FADI M. ABDEL

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Unique Dynamic biopharma executive with a unique blend of deep scientific expertise and strategic business acumen, honed over three decades in diverse settings—from academic research to Clinical Research Organizations and global leaders in drug and medical device development. Expertise rooted in oncology, with additional experience spanning cardiovascular, nephrology, gastroenterology, endocrinology, neurology, and infectious diseases.
Proven track record of success across critical areas, including high-performing team leadership, drug target identification and validation, business case development for novel therapies, and business development opportunity assessment. Demonstrated excellence in securing capital through private and public channels, navigating companies through successful IPOs, and translating preclinical science into human applications.
Extensive experience in designing and executing early clinical development programs, advancing molecules from First-in-Human studies to Proof-of-Concept, and leading regulatory submissions from IND applications to multiple successful NDAs. Known for accelerating trial timelines, reducing costs, and optimizing P&L through innovative strategies.
Driven by a steadfast commitment to building mission-focused organizations founded on transparency, trust, collaboration, and accountability.

KEY COMPETENCIES

Drug Target Identification & Validation	Early Clinical Drug Development	Biomarker Development
Translational Model Development	Clinical R&D Strategy	Strategic Project Management
Multidisciplinary Team Leadership	C-Suite/Stakeholder Communication	Cross-functional Collaboration
Contract negotiation/closings	IPO/Financing	Mergers & Acquisitions

PROFESSIONAL EXPERIENCE

SPERATUM BIOPHARMA, INC., Dover, DE 2024 - Present

Chief Development & Operations Officer

Currently leading strategic operations, innovation, and business development initiatives, reporting directly to the Chief Executive Officer. Focused on advancing three early-stage molecules through clinical development while managing comprehensive market analyses, assessing regulatory success probabilities, and negotiating critical contracts to position the company for long-term success. Current activities includes the following:

- Leadership in Clinical Development and Operations: Hired to lead the clinical development and operations teams, working closely with senior management, including the Board of Directors and scientific advisors, to drive programs forward and achieve key milestones.
- Early Clinical Development: Spearheading early clinical development across various therapeutic areas, with a focus on rare diseases in oncology and virology, ensuring innovative approaches to program advancement.
- Translational Medicine Expertise: Providing leadership in translational medicine by leveraging oligonucleotide-based therapies, including miRNA and siRNA, for drug target identification and biomarker-driven strategies to enhance therapeutic precision.
- Portfolio Expansion and Strategic Execution: Overseeing departmental efforts to expand the company's drug portfolio by identifying novel targets, while developing and executing clinical translational strategies from First-in-Human (FIH) studies to Proof-of-Concept (POC).
- Regulatory and Stakeholder Engagement: Co-authoring regulatory documents, representing the clinical function in agency meetings, and collaborating with the Board of Directors and external stakeholders to align strategic goals and maintain transparency.

ALTO NEUROSCIENCE, INC., Mountain View, CA 2021 - 2024

Senior Vice President, Innovation + Decentralized Operations

Reporting directly to the Chief Medical Officer, I was instrumental in advancing four early-stage molecules from preclinical development to Phase 2b, while scaling the organization and building the infrastructure needed to support rapid growth. I led innovations in decentralized clinical trials, enhanced operational capacity, and successfully established Alto Neuroscience as a

leader in precision psychiatry, culminating in multiple funding rounds and a successful IPO within three years. Key responsibilities included:

- Clinical Development Leadership: Acquired and advanced four molecules from Phase 0-I through clinical development to Phase 2b while developing Phase III and commercial strategies. Successfully completed 4 observational trials, 4 Phase I trials, 4 Phase II trials, and 1 Phase IIb trial, delivering milestones on time and within budget. Designed and implemented decentralized strategies for clinical trials, significantly improving patient recruitment and operational efficiency.
- Organizational Scaling and Team Leadership: Expanded the company from 12 to 56 employees, bringing in managerial and director-level talent to drive key initiatives. Grew the Alto Investigator Databank from 73 to 3,600 nationwide investigators, creating a robust network to support clinical programs. Directed cross-functional teams, including Clinical Operations, Business Development, Software Engineering, R&D, and Patient Engagement.
- Innovation and Strategic Initiatives: Led the creation of the Alto Mental Health Research Registry, recruiting over 100,000 participants to drive AI-powered mental health advancements. Developed an AI-driven mental health assistant and integrated digital biomarkers into clinical programs to enhance precision psychiatry. Innovated operational and product strategies balancing user needs, clinical requirements, and regulatory compliance.
- Regulatory and Clinical Operations Excellence: Co-authored regulatory documents and engaged with the FDA Breakthrough Devices Program for marketing authorizations. Managed clinical budgets of up to $25M, executing three fully virtual Phase 2b trials in-house without a CRO. Established a Mental Health Research Registry and R&D platform with 75,000 volunteers in under two years.
- IPO Leadership and Business Development: Played a key role in the company's successful IPO in 2024, raising significant capital through public and follow-on offerings. Negotiated critical contracts and strategic partnerships to drive growth and ensure operational success in multinational clinical trials.

