866/A3, Amirtha nagar 4th cross,
MM nagar, Hosur-635126.

8072952535

Prabudass7@gmail.com

SKILLS

- Software – Clinevo eTMF, QMS trackwise, MedRA, DMS, Nuleap
- eTMF, EDC, CTMS, IVRS, IWRS
- Microsoft Office (Word, Excel, and Power Point and MS Project)
- Regulatory Document Review
- Monitoring report review (145 report)
- Risk identification/mitigation
- Risk based monitoring
- ICH GCP Guideline Competency

CONCEPTUAL KNOWLEDGE

- Working knowledge of ICH-GCP guidelines
- New clinical trials rules 2019
- Schedule Y, E6 & 21-CFR.

EDUCATION

- Bachelor's degree in pharmacy, Dr. MGR University, Chennai, 2003
- Master's degree in business administration, Manonmaniyam Sundaramnar university, Tirunelveli (2012)
- Post diploma in Clinical research, Catalyst clinical research, Delhi (2009)

PRABUDASS. D

PROJECT MANAGER / GCP AUDITOR

RESUME SUMMARY

Accomplished Clinical Trial Manager with 7 years of experience in clinical research. Experienced in leading teams to successful clinical trial completion.
Dedicated Quality Auditor with 7 years track records of providing outstanding quality standards in Clinical trials.

WORK EXPERIENCE

Jul 2023 to till date

Name of the Company	Designation
Aurigene Oncology Limited, Bangalore	Assistant Manager

- Ensure that site selection, site initiation, site monitoring, site closeouts are conducted as per SOP requirements, Protocol and other regulatory requirements.
- Conduct of clinical trial site audits based on audit strategy.
- Effective review of Site visit reports (SVR) to ensure the reports are in quality standards, errors free and issues are escalated.
- To follow up on action items and protocol deviations and to be a liaison between CRA, CTM and PM for timely resolution of issues.
- Ensures compliance of clinical studies with internal SOPs and clinical plans and regulatory requirement in conduct of clinical trials and the quality and integrity of generated data.
- Review of essential documents Protocol, IB, ICF, eTMF, eCRF, ISF and source documents.
- Identifies and monitor quality indicators and data to identify potential trends and risks to patient safety, compliance and data integrity.
- Effectively planned and audited phase I (five studies) and phase III (one study) clinical trial for an oncology drug.
- Assist with identification of the trends emerging from the issue escalation log.

AUG 2017 to JUN 2023

Name of the Company	Designation
Apotex Research private Limited, Bangalore	Senior Executive

- Ensure that site selection, site initiation, site monitoring, site closeouts are conducted as per SOP requirements, Protocol and other regulatory requirements.
- Review of SSV report, SIV report, Site monitoring visit reports, interim report and closeout report as per SOP requirements, Protocol and other regulatory requirements.
- Conduct of clinical trial site audits based on audit strategy.

SKILLS

- Sound knowledge of human subject protection regulations, and general clinical research process.
- Have a full understanding of AE/SAE reporting procedures, productions of reports, narratives and follow up of AE/SAEs.
- Excellent interpersonal, presentation, written and communication skills.
- Very familiar with medical terminology and clinical research concepts.
- Experienced using Electronic Data Capture (EDC), IVRS & CTMS.
- Solid knowledge of GCP, ICH, FDA, NDCT and other federal regulations
- Strong Clinical Trial Computer Software experience including but not limited to Microsoft Office (Word, Excel and Power Point).

Projects handled	Phase of the study
Stage IV Non-Squamous Non-Small Cell Lung Cancer	III
Relapsed advanced malignancies (3 study)	I
Relapsed metastatic solid tumors	I
Relapsed advanced Non-Hodgkin lymphoma / Chronic Lymphocytic Leukaemia	I
Patients with Colorectal, Ovarian, and Renal Cancers	I

PERSONAL PROFILE

Name	:	D. Prabudass
Father's Name	:	A. Duraipandi
Gender	:	Male
Marital Status	:	Married
Languages Known:		English, Tamil and Kannada

- Participate in project meetings (internal and external) as Clinical Quality representative.
- Ensure accurate and consistent coding of all events for serious and non-serious cases entered in the data with the use of MedDRA.
- Review of essential documents Protocol, IB, ICF, eTMF, eCRF, ISF and source documents.
- Assists with qualification process for selected external vendors and provides oversight for outsourced clinical activities.
- Contribute day to day management of GxP quality management system including document control, risk management, deviation and CAPA management.

MAR 2010 to JUN 2017

Name of the Company	Designation
Azidus Laboratories Limited, Chennai	Senior CRA

- Conducting pre-study, site initiation, site monitoring, interim monitoring and close-out monitoring visit to ensure compliance with protocol, GCP and regulatory requirements.
- Verifying that source data/documents and other trial records are accurate, complete and maintained in accordance with the protocol on the CRFs.
- Monitor investigator sites to ensure the accuracy and validity of CRF entries in relations to the patient records/clinic notes.
- Escalates observed deficiencies and issues to the clinical management expeditiously presents potential solutions.
- Manages the essential documents, as required by local regulations and ICH GCP, before, during and after a clinical trial.
- Maintain internal trial master file and Investigator site file to ensure inspection readiness.
- Prepare and sending monitoring visit reports to the sponsor on stipulated timelines.
- Provide trial status tracking progress update reports to the Clinical Team Manager (CTM) as required.
- Facilitates effective communication between investigator sites, the client company and the sponsor team through written, oral and/or electronic contacts.
- Perform drug accountability to ensure adequate storage, dispensing, dosing and use IP's during monitoring visits.
- Prepare and submit reports from study visit, Retrieve CRF/eCRF and DCF for submission.

DECLARATION

I hereby declare that above information furnished is true to the best of my knowledge and belief.

(D.Prabudass)