MIODRAG OGNJANOVIC

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SKILLS AND SUMMARY OF QUALIFICATIONS

Clinical Research experience:

CRS and PI at 3M Health Care

CRA, Project Manager, and regional PI of the International Agency for Research on Cancer (IARC) studies (ISET, K2 and LUN)

Five+ years of clinical research experience in oncology, including pediatric and adult malignancies

Direct contact with oncology patients, including obtaining informed consent and registration on the clinical studies

Abstraction of medical records, completion of CRFs, AE forms and other study documents

Maintenance and updates of risk section of study protocols, investigator brochures and ICFs

Facilitating Data Safety Monitoring Board (DSMB) review, management of safety data and reporting

Data entry and retrieval, experience with electronic data capture systems

Preparation of documentation for IRB/ethic committee (EC) submission and communication with IRB/EC

Advanced knowledge and practice of ICH GCP

Other public health-related research experience:

Environmental Health and Safety specialist

Medical writing: Policy Guidelines, SOPs, protocols, reports and IRB documents

Analyzed and implemented OSH guidelines and developed University policies in Environmental Health and Safety

Examined environmental risk factors in large epidemiologic studies

Performed research and published in environmental sciences, public health, and biostatistics, taught and presented at international conferences and symposiums

EDUCATION

Masters of Public Health, Environmental Health Policy GPA 3.6 2011
University of Minnesota, School of Public Health

PROFESSIONAL EXPERIENCE

3M Health Care, Infection Prevention Division (www.3m.com). **Clinical Research Specialist** 2014-present

- Support Regulatory Affairs in completion of necessary regulatory documents (510k applications)
- Author clinical protocols, study documentation and clinical reports
- Support Product Development Lab with In House Clinical Study (ICS) screening and verification testing during development
- Clinical Research responsibility for marketed products, product modifications and/or assigned New Product Introduction (NPI) programs

IOCPR, International Organization for Cancer Prevention & Research (www.iocpr.org) 2008-2014

- LUN Study **Principal Investigator and Project Manager** Non-small cell Lung Cancer (LUN) study in Balkan area (500 case-control). Established by IARC. (2011-2014)
- K2 Study **Principal Investigator and Project Manager** Large clinical study (440 case-control), established by IARC, researching Cancer Genomics of the Kidney (K2) and environmental risk factors on health in Balkan region as a part of big European study. (2010–2013)
- ISET Study **Clinical Research Associate** for the region of SE Europe. Established by IARC (Lyon, France) and UMN, study collected data and samples of rare childhood cancer from the five specialized hospitals – regional referral centers (2008–2010)

- Protocol development, protocol amendments preparation, preparation of documentation and submission to ethics committees/IRB, writing of reports, review of all final documents
- Conducted project management in oncology
- Analyzed feasibility and performed site selection
- Ensured that SOPs for input, analysis, storage and reporting of clinical data were followed.
- Performed training of staff on study protocol and data acquisition process.
- Responsible for clinical safety strategy, including policies and procedures, and staff training, to assure compliance with international regulatory reporting requirements.
- Developed and reviewed safety plan for clinical protocols, and procedures for adverse event reporting and adjudication, safety event review and notification.
- Developed and written clinical study documents, including SOPs, synopses, protocols, CRFs, IBs, INDs and CSRs and reviewed final documents.
- Advance knowledge of industry standards and practices in clinical research
- Attended meetings on EU FP7 Framework Program for funding of research projects
- Collaborated with national Health Departments in several countries (Cervical cancer), and medical centers

University of Minnesota, Department of Environmental Health and Safety (www.dehs.umn.edu) 2011-2013

- **Environmental Health and Safety Specialist**. Developed EHS guidelines, SOPs and policy in accordance with federal and state regulations for safety of research workers and environmental protection
- Analyzed, refined and executed plans to assure the execution and management of EHS programs
- Performed audits and inspections, assessed safety and health risks of the processes and equipment used in research utilizing hazardous materials and gases at the UMN laboratories and performed data analyses
- Work on UMore project (EPA Superfund). Drinking water fluoridation policy analyses for Masters project
- Developed and delivered training of lab personnel. Responsible for Nanotechnology guidelines, Cryogen and Pyrophoric factsheets and Stench Chemicals guidelines.

Alma Research Ltd, Hawaii (www.almaresearch.com) **Manager, Researcher** (2005 - 2008)

- Clinical Research of antioxidants rich food products (Noni, Acai, Goji)
- Work on preparation and analysis of research documentation, statistical analyses and publishing
- Management of people and international distribution of Noni products in Balkan area of Europe
- Managing certification and promotion of products for European market

University of Hawaii, (http://hawaii.edu), Honolulu, Hawaii (2003 – 2006)
Pacific Biomedical Research Center (http://pbrc.hawaii.edu)

- Cooperated on statistical analyses of databases involving studies of several departments.

MISCELENIOUS

Dual Citizenship: USA and Serbia
Languages: English (fluent), Serbian/Croatian (fluent), Hungarian (basic)
Certification: CITI Program's Good Clinical Practice (GCP), Biomedical Responsible Conduct of Research (RCR)
Other Degrees: MS in Astronomy, University of Western Sydney, Australia (2001)