

Rimi Ghosh

CLINICAL PROJECT MANAGER - Risk Management, Regulatory Submission Expertise, Research

✉ rimigh65@gmail.com

☎ +1 (437) 663-1511

📍 [Mississauga](#)

in [LinkedIn](#)

SKILLS

- **Project Management & Methodologies:** Agile and Waterfall methodologies, project planning, execution.
- **Clinical Research & Compliance:** ICH GCP guidelines, pharmacovigilance and TMF (Trial Master File).
- **Enterprise Software :** PeopleSoft, Trello, Coupa, Veeva, Argus Safety Tool, and accounts payable systems.
- **Quality & Regulatory Standards:** GLP, GMP standards, and ensuring regulatory compliance management.

WORK EXPERIENCE

Project Management Analyst

March 2021 – December 2023

IQVIA RDS

India

- Managed 15+ global trials (\$10M–\$30M) across USA, UK, Canada, and Asia using SAS, Veeva Vault, and MS Project, ensuring alignment with scope, KPIs, and compliance with ICH-GCP, and governance standards.
- Managed financial forecasts, billing cycles, and invoice tracking via PeopleSoft and Coupa; reconciled monthly reports across cross-functional teams, while reducing variances in projections by maintaining financial accuracy.
- Generated 30+ reports with Power BI; boosted data workflow efficiency by 30% and ensured full compliance.

Operation Specialist

March 2019 – February 2021

IQVIA RDS

India

- Collaborated with cross-functional units including clinical and data management to resolve 25+ project-specific issues weekly, while ensuring operational continuity and prescriptive adherence to timelines during trial execution.
- Enabled safety data triage and submission processes for compliance with global pharmacovigilance standards; improved regulatory response time by 20% and supported life-cycle safety review via risk assessment workflows.
- Supported EMA/FDA audits by maintaining 100% data traceability and documentation, enhancing readiness.

Regulatory Affairs Associate

November 2015 – February 2019

Imed Global Solutions Pvt Ltd

India

- Drafted and reviewed CMC documentation for IND/NDA adhering to global regulatory; improved accuracy by 20% and reduced submission timelines by 15% by aligning with FDA, EMA, and ICH compliance standards.
- Audited technical documents for product release authorization and validation protocols across Beauty, Baby, Oral, and Device categories, ensuring 100% submission-ready formats for North American market launches.
- Implemented documentation for APRs, reducing review cycles 25% and improving QA communication 30%.

PROJECT EXPERIENCE

Clinical Trials Consolidation – Cardiovascular

12 Months — Project Size: \$22M

Project Manager, AstraZeneca

- Coordinated three Phase II trials and streamlined PO tracking via Coupa and PeopleSoft, decreasing financial reconciliation time by 25%. Facilitated weekly sponsor reports and dashboards using PowerPoint and SharePoint.

Early-Phase Oncology Trial Execution

10 Months — Project Size: \$15M

Project Manager, Sun Pharma

- Managed Phase-I oncology trial and tracked 100% of lifecycle documentation in Excel and Veeva Vault to ensure protocol compliance. Elevated data reporting using Power BI and Canva, improving data transparency by 35%.

Phase III Oncology Trial Management

18 Months — Project Size: \$25M

Project Lead, BeiGene (Client: Regeneron)

- Directed global trial activities, used Smartsheet and MS Project to manage project plans and stakeholder communication workflows. Delivered monthly Tableau dashboards to leadership tracking KPIs and risk indicators.

Global Regulatory Compliance and Risk Oversight

14 Months — Project Size: \$30M

Risk Analyst, Johnson & Johnson

- Conducted clinical site risk review via Veeva QMS, ensuring consistency in audit preparedness across different regions. Achieved 0 critical FDA findings by standardizing change controls, to enhance auditing.

EDUCATION

Ontario Graduate Certificate in Marketing Management

January 2024 – April 2025

Sheridan College, HMC Campus, Mississauga, Ontario

Ontario Graduate Certificate in Project Management

January 2024 – August 2024

Sheridan College, HMC Campus, Mississauga, Ontario

Master of Pharmacy (Pharmacology)

2013 – 2015

MS Ramaiah College of Pharmacy, Rajiv Gandhi University of Health Sciences, India

CERTIFICATION

- Project Management Professional (PMP)