**NAVEED**

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**PROFILE & OBJECTIVE**

I am looking for a challenging opportunity as **Senior Clinical Research Associate/Team Lead CRA**. I have excellent skills for management of clinical trials and clinical studies including feasibility, source data verification, monitoring, planning, budget development, conduct of statistical analysis and protocol development. Possess essential attributes of organizational and leadership experience, ability to coordinate with diverse resource pool, communication and procedural skills and ability to delegate and monitor tasks.

**EXPERTISE & PROFFICIENCY**

* Project management skills for Clinical Trials
* Clinical Trial protocols design (Statistical Part)and writing
* CRF and consent form design and writing
* Phase II & III clinical trials planning, management & monitoring
* Excellent communication, negotiation and interpersonal skills
* First line leadership expertise and management skills
* Biostatistics, data management, data analysis and scientific report writing
* Medical writing including project research paper for submission in medical journal
* Biostatistics, data management, data analysis and scientific report writing
* Participate in development of statistical portion of research protocol, analysis plans and report specifications
* Review, edit, checks and other forms for statistical analysis.

**CAREER SUMMARY**

* Clinical Research Associate, Worked for Sanofi Gulf, July – 2013 to July 2016
* Clinical Trial Site Manager for GlaxoSmithKline & Bayer, Pakistan Aug – 2009 to Jul 2013

**WORK EXPERIENCE**

**Clinical Research Associate Mandated for Sanofi Gulf (Jul 2013 to Jul 2016)**

**Key Responsibilities**

* Leading and managing the implementation of studies in middle east countries
* Managing clinical trial project in all their phases including feasibility process, site set-up and site training, recruitment planning, monitoring and close out.
* Accountable to ensure all relevant studies follow ICH-GCP, Client’s SOPs and local regulatory requirements.
* Maintaining relationships and monitoring the performance of site staff.
* Tracking timelines and identifying contingencies and risk planning to meet overall timeline goals.
* Developing study timelines and study implementation plans.
* Managing study start-up, conduct, & close-out.
* Managing clinical trial material and assist in forecasting (CRFs, Lab Supplies, CTM supplies)
* Ensuring timely delivery of data to the data management
* Developing content and driving execution of investigator/site staff meetings
* Leading site selection with coordinated input from appropriate stakeholders
* Managing site set up, study start up and ensure patient recruitment plans are in place
* ICF and questionnaire translation in local language
* Serving as single point contact for all Study Managers, Data Managers, Medical Monitors and Feasibility associates
* Developing and finalizing contracts with Investigators, Institutions, Laboratories and other vendors.
* Raising and tracking Investigators grant payments, site staff payments, institution payments, comparator costs and lab payments.
* Monitoring of Clinical Trials as per ICH-GCP requirement.
* Getting feasibility from different investigators in diabetic, hypertensive and oncological therapeutic areas as required by the central study team.
* Ethical and regulatory submissions of the study documents in expedited manner in order to meet the proposed timeline.
* Study documentation as per global and local SOP and ICH-GCP requirements.
* Care full site selections for the R&D projects who had done great performance in the clinical trials
* Training the site staffs including Investigators, Sub-investigators, study coordinators and lab technicians on the key principles of GCP and trials specific protocols.
* Providing study updates and milestone status to senior management and central team.
* Synopsis writing and Protocol Development for Local Studies.

**Clinical Trial Site ManagerGSK Pakistan (01Aug 2009 to Jul 2013)**

**Key Responsibilities:**

* Worked as a single point of contact for site staff (trial coordinators, Principal investigators, Co – Investigators, study nurses, pharmacy), Sponsor staff (CRAs, CTOMs) and Ethical Bodies
* Mentored and managed the site coordinators, study nurses and trial pharmacists
* Managed studies start-up & conduct in oncology unit
* Ensured that all relevant studies follow ICH-GCP, IRB and Protocols
* Compiled and disseminated information/ documents on research project activities as required by Project Coordinators and other stakeholders involved
* Corresponded with IRB, investigators and sponsor for trial submissions
* Performed key tasks of the trial i.e. patient screening, patient randomization and Investigational product management
* Correspondence with Institutional Review Board for ongoing studies like submission of clinical trial documents to IRB for approval
* Scheduling, coordinating & managing patient visits
* Attending the IRB meetings for presentation on protocol and ICF
* Correspondence with IRB for safety information of clinical trials
* Correspondence and coordination with the PI about clinical trials

**TRAININGS**

**RESEARCH TRAINING MODULES**

* eLEarn 6.1, 6.2, 6.3, 6.5, 7.0(Sanofi)
* RAMOS Basics
* Informed Consent Process
* InForm (eCRF used by GSK) 4.5 and 4.6 training
* Liver safety training for investigator &site staff
* Pharmacogenetics at GSK
* GCP training
* Pharmacovigilance
* RECIST training version 1.0 and version 1.1
* SAE and Adverse Event Reporting
* Safety, sentinel events, Adverse Events of Special Interest (AESI), pregnancy.
* IP dispensing, accountability.
* Clinfax training
* Venali system (SAE Reporting System to Study Team)
* Trainings on Biological biotracking systems (for lab samples)
* Training on FSTRF portals (Randomization Tool)

