

SUMMARY

Clinical Research Professional with in-house clinical trial management experience and strong grounding in epidemiology, research methods and lab biology. Consistently achieved high quality outcomes and on-time delivery through thorough preparation, accountability, critical thinking, communication and managing diverse partner relationships. Experienced in:

- Research Methodology
- Literature Review
- Technical Writing
- Essential Monitoring Skills
- Study Materials Development
- Vendor Management
- Document Review & IRB Submission
- User Acceptance Testing

EDUCATION

- 2007 **MS Public Health**
University of Colorado at Denver and Health Sciences Center; Denver, CO
Emphasis: Epidemiology, Research Methods, Program Evaluation
- 2000 **BA Biology**
Reed College; Portland, OR
Emphasis: Population Genetics

PROFESSIONAL EXPERIENCE

- 2007 – 2009 **Gilead Sciences, Boulder/Westminster, CO**
Clinical Research Associate (Feb 2008 – Dec 2009)
Conducted clinical trial management activities for five global and domestic multi-center drug trials at the study sponsor, including some co-monitoring. Managed vendors and performed central review and tracking of study documents, supplies, Case Report Forms (CRFs) and lab alerts. Adhered to ICH/GCP and SOPs.
- Revamped sub-study CRF collection from 50% to 99% complete and met project timelines through tracking, Contract Research Organization (CRO) management and site and CRA re-training.
 - Minimized cost overruns by completing 66% of site reactivations within two months of protocol overhaul and study screen hold lift.
 - Shortened pivotal trial enrollment timeline by two months through contributing to the planning and conduct of a study coordinator meeting and presenting on subject recruitment strategies.
 - Analyzed data listings to generate queries and documented data management issues that enabled corrective action in time for data lock.
- Clinical Project Associate** (Jun 2007 – Jan 2008)
Supported study management activities for four global trials, adhering to ICH/GCP and company SOPs.
- Accelerated global site start up through rapid review of 200 regulatory document packets.
 - Relieved manager and site monitor burden by taking initiative to resolve minor tasks and performing drug over-labeling visits as needed.
 - Spearheaded Interactive Voice Response System (IVRS) User Acceptance Testing with minimal supervision, leading two CRAs.

- 2006 **Colorado Kids Sun Care Program, Denver, CO**
Research Assistant
 Maintained tracking and communication with over 1000 subjects in a prospective epidemiological study and performed data entry. Obtained parent consent and child assent in compliance with IRB and HIPAA requirements.
- Contributed to high third year turnout for 17 mass skin exam sessions.
- 2003 – 2005 **The Qualitative Research Center, Boulder, CO**
Research Assistant & Production Manager
 Compiled qualitative market research data and managed review and production of over 50 time-sensitive summary reports on nationally and internationally known brands.
- Maintained client satisfaction through having a 100% on-time record for editing and producing hard copy reports.
- 2000 – 2003 **University of Colorado at Boulder**
Professional Research Assistant – Poyton Lab, Boulder, CO (2001 – 2003)
 Designed and conducted laboratory experiments on the molecular biology of aging in a yeast model. Managed fermentor equipment.
- Made significant contributions to four published papers.
 - Organized successful laboratory relocation.
 - Designed and constructed lab website.
 - Maintained lab compliance with university radiation safety standards.
- Professional Research Assistant – Johnson Lab** (2000 – 2001)
 Oversaw daily needs of a three-person genotyping lab, including sample collection and processing and management of mouse colony to identify quantitative trait loci for alcohol sensitivity in a mouse model.
- Accelerated genotyping turn-around time through modification of laboratory protocols.
 - Planned and executed conversion of over 5 years of handwritten mouse colony records to electronic tracking system.
- 1997 – 2000 **Reed College, Portland, OR**
Computer Help Desk Representative
 Provided first-line IT support to students using the computer center.

THERAPEUTIC EXPERIENCE

Cardiovascular

- Resistant Hypertension Phase 3
- Pulmonary Arterial Hypertension Phase 4

PROFESSIONAL TRAINING

- **Foundations of Clinical Research Coordinating & Monitoring Trials** (Unitek)
- **Basic Drug Development** (Pharmaceutical Education & Research Institute)
- **COMIRB** (University of Colorado Health Sciences)
- **HIPAA** (University of Colorado Health Sciences)
- **Essential Presentation Skills** (Zig Ziglar)
- **Radiation Safety** (University of Colorado at Boulder)

