CURRICULUM VITAE

Employee Information

Full Name:	Simona Mangia
Location:	ITMIL1
Job Title:	Mgr, Flexible Resourcing
Country of Residence:	Italy

Summary

Joined IQVIA in January 2015 as Clinical Research Associate. Previously worked as CRA in an Italian CRO, in Phase II and III Clinical Trials with indications for prodromal and mild Alzheimer's Disease, Rheumatoid Arthritis, Oncology Therapies and DMD (Duchenne muscular dystrophy). Since March 2017 working as Senior Clinical research Associate in Global Functional Resourcing IQVIA department with FSP model. Till December 2020 Italian SME for topic "Informed Consent" and involved in iCOver, a cross-team project, to develop a smarter and faster way to track ICF signature. Buddy for new colleagues to support them to familiarize with Company's and customer procedures.
In 2020 participation as Iqvia member to event "Giornata di Studio Sperimentazione Clinica" (AFI).
From July 2020 to January 2021, SPOC in a local study, with 21 sites and 4 CRAs.
On January 2021 started to work as DLM in special assignment. Since July2021 Dedicated Line Manager (permanent role) in Global Functional Resourcing IQVIA department with FSP model. Since 2020 trainer in ACE program (Italian sessions) and later trainer in CRA school in EMEA till August 2022.
Since January 2023 delegated by DLM model SPOC in KPI analysis and discussion during LOC meeting with sponsor. Appointed as Country DLM SPOC from Sep 2023.

Formal Educational History

Last Date Attended	Institution Name, Country	Education Level/Degree	Area of Study	Completion Status
03/2011	Università degli Studi di Ferrara, Italy	Master's Degree	Cellular and Molecular Biology	Completed
10/2008	Università degli Studi del Salento, Italy	Bachelor's Degree	Molecular Biology	Completed
07/2004	Liceo "C. De Georgi ", Italy	Certificate of Education	Scientific	Completed

Employment History

IQVIA and its Affiliated Companies Employment History

Date of Employment:	07/2021 - Present
Job Title:	Dedicated Line Manager
Business Title:	DLM
Key Responsibilities:	As DLM responsible to manage staff in accordance with organization's policies and applicable regulations. Responsibilities include planning, assigning, and directing work; appraising performance discussion and guiding professional development; addressing employee relations issues and resolving problems. Ensure that staff has the proper materials, systems access and training to complete job responsibilities. Provide oversight for the execution of the training plan, SOP review and mentored training experiences, as applicable. Participate in the allocation of resources to clinical research projects by assigning staff to clinical studies that are appropriate to their experience and training. Manage the quality of assigned staff's clinical work through regular review and evaluation of work product. Identifies quality risks and issues and create appropriate corrective action plans to prevent or correct deficiencies in performance of staff. Ensures that staff are meeting defined workload and quality metrics through regular review and reporting of findings as outlined by clinical operations management
Date of Employment:	01/2021 - 06/2021
Job Title:	Associate DLM
Business Title:	Associate DLM
Key Responsibilities:	As DLM in special assignment responsible to manage staff in accordance with organization's policies and applicable regulations. Responsibilities include planning, assigning, and directing work; appraising performance discussion and guiding professional development; addressing employee relations issues and resolving problems. Ensure that staff has the proper materials, systems access and training to complete job responsibilities. Provide oversight for the execution of the training plan, SOP review and mentored training experiences, as applicable. Participate in the allocation of resources to clinical research projects by assigning staff to clinical studies that are appropriate to their experience and training. Manage the quality of assigned staff's clinical work through regular review and evaluation of work product. Identifies quality risks and issues and create appropriate corrective action plans to prevent or correct deficiencies in performance of staff. Ensures that staff are meeting defined workload and quality metrics through regular review and reporting of findings as outlined by clinical operations management
Date of Employment:	03/2020 - 01/2021

