

ALEXIS MELSON, CEO

Alexis Melson, LVN

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PROFESSIONAL SUMMARY

Accomplished Chief Executive Officer with 23 years of experience in clinical research, specializing in overseeing and driving the success of complex clinical trials. Expertise spans across clinical trial management, regulatory compliance, business development, and team leadership within the clinical research industry. Proven ability to lead cross-functional teams, ensure compliance with FDA/ICH guidelines, and deliver successful outcomes across multiple therapeutic areas. Adept at securing partnerships, optimizing operational efficiency, and growing business opportunities.

CORE COMPETENCIES

- Clinical Trial Management (Phase I-IV)
 - Regulatory Compliance (FDA, ICH-GCP)
 - Team Leadership & Development
 - Business Development & Strategic Partnerships
 - Budget Management & Financial Oversight
 - Site Management & Vendor Relations
 - Psychometric Testing & Clinical Ratings
 - Neurocognitive Battery Assessments
 - Protocol Development & Training
 - Stakeholder & Executive Communication
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PROFESSIONAL EXPERIENCE**Accelerated Clinical Trials — Founder/CEO**

January 2023 – Present | Peachtree Corners, GA

- **Visionary Leadership:** Spearheaded the creation and growth of a leading clinical research company, defining its strategic direction, vision, and long-term

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goals in a competitive industry. Successfully positioned the company as a trusted partner for clinical trial management, particularly for CNS indications.

- **Operational Excellence:** Managed day-to-day operations, ensuring alignment of company-wide resources and operations to meet business objectives. Streamlined internal processes to maximize operational efficiency and reduce overhead costs.
- **Financial Stewardship:** Oversaw the development and implementation of the company's financial strategy, managing annual budgets, forecasting, and driving revenue growth. Achieved profitability within the first year of operation by securing strategic contracts and optimizing resource allocation.
- **Team Leadership & Development:** Recruited, mentored, and led a diverse team of professionals in clinical research, operations, and business development. Developed a strong company culture based on collaboration, innovation, and excellence. Instituted ongoing training programs to ensure team members remained compliant with GCP standards and industry best practices.
- **Strategic Partnerships & Growth:** Built and nurtured relationships with key stakeholders, including pharmaceutical sponsors, CROs, regulatory bodies, and clinical sites. Led the negotiation of multi-year contracts, resulting in substantial business expansion and increased market share.
- **Clinical Operations Leadership:** Oversaw the management and execution of multiple, concurrent clinical trials, ensuring sponsor/investigator obligations were met. Provided strategic oversight to ensure trials adhered to timelines, budgets, and regulatory requirements.
- **Regulatory Expertise:** Championed regulatory compliance efforts, ensuring that all clinical operations were conducted in accordance with FDA, ICH, and local regulations. Successfully led efforts for IRB submissions, site inspections, and audits.
- **Innovation & Technology Integration:** Implemented cutting-edge technologies and tools to enhance data collection, monitoring, and reporting processes. Championed the use of advanced neurocognitive testing and psychometric tools to support high-quality clinical data.
- **Stakeholder Communication:** Delivered strategic communications to internal teams, board members, and external stakeholders, fostering transparency and building trust. Regularly provided updates on company performance, clinical trial milestones, and business development efforts.

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- **Crisis Management & Problem-Solving:** Led the company through challenging situations, including tight deadlines, regulatory hurdles, and evolving market conditions. Used a proactive, solution-oriented approach to mitigate risks and navigate obstacles
- Lead and oversee all clinical operations, managing clinical trials for a variety of therapeutic areas, ensuring adherence to sponsor/investigator obligations, and compliance with FDA/ICH guidelines.
- Direct all clinical project documentation, including source documentation, SOPs, monitoring visit templates, and reports.
- Administer psychometric and neurocognitive testing for subjects, utilizing scales such as SCID-5CT, PANSS, BPRS, MADRS, YMRS, and others.
- Provide consistent communication to project management, resolve site issues, and manage project timelines.
- Oversee site file reconciliation, ensuring regulatory compliance and proper documentation.

