Contatta

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Competenze principali

Oracle Clinical
Immunology
Hematology

Languages

Inglese
Spagnolo (Elementary)

Andrea Orlando

Senior Manager Clinical Operations presso Labcorp Drug Development
Novi Ligure

Esperienza

Labcorp Drug Development
1 anno 10 mesi

Senior Manager Clinical Operations presso Labcorp Drug Development
marzo 2020 - Present (1 anno 10 mesi)

Senior Manager Clinical Operations
marzo 2020 - ottobre 2021 (1 anno 8 mesi)
Milano, Italia

• Responsible for the supervision of assigned direct reports.
• 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.
• Measure performance indicators for assigned staff.
• Identify individual training needs and assist in the conduct of training and development efforts, regionally.
• Coordinate, conduct, report and follow-up on Quality Control Visits (CQC).
• Effectively communicate management strategies, policies and procedures in conjunction with leadership teams.
• Support and assist Country Lead in local and regional duties like Staff productivity/DaysOnSite, Resourcing status and demand, Open new requisitions, Country Lead back-up if needed
• Develop and maintain effective relationships with management team to manage assigned staff in a matrix environment.
• Assist with staff recruitment through screening and interviewing
• Engage in resource management activities for direct reports or across a project team
• Accountable for expense management, expense report approval and compliance with Travel Policy
• Maintain good relationships with internal and external Clients to ensure opportunity for acquiring additional new business

Covance

15 anni 6 mesi

Manager Clinical Operations

dicembre 2018 - febbraio 2020 (1 anno 3 mesi)

Milano, Lombardia, Italia

Associate Manager, Clinical Operations

gennaio 2018 - novembre 2018 (11 mesi)

Milano, Lombardia, Italia

• Responsible for the supervision of assigned direct reports

• 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

• Measure performance indicators for assigned staff within Clinical Operations

• Identify individual training needs and assist in the conduct of training and development efforts, regionally

• Effectively communicate management strategies, policies and procedures in conjunction with leadership teams

• Develop and maintain effective relationships with management team to manage Clinical Operations staff in a matrix environment

• Maintain good working relationships with internal and external clients to ensure opportunity for acquiring additional new business

• As required, manages the conduct of on-site Clinical Quality Control Visits for Clinical Operations staff (either by performing visits or reviewing reports/ outcomes of visits)

• Assist with staff recruitment through screening and interviewing

• Accountable for expense management, expense report approval and compliance with Travel Policy

Associate Clinical Operations Manager- Early Clinical Development

maggio 2015 - dicembre 2017 (2 anni 8 mesi)

• Responsible for the supervision of assigned direct reports in Italy, Spain and Portugal

• 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"

• Management and conduct of on-site Clinical Quality Control Visits for Clinical Operations staff, including the identification, training and development of CQC Assessors from within Clinical Operations (e.g. Sr. CRAs); as well as serves as primary point of contact for ECD to CQC leadership team within the Project Management Office
• Responsible for developing and maintaining close ties with Quality Assurance group; as well as measuring performance indicators for assigned staff within Clinical Operations
• Escalate potential individual training needs and assist in the conduct of training and development efforts, regionally; as well as managing CRA teams in Italy and Spain
• Effectively communicate management strategies, policies and procedures in conjunction with leadership teams
• Assist with staff recruitment through screening and interviewing in Italy and Spain
• Accountable for expense management, expense report approval and compliance with Travel Policy

Clinical Quality Control Assessor
marzo 2013 - maggio 2015 (2 anni 3 mesi)
Roma, Lazio, Italia

LEAD CRA
novembre 2011 - aprile 2015 (3 anni 6 mesi)
Novi Ligure (AL) - Italy

Lead CRA tasks:
CRAs coordination, training and mentoring.
Site visit reports reviewing and approval
Presenting during monthly CRA calls, including preparation of agenda, writing/ reviewing minutes.
Presenting during Kick Of Meeting.
Presenting during Investigator and Study Coordinator meeting
Review internal audit report (Trial Master Files) and prepare draft audit response
PM general management
Study Setup and Plan
Mentoring and Junior CRAs support

Senior CRA
settembre 2004 - aprile 2015 (10 anni 8 mesi)
Novi Ligure (AL) - Italy

Key Responsibilities

Clinical trials monitoring in accordance with the ICH Guidelines, the current monitor guidelines and SOP' s including identifying sites, preparing documentation for necessary approvals, initiating sites and observing recruitment, performing monitoring at sites (Italy and UK), reporting visits and contacts with site, assuring the presence of all relevant documents on site, collaborating with other departments for reporting safety information, collecting Case Report Forms, following up and solving data queries, reporting the progress of the study on a regular basis and performing site close-out visits.
Monitoring visit report reviewing and approval
Mentoring and Junior CRAs support

PAREXEL Int

CRA 2

maggio 2002 - settembre 2004 (2 anni 5 mesi)

Key Responsibilities

CRA of a phase III, multi-center, randomized, double-blind, placebo-controlled trial in adult patients with dementia secondary to cerebrovascular disease; 4 sites, Italy. Responsibilities included: Monitoring and Sites management. AUDIT: During the study PAREXEL internal Audit in one involved site. No critical or major findings were reported by the Auditors.
CRA of a phase III, multi-center, randomized, double-blind, placebo-controlled trial in adult patients with acute AMI, 20 sites, Italy. Responsibilities included: First contact with Sites, Sites Selection, Sites Qualification, EC Submission, Site Initiation and Investigators training (study procedure and electronic data capture), Monitoring and Termination Visits.
CRA of a phase III, multi-center, randomized, double-blind, placebo-controlled trial in adult patients with early stage severe sepsis; 20 sites, Italy. Responsibilities included: First contact with Sites, Sites Selection, Sites Qualification, EC Submission, Site Initiation and Investigators training, Monitoring and Termination Visits.
CRA of phase III, multi-center, randomized, double-blind, placebo-controlled trial in the management of atopic dermatitis in infants aged from 3 to 24 months; 4 site, Italy. Responsibilities included: First contact with Sites, Sites Selection, Sites Qualification, EC Submission, Site Initiation and Investigators training, Monitoring and Termination Visits. AUDIT: During the study Sponsor Audit in one involved site. No critical or major finding were reported by the Auditors

Clinical Research Unit of Fondazione S. Maugeri – Gussago (BS) Italy

Project and Data Manager

marzo 2001 - aprile 2002 (1 anno 2 mesi)

Responsibilities included clinical trial monitoring coordination in Italy and abroad, data collection and quality control review of data collected at trial sites to ensure compliance with protocol, FDA regulations and GCP guidelines on:
Cardiovascular: 2 phase IV international studies:
Coordination for 51 sites in Italy and 10 sites abroad
Responsible for data entry and coordination of data entry operators

CRA Junior

OPERA srl

gennaio 2000 - febbraio 2001 (1 anno 2 mesi)

Responsibilities included clinical trial monitoring.
Cardiovascular: 1 phase IV Local study, (responsible for 5 sites)

Formazione

Faculty of Biology - University of Genova

Degree; BSc, Biology · (1990 - 1997)

British Institute

English Course – Advanced Intermediate Level, British Institute · (2009 - 2010)

University of Ferrara

Post Graduate Master, Clinical Trial Management · (2000 - 2000)