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**CAREER MISSION**

Utilize collaborative management strategies to reduce cost and time, while fostering communication, innovation, quality, and stakeholder satisfaction.

**SUMMARY OF PROFESSIONAL EXPERTISE**

Dawna is a Senior Clinical Project Manager with significant experience managing and coordinating multi center international clinical projects and project teams. She has over 18 years of experience in life sciences research including 12 years within project management, having joined inVentiv Health Clinical in January of 2016. She received her PhD in 2001, PMI Certification in 2003. Dawna has experience leading Phases II and III Central Nervous System trials in indications including Alzheimer’s disease, osteoarthritis pain, schizophrenia, epilepsy, myasthenia gravis, Type 2 Diabetes and SLE and Phase IV observational studies. Dawna has been involved in all aspects of a study management from start up to close out, across Europe, North America, and Latin America. Dawna has experience in managing site feasibility, customer and investigator relationships, client audits, investigator meetings, mentoring, ICH-GCP, clinical team training and providing oversight of study programs, study unit budget management, backlog forecasting, revenue recognition, invoicing, scope change management and reporting, trial master file management, electronic data capture management, quality and risk management, written and oral presentations.

Her responsibilities have included the coordination and management of the following service lines: Clinical Monitoring, Regulatory Affairs, Study Drug Management, Safety Surveillance & Reporting, Site Management, Data Management, Biostatistics, Epidemiology, and Third Party Vendors. Before joining the CRO industry, Dawna had gained research program leadership experience as a Program Specialist at the Texas Birth Defects Research Center of Excellence and Investigator at the University of Texas.

**EDUCATION**

University of Texas, Austin, TX Health Education Research Design/Program Evaluation Degree: Ph.D. Dissertation: *The Collaborative Transfer of a Public Health Project*

University of Pittsburgh, Pittsburgh, PA Health Services Administration/Epidemiology Degree: M.P.H. Thesis: *Marketing Management of Human Services*

Carnegie-Mellon University, Pittsburgh, PA Psychology and Mathematics Degree: B.A.

**THERAPEUTIC EXPERIENCE/PHASE Ilb-III CLINICAL TRIALS AND PHASE IV**

Nervous System: Alzheimer’s disease, Epilepsy, Insomnia, Schizophrenia, Myasthenia Gravis

Metabolic System: Type 2 Diabetes

Musculoskeletal System: Osteoarthritis, Systemic Lupus Erythematosus

Real World Effectiveness and Safety Observational Programs: Major Depressive Disorder, Multiple Sclerosis

**CERTIFICATIONS AND MEMBERSHIPS**

Project Management Institute, Association of Clinical Research Professionals, BioPharma PM

**PROFESSIONAL EXPERIENCE**

**Wright Rx Project Management Sep 2017 - current** **Austin, TX**

**Accomplishments:** In a consulting setting, conduct gap analysis and provide recommendations for managing scope, reducing recruitment barriers, capturing quality issues, and preparing corrective and preventive action plans.

**inVentiv Health Clinical Senior Project Manager 2016 – Jun 2017 Neuroscience Austin, TX**

**Accomplishments:** In a CRO setting, leading, advising, and managing pharmaceutical industry clients with global clinical trial programs. Serve as the global lead of protocol execution team and manage multiple vendors and CRO service providers.

* Reported monthly project status, constraints, variances and risks to scope, timeline, resourcing, milestones, budget/revenue, and quality to study stakeholders and executive team members
* Responsible for directing, managing and delivering the operational and financial aspects of one or more clinical studies
* Oversaw interdisciplinary clinical research programs
* Represented inVentiv Health to the customer, ensuring satisfaction levels are maintained and program deliverables are communicated effectively
* Responsible for TMF Management Plan and quality and completeness of TMF
* Accountable for all project deliverables. Coordinate activities and deliverables of all study conduct partners and proactively identify and manage issues
* Ensured studies conducted in compliance with GCP, relevant SOPs, and regulatory requirements
* Accountable for maintenance of study information on a variety of databases and systems
* Responsible for study management components of inspection readiness for all aspects of the study conduct
* Oversaw the development and implementation of project plans
* Planned, coordinated, and presented at internal and external meetings
* Implemented resource strategies to achieve project goals. Directed the activities of globally assigned Project Support staff
* Prepared project management reports for clients and management
* Conducted gap analysis and recommendation for continuous improvement
* Developed contingency plans and implemented risk mitigation strategies

**Quintiles Senior Project Manager 2013 – 2016 Neurology - Phase II-III / Real World and Late Phase Austin, TX**

**Accomplishments:** In a CRO setting, leading, advising, and managing multi-national pharmaceutical industry clients with global clinical trial and observational research programs.

