NV Sirisha Kasi

Clinical Research Associate

Contact

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Education

Masters of Science – Foods, Nutrition and Dietetics (2010)

Bachelors in Microbiology, Biochemistry and Applied Nutrition (2008)

Key Skills

Trial Oversight
Requirements Documentation
Research experience
Scheduling proficiency

Summary

Clinical Research professional with 2+ years of experience in managing different phases of Clinical trials, looking for a Clinical Research Coordinator and Assistant Regulatory Coordinator position at global healthcare organization. Capable of handling multiple sites on different therapeutic areas at a time with minimum supervision.

Experience

June 2008 – September 2010
Clinical Research Coordinator and Assistant Regulatory Coordinator
Aware Global Hospitals (India – Hyderabad)
Clients: Eli Lilly, Opko, AstraZeneca etc

- Under the direct supervision of the Clinical Research Director, Coordinate and participate in all research activities.
- Thorough knowledge and skills spanning from the study start-up, study conduct, close out activities.
- Serve as SME to resolve any issues related to studies.
- Work closely with Team to resolve issues (Supplies, Product accountability, enrollment/ randomizations etc.)
- Leading all Clinical Trail from patient enrollment and collecting data of patients from Phases II to III and various therapeutic areas of clinical trials including Infectious Disease like HIV, TB and on OCD, GI
- Proficient with using Electronic Data capture systems (EDC) like Medidata Rave, Veeva vaults, Inform etc.
- Ensure all necessary forms are submitted to the trial sponsor and the IRB.
- Provide regulatory support to new and ongoing research studies. Includes but not limited to correspondence with institutional and federal regulators and study file documentation creation and maintenance.

- Make sure team have access to Clinical trial systems Administration.
- Educated participants on studies and anticipated outcomes.
- Monitored subject enrollment and tracked dropout details.
- Monitoring progress & routinely interacting with CRA and keep them updated on study related issues that may impact the study milestone.
- Generating, resolving, and tracking queries before any IMVs.
- Worked with a diverse group of coworkers to accomplish goals.
- Maintain regulatory- related internal tracking databases and filing systems is Realtime CTMS.
- Coordinate and store protocol files including but are not limited to all protocol submission documents, correspondence from sponsor and study team, and responses/re-submissions.

Certifications

- Certified in GCP for clinical trials in investigational drugs and medical devices.

References

Available upon request.