SHANTANU PATHAK
Local Trial Manager/Senior Clinical Research Associate
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In quest of career enrichment to make significant contributions in the domain of Clinical Research through knowledge, dedication and commitment. With my Clinical Research and Management knowledge I seek to work in a leading organization where I can give best of it by Sharing and gain scope for widening the spectrum of my knowledge.

Abridgement

- A focused professional with rich experience in Managing Cardio-Vascular Out come and Anti-Diabetes Trials.
- Ample experience in site management: High subject load and number of sites.
- Accolade as **"Best Clinical Research Associate"** for year 2014 and 2015 by Novo Nordisk India Pvt. Ltd.
- Accolade as **"Best Learner Clinical Research Associate"** for year 2012 by Novo Nordisk India Pvt. Ltd.
- Possess working knowledge of ensuring compliance to quality standards.

Organizational Experience

Since Jan' 2016 with Novo Nordisk India Pvt. Ltd, Bangalore as Local Trial Manager
(Senior Clinical Research Associate)

As Senior Clinical Research Associate and LTM my core responsibility requires diligently overseeing clinical trials.

- Prepare and confirm Site Selection and feasibility- Assess qualifications and capabilities of potential sites and investigators.
- Clinical Team Management: Assigned tasks, and delegated responsibilities, identified resources and reviewed detailed timelines, to ensure timely completion of assigned studies; Implement training programs for CRAs and related clinical staff.
- Establishment of Study Local depot - Supplies management, Trial Drug Destruction(Periodic), Stock Management and Invoice review
- Allocation and Review of Country level Budget and mail communication between Affiliate to Head Quarters (HQ). Prepare weekly reports for upper management, regarding status of projects.
- Review and finalise Country Level Monitoring Plan and Monthly project update. Monitoring visit Report- Review and follow up letter for all the sites; Planning of co-monitoring/Clinical Quality Site Visit with CRAs across sites in Study.
- Protocol Deviation review: including Trend analysis and finalising Corrective and Corrective Action (CAPA).
- Negotiate study budgets, prepare & maintain the Clinical trial agreement & Investigator Payments for all the study sites in accordance with Protocol.

- Updated International Trial Manager and Regional Trial Manager on project progress and other relevant issues.
- Vendor Management- Collaborate with the vendors and assure to examine study supplies to clinical sites (includes Equipments, Temperature monitoring device etc.).
- Coordination for Data Management Team: Ensure that clean accurate data was entered into the database, which includes planning and compliance with Data Cleaning Cycle (DCC) and Data Flow Plan (DFP). Also successful completion of Data Quality and Data Base Lock.
- Review and provide comments on Country level Trial Master File and also update e-TMF
- Coordination with HQ for all global and local meeting.
- Responsible for Country Recruitment and Retention strategies,Overall planning.
- Prepare and Maintain site quality for unannounced Audit and Inspection.
- SOP deviations review and follow up regarding CAPA with CRAs.
- Country Level Over view of SUSAR/CIOMS and Safety Compensation Tracking
- Responsible for Site management, whichever site require additional support during study.
- Coordination and Prepare dossier for submission to the Ethics Committee & Health Authority along with the Regulatory Affair Team.

Oct 2012 to Dec 2015 with Novo Nordisk India Pvt. Ltd, Bangalore as Clinical Research Associate

- Implement and monitor clinical trial to ensure sponsor/investigator obligations are met and are compliant with applicable local requirements and FDA and ICH guidelines.
- Perform the risk based Source data Verification (rSDV) as per the protocol and rSDV tool.
- Verify data in source documents are in agreement with source, initiate data query resolution and confirm resolution in timely manner
- Good knowledge in Investigational Product Management (includes Drug Storage, Maintenance, dispensation, Accountability & destruction)

Oct'11 to OCT'12 with Glaxo Smith Kline Pharmaceutical Pvt. Ltd., Lucknow as Sales Executive (Vaccines)

- Managing the sales and marketing operations and accountable for increasing sales growth.
- Driving sales initiatives to achieve business goals & managing the frontline sales team to achieve them.
- Implementing sales promotional activities as a part of brand building and market development effort.