* Provided consultative services to define scope of work, timelines, deliverables in collaboration with cross functional team leaders
* Served as primary project contact with Sponsor to maintain communication and scheduled reporting
* Provided input for the development of proposals for new studies and manage project budgets
* Participated in proposal development and in bid defense process
* Developed study management plans in collaboration with cross functional team leads, ensure accountabilities, and provide oversight of project deliverables
* Prepared and presented project information at internal and external meetings
* Collected information on team performance per contract, customer expectations, and project baselines
* Ensured high performance and efficiency of the clinical team and provided mentoring
* Managed and coordinated efforts of cross functional team members to support milestone achievement, ensured process and procedures compliance, consistent use of study training materials and tools, and managed study issues and obstacles
* Analyzed operational and data quality and proposed continuous improvement
* Lead problem solving and resolution efforts including management of risks, contingencies, and issues
* Identified quality issues within the study, escalated findings and planned actions to relevant stakeholders, implemented appropriate corrective and preventive action plans
* Provided input to line managers of their project teams’ performance
* Maintained calm demeanor while under pressure

**Quintiles Project Manager 2011 – 2013 Neurology - Phase II-III Austin, TX**

**Accomplishments:** In a CRO setting, provided global project management services to pharmaceutical industry clients with global clinical trial programs with $20-50 million budgets.

* Served as global lead of cross-functional protocol execution team and as primary project contact with Sponsor
* Managed country submissions to regulatory authorities, IRBs/ECs, vendors and CRO service providers
* Participated in the development and approval of protocols, ICFs templates, final study plans and study reference documents, subject retention strategies, interim and final data cleaning schedules, and study amendments
* Coordinated study milestones, timelines, study start-up activities, monitoring and execution team meetings, sponsor meetings, KOL and investigator meetings, vendor meetings, contracts meetings, and training webinars for clinical team, study coordinators, neuro-cognitive scale raters, MRI facility personnel and investigators
* Lead and provided oversight of site communications, enrollment closure notifications, site compliance reviews, data listing reviews, protocol deviation reviews, data quality reviews and final reconciliation, eTMF reviews and final reconciliation
* Created and provided oversight of regulatory, clinical operations data management, life cycle safety, medical monitoring, vendor plans, activities and execution of deliverables
* Analyzed reporting outputs during study conduct to detect monitoring and data trends
* Developed risk mitigation and action plans to ensure subject safety and data quality, to improve protocol adherence, to achieve milestones within budget/schedule projections, and to manage stakeholder expectations
* Maintained calm demeanor while under pressure.

**Wright Rx Consulting Business Development Management 2009 - 2012, 2017**  **Austin, TX**

**Accomplishments:** In a consulting setting, provide business development strategies

* Conducted business analysis recommendation for process improvement
* Identified and advised on business development strategies and funding
* Created contents for clinical research training and online webinars
* Presented GCP certification training to investigators and study coordinators
* Assessed operations of community healthcare organization
* Served as member of advisory boards of startup and early stage medical device companies

**PPD Project Manager 2003 - 2009 Austin, TX**

**Accomplishments:** In a CRO setting, Managed multi-national pharmaceutical industry clients with clinical research operational budgets ranging up to $50 million dollars.

