Clinical Pathways

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PROFILE:

Sam has been in the clinical research industry for almost 30 years. She has worked for sites, sponsors, and CROs, including roles as a Study Coordinator, Site Director, Monitor, Auditor, Quality Manager, Trainer, Risk-Based Quality Management Manager, Director of Clinical Operations, Director of Monitoring, and Quality Inspection Readiness Lead. Sam is a well-known GCP and clinical quality system subject matter expert with a focus on inspection readiness, vendor management and risk-based quality management. Sam is a frequent speaker at industry conferences, and a contributor and author to many GCP publications. She co-owns a GCP consulting and training firm in Research Triangle Park in North Carolina since 2002 that services small to large pharma, biologic and medical device companies, technology vendors, research sites, and CROs.

CURRENT:

Clinical Research Services
Clinical Pathways LLC
February 2002 to Present

- Assist with and/or develop new or revise existing policies, procedures, quality manuals, training programs to meet current industry regulations and industry initiatives, i.e. integration of quality risk management in GCP systems.
- Performance Improvement Consultant: analysis of proposed and current organization programs/departments. Conduct performance gap and cause analysis, leading to identifying interventions, implementation and evaluations.
- Management/leadership global experience- CP staff hiring, development and oversight, multiple contractual roles in leadership for clients, e.g., quality manager (sponsor), director of monitoring (sponsor), director of clinical research (SMO), director of quality (sponsor), GCP subject matter expert for technology company (eConsent).
- Clinical research services on a contractual basis (Quality Management, Inspection Readiness, Training & Development, Monitoring, Auditing, Process Improvement, Program & Change Facilitation).
- Quality management system adaptation to promote continuous improvement.
- QA auditor for CROs, Sponsor, Sites. Qualification audits to study focused.
- CAPA development facilitation post negative inspection findings and to facilitate CAPA development for regulatory agencies.
- Design, develop, conduct clinical research and soft skills training; audience experience size range experience 1-1500. In-person, online, and eLearning.
- Competency based curriculum development and coordination.
- Home office experience since year 2000.
- Client Types: CROs, sponsors, research sites, technology vendors, training organizations, universities.

EDUCATION:

- Niagara University, 1983 BSN; NC RN License
- Capella University, 2007 MS in Education with a specialization in Training and Performance Improvement

THERAPEUTIC AREA EXPERIENCE:

Oncology

- Colorectal, Leukemia, Prostate, Endometrial: Phase II-III 2 years+
- AML: Personalized Adoptive Cellular Therapy 2 years +

Infectious Disease/Virology

- HIV, Hepatitis: Phase II-IV 2 years +

Cardiovascular

- Post-MI, Sudden Cardiac Arrest, Device, 2013 to current
- Hypertension Phase III,
- Thrombolytic Phase II
- In Vitro Diagnostics, Device
- CHF Phase III, 2 years +
- Other clinical experience: Telemetry, Angina, MI, Cardio-Thoracic surgery

Orthopaedic Surgery

- Biologic Allogenic Red Blood Cell Replacement Substitute Phase III 6 months
- Hip & Shoulder Replacement Studies Device 1 year
- Spine 2 years

Respiratory

- Asthma, COPD: Phase II-IV 3 years

Neurological/CNS

- MS, Schizophrenia: Phase II-IV 3 years
- Other clinical experience: Neuro-Trauma Closed Head Injury, CVA

Endocrine

- Diabetes: Phase II, III 1 year

Hematology

- Red Blood Cell Replacement, Anesthesiology: Phase III 6 months

Dermatology

- Moderate to severe Psoriasis: Phase III 6 months
- Device: Facial Fillers, Breast Augmentation, Obesity, Laser Hair Removal

GYN

- Endometriosis Pain: 2 Phase II 1 year+

OTHER CLINICAL AND RESEARCH EXPERIENCE:

Clinical Research Consultant

Cheval Noir & Clinical Pathways

April 2001 – February 2003

- Clinical research services provided on a contractual basis including: safety associate, monitoring, coordinating, training, site recruitment, electronic CRF use, site audits and research naive site development.

