Employee Information

Full Name:	Alessandro Ciccioli
Location:	ITMIL1
Job Title:	Assoc Dir, Site Management
Country of Residence:	Italy

Summary

Since 2007 experience in Clinical Research. Background in all aspects of project phases from Pre-award to study closure and (finance) reconciliation.
From 2011 to 2019 CRAs Line Manger with a team of (11-14) CRAs employees
Since 2020 head of Local Clinical Solutions and CARE unit with a team of 8 local Project Managers, 2 Clinical Trial Assistant, 7 CRAs and 2 Medical Writers.

Solid experience in:
- Resources management: performance oversight & assessment, resources allocation, coaching & mentoring, talents engagement & development, Projects oversight and accompany site visits.
- Project Management: study feasibility & sites identification strategies, study regulatory & start up, project finance, vendors management, project planning and risk assessment.
- Sites strategic identification: Territory Plan development, sites performance assessment (in terms of patients enrollment and start up timelines), KOLs and Institution administration relationship management.
- Clinical Operation Head's support in the country Business management and junior Managers development.
- Italian representative in Regional (EMEA) working groups for developing new business improvement strategies about patients recruitment, Region KPI, Countries productivity, Resources retention and Financial oversight.

Formal Educational History

Last Date Attended	Institution Name, Country	Education Level/Degree	Area of Study	Completion Status
11/2007	AICRO, Italy	Basic course for CRA	Cklinical Research	Completed
06/2007	University of Bologna, Italy	Biology Qualification	Biology	Completed

Last Date Attended	Institution Name, Country	Education Level/Degree	Area of Study	Completion Status
12/2006	University of Bologna, Italy	Degree	Biology	Completed
07/2000	ITIS Montani di Fermo, Italy	High School Certification	Chemistry	Completed

Employment History

IQVIA and its Affiliated Companies Employment History

Date of Employment: 02/2020 - Present

Job Title: Manager Clinical Operation

Business Title: Local Clinical Solutions & CARE Unit

Key Responsibilities: Responsible for managing a team of 8 local Project Managers, 7 CRAs, 2 Medical Writers and 2 CTAs with focus to manage the local clinical trials (both academic and profit studies).
Ensure the whole project delivery with the highest standards of quality from the study award to the closure through all the study phases.
Responsible for the Project team allocation and the oversight on the whole project management such as: Study clinical and finance Set up, Sites ID, Regulatory & Start up, initiation, patients enrollment, monitoring, close out, data analysis, clinical study reports, project finance (from set up to final reconciliation) and vendor managements.
Sales supporting during the BID, requests of proposal and costing model review.
Local Vendors management and relationship such as: Data Management, eCRF, Statistics, IP Management, Central Laboratories, Ph-Vigilance and contractors for clinical and medical monitoring.

Date of Employment: 07/2016 - 01/2020

Job Title: Site & Resources Manager

Key Responsibilities: Estabilish and follow up relationship with sites of my network. Follow up the recruitment strategy and sites business management. Line Manager for a team of CRAs performing coaching, to provide highest service's level, supervision of task and management of CRAs. Customer relationship management to provide highest service's level.

Date of Employment: 06/2015 - 06/2016

Job Title: Site Network Manager

Key Responsibilities: Estabilish and follow up relationship with sites of my network. Follow up the recruitment strategy and sites business management. Mentor for a team of CRAs performing coaching, to provide highest service's level, supervision of task and management of CRAs. Customer relationship management to provide highest service's level.

Date of Employment:	04/2013 - 05/2015
Job Title:	Manager Clinical Site Monitoring (CRA's Line Manager)
Key Responsibilities:	Coaching, to provide highest service's level.supervision, assignment of task and management of CRAs. Setting goals, assessing performance and carreer development. Customer relationship management to provide highest service's level.

