Alexandra TIZON

Freelance Senior Clinical Operations Manager
DPO Externe

CONTACT

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CERTIFICATIONS

ICH GCP Training E6(R3)

The Global Health Network Certificate

November 2025

MOOC GDPR

CNIL Certificate

November 2025

MOOC Cyber Security

ANSSI Certificate

November 2025

EDUCATION

Clinical Research Associate Certificate
University Diploma Paris, France **1998**

Biochemistry BSc Level
Bordeaux University, France **1997**

PROFESSIONAL PROFILE

- Senior Clinical Operations Project Manager with 27 years delivering complex extensive Phase I to III trials across biotech, pharma and CRO environments.
- Expertise in clinical trial strategy from feasibility until archiving, ongoing improvement operational aspects, leadership, regulatory submission (EMA: CTA, CTIS and FDA: pre-IND/IND), risk and quality management, CRO oversight and inspection readiness.
- Proven track record in ensuring high quality execution, robust TMFs and eTMFs and on time on budget delivery on fast many highly regulated environments.
- Maintain registers, draft procedures, conduct DPIAs, and manage data breaches.
- ICH-GCP, GDPR, RIA, personal data protection, cybersecurity, French anti-gift law
- Available as a freelance consultant for short- or long-term assignments.

KEY ACHIEVEMENTS

- Delivered around 30 national and international clinical studies
- Lead 3 EMA/FDA scientific advice processes with positive regulatory outcomes
- Collaborated 100% regulatory submission approvals
- Achieved 100% inspection readiness across multiple audits
- Successfully planning, organization, recovered at risks tools, improving timelines, analyzing data, managing budget and TMF completeness
- Established operational frameworks for multiple start-up and biotech companies

CORE SKILLS

- Global CPM (Phase I to III – Non interventional studies - IITs), Cross functional leadership with international study teams
- Proactive, anticipating issues and developing solutions
- CROs and vendors oversight, financial excellence
- Experience with EMA (Scientific advice, CTA/CTIS/IRIS, Eudravigilance) FDA (Scientific advice, Pre-IND, IND)
- Maintain GDPR compliance
- Risk management, mitigation strategies, IMP management and supplies strategies, project plans and SOPs set-up and updates.
- TMF set-up, QC reviews and archiving, inspection readiness
- Communication skills and ability to work on multiple projects, ability to multitask, prioritize with strong attention to detail and accuracy of information.

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THERAPEUTIC EXPERIENCE

Oncology, Sepsis, Hematology, Dermatology, Gastrointestinal Diseases, Infectious Diseases, Postpartum Hemorrhages, Orphan Diseases, Diabetes, Graft Versus Host Disease, Microbiome Restauration Therapy, Vaccines, Phagotherapy

LANGUAGES

- French: Native
- English: Fluent
- German: Elementary

SOFTWARE

CTMS, EDC (Rave, Ennov)

eTMF (Veeva, Viedoc, Ennov)

Quality (Ennov)

EXPERIENCE

Freelance Senior Clinical Operations Manager - DPO externe

BIOXELA- Since November 2025

Clinical Operations Project Manager - April 2021 – November 2025

Pherecydes Pharma - Phaxiam, Lyon, France

- Oversee CRO activities, deliverables, audits, site inspection, contract and budget negociation.
- Management of deadlines, metrics, finances and forecasting
- IMP management, Risk Management, SOPs and project plans set-up and updates, Data Management activities follow-up and participation of data review meeting, TMF set up and quality review
- Regulatory submissions (CTIS and previous regulations)
- Investigator Meetings management, DSMB management, medical writing participation to CSR, abstracts and publication.

Senior Clinical Trial Manager - September 2018 – January 2021

Genkyotex, Archamps, France

- Overall management of international studies Phase I, Phase II and Investigator Initiated Studies.
- Oversee CROs activities and deadlines, project plans creation and update, TMFs set up, quality check review and archiving.
- Regulatory: FDA and EMA scientific advice, orphan drug designation, IND and CTA/EC submission, Eudravigilance. Inspections and audits readiness.
- Set up and update SOPs, DPO clinical trials expert (record of processing activities, Privacy Impact Assessment)

Freelance Senior Clinical Project Manager - December 2017 – August 2018

Maat Pharma, Elsalys Biotech and Genkyotex, France

- Overall management of international studies Phase I, Phase II, Phase III and Investigator Initiated Study.
- Oversee CROs activities and deadlines, project plans creation, budget
- Databases creation relating to retrospective studies, data management
- Mentoring clinical project manager
- TMFs set up, quality control and archiving, inspection readiness.

Clinical Project Director - May 2017 – July 2017

DBV Technologies, France

- Implement a global strategy of a TMF. Set up SOPs. Mentoring.

Senior Clinical Development Manager- November 2016 – March 2017

- Overall management of international studies in Oncology.

Senior Clinical Project Manager November 2012 – November 2016

Covance (Labcorp) remote, France

- Overall management of international studies US, EU, Asia Pac in accordance with local regulations, approved procedures and ICH/GCP guidelines
- Management of deadlines, metrics, audits, resources, finances, contracts and forecasting activities
- Regular and proactive liaison with other internal departments (legal, safety, regulatory, data management, statistics and quality)
- Project plans creation and update, identify risks and find solutions proactively
- Audits and inspection readiness.
- Ensure cross functionnal teamwork among project team members.

From January 2008 to October 2012, **Senior Clinical Project Manager** – *Quintiles (IQVIA) in house at Pfizer*, France: management of local Pfizer clinical trials only.
From January 2005 to December 2007, **Clinical Trial Manager** – *LFB, Les ULIS*, France: management phase II and III in orphan diseases.
From March 2002 to December 2004, **Clinical Research Associate** – *LFB, Les ULIS*, France: Regulatory submissions and monitoring of a phase I and IV and a non interventional study.
From February 2001 to February 2002, **Clinical Research Associate and Data Manager** – *GERCOR*, France: preparation and management of clinical studies phase II and III in oncology.
From January 1998 to January 2001, **Clinical Research Associate** – *Bordeaux Hospital*, France: Management of a pivotal phase III study with Ribavirin in Chronic Hepatitis C. French Agency inspection.