## Contatta

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## 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
Machine Learning
Epidemiology in Public Health Practice

# Alberto Clemente

Clinical Data Management | Clinical Research
Ravenna

## Riepilogo


Versatile Data Scientist with experience in in-house and freelance settings and a solid background in Clinical Research. Successfully handled data management activities in phase I - phase III multi-centered clinical trials, specifically Oncology studies from start-up to close-out. Results-driven and team-oriented individual with a proven ability to develop processes to improve operational efficiencies and successfully widen initiatives through purpose-led collaboration. Excellent communication skills, high attention to detail, and ability to communicate results in a comprehensive manner. Fluent in English and Italian.


## Esperienza

### Premier Research
Data Scientist
dicembre 2021 - Present (7 mesi)

- Interact with internal and external project team members (including external data source vendors) for multiple projects, as appropriate.
- Facilitate clinical database development to properly execute collection, receipt, reporting, review and archiving of quality clinical trial data.
- Include eCRF planning discussions, coordination of eCRF review, planning and identification of system and protocol specific edit checks, coordination and proper execution of User Acceptance Testing, and coordination, planning and development for external data sources as needed.
- Participate in early study team planning of data risk assessment and continuous evaluation of risks throughout course of study.
- Communicate with assigned data team members to ensure tasks are coordinated and executed as per study plans and timelines as appropriate.
-Ensure training of study specific protocol requirements as appropriate. Identify and communicate gaps in training and support training of data reviewers.
- Oversee study budget applicable to functional area. Identify and communicate potential out of scope activities to project team as appropriate.

- Responsible for proper generation, review and reporting of study metrics and financials as needed

### DataRiver
Consultant Clinical Data Manager
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
Consultant Clinical Data Manager
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)