CANDACE SIMPSON, MS, MBA, PMP, CCDM

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VISIONARY & INSPIRATIONAL CLINICAL DATA EXECUTIVE

Disruptive Clinical Innovation for the Pharmaceutical Industry

Benefiting Patients: Enhancing Clinical Development by Introducing Exciting Medical Inventions

Expert in leading global research associates to ensure the flawless execution of clinical trials. Devoted to improving front-end and back-end services while providing structure to international sites/groups. Able to fix complex problems that nobody else can.

RESPECTED ACROSS THE INDUSTRY FOR:

Transforming Organizations	*Optimizing Processes & Clinical Trials*	*Directing & Motivating Global Teams*	*Using Emerging Technologies*
Eloquently evangelized and promoted operational changes to cultivate quality-focused cultures and encourage continual process improvement.	History of minimizing costs, elevating standards, and discovering efficiency opportunities for leading pharma and CRO companies.	Passionate advocate of best practices; won industry acclaim for energizing diverse teams and ensuring performance excellence.	Dedicated to modernizing pharmaceutical operations with revolutionary technical advancements while keeping apprised of all the latest trends.
Led innovative risk-based management (RBM) pilot and implemented new data scientist role.	**Decreased study build by 80%, turning it into a 2-week process. Created standardized case report form (CRF) library.**	**Honored in "100 Most Inspiring People in Life Sciences" list by MedaVOICE in 2016.**	**Cut data transfer time 96% at Rake Laboratories; reduced data extraction processing from 3 days to just 1 hour.**

COMPETENCIES

Data Management (DM)	Global Project Leadership	Quality / Process Optimization
eClinical Systems	Clinical Research Trends	Team Building / Motivation
Thought Leadership	Careful Risk Mitigation	Stakeholder Mobilization
GCP / ICH Guidelines	Complex Problem Resolution	Budget / Contract Management
Strategic Influence	Regulatory Compliance / Audits	Staff Training / Mentoring

CAREER HISTORY

Pharma Information Management Systems, Chicago, IL — **2017 to Present**

Senior Director and Business Product Owner – Global Projects

Spearhead global transformation for all enterprise clinical operations across 96 countries.

Steer the CEO's top priority project. Determine the best strategies for using a new system impacting 20,000 users and 800+ clinical trials annually. Partner with leading electronic trial master file (eTMF) company to deliver state-of-the-art solutions guaranteed to resolve challenging bottlenecks. Strategize product development/testing and change management approach while training teams.

Worked with 100+ stakeholders in every business unit to develop universal clinical trial system.

- **Synthesized all predictable clinical trial situations in just 6 months.**

Placebo Corporation, Chicago, IL — **2013 to 2017**

Senior Director – Clinical Sciences and Operations

Owned and optimized Placebo's data management (DM) operations and closeout process. Hand-picked to serve as Business Process Owner (BPO) in Clinical Quality Group while holding high-profile role on Data Monitoring and Management Leadership Team.

Established controls and operational practices that greatly enhanced clinical DM for 500+ global study teams. Continually analyzed quality management (QM) escalations and supported audits/inspections to identify and capitalize on BPO improvement opportunities. Maximized clinical data quality, visibility, and accessibility across the enterprise by deploying efficient clinical systems.

RECOGNITIONS

MedaVOICE – 100 Most Inspiring People in Life Sciences, 2016

Placebo – Clinical Excellence and Innovation Award, 2015

Surpassed ambitious goals for compliance and technology initiatives as a respected thought leader and subject matter expert (SME) for data management conduct and closeout.

- **Raised the bar for quality excellence across 500+ annual clinical trials.**
- **Greatly improved studies, quality standards, clinical systems, and DM infrastructure.**
- **Reduced negative QM system events, prevented problematic audit findings, and decreased database unlocks.**

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ORGANIZATIONS

Board Director – *Crystal River Foundation*

Risk-Based Monitoring Workstream Member – *TransCelerate*

Former Trustee – *Society for Clinical Data Management*

EDUCATION

MS in Pharmacology & Toxicology
ILLINOIS STATE UNIVERSITY

MBA in Management
UNIVERSITY OF CHICAGO

MS in Information Systems
NORTHWESTERN UNIVERSITY

BA in Psychology; Minor in Biology
LOYOLA UNIVERSITY

CERTIFICATIONS

Project Management Professional (PMP)

Certified Clinical Data Manager (CCDM)

Certified in Risk Management for Clinical Trials

PERSONAL TRIUMPHS

Delivered 14 presentations at global conferences and featured in 12 publications. Addendum available upon request.