CRA Field Trainer

2000-2001

PharmaResearch Corporation

- Mentor and co-monitor with current CRAs on all study teams
- Development, implementation, and performance review of the departmental training
- Function as a focal point for all clinical training and safety surveillance training
- Delivers in-house and Field Training
- Coordinates training on CRO Project Tracking and Report Writing Oracle System
- Oversees the Training of New clinical employees, Evaluates on-site performance of CRAs
- Monitored Phase II, III and IV

Senior Clinical Research Associate

1999-2001

PharmaResearch Corporation

- Project specific field instruction, in-services and mentoring for CRA trainees
- Review of monitoring visit reports
- Literature review for potential studies
- Cross-monitoring multiple studies
- Assisting project management in protocol-specific tasks
- Participate in the conduct of multi-center clinical research studies
- Review of project related materials & literature to develop a basic understanding of protocol & therapeutic areas
- Participates and presents at investigator meetings for assigned studies.
- Assist in investigator recruitment
- Site Management: Evaluates, initiates, monitors and closes out sites according to applicable SOPs and FDA guidelines
- Review Case Report Forms for completeness, clarity, legibility, conformity to available source documents and adherence to protocol requirements
- Query resolution: Resolves Case Report Form discrepancies and/or clarifications via site visits
- Verifying completeness of critical documents and report adverse events
- Perform sponsor master file and investigator file audits
- Phase II, III and IV trials

Clinical Research Associate

1998-1999

PPD Pharmaco, Inc

- Participates in the conduct of multi-center clinical research studies
- Review project materials and literature to develop an understanding of protocol and therapeutic areas
- Participate and presents at investigator meetings for assigned studies
- Assists in investigator recruitment
- Site Management: Evaluates, initiates, monitors and closes out sites according to applicable SOPs and FDA guidelines
- Review Case Report Forms for completeness, clarity, legibility, conformity to available source documents and adherence to protocol requirements
- Query resolution: Resolves Case Report Form discrepancies and/or clarifications via site visits
- Perform drug accountability at site visits
- Verify completeness of critical documents and report adverse events
- Perform sponsor master file and investigator file audits

Clinical Research Coordinator

1995-1998

Alamance Regional Medical Center (Duke TAMI Trials)

- Coordinates clinical research studies for multiple clinical investigators

Registered Nurse

1983-1998

- Intensive care unit (ICU)

MEMBERSHIP, CERTIFICATIONS, APPOINTMENTS:

- Adjunct Instructor in Clinical Research and Leadership, George Washington University, 2014 to present
- Metric Champion Consortium (MCC) Ambassador 2015 to 2021
- Association for Clinical Research Professionals (ACRP): dual certified
  - Certified Clinical Research Associate (CCRA) 20+ years
  - Certified Clinical Research Coordinator (CCRC) 20+ years
- ACRP Fellow Award 2019 to present
- ACRP Academy Board of Trustees 2013 to 2018, Treasurer (2 terms)
- ACRP Regulatory Affairs Committee (RAC), 2013 to 2017, Vice-chair (2016)
- ACRP Certification Item Writing & CRA Exam Committee 2003-2012

PUBLICATIONS:

