Mariyam Peter Mohan

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OBJECTIVE

Experienced professional with more than 6 years in centralized monitoring and eTMF management across phases I-III. Skilled in feasibility, startup, maintenance, and closeout stages. Strong knowledge of drug development, patient safety, ICH GCP guidelines, and regulatory protocols. Proven proficiency in eTMF management, including document handling, milestones, TMF QCs, quality issues, and overall TMF health. Proficient in using eTMF tools such as Veeva Vault, Wingspan eTMF understanding of Client eTMFs. Experienced in centralized monitoring with expertise in using clinical trial management systems, including RAVE, BRACKETT, and Fircrest, to oversee data integrity, compliance, and quality in clinical trials. Skilled in remote monitoring, data review, and ensuring adherence to regulatory standards. Served as a Subject-Level Data Reviewer in COVID-19 studies for the Pfizer vaccine, ensuring high-quality, consistent data at the subject level for regulatory submission and analysis. Experienced and recognized global subject matter expert (SME) specializing in Investigator Site File (ISF) management, with a deep understanding of regulatory requirements, industry best practices, and operational efficiency.

PROFESSIONALEXPERIENCE

ICON **October 2022- September 2024**
TMF Specialist

- Supports the maintenance of study specific documentation and global support with specific systems, tools and trackers including but not limited to study team lists, tracking of project specific training requirements, system access management for organization/vendor/client, and tracking of project level activity plans in appropriate system.
- Ensures (e) TMF is up to date by following file review schedules and documents findings in appropriate system.
- Ensures a complete, accurate and high-quality Trial Master File (TMF) as the subject matter expert through proper, consistent documentation and proactive partner relationship with the study team.
- Provides feedback, support and training to study teams in order to build knowledge and awareness of good, quality documentation management practices for clinical trials.
- Clinical study team member works closely with the Clinical Trial Manager (CTM) and is responsible for coordination, logistics, tracking and administrative tasks in support of clinical trials. Tracks study status, enrollment, regulatory documentation, and site start-up status for assigned clinical projects.
- Provides system support i.e., GoBalto and eTMF.
- Supports RBM activities. Serves as the primary point of contact for study specific eTMF- related support.
- Distributes eTMF queries to the clinical study team and follows up until resolution.
- Performs QC on the documents for the team and maintain study level dashboards.
- Coordinated training for new joiner in the team.
- Collaborated with the study team to adhere to the TMF Plan and to update the Study Master TMF Index as appropriate.
- Worked proactively and prospectively with TMF Contributors at Study, Country and Site level to ensure timely uploading of all Essential Documents in the TMF.
- Demonstrate ability to make decisions, deliver on commitments, share knowledge, and collaborate with peers in order to meet objectives or timelines in a rapidly changing environment.
- Performs administrative tasks on assigned trials including but not limited to: timely processing of documents sent to Client (e) TMF as assigned, performing (e) TMF reviews, performing mass mailings and communications

as needed, providing documents and reports to internal team members.

- Monitor TMF throughout the study duration, identify and record quality problems to Develop and manage clinical tools and documentation. Customize clinical tools and template.
- Handson experience on Veeva Vault and Wingspan.
- Prompt attention to business-critical activities to ensure compliance and appropriate documentation of regulatory approvals.
- POC for studies on Veeva Vault.