* Ability to accept feedback and act positively. Maintains calm demeanor while under pressure.
* Participated in proposal presentations to potential clients and prepared Kick-Off Meeting materials upon award.
* Served as the primary customer contact, managed the communication of study progress, metrics, and milestone achievement.
* Lead the initiation, implementation, execution, reporting, data quality control, overall risk management, and integration of database lock, dataset transfers, and delivery of final study report.
* Fostered collaboration with global cross functional team leaders, prioritized tasks, processes, transactions and managed a heavy workload. Reliable, worked independently, while delegating assigned responsibilities to project team members.
* Prepared resource, time and cost estimates and monitored time lines and project metrics.
* Analyzed and oversaw cost, personnel hours and project needs. Prepared contract modifications to capture most cost effective and efficient means to operate and complete projects successfully.
* Represented PPD and Client as professional, efficient and responsive to investigators, project vendors at Investigator Meetings, teleconference meetings, progress meetings, and conferences.
* Forecast potential issues and escalated pro-actively. Identified potential risks and worked with the project team to develop contingency plans and communicated to project team. Designed plans of action, presented systems/solutions, identified appropriate people and follow up.
* Prepared and supervised clinical trial document completion, communication, and management of start-up, execution, and control processes including: contracts and budgets, protocol preparation, IRB submissions, regulatory affairs, Investigators Meeting training material, medical and SAE monitoring, vendor selection, data collection instruments (diaries, CRFs, rating scales), automated reporting systems, monitoring reports of site progress, outstanding issues, and data cleaning/query resolution.
* Trained and coached team users of web-based clinical trial management system for essential document tracking, site management, CRF activity and subject visit tracking, protocol deviation-violation tracking, and investigative site payments.
* Prepared and reviewed monitoring trip reports, developed project tools, documents, monitoring forms, CRF Guidelines, site visit management tools, and team training materials.
* Communicated with study sites regarding issues such as quality audit-readiness, protocol adherence, patient participation, case report form completion, drug randomization and accountability, IVRS, GCP Guidelines, and other study-related issues. Coordinated production and writing of study newsletters.
* Trained and co-monitored investigative sites with junior CRAs. Conducted evaluation, initiation, interim monitoring, and closeout visits of investigative sites.
* Ability to accept feedback and act positively. Maintains calm demeanor while under pressure.

**TDH -Texas Center for Birth Defects Research Program Specialist/Investigator 1997-2003 Austin, TX**

**Accomplishments:** In a state government setting, developed grant applications and monitored the fulfillment of the $5 million dollar, Five-Year Cooperative Agreement awarded by the Centers for Disease Control and Prevention CDC. Served as principal investigator to conduct epidemiological studies or served as a collaborator of a research team.

* Managed research teams, study protocol development and implementation of observational and case-control studies.
* Developed priorities, plans, schedules, budgets, guidelines, and contractual performance standards. Managed the operational and scientific infrastructure, and provided research project management leadership.
* Determined trends, oversaw the completion of scope of work, and monitored required performance reports.
* Monitored, evaluated, identified, and solved operational and research methodological problems.
* Performed highly advanced or managerial consultative work requiring specialized knowledge in establishing short-, mid-, and long-range goals and objectives.
* Exercised extensive independent judgment for advising and preparing recommendations and justifications for changing program operations including contractual budgets, scope of work, personnel, policies, and for improving study protocols and procedures.
* Provided technical oversight and consultation for all research related activities, including protocol development and monitoring, clinical record abstraction, case-control eligibility, clinical data entry, confidentiality and rights of study participants, data transfer and security, data analysis and reporting.
* Convened research design and data analysis teams.
* Served as a scientific liaison with state and national organizations related to birth defects research and prevention, data confidentiality and information privacy. Represented the Center at scientific meetings, conferences, seminars, and committees.
* Served as Institutional Review Board member, consulted with Office of General Council, and committees regarding privacy and confidentiality policy and practices.
* Developed, awarded, and managed multiple professional services and institutional contracts with budgets of $500,000. Monitored implementation and progress of research contracts, conducted evaluations, and identified problems.
* Prepared detailed and comprehensive reports on the accomplishment and problems of the Center operations, research activities, and related public health interventions. Presented oral reports and research summaries. Prepared research manuscripts for scientific publication.
* Planned, assigned, and coordinated the management of several databases containing confidential data. Hired, trained, delegated, and supervised public health assigned to databases.

**University of Texas at Austin Principal Investigator 1995-1997 / Graduate Research Assistant 1993-1996 Austin, TX**

**Accomplishments:** In an academic setting, conducted case study doctoral research of health promotion program implementation and the collaborative transfer of the Texas Cancer Awareness and Prevention Project. Conducted literature review, presented case study proposal and study protocol. Conducted interviews among diverse organizational stakeholders, retrieved documents, entered and analyzed qualitative and quantitative data for interpreting the longitudinal patterns, processes, and outcomes.

