Curriculum Vitae

Manager of Clinical Operations since Jan-2022 with 10 years' experience in clinical research environment. Clinical Research Associate since 2012 covering a senior CRA role since April 2020. Responsible, as CRA, for Monitoring activities on Phase III International Studies on Oncoematology and Oncology, Phase IV study with a medical device in Dermatology and different International Late Phase Studies on the following therapeutic areas: Gastroenterology, Cardiology, Neurology and Urology. Involved in several activities spanned from startup activities, as contacting the Ethics Committees and the local administrations to prepare the necessary documentation for ethical approval and review required agreements for sites activation, to Close Out Visit.
From January 2009 to December 2011 PhD researcher in Biochemistry.

Work History

Title	Manager of Clinical Operations
Company/Location	ICON, formerly PRA Health Sciences, Milan, Lombardia, ITALY
Dates	Jan 2022 - Present 8 mos
Responsibilities	Responsible for recruitment, growth, and development of Clinical Operations employees. Providing leadership in the implementation of ICON's quality initiatives and business processes, achievement of its management goals and objectives within the framework of the company mission, policy and philosophy.

Title	Clinical Research Associate 3
Company/Location	ICON, formerly PRA Health Sciences, Milan, Lombardia, ITALY
Dates	Apr 2020 - Jan 2022 1 yr, 9 mos
Responsibilities	Reviews and verifies accuracy of clinical trial data collected, either onsite or remotely Provides regular site status information to team members and trial management Completes required monitoring activity documents Works to facilitate timely resolution of trial and/or clinical issues Performs essential document site file reconciliation, source document verification and query resolution Assesses IP accountability, dispensation, and compliance at the investigative sites Verifies Serious Adverse Event (SAE) reporting according to trial specifications and ICH-GCP guidelines. Besides ordinary monitoring activities, mentoring of junior CRAs on the study in planned sessions or during the monitoring visits.

Title	Clinical Research Associate
Company/Location	ICON, formerly PRA Health Sciences, Milano, Milano, ITALY
Dates	Nov 2016 - Mar 2020 3 yrs, 4 mos
Responsibilities	Implements and monitors clinical trials to ensure sponsor and investigator obligations are being met and are compliant with applicable local regulatory requirements and ICH-GCP guidelines Assesses the qualification of potential investigative sites, initiates clinical trials at investigative sites, instructs site personnel on the proper conduct of clinical trials, and close clinical trials at investigative sites Reviews and verifies accuracy of clinical trial data collected, either onsite or remotely Provides regular site status information to team members and trial management Completes required monitoring activity documents Works to facilitate timely resolution of trial and/or clinical issues Performs essential document site file reconciliation, source document verification and query resolution Assesses IP accountability, dispensation, and compliance at the investigative sites Verifies Serious Adverse Event (SAE) reporting according to trial specifications and ICH-GCP guidelines

Title	Clinical Research Associate
Company/Location	Hippocrates Research, Genova, Genova, ITALY
Dates	Dec 2011 - Oct 2016 4 yrs, 10 mos
Responsibilities	Implements and monitors clinical trials to ensure sponsor and investigator obligations are being met and are compliant with applicable local regulatory requirements and ICH-GCP guidelines Assesses the qualification of potential investigative sites, initiates clinical trials at investigative sites,

instructs site personnel on the proper conduct of clinical trials, and close clinical trials at investigative sites
Reviews and verifies accuracy of clinical trial data collected, either onsite or remotely
Provides regular site status information to team members and trial management
Completes required monitoring activity documents
Works to facilitate timely resolution of trial and/or clinical issues
Performs essential document site file reconciliation, source document verification and query resolution
Assesses IP accountability, dispensation, and compliance at the investigative sites
Verifies Serious Adverse Event (SAE) reporting according to trial specifications and ICH-GCP guidelines

Education

- **Doctorate, Biochemistry PhD**
  Università degli Studi di Genova, Genova, Genova, ITALY

- **Graduate, Master degree course in Health Biology**
  Università degli Studi di Genova, Genova, Genova, ITALY

