Asem M. Bala

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PROFESSIONAL PROFILE

A dedicated and patient focused Clinical Research Professional with substantial success in managing clinical research projects. Experience includes regulated multi-site clinical trials, and investigator-initiated and pharma sponsored projects. Combines attention to detail, in-depth knowledge of field literature and industry developments, and a strong background in medical procedures, terminology, and diseases. Documents and maintains accurate study records, applies an analytical approach to solving problems, and develops and inspires cross-functional teams to success. Cultivates trusted relationships with key stakeholders, collaborates effectively in multidisciplinary healthcare teams, and is committed to service excellence.

CORE COMPETENCIES

- Strategic Leadership
- Medical Procedures
- Information & Data Analysis
- Stakeholder Engagement
- Report Development
- Clinical Research & Planning
- TCPS, ICH, FDA & TPD Regulations
- Quality Assurance
- Data Management
- Team Management & Development
- Monitoring and auditing
- Strategy Development
- Financial Management
- Clinical Project Management
- EDC Systems

PUBLICATIONS:

- Bharwani A, Bala A, Surette M, Bienenstock J, Vigod SN, Taylor VH. Gut Microbiome Patterns Associated With Treatment Response in Patients With Major Depressive Disorder. Can J Psychiatry. 2020;65(4):278-280. doi:10.1177/0706743719900464

CAREER SUMMARY

Clinical Research Associate III

(July 2020 – Present)

University of Calgary, Calgary, AB

- Plan, organize, direct, control and evaluate the activities and operations of a research program, including quality control
- Develop and implement policies, standards and procedures for the scientific and technical work performed
- Directly participate in design, development of scientific projects and clinical trial protocols
- Implement and maintain systems for data collection and analysis in support of research protocols, and prepared applications for the Research Ethics Board
- Ensure the appropriate creation, delivery, maintenance and disposal of all related data, documents, equipment and tools, including protocols, SOPs, informed consent forms, case report forms and instructions
- Develop and/or participate in the development of project communications, training, regulatory submissions and/or audits and coordinate requests for regulatory audits
- Engage with other departments within the university to exchange study information, plan study activities and negotiate courses of action on behalf of clinical research teams

Clinical Trials and Quality Assurance Specialist (July 2018 – present)
Women's College Hospital, Toronto, ON

- Lead the WCH Clinical Trials activation process, including the intake, tracking, and review of all clinical trials, conduct of the Trial activation meetings and review of clinical trial agreements and budgets.
- Assess the operational feasibility of clinical trials using WCH's established framework and make recommendations for project approval/execution
- Develop risk mitigation plans and provide recommendations to senior leadership for decision making
- Engage with other departments within the hospital to exchange study information, plan study activities and negotiate courses of action on behalf of clinical research teams
- Liaise with investigators to ensure that trials are conducted in compliance with the approved protocol, Good Clinical Practice (GCP) and applicable regulatory requirements
- Work with the research operations field experts to ensure all project activities comply with applicable regulations, guidelines, and corporate policies
- Develop and/or participate in the development of project communications, training, regulatory submissions and/or audits and coordinate requests for regulatory audits
- Ensure the appropriate creation, delivery, maintenance and disposal of all related data, documents, equipment and tools, including protocols, SOPs, informed consent forms, case report forms and instructions.
- Lead in-house monitoring activities, including but not limited to review of study documentation, source documents and Trial Master File (TMF) verification and conduct of routine monitoring visits and close-out visits to ensure the integrity of the clinical data, adherence to Good Clinical Practice and the study protocol.
- Oversee monitoring visits for non-WCH sponsored trials including escorting the visitor and providing requested information and access as appropriate
- Propose new processes and frameworks to support effective and efficient development and management of clinical trials at WCH

Clinical Research Coordinator II (2015 – July 2018)
Women's College Hospital, Toronto, ON

- Coordinated the launch of research study protocols, and the establishment of operating policies and procedures
- Prepared and processed all documentation required by Health Canada, including CTA , amendments, notifications and serious adverse event reporting
- Implemented and maintained systems for data collection and analysis in support of research protocols, and prepared applications for the Research Ethics Board
- Designed case report forms for each clinical research study optimizing the amount of correct data captured at each patient visit
- Recruited, instructed, and coordinated research subjects and/or volunteers, as appropriate to the specific objectives and work scope of each study
- Supervised and trained junior staff and summer students
- Maintained smooth and efficient day-to-day operations of research and data collection activities
- Served as the primary administrative point of contact for internal Research staff and as the principal operational liaison for other research organizations, funding agencies, and regulatory bodies
- Monitored the progress of research activities, and created and maintained accurate records
- Prepared periodic and ad hoc reports as required by investigators, administrators, funding agencies, and/or regulatory bodies
- Implemented the quality control process throughout the execution of each trial