TECHNICAL SKILLS

- MS Office: Word, Excel, PowerPoint, Publisher, Access
- Medidata Rave (EDC/eCRFs)
- Interactive Voice Response Systems (IVRS)
- Adobe Acrobat
- SAS
- SPSS
- PubMed
- Lab: Bioreactor yeast cell culture, DNA/RNA/protein isolation; Northern & Western blotting, DNA sequencing, PCR-based genotyping (microsatellite, restriction digest), Microarray analysis

HONORS

Values at Work Award, 2009 • Diversity Scholarship, 2006 • Phi Beta Kappa Honor Society 2000 • 1999-2000 HHMI undergraduate grant • Reed College Presidential Scholar, 1996 • National Merit Scholar, 1996

CLINICAL TRIALS & EPIDEMIOLOGICAL STUDIES

ATHENA-1 - An Open-label, Multicenter Study of Ambrisentan and a Phosphodiesterase Type-5 Inhibitor Combination Therapy in Subjects With Pulmonary Arterial Hypertension Who Have Demonstrated a Sub-Optimal Response to a Phosphodiesterase Type-5 Inhibitor (Gilead Sciences)

The Colorado Kids Sun Care Program (University of Colorado Health Sciences Center)

DORADO - A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multi-Center, Parallel Group Study to Evaluate the Efficacy and Safety of Fixed Doses of Darusentan in Subjects With Resistant Systolic Hypertension Receiving Combination Therapy With Three or More Antihypertensive Drugs, Including a Diuretic (Protocol Gilead Sciences; Protocol DAR-311)

DORADO-EX - A Dose-Blinded, Long-Term Safety Extension Study of Fixed Doses of Darusentan in Subjects With Resistant Systolic Hypertension Receiving Combination Therapy With Three or More Antihypertensive Drugs, Including a Diuretic (Gilead Sciences; Protocol DAR-311-E)

DORADO-AC - A Phase 3 Randomized, Double-Blind, Placebo- and Active-Controlled, Multi-center, Parallel Group Study to Evaluate the Safety and Efficacy of Darusentan in Subjects With Resistant Hypertension Receiving Combination Therapy With Three or More Antihypertensive Drugs, Including a Diuretic, as Compared to Guanfacine or Placebo (Gilead Sciences; Protocol DAR-312)

DORADO-AC-EX - A Double-Blind, Active-Controlled, Long-Term Safety Extension Study of Optimized Doses of Darusentan in Subjects With Resistant Hypertension Despite Receiving Combination Therapy With Three or More Antihypertensive Drugs, Including a Diuretic, as Compared to Guanfacine (Gilead Sciences; Protocol DAR-312-E)

PUBLICATIONS

Dodd A, Morelli J, Mokrohisky ST, Asdigian N, Byers TE, Crane LA. "Melanocytic Nevi and Sun Exposure in a Cohort of Colorado Children: Anatomic Distribution and Site-Specific Sunburn" *Canc. Epi. Biom. Prev.* (2007) 16; 2136-43.

Dirmeier R, O'Brien KM, Engle M, Dodd A, Spears E, and Poyton RO. "Measurement of oxidative stress in cells exposed to hypoxia and other changes in oxygen concentration" *Meth. Enzymol.* (2004) 381: 589-603.

Poyton RO, Dirmeier RP, O'Brien KM, David P, and Dodd A. "Experimental strategies for analyzing oxygen sensing in yeast" *Meth. Enzymol.* (2004) 381: 644-62.

Hon T, Dodd A, Dirmeier R, Gorman N, Sinclair PR, Zhang L, Poyton RO. "A mechanism of oxygen sensing in yeast: Multiple oxygen responsive steps in the heme biosynthetic pathway affect Hap1 activity" *J. Biol. Chem.* (2003) 278 (50): 50771-80.

Dirmeier RP, O'Brien KM, Engle M, Dodd A, Spears E, and Poyton RO. "Exposure of yeast cells to anoxia induces transient oxidative stress: Implications for the induction of hypoxic genes" *J. Biol. Chem.* (2002) 277: 34773-84.

PRESENTATIONS

"Recruitment Strategies." DORADO-AC/EX Study Coordinator Meeting, April 2008.

"A phylogeographic study of *Delphinium nuttallii* in Washington and Oregon using nested clade analysis." Poster presented at the annual conference of the Botany Society of America, August 2000.

"Phylogeography of Big Brown Bats in North America." Presented at the Boston University Department of Biology NSF-REU Summer Research Symposium, August 1999 and by invitation at the Reed College Department of Biology Summer Student Research Seminar, October 1999.