Prerana Rout, M.Sc (Bioinformatics)

CRA II (Senior Research Associate), Syngene

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SUMMARY

A dedicated **Risk Based/ Onsite Monitor** with almost **4.8 years' experience** of supporting clinical team on II/III/IV phase trials in various indications. Talents include in-depth knowledge of **Risk Based Monitoring (RBM)**, ICH guidelines not limited to R2, Local and global regulations.

THERAPEUTIC EXPERIENCE

Neurology **:** Multiple sclerosis
Oncology **:** Myelodysplastic Syndromes, Chronic Lymphocytic Leukaemia
Indication **:** Bone complication on Metastatic Disease Phase IV, Multiple Myeloma Phase Ill & IV
Acute Lymphoblastic Leukemia Phase IV, Myelodysplastic Syndromes Phase Ill
Chronic Lymphocytic Leukemia Phase Ill, Non-Small Lung Cancer Phase Ill

KEY SKILLS AND COMPETENCIES

- Thorough understanding of **Risk Based/ Onsite Monitoring** and Remote Data Review.
- In depth knowledge of **Key Risk Indicator Review** and Central Monitor report writing.
- **SME**, Expert, **Analyst**, Mentor and Trainer of Risk Indicator Review and Specialist of **SDR/SDV schema.**
- Worked as a Vital Player in getting an **additional Risk Indicator**, also drafted a guideline on writing Central Monitoring report.
- Designated as Primary point of Contact to address any queries related to Risk Review.
- In depth knowledge of **Project administration**, **File review** and Preparing Minute of Minute (MoM) Expertise in File review on **Cascade System and CTMS**.
- Trainer of eTAL and **File Review Process** of the department.
- Served as Key player in sending **MSR (Monthly Status Report)** at project level to study team.

PROFESSIONAL EXPERIENCE

CRA II (Senior Research Associate)
Syngene, Bengaluru, Karnataka, India ***Jan 2020- Jun 2020***

Responsibilities and Duties:

- Performs site selection, initiation, visits in accordance with contracted scope of work, SOPs and good clinical practices
- Conduct of monitoring visits and site management for a variety of protocols, sites and therapeutic areas

- Completes appropriate therapeutic, protocol and clinical research training to perform job duties
- Administers protocol and related study training to assigned sites and establishes regular lines of communication with sites to manage ongoing project expectations and issues
- Evaluates the quality and integrity of study site practices related to the proper conduct of the protocol and adherence to applicable regulations. Escalates quality issues to CPM
- Manages the progress of assigned studies by tracking regulatory submissions and approvals, recruitment and enrolment, CRF completion and submission, and data query generation and resolution
- Creates and maintains appropriate documentation regarding site management, monitoring visit findings and action plans by submitting regular visit reports and other required study documentation
- Provide assistance to the Clinical Project Manager with design of study tools, documents and processes
- Timely submission of timesheets for Project specific and other tasks

Centralized Monitor

IQVIA, Bengaluru, Karnataka, India

May 2018 – Dec 2019

Responsibilities and Duties:

- Conduct periodic review of site level KRIs and historic site performance according to Central Monitoring Plan
- Early identification of site-level risk/issue(s) occurring during study conduct and responsible for identification of risk
- Monitor site performance and make recommendations for timely corrective actions (e.g. Site Telephone Contact or Triggered Onsite Monitoring Visit)
- Review the effectiveness of the recommended actions and take appropriate additional actions if no effect is observed
- Evaluate the quality and integrity of study site practices related to the proper conduct of the protocol and adherence to applicable regulations
- Project Oversight to site management activities on assigned projects and evaluate the quality and integrity of the study as per the protocol, SOPs, respective regulation& guidelines
- Support the CL to perform oversight on clinical deliverables on assigned projects as per the protocol, SOPs, respective regulation/guidelines and project Clinical Operation Plan (COP)
- Perform functional lead responsibilities for assigned project deliverables for specific customers or projects/specified
- Contribute and/or oversee to the development and use of study management plans and/or DTE specific tools and templates and/or other study specific plans to evaluate the quality and integrity of the study
- Manage and monitor operational insight of the assigned project(s) and complete/oversee the study/site metrics trending (trend analysis of clinical aspects of the trial, share trends and agree on action plan, review, triage and action clinical study alerts, monitor clinical operation plan (COP) compliance etc.)

