Giorgio Fantin

Associate Manager, Italy

Employment History

Fortrea (formerly Labcorp), Milano, Italy – May 2014 – Present

Associate Manager – Mar 2023 –

- Responsible for the supervision of assigned direct reports within Clinical Operations, Flexible Solutions or Medical Device & Diagnostics.
- Responsible for detailed performance review and management of assigned direct reports including: Annual Performance Management and Development (PMD), Individual Development Plan (IDP), Line of Sight Goals and "Shoves & Tugs"
- Responsible for appropriate management and resolution of performance issues
- Effectively communicate management strategies, policies and procedures in conjunction with leadership teams
- Develop and maintain effective relationships with management team to manage assigned staff in a matrix environment
- Maintain good working relationships with internal and external clients to ensure opportunity for acquiring additional new business

Sr. Clinical Research Associate II – Jul 2022 – Feb 2023

- Responsible for all aspects of study site monitoring including routine monitoring and close-out of clinical sites, maintenance of study files, conduct of pre-study and initiation visits. Liaise with vendors and other duties, as assigned.
- Responsible for all aspects of site management as prescribed in the project plans.
- General On-Site Monitoring Responsibilities. Ensure audit readiness at the site level
- Ensure the study staff who will conduct the protocol have received the proper materials and instructions to safely enter patients into the study.
- Ensure the protection of study patients by verifying that informed consent procedures and protocol requirements are adhered to according to the applicable regulatory requirements.
- Ensure the integrity of the data submitted on Case Report Forms (CRFs) or other data collection tools by careful source document review. Monitor data for missing or implausible data.
- Ensure the resources of the Sponsor and organization are spent wisely by performing the required monitoring tasks in an efficient manner, according to SOPs and established guidelines, including managing travel expenses in an economical fashion according to travel policy.
- Review progress of projects and initiate appropriate actions to achieve target objectives. Manage small projects under direction of a Project Manager/Director as assigned .
- Negotiate study budgets with potential investigators and assist the legal department with statements of agreements as assigned.

- Serve as lead monitor for a protocol or project, and may assist in establishing monitoring plans and trip report review as assigned.
- Track and follow-up on Serious Adverse Event (SAE) reporting, process production of reports, narratives and follow up of SAEs.

Unblinded Service Specialist – Apr 2020 - Jun 2022

- Accountable for the execution and oversight for the delivery of all services within an FSP model, in line with the current Clinical Service Agreement (CSA).
- Responsible for service delivery oversight and management of the operational study management teams per study for the unblinded monitoring.
- Responsible for providing instructions and direction on all tasks and activities related to the unblinded CRAs (uCRAs) roles.
- Primary point of contact (POC) for uCRAs in case of issues with tasks assigned.
- Primary POC for client Managers regarding unblinded monitoring services.
- Identification of projected unblinded units, appointment and onboarding of any
- Assign and allocate required resources (uCRAs) to tasks / protocols to fulfil unit services
- Responsible for the development and delivery of Training Materials for uCRAs and
- Reviewer / Approver of unblinded monitoring visit reports in accordance with monitoring plans, ICH GCP and good documentation practice.
- Manages the successful design, implementation, tracking and revision of the project plans to achieve project objectives (patient recruitment / safety, site compliance, study milestones).
- Set up and maintain the communication plan with the client. Conduct quarterly cluster review meetings with the dedicated client manager team to monitor, track and report progress against client project metrics related to clinical operations deliverables and agreed KPIs as per CSA.
- Works collaboratively with client managers for forecasting, planning and execution of all services, as per CSA.

Sr. Clinical Research Associate II – Aug 2019 - Mar 2020

- Responsible for all aspects of study site monitoring including routine monitoring and close-out of clinical sites, maintenance of study files, conduct of pre-study and initiation visits. Liaise with vendors and other duties, as assigned.
- Responsible for all aspects of site management as prescribed in the project plans.
- General On-Site Monitoring Responsibilities. Ensure audit readiness at the site level
- Ensure the study staff who will conduct the protocol have received the proper materials and instructions to safely enter patients into the study.
- Ensure the protection of study patients by verifying that informed consent procedures and protocol requirements are adhered to according to the applicable regulatory requirements.
- Ensure the integrity of the data submitted on Case Report Forms (CRFs) or other data collection tools by careful source document review. Monitor data for missing or implausible data.
- Ensure the resources of the Sponsor and organization are spent wisely by performing the required monitoring tasks in an efficient manner, according to SOPs and established guidelines, including managing travel expenses in an economical fashion according to travel policy.

- Review progress of projects and initiate appropriate actions to achieve target objectives. Manage small projects under direction of a Project Manager/Director as assigned .
- Negotiate study budgets with potential investigators and assist the legal department with statements of agreements as assigned.
- Serve as lead monitor for a protocol or project, and may assist in establishing monitoring plans and trip report review as assigned.
- Track and follow-up on Serious Adverse Event (SAE) reporting, process production of reports, narratives and follow up of SAEs.

