Contatta

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Competenze principali

Oncologia
Ricerca clinica
Neurologia

Languages

Italian (Native or Bilingual)
English (Full Professional)

Nadia Monacelli

Associate Director - FSP Country Head ITALY at IQVIA
Gualdo Tadino

Riepilogo

2016 Covance Way Award Winner

Esperienza

IQVIA
Associate Director - FSP Country Head ITALY at IQVIA
giugno 2022 - Present (2 mesi)

Covance
16 anni 8 mesi

Senior Clinical Operation Manager Labcorp Drug Development
aprile 2018 - maggio 2022 (4 anni 2 mesi)

Partner CRO Manager for EMEA (Europe, former Soviet Union region (FSU), Middle East), North Africa
settembre 2017 - maggio 2018 (9 mesi)

Manage Clinical Operations Vendor Selection, contract management, performance & quality oversight within CDS for subCROs PartnerCROs and contractors who directly support clinical studies in EMEA region (Europe, Former Soviet Union region (FSU), Middle East and Africa:) Algeria, Belarus, Bosnia Montenegro, Croatia, Georgia, Greece, Jordan, Kuwait, Lebanon, Macedonia, Middle and Central Africa, Morocco, Oman, Poland, Qatar, Saudi Arabia, Serbia, Slovenia, Syria, Tunisia, Turkey, United Arab Emirates).

• Selects and ensures qualification of Partner-CROs which work on behalf of Covance within the EMEA region in countries where Covance does not have local presence

• Ensures that all contracts are in compliance with Vendor Management policies and SOPs, supports a timely and efficient sign-off of contracts and amendments

• Owns performance management of studies and staff managed through subCROs

• Owns quality oversight, ICH-GCP compliance and Inspections Readiness of countries where Partner CRPs operate

• Is responsible to develop and execute a quality plan for subCRO management, which is aligned to the same standards as Covance regional quality plans
• Conducts selected Clinical Quality Control Visits (CQC visits) with subCROs CRAs
• Owns issue escalation, issue resolution and CAPA management for subCROs in EMEA
• Supports Business Development and Proposal development for RFPs for the geographic area where we operate through partner CROs
• Owns profitability of subCROs collaboration and collects regularly the related metrics and initiates any process improvements to increase profitability
• Supports contractor / subCROs in-sourcing for Clinical Operations, GSS and CoSource in times of resource shortage
• In close collaboration with the Covance Vendor Management Group, serves as primary vendor management contact in EMEA.
• Instills traditional procurement discipline/practice (Defined infrastructure, Utilization of strategic supplier partnerships)

Clinical Operations Manager at Covance
giugno 2016 - aprile 2018 (1 anno 11 mesi)

Associate Clinical Operations Manager at Covance
marzo 2014 - giugno 2016 (2 anni 4 mesi)

Responsible for the line management of Client (Point Of Contact of one Client at Local Level) and in-house direct reports (CPAs, CRAs, CTLs), from 18 to 25 reports.
Responsible for performance review and management of direct reports including: Annual Performance Management and Development (PMD), Individual Development Plan, resolution of performance issues.
Measure performance indicators for assigned staff within ClinOps and Flexible Solutions and identification of training needs and assist in the conduct of training and development efforts, regionally.
Effective communicate management strategies, policies and procedures in conjunction with leadership teams.
Develop and maintain effective working relationship with internal and external Clients to acquire new Business.
Manage the conduct of on-site Clinical Quality Control Visits for ClinOps and Flexible Solutions Staff.
GCP oversight of direct reports GCP training execution, understood and implemented with identification and escalation of identified GCP issues.

Ensure training record compliance.
Provide input to rSOPs and standard plans/templates for use by Project Mgmt and ClinOPs staff.
Assist with on-boarding of new direct reports.
Hold staff accountable for GCP issue escalation, sponsor and QA.
Hold ClinOs staff for quality and compliance with project Plan an Report quality and on time deliverables.
Coach staff to own effective Investigator relations and Investigator oversight.

