Shahajad Ali

Title - Clinical Research Associate
Current Organization- Veeda Clinical Research Pvt.ltd.
Total Experience = 7 years
Qualification: M.Sc. Clinical Research Management & B. Sc. Biotechnology
Mobile: +91- 7289939291 Email: ashahaiad786@,gmail.com

Objective

To work in a well -managed organization for personal as well as organizational growth that gives work satisfaction, scope for experience, and contribute to my career growth.

Education snapshot

Education	BOARD/UNIVERSITY	YEAR OF PASSING
M. Sc (Clinical Research Management)	PRIST University	2011
One Year Diploma in pharmaceutical Marketing and Management	ICRI Delhi	2010
B.Sc (Biotechnology)	C.C.S .University	2009
Intermediate	U.P.Board	2006
High School	U.P Board	2003

Trainings

- **Auriga Research Pvt.Ltd.**

Four month internship in BA/BE Study as Trainee CRC

15th February 2011 to 4th June 2011

- **D .A.V Collage Muzaffarnagar**

14 days Training in recent technique in biotechnology.

27thNovember2007to 10th December2007

Work experience

- **Clinical Research Associate** ,Veeda Clinical Research ,Ahemadabad

16 April, 2018 to till date

- **Sr.Clinical Process Associate** at Quintiles Research Pvt.ltd,Mumbai , India

12 September 2016, to 31 March, 2018

- **Research Fellow** GB pant Hospital, New Delhi

June 23, 2014 to 31 July 2016

- **Clinical Research Coordinator** at Pushapanjali Crosslay Hospital,

December 1, 2011 to June 15, 2014

Special Skills

- Excellent Communication Skill

- Excellent Leadership Skills
- Team work and Positive Attitude
- Proactive Support

IT Skills

- MS Office (Word, Excel and Power Point & MS Access)
- Oracle Clinical (OC-RDC)
    - CTMS

Roles and Responsibilities as Clinical Research Associate

- **Assesses site qualification potential:** Reviews study requirements, conducts pre-study visits and drafts pre-study evaluation reports.
- **Participates in the implementation of clinical studies:** Communicates with investigators and their staff; ensures compliance with terms and conditions; properly trains site personnel and writes initiation visit reports

- **Supervises the conduct of clinical studies:** Acts as liaison between site personnel and the sponsor; performs monitoring in the field; ensures compliance with protocols, regulatory requirements, and good clinical practices; writes follow-up visit reports.
- **Ensures the quality of the project:** Verifies materials and data integrity; assists site personnel with internal audits or regulatory inspections; and perform ongoing follow-up with the in-house project team.

- **eCRF :** Reviews and approve with verification of source data.

- **Closes clinical studies:** Verifies the integrity of investigator files; ensures availability of clinical and non-clinical materials; jointly reviews with investigators the obligations inherent at the end of the study and writes closure visit reports.
- **Team Meetings and Vendors Meetings:** Attends Team Meetings, Contribute to create PMP, Meetings with sponsors and other vendors.

Roles and Responsibilities as Sr. Clinical Process associate

- Proactive support to CRA and Site to conduct the study according to protocol.
- Inbound & Out bound communication with vendors
- eTMF Management on ELVIS
- Document collection from site and uploading in eTMF
- Use of Infosario and SharePoint to keep oversight
- Site management and support by CTMS,
- eCRF Review and Query management on eDC
- Investigator payment process
- Study oversight, Compliance and Maintenance

Roles and Responsibilities as Research Fellow (Oncology)

- To perform Fluorescent in Situ Hybridization (FISH) for expression of HER 2 neu gene in Breast and Gallbladder cancer.
- Immunohistochemistry (IHC) process to see the expression of HER2 neu gene expression in Breast and Gallbladder cancer samples.
- DNA and RNA Extraction from paraffin embedded cancer sections.
- To Perform Polymerase Chain reaction (PCR) for mutation detection of EGFR in stomach cancer.
- To Design Protocol, Case report form, Patient Information Sheet and Inform consent form. • Communication with Regulatory Authority for Study Approval.
- Communication with Ethics Committee for Study Approval.
- Inform consent process, Patient Enrolment and Follow Ups

Roles and Responsibilities as CRC

- To Follow ICH-GCP ,Indian GCP and Schedule -Y Guideline for Conducting ^Recording and Reporting Clinical Trials
- To coordinate in Clinical Trial Confidentiality Agreement Process.
- To Coordinate in Site Feasibility ,Site Selection and Initiation Process
- To communicate with Ethical Committee for Project Approval
- To Coordinate for Inform consent process
- Source documents Collection from patients
- To perform Study Subject screening, Enrolment and Follow up process.
- Investigational Product (IP) handling, storage and Accountability.
- Coordination for Drug Dispensing and Documentation
- Coordination for Adverse Event (AE) and serious adverse event (SAE) reporting and Recording.
- Writing of Source notes Source Notes for ICF and Study Subject Visit.
- Discrepancy management and Protocol Deviation recording and reporting.
- e-CRF Completion on oracle clinical