Scholastics

- M.Pharm. (Pharmacology) from Integral University, Lucknow in 2011 with 82.4%.
- B.Pharm. from Integral University, Lucknow in 2009 with 71.67%.
- 12th (PCBM) from CBSE Board, Kanpur in 2004 with 60%.
- 10th from CBSE Board, Kanpur in 2002 with 68.6%.

Dissertation/ Project

- Currently working on two projects as **Local Trial Manager (LTM)**:
  - Phase 2 Growth Hormone treatment, Once weekly injectable
  - Phase 3b cardiovascular outcome study of Ultra long acting Insulin.

- Worked on Two Anti-Diabetes Long term projects as CRA:
  - Phase 3b cardiovascular outcome study of a GLP-1 analogue.
  - Phase 3b cardiovascular outcome study of Ultra long acting Insulin.

- Worked on Phase 3a cardiovascular study of GLP-1 analogue, especially start up activities which include site selection, HA submissions, EC submissions and Site training visits.

The details of successful monitoring visits conducted till date:

S. No	Project name	Role	Monitoring visit	Audit	SDV load with no. of Sites
1	Phase 2 Growth Hormone treatment, Once weekly injectable	LTM	9 (SIV and Co-monitoring visit)	NA	06 subjects with 3 sites
2	Phase 3a cardiovascular study of Oral GLP-1 analogue	LTM	21 (SIV and Co-monitoring visit)	NA	20 subject with 2 sites
3	Phase 3b cardiovascular outcome of Ultra long acting Insulin.	CRA	62 (02 start-up visit/ 55 monitoring visit, 05 close outs)	01 System Audit, 01 GCP Audit	83 subjects and 5 sites
4	Phase 3b cardiovascular outcome study of a GLP-1 analogue.	CRA	72 (ongoing monitoring visit and 06 close out visits)	01 CDSCO Inspection	42 subjects and 6 sites
5	Phase 3a cardiovascular study of once weekly GLP-1 analogue	CRA	05 (start-up/site training visits)	NA	NA

Knowledge Enhancement Schedules

- Delivered the paper presentation at National Seminar on Unani System of Medicine held in Lucknow by Dept. of Ayush, Ministry of Health & Family Welfare, Govt. of India on Mar'11.
- Actively participated in the National Seminar on Unani System of Medicine held at Lucknow by Deptt. of Ayush, Ministry of Health & Family Welfare, Govt. of India on 12th & 13th Mar'11.
- Underwent the seminar in the IV Indian Pharmacist Association Conference in 2005 held at Lucknow.

Other Accolades

- Bagged the ***"Gold Medal"*** in M. Pharm. (Pharmacology).
- M. Pharm in Pharmacology with *"Honours".*
- Rendered services as the Faculty of Pharmacy Team as Captain in Cricket and Football.
- Played School Games Federation of India (SGFI) under-14 Cricket Tournament in 1999 held in M.P.
- Proactively participated in the 'National Pharmacy Week' Rx Celebration Event in 2006.

IT Skills

- Strong computer including but not limited to the knowledge of Clinical Trial Management Systems (CTMS):
  - Electronic Document Management System (EDMS).
  - Electronic Data Capture (EDC)/ eCRF.
  - Interactive Web Response Systems (IWRS).
  - Set-up and maintenance of tracking systems for studies.
  - Set up and conducting WebEx meetings with site & Vendors
- Applications: M.S. Office Packages (MS Word, Excel, PowerPoint, Outlook Services)
- Operating Systems: Window 7, Windows 98/2000, Windows XP

Personal skills and competences

- Languages Skills: English, Hindi
- Social and Organisational skills and competences:
  - Familiar with working in an international environment and interacting with people from different cultural backgrounds.
  - Highly organised as demonstrated by:- The successful management of international clinical studies for 04 years.
- Ability to prioritize multiple tasks and achieve project timelines, utilizing strong analytical skills to make decisions autonomously decisions in ambiguous situations.
- Willingness to work in a matrix environment and to value the importance of teamwork.

Personal Dossier

Date of Birth:	10th February 1987
Father's Name	Mr. P .K. Pathak
Spouse's Name	Mrs. Antara Biswas
Nationality	Indian
Sex	Male
Marital Status	Married
Address:	310-B, Opposite Kali Bari, Harjender Nagar, Kanpur-208007, U.P. India