

# DR. JESTINA ANN JACOB

Pharm D | CCRPS | Clinical Research Associate

Pharm D graduate and CCRPS-certified Clinical Research Associate with specialized training in risk-based monitoring, source data verification (SDV), and source data review (SDR). Skilled in protocol deviation analysis, inspection-ready monitoring documentation, and regulatory compliance oversight. Demonstrated ability to identify site risk patterns, escalate appropriately, and support sponsor-defensible oversight. Committed to patient safety and data integrity while seeking a CRA I or CRA Trainee position with structured mentorship and professional development opportunities.



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## CLINICAL MONITORING EXPERIENCE

### Clinical Monitoring Training Program

Advanced CRA Training (CCRPS - ACRA)

*Key Duties and Responsibilities*

- Conducted simulated monitoring visits using Risk-Based Monitoring (RBM) principles, prioritizing critical data and protocol-critical processes.
- Performed Source Data Verification (SDV) and Source Data Review (SDR) exercises on sample case report forms, identifying transcription errors and ensuring clinical plausibility.
- Drafted monitoring report narratives with clear risk categorization and defensible escalation language.
- Identified and escalated protocol deviations using standardized classification frameworks.
- Supported Trial Master File (TMF) quality checks, evaluating document completeness and regulatory compliance.
- Applied ICH-GCP and 21 CFR Part 11 knowledge to ensure inspection-ready documentation.

## PROFESSIONAL EXPERIENCE

### Health Content Writer

Astrian Innovations | Part-time

2025

*Key Duties and Responsibilities*

- Experienced in clinical data collection, auditing, and fact-checking medical information for accuracy.
- Applied data literacy, research interpretation, statistical review, and data visualization skills.
- Developed and executed a multi-channel digital content strategy to build brand authority in the niche sector.
- Created detailed tracking logs and dashboards in Excel to monitor project timelines.
- Ensured all deliverables were met according to schedule through effective project management.
- Maintained accuracy and compliance with medical and regulatory standards in all content.

### Community Pharmacist

Ann Medicals

2021-2024

Kerala, India

*Key Duties and Responsibilities*

- Ensured compliance with regulatory requirements and department policy.
- Monitored and trained 5 junior pharmacists, improving their knowledge and performance.
- Implemented cost-saving analysis that led to 15% reduction in pharmacy expense over 6 months.
- Conducted a thorough analysis of medication ordering and dispensing processes.
- Maintained accurate records and documentation for regulatory inspections.
- Provided patient counseling and medication therapy management services.

### Clinical Pharmacist (Neurology and Nephrology)

Believers Church Medical College Hospital

2021

*Key Duties and Responsibilities*

- Led the successful implementation of a medication therapy service serving over 3000 patients in 6 months.
- Prepared and maintained NABH deficiency files, collected evidence, tracked corrective action plans, and ensured timely closure of non-conformities.

- Conducted internal audits and external assessments over 5000 patient files.
- Conducted and co-authored an observational study among 300 patients on the incidence of newly detected diabetes among COVID-19 patients.
- Collaborated with multidisciplinary teams to optimize medication therapy outcomes.
- Ensured adherence to hospital protocols and regulatory standards in patient care.

## EDUCATION AND CERTIFICATIONS

**Doctor of Pharmacy (Pharm D) |** 2015-2021 | Rajiv Gandhi University of Health Sciences, Karnataka, India

**Advanced Clinical Research Associate Certification (ACRAC) |** CCRPS

**Introduction to Informed Consent |** Global Health Training Centre | 2025

**Good Clinical Practice |** NIDA Clinical Trials Network | 2025

**Diploma in Modern Applied Psychology |** The Academy of Modern Applied Psychology

**Certified Professional Coder (CPC) Training |** Skyline Medical Coding Institute, Dubai | 2023

**Certified Clinical Trauma Specialist (CCTS-I) |** International Institute for Trauma and Addiction Professionals, Arizona

**First Aid and Basic Life Support |** Indian Red Cross Society (IRCS)

## PUBLICATIONS

- Biju RA, Jacob JA. Incidence of newly detected diabetes among COVID-19 patients in a tertiary care hospital. J. Global Trends Pharm. Sci. 2024; 15(2): 522-527.
- Jacob JA. Comparative studies between fluoroquinolones and other classes of antibiotics and their dysglycemic effect in Type 2 DM patients in a tertiary care hospital.

## CORE COMPETENCIES

- Clinical Monitoring and Site Oversight
- Risk-Based Monitoring (RBM) Principles
- Source Data Verification (SDV) and Source Data Review (SDR)
- ICH-GCP and 21 CFR Part 11 Knowledge
- Trial Master File (TMF) Management
- Electronic Data Capture (EDC) and CTMS Systems
- Protocol Deviation Identification and Escalation
- Query Resolution and Data Reconciliation
- Monitoring Report Documentation
- Audit Support and Inspection Readiness

## PROFESSIONAL SKILLS

- Clinical data collection, auditing, and fact-checking
- Research interpretation and statistical review
- Data literacy and visualization
- Regulatory compliance oversight
- Patient safety and data integrity focus
- Risk categorization and escalation
- Documentation and report writing
- Project tracking and timeline management
- Microsoft Excel and dashboard creation
- Team training and mentorship
- Process analysis and cost optimization
- NABH accreditation support

## ADDITIONAL INFORMATION

- Available for immediate joining
- Willing to relocate as required