Conferences

- Awarded certificate for participation in the International Symposium on ‘India-An Emerging Destination for Clinical Trails’ sponsored by Ministry of Science & Technology, Govt. of India organized by ICRI, New Delhi held on January 14th, 2010 at India Habitat Centre, Lodi Road, New Delhi, India.
- Awarded ASSOCHAM certificate for attending the two day International Summit on 7 the Global Knowledge Millennium of Bio-Pharma on Emerging Health Threats: The Solution? On 26-27 November, 2009.
- Awarded Certificate in “New Generation Diagnostics in Anatomic Pathology” held at G.B.Pant Hospital, New Delhi on October 10, th 2014.

Presentation as Co Author

- Stage of fibrosis as a guide to initiate therapy, irrespective of serum trans-aminase levels or viral RNA titers in patients with incidentally detected HCV infection.
- Study of histomorphological characteristics & it’s correlation with clinical, biochemical, serological & IHC parameters in incidentally detected asymptomatic Hepatitis B subjects.
- Immunohistochemical preferences of Rectal Neuroendocrine tumors.
- Ductular Reaction and the K7-19 progenitor cell sequence in vascular liver disease: A new perspective to pathogenetic mechanisms of injury and repair.

Abstracts

- **Progenitor repopulation by K7, K19 and Glutamine synthetase expression in hepatic vasculopathies.**Kaushik Majumdar, Kavita Gaur, Puja Sakhuja, **Shahajad Ali**, Amarender S. Puri, Anil K. Agarwal, Pramod K. Mishra. Abstracts of the 25th Annual Conference of APASL, February 20-24, 2016, Tokyo,Japan. Hepatol Int. 2016 Feb;10 Suppl 1:1-506. doi: 10.1007/s12072-016-9707-8. PubMed PMID: 26856325.
- Stage of fibrosis as a guide to initiate therapy, irrespective of serum transaminase levels or viral RNA titers in patients with incidentally detected HCV infection Kaushik Majumdar, Rakesh K Gupta, Puja Sakhuja, **Shahajad Ali**, Siddharth Srivastava*, Barjesh C Sharma*, Amarender S Puri (Abstracts--HCV infection and disease, APASL STC Conference, Dec 18-20, New Delhi. Hepatol Int. 2016 Jan;10(1):196-237. doi: 10.1007/s12072-016-9702-0.PubMed PMID: 26746869.)
- **Disease activity and fibrosis in incidentally detected HCV: can liver histology decide management and prognosis?** Kaushik Majumdar, Puja Sakhuja, Rakesh K. Gupta, **Shahajad Ali**, Siddharth Srivastava, Barjesh C. Sharma, Amarender S. Puri (Abstracts--HCV infection and disease, APASL STC Conference, Dec 18-20, New Delhi. Hepatol Int. 2016 Jan;10(1):196-237. doi:10.1007/s12072-016-9702-0.PubMed PMID: 26746869.)

Research Papers

- **Gupta RK,** Ali S**, Sakhuja P, Mukherjee D, Agarwal AK, Puri AS.** Colorectal carcinoma up to the second decade of life: An 8-year experience in a tertiary care center. **Indian J Cancer. 2014 Oct-Dec;51(4):557-9. doi:10.4103/0019-509X.175313. PubMed PMID: 26842194**

- Ductular Reaction and the K7-19 Progenitor Cell Sequence in V ascular Liver Disease: A New Perspective to Pathogenetic Mechanisms of Injury and Repair **Kavita Gaur, Puja Sakhuja,** Shahajad Ali**, Amarender Puri, Anil Agarwal, Pramod Mishra Amarender Puri, Anil Agarwal, Pramod Mishra (Journal of clinical and experimental hepatology, June-July, 2015Volume 5, Supplement 2, Page S53)**

- Is Non Cirrhotic Portal Fibrosis Actually Cirrhosis in Regression? A Histopathological Study of the "Hepatic Repair Complex" in Indian Patients, **Kavita Gaur .**Shahajad Ali**,Puja Sakhuja Kaushik Majumdar,Anil Agarwal Amarender Puri, (Journal of clinical and experimental hepatology July 2016 Volume 6, Supplement 1, Page S97)**

Personal Synopsis

Date of Birth	07 - July - 1986
Gender	Male
Marital Status	Married
Permanent Address	B 1/10,Kabir Nagar,Shahdra,New Delhi-94
Salary	Negotiable

Shahajad Ali **24-Aug -2019**