Employee Information

Full Name:	Matteo Romagnoni, MBA
Location:	ITMIL1
Job Title:	Clin Project Mgmt Dir
Country of Residence:	Italy

Summary

Matteo Romagnoni has joined IQVIA in June 2022 as Project Director.

Additionally Matteo Romagnoni has 15 years in Project Leadership experience in the Contract Research Organizations (CROs) industry as Project Director, Associate Project Director and Senior Project Lead for Phase I-III studies within the Internal Medicine Therapeutic Area.

Matteo Romagnoni has 6 years of experience as Budget and Resources Management within the Clinical Department in one of the top pharma company worldwide.
Furthermore Matteo Romagnoni was a CRA in pharma company and in the CROs industries for 3 years.

In the recent years Matteo Romagnoni lead his teams in successful deliveries in a competitive environment including BID Defenses, Submissions, Recruitment, final Clinical Study Reports and eTMF deliveries phases in several Clinical programs. These accomplishments granted to Matteo Awards both from the sponsor side as well as from his Organization side.

Furthermore Matteo Romagnoni was the Project Director for the FDA-EMA Inspections preparations and the Inspection Management in regards to 3 Submissions (Biologicals License Applications) to the regulatory Authorities leading to the FDA and EMA biosimilar compound approvals.

In terms of sharing knowledge, Matteo Romagnoni is taking Universities speeches in Clinical Research, Project Management, Health Care System, on Intellectual Property Rights in the pharma environment.
In addition to that, Matteo Romagnoni is part of AICRO Clinical Resources School as Teacher and Oversight.

His Therapeutic area experiences include: Central Nervous System, Rare Diseases Internal Medicine, Immunology, Dermatology and Oncology

Central Nervous System
Schizophrenia
Sleep Disorder

Attention-deficit/Hyperactivity Disorder
Parkinson's Disease
Multiple Sclerosis

Rare Diseases
Hereditary Angioedema

Internal Medicine:
Hemophilia, Diabetes Mellitus Type 1

Immunology
Vasculitis, Systemic Lupus Erythematosus, Rheumatoid Arthritis

Dermatology
Hidradenitis Supportativa, Chronic Urticaria, Plaque Psoriasis and Prurigo Nodularis

Oncology
Breast Cancer, Non Small Cells Lung Cancer

Formal Educational History

Last Date Attended	Institution Name, Country	Education Level/Degree	Area of Study	Completion Status
05/2005	SDA Bocconi, Italy	Diploma	Project Management - Advanced	Completed
05/2004	SDA Bocconi, Italy	Diploma	Project Management	Completed
07/2003	MIP - Politecnico di Milano Business School, Italy	Master of Business Admin	Business and Administration	Completed
07/1996	Università Statale di Milano, Italy	Masters Degree	Biology	Completed

Employment History

IQVIA and its Affiliated Companies Employment History

Date of Employment: 06/2022 - Present

Job Title: Clinical Project Director

Key Responsibilities: Program Oversight in Central Nervous System

Date of Employment:	04/2016 - 01/2021
Job Title:	Associate Clinical Project Management Director
Key Responsibilities:	Manage the execution of the assigned medium to large multi regionally-based clinical study(ies) per Contract, from initiation through to closeout. Ensure that all clinical study management and project deliverables are completed to the Sponsor's satisfaction, ensuring quality deliverables on time and within budget and in accordance with SOPs, policies and practice Involvement on Cross Studies Tasks for Inspection Preparation activities and coordination: member of the joint QuintilesIMS and Sponsor Inspection Preparation Team. The activity is focused to prepare and to coordinate the studies team members for the Regulatory Authorities Inspections that will follow the FDA and EMA submissions done on Biosimilar compounds

Date of Employment:	09/2012 - 03/2016
Job Title:	Senior Clinical Project Manager
Key Responsibilities:	Manage the execution of the assigned medium to large multi regionally-based clinical study(ies) per Contract, from initiation through to closeout. Ensure that all clinical study management and project deliverables are completed to the Sponsor's satisfaction, ensuring quality deliverables on time and within budget and in accordance with SOPs, policies and practice

Non-IQVIA Employment History

Date of Employment:	01/2021 - 06/2022
Name of Employer:	Syneos Health
Job Title:	Project Director
Key Responsibilities:	Project Oversight for multiple programs ensuring the deliveries according to the Budgets, timelines and Quality. Single Point of Contact for the Sponsor at account level Resources allocation across the program Line Manager for Associate Directors and Senior Project Managers

