MADHUPARNA GANGULY

Clinical Trial Operations Manager | Project Manager | Clinical Data Manager

Address: Rütistrasse 26, 8134 Adliswil, Zürich, Switzerland
(Willing to travel & relocate)
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DOB: 03 November 1991; **Nationality:** Indian
Residence Permit: Swiss **B**-Permit
(eligible for full-time work, no sponsorship required)
CH Driving License holder

CAREER SUMMARY

PMP® and **Lean Six Sigma Black Belt**–certified **Clinical Operations & Project Manager** with **8+ years of experience** in **global clinical trial operations (Phase I to IV)**, **leading end-to-end project** management across study start-up, conduct, and close-out, with strong expertise in **quality oversight, regulatory affairs** and **clinical data management**. Proven in leading cross-functional study teams, coordinating site-facing activities, ensuring **ICH-GCP** and regulatory compliance (**FDA, EMA, and Swissmedic**), consistently delivering clinical projects to time, cost, and quality expectations. **Certified in Clinical Trial Management**, with a strong background in study planning, risk and issue management, TMF oversight, audit readiness, and stakeholder leadership across CRO, sponsor, and sites. Based in **Zürich**, holding a **Swiss B Permit**, fluent in **English**, intermediate in **German** (B1), elementary in **French** (A1), and can start immediately.

CORE COMPETENCIES

- **Clinical Operations & Data Management**: Site operations, protocol & ICF development, site monitoring, CTMS/CDMS/TMF management (OnCore, Allegro, Clinical Conductor, OpenClinica, Medidata Rave, Veeva Vault, REDCap), EDC, eCRF design, edit checks programming, data monitoring, database validation & lock, inspection readiness, CSV, CDISC standards (CDASH, SEND, SDTM, ADaM), source data review, eSource, eCOA, ePRO, MedDRA, CTA, CMC and medical devices.
- **Clinical Trial Management & Delivery**: Phase I–IV study delivery, clinical trial planning, study start-up & site activation, conduct & close-out, cross-functional leadership, country/site operational coordination, safety & pharmacovigilance, scientific writing, developed patient calendars, timelines & milestones, budgets, risk and issue management.
- **Project & Program Management**: PMP® certified with expertise in end-to-end project and program management using Predictive (Waterfall), Agile, and Hybrid methodologies. Skilled in planning & forecasting, managing scope, schedule, budget, risk, resources, quality, vendor (procurement), change management & stakeholder engagement.
- **Regulatory, Quality & Compliance:** Lean Six Sigma Black Belt certified with experience and strong knowledge of ICH-GCP, HIPAA, GDPR, GDoCP, GLP, GVP & GMP guidelines, ALCOA+, FDA/EMA/Swissmedic frameworks, IND/NDA/BLA submissions, De Novo, 510(K), PMA submissions for medical devices, ethics/IRB support, safety management (pharmacovigilance), QMS, audit & inspection readiness, CAPA, QC/QA reviews, UAT, gap assessment and continuous process improvement.
- **Team Leadership & Training**: Led cross-functional teams of up to 15 members; developed and managed resources, training & mentoring, KPI & performance management, created SOPs & processes, documentation control, communications, query management.
- **Customer & Stakeholder Engagement**: Collaborated with 100+ global clients (CROs, research sites, investigators and sponsors), ensuring high satisfaction and timely project execution through effective communication and proactive coordination.
- **Business Tools:** MS Office (Excel, PowerPoint, MS Project, Visio, Outlook, Planner), Jira, SharePoint, Slack, Zendesk, Salesforce, Bizagi, Banana Accounting, Generative AI tools, ML basics, Python basics, Salesforce, SQL basics, SAS etc.

PROFESSIONAL EXPERIENCE

Clinical Research Scientist – Quality Assurance & Regulatory Affairs (DAS Program- Intern) Mar 2026 - Ongoing
University of Geneva & ABCDx SA MedTech, Geneva, Switzerland

- Supporting **quality** and **regulatory planning** for a D-dimer rapid diagnostic IVD, contributing to **FDA Q-Submissions, 510(k),** and **De Novo strategies.**
- **Designing clinical performance** and **analytical validation study frameworks** aligned with FDA, GCP, and CLSI standards, using large datasets (~600 subjects) in pulmonary embolism and stroke to define study objectives, endpoints, and statistical rationale.
- Preparing **key analytical, clinical,** and **regulatory** documents **(e.g., Q-Submissions, 510(k)/De Novo submissions, study protocols, CRFs, ICFs, DMPs, and Ethics Committee submissions**) while collaborating cross-functionally to ensure regulatory alignment.

