PROFESSIONAL SUMMARY

Clinical Research and Analytics Professional with over 20 years of expertise in managing complex clinical trials and analyzing healthcare data across global markets. Demonstrated success in coordinating large-scale data collection, validation, and analysis for pharmaceutical and medical device companies. Expert in clinical data management systems and statistical monitoring approaches. Currently leveraging this strong analytical foundation to transition into advanced data science and AI applications in healthcare.

CORE COMPETENCIES

Data Analysis & Management

- Statistical monitoring with descriptive analytics and trend analysis
- Complex clinical trial data validation and quality assurance
- Multi-site data coordination and standardization
- Electronic Data Capture (EDC) systems expertise
- Clinical database design consultation
- Site performance statistical tracking and reporting

Project Leadership

- Concurrent management of multiple clinical trials
- Concurrent coordination spanning large portfolio (30-40+) of research sites
- Cross-functional team collaboration
- Site performance analytics and optimization
- Risk-based monitoring implementation
- Regulatory compliance verification

SELECTED ACHIEVEMENTS

- Ensured data integrity and regulatory compliance across 30+ research sites through comprehensive analysis and validation
- Structured risk-based monitoring approaches to identify and prevent data quality issues across clinical programs
- Resolved critical data integrity issues for 1000-patient site under tight regulatory timelines, preventing delays in program submissions and addressing unreported safety concerns
- Designed validation protocols integrating regulatory requirements with site-specific monitoring needs
- Strengthened clinical program oversight across trial phases by developing targeted quality assurance approaches

TECHNICAL SKILLS

Programming & Analytics

- Python (via IBM Data Science Certificate)
- SQL for database queries
- Basic R for statistical analysis
- Advanced Excel (statistical functions, pivot tables, data visualization)

Statistical Analysis

- Descriptive statistics and trend analysis
- Pharmacovigilance
- Risk-based monitoring
- Site performance metrics
- Protocol compliance analytics

PROFESSIONAL EXPERIENCE

Owner & Principal Clinical Research Consultant
Critical Point Research Solutions Inc., Vancouver, BC (2006 – Present)

Independent clinical research consultancy expertly balancing complex trial operations across pharmaceutical and medical device sectors. Distinguished by ability to manage concurrent programs while maintaining exceptional site operations, quality oversight, and stakeholder relationships throughout diverse sponsor portfolio. Currently expanding capabilities into advanced analytics and AI applications in healthcare.

Selected key partnerships and long-term engagements include:

Edwards Lifesciences Portfolio, Irvine, CA (2011 – 2022)

- Provided comprehensive site management spanning multiple concurrent trials across extensive network of North American and Australian clinical sites
- Coordinated research activities for assigned sites (30+) throughout device development pathway
- Applied risk-based monitoring strategies to optimize site oversight and quality standards
- Supported trial execution from early feasibility through post-market studies
- Navigated essential communications throughout complex network of stakeholders including clinical sites2, core labs, sponsor teams, CROs, and regulatory stakeholders assuring operational excellence and timely resolution of challenges

Robarts Research Institute (Otsuka, GSK), London, ON (2006 – 2013)

- Provided comprehensive site management across extensive North American network of gastroenterology research programs
- Coordinated complex trial operations for large-scale patient populations throughout multiple concurrent studies
- Spearheaded essential communications throughout diverse stakeholder network including academic research teams, multiple sponsors, and clinical sites
- Implemented performance metrics and quality oversight across broad geographic distribution of research centers

Medtronic, Santa Rosa, CA (2006)

- Coordinated comprehensive pharmacovigilance review and report generation across multiple trial sites

- Oversaw team efforts in safety data audit, compilation, and analysis to support regulatory requirements
- Led systematic review of safety documentation and reporting procedures across study sites

Manager, Cardiology Research
Providence Health, Vancouver BC (2006)

Clinical Research Associate
Altana Pharma (Previously Byk Gulden), Oakville ON (2000 – 2003)

Senior Clinical Research Coordinator
Providence Health, Vancouver BC (1999 – 2000)

Registered Nurse, Critical Care, ER, Medicine, IV Therapist
Providence Health, Vancouver, BC (1995 – 2000)

Financial Accounting Clerk / Banking Customer Service Representative (Seasonal, Part-Time)
Scotiabank, Vancouver, BC (1986 – 1994)

EDUCATION

Formal Education

Bachelor of Health Sciences -- Clinical Research Administration
George Washington University, Washington DC (2009-2013)

- Foundational coursework in biostatistics and research methodology
- Training in clinical trial design and statistical principles
- Focus on regulatory compliance and data integrity

Specialty Certificate – Critical Care Nursing
British Columbia Institute of Technology, Burnaby, BC (1998)

Diploma of Technology - Nursing
British Columbia Institute of Technology, Burnaby, BC (1993 - 1995)

Current Professional Development

- IBM Data Science Professional Certificate (In Progress)
- Johns Hopkins Advanced Mathematics Coursework (Calculus, Statistics, Advanced Algebra)
- Oxford/Said Business School - MBA Fundamentals (In Progress)