Job Title:	Sr Clinical Research Associate III
Business Title:	Sr Clinical Research Associate III
Key Responsibilities:	Perform site initiation, monitoring and close-out visits in accordance with contracted scope of work and good clinical practice. Provide monitoring visits and site management for a variety of protocols, sites and therapeutic areas. Administer protocol and related study training to assigned sites and establish regular lines of communication with sites to manage ongoing project expectations and issues. Evaluate the quality and integrity of study site practices related to the proper conduct of the protocol and adherence to applicable regulations. Escalate quality issues as appropriate. Manage the progress of assigned studies by tracking regulatory submissions and approvals, recruitment and enrollment, case report form (CRF) completion and submission, and data query generation and resolution. Create and maintain appropriate documentation regarding site management, monitoring visit findings and action plans by submitting regular visit reports, generating follow-up letters and other required study documentation. Build awareness of features and opportunities of study to site. Collaborate and liaise with client study team members for project execution support as appropriate.
Date of Employment:	03/2018 - 03/2020
Job Title:	Sr Clinical Research Associate II
Business Title:	Sr Clinical Research Associate II
Key Responsibilities:	Perform site initiation, monitoring and close-out visits in accordance with contracted scope of work and good clinical practice. Provide monitoring visits and site management for a variety of protocols, sites and therapeutic areas. Administer protocol and related study training to assigned sites and establish regular lines of communication with sites to manage ongoing project expectations and issues. Evaluate the quality and integrity of study site practices related to the proper conduct of the protocol and adherence to applicable regulations. Escalate quality issues as appropriate. Manage the progress of assigned studies by tracking regulatory submissions and approvals, recruitment and enrollment, case report form (CRF) completion and submission, and data query generation and resolution. Create and maintain appropriate documentation regarding site management, monitoring visit findings and action plans by submitting regular visit reports, generating follow-up letters and other required study documentation. Build awareness of features and opportunities of study to site. Collaborate and liaise with client study team members for project execution support as appropriate.
Date of Employment:	03/2017 - 03/2018
Job Title:	Sr Clinical Research Associate
Business Title:	Sr Clinical Research Associate

Key Responsibilities:	Perform site initiation, monitoring and close-out visits in accordance with contracted scope of work and good clinical practice. Provide monitoring visits and site management for a variety of protocols, sites and therapeutic areas. Administer protocol and related study training to assigned sites and establish regular lines of communication with sites to manage ongoing project expectations and issues. Evaluate the quality and integrity of study site practices related to the proper conduct of the protocol and adherence to applicable regulations. Escalate quality issues as appropriate. Manage the progress of assigned studies by tracking regulatory submissions and approvals, recruitment and enrollment, case report form (CRF) completion and submission, and data query generation and resolution. Create and maintain appropriate documentation regarding site management, monitoring visit findings and action plans by submitting regular visit reports, generating follow-up letters and other required study documentation. Build awareness of features and opportunities of study to site. Collaborate and liaise with client study team members for project execution support as appropriate.

Date of Employment:	01/2015 - 03/2017
Job Title:	Clinical Research Associate
Business Title:	Clinical Research Associate
Key Responsibilities:	Perform site initiation, monitoring and close-out visits in accordance with contracted scope of work and good clinical practice. Provide monitoring visits and site management for a variety of protocols, sites and therapeutic areas. Administer protocol and related study training to assigned sites and establish regular lines of communication with sites to manage ongoing project expectations and issues. Evaluate the quality and integrity of study site practices related to the proper conduct of the protocol and adherence to applicable regulations. Escalate quality issues as appropriate. Manage the progress of assigned studies by tracking regulatory submissions and approvals, recruitment and enrollment, case report form (CRF) completion and submission, and data query generation and resolution. Create and maintain appropriate documentation regarding site management, monitoring visit findings and action plans by submitting regular visit reports, generating follow-up letters and other required study documentation. Build awareness of features and opportunities of study to site. Collaborate and liaise with client study team members for project execution support as appropriate.