Date of Employment:	02/2008 - 08/2012
Name of Employer:	World Wide Clinical Trials
Job Title:	Senior Project Manager
Key Responsibilities:	Involved in international clinical studies run in West Europe, Central Europe and in MENA Regions, mainly in Internal Medicine and in CNS. Bid Defense Meetings. Main contact point with the Sponsor: from the RfP to the Contract signature

Date of Employment:	10/2007 - 01/2008
Name of Employer:	Kendle (now Syneos Health)
Job Title:	Project Financial Analyst

Key Responsibilities:	Responsible for reviewing project financials including Actual Budgeted, Margin Analysis reports, Impact of Budget Revision Changes reports and margin trend analysis. He was also involved into the review of proposal and final contracts with the sponsor
Date of Employment:	06/2001 - 10/2007
Name of Employer:	AstraZeneca
Job Title:	Budget, Resources and Project Management Assistant
Key Responsibilities:	Reporting directly to the Clinical Research Director, responsible for resources allocation, budget process and KPI evaluation, starting from 2002 the activities covered the South Europe Region also
Date of Employment:	07/1999 - 12/2000
Name of Employer:	AstraZeneca
Job Title:	Clinical Research Associate
Key Responsibilities:	Responsible for the project management together with the medical Advisor, being involved also in evaluating study feasibility and site selection for Oncology Studies Phase II and Phase III
Date of Employment:	07/1998 - 07/1999
Name of Employer:	Innovex (now IQVIA)
Job Title:	Clinical Research Associate
Key Responsibilities:	Responsible for cardiovascular and infectious disease studies: monitoring, ethics committee submissions and subsequent EC communications
Date of Employment:	01/1998 - 06/1999
Name of Employer:	FDM Farmaceutici
Job Title:	Clinical Research Associate
Key Responsibilities:	Clinical Trials Monitoring
Date of Employment:	01/1997 - 06/1998
Name of Employer:	Klippen Studio
Job Title:	Scientific Writer
Key Responsibilities:	Writer for multimedia Scientific Encyclopedia

Clinical Trial Experience

IQVIA and its Affiliated Companies Clinical Trial Experience

Study Phase:	Phase 3

Indication:	Schizophrenia
Drug Class:	Antipsychotic Agents
# of Countries:	9
# of Sites:	126
# of Patients:	400
Role:	Project Director
Key Responsibilities:	Program Oversight

Study Phase:	Phase 3
Indication:	Schizophrenia
Drug Class:	Antipsychotic Agents
# of Countries:	9
# of Sites:	126
# of Patients:	280
Role:	Project Director
Key Responsibilities:	Project Oversight

Study Phase:	Phase 3
Indication:	Schizophrenia
# of Countries:	6
# of Sites:	63
# of Patients:	435
Role:	Project Director
Key Responsibilities:	Project Oversight

Study Phase:	Phase 3
Indication:	Schizophrenia
# of Countries:	8
# of Sites:	77
# of Patients:	462
Role:	Project Director
Key Responsibilities:	Project Oversight

Study Phase:	Phase 3
Indication:	Schizophrenia
# of Countries:	4

# of Sites:	52
# of Patients:	305
Role:	Project Director
Key Responsibilities:	Project Oversight

Study Phase:	Phase 3
Indication:	Schizophrenia
# of Countries:	8
# of Sites:	115
# of Patients:	487
Role:	Project Director
Key Responsibilities:	Project Oversight

Study Phase:	Phase 1
Indication:	Sleep Disorder
# of Countries:	3
# of Sites:	25
# of Patients:	233
Role:	Project Director
Key Responsibilities:	Project Oversight

Study Phase:	Phase 4
Indication:	Disorder of Nervous System
Special Population:	Minors
# of Countries:	9
# of Sites:	47
# of Patients:	274
Role:	Project Director
Key Responsibilities:	Project Oversight

Study Phase:	Phase 3
Indication:	Urticaria
Drug Class:	Biosimilars
# of Countries:	7
# of Sites:	65
# of Patients:	600

Role:	Associate Director, Project Management
Key Responsibilities:	Customer Facing and Project Leader for a full service study with the exception of eTMF and DM