Date of Employment:	12/2011 - 03/2013
Job Title:	Associate Manager Clinical Operation
Key Responsibilities:	Coaching, to provide highest service's level.supervision, assignment of task and management of CRAs. Setting goals, assessing performance and carreer development. Customer relationship management to provide highest service's level.

Date of Employment:	04/2011 - 12/2011
Job Title:	Senior Clinical Research Associate
Key Responsibilities:	Main contact with sites, performing site visits from initiation to close-out, evaluates and ensures patient safety, data quality, adherence to the protocol and agreed SOPs. Complies with overall study timelines to maintain recruitment progress, data cleaning and appropriate IMP management. Creates, distributes and maintain all relevant study documentation.

Date of Employment:	04/2011 - 12/2011
Job Title:	Senior Clinical Research Associate
Key Responsibilities:	Main contact with sites, performing site visits from initiation to close-out, evaluates and ensures patient safety, data quality, adherence to the protocol and agreed SOPs. Complies with overall study timelines to maintain recruitment progress, data cleaning and appropriate IMP management. Creates, distributes and maintain all relevant study documentation.

Date of Employment:	03/2008 - 04/2011
Job Title:	Clinical Research Associate
Key Responsibilities:	Main contact with sites, performing site visits from initiation to close-out, evaluates and ensures patient safety, data quality, adherence to the protocol and agreed SOPs. Complies with overall study timelines to maintain recruitment progress, data cleaning and appropriate IMP management. Creates, distributes and maintain all relevant study documentation.

Non-IQVIA Employment History

Date of Employment:	10/2008 - 03/2008
Name of Employer:	MDS Pharmaceutical
Job Title:	Clanical Research Associate

Key Responsibilities:	Main contact with sites, performing phone monitorinhg visits, evaluates adherence to the protocol and agreed SOPs. Creates and distributes all relevant study documentation.

Clinical Trial Experience

IQVIA and its Affiliated Companies Clinical Trial Experience

Study Phase:	Phase 2
Indication:	PAH
# of Countries:	7
# of Sites:	14
# of Patients:	48
Role:	CRA
Key Responsibilities:	Main contact with sites, performing site initiation and monitoring visits, evaluates and ensures patient safety, data quality, adherence to the protocol and agreed SOPs. Complies with overall study timelines to maintain recruitment progress, data cleaning and appropriate IMP management. Creates, distributes and maintain all relevant study documentation.

Study Phase:	Phase 2
Indication:	PAH
# of Countries:	8
# of Sites:	9
# of Patients:	44
Role:	CRA
Key Responsibilities:	Main contact with sites, performing site visits from initiation to close-out, evaluates and ensures patient safety, data quality, adherence to the protocol and agreed SOPs. Complies with overall study timelines to maintain recruitment progress, data cleaning and appropriate IMP management. Creates, distributes and maintain all relevant study documentation.

Study Phase:	Phase 2
Indication:	Cystic Fibrosis
# of Countries:	6
# of Sites:	45
# of Patients:	200
Role:	CRA
Key Responsibilities:	Main contact with sites, performing site monitoring visits, evaluates and ensures patient safety, data quality, adherence to the protocol and agreed

	SOPs. Complies with overall study timelines to maintain recruitment progress, data cleaning and appropriate IMP management. Creates, distributes and maintain all relevant study documentation.
Study Phase:	Phase 3
Indication:	Cardiovascular
# of Countries:	11
Role:	CRA
Key Responsibilities:	Monitoring visits to FDA request follow up.
Study Phase:	Phase 3
Indication:	Cancer - Colorectal
Role:	CRA
Key Responsibilities:	Main contact with sites, performing the unblinded monitoring visits, evaluates and ensures patient safety, data quality, adherence to the protocol and agreed SOPs. Complies with overall study timelines to maintain recruitment progress, data cleaning and appropriate IMP management. Creates, distributes and maintain all relevant study documentation.
Study Phase:	Phase 3
Indication:	Parkinson's Disease
Role:	CRA
Key Responsibilities:	Main contact with sites, performing the site selection visits. Creates and distributes all relevant study documentation.
Study Phase:	N/A
Indication:	Haemophilia A or B
Role:	CRA
Key Responsibilities:	Main contact with sites, performing phone monitorinhg visits, evaluates adherence to the protocol and agreed SOPs. Creates and distributes all relevant study documentation.
Study Phase:	Phase 3
Indication:	Cancer - Breast
Role:	CRA
Key Responsibilities:	Main contact with sites, performing site monitoring visits, evaluates and ensures patient safety, data quality, adherence to the protocol and agreed SOPs. Complies with overall study timelines to maintain recruitment progress, data cleaning and appropriate IMP management. Creates, distributes and maintain all relevant study documentation.

