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CLINICAL OPERATIONS LEADERSHIP SUMMARY

CLINICAL OPERATIONS LEADER WITH MORE THAN 12 YEARS OF EXPERIENCE IN OPERATIONAL MANAGEMENT AND MONITORING OF MULTIPLE STUDIES, PHASES 1-4, OVERSIGHT OF PROJECT TIMELINES AND CRITICAL MILESTONES, VENDOR MANAGEMENT, BUDGET DEVELOPMENT AND MANAGEMENT, CONTRACT DEVELOPMENT AND NEGOTIATIONS, DEVELOPMENT OF PROJECT PLANS AND CHARTERS, CREATION AND IMPLEMENTATION OF PROJECT GOALS.

- **CRO/Vendor Management –** Vendor identification and strategy, RFP process, proposal analysis, agreement negotiations and vendor selection. Successfully directed CRO/Vendors in delivering project specific goals and timelines.
- **Budget Management –** Development and management of project budgets
- **Therapeutic Areas –** Endocrinology (Diabetes, Obesity, Lipidemia), Pain, CNS (Alzheimer's Disease, Multiple Sclerosis, Migraines, Restless Leg Syndrome), GI/GU, Vaccines, Cardiology, Sexual Dysfunction (Male and Female), Oncology, Lupus, Gout, COPD, Psychiatry (Anxiety Disorder, Depressive Disorder)
- **Trial Recruitment –** Development of recruitment strategies for studies with challenging enrollment objectives.
- **Study Documents –** Extensive experience with site identification, feasibility questionnaires, protocol development, Investigational Brochure content, charter creation, study manuals, project plans, and clinical study reports.
- **Staff/Team Development** – Team mentoring and coaching resulting in cohesive and productive team members. Skilled in empowering people to reach individual and company goals.

Clinical Research Professionals — Current

VP Clinical Operations

- ➢ **Site Management Organization development and oversight**
- ➢ **SOP/infrastructure creation for clinical research investigative sites**
- ➢ **Research naïve site organization and training**
- ➢ **Budget and contract development and negotiation**
- ➢ **Staff training including GCP, basic research, therapeutic areas, protocol specific**
- ➢ **Employee hiring and mentoring**
- ➢ **Monitoring**
- ➢ **Physician recruitment**
- ➢ **Investigator database profile creation**

Lantheus Medical Imaging (previously Bristol-Myers Squibb) — 2009-2013

Associate Director of Clinical Operations/Trial Safety

- ➢ **Developed and managed recruitment strategies for enrolling trials resulting in meeting enrollment goals per study timeline. Sites were located in USA, Canada, Europe, (Northern and Central), South America, Puerto Rico, Australia.**
- ➢ **Managed multiple outsourced vendors including IVR, nuclear manufacturing facilities, cardiac monitoring, imaging analysis, trial SAE monitoring, central laboratory, outsourced medical monitor and multiple CROs.**
- ➢ **Managed department for site identification, feasibility development and study enrollment.**
- ➢ **Created and implemented a system for safety review of clinical trial data and organized this review cross functionally.**
- ➢ **Successfully created and led multiple adjudication committees including identification and recruitment of physicians, process development and training of committee members.**
- ➢ **Facilitator and committee member of Clinical Quality Board.**
- ➢ **Coordination and management of Data Monitoring Committee (DMC) and related deliverables.**
- ➢ **Chair of training committee - designated training modules per job description/roles.**

- **SOP Committee Member – creation and updating of SOPs for large clinical department.**
- **Content development of protocols, Investigator Brochure, study manuals, DMC Charter, Adjudication Committee Charters, Project Management Plans and Study Reports.**
- **Developed the clinical operations infrastructure and personnel hiring (28 people) to form a cohesive, motivated team for 9 clinical trials.**
- **Oversaw all aspects of clinical trials from the RFP process through close out and CSR completion.**
- **Creation of ICFs, budgets, CRFs, metric trackers.**
- **Closure of legacy studies – identified billing issues which led to credits of over $250,000.**
- **Site audit remediation**

Radiant Research, Inc.

Site Director **2004-2008**

- **Under my direction, site experienced a 300% growth.**
- **Met 97% recruitment goals on 95% of studies. Successfully managed recruitment department.**
- **Business development and oversight – averaged 70 concurrent studies in multiple indications.**
- **Quality assurance, site audits, internal monitoring – responsible for successful audit responses for 3 FDA audits.**

Washington University School of Medicine

Regulatory Specialist **2001-2004**

- **Set up media promotion for large study that created a bonus for the University of $26,000.**
- **FDA annual reports for multiple research physicians.**
- **Developed relationships with television stations and promoted study recruitment through these relationships.**

Catholic Charities/Nurses and Company

Home Health Director **1996-2001**

- **Operational management of 75 employees providing services in skilled nursing, OT, PT, ST, aides, and health promotion for pediatric, adult and maternal/child populations.**
- **Designed and managed programs in telephonic case management, high risk pregnancy, mental health and lead case management.**
- **Contract negotiations with Medicare, Medicaid and private insurance companies.**
- **Grant writing – awarded $90,000 grant for home health and social service program.**

Nursing Experience

NICU, Pediatrics, ER, Oncology, Medical/Surgical **1993-1996**

- **Level 3 NICU.**
- **Charge nurse duties.**
- **Served on action committee resolving conflicts for patients and/or employees. Developed plan for patient satisfaction and quality assurance.**
- **Served on Breast Feeding Committee.**

PRN Positions

Grant Writer/Initiator
Corporate Trainer

Committees

- **State of Missouri Perinatal Substance Abuse Committee –** designed educational information regarding drug exposure for physicians and facilities to use in the care of pregnant women.
- **Mercy Caritas Grant Committee –** created a grant program for high risk pregnant women to provide social services.
- **Washington University Medical Center Institutional Review Board –** subcommittee member responsible for approval of new research studies, renewal of ongoing studies, review and approval of protocol changes, and ongoing research monitoring.
- **Clinical Quality Board –** Oversight of quality across functional groups of pharmaceutical operations.
- **Data Monitoring Committee –** Facilitator and contributor for DMC Committee for Phase 2 and Phase 3 trials.

Education, Certifications and Licenses

Registered Nurse, St. Louis Community College
Bachelor of Science, Industrial Psychology, Cum Laude, Upper Iowa University
ADAS-cog Certified Rater – December 2004
CDR Certified Rater – December 2004
CIBIC – Plus Rater Certification – June 2006
Expert Certification – Female Sexual Dysfunction – January 2006
Certified Nutritional Counselor - Johnson & Johnson – May 2006
ACRP CCRA Certification #208906

Professional and Academic Appointments

Alzheimer's Association – certified Volunteer Presenter
Alzheimer's Association – certified Support Group Facilitator
Association of Clinical Research Professionals (ACRP) Member
Drug Information Agency (DIA) Member
Missouri Teacher's Association 2006 – annual conference presenter – "The Future of Research"
Radiant Research WebEx presentation – "Clinical Performance Management"
St. John's Medical Center, Washington presentation – "How to Motivate Employees"
St. Louis City Schools presentation – "Employee Cohesiveness; Overcoming Negativity In the Workplace"