Susan Wamucii IchugU

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Experience

NOVEMBER 2022 - Present

• Family Planning

Premier Research, Dallas, Texas - *Remote Clinical Research Associate I*

JULY 2021 - JULY 2022

• Deliver quality, timely monitoring reports for sponsor approval per the Clinical Monitoring Plan timelines using Remarque system • Responsible for the validity, correctness, and completeness of the clinical data reviewed and collected at assigned sites as dictated by ICH GCP/ISO14155, protocol and client requirements • Monitor (remote, onsite or other approved mode of monitoring) with a focus on data integrity and patient safety in accordance with specific country regulations • Prepare for and conduct on-site qualification, study initiation, interim monitoring and close-out monitoring visits at investigator sites as required by clinical monitoring plan • Monitor with knowledge of quality/scope/timeline and budget parameters • Maintain Trial Master File (TMF)/electronic Trial Master File (eTMF) as defined by the organization's processes per filing guidelines. Understands the required essential documents according to ICH/GCP Section 8. Review site documents and verify they are accurate, complete, current, and include required updates using Trial Interactive • Maintain project tracking system of subjects and site information using ACM systems and smartsheet • Maintain communication with study sites as directed per CMP, and in agreement with the study site and complete documentation of contacts • Ensure site visit metrics and utilization are maintained as required and escalates available time as necessary to line manager • Maintain high level of attention to detail to ensure subject safety for our projects and delivery of quality data for our clients • Review IP accountability and applicable logs (subject and site level) as directed per the Clinical Monitoring Plan • Manage and track Case Report Forms, queries, and clinical data on Medidata RAVE • Complete all required internal training (general and study-specific) on-time • Act as a resource for other CRAs and shares knowledge base and best practices • Other activities as designated

PRA Health Sciences, Raleigh, North Carolina - *Remote Lead eTMF Specialist*

MARCH 2021 – JULY 2021

•Set up the TMF and TMF index by collaborating with relevant members of the study team and act as the primary contact and point of escalation for project specific TMF issues •Create, maintain, and facilitate sponsor approval of the TMF plan and filing structure and interact with sponsors/vendors as needed to ensure required TMF deliverables are provided in accordance with study timelines •Oversee the quality review process of the study ensuring adherence to TMF Plan, quality standards and study timelines •Provide regular status reporting on TMF quality, completeness, and audit readiness while identifying and mitigating potential risks and communicating as needed to study team •Provide feedback, support, and training to study teams in order to build knowledge and awareness of good, quality documentation management practices for clinical trials •Ensure all TMF related tasks meeting expectations and are deliver in accordance with the contract

FHI Clinical, Durham, North Carolina - *Remote Clinical Trials Associate*

APRIL 2020 – MARCH 2021

• Worked on COVID-19 treatment trial and oncology study that focused on Non-Hodgkins Lymphoma
• Assisted the clinical project management team with written and verbal communications with study staff and sites
• Assisted the clinical project management team with the creation of study-specific documents and materials, and with the acquisition of study supplies
• Provided study materials and supplies to the study sites and Clinical Research Associate (CRAs)
• Prepared and issued meeting minutes, including action items, under the direction of project management
• Maintained the study-specific Trial Master File and associated electronic archives
• Assisted the clinical project management team with the organization of meetings
• Supported the clinical operations teams with ongoing conduct of studies
• Assisted in the close-out of projects and performed final Quality Control (QC) of the Trial Master File (TMF), identified items and issues for review and/or follow-up by the CRAs and/or project management
• Assisted in the production of slides, overheads, etc. as needed for department, project, and sponsor and or business development
• Assisted clinical team with maintaining accurate updated clinical systems that tracked site compliance and performance within timelines
• Prepared and presented project information at internal meetings
• Accurately updated annotated checklists and maintained clinical systems that tracked site compliance and performance within project timelines for Clinical Research Associates and RSU (Regulatory and Start-Up)
• Submitted and approved documents into TMF portals such as Elvis, Health check, and Wingspan
• Managed and tracked Case Report Forms, queries, and clinical data
• Accompanied Clinical Research Associates on site visits to assist with clinical monitoring duties upon completion of required training and approval

IQVIA, Durham, North Carolina – *Clinical Trials Assistant*

JULY 2019 – JAN 2020

• Assisted Clinical Research Associates (CRAs) and Regulatory and Start-Up (RSU) team with accurately updating and maintaining clinical documents and systems (e.g., Trial Master File (TMF))

that track site compliance and performance within project timelines.
• Assisted the clinical team with the preparation, handling, distribution, filing, and archiving of clinical documentation and reports according to the scope of work and standard operating procedures.
• Assisted with periodic review of study files for completeness.
• Assisted CRAs and RSU with preparation, handling and distribution of Clinical Trial Supplies and maintenance of tracking information.
• Assisted with the tracking and management of Case Report Forms (CRFs), queries and clinical data flow.
• Acted as a central contact for the clinical team for designated project communications, correspondence and associated documentation.
• May accompany CRAs on site visits to assist with clinical monitoring duties upon completion of required training.

Education

Wake Forest University, Winston Salem, North Carolina - *bachelor's degree*

AUGUST 2008 - MAY 2012

Appalachian State University, Boone, North Carolina - *master's degree*

AUGUST 2012 - MAY 2014

Skills

microsoft excel
research
communication
CTMS (Clinical Trial Management System)
microsoft office
pharmaceutical industry
veeva vault
elvis system
quality control
critical thinking
data collection
microsoft outlook
data analysis
TMF (Trial Master File)
clinical trials
good clinical practice
phlex
Montrium
data management
organization skills