Alexander Anikin MD, PMP

Contact

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Core Skills

Project Management
- PMP
- PRINCE2 Agile
- Risk-Based Management

Data & Analytics
- Google Data Analytics
- Tableau
- Data Analysis with R

PROFESSIONAL SUMMARY

As an MD, PMP, and Pharma MBA candidate, I bridge the gap between high-level medical strategy and flawless, on-the-ground project execution.

With deep experience in both the pharmaceutical and CRO industries, I am a hands-on leader dedicated to driving complex, global clinical trials to success, ensuring they are delivered on time, on budget, and in full compliance.

MY CORE AREAS OF EXPERTISE:

► Global Trial Leadership: Leading all operational, financial, and data aspects of complex, multi-center international clinical trials.
► Process & Compliance: Expert in process improvement, workflow optimization, and ensuring rigorous adherence to ICH GCP & FDA standards.
► Stakeholder & Vendor Management: Serving as the primary sponsor contact, leading high-level stakeholder engagement, and managing contract/budget negotiations.
► Strategic Problem-Solving: Using analytical skills to proactively identify risks and implement solutions in high-pressure environments.

MY CURRENT SITUATION:

Based in Düsseldorf with a Blue Card, I am currently on garden leave and actively exploring new senior leadership opportunities in Clinical Operations or Project/Program Management where I can help drive your clinical portfolio forward.

PROFESSIONAL EXPERIENCE

06/2021 - Present

IQVIA
Clinical Trial Lead,
► Prevented a projected 18% budget overrun by using a bottom-up EAC as an early warning system; led an RCA to identify hemolyzed samples (central lab scope creep) as the root cause, implementing a fix that saved the budget and data quality.
► Led an emergency crisis-response to the war in Ukraine, securing 24-hour sponsor approval and managing a new vendor to transfer all original ISFs from Kyiv to a secure facility in Poland with zero data loss.
► Led a "tiger team" to resolve complex, high-risk CTIS RFIs from France & Spain, creating a "consistency matrix" to ensure 100% on-time, non-conflicting submissions and secure study approval.
► Facilitated a high-stakes sponsor audit that concluded in 3 days with zero major or minor findings by fostering an "always-ready" quality culture and proactively presenting a transparent analysis of known TMF gaps.
► Proactively identified a critical protocol barrier (caffeine restriction) by presenting cultural and operational risk data, successfully influencing the medical team to remove it and securing a top-enrolling site.

02/2020 - 05/2021

Alexion Pharmaceuticals
CRO Oversight Lead,
► Solved a "study-killer" roadblock by securing the only eligible diagnostic facility in the country; led a cross-functional team (logistics, contracts) to

Languages

English — Full Professional

German — B1 Certificate

Russian — Native

Certifications

- Project Management Professional (PMP)
- PRINCE2 Agile™ Practitioner
- Goethe-Zertifikat B1 (Zertifikat Deutsch)
- Google Data Analytics Professional Certificate

coordinate complex patient travel (3000km), achieving the first patient enrolled globally.
► Championed a new TMF quality control system (weekly scorecard, accountability calls) to address poor performance, driving completeness scores to 97% ahead of schedule and successfully passing a pre-inspection QA review.

09/2019 - 01/2020

Career Break: Professional Development & Advanced Studies

09/2018 - 08/2019

Smooth Drug Development
Clinical Project Manager,
► Pivoted from a regulatory roadblock in Kazakhstan by sourcing, vetting, and contracting a local freelance CRA to manage an evolving submission process, avoiding a major study delay.

07/2016 - 08/2018

AbbVie
RWE Study Lead,
► Championed and implemented a new vendor-hosted agile "Study Project Dashboard"; built the business case, secured IT/Finance approval, and drove adoption, reducing start-up timelines by 3 weeks.
► Led a successful turnaround of a low-performing Data Management CRO by mapping a clear remediation plan and new SLAs, improving data quality and meeting all interim database milestones.
► Designed and implemented a dynamic R/Y/G site health dashboard and bi-weekly review process, shifting the team from "firefighting" to proactive management and reducing late deliverables by 35%.
► Led cross-functional alignment (Medical, Biostats, Marketing) for a large epidemiological study publication, translating diverse stakeholder needs into a unified data narrative used to successfully present drug advantages to the government.

04/2015 - 07/2016

Quintiles
Senior Clinical Research Associate

09/2012 - 03/2015

Quintiles
Clinical Research Associate

EDUCATION

2025 - 2027

Goethe Business School - Goethe University Frankfurt
Pharma MBA.
Focus: Complementing my MD/PMP credentials with deep expertise in commercial strategy, pharmaceutical management, and finance.

2010 - 2012

Moscow Research Institute of Psychiatry
Medical Doctor, Psychiatry

2004 - 2010

Sechenov University, Moscow
Medical Doctor, Medicine