Contatta

vivianaapicella@libero.it

www.linkedin.com/in/vivianaapicella (LinkedIn)

Competenze principali

Clinical Research

PowerPoint

Teamwork

Languages

Italiano (Native or Bilingual)

Inglese (Limited Working)

Francese (Elementary)

Viviana Apicella

CRA Manager presso Medpace

Milano

Esperienza

Medpace

3 anni 3 mesi

Clinical Research Associate Manager

novembre 2021 - Present (1 mese)

Milano, Lombardia, Italia

Lead CRA

luglio 2019 - Present (2 anni 5 mesi)

Working as LCRA on a project acting as the primary contact for all monitoring-related questions for the monitoring team,preparing monitoring tools and Monitoring Plan and facilitating the training for the CRAs team.

CRA - Experienced

settembre 2018 - novembre 2021 (3 anni 3 mesi)

Milano, Italia

ICON plc

4 anni

In house CRA/CRA

ottobre 2015 - agosto 2018 (2 anni 11 mesi)

• CRA on Phase IIa-III Oncology studies focused on Advanced Non-small Cell Lung, Esophageal and Head and Neck Cancer

• Maintained responsibility for identifying, selecting, initiating, and closing out appropriate investigational sites for clinical studies

• Monitored sites in order to ensure that studies were carried out according to the study protocol and in accordance with company Standard Operating Procedures (SOPs) and Work Procedures, applicable regulations, and the principles of International Conference on Harmonisation-Good Clinical Practice (ICH-GCP)

• IHCRA on a Cardiovascular Pilot program focused on Familial Hypercholesterolemia, Dyslipidemia, and CV outcomes

• Maintained responsibility for in-house contact and site management, working closely with the Clinical Trial Manager and CRAs by providing centralized support to regional team members
• Served as first line of contact to direct or address sites' questions
• Built relationships with investigators and site staff remotely
• Monitored site performance and implemented action plans when needed
• Reviewed recruitment plan and enrollment updates
• Assessed drug and laboratory sample supply status
• Performed regular review of data according to monitoring guidelines
• Performed essential document collection, review, maintenance, and close-out activities
• Confirmed and tracked that site personnel completed project-specific training
• Documented site and Sponsor contact in a timely manner
• Assisted with resolution of site and data queries, action items, and pending issues
• Processed new FDA 1572 form
• Maintained responsibility for the quality and completeness of data in Clinical Trial Management System (CTMS) and the Trial Master File (TMF)

Clinical Trial Assistant
settembre 2014 - settembre 2015 (1 anno 1 mese)

• Contributed to the preparation and maintenance of Investigative Site Files (ISFs)
• Supported site management from pre-study visit to close-out visit
• Ensured study-related supplies and documents were accurately prepared, tracked, and shipped to study sites on time
• Provided efficient and proactive in house support to CRAs to enable increased CRA productivity
• Ensured all study files, including investigator files, electronic TMF, and eRoom and/or Y Drive, whether paper or electronic, were updated and maintained in line with the appropriate SOP to ensure inspection readiness at any time
• Ensured inspection readiness and high quality of essential documentation according to requested timelines
• Assisted CRA with site's payments

Roche Pharmaceuticals
Country Clinical Trial Assistant - Oncology and Hematology
settembre 2013 - agosto 2014 (1 anno)

- Support CSMs (Country Study Managers), CTMs (Clinical Trial Monitors) and EATU (Ethics and Administration Trial Unit);
- Support CSMs in budget management of clinical trials (purchase order creation, invoices, payments);
- Reconcile / track essential documents for the country level Trial Master Files according to ICH-GCP and Roche procedures, ensure quality of TMF documentation, and archive;
- Organize and coordinate the logistic of internal and external meetings (team meetings and Investigators meetings);
- Keep databases/track systems/tools up-to-date;
- Update of suppliers database;
- Support in drug management for clinical trials;
- Support in the safety documents management.

Pharm-Olam International
Clinical Trial Associate
aprile 2013 - agosto 2013 (5 mesi)

- Manage all aspects of trial administration for assigned studies
- Perform feasibility studies
- Perform essential document collection, review and maintenance, ensuring compliance with POI SOPs, local regulatory requirements and ICH-GCP guidelines
- Contribute to the preparation and maintenance of Investigative Site Files
- Support investigators in fulfilling regulatory submissions, according to local regulatory and IRB/IEC requirements
- Ensures all essential trial documentation is prepared and dispatched
- Performs study tracking of all essential documentation received and sent
- Provide investigative sites with study documents

IBMM Institut des Biomolécules Max Mousseron
Stage
gennaio 2011 - giugno 2011 (6 mesi)

Farmacia Terzi
Pharmacy Internship
ottobre 2009 - dicembre 2009 (3 mesi)

Formazione

Post-degree course ”Scienziati in Azienda”– 13th edition ISTUD BUSINESS SCHOOL - Baveno (VB)

· (settembre 2012 - dicembre 2013)

Università degli Studi di Napoli 'Federico II'

Master’s degree in Pharmaceuticals Chemistry and Technology (110/110 cum laude) · (2006 - 2011)