Study Phase:	Phase 3
Indication:	MDS - related Thrombocytopenia
Role:	CRA
Key Responsibilities:	Main contact with sites, performing site initiation and monitoring visits, evaluates and ensures patient safety, data quality, adherence to the protocol and agreed SOPs. Complies with overall study timelines to maintain recruitment progress, data cleaning and appropriate IMP management. Creates, distributes and maintain all relevant study documentation.

Study Phase:	Phase 3
Indication:	Traumatic Brain Injury
Role:	CRA
Key Responsibilities:	Main contact with sites, performing site initiation and monitoring visits, evaluates and ensures patient safety, data quality, adherence to the protocol and agreed SOPs. Complies with overall study timelines to maintain recruitment progress, data cleaning and appropriate IMP management. Creates, distributes and maintain all relevant study documentation.

Study Phase:	Phase 3
Indication:	Gastrointestinal Disorders
Role:	CRA
Key Responsibilities:	Main contact with sites, performing site monitoring visits, evaluates and ensures patient safety, data quality, adherence to the protocol and agreed SOPs. Complies with overall study timelines to maintain recruitment progress, data cleaning and appropriate IMP management. Creates, distributes and maintain all relevant study documentation.

Study Phase:	N/A
Indication:	PAH
Role:	CRA
Key Responsibilities:	Main contact with sites, performing site monitoring visits, evaluates and ensures patient safety, data quality, adherence to the protocol and agreed SOPs. Complies with overall study timelines to maintain recruitment progress, data cleaning and appropriate IMP management. Creates, distributes and maintain all relevant study documentation.

Study Phase:	N/A
Indication:	Cancer - Breast
Role:	CRA
Key Responsibilities:	Main contact with sites, performing site monitoring visits, evaluates and

ensures patient safety, data quality, adherence to the protocol and agreed SOPs. Complies with overall study timelines to maintain recruitment progress, data cleaning and appropriate IMP management. Creates, distributes and maintain all relevant study documentation.

Study Phase:	Phase 3
Indication:	Malignant Melanoma
Role:	CRA
Key Responsibilities:	Main contact with sites, performing site initiation and monitoring visits, evaluates and ensures patient safety, data quality, adherence to the protocol and agreed SOPs. Complies with overall study timelines to maintain recruitment progress, data cleaning and appropriate IMP management. Creates, distributes and maintain all relevant study documentation.

Study Phase:	Phase 3
Indication:	Deep Venous Thrombosis
Role:	Senior CRA 2
Key Responsibilities:	Main contact with sites, performing site visits initiation and monitoring, evaluates and ensures patient safety, data quality, adherence to the protocol and agreed SOPs. Complies with overall study timelines to maintain recruitment progress, data cleaning and appropriate IMP management. Creates, distributes and maintain all relevant study documentation.

Non-IQVIA Clinical Trial Experience

Study Phase:	N/A
Indication:	Osteoperosis
Role:	CRA Junior
Key Responsibilities:	Main contact with sites, performing phone monitorinhg visits, evaluates adherence to the protocol and agreed SOPs. Creates and distributes all relevant study documentation.