Non-IQVIA Employment History

Date of Employment:	06/2012 - 12/2014
Name of Employer:	Farmastudio
Job Title:	Clinical Research Associate
Key Responsibilities:	Monitoring of Phase II and III Clinical Trials with indications for prodromal

	Alzheimer's Disease, Rheumatoid Arthritis, Oncology Therapies and Duchenne muscular dystrophy (DMD). Knowledge of methods and regulations on clinical trials in relation to the GCP guidelines (Good Clinical Practice). Experience with initiation, monitoring and close out visits.
Date of Employment:	11/2011 - 05/2012
Name of Employer:	Farmastudio
Job Title:	CRA Internship
Key Responsibilities:	Acquisition of knowledge on Technical- Scientific topics related to clinical trials and specific training on clinical trials subject to monitoring. Perform co-monitoring visits, archiving documents.
Date of Employment:	02/2010 - 02/2011
Name of Employer:	Università degli studi di Ferrara
Job Title:	Student Internship
Key Responsibilities:	Use of equipment and laboratory techniques. Knowledge of structure, functions and analysis of biological molecules and cellular processes. Acquired techniques: PCR, RT-PCR, electrophoresis, RNA extraction, cloning and transformation of competent cells, extraction of genomic DNA (miniprep).

Clinical Trial Experience

IQVIA and its Affiliated Companies Clinical Trial Experience

Study Phase:	Phase 3b
Indication:	Hepatocellular Carcinoma
# of Countries:	1
# of Sites:	20
Role:	CRA
Key Responsibilities:	Pre-activation, Site activation, remote and on-site monitoring activities, SPOC role
Study Phase:	Phase 2
Indication:	Multiple Sclerosis
Special Population:	Minors
Role:	Clinical Research Associate
Key Responsibilities:	Site activation visit, Monitoring activities (remote and on-site) of phase II pediatric study, open label
Study Phase:	Phase 2

Indication:	Spinal muscular atrophy
Role:	Clinical Research Associate
Key Responsibilities:	back-up monitor

Study Phase:	Phase 3
Indication:	Alzheimer's Disease
Role:	CRA
Key Responsibilities:	back-up monitor

Study Phase:	Phase 3
Indication:	Alzheimer's Disease
Role:	Clinical Research Associate
Key Responsibilities:	onsite pre-activation visits, site activation visits, remote and onsite monitoring

Study Phase:	Phase 3b
Indication:	Type B Viral Hepatitis
Role:	Clinical Research Associate
Key Responsibilities:	bac-up monitor

Study Phase:	Phase 3
Indication:	Alzheimer's Disease
Role:	Clinical Research Associate
Key Responsibilities:	onsite pre-activation visits, site activation visits, remote and onsite mnitoring

Study Phase:	Phase 1
Indication:	Hematologic Malignancy
Role:	Clinical Research Associate
Key Responsibilities:	remote monitoring and COV

Study Phase:	Phase 3b
Indication:	Hematologic Malignancy
Role:	Clinical Research Associate
Key Responsibilities:	remote monitoring and on-site monitoring

Study Phase:	Phase 3
Indication:	Alzheimer's Disease

Role:	Clinical Research Associate
Key Responsibilities:	Initiation visit, on-site and remote monitoring, drug accountability, close-out visit.

Study Phase:	Phase 3
Indication:	Alzheimer's Disease
Role:	CRA
Key Responsibilities:	remote and onsite monitoring, close-out visits

Non-IQVIA Clinical Trial Experience

Study Phase:	Phase 3
Indication:	Rheumatoid Arthritis
# of Sites:	Large
# of Patients:	Large
Role:	Clinical Research Associate
Key Responsibilities:	Monitoring and close-out visits, remote monitoring, drug accountability.

Study Phase:	Phase 2
Indication:	Alzheimer's Disease
# of Sites:	Large
# of Patients:	Large
Role:	CRA
Key Responsibilities:	Initiation visit, on-site and remote monitoring, drug accountability.

Study Phase:	Phase 3
Indication:	Alzheimer's Disease
# of Sites:	Large
# of Patients:	Large
Role:	CRA
Key Responsibilities:	On-site and remote monitoring, drug accountability.