Sorrento Therapeutics — Senior Manager, Clinical Operations

April 2022 – January 2023 | Atlanta, Georgia

- Lead clinical activities for 5 active human clinical studies in the Sofusa Lymphatic Drug Development Division.
- Manage cross-functional communication between CROs, regulatory teams, clinical sites, and external stakeholders to ensure successful execution of studies.
- Oversee clinical budgets, timelines, and study quality, ensuring compliance with GCP standards and FDA requirements.
- Collaborate with the Regulatory team on IND and DSUR submissions in eCTD format.
- Provide “voice of the customer” feedback into device design requirements for R&D and manufacturing teams.

Atlanta Center for Medical Research — Senior Clinical Operations Manager / Psychometric Rater

June 2021 – April 2022 | Atlanta, GA

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- Led clinical operations at a multi-site research center, ensuring the successful execution of clinical trials.
- Delivered guidance and training to site staff and investigators, optimizing recruitment and enrollment for clinical trials.
- Managed site financial performance and maintained P&L accountability.
- Conducted neurocognitive assessments and rating scales for subjects with CNS indications, including SCID-5CT, PANSS, and others.

Synexus Clinical Research

July 2019 – June 2021 | Atlanta, GA

Site Director / Psychometric Rater

- Coordinated site expansion and optimized patient recruitment strategies to increase site productivity and study load.
- Achieved fiscal year revenue target of \$2.3 million with minimal loss.
- Managed vendor selection and procurement for clinical trials, including cardiologists, MRI/PET scanning facilities, and more.

Clinical Research Coordinator Manager / Psychometric Rater

May 2019 – July 2019 | Atlanta, GA

- Led clinical research teams to ensure study milestones were met on time and within budget.
- Provided leadership and oversight for the recruitment and enrollment process for clinical trials.

Additional Experience:

Atlanta Center for Medical Research- Senior Research Coordinator / Psychometric Rater

November 2014 – May 2019 | Atlanta, GA

- Managed the setup, execution, and monitoring of clinical trials, ensuring compliance with regulatory and sponsor requirements.
- Delivered high-quality psychometric and clinical testing services, including various CNS-related scales.

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Pro Science Clinical Research Group- Senior Clinical Research Coordinator / Psychometric Rater

February 2014 – August 2014 | Atlanta, GA

- Managed regulatory submissions, including IRB submissions and monitoring compliance with ICH/GCP guidelines.

Apostle Clinical Trials, Inc.- Senior Clinical Research Coordinator/Rater

September 2018- February 2014

- Planned and executed clinical trials including psychiatry, internal medicine, and neuroscience indications such as MMSE, MADRS, PANSS, YMRS, COSS, CADSS, ISI, CSSRS, BPRS, NSA, Cogstate, MCCB, CAPS-5, Cogstate, YMRS, MADRS, CGI-S, CGI-I, HAM-D, HAM-A, HVLT, and SCID

EDUCATION

Vocational Nursing (LVN)

American Career College — Degree Conferred: January 2006

TRAINING & CERTIFICATIONS

- **Good Clinical Practice (GCP)** — Completed May 2023
- **Columbia-Suicide Severity Rating Scale (C-SSRS)** — Completed June 2023

RESEARCH EXPERIENCE

- **Phases of Clinical Trials:** Phase I, Phase I/II, Phase II, Phase III, Phase IV
- **Therapeutic Areas:** Schizophrenia, Schizoaffective Disorder, Depression, Alzheimer's Disease, Anxiety, Pain Management, Parkinson's Disease, Oncology (Cutaneous T-cell Lymphoma, Metastatic Melanoma), Autoimmune Disorders (Rheumatoid Arthritis, Lupus), and more.

TECHNICAL SKILLS

- **Clinical Data Management Systems (CDMS)**
- **EHR & EMR Systems**

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- **Clinical Trial Management Software**
 - **Microsoft Office Suite (Excel, PowerPoint, Word)**
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KEY ACCOMPLISHMENTS

- Successfully led and scaled clinical research operations, managing large teams and complex trials across diverse therapeutic areas.
- Consistently met and exceeded financial targets, improving site revenue through effective business development and vendor relationships.
- Ensured successful IND submissions and regulatory compliance for multiple trials.

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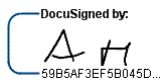
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Founder/CEO

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