Clinical Research Coordinator I (2013 - 2015)
Women's College Hospital, Toronto, ON

- Recruited, instructed, and coordinated research subjects and/or volunteers, as appropriate to the specific objectives and work scope of each study
- Maintained smooth and efficient day-to-day operations of research and data collection activities
- Coordinate, organize and maintain all study documentation including source documentation, case report forms, study and regulatory binders and patient binders.
- Planed/Implemented & Coordinated all aspects of data collection and source documentation as per hospital & ICH/GCP guidelines
- Responsible for regulatory documents to sponsor & REB/IRB
- Reviewed the contract budget for the clinical research trials assigned
- Invoiced sponsors for patient visits according to the research contract budget
- Prepared and processed all documentation through WCH Research Ethic Board, including submissions, continuing reviews, amendments and serious adverse event reporting

Clinical Research Coordinator Associate (2012 - 2013)
PRACS Institute, Toronto, ON

- Conducted study visits procedures and monitored in-house participants
- Assisted with dosing, sampling, and sample processing, and helped with the preparation of the associated paperwork
- Participated in the compilation and maintenance of study binders to ensure content, organization, and timeliness
- Prepared study documents, which included the Study Binder, and Protocol Review
- Ensured compliance with appropriate SOPs, GCP, and ICH guidelines and requirements

Clinical Research Assistant (2012 - 2012)
Pharma-Medica Research Inc., Toronto, ON

- Examined files at different stages of each study for completion, accuracy, and compliance with SOPs and protocols
- Reviewed and documented protocol and SOP deviations as identified by the QC Department and assisted with responses to QA/QC findings
- Ensured that the MLA and other technical staff executed duties in accordance with SOP/GCP requirements
- Provided assistance in the filing of clinical trial documents and in the completion of the master file
- Assisted in all clinic procedures required in each study

Family Dentist (2002 - 2005)
Royal Commission Hospital, Jubail & Yanbu, Kingdom of Saudi Arabia

- Successfully oversaw operations at a two-unit clinic in the Dental Center of the Hospital
- Provided general dental treatment to patients of all ages, and instructed school age children in good oral health

Assistant Medical Director (2001 - 2002)
Khartoum Dental Teaching Hospital, Khartoum, Sudan

- Contributed to the development of strategic plans and to overall Hospital management

- Delegated responsibilities to new Doctors, and managed the daily operations of the Emergency Department

Clinical Research Assistant (Part Time) (1999 - 2001)
Oral Cancer Research Center, Khartoum, Sudan

- Conducted surveys, collected data and organized two projects:
- The Prevalence of Oral Cancer In Sudan, and The Prevalence of Smoking Among Medical Professionals
- Collected cancer biopsy samples, and contributed to initiatives aimed at patient education
- Translated international research materials and questionnaires from English to Arabic

General Dentist (2000 – 2001)
Al-Damazine Civil Hospital, Damazine, Sudan (2000 – 2001)

- Oversaw operations, and managed the only clinic in the City
- Provided dental treatment to all civil and military personnel in all fields of general dentistry

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EDUCATION

- **Post Graduate Clinical Research Certificate (Honors), 2012**
  Humber College, School of Health Sciences, Toronto ON

- **Master of Science in Orthodontics/Orthodontology (M.Sc. (Ortho)), 2009**
  University of Alexandria, Faculty of Dentistry, Alexandria, Egypt
- Orthodontics Resident, 2006 - 2009

- **Bachelor of Dental Surgery (BDS), 1999**
  University of Khartoum, Faculty of Dentistry, Khartoum, Sudan

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LANGUAGES: English, Arabic

ADDITIONAL CERTIFICATES

- SOCRA Certified in Clinical Research (CCRP)
- Certificate of Achievement for Health Canada Division 5 (CITI Program)
- Certificate of Achievement for Transportation of Dangerous Goods TDG-IATA (CITI Program)
- Certificate of Achievement for Canada Biomedical (CITI Program)
- Certificate of Achievement for Responsible Conduct of Research (RCR) (CITI Program)
- Certificate of Achievement for Tri Council Policy Statement (TCPS 2)
- Certificate of Achievement for Biomedical–Clinical Research Personnel (CITI Program)
- Certificate of Achievement for Canada Good Clinical Practice (CITI Program)
- CPR/AED Health Care Provider