Lead Clinical Research Associate – Jul 2017 - Mar 2020

- Serves as lead Clinical Research Associates for protocols â€“ which includes training other CRAs on study specifics, ensuring consistency at study sites, responsibility for overseeing CRA performance and key performance indexes, leveraging best practices
- Clinical Research Associates coordination, training and mentoring
- Site visit reports reviewer
- Trial Master File reviewer
- TAQ reports reviewer

Sr. Clinical Research Associate – Sep 2016 - Jul 2019

- Manages all aspects of site monitoring responsibilities for clinical trials, according to Covance standard operations procedures, ICH guidelines and GCP, including pre-study qualification, initiation, routine/interim monitoring and close-out visits
- Generates and assures implementation of Project Plans related to the Clinical Monitoring responsibilities
- Tracks progress of projects and initiates appropriate actions to achieve target objectives, including fiscal responsibility for tracking monitoring expenses against the project budget
- Mentoring and supervisory activities to junior CRA
- Participates in identification/feasibility and recruitment of investigator sites, collection of investigator documents, pre-study visits and site management responsibilities

Labcorp (formerly Covance), Milano, Italy – May 2014 -

Clinical Research Associate II – May 2014 - Aug 2016

- Responsible for all aspects of study site monitoring including routine monitoring and close-out of clinical sites, maintenance of study files, conduct of pre-study and initiation visits; liaise with vendors; and other duties, as assigned.
- Responsible for all aspects of site management as prescribed in the project plans.
- Ensure the study staff who will conduct the protocol have received the proper materials and instructions to safely enter patients into the study.
- Ensure the protection of study patients by verifying that informed consent procedures and protocol requirements are adhered to according to the applicable regulatory requirements.

- Ensure the resources of the Sponsor and organization are spent wisely by performing the required monitoring tasks in an efficient manner, according to SOPs and established guidelines, including managing travel expenses in an economical fashion according to travel policy.
- Recruitment of potential investigators, preparation of EC submissions, notifications to regulatory authorities, translation of study-related documentation, organization of meetings and other tasks as instructed by supervisor.
- Independently perform CRF review; query generation and resolution against established data review guidelines on organization or client data management systems as assigned by management.
- Coordinate designated clinical projects as a Local Project Coordinator (with supervision, if applicable), and may act as a local client contact as assigned.
- Assist with training, of new employees, e.g. co-monitoring.
- Track and follow up on Serious Adverse Event (SAE) reporting, process production of reports, narratives and follow up of SAE.

Opis srl, Desio, Italy – Oct 2010 – May 2014

Clinical Research Associate – Sep 2011 – May 2014

- Monitoring for clinical trials

Clinical Research Associate – May 2011 – Sep 2011

- Monitoring for observational studies
- Training activities for achievement of CRA requirements as per Decree DM 31.03.2008

Data Manager – Oct 2010 – Apr 2011

- Training activities at Data Management Department

Therapeutic Experience

- **Immune Mediated Infiammatory Disease (IMID):** Infiammatory Bowel – Crohn's (Phase III)
- **CardioMetabolic:** Cardiovascula Disease – Acute Coronary Syndrome (ACS) (Phase III)
- **NeuroScience:** Neurology – Alzheimer's (Phase II)
- **Infectious Disease:** Anti-Viral Therapy – HPV (Phase III), RSV (Respiratory Syncytial Virus) (Phase IIb)
- **Oncology**: Solid Turmors - Breast (Phase III), Colorectal (Phase III), Neuro Endocrine Tumor (Phase III), Genito-Urinary Tumors – Prostate Cancer (Phase II), Ovarian Cancer (Phase III), Melanoma (Phase I, III), Thoracic Tumors- Non-Small Cell Lung Cancer (Phase II, III), Hematologic Malignancies – Leukemia (AML) (Phase I), non-Hodgkins Lymphoma (Phase I), Myelofibrosis (Phase Ib)

- **Other**: Ophthalmology – Dry Eye syndromes (Phase III)

Systems Experience

- Medidata Rave, iMedidata, Inform, 13 years
- IRT - Almac, Endpoint, Bracket, Perceptive, Suvoda 13 years
- CTMS, 9 years
- Veeva Vault, 9 years
- ERT, 5 years
- SPEED, 5 years
- Clario, Bioclinica 5 years

Language Capabilities

- English - ILR 3 (Professional Working Prof)
- Italian - ILR 5 (Native or Bilingual)

Education

- Bachelor Degree, Pharmaceutical Biotechnology, University of Milan, Italy

Training

- ICH GCP online training, Labcorp, 2021
- ICH GCP online training meeting "minimum criteria for ICG E6 GCP Investigator Site Personnel Training", Labcorp, 2015
- ICH-GCP Complinace Training (Advance), Opis, 2011

Employee Signature: Giorgio Fantin

Date: 18/JAN/2024