**Clinical Research Projects**

* ALTTO (Adjuvant Lapitinib and / or Trastuzumab Treatment Optimization) study. A randomized, multi-center, open – label, phase III study of adjuvant lapatinib, transtuzumab, their sequence and their combination in patients with HER2 / ErbB2 positive primary breast cancer. (EGF 106708). A Clinical trial organized & conducted by Breast International Group (BIG), North Central Cancer Treatment Group (NCCTG) and Glaxo Smith Kline.
* A randomized, multicenter, double blind, placebo-controlled, phase III study of lapatinib (GW572016) in combination with paclitaxel versus paclitaxel plus placebo in subjects with ErB2 amplified metastatic

breast cancer. (EGF 104535). Sponsored by Glaxo Smith Kline.

* A randomized, multicenter, phase III study comparing the combination of pazopanib and lapatinib versus lapatinibmonotherapy in patients with ErB2 over-expressing inflammatory breast cancer. (VEG108838). Sponsored by Glaxo Smith Kline.
* A phase 3 multicentric placebo controlled trial of Sorafinib (BAY 43-9006) in patients with relapsed or refractory advanced predominantly non squamous non-small cell lung cancer (NSCLC) after 2 or 3 previous treatment regimens. Sponsored by Bayer Healthcare.
* Assessing the improvement of glycemic control in people with type 2 diabetes upon commencing or adjusting insulin regimen in local clinical practice in gulf. Sponsored by Sanofi Gulf
* Management of essential hypertension in Gulf using CoAprovel in Gulf Countries registry. A study sponsored by Sanofi Gulf.
* Compliance and adherence to Irbesartan/Hydrochlorothiazide fixed dose combination in the treatment of Essential Hypertension. A study sponsored by Sanofi Gulf.
* Blood pressure goal achievement in hypertensive patients under fixed combination of Ramipril/Hydrochlorothiazide. A study sponsored by Sanofi Gulf.

**TRAINING WORKSHOPS**

* Training workshop on “Composition, Functions and Operations of IRB/ IEC. Held on 16thNovember

2011 at Lahore Medical & Dental College, Lahore, Pakistan.

* A training workshop on “Basics of Research Methodology” held on 15th July 2011 at King Edward

Medical University, Lahore, Pakistan.

* A short course on “Research Methodology and Synopsis Writing” Held on 4th to 6th July 2011 at King

Edward Medical University, Lahore, Pakistan.

* Training workshop on “Composition, Functions and Operations of institutional Review Board (IRB) / Independent Ethics Committee (IEC)”. Held on 15th June 2011 at King Edward Medical University,

Lahore, Pakistan.

* “First Clinical Symposium” Held on 20th February 2010 at Gujranwala Institute of Nuclear Medicine

(GENUM), Gujranwala, Pakistan.

* “Role of Biostatistics in Health Care Sector” Held on 20th June 2009 at college of Statistical and Actuarial Science, University of the Punjab, Lahore, Pakistan.
* Third International Conference on “Statistical Data Produced and Applications of Statistics” held in

September 2007, at College of Statistical and Actuarial Sciences, University of the Punjab, Lahore.

* First International Conference on “Statistical Data Produced and Applications of Statistics” held in

September 2007, at College of Statistical and Actuarial Sciences, University of the Punjab, Lahore.

**RESEARCH PUBLICATIONS**

* S. Kanwal,Shaharyar, G. M. Gilani, N. Akbar et al., “Breast Cancer Survival Results According to Stage: How Encouraging the Results Are?” Presented in 3rd international conference on “Statistical Sciences”. November

25-27: 2010 (P.9)

* M. Masood, Shaharyar, N. Akbar, M. Hafeez et al., “Young age at first live birth and long duration of breast feeding: are they universally accepted protective factors against breast cancer? A case control study of the cancer research group Pakistan.”(ASCO 2010) Vol 28, No 15-suppl(May 20 Supplement), 2010:1572 2010 American Society of Clinical Oncology
* S. Ahmed,H.Mahmood, N. Akbar, M. Hafeez et al.,“Relationship of age at first live birth, parity and duration of breast feeding with non familial breast cancer in Pakistani women”. Cancer Research 2009;69 (24

Supplement): Abstract No:2071.

* Shaharyar, M.Hafeez, Naveed Akbar, et al. “Risk Factor of Breast Cancer among the Pakistani Females”.
* Kafait Ahmad, Shaharyar, N. Akbar, M.Hafeez, et al. ”Socio- economic factors and stage at presentation of Breast Cancer among the Pakistani females presented at Oncology Dept. Mayo Hospital, Lahore”.

**ACADEMIC QUALIFICATION**

* Masters in Biostatistics 2006 – 2008–College of Statistical and Actuarial Sciences, University of the Punjab, Lahore, Pakistan.
* Bachelors of Science 2004 – 2006–University of the Punjab, Lahore, Pakistan.