Sahana NJ

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OBJECTIVE

To be associated with CRO/Pharma industry that provides an opportunity for a challenging and rewarding career by Applying my knowledge, skills and potential in this profession. I would also like to make positive contribution towards your organization while promoting team spirit and own professional growth.

WORK EXPERIENCE

- **Centralized Study Associate II- Labcorp Drug Development India Pvt Ltd.**

Duration: Feb 2023 to June 2023

- **Clinical Research Coordinator-Trial Lead** at ChanRe Rheumatology and Immunology Centre and Research.

Duration: November 2020 to Feb 2023

EDUCATION

Bachelor of Engineering in 2012 from Sapthagiri college of Engineering, VTU

CERTIFICATION

- **SAS Global Certification Program**
  Recognized as a SAS certified Base Programmer for SAS 9.4

- Post Graduate diploma in **Clinical Research and Clinical Data Management** from **ICBIO** Clinical Research **Pvt Ltd Bangalore**

PUBLICATIONS

- **NJ , Sahana. "** Use of Tacrolimus for managing csDMARD-failed Rheumatoid Arthritis: A real-time experience from a single tertiary care centre" **IJRCI. 2022;10(1): OR1DOI: 10.15305/ijrci/v10i1/353**

SKILLS

- Good Clinical Practices (GCP)- Clinical Trails
- Good Documentation Practice and GDP principle.
- Electronic Data Capture (EDC)
  Oracle Inform
  Veeva Vault CDM
  Medidata Rave
- Manage Clinical Systems and Access Management
- Maintain study databases(CTMS,IWRS,EDC etc)
- Support study team in data review and support activities
- Generate study reports
- Clinical Data Management
- Regulatory affairs and New drugs and Clinical trial Rules 2019.
- Comprehensive knowledge about Pharmacovigilance
  - Detection and assessment of an ADR/AE, SAR/SAE
  - Serious Adverse Event Reporting

STUDY EXPERIENCE

(DEPARTMENT)

Rheumatology& Immunology

- Data Extraction, Data Analysis for Institutional studies
- Ankylosing Spondylitis and Psoriatic Arthritis-**PhaseIV**
- Systemic lupus erythematosus-**Phase III**
- Institutional Studies

- Trained on ICH GCP, Schedule – Y, ICF Process, SAE Reporting.
- Screening and enrollment of study subject.
- Study drug accountability.
- Sample labeling and dispatching.
- Collection of documents needed to initiate the study and submit to the sponsor (FDA Form 1572, study team CVs etc.)

TRIAL RELATED EXPERIENCE:

- AE Monitoring, reporting and follow up study.
- IEC/IRB Correspondence including SAE submission, all essential documents.
- EC notification and progress report for Ethics committee.
- Keep track of study activities to make sure compliance

with protocols and ICH GCP and all other applicable guidelines.

- Conduct and participation in the informed consent process, obtaining appropriate signatures and dates of forms, also assures that amended consent forms are appropriately implemented and signed.
- Preparation of other study materials informed consent document, case report forms (CRFs), enrollment logs, and drug/device accountability logs as requested by the PI.
- eCRF data within the project timelines and coordinate with sponsor to resolve and answer queries.
- Screens subject for eligibility using protocol specific inclusion and exclusion criteria, documenting each potential participant's eligibility or exclusion.
- SAE reporting on SUGAM portal as per user manual.
- Response to DCFs raised by DM team.

STUDY-CLOSEOUT ACTIVITIES

- Assist the principal investigator in submission of accurate and timely closeout documents to sponsor/CRO.
- Arranges secure storage of study documents that will be maintained according to the contracted length of time, whichever is longer.
- Archival of SSF.

AREA OF INTEREST

- Clinical Data Analyst
- Clinical Data Management
- Regulatory Affairs

DECLARATION

I hereby declare that the above-mentioned information is correct up to my knowledge and I bear the responsibility for correctness of the above- mentioned particulars.

Your faithfully

Place: Bangalore

[Sahana N J**]**