

Aarti Kant Sonwani

Clinical Research Coordinator



5 Years 0 Month



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Profile Summary

Perform startup/ conduct / Close out activities under supervision and quality checks, data reconciliation, SAE reconciliation, third party reconciliation, data abstraction, data validation, Centralized monitoring activities, data cleaning, secondary research, Oversight of data discrepancy management etc.



Education

B.Pharma, 2017

J. L.Chaturvedi priyadarshani College of
Pharmacy

12th, 2012

Maharashtra,
English

10th, 2010

Maharashtra,
English



Work Experience

Jan 2022 - Feb 2024

Clinical Research Coordinator
Vasta Bio Informatics Pvt Ltd

- *Worked as a Clinical research coordinator responsible for management of designated clinical trial of study.
- *Centralized monitoring activities for the assigned projects.
- *Preparation related documents per protocol and CRF.
- *Data reconciliation, SAE reconciliation, vendor data reconciliation etc.
- *Owner of study documentation, including completeness, accuracy, and performing review, follow up, data lock using database RAVE, I MEDIDATA, EDC, EMR,PIMS etc.
- *Perform start up/ conduct / Close out activities under supervision and quality checks.
- *Oversight of data discrepancy management.
- *Performs data abstractions and data entry for designated clinical trials, preparation of trial related documentation per



Key skills

- Clinical Monitoring
- Monitoring
- Pims
- MedDRA
- EMR
- EDC
- Rave
- Medidata Rave
- Clinical Trials
- Argus
- Sapphire
- GCP
- Clinical Data Management
- Pharmacovigilance
- CRF
- Case Processing
- Clinical Operations
- Drug Safety
- ICH-GCP Guidelines
- Data Reconciliation



Personal Information

City **Nagpur**

Country **INDIA**



Languages

- English
- Hindi
- Marathi

protocol and Case report forms (CRF) as per protocol requirements and timelines.

*Tracking completed CRFs and setting up systems whereby completed CRFs are rapidly entered into the database. Ensure that queries generated during cleaning are responded to in a timely fashion and in compliance with ICH-GCP guidelines.

*Participates and contributes to team meetings and learning sessions.

*Self reports activities like time spent on records, audits completed including all relevant details and any other reporting functions assigned by Operations and QA management teams.

Mar 2021 - Nov 2021

Safety Associate

IQVIA

Traiger, case data entry, labelling, Data review of ICSR cases, approval numbers ,coding ,narrative writing case quality review training and SME activities.

Apr 2020 - Oct 2020

Pharmacist

Gajanan Enterprises

*Dispensing medicine to the patient as per prescription.

*Quality of medicines supplied to patients, ensuring that the medicines prescribed to patients are suitable, gave information about the dosing, advising patients about medicines, including how to take them, what reactions may occur and answering patients' questions.

Dec 2019 - Mar 2020

Clinical Research Coordinator

Central India Clinical research services

*Subject recruitment, Subject randomisation.

*Completing source documents ,updating site master file, inform consent form,subject follow up, dispensing IP dairy card.

*Completing CRF,EC notification ,EC deviation,EC submission etc

*Recording adverse events and concomitant medication, resolving queries of SMV and follow up etc.

Jan 2019 - Jul 2019

Clinical Research Coordinator

Central India Clinical research services

*Subject recruitment, Subject randomisation.

*Completing source documents ,updating site master file, inform consent form,subject follow up, dispensing IP dairy card.

*Completing CRF,EC notification ,EC deviation,EC submission etc

*Recording adverse events and concomitant medication, resolving queries of SMV and follow up etc.



Projects

151 Days

Scizophrenia Or Schizophrenic Disorder

Established multiple dose bioequivalence of bioequivalent doses of test and RLD.. safety and tolerability of RLD and test.

61 Days

SARS COV2 Vaccine Phase I/II

To evaluate safety and immunogenicity of Novel Corona Virus 2019 nCov

215 Days

Hepatitis B Vaccine

To evaluate the immunogenicity and safety

212 Days

Essential Hypertension

To check safety efficacy and tolerability of study drug.



Certification

- Clinical Research Training Course,