Study Phase:	Phase 2
Indication:	Acne
Drug Class:	Biologic (Antibody)
# of Countries:	8
# of Sites:	45
# of Patients:	175
Role:	Associate Director, Project Management
Key Responsibilities:	Project Leader and then Project Director

Study Phase:	Phase 3
Indication:	Hemophilia
Drug Class:	Biologics
# of Countries:	25
# of Sites:	87
# of Patients:	116
Role:	Associate Director, Project Management
Key Responsibilities:	Project Leader for Full Service study

Study Phase:	Phase 3
Indication:	Rheumatoid Arthritis
Drug Class:	Biosimilars
# of Countries:	14
# of Sites:	94
# of Patients:	462
Role:	Associate Director, Project Management
Key Responsibilities:	Inspection Preparation and Inspection Management

Study Phase:	Phase 3
Indication:	Rheumatoid Arthritis
Drug Class:	Biosimilars
# of Countries:	3
# of Sites:	32

# of Patients:	70
Role:	Associate Director, Project Management
Key Responsibilities:	inspection Preparation

Study Phase:	Phase 3
Indication:	Psoriasis
Drug Class:	Biosimilars
# of Countries:	9
# of Sites:	58
# of Patients:	365
Role:	Associate Director, Project Management
Key Responsibilities:	Inspection Preparation

Study Phase:	Phase 1
Indication:	Rheumatoid Arthritis
Drug Class:	Biosimilars
# of Countries:	2
# of Sites:	2
# of Patients:	162
Role:	Associate Director, Project Management
Key Responsibilities:	Customer Facing and Project Leader for the following services: RSU, Data Management, Bios, Clinical Operations, Medical Services and Medical Writing Inspection Preparation and Inspection Management

Study Phase:	Phase 1
Indication:	Rheumatoid Arthritis
Drug Class:	Biosimilars
# of Countries:	1
# of Sites:	1
# of Patients:	71
Role:	Project Manager
Key Responsibilities:	Customer Facing and Project Leader for the following services: RSU, Data Management, Bios, Clinical Operations, Medical Services and Medical Writing Inspection Preparation and Inspection Management

Study Phase:	Phase 3

Indication:	Rheumatoid Arthritis
Drug Class:	Biosimilars
# of Countries:	3
# of Sites:	32
# of Patients:	70
Role:	Associate Director, Project Management
Key Responsibilities:	Inspection Preparation

Study Phase:	Phase 3
Indication:	Rheumatoid Arthritis
Drug Class:	Biosimilars
# of Countries:	9
# of Sites:	58
# of Patients:	365
Role:	Associate Director, Project Management
Key Responsibilities:	Inspection Preparation

Study Phase:	Phase 2
Indication:	Lupus Erythematosus
Drug Class:	Biologics
# of Countries:	19
# of Sites:	110
# of Patients:	279
Role:	Project Manager
Key Responsibilities:	Customer Facing and Project Leader for the following services: RSU, Data Management, Bios, Clinical Operations and Medical Services

Study Phase:	Phase 1
Indication:	Rheumatoid Arthritis
Drug Class:	Biosimilars
# of Countries:	2
# of Sites:	2
# of Patients:	162
Role:	Associate Director, Project Management
Key Responsibilities:	Inspection Preparation and Inspection Management

Study Phase:	Phase 3
Indication:	Acne
Drug Class:	Biologics
# of Countries:	20
# of Sites:	92
# of Patients:	324
Role:	Associate Director, Project Management
Key Responsibilities:	Project Leader for full service Study

Study Phase:	Phase 3
Indication:	Rheumatoid Arthritis
Drug Class:	Other
# of Countries:	16
# of Sites:	202
# of Patients:	913
Role:	Project Manager
Key Responsibilities:	Project Leader for the following services: RSU, Data Management, Bios, Clinical Operations and Medical Services

Non-IQVIA Clinical Trial Experience

Study Phase:	Phase 3
Indication:	Prurigo nodularis disorder
Drug Class:	Biologic (Antibody)
Geographic Region:	Europe/Middle East/Africa (EMEA)
Role:	Project Director
Key Responsibilities:	Project oversight

Study Phase:	Phase 2
Indication:	Angioedema
Special Population:	Minors
Drug Class:	Biologics
Role:	Project Director
Key Responsibilities:	Project oversight

Study Phase:	Phase 3
Indication:	Urticaria
Drug Class:	Biosimilars

Geographic Region:	Europe/Middle East/Africa (EMEA)
Role:	Project Director
Key Responsibilities:	Project oversight