Study Phase:	Phase 2
Indication:	Duchenne Muscular Dystrophy
Special Population:	Minors
# of Sites:	Small
# of Patients:	Medium
Role:	CRA

Key Responsibilities: Identification, site activation and monitoring.

Study Phase: Phase 3
Indication: Gastrointestinal Cancer
# of Sites: Large
# of Patients: Large
Role: CRA
Key Responsibilities: Initiation visits, Monitoring and close-out visits, remote monitoring, drug accountability as unblinded CRA.

Therapeutic Experience

Therapeutic Area	Years Exp	Experience (Roles)
Duchenne Muscular Dystrophy		Pre-activation visit and remote activities.
Spinal muscular atrophy		back-up monitor
Medical Genetics		
Neurology	***8.0***	
Alzheimer's Disease	8.0	Monitoring of a phase II-III randomized, double-blind, placebo controlled, parallel-group,multicenter efficacy and safety study of a molecular in patients with prodromal AD.
Alzheimer's Disease	8.0	Monitoring of a phase III randomized, double-blind, placebo controlled, parallel-group,multicenter efficacy and safety study of a molecular in patients with mild AD.
Multiple Sclerosis	0.5	Site activation visit, Monitoring activities (remote and on-site) of phase II Site activation visit, Monitoring (remote and on-site) of phase II pediatric study, open label
Gastrointestinal	***1.5***	
Gastrointestinal Cancer	1.5	Initiation visits, monitoring and close-out visits of a phase III trial as part of unblinded team.
Hematology	***0.5***	
Hematologic Malignancy	0.5	remote monitoring, on-site visits
Hepatology	***0.5***	
Hepatocellular Carcinoma	0.5	CRA , SPOC
Infectious Disease	***0.5***	
Type B Viral Hepatitis	0.5	back up monitor
Rheumatology	***0.5***	

Therapeutic Area	Years Exp	Experience (Roles)
Rheumatoid Arthritis	0.5	Monitoring and close-out visits, remote monitoring, drug accountability.

Department Specific Experience

Department: Clinical

Category	Experience
Inform	<1
Medidata Rave	>5
OC-RDC	<1
EDC-Other	1-2
In-House Monitoring Experience: ≥5 Years	Yes
Audits and/or Regulatory Inspection	Yes
Closure Visits	Yes
Collection and Review of Regulatory Packages	Yes
Conducting CRA Training	Yes
Conducting GCP Training	Yes
Drug Accountability	Yes
Initiation Visits	Yes
International Project Experience	Yes
Investigator Meeting Attendance	Yes
Liaising with Customer and/or External Vendors	Yes
Management of SAEs	Yes
Query Resolution	Yes
Study Files Maintenance	Yes

Language(s)

Language	Speaking	Reading	Writing
Italian	Fluent	Fluent	Fluent
English	Business Level	Business Level	Business Level

Other Relevant Information

Licenses and Certifications

- CTMS Site Management Training, 2012

- CRA certification according to D.L. 15th November 2011, 2012
- GCP training certification, 2012
- Rave Training for Monitors, 2012
- Good Clinical Practice for Clinical Trials: Expert (Barnett International GCP, 2015), 2015
- Good Clinical Practice for Clinical trials: expert (Barnett international GCP, 9 Nov 2016), 2016
- DM 15November 2011: document of acknowledgment, 2018
- Good Clinical Practice for Clinical trials: Expert (Barnett Intenational GCP, 12 Jun 2018), 2018
- Good Clinical Practice for Clinical trials: Expert (Barnett Intenational GCP, 19 Jun 2020), 2020
- certificate Participation GIORNATA di STUDIO SPERIMENTAZIONE CLINICA 13feb2020 (AFI), 2020
- GCP CERTIFICATION EXAM 22 Jul 2022, 2022

Awards and Honors

- Above & Beyond Nomination for Alzheimer study protocol, 2020, 2020