Contatta

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www.linkedin.com/in/simona-bertola-zanetto-06143285 (LinkedIn)

Competenze principali

Clinical Trials

Start-up

Line Management

Languages

Inglese

Certifications

Pharmacist

Simona Bertola Zanetto

Senior Manager Clinical Operations presso PPD

Milano

Esperienza

PPD

17 anni 2 mesi

Senior Manager Clinical Operations

novembre 2011 - Present (10 anni 1 mese)

Milano, Italia

Leads and manages the local start-up team in Italy. Acts as the main point of contact for information and escalation of issues related to Italy. Coordinates with Contract Managers, Regulatory Specialists and other key site activation stakeholders to ensure technical risks and issues are properly routed and resolved and to confirm local hires reflect the necessary technical skills and experience. Provides local expertise for the execution of site activation activities. Responsible for oversight and delivery of site activation deliverables for Italy.

Principal/Senior Clinical Research Associate Site Start Up

2009 - 2012 (3 anni)

Performed and coordinated identification and selection of study sites. Worked to prepare investigational sites for initiation. Represented PPD in the global medical research community and developed collaborative relationships with investigational sites. Supported local Clinical Management in the mentorship, training and work direction of local start-up team members. Authorized to conduct Performance Assessment Visits to provide ongoing training, evaluation and development of the PPD monitor. Acted as a point of reference for operational and role-specific questions. Performed a final and independent quality control of essential documents required to start and maintain a clinical trial. Co-ordinated Regulatory Compliance Review activities within Italy and Greece. Identified mentors, assigned and advised reviewers in the process.

Clinical Research Associate

ottobre 2004 - 2009 (5 anni)

Reviewed project-related materials. Identified additional potential investigators and performed one evaluation visit. Kept contacts with ECs and Investigators during the period of start-up. Prepared and submitted EC applications (including amendments applications), updated ICFs accordingly ECs requests

and Sponsor amendments, reviewed ICFs translations, negotiated contracts with the Sponsor and the sites. Obtained and reviewed essential documents for Regulatory Compliance Review packages. Performed initiation visit and ensured administrative set-up of sites and equipment. Performed interim monitoring visits, drug accountability verification, ongoing site staff training and site management. Verified data versus source documents, generated and resolved queries, performed listing review. Ensured that the proper essential documents were in place on an ongoing basis. Attended CRA and Investigator Meetings. Entered and maintained trial status information in CTMS. Facilitated and responded to client audits. Performed site close out visits and relevant administrative duties. Administered investigator payments.

OPIS s.r.l.
Clinical Research Associate
gennaio 2004 - ottobre 2004 (10 mesi)
Desio, Italy

University of Milan
Research Fellowship
2002 - 2004 (2 anni)

Research Activity at College of Veterinary Medicine, Biotechnology of Reproduction Laboratory on projects concerning cellular and molecular effects of endocrine disruptors on different cellular models related to developmental and reproductive function. Gained experience in cell line culture and Molecular Biology.

Formazione

Università degli Studi di Milano
Pharmaceutical Chemistry and Technology, Faculty of Pharmacy · (2002)