- oversee the IP management for the assigned study to identify risk and proposed mitigation (including re-supply, re-labelling, Import/export licenses etc.)
- Monitor operational triggers/Key Data Points/data trends and monitor their compliance check by performing regular Quality Check

Central Project Assistant-II

PPD, Bengaluru, Karnataka, India

Oct 2015 – May 2018

Project Administration:

- Primary point of contact for PM/CTM and clinical team. Provide guidance, support and training to clinical team on study administrative procedures
- Create and maintain PPD and client project team list (e.g. add new team members' contact details and start and stop dates for departing team members) Create and maintain team distribution lists in Outlook
- Create and maintain internal management trackers for items that cannot be extracted from CASCADE / CTMS (e.g. team contact list, team training, systems access, vacations calendars, site allocation lists, etc.) as needed
- As required by project and/or given timelines, send the updated project trackers (team availability calendar/outlook team calendar, team list, etc.) to the CTM/PM or to the CTM PA/PM PA
- Assist PM/CTM with the creation of study documents, checklists, and reports as needed
- Assist in the creation of study specific documents and plans (e.g. Communication Plan, Project Plan, Monitoring Plan, etc.), study logs (e.g. Drug Accountability Log, Site Visit Log, etc.), study trackers (e.g. training tracker, FAQ, etc.)
- Distribute the study Q&A / Directives log to project team and/or notify project team of where updated version can be located
- Create and maintain a Task List for the study and continue to manage progress of the clinical administration deliverables
- If required, assist with travel arrangements for CTM/PM
- For project management related expenditures: generate purchase order (PO) before the purchase and obtain approval from CTM/PM. Forward PO with the relevant invoice to Finance Department

Meetings and Teleconferences

- Schedule clinical internal meetings
- Clinical internal meetings - take, distribute and file minutes
- Schedule client meetings
- Client meetings - take, distribute and file minutes and track in CTMS

CASCADE / CTMS

- Run on a regular basis crystal / OBI / Preclarus/BI Publisher reports as agreed with PM or CTM and follow up with the team to request updates (when needed) to ensure current and accurate data is received or entered in CASCADE/CTMS

File Review:

- Performing file reviews (LA/NA regions = all file types, APAC/EMEA Central and Internal Files only). Submission of documents to Central and Internal files and update in CTMS
- Assist CTM / PM to identify and coordinate documents needed for retention as per PPD retention schedule. Coordinate project team and/or Records Management to ensure all documents required for retention are copied prior to final return of files to the client
- Coordinate with Records Management and project team to send the Central / Country / Investigator Files to the sponsor. Assist with archiving arrangements where files/documents are to remain with PPD

Finance:

- Collect all purchase orders and payment request forms (including email approvals) approved/signed by the PM and if required set up a financial tracker
- Assist PM with final check/tracking/reconciliation of study payments in CASCADE/CTMS and passthrough costs
- Assist the PM in retrieval of any missing finance related documents (POs, payment request forms, payment request forms)

REWARDS AND RECOGNITION

- Received 3 Consecutive Applause at IQVIA for maintaining High Quality Deliverables, Determination & commitment towards maintaining productivity.
- Received Recognition for successfully completing UAT of Spotfire Dashboard.
- Nominated for Capability programme and completed successfully.
- Received Employee of the Month (Feb 2017 and Feb 2018) in PPD.
- Received Spot Cash (CEO award Nominee) award in Jul 2017 in PPD.
- Received numerous Appreciation and Badges from the Study team and Sponsor.

PROFESSIONAL DEVELOPMENT

- Completed training programme on Plant Hybridization, 2012.BIOINFORMATICS DIVISION, Bhubaneshwar, Orissa.

EDUCATION

Advance program in Clinical Research and Clinical Data Management, 2015
ClinIndia, Bangalore, India.

M.Sc. Bioinformatics), 2014
BJB Autonomous College, Odisha, India.

B.Sc. Bioinformatics, 2012,
BJB Autonomous College, Odisha, India.

TECHNICAL COMPETENCIES

MS Office, XL, EDCs (Rave, Inform), Bracket, IVRS, CTMS, Cascade, ePIP, eTMF, Spotfire (Preclarus), OC RDC and other study systems

DECLARATION

I hereby declare that the information given above is true to the best of my knowledge.

Date:
Place: Bangalore **(Prerana Rout)**