* Served as member of evaluation team to coordinate/monitor implementation processes, training reviews, and measure outcomes of organizational implementers and targeted end users.
* Reviewed relevant literature, co-developed monitoring and evaluation plans, developed interview and survey data collection instruments, protocols, code books, and analysis plans. Completed baseline implementation surveys. Prepared oral and written monthly and quarterly progress reports. Prepared an extensive written analysis and interpretation reporting evaluation of findings.
* Attended monthly research team meetings. Managed the budget, prepared and presented quarterly written and oral progress and fiscal reports.
* Maintained written communications and telephone conferencing with implementers and attended quarterly meetings with staff decision-makers. Coordinated production and writing of newsletters.

**CERTIFICATIONS/AWARDS**

Project Management Institute: Project Management Professional Certification # 59548, 2003-2019

Quintiles Work Worth Doing Awards - 2012, 2013, 2014 for Leadership, Team work

PPD 2006 Employee Recognition Letter from Fred Eshelman

**PROFESSIONAL DEVELOPMENT**

Project Management Training: Business Acumen, Bid Defense Basics, Influencing Without Authority, Project Client Relationship Management, Project Management Professional (PMP) Certification, Project Metrics Reporting, Predicting Project Outcomes, Global Risk Management and Project Review, Risk Management, Measuring Global Project Performance and Value, Managing Up, Global Project Management Capabilities, Managing Project Finances, Change Management and Change Notification, Office of Civil Right Discrimination Training, Managing Teams, Time Management, Supervising Others, Fundamentals of Successful Project Management, Presentation Skills, Effective Communication Skills.

Clinical Operations Training: Belmont Report, Declaration of Helsinki, Global Clinical Trial Regulations, Barnett Accreditation – Expert GCP Exam for Managers and Staff interacting with Investigational Sites, ICH-GCP Guidelines, Adverse Event Reporting, Essential Documents, Source Document Verification, Variance Trending, Tracking Out of Scope, Monitoring Plan, Communication Plan, Trial Master File Management Plan, Recruitment and Retention Plan, Rater Training, Safety Reporting, Quality Assurance Plan, TrackWise, Effectiveness Check, Corrective Action and Preventive Action Plan, Team Member Transition Plan, MRI Facility Qualification Plan, EDC Central Reading Plan, Central Laboratory Plan – Manual, Electronic Data Capture, EDC Quality Control, Data Quality/Validation Plan, Query Generation and Resolution, Data Listings Review

Research/Evaluation Training: Statistics, Analytic Epidemiology, Congenital Anomalies Epidemiology, Chronic Disease Epidemiology; SAS Programming Concepts, SPSS, Models of Program Evaluation, Qualitative Methods.

**PUBLICATIONS AND PRESENTATIONS**

Smith, A, Wright, D, O’Broin, S. (2003). Measuring Venous and Dried Blood Folate (unpublished) Wright, D, Smith, A. (2003). Feasibility of Conducting Field Collection of Dried Blood Folate (unpublished)

Wright, D. (2000). African-American Mothers Talk to their Teens about Sex, TDH Focus Group Report Wright, D. (1998). Texas Women’s Awareness and Use of Folic Acid, *TDH Epidemiology Report*

Gottlieb, N., Sneden, G., Wright, D. (1996). Using PRECEDE/PROCEDE for Diffusion Implementation Planning of Top Priority, *Health Education Quarterly*

Wright, D. (1993). Descriptive Epidemiology of Classic Kaposi's Sarcoma in Aging Men of Mediterranean Descent (unpublished) Wright, D. (1992). Determinants of African-American Male Participation in Prostate Cancer Screening (unpublished)

Sponsor Investigator Meetings: ICH-GCP Guidelines, Regulatory Documents, Source Documentation, Monitoring Plan and Expectations

Certification Training: Study Coordinator Responsibilities in Clinical Research, Association for Good Clinical Practice in Nigeria (AGCPN) Professional Association

**COMPUTER EXPERIENCE**

Windows 2012, MS Word, Excel, PowerPoint, Outlook, MS Project 2016, Skype for Business, Adobe Professional, Clinical Trial Management System, Infosario Analytics, Medidata RAVE EDC, Oracle Clinical Remote Data Capture (RDC), Veeva eTMF, PeopleSoft Financials, Online Survey, Social Media, Blogging, Web Conferencing, WebEx.

