Pooja Iyer

Clinical Research Associate II

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Personal statement

Clinical research associate with 5 years of experience, including 3 years of independent site monitoring for Phase II and III oncology and diabetes trials across South India. Experienced in ICH-GCP, New Drugs and Clinical Trials Rules 2019, site initiation to close-out, SDV and EDC query management, with consistently clean audit outcomes.

Certifications

ICH Good Clinical Practice (GCP) training · Recognised GCP training provider — Apr 2025

Work experience

Clinical Research Associate II · Clinova Research Services Pvt Ltd, Bengaluru — Jul 2023 – Present

- Monitor 7 sites across Karnataka, Tamil Nadu and Kerala for a global Phase III oncology trial, conducting SIVs, IMVs and COVs as per the monitoring plan.
- Complete 100% SDV for critical data points and keep open EDC queries under 15 days old, ahead of the 30-day study target.
- Helped sites raise enrolment from 1.1 to 1.8 patients per site per month through pre-screening logs and investigator follow-ups.
- Supported a sponsor audit at 2 sites with no critical findings and closed all major findings within 21 days.

Clinical Trial Coordinator, then CRA I · Medivista Clinical Trials India, Chennai — Aug 2021 – Jun 2023

- Coordinated a Phase II type 2 diabetes trial at a 600-bed hospital site, managing consent, visits, IP accountability and EDC entry.
- Prepared EC submissions and maintained the investigator site file, which scored "no findings" at the sponsor audit.
- Moved to CRA I in 2022 and co-monitored 4 sites, writing visit reports within 5 working days.

Education

M.Pharm in Pharmacology · College of Pharmacy, Chennai — 2019 – 2021
Grade: 8.2 CGPA

B.Pharm in Pharmacy · College of Pharmacy, Madurai — 2015 – 2019
Grade: 7.9 CGPA

Skills

- ✓ ICH-GCP E6
- ✓ New Drugs and Clinical Trials Rules 2019
- ✓ Site monitoring (SIV, IMV, COV)
- ✓ Source data verification
- ✓ EDC query management
- ✓ CTMS and eTMF
- ✓ IP accountability
- ✓ Ethics committee submissions

Languages

English · Fluent | Tamil · Native | Kannada · Conversational | Hindi · Conversational

Core skills

- Site relationship management
- Risk-based monitoring
- Report writing
- Audit readiness
- Travel and time management

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