Prachi Sharma, B.Sc, M.Sc, CCRA

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# Education

Certified Clinical Research Associate (CCRA)

McMaster University, Canada April 2006 to Present

276-001  Clinical Trial Research Coordinator

276-002  Research Ethics and Regulatory Affairs

276-003  Clinical Trial Methodologies in Practice

276-004  Statistics, Databases, and the Internet in Clinical Research

276-005  Critical Analysis and Advancement of Writing & Communication Skills

Master of Science (Molecular Biology) Sept 2005 to Dec 2007

McMaster University, Canada

Masters of Science (Biochemistry & Microbiology) July 1999-Jun 2001

Vikram University, India

Bachelor of Science (Biochemistry & Microbiology) June 1996 to July 1999

D.A.V.V University, India

# Professional Experience

Maternity Leave and home basement flooding management 2014-Present

## PRACS Institute (formerly Cetero Research) Mississauga, ON. Dec 2011-Mar 2013

Clinical Research Associate I

* Assisted clinical trial team in managing single center and multi center studies with oversight from Clinical Trial Manager, Phase 2 to 4
* Worked closely together with Clinical Trials Specialist to initiate the feasibility process. QCed Clinical Trial Agreements (CTA) and assisted with the distribution of feasibility packages to sites
* Conducted site qualifying visits to assess the suitability of investigator and site by ensuring the investigator has the staff, time, patient population and facility to complete the study successfully according to GCP
* Assisted Clinical Trials Specialist with the collection of regulatory documents required for drug shipment clearance, as required
* Worked with the Quality Assurance group in the development/revision and implementation of SOPs and internal audits
* Coordinated Clinical Trials Specialist in collection of Financial Disclosure form, QIU, CTA, 1572 and QCed for any discrepancies
* Reviewed regulatory documents as required during routine monitoring and audits, ensuring investigator files (ISF) are accurate, current and identical to Trial Master File
* Conducted study initiation visits to review all study procedures with the investigative team and to ensure expectations of study are understood
* Conducted routine monitoring to verify rights and wellbeing of patients are protected, ensure accuracy of study data and that the study is conducted according to the protocol , GCP and Regulatory requirements
* Conducted study closeout visits to ensure all essential documents are in appropriate files, to ensure investigator understands ongoing responsibilities and remove all relevant study materials from the site
* Ensured that all visits are conducted according to FDA regulations and ICH guidelines, company or client Standard Operating Procedures (SOPs), as defined by the contract and /or monitoring plan established for the trial
* Prepared protocol specific training and regular updates to CRAs and other staff, as required
* Extensively used EDC (Electronic Data Capture) system for monitoring data from all study sites
* Provided Manager, Clinical Monitoring with monitoring reports of activities and elevate site or study issues
* Scheduled study team meetings, drafted agendas and created and finalized meeting minutes
* Tracked all time and expenses and submitted in a timely manner
* Communicated with the study site personnel and study team members as appropriate and maintained a good rapport with each

## KGK Synergize Inc. Jul 2008 to Nov 2011

Clinical Research Associate/ Clinical Trial Coordinator

* Helped with designing and conducting clinical trial and reviewed protocol
* Conducted study visits and collected informed consent and helped with subject recruitment
* Assisted Regulatory Affairs Manager in creation and collection of regulatory documents for different study sites
* Excellent knowledge of research ethics, legislative guidelines and regulatory issues
* Ensured compliance with appropriate Company SOPs GCP and ICH guidelines
* Helped clinical team in performing internal monitoring, site initiation visit, and close out visits
* Assisted with protocol writing, developing and managing source documents
* Attended investigator meetings and conferences and gave presentations on behalf of company
* Tracked all time and expenses for clinical research team and submitted in a timely manner. Provided monthly metrics reports to the revenue department. Provided budget estimates for clinical studies
* Scheduled study team meetings, draft agendas and create and finalize meeting minutes
* Performed interpretation of obtained data, simple statistical analysis and documentation of results as a final report
* Performed literature review
* Worked on manuscript writing and journal submissions
* Worked with the Project Management Team to train and mentor new CRAs as needed and participated in training sessions
* Communicated effectively with Principle Investigators, clinicians, nursing and laboratory staff

## Juravinski Cancer Hospital, Hamilton, ON Dec 2007 to Jun 2008

Clinical Research Assistant

* Collected non-small cell lung cancer (NSCLC) cell samples for *in-vitro* testing from patients and performed *in-vitro* assays on cultured cancer cells
* Ensured compliance with appropriate hospital SOPs, GCP and ICH guidelines
* Tracked all time and expenses related to ordering supplies for clinical research team and submitted in a timely manner
* Interpretation of obtained data, simple statistical analysis and documentation of results as a final report
* Gave timely PowerPoint presentations of results obtained, in front of hospital staff and researchers
* Performed literature review

Manuscript writing and journal submissions

## Tata International Limited, India Nov 2002 to Mar 2005

Research Associate

* Independently planned, conducted and analysed research on microbial samples in the R&D department
* Microbial culture and isolation of species from biomethanation plant to be used for effective waste water management
* Worked on environmental monitoring and waste water treatment analysis obtained from leather industry.

Performed chemical analysis of waste water by BOD and COD procedures

## Serum Institute of India Ltd, India 2001 to 2002

Research Trainee

* Institute Objective : Serum Institute aimed at total indigenization to make India achieve self-sufficiency in life-saving drugs

**Clinical trials on mice** - Project involved clinical trials of produced vaccine on experimental mice with data collection and analysis of experimental results at regular intervals. I worked on the project “Production of Pertussis Vaccine” The project aimed at the production of good whole cell pertussis vaccine by Fermenter and Shake Flask Methods through process optimization. It included the study of growth patterns of bacteria in both the methods under same experimental conditions, with or without variation in composition of production medium.

## Ranbaxy Pharmaceutical Laboratories Ltd. India Feb 2001

Internship

* Worked on project titled: “Injectable Water ampoule making, sterilization and quality control”.

# Certifications and Licenses

SOCRA Certificate of module completion on “Regulatory Updates for Clinical Research Professionals” Dec 2015

CPR and first aid training Aug 2015

Good Clinical Practice (GCP)/ Good documentation Practice (GDP) training Jan 2013

Quintiles Certification of Course Completion-Good Clinical Practice Guidelines Oct 2011

Intravenous Catherization Training Nov 2009

Participated in clinical trials workshop as Clinical Coordinator May 2009

Certificate of Achievement-Phlebotomy Work Shop Apr 2009

ISO 9001: 2000 Internal Auditor Training Oct 2008

Certificate of Attendance – EMERGE North American Investigator Meeting Aug 2008

WHMIS training certificate, Health care and safety association of ON Apr 2008

Biohazard Training Certificate Sept 2005

# Professional Societies

Member of Canadian Cancer Society

# Publications/Abstracts/Posters/Presentations

10 Publications and 7 Presentations will be provided upon request.

# Therapeutic Experience

Oncology, allergy, infectious diseases, metabolic syndrome, cardiovascular diseases, arthritis, digestive health, dermatology, oxidative stress and bioavailability studies.

Proficiency in computer skills includes Microsoft Outlook, MS Office and EDC. Aptitude to learn new software programs and databases.