

Clinical Project Manager



Clinical Data Management

Clinical IT Support Management

Clinical Study Project Management

International Team Operational and Line Management



LinkedIn

Multi-skilled in clinical research (clinical activities, data management, application support) I have been working in clinical research for 10 years from Data Manager up to Project Manager and I would like now to meet new challenges.

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Experiences

CEO - Digital project manager

JV3D - November 2021 to October 2025 - Full-time - Saint André de Sangonis



- ▶ Creation of the company. Team recruitment and management. Accountability, business development
- ▶ Supporting clients in their needs for creating communication tools
- ▶ Support creators, whether they are artists or industrial designers.
- ▶ 3D printing, FDM, SLA, FGF, SLM, SLS
- ▶ 3D design/CAO (Fusion360, Shapr3D)

University lecturer

Sorbonne University - Since October 2013 - Consultant - Paris - France



- ▶ Introduce clinical research to a 20-student classroom
Present and explain the main jobs working on the clinical research
Make the clinical research interesting for students who barely know about it and who have a negative image from it
- ▶ Introduce the Data Management activities to a 200-future CRA classroom.
Present and explain the role and actions of the Data Management team and make the future CRA understand better about their future colleagues as today there is a gap between CRA and DM understanding.

Data Manager

Sanofi - April 2020 to October 2021 - Consultant - Montpellier



- ▶ Phase II studies
- ▶ Neurology and rare disease
- ▶ International operational teams (vendors) management and support
- ▶ International CRO management for Data Management activities

Senior Project Manager

Median Technologies - January 2020 to February 2020 - Full-time - Sophia-Antipolis - France



- ▶ Management of imaging projects
- ▶ Line management (3 employees)
- ▶ Bid defense with sponsor

Service Delivery Lead

Cognizant Technology Solutions - July 2018 to January 2020 - Full-time - Paris - France



- ▶ IT Support Management
- ▶ Overview of set of 160 clinical applications
- ▶ First point of contact for application owners and domain leaders (customer)
- ▶ Application support transition (Knowledge transfer and Knowledge Acquisition)
- ▶ Automation and elimination management
- ▶ Enhancement and improvement of the application's support
- ▶ Identify and create metrics and dashboards for efficient reporting
- ▶ Internal and external reporting on the deliveries (KPI)
- ▶ Onboardin/Offboarding of application in portfolio
- ▶ Line management

Clinical Data Project Manager

Cognizant

Cognizant Technology Solutions - November 2013 to June 2018 -
Full-time - Paris - France

- Project management (budget, resource, timelines)
- Phases I, II and III study management
- Asthma, diabetes, oncology therapeutic areas
- Set-up, Conduct and Close-out phases
- First point of contact for sponsors (pharmaceutical companies)
- CRA training (material and presentation)
- Support to operational teams (near-shore - Budapest, and offshore - India)
- Process review and optimization
- Documentation review and optimization
- Third Party Vendors management
- Development of new data management tools (reporting)
- CDISC, SDTM conversion management
- eTMF management

Clinical Trial Operations Manager



Sanofi - November 2011 to October 2013 - Consultant - Chilly-Mazarin -
France

- Paper-based study, phase IIIb, on Oracle Clinical 4.5 (multiple sclerosis) with CDISC
- Dedicated contact for local clinical teams
- International operational teams (vendors and monitoring teams) management and support
- International CRO management for Data Management activities
- Study documentation review (CRF, guidelines, Monitoring plan, load specifications...)
- Core phase lock organization and extensions set-up
- Validation plan review (edit checks, SAS checks)
- Medical review meetings lead and follow-up
- Safety (SAEs) and external vendor data reconciliation processes optimization
- Biostatistics issues review and follow-up
- SAS listings programming for data review (medical review, discrepancies follow-up)

Data Operations Coordinator - Data Management



Quintiles - May 2010 to October 2011 - Full-time - Illkirch-
Graffenstaden - France

