SWETA RODRIGUES

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PROFESSIONAL SUMMARY

Clinical Research and Regulatory Affairs professional with 7 years of experience in international clinical trials focused on Cardiology, Nephrology, Diabetology, Neurology, Stem cells, Allergy and Infectious Diseases (COVID-19). Well versed with ICH-GCP and Health Canada Division 5 guidelines. Extensive hands-on experience in start up to close out activities in clinical operations including databases such as Oracle Clinical, Inform, RAVE, CTMS and TMF. Monitored and reviewed the clinical data remotely on real-time basis using CTMS and Infosario

PROFESSIONAL EXPERIENCE

1. Clinical Research and Project Coordinator January 2021 to August 2021

Red Maple Trials, Ottawa, Canada.

- Identified and recruited potential study participants
- Reviewed patient charts to determine eligibility and obtain informed consent
- Performed data entry and completed eCRF
- Performed venipuncture, spirometry, ECG, allergy testing (skin prick test), administered Intramuscular (IM) & subcutaneous injections and other study procedures as required by the protocol
- Prepared source documents and developed CRF templates
- Maintained Investigator Site File and study related logs
- Assisted with various Internal Research and Development study activities
- Attended internal & sponsor meetings, prepared meeting minutes and action items
- Filed protocol deviations and research documents for Institutional Review Board (IRB) approval
- Systematized site documents as per protocol requirements, study procedures and relevant guidelines for monitoring & audit purposes

2. Centralized Monitor December 2018 to March 2019

IQVIA, Mumbai, India.

- Prepared Site Information Pack, which helps CRAs to execute monitoring efficiently
- Managed key risk indicators and triggers to oversee risk throughout the trials
- Reviewed in-depth subject-level data to ensure medical congruency
- Analyzed predictive data to proactively identify risks and prevent prospective issues
- Provided site support with enhanced data flow for increased study compliance

3. Clinical Research and Institutional Review Board Coordinator February 2012 to August 2015

Asian Heart Institute and Research Centre, Mumbai, India.

- Prepared trial protocol, site manuals and Informed Consent Forms.
- Performed protocol evaluations and feasibility check
- Implemented clinical trial tools such as Electronic Data Capture, IVRS, etc.
- Involved in recruitment and coordination of trial subjects, ensuring completion of patient visits as per protocol, communication with sponsors, CRO’s and regulatory authorities, product accountability etc.

- Managed IRB meetings including scheduling, agenda creation and minutes of meeting
- Registered and managed Adverse Events (AEs), monitoring visits, queries and records archival process
- Close out of clinical trials including audit preparations, reporting to regulatory authorities and assisting in the final study report
- Successfully documented and submitted regulatory records to Central Drugs Standard Control Organisation (CDSCO) for registering IRB
- Assisted with site contract negotiation and handling of clinical trial supplies

Audit Involvement:
Prepared Clinical Research and IRB manual as per the international regulatory guidelines. Active Involvement in audit conducted by the Joint Commission Organization (JCI) in Nov 2012, International Organization for Standardization (ISO 9001:2000) conducted in Apr 2012: accredited by Orion Registrar Inc., USA and National Integrated Accreditation for Healthcare Organizations (NIAHO) conducted in Apr 2012: accredited by DNV Healthcare Inc.

4. Clinical Research & Regulatory Affairs Coordinator November 2010 to February 2012

Regenerative Medical Services, Mumbai, India.

- Periodically monitored sites undergoing stem cell research specifically in bone and cartilage regenerations
- Prepared protocol & Informed Consent documents and managed data entry
- Processed regulatory submissions to Drug Controller General of India seeking approval of cell therapy
- Performed technical article and Newsletter writing
- Created medical presentations and case reports for marketing

5. Clinical Research Coordinator July 2009 to July 2010

P.D. Hinduja National Hospital & Medical Research Centre, Mumbai, India.

- Collected patient data in compliance with established study protocol and completion of eCRF
- Assisted PI in all aspects of patient recruitment, consenting, answering participant questions, scheduling appointments, biospecimen collection and training staff as per SOPs
- Ensured study protocols are adhered to and documentation is accurately performed in timely manner
- Reported SAEs to Ethics Committee within desired timelines

ACADEMIC BACKGROUND

Post-Graduate in Clinical Research May 2009
Indian Pharmaceutical Association, India **GPA 3.8**

Bachelor of Science in Microbiology June 2007
Mumbai University, India **GPA 3.7**

COMMUNITY ACTIVITIES

- Volunteered for couple of marathons sponsored by Standard Chartered to help raise funds for various NGO's associated with disability, wildlife, health, women, children welfare etc.
- Coordinated and organized art exhibition fundraiser event to assist old age homes
- Participated in weekly Sunday School program to inculcate spiritual essentials and teach catechism to kids