Daniela Renna

Senior Project Manager - Italy

Employment History

Fortrea (Formerly Labcorp), Italy – Apr 2019 – Present

Senior Project Manager – Apr 2019 – Present

- Accountable for project delivery with regards to agreed time, scope, cost and quality
- Serve as key client contact for assigned projects, establishing working relationships with client project teams which result in client satisfaction, operational excellence and thereby increase potential for repeat business
- Lead core project team(s) and facilitate team's ability to lead extended project team(s), ensuring effective cross-functional teamwork among project team members including both internal and external stakeholders. Depending on size and scope of project(s), this job duty may be performed in collaboration with a Project Director
- Serve as escalation point for project issues to internal and external stakeholders, as appropriate
- Proactively identify and resolve conflicts as needed
- Understand the project delivery strategy, costing assumptions and resulting budget for assigned project(s)
- Deliver project(s) to scope, schedule and costs, ensuring all remain on track with the contract and with financial performance targets. Initiate and implement appropriate actions to proactively manage the change control process both internally and externally
- Proactively lead both quality control and risk assurance activities to ensure project deliverables are met according to regulatory, Covance and client requirements
- Create and manage variance to required project plans. Per SOPs, implement and monitor progress against project plans and revise as necessary. Ensure that all staff allocated to assigned project(s) adheres to professional standards and SOPs, providing performance feedback to team member's respective supervisors
- Aid in development and maintenance of key project performance indicators for client specified metrics, ensuring that the KPIs are within scope of the project contract

InnoPharma srl, Desio (MB), Italy – Dec 2013 – Mar 2019

Clinical Project Management Director, Sep 2015 – Mar 2019

- Provided line management of a team of Clinical Project Management personnel; ensured productivity and competency levels were maximized
- Agreed SMART objectives and training and development plans with direct reports and reviewed regularly
- Planned and conducted interviews to recruit high quality personnel
- Hold the CPMs accountable for any GCP issues and ensured escalation to the Upper Management team, the Sponsor and QA, as appropriate; assisted in the preparation of budgets and bid defense proposals
- Developed direct reports and rewarded individuals based on achievement of results and behavior consistent with company values
- Participated to successful Bid Defense Meetings
- Established 'Best Practices' for the CPMs to ensure consistency and quality in the deliverables to the Sponsor

- In association with the QA, ensured Project Management SOPs and related Quality documents were reviewed and updated in compliance with company timelines
- Participated in teleconferences and meetings with Sponsors
- Provided information and updates to the Project Management team to develop common purpose and drive results; reviewed workloads of direct reports, communicating concerns to the management team to ensure optimal project delivery and individual performance

International Clinical Project Manager – Dec 2013 – Aug 2015

- Managed Phase I, II and Phase III multinational clinical trials conducted in EU and US (including a phase III neurology trial conducted in over 15 countries)
- Ensured trials were conducted in compliance with GCP, regulatory requirements and procedures to generate high quality data, in line with Sponsor objectives and agreed budget
- Presented at and participated in Investigator Meetings, other study trainings and meetings as required
- Proactively prevented and identified issues related to the clinical portion of the study, including study processes, monitoring or site issues
- Implemented strategies for quality control and improvement
- Coordinated the preparation for and follow up of sponsor / investigational site audits and inspections

Pierrel Research Italy, Cantù (CO), Italy – Jan 2008 – Nov 2013
International Clinical Project Manager – Feb 2009 – Nov 2013

- Planned and managed Phase II and III international clinical trials
- Implemented communication lines with sponsor representatives and project team
- Planned and managed resource allocation
- Planned and managed trial budget
- Prepared project plans in cooperation with the sponsor and tracked project progress
- Defined, developed and implemented project-specific training of the members of the Clinical Monitoring team
- Organized and conducted periodic project meetings with sponsor as well as Pierrel Research project team
- Managed investigational site selection and competent external vendors
- Took personal responsibility of the quality of work and performance standards

National Clinical Project Manager – Jan 2008 – Feb 2009

- Managed designated clinical studies, including set-up of the trial, study feasibilities, selection of the sites, start-up, monitoring to ensure satisfactory performance and completion of local clinical trials

OPIS srl Desio (MB), Italy – Nov 2005 – Dec 2007
Clinical Research Associate – Nov 2005 – Dec 2007

- Managed all aspects of study site monitoring including conduct of pre-study and initiation visits, routine monitoring and close-out of clinical sites
- Managed all aspects of site management as prescribed in the project plans

- Managed local recruitment, site quality and data cleaning
- Interacted with the Investigators and Sponsor headquarter
- Involved in Clinical Trial Application preparation in start-up phase and followed up to approvals
- Set up/ maintained project and investigator's files
- Managed drug supply process
- Managed Serious Adverse Event reporting

Therapeutic Experience

- Ophthalmology - Glaucoma (Phase III) – Geographic Atrophy secondary to Age Related Macular Degeneration (Phase III) – Geographic Atrophy (Phase III) – Neovascular Age Related Macular Degeneration (phase III)
- **Immune Mediated Inflammatory Disease (IMID):**
    - Systemic IMID – Rheumatoid Arthritis (Phase III); Gout (Phase IV)
    - Dermatologic IMID– Mastocytosis (Phase III)
    - Inflammatory Respiratory – Asthma (Phase III)
- **Cardiometabolic:** Metabolic and Cardiovascular Risk – Metabolic Syndrome (Phase III), Type II Diabetes (Phase III)
- **Neuroscience:** Neurology – Super Refractory Status Epilepticus (Phase III)
- **Oncology:** Solid Tumors – Advanced non-hematological malignancies (Phase I); Breast, Gastric (Phase III)
- Respiratory Diseases: Chronic Sinusitis (Phase III)
- Non-Inflammatory, Non-Infectious Dermatology: Acne (Phase III)
- Rare Disorders: Alport Syndrome, Overgrowth diseases and vascular anomalies (Phase I, II)
- Men's Health – BPH (Phase IV)
- Musculo-Skeletal Disorders – Orthopedic Medical Devices (Phase III)
- Non-Interventional Trials – Liver Transplantation, Coronary Disease, Multiple Sclerosis

Systems Experience

- IWRS Endopoint, 4G: > 5 years
- EDC Medidata Rave (>5 years), Veeva Vault (1 year)
- CTMS ePharma 3.6: > 5 years
- eTMF Veeva Vault: > 5 years
- Invoice Management System iGPS: > 5 years

Language Capabilities

- Italian - Native
- English – Full professional proficiency

Education

- Master Graduation in Medical Biotechnology, University of Milano Bicocca, Milan, Italy
- Bachelor Graduation in Medical Biotechnology, University of Milano Bicocca, Milan, Italy
- Scientific Diploma “Liceo Scientifico M.G. Agnesi”, Merate (LC), Italy

Training

- GCP Training, Fortrea (Nov 2024)

Memberships/Awards

- Italian Society of Pharmaceutical Medicine (Simef), Associate

Employee Signature: _____

Signed by Daniela Renna

Date: _____ Daniela Renna | I approve this document
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