



Via S.Francesco D'Assisi 10
Cernusco Sul Naviglio,MI
20063
martina.gravina@hotmail.it
00393498396327

Clinical Lead /Professor

Clinical Research Associate since 2016 at Clinical Research Technology (CRT). Started working in Iqvia as Clinical Research Associate on the 14th November 2016. Clinical Monitoring experience (included unblinded monitoring) in both interventional and observational studies on oncology, CNS,internal medicine ,gastrointestinal Tract and infection disease area. Experience as Lead CRA,Buddy/Mentor, audits and EMA pre inspection preparation as QA support, Action Items Country Owner.Senior CRA from March 2019 and CAPA champion since June 2020.Speaker at University classes to the Master for Clinical Research.From April 2021 Professor at Tor Vergata University, at Faculty of Pharmacy. From Nov 2021 the role of Associate Clinical Lead.Starting From July 2022 as Clinical Lead.

Clinical Lead

**Martina
Gravina**

Clinical Lead

IQVIA

July 2022 - Ongoing

Acting to ensure overall project meets delivery requirements.Represent clinical delivery with the customer.Manage the operational aspect of the project.Responsible for tracking financial deliverables reporting and invoicing on projects. Ensure appropriate subject recruitment plan are in place.Guide CRAs on critica specific study issues.Accountable for approving final sites list .Develop risk management plan.provider training on ongoing basis.Acting as global CL for a phase II study managing all the Countries involved in the study .Working as regional CL on a phase II study manage site activations and recruitment. Conduct team meeting an Sponsor call.

Associate Clinical Lead

IQVIA

Nov 2021 - Jun 2022

Clinical poi ti of contact with Customer. Support drive for high performance and efficiency to the Clinical team through CRA project objectivies including SMV.Support PL in ensuring the financial success of the project. I' ve been a global CL for 2 studies one in phase II and one in phase I working for al the Countries involved in both studies.

For both I've managed premature discontinuation and different Interym analysis. For one of them I lead the team for the final data base lock and COVs preparation. Conduct team meeting an Sponsor call.Develop risk management plan and provide ongoing training.

Professor

University of Rome Tor Vergata

Apr 2021 - Present

Professor of Clinical Monitoring in Clinical Trials at the Faculty of Pharmacy. The entire course and exams are performed in English language.



Senior Clinical Research

IQVIA

April 2019 - Present

Perform SIV, SMV, SSV telephonic ,Pharmacy visits and COV in accordance with contracted scope of work and good clinical practice. Administer protocol and related study training to assigned sites and establish regular lines of communication with sites to manage ongoing project expectations and issues. Assess the proper management and handling of IPs on sites level as per protocol requirements. 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 to study responsible.

Manage the 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 and other required study documentation. Audits preparation and conduction, pre EMEA Inspection visits conduction in accompany with QA. Capable of work under pressure responsible the global top enroller site with high number of patients, managing multiple DBLs activities , reaching the FDA approval. -CRA's Buddy: responsible of junior CRA or CRA trainee training, supporting and managing their activities and plans. Mentoring activities. -Lead CRA : responsible of all project activities with sites managing, first point of contact with study team and responsible for coordination of local team and CRAs allocated on the study . Responsible of Contacts and relationship with local Sponsor representative.

-CAPA Champion: Main contact for Italian CRAs supporting the CAPA writing , managing and follow up of Quality Issues . Participating to the calls with Quality Assurance, Quality Manager and Clinical Team. - Speaker on different University classes on Clinical Research

Clinical Research Associate

IQVIA

November 2016 - April 2019

Perform SIV, SMV, Pharmacy visits and COV in accordance with contracted scope of work and good clinical practice. Administer protocol and related study training to assigned sites and establish regular lines of communication with sites to manage ongoing project expectations and issues. Assess the proper management and handling of IPs on sites level as per protocol requirements. 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 to study



responsible. Managing Audits preparation, conduction and Follow up. Manage the 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 and other required study . Selected as responsible of remonitoring activities in order to ensure quality of the past Monitoring visits.

Responsible of Italian Country Action Items performace, principal support in managing and finding strategies with all Italian CRAs in order to reduce AIs and reach Italian KPI.

Conduction of patient enrollment strategies discussion at International Investigators Meeting with International Key Opinion Leader.

Selected to conduct EMA pre inspection preparation ad support of Quality Assurance performing on site visits in accompany with QA in order to get sites inspection ready.

Clinical Research Associate Intern

Trial Form Support

May 2016 - October 2016

Monitoring activities and management of clinical trials in phase III and observational studies.

Clinical Research Associate Intern

Clinical Research Technology

November 2015 - March 2016

10 Monitoring Visits in accompany with Sr.CRA.



Degree

Master Degree on Pharmacy

University of Study of Rome Tor Vergata, Italy November 2009 - May 2015

Master Degree on Pharmacy , the entire course was in English.

Erasmus experience

Debrecen University, Hungary
September 2012 - Jun 2013

Performed one year of study exchange at Debrecen University, Hungary at faculty of Pharmacy.

High School licence

Liceo Scientifico Galileo Galilei 2003 - 2008

High School licence On scientific area.

Certifications

- Ielts Certification B2 Level, 2016
 - ECDL Full Standard Certificate, 2016
 - Regulatory and Quality Aspects of Clinical Trials, 2014
 - Experimental Methodology in Clinical Researches, 2014
 - Clinical Monitoring in Clinical Trials, 2014
 - Contract Research Organization (CRO) Business Management, 2014 -
 - Ethical and Legato Problems of Clinical Trials in Adults and Children, 2014 -B
 - Driving Licence
 - Italian Pharmacist Register
 - In possession of the requirement in art.4,paragraph 1,letter c,of the Ministerial Decree of November 15,2011. -Firearms licence
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Skills

- Flexibility
- Proactivity
- Problem solving
- Team work
- Concretness
- Multitasking
- Critical Thinking
- Mentoring
- Pubblic Speaking
- Dedicating
- Decision Making

Agreement

I Authorize the use of personal data present in my CV following the art. 13 del D. Lgs. 196/2003 e all'art. 13 GDPR 679/16

Herbifraus

04/02/2023

