Dr. Hemal Magdalia

Clinical Research Associate

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Summary

- A Clinical Research Associate with strong demonstrating expertise in managing and coordinating clinical studies across diverse therapeutic areas well versed in ensuring strict adherence to study protocols, local regulations, and ICH-GCP guidelines. Proficient in establishing and nurturing relationships with research sites, conducting thorough site visits, and monitoring site performance. Skilled in efficiently collecting and evaluating regulatory documentation, effectively communicating with investigators and staff, and adeptly resolving any performance or compliance concerns that arise.

Key Skills

- Site Management
- Subject requirement quality
- Identify issues & effective solutions
- Initiative-driven
- Emotional Intelligence
- Excellent timekeeper
- Mentorship
- Strategic Planner
- Communication
- Organizational
- Collaborative
- Adaptive

Area Of Expertise

- Comprehensive understanding of clinical research regulations, ICH-GCP guidelines FDA/EU supervision.
- Familiarity with Clinical research software, including Electronic Data Capture (EDC) system, Clinical Trial Management Systems (CTMS), and Electronic Trial Master File (eTMF).
- Knowledge of Microsoft Office applications.

Therapeutic Exposure

Therapeutic Indication	Type of Study	Submission	Role
Relapsed Advanced Lymphoma	Phase 1, Dose Escalation	DCGI	Clinical Research Associate
Secondarily Infected Traumatic Skin Lesions (Antimicrobial)	Clinical Endpoint Bioequivalence	USFDA	Clinical Research Associate Clinical Trial Assistant Trainee-Clinical Trial Assistant
Schizophrenia (Antipsychotic)	Pivotal Steady-State Bioequivalence	EU	Clinical Trial Assistant Trainee-Clinical Trial Assistant
Dermatophyte (Antifungal)	Bioequivalence with clinical endpoint	USFDA	Clinical Research Associate Clinical Trial Assistant
Schizophrenia (Antipsychotic)	Phase 1 Bioequivalence	USFDA	Clinical Research Associate

Instruments	Type of Study	Submission	Role
Spirometer	Observational study	—	Clinical Research Associate Clinical Trial Assistant

Total Monitoring

Type of Monitoring	No. of Visits(days)	Total Hrs.
Site Selection Visits	12 (12 days)	72 Hrs.
Site Initiation Visits	9 (18 days)	108 Hrs.
Site Monitoring Visits	42 (101 days)	808 Hrs.
Site Close-out Visits	20 (42 days)	336 Hrs.
Co-Visits with Sr. CRA for Monitoring Experience	15(30 days)	240 Hrs.
Total Hrs. of Monitoring experience		1564 Hrs.

Professional Experience

Clinical Research Associate, Cliantha Research, April 2022 – present

As a Clinical Research Associate, played a critical role in the successful execution of multiple clinical trials.

- Background in conducting **all types of site visits** per the monitoring plan, ensuring adherence with research management, protocol, ICH GCP, and local/global regulatory requirements.
- Built **positive relationships** with the site team and other organizational departments, leading to the **timely resolution of issues** and achievement of project milestones with data perfection.
- **Provided training** on the study protocol, key activities, study plans, and the recording and upkeep of key documents by standards.
- **Verified** the subject **consent forms and patient eligibility**, checked protocol needs, and examined AEs/SAEs for 350 study participants and above, securing the **protection of rights and wellness**.
- Implemented a **streamlined process** to check IP and source documents following applicable plans & SOPs resulting in a successful EDC review and query resolution time by 90%.
- Maintained 100% **backup of the Central Investigator File** and ensured consistency with the Site Investigator file to keep track of all crucial documents.
- Finalized 60-plus **visit reports** promptly and with excellent content too.
- Monitored and tracked project-related issues, resulting in a 95% compliance rate with escalation procedures.

Clinical Trial Assistant, Cliantha Research, June 2021 - March 2022

As a Clinical Trial Assistant, responsible to improve study processes.

- **Prepared** source documents and **developed** various logs and forms linked to the study protocols, resulting in smooth study proceedings and **improved data reporting with quality**.
- Implemented **tracking matrices** to ensure appropriate documentation traceability, resulting in improved data completeness and audit readiness.
- Crafted concise **meeting minutes** for **40+ sponsor and internal meetings**, ensuring accurate documentation of key decisions and action items.

Trainee-Clinical Trial Assistant, Cliantha Research, September 2020 - May 2021

As a Trainee-Clinical Trial Assistant, responsible to pick up additional tasks to aid skill development.

- Undertook **additional accomplishments** to foster personal and professional growth by participating in crucial study sessions.
- Spearheaded **team communication** initiatives and pioneered novel **analytical strategies** increasing overall operational efficiency.
- **Maintained records** of Trial Master Files with 100% accuracy, meeting all regulatory requirements.

Achievements And Awards

- **Recognized** by management for resilient attitude and managing four projects exhibiting very **strong groundwork & delegation**.

Education

Doctor of Pharmacy (PharmD), May 2021.

K.B Institute of Pharmaceutical Education and Research, Gujarat, India

Declaration

I hereby declare that all the above-mentioned information provided is true to the best of my knowledge and belief.

Dr. Hemal Magdalia

Date:- 6 July 2023