SENIOR CLINICAL RESEARCH PROJECT SUPPORT SPECIALIST CV Sample www.timesresumes.com

Address: House # 110, 2nd Floor, 4th XXX, xyz, Bangalore, India
Mobile: +91 9999999999 **Email**: xyz@gmail.com

Senior Clinical Research Project Support Specialist with around 8 years of progressive experience in the Healthcare Industry including 7+ years in Clinical Research, working for Global Sponsors and 1 year in Medical Transcription. Perform the role of Lead CRA for Global projects. Hands-on experience in developing and presenting trail protocols and designing data collection forms. Well versed in liaising with healthcare professionals and setting up clinical trails. Profound know how of handling filing and collating duties to manage appropriate documentation. **Seeking** a challenging position as **Associate Project Manager** (Clinical Research) with on going growth potential, in an innovative and flexible organization, where my education, experience and personal skills can be effectively utilized.

CAPABILITIES & SKILLS

- **Detailed** organizer, coordinator and advocate in promoting program compliance.
- **Efficiently** recognize program problem areas and generate solutions.
- **Forward-looking and pioneering,** with a passion for challenging projects.
- **Design effective systems and processes** and successfully apply them to achieve desired results.
- **Excellent** oral and written communication, presentation, negotiation, and team building qualifications.
- **Research, Analyze, Plan, Implement** and employ proactive management, strong leadership techniques and people management skills to successfully develop research ideas, frame hypothesis, **analyze and compile** quantitative and qualitative data and synthesize findings.
- **Extensive experience** in expert interviews, case study research, text analytics, and big data.
- **Expert** in Patient Recruitment, Clinical Monitoring and Mentoring Junior staff.
- **Experience in Clinical Trials** in Therapeutic Indications that include NSCLC, SCLC, Breast Cancer, Colorectal Cancer, Cardiology, Bone Fracture, Osteoporosis & Diabetes Mellitus involving active Site Management of Resources, Monitoring of Study Data & Mentoring the Study Team at Sites for overall quantity and good conduct of Studies.
- **Technical skills** include sound knowledge of ICH-GCP, Managing Clinical Operations & CRA Teams for studies, Project Management, Customer & Vendor Management, eCRF & CTMS, Study Finance (both site & study level), expert in handling Oncology Therapeutic area..
- **Computer skills** include Microsoft Office (Word, Excel, Outlook & PowerPoint), Email, Internet browsing, share point management. Good typing speed.
- **Languages**: English, Hindi, Malayalam (basic).

HONORS & AWARDS RECEIVED

- "Work Worth Done Award" from Quintiles for Distinguished Performance in 2011 (Quality & Support and managing high workload).
- "Outstanding Achievement Award" for Customer Service in 2012 (Quality, Support & Managing High Work Load)
- Gold Medalist in MSc from Gujarat University (Mol. Cell Biology, Cytogenetics and Biotechnology), Year 2005.

EDUCATION

Post Graduate Diploma, Clinical Research and Regulatory Affairs - ABC University, India 2009
MSc, Molecular Cell Biology & Biotechnology - School of Sciences, XYZ University, India 2005
BSc, Zoology - XYZ College, Kerala, India 2003

CERTIFICATIONS

Barnett Accreditation – Expert Exam for Managers and Staff interacting with investigational sites (13th June 2012)

PROFESSIONAL EXPERIENCE

ABC, Bangalore, India

Sr. Clinical Project Support Specialist July 2013 to present

- **Promoted** as Sr. Clinical Project Support Specialist in July 2013.
- **Conduct** Study on Non-Hodgkin's Lymphoma as a Clinical Team Lead providing support and assistance for assigned projects/project teams and act as a primary backup contact for internal project team and customers.
- **Establish** all project documentation including all files, records and reports according to the scope of work and SOPS.
- **Conduct** periodical audit/review of files for accuracy and completeness.
- **Track** all information, communications, documents, materials and supplies for assigned projects.
- **Update** and maintain internal systems, databases, tracking tools, timelines and project plans with project specific information.
- **Assist** Project Managers with budget allocation and approval of invoices.
- **Coordinate** for Customer meetings, prepare presentation materials, project summary data and conduct presentations.
- **Serve** as primary backup contact for internal project team and for external stakeholders/customers.
- **Train** and mentor junior project staff and coordinate their work.

