CURRICULUM VITAE

Annamaria Muroni

Professional Experience Summary

- Nearly 20 years of global experience in clinical drug development, in all phases of clinical trials – from phase I (including first-in-man oncology) to IV.
- Broad therapeutic area expertise, including oncology, gene therapy, metabolic disease, cardiology, infectious diseases, paediatrics, nephrology, immunology, ophthalmology and respiratory.
- Recently completed MSc in Cancer Therapeutics

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Detailed Professional Experience

Senior Manager, Clinical Operations Jan 2022 – present

Orchard Therapeutics, London, UK

Main Job Duties:

- Lead, manage and coordinate the conduct of a global gene therapy programme, MPS-IH - a paediatric rare genetic neurometabolic disease.
- Collaborate with cross-functional (statistics, medical, PV, data management, finance and QA) team to ensure alignment of activities with project timelines and to provide overall oversight of activities and delivery of programme milestones.
- Develop and approves study plans (including monitoring plan, deviation plan and risk management plan)
- Coordinates medical writing and all the activities necessary for delivering of trial documentation (study protocol, PIS-ICF etc.)
- Manages data management and statisticians ensuring data base maintenance, interim and final database locks.
- Manage study budget and timelines
- Manages clinical sites and academics institutions, ensures adherence for keeping clinical records, source documents, data entry, manages clinical trial logistics, applications (IRB/IEC, local agencies)
- Manage interactions with outside consultants, vendors (including CROs) and other groups.
- Contribute to the development, review and revision of Standard Operating Procedures (SOPs), guidelines, and departmental policies.
- Assist in audit preparation and audit responses.
- Provide clinical content input to:
    - Regulatory documents
    - Safety interactions and documents
    - Clinical Study Reports
- Communicate with senior and/or executive management regarding progress of the project.

Senior Manager, Clinical Operations Aug 2020 – Dec-2021

Intercept Pharmaceuticals, London, UK

Main Job Duties:

- Manage clinical team/CROs contracted for the management of Intercept global studies in non-viral liver disease.
- Contribute to the development, review and revision of clinical documents (e.g. protocols, study reference manuals, documents to be submitted to Regulatory Agencies or Ethics boards), Standard Operating Procedures (SOPs), guidelines, and departmental policies.
- Manage interactions with outside consultants, vendors and other groups.
- Assist in audit preparation and audit responses.

Manager, Clinical Operations Dec 2017 – July 2020

Intercept Pharmaceuticals, London, UK

Main Job Duties:

- Management of Intercept studies in Europe and Australasia in non-viral liver disease.
- Manage interactions with outside consultants, vendors and other groups as required.
- Liaise with other cross-functional departments.
- Proactively identifies potential study issues/risks and recommends solutions.
- Interact with other Intercept team members – participate in meetings and ensure that team(s) are aware of relevant issues.
- Works directly with rest of the study team to oversee project timelines and vendor activities.

Senior Clinical Research Associate (SCRA) /Regional Manager May 2015 – Dec 2017

Intercept Pharmaceuticals, London, UK

Monitoring and managing Phase II & III studies in non-viral liver disease and paediatrics (EU region).

Clinical Research Scientist (CRS) Sep 2012 – May 2015

Mitsubishi Tanabe Pharma Europe (MTPE), London, UK

Phase I and III in the following therapeutic areas: cardio-pulmonary, immunology and paediatric nephrology.

Senior Clinical Research Associate (SCRA) Jan 2008 – Jun 2012

Clinical Network Services (CNS), Brisbane, Australia

As an Early-phase (including first-in-man) clinical trials primarily in oncology but also immunology, endocrinology, ophthalmology, cardiology, respiratory and gastro-infectious diseases, involving both healthy and non-healthy volunteers.

Assistant Project Manager Nov 2006 – Nov 2007

Medical Trials Analysis, Ferrara, Italy

Global phase III cardiology clinical trial.

Clinical Research Associate (CRA) Jan 2005 – Nov 2006

Theradex (Europe) Ltd, Crawley, UK

Phase II and III oncology studies.

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Education & Affiliations:

2022 – Master of Science – Cancer and Therapeutics (Final grade pending – Distinction projected)
Barts Cancer Institute, Faculty of Medicine and Dentistry, Queen Mary University of London, UK

2009 - Certified Clinical Research Associate (CCRA)

Association of Clinical Research Professionals (ACRP), USA

2004 - Bachelor of Science - Biological Sciences (grade: 2.1)
University of Brighton, UK

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Languages Spoken –Italian (fluent), French (intermediate), Spanish (basic)

Residence Status – British Citizen, EU National