IQVIA **January 2019 – July 2022**
Associate Centralized Monitor

- Conducted Remote Monitoring Visits.
- Monthly Contact Call with the site.
- Performs department, Internal, Country and Investigator file reviews as assigned and documents findings in appropriate system.
- Ensures allocated tasks are performed on time, within budget and to a high-quality standard. Proactively communicates any risks to project leads and line manager as appropriate.
- Supports scheduling and organization of client and/or internal meetings with completion of related meeting minutes.
- Reviews and tracks local regulatory documents. Transmits documents to client and centralized IRB/IEC.
- Analyzes and reconciles study metrics and findings reports. Assists with clarification and resolution of findings related to site documentation. Maintains vendor trackers.
- Assists with coordination, compilation and distribution of Investigator Site File (ISF) and Pharmacy binder materials and non-clinical study supplies to sites. Assists with study-specific translation materials and translation QC upon request.
- Responding to protocol questions and eCRF guidance and support
- Targeted Site Support.
- Create I Site Pack preparation for CRA to perform onsite and remote monitoring visit
- Participate in team meetings to discuss the recruitment status and various study updates
- Alert Management for Key risk indicators affecting the safety of subjects.
- Action item creation for CRA to be performed during their site visit, follow up and resolution
- Data review for eCRF completion Adverse event, Drug dosing pattern, Subject missed visits.
- Supporting CRA's in site queries, Source data verification backlog (SDV), eCRF completion.
- Weekly site follow-up ensuring quality in data entry. Management of Protocol deviations and Adverse event
- Managing SMV RMV forecaster assisting CRA to schedule site visit based on site tier.
- Supporting project management team in DMC task, communication with sites in completion of pending data entries.
- Subject data review in EDC system (RAVE) (Comorbidities, Vital parameters, Inclusion/Exclusion criteria, Adverse events, randomization eligibility criteria as per protocol, past medical and medication history).
- Assisting with medical data review and managing (e.g. entering, closing) queries and re-queries in EDC
- Running query reports and following up on queries, as agreed
- Providing query reports to designated medical team members.
- Other query tasks, as provided by the medical team.
- Assisting with tracking of projects, their status and deliverables, as requested
- Assisting with Medical project-specific reports and/or preparations of slides and presentations
- Review data discrepancies generated by study specific edit checks for laboratory data and assist in preparation of data clarification forms sent to the site or the central lab. Also, review missing/updated central laboratory data for potential request and substitution of local laboratory data.

- Conducting manual data review for Clinical Data Management customers.
- Issuing queries based on manual data review requirements for each assigned study
- Participating in project team meetings as necessary.
- Generating metrics and reports for current state of study database
- Adhering to Clinical Data Management processes and standards by using implemented systems.
- Reading, understanding and adhering to organizational Standard Operating Procedures (SOPs).
- Attending and participating in applicable company-sponsored training
- Performing other duties as assigned.
- Raising queries on checkpoints for the site to rectify for data accuracy.
- Reviewing key risk factors affecting the subject safety and notifying the CRA.
- Access management (Q2 solution, RAVE, Brackett, Wingspan)
- Clinical Trackers and Report maintenance.
- Review of FDA 52 form from site.
- Site and subject Payment batch review with Clinical trial agreement.
- Investigational product and lab supply tracker maintenance.
- E training management.
- Site readiness preparation assisting CRA during the site start up visit.

Technical Skills

Veeva Vault, Wingspan, RAVE, Brackett, Firecrest

Achievements

- Rewarded scholarship for the project assistance fund by the Kerala State Council for Science, Technology and Environment (4/SPS 61/2017/KSCSTE) for my final year dissertation "Pharmaceutical Care Plan and Pharmacist Interventions against medication errors in geriatric patients"
- Achieved bronze and silver awards for Quality work and meeting timeline- 2019 and 2020.
- Achieved second prize for Intercollege Debate Competition conducted by Navodaya Group of Institutions, India.
- Achieved second prize for elocution conducted by the Pharmacy College Management Association, India.
- Participated as a Delegate in the 69th Indian Pharmaceutical Congress.

Certifications & Courses

- Fundamental GCP Accreditation Exam (English) 4.0- 2020
- Fundamental GCP Accreditation Exam (English) 3.0- 2018

Honors & Awards

- Applause award received from Biogen Study Sponsor for excellent and timely delivery of project requirements and collaboration.
- Collaboration award from the UCB and Arcus study team for proactive and timely delivery of project requirements.

Publications

Pharmaceutical Care Plan and Pharmacist Interventions Against Medication Errors in Geriatric Patients. Asian Journal of Pharmaceutical and Health Science (AJPHS).

Education

- Doctor of Pharmacy Post Baccalaureate
  Al Shifa College of Pharmacy, India
- Bachelor of Pharmacy BPharm Pharmacy
  N.E.T College of Pharmacy, India