- *The CRCs Guide to Coordinating Clinical Research*, Third Edition, October 2016
- *Good Clinical Practice: A Question & Answer Reference Guide*. Cambridge Health Institute (CHI). Author sections: HIPAA 2008, 2009, 2010, 2011, 2012, 2013, 2014, 2015, 2016, 2017, 2018, 2019, 2020; Use of NTF 2009-2013; Computerized Systems 2010.
- *HIPAA and U.S. Clinical Trials: A Question & Answer Reference Guide*, CHI, March 2014.
- Association of Clinical Research Professionals (ACRP), The Monitor, *Globalization's Influence on the Standards of Research*: ICH GCP, February 2010.
- ACRP, The Monitor, *Recent Developments in Subject Data Privacy and Security*, August 2013.
- The Journal of Clinical Studies, Volume 6, Risk-based Monitoring Roundtable, May 2014.
- ACRP, Clinical Researcher, (formally The Monitor), Quality Risk Assessment, Why Should Sponsors Have All the Fun?, August 2014.
- Clinical Leader article, *An ISO 14155:2020 Primer — Good Clinical Practice For Medical Device Trials*, Feb. 2021.
- Medical Device Online article, *An ISO 14155:2020 Primer — Good Clinical Practice For Medical Device Trials*, Feb. 2021.
- Clinical Leader article, *Safeguarding Participant Data During Risk-based Monitoring — Practical Considerations*, Sep. 2020.
- Clinical Leader article, *Remote Monitoring In The Wake Of COVID-19 — Practical & Regulatory Considerations*, June 2020.
- Clinical Leader article, *Clinical Trial Root Cause Analysis: Can't We Do Better Than Five Whys?*, January 2020.
- ACRP, Clinical Researcher, *Risk-Based Monitoring of Clinical Trials: COVID-19 and Paving the Road to the Future*, Sep. 2020.
- Many recent articles 2016-2018 electronic consent.

SAMPLING OF CURRENT COURSE DEVELOPMENT & PRESENTATIONS:

- Remote Monitoring During the COVID-19 Crisis
- Adequate Sponsor Monitoring Systems In Anticipation of Sponsor GCP Inspections Adverse Event Monitoring for CRAs
- Approaches to Address Challenges in Vendor Management

- Clinical Research Site Quality Improvement Strategies: Developing Proactive Project Study Plans Corrective Action Plans: Essential Documentation of a Site's Response to GCP Deficiencies
- CRA Current Practice Update: Impact of the FDA BIMO Program CRA Site Performance Improvement Monitoring Model
- CRC & PI Current Practice Update: Impact of the FDA BIMO Initiative CRC Role/Responsibilities Training
- Developing and Negotiating Research Site Clinical Study Budgets and Contracts
- Electronic Medical Records: Ensuring Source Document and 21 CFR Part 11 Required Components Essential Documentation in Clinical Trials (Site and Sponsor Trial Master Files)
- Facilitation Skills
- FDA Regulatory Guidance Update
- Final AE Regulatory Guidance: Reporting/Communication of Safety Information from Clinical Trials to IRBs Final FDA Guidance: Supervisory Responsibilities of Investigators
- GCP Training: Core Human Subject Protection Training Good Documentation Practices
- Global Regulatory Developments
- HIPAA Team Training: Fundamental Training Specifically for Clinical Research Settings
- HIPAA Requirement Changes and Enforcement: Direct and Indirect Impact Analysis for Research Centers Informed Consent Content & Process Requirements
- Investigational Product Accountability Training for Research Site Personnel Investigator Initiated Trials
- Key Components of a Successful Study Site Start-up, Management and Maintenance Strategy Managing CRAs to Improve Performance & Study Outcomes
- Meeting HIPAA & FDA Requirements for Case Histories Monitoring Informed Consent: The Process and Document Monitoring Phase I Clinical Trials
- Monitoring Plan Development
- Monitoring Reports: 10 Rules of Effective Report Writing

SAMPLING OF CURRENT COURSE DEVELOPMENT & PRESENTATIONS: CONTINUED

- Risk-based Study Management: Site and Sponsors Quality Systems Risk Management
- Root Cause Analysis: Applying the Concept for Better Study Compliance Management Root Cause Analysis in Proactive Risk Management
- Presentation Skills Training for Clinical Research Professionals Preparing Clinical Research Sites for FDA Inspections Principal Investigator Training: Roles and Responsibilities Source Documentation: What is Adequate & Accurate?
- Sponsor Management of Investigator Non-Compliance Strategies for Managing Difficult Clinical Research Sites Special Considerations in Pediatric Trials for CRAs
- Train-the-Trainer: Successful Web-Based Training Strategies
- Trial Master File (TMF) for Research Sites: Set-Up and Maintenance Trial Master File (TMF) for Sponsors: Set-Up and Maintenance
- Use of Notes to File in Clinical Trial Essential Documentation Pharmacovigilance: Pre and Post Marketing

References upon request.