**CLINICAL TRIAL EXPERIENCE**

Nervous System: Randomized, Double-Blind, Placebo Controlled, Multi-Center Registration Trial to Evaluate the Efficacy and Safety Of XXX In Patients With Mild Alzheimer's Disease Receiving Acetylcholinesterase Inhibitors and/or Memantine (800 patients, 130 global sites, 7 countries)

Nervous System: A Multicenter Real World Effectiveness and Safety Observational Program (3000 patients, 300 global sites, 14 countries)

Nervous System: Phase 4, Open Label Study to Evaluate the Effectiveness of XXX on Goal Achievement After Switching Anti-Depression Medication for the Treatment of Subjects with Major Depressive Disorder (40 US sites)

Nervous System: A Multicenter, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of XXX as a Corticosteroid Sparing Agent in Corticosteroid Dependent Patients with Generalized Myasthenia Gravis (23 EU sites/35 US sites)

Nervous System: A Multi-center, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of XXX in Symptomatic Subjects with Generalized Myasthenia Gravis (23 EU sites/35 US sites)

Nervous System: Interventional, Randomized, Double-blind, Parallel-group, Placebo-controlled, Active-reference, Flexible-dose Study of XXX in Patients with Acute Schizophrenia (91 US/EU/UK sites)

Nervous System: Interventional, Open-label, Flexible-dose Extension Study of XXX in Patients with Schizophrenia (50 US/EU sites)

Nervous System: A Randomized, Double-Blind, Placebo Controlled, Parallel-Group, Multicenter, Phase II Study to Evaluate the Impact of XXX on Brain Amyloid Load and Related Biomarkers in Patients with Mild to Moderate Alzheimer's Disease (27 US/EU sites)

Nervous System: A Randomized, Double-Blind, Placebo Controlled, Parallel-Group, Multicenter, Phase II Study to Evaluate the Impact of XXX in Patients with Mild to Moderate Alzheimer's Disease (91 North America/EU/UK sites)

Nervous System: An open label, exploratory, dose-escalation, multi-center study examining the safety, tolerability and efficacy of an AED in adult subjects (18 -65 years) with refractory epilepsy suffering from partial onset seizures who are currently receiving an AED but still experiencing seizures (25 sites).

Nervous System: A Phase III, Randomized, Double-Blind, Placebo-Controlled, Outpatient Study to Access the Efficacy and Safety of an Immediate Release Formulation of XXX in Elderly Primary Insomnia Patients with Sleep Maintenance Difficulties (75 sites).

Nervous System: Phase 3 Multicenter, Randomized, Double-Blind, Placebo-Controlled Study of the Effect of Daily Treatment with XX-XXX on Measures of Cognitive and Global Function in Subjects with Mild to Moderate Dementia of the Alzheimer’s Type (110 sites).

Endocrine/Metabolic: Phase II, Double-Blind Randomized, Placebo-Controlled, Parallel Group, Multicenter Study to Evaluate Treatment with XXX in Subjects with Type 2 Diabetes (140 US and Latin America sites).

Endocrine/Metabolic: Phase III, Double-Blind Randomized, Placebo-Controlled, Two-Year Durability, Multicenter Study to Evaluate Treatment with XXX in Subjects with Type 2 Diabetes taking Metformin in comparison with Glipizide (180 US/Canada/Latin America sites).

Musculoskeletal: Multi-center, Randomized, Double-Blind, Active and Placebo-Controlled Phase III, Efficacy and Safety Study of an Opioid in Patients with Moderate to Severe Chronic Pain due to Osteoarthritis of the Hip or Knee. (60 sites).

Musculoskeletal: Mechanism-Of-Action Research Project in Association with Studies of XXX in Systemic Lupus Erythematosus and Lupus Nephritis (50 sites).

Musculoskeletal: A Randomized, Double-Blind, Placebo-Controlled, Multicenter Phase II/IIII Study to Evaluate the Efficacy and Safety Of XXX in Subjects with Moderate to Severe Systemic Lupus Erythematosus (SLE) (50 sites).