Contatta

Italy
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www.linkedin.com/in/albertoclemente (LinkedIn)
github.com/albertoclemente (Other)

Competenze principali

Clinical Trials
Clinical Data Management
Electronic Data Capture (EDC)

Languages

French (Elementary)
Italian (Native or Bilingual)
English (Full Professional)

Certifications

Fundamentals of Clinical Data Management
Statistical Reasoning for Public Health 1: Estimation, Inference, & Interpretation
Importing and Cleaning Data with R
Data Analysis with Python
Machine Learning

Alberto Clemente

Lead Clinical Data Manager | Clinical Research & Data Management Innovator | Dedicated to Data Excellence
Ravenna, Emilia Romagna, Italia

Riepilogo

As an accomplished data scientist with a proven track record in clinical research, I have gained extensive experience in managing data for phase I to phase III clinical trials, with a particular focus on Oncology, Rare Diseases and Medical Devices. My results-driven and collaborative approach has enabled me to develop and implement streamlined processes that drive operational efficiencies and deliver successful outcomes.

I possess a keen eye for detail and excellent communication skills, which allow me to articulate complex data and insights to diverse stakeholders effectively. My proficiency in both English and Italian further facilitates my ability to communicate and collaborate with global teams.

With a track record of success in both in-house and freelance settings, I am confident in my ability to add value to any organization seeking a dynamic and results-oriented data scientist. I am a creative problem-solver, committed to fostering a culture of innovation and excellence in everything I do.

Esperienza

Alira Health
Senior Clinical Data Manager
agosto 2024 - Present (1 anno 5 mesi)

Premier Research
2 anni 9 mesi

Senior Clinical Data Scientist
aprile 2023 - agosto 2024 (1 anno 5 mesi)

- Comprehensive Leadership & Oversight: I lead cross-functional teams to ensure operational efficiency and compliance across all phases of clinical

database and eCRF design processes. My strategic management includes overseeing risk assessments, aligning training for data teams, and managing budgets to enhance data integrity and project outcomes.

- Advanced Data Management: I am at the forefront of designing and enhancing AI-driven solutions to advance data analytics platforms, with a focus on automating data cleaning processes, thereby boosting efficiency and accuracy in data handling.

- Innovation Leadership: I play a crucial role in driving company-wide initiatives, leading the development of advanced AI applications to revolutionize clinical trial data management and reporting systems.

- Mentorship & Development: I mentor junior data scientists and managers, guiding their development into complex roles and ensuring a high standard of data science expertise within our team.

- Strategic Implementation: Collaborating closely with IT and biostatistics departments, I work to integrate innovative technologies and methodologies into our existing data management frameworks, significantly enhancing operational efficiency and data accuracy.

- Operational Excellence: I continuously evaluate and refine data processes and systems to meet the dynamic needs of clinical research projects and adhere to stringent regulatory standards.

Clinical Data Scientist (Lead Data Manager)
dicembre 2021 - aprile 2023 (1 anno 5 mesi)

- Collaborate with internal and external stakeholders (including vendors of external data sources) on multiple projects as needed.

- Ensure the quality and integrity of clinical trial data by overseeing the clinical database development process, which includes eCRF design, review and testing, edit check specification and implementation, and external data source integration and management.

- Contribute to the data risk assessment and mitigation plan at the early stage of the study and monitor the data risks throughout the study lifecycle.

- Coordinate and communicate with the assigned data team members to align on the appropriate tasks and timelines per the study plans.

- Provide training on the study-specific protocol requirements as needed and identify and address any training gaps among the data reviewers.

- Manage the study budget related to the functional area and report any potential out-of-scope activities to the project team as appropriate.

- Generate, review, and report on the study metrics and financials as needed.

DataRiver
Clinical Data Manager (Consultant)
gennaio 2021 - novembre 2021 (11 mesi)

• Oversee Standard Operating Procedures and ensure high data quality standards and regulatory compliance.
• Coordinate the eCRF Design in collaboration with the study stakeholders (PI, Project Manager and Biostatistics department).
• Create, review and maintain the Data Management Plan (DMP).
• Design and implement Data Cleaning/Data Quality procedures through the creation of ad hoc automatic and manual validation
rules.
• Design, review and maintain Serious Adverse Event Reconciliation Plan and conduct reconciliation between the study database
and the pharmacovigilance database.
• Prepare data cleaning report for the Sponsor.

GOIRC - Italian Oncology Group for Clinical Research
Clinical Data Manager (Consultant)
dicembre 2020 - novembre 2021 (1 anno)

• Orchestrate the Data management project development of Oncology trials related to breast and lung cancer.
• Contribute to the eCRF design in collaboration with all study stakeholders (ChI, PM, Biostat).
• Design, review and implement Data Quality processes through edit checks and manual data checks.
• Train site’s personnel on the functionalities of the EDC system and data entry procedures.

IRCCS Istituto Romagnolo per lo Studio dei Tumori "Dino Amadori" - IRST Srl

2 anni 11 mesi

Clinical Data Manager

luglio 2019 - novembre 2021 (2 anni 5 mesi)

Meldola

• Design Standard Operating Procedures for Data Cleaning activities to be implemented at the Data
Coordinating Center (e.g. Study Protocols, Case Report Forms and Reports).
• Expertise in designing Clinical Data Management Plans for phase I-III clinical trials
• Support the Biostatistics Unit in developing and reviewing Statistical Analysis Plans for phase I
Clinical Trials.
• Lead the Data Management Unit for a study involving more than 80 clinical centers and 1000
patients throughout Italy.
• Develop clinical trial data specifications, including eCRF design, user requirements and validation
checks for phase I-III clinical trials.
• Design and implement manual data validation requirements by the R programming language.
• Perform Data Cleaning activity on study databases for identifying inaccurate, incomplete and
inconsistent data.
• Manage and review discrepancy notes until their resolution throughout the entire conduct of the
trials.
• Evaluate data to ensure that protocol required events took place and monitor the data reporting for
accuracy, consistency, completeness and timeliness.
• Create reports and presentations for describing data management procedures to the Medical -
Scientific Board.

Clinical Research Assistant

gennaio 2019 - giugno 2019 (6 mesi)

Meldola (Italy)

• Provide clinical data management support to clinical research and biostatistics teams.

• Support data cleaning activities by creating edit checks, reviewing data listings and generating
queries.
• Assist the clinical research team in the preparation, handling, distribution, filing and archiving of
clinical documentation and reports according to the scope of work, ICH-GCP guidelines and
standard operating procedures.
• Evaluate data to ensure that protocol required events took place and monitor the data reporting for
accuracy and completeness.
• Track progress of non-profit clinical trials ensuring projects timelines and quality expectations are
achieved.
• Manage high priority projects and resolve data discrepancies, errors and omissions with
thoroughness and expedience.
• Assist in the set-up, maintenance and archiving of Trial Master Files

Formazione

The Open University
BSc, Health Sciences · (2018 - 2021)

The Open University
Certificate of Higher Education , Health Sciences · (2018)

Liceo Scientifico 'Enrico Fermi', San Marco in Lamis
High School Diploma , Scientific Studies · (1992 - 1997)