Productivity and Financial Management
Communicate status of assigned workload of reports for metric reporting by Resource Forecast Tool.
Review of billable hours and monthly review of utilization.
Available workload hours, in context of Project allocation, supply and demand to Management Team.
Assist with staff Recruitment through screening and Interviewing.
Accountable for expense mgmt., expense report approval and compliance with Travel Policy.
Liaise with Internal and external Customers in relevant process improvement initiatives.

Lead CRA
luglio 2010 - marzo 2014 (3 anni 9 mesi)

Lead CRA with Clinical Team Lead tasks

Responsible for IP Package submission, Visit scheduling, Trip Reports, Billing Guides, Study Files, Issue escalation, Investigator Site Payments, Quality Assurance, Site Management.
Coordinates Clinical Resources needs of CRAs, CRA Assistant and CPAs (Belgium, Bulgaria, Germany, Hungary, Israel, Italy, Poland, UK, Russia and South Africa).
Ensures activities performed by the team within the budget (TAQ review).
Trip Report reviewer.
Project Meetings (Internal, Client, Investigators, Vendors)
Responsible for trainings of the ClinOps team, quality and Corrective and Preventive Action (CAPA) Plans, Client Audit and Quality Control Visits.
Global primary contact of the Clinops team with Vendors.
Clinical Operation Plans – Developed training material and CTL tools.
Data Management Oversight.

IMP and Non-IMP Management - Appointed for local supply of non-IMP.
Primary point of contact for local suppliers and Regulatory (Import Licenses/ cost/purchase) for Russia, Bulgaria and South Africa.
Responsible for Payments to assigned Countries.
Support to Global start up Service.

Therapeutic Experience

Cardiovascular : atherosclerosis/arteriosclerosis/coronary artery disease/ coronary heart disease (Phase II and Phase III)
Cardiovascular: hypertension-systolic or diastolic (Phase II and Phase III)
Infectious Disease: AIDS/HIV (Phase II)
Neurology/Psychiatric : MDD (Phase III)
Neurology/Psychiatric: Schizophrenia (Phase III)
Neurology/Psychiatric: Stroke-ischemic/Stroke-Hemorrhagic/TIA/ cerebrovascular disease (Phase II and Phase III)
Oncology: Breast cancer (Phase II and Phase III)
Oncology: Colorectal cancer (Phase II and Phase III)
Oncology: Head and Neck cancers (Phase II)
Oncology (Lung – NSCLC): (Phase I, Phase II and Phase III)
Pulmonary/Respiratory: COPD (Phase III)
Pediatric: Pulmonary (Phase III)

Senior CRA
marzo 2010 - luglio 2010 (5 mesi)

Conduction of feasibilities
Investigator selection
Country specific Informed consent preparation
Submission, Amendment and follow-up for approval of the Ethic Commitees
Contract negotiation
Full trial site responsibility
Site initiation visit
Monitoring visit
Close out visit

CRA2
ottobre 2005 - marzo 2010 (4 anni 6 mesi)

Conduction of feasibilities
Investigator selection
Country specific Informed consent preparation
Submission, Amendment and follow-up for approval of the Ethic Commitees

Contract negotiation

Full trial site responsibility

Site initiation visit

Monitoring visit

Close out visit

Free lancer

CRA

ottobre 2000 - ottobre 2005 (5 anni 1 mese)

Conduction of feasibilities

Investigator selection

Full trial site responsibility

Site initiation visit

Monitoring visit

Close out visit

Pfizer

Marketing Representative

ottobre 1998 - settembre 2000 (2 anni)

Sanofi

Specialist Marketing Representative

ottobre 1996 - ottobre 1998 (2 anni 1 mese)

Neurology Marketing Specialist

Formazione

University of Studies of Perugia (Italy)

•Qualification as Pharmacist · (1997)

University of Studies of Perugia (Italy)

Degree in Pharmaceutical Chemistry and Technology, Biochemistry and molecular Biology · (1996)