Sr. Clinical Research Associate II Oct 2012 to June 2013

- **Promoted** as Sr. Clinical Research Associate in October 2012.
- **Assisted** the CTL with design of study tools, documents and processes.
- **Performed** site selection, initiation, monitoring and close-out visits in accordance with contracted scope of work and good clinical practice.
- **Provided** monitoring visits and site management for a variety of protocols, sites and therapeutic areas.
- **Administered** protocol and related study training to assigned sites and established regular lines of communication with sites to manage ongoing project expectations and issues.
- **Evaluated** the quality and integrity of study site practices related to the proper conduct of the protocol and adherence to applicable regulations.
- **Escalated** quality issues to Clinical Team Lead (CTL) and/or Line Manager.
- **Managed** the progress of assigned studies by tracking regulatory submissions and approvals, recruitment and enrollment, case report form (CRF) completion and submission, and data query generation and resolution.
- **Created** and maintained appropriate documentation related to site management, monitoring visit findings and action plans by submitting regular visit reports and other required study documentation.
- **Trained** and Mentored clinical staff.

Sr. Clinical Research Associate I Apr 2011 to Sept 2012

- **Performed** site selection, initiation, monitoring and close-out visits in accordance with contracted scope of work and good clinical practice.
- **Provided** monitoring visits and site management for a variety of protocols, sites and therapeutic areas.
- **Administered** protocol and related study training to assigned sites and established regular lines of communication with sites to manage ongoing project expectations and issues.
- **Evaluated** the quality and integrity of study site practices related to the proper conduct of the protocol and adherence to applicable regulations.
- **Escalated** quality issues to Clinical Team Lead (CTL) and/or line manager.
- **Managed** the progress of assigned studies by tracking regulatory submissions and approvals, recruitment and enrollment, case report form (CRF) completion and data query generation and regulation.
- **Created** and maintained appropriate documentation regarding site management, monitoring visit findings and action plans by submitting regular visit reports and other required study documentation.
- **Mentored** clinical staff and conducted co training visits.
- **Assisted** the CTL with design of study tools, documents and processes.

Sr. Clinical Research Associate II March 2010 to Mar 2011

- **Performed** site selection, initiation, monitoring and close-out visits in accordance with contracted scope of work and good clinical practice.
- **Provided** monitoring visits and site management for a variety of protocols, sites and therapeutic areas.
- **Administered** protocol and related study training to assigned sites and established regular lines of communication with sites to manage ongoing project expectations and issues.
- **Evaluated** the quality and integrity of study site practices related to the proper conduct of the protocol and adherence to applicable regulations.
- **Escalated** quality issues to Clinical Team Lead (CTL) and/or line manager.
- **Managed** the progress of assigned studies by tracking regulatory submissions and approvals, recruitment and enrollment, case report form (CRF) completion and data query generation and regulation.
- **Created** and maintained appropriate documentation regarding site management, monitoring visit findings and action plans by submitting regular visit reports and other required study documentation.
- **Mentored** clinical staff and conducted co training visits.
- **Assisted** the CTL with design of study tools, documents and processes.

XYZ Ltd.(Biocon), Bangalore, India

Sr. Clinical Research Associate II Jan 2008 to Mar 2010

Sr. Clinical Research Associate I Aug 2007 to Jan 2008

ABC India Pvt. Ltd, Bangalore, India

Medical Transcriptionist June 2006 to June 2007

REFERENCES - Available upon request.