Enabled wheelchair-bound family member, who had been misdiagnosed by numerous doctors, to walk for the first time in 3 years after persistently researching possible causes of his condition.

Raised record amount of funds ($130,000) for the Crystal River Foundation to find a cure for diffuse intrinsic pontine glioma (DIPG) and to make wishes come true for terminally ill children.

Revamped Bansen Pharmacy's layout as a teenager, enabling pharmacists to fill double the prescriptions in half the time; reorganized medications for more expedient service.

Data Quality Excellence (DQE): Led 3-year, multimillion-dollar initiative across the enterprise.

- **Steered 200+ SMEs, ensuring efficient process improvement and project management.**
- **Created game-changing business case and designed strategic transformation roadmap.**
- **Cut $600,000 in expenses, eliminating all costs associated with risk management software.**

"Given the fast-paced and ever-changing nature of marketing clinical trials, Candy's motivational communication skills and ability to come up with innovative solutions to new problems were invaluable for helping the department meet its tight delivery schedules. Her work was always of the highest quality." ***– Henry Stanton, Placebo Corporation***

Acme Clinical Research, Chicago, IL **2011 to 2013**

Director – Clinical and Strategic Operations (2012 to 2013)
Director – Biometrics (2011 to 2013)

Hired to improve DM and swiftly promoted to optimize business development processes.

Oversaw proposal development, presentation design, budgeting, and relationship management for major clinical studies. Maximized thought leadership and market influence by forging mission-critical partnerships with vendors. Enhanced biometric services delivery and guided business development for a $60 million proposal portfolio. Led, developed, and motivated team of 8 to peak performance levels.

Radically improved biometrics service delivery and project management by building a world-class clinical operations organization.

- **Drove $26 million in revenue gains and introduced profound process improvements.**
- **Saved 17% for clinical studies while increasing study enrollment and quality.**
- **Streamlined processes for study impacting 500 patients, 80 sites, and a $12 million budget.**
- **Shrank study cycles from 12 weeks (industry standard) to 2 weeks by creating CRF library.**
- **Reduced expenses by $300,000 while running public relations and marketing functions.**

EEE Neuroscience Division, Chicago, IL **2009 to 2011**

Consultant / Senior Project Data Manager

Contracted to implement global DM strategy and enable FDA medication approval.

Empowered global stakeholders by sharing best practices to domestic/international teams. Oversaw data collection, validation documentation, discrepancy management, quality control, medical coding, and data archiving.

Completed time-sensitive clinical trials while improving data quality and delivery speed.

- **Maximized ROI for outsourced vendor services by raising standards/expectations.**

Rake Laboratories, Chicago, IL **2005 to 2009**

Clinical Data Management Consultant

Ensured the success of major clinical studies across a $60 million clinical trial portfolio.

Won buy-in from top-level executives/stakeholders across the enterprise to make drastic, systemic revisions within a change-averse environment; authored and presented convincing business cases. Optimized cross-therapeutic synergies within clinical trials while enhancing data integrity and supporting publications.

Radically improved biometrics service delivery and project management by building a world-class clinical operations organization.

- **Boosted system performance 70%+ for 150+ employees across 40+ sites.**
- **Slashed $550,000 after refining DM processes and training teams on best practices.**
- **Saved $400,000 annually by building an outsourced clinical DM operation.**
- **Cut reporting time from 2 days to 3 hours with new electronic data capture (EDC) processes.**

Résumé Strategy

This client was a superhero in clinical data management in the pharmaceutical industry, and had advanced expertise across a broad array of specialties.

To keep the introduction easy to read and visually exciting, I broke up the summary and associated achievements into 4 separate groups. Through these sections I employed a value-scale color scheme that would naturally guide the eye through all categories.

I created a sidebar on the 2nd page that focused on board/association leadership roles and credentials. I also included a "Personal Triumphs" section to discuss some of the more fascinating stories I learned about my client through extensive phone interviews. I felt this rounded out her candidacy and gave potential interviewers something to break the ice with.

Since she wanted to continue her career in the pharmaceutical industry, I merged the color text boxes with a background image comprised of a seamless pill pattern. I also replaced the bullet points with different pill icons. I carried on this theme while designing a global map, which highlights her countries of oversight in teal, framed in a pill-patterned text box.