Relocation break (India to Switzerland): MBA, DAS, German (A1–B1), ECS Life Sciences Ambassador Nov 2023 - Feb 2026

Manager – Business Operations Services (Clinical Operations, Quality & Project Management) Jul 2016 - Oct 2023
Advarra, **Bangalore, India**

- Led operational delivery of **50+ global Phase I–IV clinical trial projects** across multiple therapeutic areas, serving as **primary point of contact** for **100+ global clients,** coordinating cross-functional teams and delivering clinical site and digital technology solutions.
- Managed **end-to-end delivery** of up to **15 clinical studies** at a time, overseeing scope, timelines, budgets, risks, quality, and site operations including start-up, protocol execution, system deployment, and issue or query resolution.
- **Accelerated study start-up by ~28%**, saving ~2 person-days per study, while leading and mentoring cross-functional teams of up to **15 members**, driving performance, **KPI tracking,** and productivity initiatives that improved team output by **~50%.**
- Ensured continuous **ICH-GCP compliance** and **inspection readiness** through proactive **TMF oversight, documentation control, CAPA management,** and regulatory/client **audit support**, consistently maintaining **100% monthly SLA** and **quality compliance**.

Member of Technical Staff/ SME (Clinical Data Management, Quality & Regulatory Affairs) Jul 2015 - May 2016
PointCross Life Sciences, **Bangalore, India**

- Standardized and validated **pre-clinical** and **clinical data** per **CDISC guidelines** for regulatory submissions, supporting **study start-up, UAT,** and **quality reviews** to ensure quality and compliance.
- Provided **consultation on SDLC** and **clinical tool development** to IT and PS teams; **trained team members** and conducted **QC** reviews to ensure data standardization, consistency, and compliance.

EDUCATION

Master of Business Administration (MBA), Swiss Tropical and Public Health Institute, Switzerland May 2025 - Ongoing
Specialization: **International Health Management**

- Part-time MBA program for working professionals in collaboration with the **University of Basel**.

Master of Research (MRes), The University of Nottingham, United Kingdom Sep 2012 - Sep 2013
Specialization: **Stem Cell Biology**

- Research project entitled "To determine the role of Id4 protein in the fate of neural stem cells using zebrafish as a model".

Bachelor of Science (BSc Honors), University of Calcutta, India Mar 2009 - Mar 2012
Specialization**: Physiology**

DIPLOMAS & PROFESSIONAL CERTIFICATIONS

- **DAS** in **Management of Clinical Trials**, University of Geneva, Switzerland. Sep 2025 - Apr 2026
- **Supply Chain Management**, Six Sigma Academy Amsterdam May 2025
- **PMP® (Project Management Professional),** Project Management Institute Oct 2024
  - Achieved a rating of 'Above Target' in all three domains- People, Process and Business.
- **Lean Six Sigma Green** & **Black Belt,** Six Sigma Academy Amsterdam Jul 2024 - Nov 2024
- **Post Graduate Diploma,** Institute of Pharmaceutical Management, Mumbai, India Sep 2020 - Mar 2021
  Specialization: **Pharmaceutical Regulatory Affairs**
- **Advance Diploma** & **On Job Training,** ICBio Clinical Research Pvt. Ltd., Bangalore, India Jan 2015 - Apr 2015
  Specialization: **Clinical Research and Clinical Data Management**

STRENGTHS

• Leadership • Collaboration • Communication • Problem solving • Attention to detail • Adaptability • Quick learner

AWARDS & SCHOLARSHIPS

- **Customer Champion** (2x), Advarra Oct 2020 & Jun 2023
- **GEM Award,** Advarra Aug 2021
- **Forte Excellence Award,** Advarra Feb 2018
- **Reviewer of the Month**, Advarra Nov 2017
- **Star Performer of the Month,** Advarra Oct 2017
- **Developing Solutions Scholarship** & **School of Biology Scholarship**, The University of Nottingham Jan 2013
- **Best in General Proficiency Award**, Indira Gandhi Memorial High School Mar 2008

RELEVANT TRAININGS & WORKSHOPS

- **Good Clinical Practice (ICH GCP) E6 (R3)** by University of Geneva (2025).
- **Medical Writing for Healthcare Professionals** and **Clinical Trials in Oncology** by Udemy (2025).
- **Practical Application of Generative AI for Project Managers** and **Prompt Engineering for Project Managers** by PMI (2025).
- **HIPAA** for patient health information data protection and **ICH GCP E6 (R2)** by Advarra (2021-2022).
- **Creation of Edit checks specifications for Electronic Data Capture (EDC) studies** workshop by ISCR (2021).
- **Transitioning from a Manager to a Leader** training by Thought Labs conducted at Advarra (2020).
- **People building & Leadership skills** workshop **by Dale Carnegie** (2018) & **Agile Project Management** by Udemy (2020).

INVITED TALK

Guest presenter at the **University of Sheffield** and **Open University, UK** (2013)- Delivered a talk on master's research project.

LANGUAGE PROFICIENCY

English: Native or Bilingual proficiency; **German:** B1 (pursuing); **French:** A1 (pursuing); **Bengali:** Native or Bilingual proficiency**;**
Hindi: Limited working proficiency

REFERENCES

Available upon request.