to meet pre-defined metrics.
- Competently provided active functional support, and defined & initiated projects, assigned resources to control timelines and performance of component projects, while working to make sure the ultimate success of the programs.
- Monitored and controlled risk plans, provided oversight to ensure mitigation plans were in place and

working. Escalated risks identified by the study team to stakeholders.

- Liaison between patient advocacy groups and clinical education department to develop protocol specific patient recruitment and education tools and promotional activities.

GCP & Industry Manager 1995 - 2006

Adroitly coordinated all regulatory agency correspondence; liaised between legal groups; observed and planned all industry-related meetings. Ensured the ECOG Coordinating Center maintains GCP compliance in all areas, including coordination of all GCP audits at ECOG sites. Supervised data flow and transfer from ECOG sites to industry sponsor.

- Self-assuredly managed and supervised multiple departments, including recruitment, training, and supervision; coordinated all pharma activities for ECOG including fiscal oversight; oversaw fiscal of all ECOG industry clinical trials involving the pharmaceutical industry, including budget preparation and monitoring.
- Effectively participated in the preparation of standard operating procedures, manuals, and standards for the ECOG Coordinating Center, ECOG sites, and industry sponsors, as well as monitored the development of all ECOG protocols involving the pharmaceutical industry (30 – 40) and managed related protocol amendments.
- Delivered services as the central liaison to all industry site project managers, principal investigators, committee chairs, and NCI staff; implemented quality assurance initiatives and reporting their status to senior management; prepared sections of the ECOG grant renewal, and organized the grant-related site visit to the statistical/coordinating center.

Clinical Research Associate / Protocol Specialist I / II 1992 - 1995

Performed all facets of data management (query generation and resolution, creation of data listings, review of operative and pathology source documentation to confirm patient eligibility, internal quality assurance audits). Practiced with adverse event documents including coding forms, adjudicating events, processing SAE's forms, narrative documentation and report generation. Trained new employees in general data management responsibilities & study-specific procedures.

- Created study documentation, SOPs, internal worksheets, and standardized manual query text. Initiated and contributed significant changes to melanoma, sarcoma and head and neck trial protocols, standard operating procedures (SOPs), internal documents and Case Report Forms, leading to higher quality clinical data.
- Functioned with the PI & statistician to ensure CRFs better captured critical data points; cross-functional teams to revise consents, protocols and case report forms for protocol amendments and to revise edit checks for the clinical database, and more overly collaborated with the regulatory group to find solutions in urgent patient care challenges.
- Mastered SOPs and protocol, ensuring that institutions understood and adhered to protocol guidelines, established performance monitoring tools to ensure consistent quality control among the team and organized team priorities, additionally participated in protocol development of melanoma, sarcoma and head and neck cancer protocols.

Education

University of Lowell, Lowell, MA 1992

Bachelors of Science, Community Health Education