

Shamika Naik

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EDUCATION

- MSc, Biotechnology** • Guru Nanak Khalsa College, Mumbai 2018–2020
- Dissertation: **In-Vitro Antimicrobial Activity of Curcuma Amada** on clinical isolates from burns wounds – published in IJPSR
- BSc, Biotechnology** • Guru Nanak Khalsa College, Mumbai 2015–2018

WORK EXPERIENCE

- Research Scientist II** | Government Medical College & Hospital, Aurangabad *Aug 2025 – Sep 2025*
- **Prepared & submitted** study initiation and regulatory documents to the Ethics committee and created SOPs for the study.
- Research Scientist I & EC Coordinator** | Bai Jerbai Wadia Hospital for Children, Mumbai *Jan 2024 – Jan 2025*
- **Trained 2 research staff** on GCP compliance and neurodevelopmental assessment tools, improving team competency scores by **~25%**.
 - **Drove 6% annual increase** in subject recruitment by building site-specific tracking plans and conducting weekly enrolment follow-ups.
 - Managed the preparation and review of annual and interim reports and delivered project status presentations to the Sponsor and Principal Investigator.
 - **Managed end-to-end IEC submissions** for **200+ protocols**, achieving **100% on-time approvals** and same-day decision communication to investigators.
 - **Co-authored 4 updated SOPs** aligned with NDCT Rules 2019, adopted across the **12-member** research department.
 - **Led dual-role responsibilities** (Research Scientist + EC Coordinator) with **zero process lapses**.
 - Assisted in study closeout processes and facilitated annual audits by the sponsor and lead centre of the multicentre study.
 - Handled **250+ ethics submissions** and functioned as a key point of contact between the Ethics committee & Investigator.
- Study Coordinator & EC Coordinator** | Bai Jerbai Wadia Hospital for Children, Mumbai *Jan 2021 – Dec 2023*
- Prepared and reviewed regulatory documents including Protocols, **CRFs, ICDs, and PIS** for clinical studies.
 - **Screened & recruited 350+ patients** for a multicentre Cardiac Surgery study. Conducted 1500 Neurodevelopmental assessment of paediatric patients ranging from 6 month to 3 years and did the cluster analysis for the same.
 - **Completed 100% of CRFs** with zero data discrepancies, adhering to ALCOA+ principles.
 - **Conducted 5 Site Monitoring Visits (SMVs)**, resolving **30+ data queries** per visit and ensuring protocol adherence at all sites.
 - **Facilitated NABH audit preparations**, contributing to a **successful re-accreditation** with no critical observations.
 - **Led scientific literature screening** for adverse drug reactions and safety signals.
- Research Intern** | Bai Jerbai Wadia Hospital for Children, Mumbai *Nov 2019 – Feb 2020*
- **Conducted literature reviews** and phytochemical extraction using Soxhlet and cold extraction methods.
 - **Performed GC-MS & FTIR analysis** on **15+ samples**; results contributed to a peer-reviewed publication in IJPSR.

PUBLICATIONS

- **Neurodevelopmental outcomes after infant heart surgery for congenital heart disease; a hospital based multicenter prospective cohort study from India-** BMJ Pediatrics Open.
- **In-Vitro Antimicrobial Activity of Curcuma Amada on the Clinical Isolates Obtained from Burns Wounds** - International Journal of Pharmaceutical Sciences and Research.

CERTIFICATIONS

- **GCP – NIDA Clinical Trials Network (2025).**
- **New Drug & Clinical Trial Certification – B.J. Wadia Hospital for Children, Mumbai (2024).**
- **ICMR Ethical Guidelines Certification (2023).**
- **Drug Regulatory Affairs Chemist – (LSSSDC Program) Pollux Life Sciences, Mumbai (2019- 2020).**

LANGUAGES, SKILLS & TECHNICAL PROFICIENCIES

Skills: Clinical Study Protocol Writing • Clinical Study Report (CSR) Writing • Synopsis Preparation • Investigator Brochure Preparation & Review • Informed Consent Document (ICD) Writing • Patient Information Sheet (PIS) Preparation • Patient Diary Card Development • Statistical Analysis Plan Review • Interim Reports & Summary Reports Writing • Report Archiving / e-Archiving

Regulatory & Clinical: ICH-GCP • NDCT Rules 2019 • TMF/ISF Maintenance • SDV • CRF Completion (ALCOA+) • IEC Submissions • Protocol Amendments • Feasibility Studies

Technical: MS Excel • MS Word • PowerPoint • Reference Management Tools • eCTD Documentation Systems • Scientific Literature Review.
Languages: English (Professional) • Hindi (Native) • Marathi (Fluent) • French (A2).