Claudia La Mantia
claudialamantia1000@gmail.com
+[redacted]
https://www.linkedin.com/in/claudia-la-mantia/

Experience

- Palermo, Italy | *2017- Present*

Clinical Trial Coordinator

Paolo Giaccone Polyclinic University Hospital

Responsible for the management of clinical interventional studies (Phase II, Phase III, and Phase IV) and observational profit and non- profit studies in accordance with Good Clinical Practice (GCP), my role involves various essential activities.

- ***Feasibility Activities:***

Conduct feasibility analysis of proposed clinical studies to assess their viability and suitability for the operating unit. Identify the target study population that meets the inclusion and exclusion criteria. Determine the necessary instrumentation and resources required for conducting the research protocols successfully.

- ***Start-Up Activities:***

Prepare all the documentation required for submission of clinical studies to the competent authorities (e.g., Institutional Review Boards, Ethics Committees, Regulatory Agencies). Ensure compliance with all regulatory requirements and guidelines. Collaborate with the PI and department to prepare a categorized budget and justification. Confirms accuracy and completeness of budgeted costs.

- ***Management Activities:***

Handle the shipment and management of experimental drugs and biological samples.Oversee data collection, which includes both electronic and paper Case Report Forms (CRFs).

Address queries and resolve issues related to the data collected during the study. Provide training to patients on the study protocols to ensure proper compliance and understanding. Investigational Product management and accountability.

Ensure timely notification and reporting of any serious adverse events that occur during the study.

Take charge of archiving all study-related documentation and maintaining an updated Investigator Site File. Supervise and ensure the implementation of all procedures mandated by the research protocol.

• ***Regulatory Activities:***

Facilitate communication with the competent authorities regarding the study and its progress. Prepare site regulatory documents, reviewing for completeness and accuracy.

• ***Coordination Activities:***

Coordinate and liaise with the various departments and units involved in conducting the clinical trials, including the Laboratory, Scientific Directorate, Pharmacy, and Clinical Engineering.

Establish effective communication with study sponsors and promoters.

Support to Principal Investigator. Assist CRAs during monitoring visits to the research sites to ensure compliance with the study protocol and GCP guidelines. Address any issues or discrepancies identified during the monitoring visits.

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I actively participated in more than 15 Investigator Meetings in Europe. I prepared and coordinated two AUDIT inspections at site.

I coordinated activities for over 25 investigational clinical trials in the following diseases: *Hepatocellular carcinoma, Hepatitis B, Hepatitis C, Non- alcoholic steatohepatitis, Crohn's disease, Portal hypertension, Primary Biliary Cholangitis, and Primary Sclerosing Cholangitis.*

- Palermo, Italy |*Gen 2024 – Present*

Additional contributor to the project PNRR-MAD-2022-12375656

RATIONAL : Risk stratification of non alcoholic fatty liver

Responsabile Scientifico: Prof.re Salvatore Petta

AOU Policlinico Paolo Giaccone

- Palermo, Italy |*Apr 2022 – Jun 2022*

Teacher Assistant in Clinical Research

University of Palermo, School of Gastroenterology

- Palermo, Italy | *Feb 2020 - Mar 2022*

Research fellowship

Polyclinic Paolo Giaccone Hospital

-Development of an Italian Clinical/Diagnostic network focused on the prevention and management of virology failures in hepatitis C virus (HCV) patients treated with Direct Antivirals Agents (DAAs)

Sector: Healthcare

- Palermo, Italy | *Jul 2019 - Nov 2019*

Pharmacist

Pharmacia Renda

- *Palermo, Italy | Apr 2018 - Jul 2018*

Pharmacy Advisor

Fidia Pharmaceutics spa

• Organization of appointments with pharmacies in the portfolio independently

• Compilation of corporate reports from visits

Education

2019

2 Level Master's degree in Pharmacovigilance and Regulatory Affair of Drugs

University of Verona

2010 - 2017

Single cycle master's degree in pharmacy and industrial pharmacy
University of Palermo

Sep 2014- Jul 2015

Erasmus Traineeship

Semmelweis University, Budapest

2009

Classical High school Diploma

Skills

Excellent mastery of the following CRF, IWRS and Portal : Medidata, Medidata Rave , Inform Oracle, Veeva Vault, Almac, endpoint, CLIN phone , ERT, Bioclinica , Suvoda Cenduit, SIP.

- Understanding of ICH-GCP, EU and FDA requirements
- Solid knowledge of Microsoft Office and the ability to learn appropriate software
- Good oral and written communication skills, with the ability to communicate effectively with medical personnel.

- Teamwork
- Problem-Solving
- Data collection and analysis
- Communication
- Attention to detail.
- Time management
- Clinical trials
- GCP guidelines
- Document review
- Project development and management
- Record keeping
- Effective interpersonal skills

English: Professional
Drive License B, Flexibility to travel.

Certification

May 2023

- Corso CTIS - Scenario Comitati Etici
  AIFA Agenzia Italiana del farmaco

Jan 2023

- IATA Training
  Mayo Clinic

Jan 2023

- Transporting Dangerous Goods Training
  Mayo Clinic

2018

- ICH GOOD CLINICAL PRACTICE

Jun 2014

- ENGLISH -LCCI JETSET 5 (B2) PEARSON CERTIFICATEENGLISH -LCCI JETSET 5 (B2) PEARSON CERTIFICATE
  Pearson EDI level1 Certificate in ESOL International (CEF B2) Pearson EDI level1 Certificate in ESOL International (CEF B2)
  ID 500/3328/1

Publication

I collaborated on the publication of **20** scientific articles in the field of Gastroenterology and hepatology.

Claudia La Mastra

12/12/2024

I authorize the processing of my personal data in accordance with Art. 13 Dlgs 196 of June 30, 2003 and Art. 13 GDPR (EU Regulation 2016/679) for the purpose of personnel search and selection.