Protocol Therapeutic Experience

Therapeutic Area	Indication Group	Primary Indication	Role	Number of Studies	Duration	Phase	Subject Population
Cardio-Metabolic Diseases	Arrhythmia	Atrial Arrhythmia	Clinical Research Associate	1	2 yrs, 0 mos	Not Applicable	ADULTS
Cardio-Metabolic Diseases	Arrhythmia	Atrial Arrhythmia	Clinical Research Associate	1	2 yrs, 3 mos	Not Applicable	ADULTS; GERIATRICS
Cardio-Metabolic Diseases	Diabetes	Diabetes Mellitus - Type II		1	2 yrs, 4 mos	III	ADULTS; PEDIATRICS; Adolescence
Dermatology	Skin Infections	Skin lesions	Clinical Research Associate	1	2 yrs, 0 mos	IV	Ambulatory care;ADULTS; GERIATRICS
Genitourinary	Women's Health	Endometriosis		1	1 yr, 4 mos	III	Female Only; Out-patients; ADULTS
Genitourinary	Women's Health	Uterine Myoma		1	1 yr, 9 mos	III	Female Only; Out-patients; ADULTS
Hematology	Lymphoma	Follicular Lymphoma		1	10 mos	IIIB	Oncology Subjects;Rare Disease; ADULTS
Hematology	Myeloproliferative Disorders	Myelofibrosis	Clinical Research Associate	1	1 yr, 8 mos	III	Out-patients; ADULTS
Hematology	Plasma Cell Dyscrasias	Multiple Myeloma	Clinical Research Associate	1	10 mos	IIIB	ADULTS
Hepatology	Hepatology Group	NASH (nonalcoh steatohepatitis)	Clinical Research Associate	1	3 yrs, 2 mos	III	ADULTS
Immunology	Autoimmune Disorders	Ulcerative Colitis	Clinical Research	1	2 yrs, 11 mos	II	Male Only; ADULTS

Therapeutic Area	Indication Group	Primary Indication	Role	Number of Studies	Duration	Phase	Subject Population
			Associate				
Infectious Diseases	Antivirals	Hepatitis B	Clinical Research Associate	1	2 yrs, 8 mos	IIIB	Hepatic Subjects; ADULTS
Musculoskeletal	Other Musculoskeletal	Spinal Muscular Atrophy	Clinical Research Associate	1	9 mos	II	Rare Disease; PEDIATRICS
Musculoskeletal	Other Musculoskeletal	Spinal Muscular Atrophy	Clinical Research Associate	1	6 mos	II	Rare Disease; PEDIATRICS
Neurology	Movement Disorders	Parkinson's Disease	Clinical Research Associate	1	1 yr, 8 mos	Not Applicable	GERIATRICS
Oncology	Solid Tumors	Head & Neck	Clinical Research Associate	1	7 mos	IIIB	ADULTS
Oncology	Solid Tumors	Hepatocellular Carcinoma		1	10 mos	III	

Geographic Experience

Country or Region	Therapeutic Area	Role
AUSTRIA	Cardio-Metabolic Diseases, Oncology	Clinical Research Associate
BELGIUM	Cardio-Metabolic Diseases	Clinical Research Associate
FRANCE	Oncology, Cardio-Metabolic Diseases	Clinical Research Associate
GERMANY	Cardio-Metabolic Diseases, Oncology	Clinical Research Associate
ISRAEL	Hematology	Clinical Research Associate
ITALY	Hematology, Neurology, Cardio-Metabolic Diseases, Dermatology, Oncology	Clinical Research Associate
NETHERLANDS	Cardio-Metabolic Diseases	Clinical Research Associate
SPAIN	Cardio-Metabolic Diseases, Oncology	Clinical Research Associate
SWITZERLAND	Cardio-Metabolic Diseases	Clinical Research Associate
UNITED KINGDOM	Cardio-Metabolic Diseases, Oncology	Clinical Research Associate
CANADA	Immunology, Genitourinary, Hepatology, Musculoskeletal, Cardio-Metabolic Diseases, Infectious Diseases	Clinical Research Associate
CENTRAL EUROPE	Infectious Diseases, Immunology, Genitourinary, Hepatology, Musculoskeletal, Cardio-Metabolic Diseases	Clinical Research Associate
EASTERN ASIA	Genitourinary, Cardio-Metabolic Diseases	
EASTERN EUROPE	Infectious Diseases, Immunology, Genitourinary, Hepatology, Cardio-Metabolic Diseases	Clinical Research Associate
LATIN AMERICA	Immunology, Genitourinary, Hepatology, Musculoskeletal, Cardio-Metabolic Diseases	Clinical Research Associate
UNITED STATES	Genitourinary, Infectious Diseases, Immunology, Hepatology, Cardio-Metabolic Diseases, Musculoskeletal	Clinical Research Associate
WESTERN ASIA	Infectious Diseases	Clinical Research

