Fortrea

Stefania Donnini

Senior Start-up Specialist, Italy

Employment History

Fortrea (Formerly Labcorp), Milan, Italy – Oct 2019 – Present
Senior Start-up Specialist – Oct 2019 – Present

- **Provide expertise for local regulations, ICH/GCP and relevant study and Sponsor requirements; when delegated by Start-up Country Manager (SUCM), oversee and ensure quality data and audit readiness**
- **Anticipate and prevent issues and service failures from developing in their study, escalating when appropriate, negotiating when required. When appropriate, take a lead in team meetings to resolve issues and progress the trial**
- **Ensure efficient in country execution and local improvements aligned with global requirements**
- **Review and approve projections and timelines to study teams, ensuring that they accurately represent the country's performance and suggests mitigation actions in agreement with SUCM**
- **Develop project specific plans for the Site Activation component of assigned studies**
- **Review and approve Country and Site Specific patient informed consents for compliance to local requirements and protocol with agreement by SUCM**
- **Proactively resolve informed consent and contractual language issues plus other significant barriers to study execution with study sites**
- **Oversee start up activities (possibly across a range of studies) to ensure issues are identified, managed and, if necessary, escalated to the appropriate individual**
- **Ensure appropriate systems are updated accurately and compliantly, with site information and study dates (projected and actual) ensuring others follow established processes**
- **Coach other start-up team members. If required, may take country start up lead role for larger/more complex projects; may have line management responsibilities for a small number of staff, including performance management, career development, regular one to one's salary and promo recommendations**

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OPIS s.r.l., Desio, Monza e Brianza, Italy – Sep 2006 – Oct 2019
Trial Start-Up Coordinator – Jun 2018 – Oct 2019

- **Coordinate the activities relevant to the delegated studies and the resources. Manage resource allocation, in collaboration with the Head of Trial Start-Up and Regulatory Unit**
- **Participate to meeting and teleconferences with the Sponsor**
- **In collaboration with the Head of Trial Start-Up and Regulatory Unit, verify quality and adequacy of the documentation regarding to: Applications for ethical/administrative authorization of protocol and amendments; Ethical/administrative submission status, before sending it to the Sponsor; Protocol "Ready-to-Go"; Amendment "Ready-to-Go"**
- **Prepare and send to the Sponsor for approval the fac simile of the application letter for: Initial submission; Substantial amendments. Prepare and send to the Sponsor for approval the fac simile of the letter for the communication of Non substantial amendments; Miscellaneous communications. Prepare and send to the Sponsor for approval the fac simile of the financial agreement/addendum to the financial agreement draft**
- **If necessary, intervene actively in the resolution of issues relating to the allocated studies/activities**
- **Verify the study documentation present at the Documentation Unit and/or electronically filed whenever necessary, in collaboration with the Head of Trial Start-Up and Regulatory Unit**
- **If necessary, directly manages ethical/administrative submissions**
- **Contribute to hiring and on-boarding of new associates and act as a mentor for junior staff**
- **Enter all the information required in the Company/Sponsor system on an ongoing basis**

Trials Quality Coordinator – Jan 2011 – May 2018

- **Reference person for ICH-GCP related questions/issues**
- **Proactively interact and communicate with Company staff, in particular with the Clinical Operations Department, to identify and manage potential gaps/issues related to ICH-GCP and to the relevant Company SOPs**
- **Define and manage the internal Trial Quality Plans, follow-up on any issues until resolution, and maintain the relevant documentation**
- **Support the Clinical Team in the management of Site Audits/Inspections and of the relevant CAPAs**
- **Support the organization and management of basic and periodic training relevant to the areas of competence**

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- Organizes and manages Quality Services provided to the Sponsor, as required, and proactively maintain internal and external communications on such services
- Support the System Quality Coordinator and the Biometrics Quality Coordinator in their activities, as needed
- Provides Administration with the information necessary for invoicing
- Contribute to hiring and on-boarding of new personnel for the Department and act as a mentor for junior staff

Quality Management Assistant – May 2008 – Dec 2010

- Support for preparing for audits/inspections conducted at study centers
- Support for preparing for audits by Sponsors conducted at the Company
- Review/reply/closure of CAPAs following audits/inspections
- Verification of study documentation (TMF site, TMF country)
- Review of visit and contact reports completed by CRAs
- Training (GCP)
- Distribution of Sponsor procedures
- Assistance to company Quality System

Clinical Research Associate – Sep 2006 – Apr 2008

- Monitoring of clinical studies

Therapeutic Experience

- Immune Mediated Inflammatory Disease (IMID): Systemic IMID – Rheumatoid Arthritis (phase III); Ankylosing Spondylitis (phase III), Psoriatic Arthritis (phase III), Dermatologic – Psoriasis (phase II), Inflammatory Respiratory – COPD (phase II)
- CardioMetabolic: Metabolic and Cardiovascular Risk – Hypertension (phase III), Cardiovascular Disease – Heart Failure (phase II and III)
- NeuroScience: Neurology - Parkinson's (phase II), Multiple Sclerosis (phase III)
- NeuroScience: Psychiatry - Schizophrenia (phase III)
- Oncology: Solid Tumors – Gastro-intestinal Tumors – Pancreatic Cancer (phase III), Genito-Urinary Tumors – Prostate Cancer (phase IV), Melanoma (Metastatic) (phase III), Thoracic Tumors – Non-Small Cell Lung Cancer (phase III), Hematologic Malignancies – DLBCL (Diffuse Large B-Cell Lymphoma) (phase I), non-Hodgkins Lymphoma (Mantle Cell Lymphoma) (phase III and non-interventional)

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- **Pulmonary/Respiratory: COPD (Chronic Obstructive Pulmonary Disease) - Chronic Respiratory Disorders (Phase III)**
- **Other: Non-Inflammatory Immunology - Transplantation (phase III), Ophtalmology – Macular Degeneration (phase IV)**

Systems Experience

- **Clinical Trial Management System: 5**
- **Veeva Vault: 4**

Language Capabilities

- **Italian - 5**
- **English - 3**

Education

- **Bachelor's Degree in Industrial Biotechnology, University of Milano Bicocca, Milan, Italy**

Training

- **ICH-GCP Training, Fortrea, 2023**

Memberships/Awards

- **Not Applicable**

Other

- **Not Applicable**

Employee Signature: Stefania Donnini

Date: 17 Oct 2023

Fortrea will become the new brand identity for Labcorp's Clinical Development business in connection with the spin-off from Labcorp, which is expected in mid-2023. Fortrea's spin-off from Labcorp is subject to the satisfaction of certain customary conditions, including, among others, the receipt of final approval by Labcorp's Board of Directors, the receipt of appropriate assurances regarding the tax-free nature of the separation and effectiveness of any required filings with the Securities and Exchange Commission. There can be no assurances regarding the ultimate timing of the transaction or that the spin-off will be completed. Until the spin-off is complete, Fortrea's products, services and offerings are still owned and operated by Labcorp.