Study Phase:	Phase 3
Indication:	Rheumatoid Arthritis
Drug Class:	Biosimilars
Geographic Region:	Europe/Middle East/Africa (EMEA)
Role:	Project Director
Key Responsibilities:	Project oversight

Study Phase:	Phase 3
Indication:	Multiple Sclerosis
Drug Class:	Other
Geographic Region:	Europe/Middle East/Africa (EMEA)
Role:	Project Manager
Key Responsibilities:	PL for full service study except Medical Writing

Study Phase:	Phase 4
Indication:	Parkinson's Disease
Special Population:	Elderly
Role:	Project Manager
Key Responsibilities:	Project Manager for Start up: Protocol Writing, CRF design, ICF development, Regulatory Submission (CA and EC)

Study Phase:	Phase 2
Indication:	Diabetes Mellitus
Special Population:	Transplanted Patients
Drug Class:	Anti-inflammatory Drugs
Geographic Region:	Europe/Middle East/Africa (EMEA)
Role:	Project Manager
Key Responsibilities:	Project Leader for full service study with the exception of Medical Writing

Study Phase:	Phase 3
Indication:	Diabetes Mellitus
Special Population:	Transplanted Patients

Drug Class:	Anti-inflammatory Drugs
Role:	Project Manager
Key Responsibilities:	Project Manager role for the following services: Feasibility, Regulatory, SIV, Monitoring, Data Management, Statistics, CSR, QA and TMF

Study Phase:	Phase 2
Indication:	Not applicable
Special Population:	Elderly
Role:	Project Manager
Key Responsibilities:	Project Leader role for the following activities: Feasibilities, SIV, Monitoring, Data Management, Statistics and TMF

Study Phase:	Phase 2
Indication:	Hemophilia
Special Population:	Minors
Drug Class:	Biologics
Geographic Region:	Europe/Middle East/Africa (EMEA)
Role:	Project Manager
Key Responsibilities:	Project Leader for Feasibility, SIV, Monitoring, and Regulatory

Study Phase:	Phase 3
Indication:	Psoriasis
Role:	Project Manager
Key Responsibilities:	Project Lead for for feasibilities, SIV, Monitoring, COV and TMF

Study Phase:	Phase 3b
Indication:	Non-Hodgkin Lymphoma
Drug Class:	Biologics
Geographic Region:	Europe/Middle East/Africa (EMEA)
Role:	Project Manager
Key Responsibilities:	Project Leader for Start-up activities

Study Phase:	Phase 2
Indication:	Pneumonia
Drug Class:	Anti-infectives - Antibiotics
Geographic Region:	Europe/Middle East/Africa (EMEA)

Role:	Project Manager
Key Responsibilities:	Project Leader for for Regulatory, SIV, Monitoring and TMF

Study Phase:	Phase 2
Indication:	Arthritis
Special Population:	Immunocompromised Patients
Geographic Region:	Europe/Middle East/Africa (EMEA)
Role:	Project Manager
Key Responsibilities:	Project Leader for start-up activities

Study Phase:	Phase 2
Indication:	Hemophilia
Drug Class:	Biologics
Geographic Region:	Europe/Middle East/Africa (EMEA)
Role:	Project Manager
Key Responsibilities:	Project Leader for Start-up activities

Study Phase:	Phase 3
Indication:	Malignant Tumor of Breast
Drug Class:	Hormones
Geographic Region:	Europe/Middle East/Africa (EMEA)
Role:	Clinical Research Associate
Key Responsibilities:	RSU, SIV and Monitoring

Study Phase:	Phase 2
Indication:	Malignant Tumor of Breast
Drug Class:	Hormones
Geographic Region:	Europe/Middle East/Africa (EMEA)
Role:	Clinical Research Associate
Key Responsibilities:	Start-up SIV and Monitoring

Study Phase:	Phase 2
Indication:	Malignant Tumor of Lung
Drug Class:	Other
Geographic Region:	Europe/Middle East/Africa (EMEA)
Role:	Clinical Research Associate

Key Responsibilities: RSU, SIV and Monitoring

Non-IQVIA Medical Device Trial Experience

Clinical Stage: Post market

Indication: Incontinence of Feces

Special Population: Unconscious

Study Type: Observational

Device Class: N/A

Geographic Regions: Europe/Middle East/Africa (EMEA)

