



Simona Cimbro

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ABOUT ME

15 years' experience within clinical research environment. Self-attitude to constant personal and professional development allowed her to move from CRA to full line management and departmental responsibilities. Leadership skills, good planning and organization skills, good communication attitude, ability to work in team, good interpersonal skills, ability to travel. During her career covered also Training and Quality Management roles.

WORK EXPERIENCE

Senior Manager, Start-Up Operations (Start-Up Country Manager)

Labcorp Clinical Development [1 Aug 2021 – Current]

City: Milan

Country: Italy

- Overall line management responsibility for all start-up staff in country or in cluster of countries
- Overall accountability for delivery of all country level start-up deliverables and timelines
- Overall accountability for quality, performance and GCP compliance for start-up operations staff
- Overall accountability for regulatory requirement compliance for study activation and maintenance
- Responsibility for issues and resolution with proper oversight
- Develop and measure performance indicators for assigned staff
- Effectively communicates management strategy, policies and procedures in alignment with the leadership team
- Overall recruitment, allocations, coaching, trainings and talent development responsibility for SU Ops staff
- Responsible for resource and utilization management of start-up operations staff
- Identify individual training needs and assist with coordination and development efforts
- Local contact for business development/client relations, works closely with strategic clients and ensures client satisfaction

Senior Manager, Clinical Operations

Covance CAPS [1 Jul 2019 – 31 Jul 2021]

City: Milan

Country: Italy

- Overall line management responsibility for assigned direct reports
- Responsible for selection, training, development and performance management for assigned staff
- Responsible for appropriate management, escalation and resolution of performance issues
- Develop and measure performance indicators for assigned staff
- Ensure that the assigned staff work to the highest standard in compliance with current SOPs, relevant guidelines/policies and regulatory requirements
- Ensure that staff and teams meet project delivery directives
- Effectively communicate management strategies, policies and procedures in conjunction with leadership teams
- Develop and maintain effective relationships with management team to manage assigned staff
- Maintain good working relationships with internal and external clients to ensure opportunity for acquiring additional new business
- Actively participate in new staff selection and onboarding processes
- Act as local Clinical Quality Control Assessor
- Prepare and support sites' audit and Regulatory Inspections
- Effective leader in a complex environment, demonstrates ability to influence peers and other departments, set clear expectations, coach and mentor for success, consistently communicate and connect, foster a continuous learning environment
- Inspiring leader that is an effective line manager that attracts, selects, on-boards, develops and retains high performing talents

Senior Manager, Clinical Operations

Chiltern International Srl [1 Apr 2016 – 30 Jun 2019]

City: Milan

Country: Italy

- Permanent line management team of CRAs, CTAs as appropriate
- Ensure that team members are complying with all requirements of their job description, Company objectives and metrics, ICH-GCP, applicable regulations and timelines
- Monitor the quality of team member's work on an ongoing basis (review of appropriate documentation and accompanied visits) and support delivery on awarded projects
- Develop and put in place, if necessary, risk management and contingency plans, identifying root causes and CAPAs for issues in the country
- Prepare and support sites' audit and Regulatory Inspections
- Build good relationships with other departments, Clients and Institutions to support site engagement and performance and ensure Clients' satisfaction
- Attend global meetings, representing the country and the local staff to provide study teams and/or senior management with feedback from a country perspective
- Support sites' identification and selection by involvement in feasibility process at Country and Site level
- Maintain ongoing responsibility for the identification and provision of requested resources for study conduction
- Actively participate in new staff selection and onboarding processes
- Basic understanding of finance for clinical

Manager, Clinical Operations

Chiltern International Srl [1 Apr 2014 – 31 Mar 2016]

City: Milan

Country: Italy

- Permanent and full line management of CRAs, CTAs as appropriate

Country Training Representative

Chiltern International Srl [1 Jun 2011 – 30 Sep 2015]

City: Milan

Country: Italy

- Be the local expert on training and development
- Liaise with the global Training Department
- Deliver training, when appropriate
- Arrange a yearly training plan for country specific trainings, by understanding the local needs
- Liaise with QA, analyze audit findings and determine whether specific trainings are needed
- Encourage the local office to keep accurate and up-to-date training record and conduct occasional quality checks on training records and monitor corrections, escalating issues to local and training management

Associate Manager, Clinical Operations

Chiltern International Srl [1 Apr 2013 – 31 Mar 2014]

City: Milan

Country: Italy

- Permanent and full line management of CRAs, CTAs as appropriate

Interim Manager, Compliance, Clinical Monitoring Operations (Global)

Chiltern International Srl [1 Sep 2012 – 1 Sep 2013]

City: Milan

Country: Italy

- Develop and implement a suite of Global Clinical Monitoring Metrics and Key Performance Indicators (visit report turnaround timelines, Visit productivity, Quality Assessment visits). Perform monthly analysis and report to Senior Management
- Review management reporting on issue escalation
- Review CAPA & Serious GCP Breach trends relevant to Global Clinical Monitoring and provide feedback and guidance to Clinical Monitoring Managers
- Responsible (Process owner) for establishing and maintaining the Global Clinical Monitoring SOPs, Work Instructions, Guidelines, Forms & Templates
- CMO SOP Matrix Reviewer
- Management of Global Clinical Monitoring Job Descriptions and Competencies

Principal Clinical Research Associate

Chiltern International Srl [1 May 2012 – 31 Mar 2013]

City: Milan

Country: Italy

- Dual position of line management of some or all of the following – Trainee CRA, CRA1, CRA2, Senior CRA plus SCRA tasks

Clinical Research Associate

Chiltern International Srl [1 Feb 2010 – 30 Apr 2012]

City: Milan

Country: Italy

- Plan and perform all type of site visits, initiation, close-out and interim monitoring visits
- Sites' validation and selection
- Protocol feasibility evaluation
- eCRF, Queries, Central Laboratory and IXRS management
- Training of trainee CRAs
- Support sites for Sponsor's audits
- Support to local ECs and competent authorities' authorization
- Site payments requests

Clinical Project Manager

Innopharma Srl [1 Oct 2007 – 31 Jan 2010]

City: Desio (MB)

Country: Italy

- Supervision of start up activities
- Coordination of internal/external CRAs' activities
- Contacts with the Sponsors
- Contacts with the centers
- Archiving/Management of study files
- Study Updates Management
- Management of administrative activities

Clinical Research Associate

Innopharma Srl [1 Apr 2007 – 31 Jan 2010]

City: Desio (MB)

Country: Italy

- Plan and all type of site visits, initiation, close-out and interim monitoring visits
- Sites' validation and selection
- eCRF, Queries, Central Laboratory and IXRS management
- Site payments requests

Academic Researcher

Università degli Studi di Milano [1 Oct 2005 – 31 Mar 2007]

City: Milan

Country: Italy

EDUCATION AND TRAINING

PhD post-degree in Animal Biology

Università degli Studi di Milano [Sep 2002 – Sep 2005]

Address: Milan (Italy)

Degree in Biological Sciences

Università degli Studi di Milano [Sep 1993 – Sep 2001]

Address: Milan (Italy)

High School Diploma

Liceo-Ginnasio Statale "S.M. Legnani" [Sep 1988 – Jul 1993]

Address: Saronno (VA) (Italy)

LANGUAGE SKILLS

Mother tongue(s): **Italian**

Other language(s): **English**

DIGITAL SKILLS

Microsoft Powerpoint / Microsoft Excel / Outlook / Microsoft Office