Angela Germinario, MS

Experience

Medpace – Milan, Italy
Sr. Regulatory Submissions Manager *July 2022 – Present*

- Review study protocols and understand the project delivery strategy to develop proactive solutions to site activation risks in accordance with pertinent regulations and guidelines
- Coordinate and oversee clinical trial submission activities, which include providing advice and guidance to Medpace and Sponsor teams to ensure compliance with appropriate regulations and requirements
- Prepare project/country-specific Informed Consent templates and negotiate/review content changes with applicable parties
- Develop and maintain accurate site activation timelines
- Provide oversight of Regulatory Submissions Coordinators and Project Assistants

IQVIA RDS – Milan, Italy
Single Point-of-Contact, Country Operation Lead *March 2020 – July 2022*
Sponsor Dedicated

- Assisted clients with providing value-added input and developed business opportunities for the delivery of models at the country level
- Provided oversight of key performance indicators, metrics, financials, headcount, recruiting, and accountability for profitability maximization
- Managed customer relationships to improve client satisfaction and provided the highest level of service, ensuring individual project targets were met and that policies and procedures were followed

Sr. Manager Clinical Operation *June 2014 – July 2022*

- Managed regulatory and start-up specialists in accordance with the organization's policies and applicable regulations
- Planned, assigned, and directed the work of employees, as well as appraised their performance, guided their professional development, rewarded and disciplined them, and addressed and resolved employee relations issues
- Oversaw clinical trial country submissions and financial contract negotiations
- Reviewed essential documents for submission to meet local regulations and site-specific requirements
- Developed local language materials, including informed consent forms
- Interacted with ethics committees (ECs) and regulatory authorities for assigned protocols as necessary
- Developed solutions and operational workflows, defined specific guidelines, and streamlined the approaches to be taken
- Managed clinical research associates (CRAs) and contributed to partnership start-up

Clinical Project Manager *November 2003 – May 2014*

- Established appropriate clinical tools and processes for the study team to support the execution of clinical deliverables and study timelines
- Managed clinical study set-up and follow-up study activities through ongoing tracking and review of study progress
- Reported progress to the appropriate clinical management and project management forums
- Collaborated with other functional groups within the company, such as data management, pharmacovigilance, and biostatistics, to support milestone achievement and monitor study issues and obstacles
- Provided ongoing training and support to the clinical team

- Established study tools and training materials
- Conducted frequent team meetings and ensured regular communication
- Developed a risk management plan from a clinical perspective and coordinated the escalation and resolution of clinical issues with the project manager
- Ensured high performance and efficiency of the clinical teams through the scheduling of co-monitoring and accompanied site visits and by providing mentoring to CRA team members
- Developed proactive contingency plans to mitigate clinical risk
- Identified quality issues within the study through regular review of the clinical team's communications
- Tracked clinical budget consumption through regular review of project budget reports
- Escalated out-of-scope requests to the applicable project manager and implemented corrective action plans according to the manager's clinical costs
- Mentored inexperienced clinical team leads (CTLs)

Clinical Trial Coordinator, Clinical Research Associate *October 2001 – October 2003*

- Performed site selection, initiation, monitoring, and close-out visits in accordance with the contracted scope of work and Good Clinical Practice
- Performed monitoring visits and site management for a variety of protocols, sites, and therapeutic areas
- Escalated quality issues to CTLs and/or line managers
- Managed the progress of assigned studies by tracking regulatory submissions and approvals, recruitment, and enrollment
- Conducted quality assessments and training visits for a variety of protocols and study teams
- Acted as a designated trainer within a specific client assignment
- Worked with a clinical team and clinical operations management to develop quality monitoring practices across studies

Abbott S.p.A. – Rome, Italy

Clinical Trial Lead *October 2000 – October 2001*

- Prepared and submitted regulatory packages for the monitoring of Phase III-IV trials
- Co-monitored sites to ensure adherence to GCP, investigator integrity, and compliance with the protocol and all study procedures
- Identified and resolved problems in the study monitoring process and coordinated monitoring activities across projects
- Supported the marketing division

Vanasia S.r.l. – Milan, Italy

Clinical Research Associate *November 1998 – October 2000*

- Performed site selection, initiation, monitoring, and closure visits and study start-up of all studies, including obtaining EC approval and financial agreements
- Organized and participated in local and international investigator meetings
- Liaised with local and international sponsors

Education

University of Florence – Florence, Italy

Master of Science in Biological Science *October 1998*

Computer/Other Skills

- Microsoft Office application
- Languages: Italian (native), English (fluent)

Other Training

- GCP Accreditation training, Barnett International – Milan, Italy (June 2022)

Publications & Presentations

- A. Germinario, U. di Luzio Paparatti, P. Chevallier, A. Lazzarin. "Initial Efficiency and Safety Results from the Lopinavir and Ritonavir (ABT378/r) Early Access Program in Italy," 8th European Conference on Clinical Aspects and Treatment of HIV Infection, Athens, 2001 (abstract and poster).
- P. Bogani, A. Simoni, P. Liò, A. Germinario, M. Buiatti. "Molecular Variation in Plant Cell Population Evolving in vitro in Different Physiological Contexts," Genome, 2001; 44: 1-10.