

# Rimi Ghosh

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

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## 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)