Country or Region	Therapeutic Area	Role
		Associate
WESTERN EUROPE	Cardio-Metabolic Diseases, Oncology, Genitourinary, Hepatology, Musculoskeletal, Infectious Diseases, Hematology, Immunology	Clinical Research Associate

Drug Type Experience

Drug Type	Therapeutic Area	Subject Population
Biologic	Hematology	Oncology Subjects;Rare Disease;ADULTS
Chemical Entity	Hepatology, Cardio-Metabolic Diseases, Genitourinary, Infectious Diseases, Immunology, Oncology, Hematology	ADULTS, ADULTS; PEDIATRICS;Adolescence, Female Only;Out-patients; ADULTS, Hepatic Subjects; ADULTS, Male Only; ADULTS, ADULTS; GERIATRICS, Out-patients; ADULTS
Device	Dermatology	Ambulatory care;ADULTS; GERIATRICS
No Study Drug Involved	Cardio-Metabolic Diseases, Neurology	ADULTS, GERIATRICS
RNA Med (RNAi;Antisense oligo)	Musculoskeletal	Rare Disease;PEDIATRICS

Environment Experience

Environment	Therapeutic Area	Subject Population
In-patient	Oncology, Hematology	ADULTS
Out-patient	Hepatology, Musculoskeletal, Cardio-Metabolic Diseases, Genitourinary, Infectious Diseases, Hematology, Immunology, Oncology, Neurology, Dermatology	ADULTS, Rare Disease;PEDIATRICS, ADULTS;PEDIATRICS;Adolescence, Female Only;Out-patients;ADULTS, Hepatic Subjects;ADULTS, Oncology Subjects;Rare Disease;ADULTS, Male Only;ADULTS, GERIATRICS, Ambulatory care;ADULTS; GERIATRICS, ADULTS;GERIATRICS, Out-patients;ADULTS

System Experience

Type	System Name
Clinical Trial Management Systems	Client Proprietary System
EDC	Client Proprietary System, Medidata RAVE, BioClinica Express, Oracle Inform
IVRS/IWRS/RTSM	Clinitec, Almac, ClinPhone IVRS

Certificates

- **Certified Clinical Research Associate (CCRA),** Hippocrates Research, ITALY
  Acquired Date: Apr 2012
  Expiration Date:

Posters

- **"A NOVEL SIGNALLING MECHANISM PROMOTING Ca2+ DRIVEN CELL RESPONSES THROUGH high-mobility group box-1/NMDA RECEPTOR INTERACTION"**, Colamassaro Diego, Marco Pedrazzi, Monica Averna, Mauro Patrone, Edon Melloni, Sandro Pontremoli and Bianca Sparatore, FEBS 2011, Torino 25-30 June 2011, 2011

Publications

- **Selective proinflammatory activation of astrocytes by high-mobility group box 1 protein signaling**, Pedrazzi M, Patrone M, Ranzato E, Colamassaro D, Sparatore B, Pontremoli S, Melloni E, Pedrazzi M., 2007. J Immunol 179, 2007

Vendor Experience

Type	Name
Central Imaging Services	ERT, Bioclinica
Central Lab Services	Covance
Clinical Sample Testing Services	KCAS
EDC / eDiary / e-PRO	Medidata, Medidata, Bioclinica Express, CRFHealth, ERT, Dreamslab, Oracle
IXRS	Suvoda, Bracket, Perceptive, Oracle

Languages/Fluency

Language	Conversational	Reading	Writing	Medical Records /Terminology
English	Medium	Medium	Medium	Medium
Italian	High	High	High	High