- Phase IIIb paper based clinical study set-up and coordination with CDISC
- Set-up, conduct, and the lock of the study
- Guidelines creation
- Validation plan creation, correction, and validation (edit checks)
- International operational teams (vendors, sponsor, and monitoring teams) management
- Validation documents (CRF, DCF) follow-up with internal team
- Clinical data review, clarifications requests, database updates according to answers
- Medical terms coding and review (MedDRA and WhoDrug)
- External vendors data reconciliations
- Safety data reconciliation follow-up
- Internal and external audit preparation
- Database lock management

Skills

Management

- International client management



- Leadership ★★★★★
- Team management (line and operational management) ★★★★★
- International team management (India, South Africa, Hungary) ★★★★★
- Process creation and improvement ★★★★★
- SOP/SWI documents writing and validation ★★★★★☆
- Administrative management ★★★★★
- Conflicts management (identify, clarify, provide) ★★★★★

Clinical Research

- Main point of contact for client ★★★★★
- Written and Oral Communication (sponsor, vendor, CRO, monitoring team...) ★★★★★
- GCP accreditation ★★★★★
- Clinical study set-up, conduct and close-out management ★★★★★
- CDISC uses ★★★★★
- GDPR compliant ★★★★★☆

Therapeutic areas

- Oncology ★★★★★☆
- Diabetes ★★★★★☆
- Asthma ★★★★★☆
- Multiple sclerosis ★★★★★☆

IT

- ITIL foundation ★★★★★
- Service Now (user) ★★★★★☆
- Automation and Transformation Management ★★★★★☆
- Incident Management ★★★★★☆
- Knowledge Transition Management ★★★★★☆
- Change Management ★★★★★☆

Languages

- French ★★★★★
- English ★★★★★☆
- Spanish ★☆☆☆☆

Informatic

- MS Office (Word, Excel, PowerPoint) ★★★★★☆
- MS Project Plan ★★★★★☆
- SAS / SQL programming ★★☆☆☆
- Rave Medidata ★★★★★☆
- Oracle Clinical and RDC ★★★★★☆
- Inform ★★★★★☆
- OpenClinica ★☆☆☆☆
- Formedix ★☆☆☆☆
- ServiceNow ★★★★★☆

3D design

- Fusion360 ★★★★★☆
- Shapr3D ★★★★★☆
- Solidworks ★★★★★☆
- Impression 3D ★★★★★

Education

University diploma

Université Pierre et Marie Curie

October 2017 to May 2018

The objective is to train clinical research assistants (CRAs) who are responsible for monitoring clinical trials of drugs.

Master Business Administration (MBA)

Graduate Sorbonne Business school

September 2009 to September 2010

This generalist qualification aims to bring another management skills to young graduates of higher education. It is part of a continuity of study and completes the initial degree of the student, allowing them to benefit from double positioning professional competence as sought by companies. In existence for nearly half a century, the MBA has naturally found its place within professional diplomas that issue the IAE within Universities. Real career booster, general management degree, 2nd competence training, the MBA of the IAE de Paris leads logically to the international level by the term "MBA", Master of Business Administration.

Master degree on Health-Biology (Biotechnologies)

University Montpellier 2 Sciences et Technique du Languedoc

September 2007 to June 2009

Master Biology and Health training is co-authorized by the University of Montpellier 1 and Université Montpellier 2. The M1 is common to the specialties offered in M2. Four different specialties are open in M2: a specialty Research (BIOMED M2R) and 3 professionalizing specialties (Biotechnology, Food Nutrition in Public Health, Industrial Pharmacy).

Interests

Computer

- Photo editing (TheGimp, PhotoShop, Affinity Photo)
 - Video editing (Pinacle, Final Cut Pro)
 - Vector images creation (Inkscape)
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Travels

- Austria
 - Czech Republic
 - England
 - Germany
 - Hungary
 - India
 - Italia
 - Portugal
 - Slovakia
 - Spain
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