

RESUME

Santoraj Kapadnis

Clinical research specialist

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OBJECTIVE

Knowledgeable clinical research coordinator adept at recognizing clinical values and abstract data from source documents. Uses analytical skills to identify data or patient safety issues. Seeking a full-time position that offers professional challenges utilizing interpersonal skills, to help team achieve company goals.

Experience

CTA-I operation department (Jun21 – FEB23)

Klinera Global service organization

Supported research team in efficiently managing clinical documentation and reports, adhering to SOPs and project scope, while ensuring accurate handling, distribution, filing, and archiving.

KE CRC (ADMINISTRATIVE ROLE) (JAN21-JUN21)

Klinera Global service organization

Supervised site activities, ensuring the collection and organization of essential documents such as EC submissions and notifications into the ICF file as per TOC sections. Conducted ISF file reviews and updates while efficiently addressing IMV visit findings and resolving pending action items from reports.

SR SITE COORDINATOR (JUL20-SEP20)

S4 Research clinical research organization

Conducted clinical trials in strict adherence to protocol, ICH GCP, and regulatory guidelines, ensuring the highest standard of research integrity. Additionally, provided ongoing support and follow-up to subjects, addressing health issues and adverse events with utmost care and attention.

CLINICAL RESEARCH COORDINATOR

JCDC PVT LTD organization (Jan 20 to Mar 20)

Global Drug Development PVT LTD organization (Jan 19 to Sep 19)

JSS PVT LTD organization (Oct 17 to Sep 18)

Xylem Clinical Research Pvt. Ltd (Jun 14 to Aug 15)

Managed diverse responsibilities, including ICF processing, subject recruitment, lab report collection, source documentation, lab sample collection, and accurate EDC data entry with prompt query resolution.

Facilitated EC submissions and notifications, actively participated in monitoring visits, and efficiently handled subject reimbursement to streamline financial processes. Additionally, demonstrated meticulous care in regularly following up with subjects for health issues, including adverse events (AE) or serious adverse events (SAE).

ASSOCIATE RECORD INFORMATION MANAGEMENT(SEP15-DEC16) AT Syntel PVT LTD organization

To verification of essential and non-essential documents via using Etmf software tool

sorting them according to doc type for importing, importing documents upload in to CREDI system etc

About Me

Knowledge of Clinical SAS with Base+ADV+ R programme. Clinical research specializing in CTA, Clinical research coordinator, pharmacovigilance, record Management with 5 years' experience working in leading pharmaceutical companies

EDUCATION

2012: Graduate in Bachelor of Science (Chemistry)

2007: Diploma in Pharmacy

2004: HSC - CBSC board

2002: SSC - CBSC board

Certification and courses

1. Clinical SAS with Base + ADV+R Programme (Online class covalent tech Hyderabad)

2. Clip PV course in Cytel institution

3. Post Graduate Diploma in Clinical Trial operation and Clinical Data Management at Jehangir Centre for Learning (JCL), Pune

INTERNSHIP

2013: Clinical research coordinator internship in Nashik.

2008: Medical pharma internship from Satana.

SKILL

1. Document handling and archiving SOP compliance

2. Tracker maintenance

3. Site coordination

4. Invoicing and payment processing

5. Quality assurance

6. Record keeping and tracking

7. Uploading documents using etmf tool

8. Base SAS ,ADV SAS, Proc SQL,

TOOLS

Microsoft Office, Word, Excel

Seeking the Microsoft Power BI