Role: Project Manager

Key Responsibilities: Project Leader for Protocol Writing, CRF design, ICF writing, Regulatory and Monitoring

Therapeutic Experience

Therapeutic Area	Years Exp	Experience (Roles)
Dermatology	***3.5***	
Psoriasis	2.5	Project Leader for feasibilities, SIV, Monitoring, COV and TMF. Project Director for Inspection Preparation
Urticaria	2.0	Project Director and project Leader
Oncology	***3.0***	
Malignant Tumor of Breast	3.0	CRA
Malignant Tumor of Lung	1.0	CRA
Non-Hodgkin Lymphoma	0.5	Project Leader for Start up activities
Hematology	***2.5***	
Hemophilia	2.5	Project Leader for for Hemophilia full service study and Project Leader for Feasibility, SIV, Monitoring and Regulatory
Rheumatology	***2.5***	
Rheumatoid Arthritis	2.5	Project Leader for Phase I RA on Biosimilar and for Phase III RA on Biologics
Endocrinology	***2.0***	
Diabetes Mellitus	2.0	Project Leader for the following services: SIV, Monitoring, Data Management, Statistics and TMF
Immunology	***1.5***	
Lupus Erythematosus	1.5	Project Leader for SLE study
Neurology	***1.0***	

Therapeutic Area	Years Exp	Experience (Roles)
Multiple Sclerosis	1.0	Project Leader for Feasibilities, SIV, Monitoring, Regulatory, QA and TMF
Parkinson's Disease	0.5	Project Leader for Start up: Protocol Writing, CRF design, ICF development, Regulatory Submission (CA and EC)
Respiratory	***1.0***	
Pneumonia	1.0	Project Leader for regulatory, SIV, Monitoring and TMF
Psychiatry	***0.5***	
Schizoaffective Disorder	0.5	Project Director

Department Specific Experience

Department: Clinical

Category	Experience
Medidata Rave	>5
On-Site Monitoring Experience: ≥2 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
Feasibilities	Yes
ICF/Study Document Development	Yes
Initiation Visits	Yes
International Project Experience	Yes
Investigator Meeting Attendance	Yes
Liaising with Customer and/or External Vendors	Yes
Management of SAEs	Yes
Monitoring Visits & Source Data Verification	Yes
Query Resolution	Yes
Reg Body and/or Ethics Comm Submissions	Yes
Re-labeling and/or IP Recall Process	Yes
Site Contracting	Yes
Site Selection Visits	Yes

Category	Experience
Study Files Maintenance	Yes

Department: Project Management

Category	Experience
Project Management	10-15
EDC Experience	10-15
Program Management	3-5
Protocol Writing	5-10
CSR Development	5-10
Drug Development	N/A
Global Project Experience	10-15
Western Europe	10-15
Eastern Europe	10-15
Africa	3-5
North America	10-15
Asia Pacific	5-10
Latin America	5-10
Study Phase Design	Yes
Initiation & Planning	Yes
Execution / Control	Yes
Close Out	Yes
# of Programs managed	6
# of NDA submissions	3
# of Global Study Start Up	>10
# of Transition Studies Managed (i.e. transfer of ongoing trial)	3

Language(s)

Language	Speaking	Reading	Writing
Italian	Fluent	Fluent	Fluent
English	Fluent	Fluent	Fluent

Other Relevant Information

Licenses and Certifications

- GCP Certification Exam, 2022

- Barnett GCP Accreditation, 2018
- Barnett GCP Accreditation, 2016
- Barnett GCP Accreditation, 2014
- Barnett GCP Accreditation, 2012

Awards and Honors

- Bronze Awards, 2020
- Shout Out! Award, 2019
- Sponsor Recognition Certificate, 2019
- Shout Out! Award, 2019
- Sponsor Recognition Certificate, 2019
- Sponsor Appreciation Nomination - CONGRATULATIONS, 2018
- Shout Out! Award, 2018
- Bravo! Award, 2018
- Shout Out! Award, 2018

Other

BID Defense Participation as F2F meeting in USA, India, South Korea and Europe.
University Speeches on Clinical Development and on the Intellectual Property Rights.
AICRO Clinical Research School, teacher and oversight.

Involvement into the Proposal process and Sponsor discussion with a new client for IQVIA (introduced by Matteo) in regards to a Phase II Diabetes Study and in regards to a Respiratory Program