MELISSA AIT AMMAR GUIGON

Clinical Data Manager

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Professional Summary

Clinical Data Manager with over 5 years of experience in phase I, II and III clinical trials, including first-in-human studies, for a major pharmaceutical sponsor (SANOFI), and a first experience in oncology at a cancer institute. Skilled in the full data management cycle: EDC study setup (Medidata Rave), eCRF design, edit checks programming, User Acceptance Testing, data review, queries management and migrations following protocol amendments. Solid knowledge of ICH-GCP, Good Clinical Data Management Practices and CDISC/SDTM standards. Experienced in training new Data Managers and working closely with study teams.

Core Competencies

- Clinical Data Management (phase I, IIa, IIb, III)
- EDC study setup and configuration (Medidata Rave)
- eCRF design and implementation, eCRF completion instructions
- Edit Checks Programming, Dynamics, Derivations
- Data Management Plan (DMP), Data Validation Plan
- Data Review, Data Validation, Audit Trail Review, Data Reconciliation
- Queries Management, Discrepancy Resolution, Data Cleaning
- User Acceptance Testing (UAT), eCRF testing
- Protocol Amendments Management, Migrations
- SAE reporting forms
- CDISC / SDTM
- GCP Compliance / ICH-GCP, Good Clinical Data Management Practices (GCDMP)
- Quality Management, ISO 9001
- Training and support of new Data Managers

Technical Skills

- Clinical systems: Medidata Rave, Ennov Clinical, Clintrial, Veeva Vault eTMF
- Standards: CDISC / SDTM

- Programming: SAS, SQL, PL/SQL, Python, VBA, R Commander
- Databases and office: Access, Microsoft Office

Professional Experience

Data Manager Contributor | AIXIAL (for SANOFI, Early Phase Department), Montpellier, France

2024 – September 2026

Data Manager (DMDS), Technical Team | AIXIAL (for SANOFI, Early Phase Department), Montpellier, France

April 2022 – 2024

- Implementation of phase I (including first-in-human), IIa, IIb and III clinical trials in immunology, dermatology, gastroenterology and diabetes, including studies requiring FDA authorization before study start
- Participation in study team meetings; study setup progress during FDA review and implementation of changes following FDA feedback
- Analysis and review of study protocols
- Setup of edit checks, dynamics and derivations in Medidata Rave
- Drafting of eCRF completion instructions and serious adverse event (SAE) reporting forms
- Management and execution of User Acceptance Testing (UAT) plans, including eCRF testing
- Migrations related to protocol amendments
- Data cleaning and data review on ongoing clinical trials: queries management, discrepancy resolution, data consistency checks
- Validation listings and data reconciliation
- Training of newcomers and apprentices

Data Manager | Montpellier Cancer Institute, France

2021 – 2022

- eCRF development and management (oncology: breast, digestive and prostate cancers)
- Edit checks programming
- Data validation and queries management

- Contribution to ISO 9001 certification

Data Manager Apprentice | Montpellier Cancer Institute, France

2020 – 2021

- eCRF design
- Queries management
- Data Validation Plan design

Clinical Research Associate Internship, Radiotherapy Unit | Montpellier Cancer Institute, France

2020 (6 months)

- Introduction to hospital clinical research
- Screening, inclusion and follow-up of patients
- Clinical data management and data entry into CRF

Trainee Student | Anatoscope (start-up), Montpellier, France

2019 (3 months)

- Image segmentation and registration for 3D breast tomography
- Programming in Python
- Statistical analysis with R Commander

Education

Master's Degree, Data Management | University of Montpellier | 2019 – 2021

Data management and clinical operations management, monitoring and pharmaceutical legislation; PL/SQL and SAS programming, project management, quality management, Good Clinical Data Management Practices, CDISC/SDTM standards.

Bachelor's Degree, Health Engineering | University of Montpellier | 2016 – 2019

Statistics, biochemistry, physiology, analytical and therapeutic chemistry.

PACES, Common First Year of Health Studies | 2014 – 2016

Languages

- French: native
- English: professional working proficiency

- Arabic: elementary proficiency
- Italian: basic knowledge