Therapeutic Experience

Therapeutic Area	Years Exp	Experience (Roles)
Deep Venous Thrombosis		Main contact with sites, performing site initiation and monitoring visits, evaluates and ensures patient safety, data quality, adherence to the protocol and agreed SOPs. Complies with overall study timelines to maintain recruitment progress, data cleaning and appropriate IMP management. Creates, distributes and maintain all relevant study documentation.

Therapeutic Area	Years Exp	Experience (Roles)
PAH		Main contact with sites, performing visits, from initiation to close-out, evaluates and ensures patient safety, data quality, adherence to the protocol and agreed SOPs. Complies with overall study timelines to maintain recruitment progress, data cleaning and appropriate IMP management. Creates, distributes and maintain all relevant study documentation.
Cardiovascular		
Cystic Fibrosis - Pancreatic Exocrine Insufficiency		Main contact with sites, performing site monitoring visits, evaluates and ensures patient safety, data quality, adherence to the protocol and agreed SOPs. Complies with overall study timelines to maintain recruitment progress, data cleaning and appropriate IMP management. Creates, distributes and maintain all relevant study documentation.
Gastrointestinal Disorders		Main contact with sites, performing site monitoring visits, evaluates and ensures patient safety, data quality, adherence to the protocol and agreed SOPs. Complies with overall study timelines to maintain recruitment progress, data cleaning and appropriate IMP management. Creates, distributes and maintain all relevant study documentation.
Gastrointestinal		
Haemophilia A or B		Main contact with sites, performing phone monitorinhg visits, evaluates adherence to the protocol and agreed SOPs. Creates and distributes all relevant study documentation.
MDS - related Thrombocytopenia		Main contact with sites, performing site initiation and monitoring visits, evaluates and ensures patient safety, data quality, adherence to the protocol and agreed SOPs. Complies with overall study timelines to maintain recruitment progress, data cleaning and appropriate IMP management. Creates, distributes and maintain all relevant study documentation.
Malignant Melanoma		Main contact with sites, performing the site initiation and monitoring visits. Creates and distributes all relevant study documentation.
Hematology / Oncology / Transplantation		
Parkinson's - L-dopa induced dyskinesias		Main contact with sites, performing the site selection visits. Creates and distributes all relevant study documentation.
Traumatic Brain Injury		Main contact with sites, performing site initiation and monitoring visits, evaluates and ensures patient safety, data quality, adherence to the protocol and agreed SOPs. Complies with overall study timelines to maintain recruitment progress, data cleaning and appropriate IMP management. Creates, distributes and maintain all relevant study documentation.
Neurology		

Therapeutic Area	Years Exp	Experience (Roles)
Cancer - Breast		Main contact with sites, performing the monitoring visits, evaluates and ensures patient safety, data quality, adherence to the protocol and agreed SOPs. Complies with overall study timelines to maintain recruitment progress, data cleaning and appropriate IMP management. Creates, distributes and maintain all relevant study documentation.
Cancer - Colorectal		Main contact with sites, performing the unblinded monitoring visits, evaluates and ensures patient safety, data quality, adherence to the protocol and agreed SOPs. Complies with overall study timelines to maintain recruitment progress, data cleaning and appropriate IMP management. Creates, distributes and maintain all relevant study documentation.
Oncology		

Department Specific Experience

Department: Clinical

Category	Experience
Inform	>5
Medidata Rave	3-5
OC-RDC	3-5
EDC-Other	3-5

Language(s)

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

Current Memberships in Professional Organizations

- Biologist's Orders

Publications, Doctoral Thesis (selected items)

Complete list of publications is available upon request

- No Pubblications

Other Relevant Information

Licenses and Certifications

- Biology Degree, 2006
- Chemistry high school certification, 2000
- GCP Barnett Certification, 2010
- GCP Barnett Certification, 2012

Awards and Honors

- British school certification 2007
- Jhons Hopkins University 2011