JANSSEN PHARMACEUTICALS (JOHNSON & JOHNSON). Titusville, NJ 2016 - 2021

Sr. Director, Business Support Leader (2019-2021) & Director, Global Program Leader (2016-2019)

Oversaw strategic operational planning and innovation for global clinical trials, including spearheading the Trials2You initiative, which integrated decentralized clinical trials and Direct-to-Patient opportunities into Janssen's clinical trial strategy. Led multi-functional teams across multiple regions, managed high-priority compounds, and ensured alignment with corporate objectives, regulatory compliance, and operational excellence. Key contributions and responsibilities included:

- Strategic Planning and Innovation: Served as global operations & development clinical lead for large- and small-molecule compounds to treat mental health diseases within the neuroscience space. Directed the Trials2You initiative, introducing decentralized clinical trials and Direct-to-Patient opportunities into Janssen's operational strategy. Developed and implemented long-term strategies aligned with J&J Innovative Medicines R&D and Global Development objectives.
- Global Clinical Trial Leadership: Managed the execution of mega-compounds such as Tremfya®, Spravato®, and Seltorexant through Phase I-III trials, from early development to commercialization. Oversaw multi-functional departments spanning North and South America, Europe, APAC, the Middle East, and Australia, ensuring adherence to timelines, budgets, and regulatory standards.
- Operational and Compliance Excellence: Ensured the planning, execution, and monitoring of clinical trials met ICH-GCP, SOP, and regulatory requirements, maintaining inspection readiness. Provided quality oversight, timely escalation of issues, and compliance with organizational policies and financial processes. Interpreted and integrated preclinical/clinical data into clinical protocols and development plans and developed model-based approach to estimating phase I-III clinical outcomes from POC/RWE data to enable rapid decision-making for the neuroscience global portfolio.
- Team Leadership and Development: Managed and developed global teams, including goal setting, performance evaluations, and talent development initiatives. Grew and trained staff, fostering a culture of collaboration and continuous improvement.
- Process Innovation and Relationship Building: Improved clinical trial management processes and standards, leading their global rollout. Built strong partnerships with Global Development, Local Operating Companies, and Medical Affairs to advance organizational goals and enhance trial success.

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NOVARTIS PHARMACEUTICALS, INC./SANDOZ BIOPHARMACEUTICALS, East Hanover, NJ 2002 - 2016

Director, Global Clinical Development & Operations

Contributed to the successful execution of global clinical trials across multiple therapeutic areas, ensuring they were delivered on schedule, within budget, and in compliance with quality standards. My leadership drove operational excellence through process improvement, risk mitigation, and cross-functional collaboration, while building and expanding the global biosimilar development department in the U.S. Key contributions and responsibilities included:

- Global Clinical Trial Leadership: Directed all aspects of global clinical trials, from start-up to close-out, across therapeutic areas including immunology, cardiology, oncology, respiratory, ophthalmology, and infectious diseases. Managed study timelines, budgets, and quality metrics, ensuring compliance with SOPs and regulatory standards. Led trial activities as a core member of the Clinical Trial Team, including site selection, protocol development, CRF design, and informed consent documentation.
- Operational Excellence and Process Improvement: Drove process improvements and implemented knowledge-sharing strategies to optimize clinical trial operations. Ensured audit readiness and proper documentation of Trial Master Files, while addressing site management and final drug accountability. Proactively developed contingency and risk mitigation plans to address operational challenges.
- Team Building and Departmental Growth: Established and expanded the U.S. global development and operational department for the biosimilar organization, growing the team from inception to 50 employees. Recruited and mentored clinical trial leaders, managers, and research associates, fostering a high-performance team culture.
- Therapeutic Expertise and Product Development: Delivered operational excellence across trials for key products such as Cosentyx® (immunology), Diovan® (cardiology), Lucentis® (ophthalmology), Kymriah® (oncology), and Xolair® (respiratory). Oversaw technical reporting, adverse event management, and marketing sample distribution for assigned products.
- Compliance and Knowledge Sharing: Championed adherence to clinical standards, proactively educating teams and implementing best practices. Facilitated knowledge sharing to enhance clinical operations and support trial success.

PRA INTERNATIONAL (FORMERLY CROMEDICA, INC.), Victoria, BC Canada 2000 - 2002

Associate Director, Clinical Trial Management

Led Clinical Trial Management (CRA Development) and Alliance Management spearheading strategy development and implementation.

1995-2000 ADDITIONAL WORK EXPERIENCE AVAILABLE UPON REQUEST

PART-TIME CONSULTING HIGHLIGHTS

Executive Senior Scientific Advisor for SAMA THERAPEUTICS 2024 - present

As an Executive Senior Scientific Advisor for this pioneering AI biotechnology company specializing in biowearables and sensors, I play a critical role in shaping the development and strategic direction of innovative technologies. My responsibilities include evaluating biotechnology protocols, authoring and refining ICH-GCP/GMP-compliant protocols, and conducting comprehensive assessments of investment opportunities. This involves performing due diligence across scientific, medical, and financial dimensions, including feasibility analysis, medical need assessment, and financial modeling, to support the advancement of new medical devices and drug compounds.

Executive Board Member & Advisor for DELVE HEALTH 2024 - present

As an Executive Board Member and Advisor for Delve Health, I provide strategic guidance and oversight to this innovative company specializing in digital health solutions. My responsibilities include advising on the development and implementation of decentralized clinical trial platforms, ensuring alignment with regulatory standards, and driving the adoption of patient-centric technologies. I contribute to evaluating market trends, identifying growth opportunities, and shaping long-term business strategies. Additionally, I support the team in optimizing operational efficiencies, fostering partnerships, and enhancing their digital solutions to address evolving healthcare needs.

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KEY TRANSACTIONS AND ACHIEVEMENTS

Successful IPO: Led the IPO of Alto Neuroscience, Inc. (NYSE: ANRO) on February 2, 2024.
Funding Leadership: Secured $5M+ in Series B and C funding from organizations such as Eli Lilly, InVivium Capital, Alexandria Venture, and Alpha Wave Global.
Asset Acquisition & Collaborations: Managed major acquisitions and collaborations, including:

- $13M Phase I asset acquisition (MEDRx Co. Ltd)
- $35M+ drug development collaboration (Sanofi-Novartis)
- $125M acquisition by Amgen (Tularik)

Clinical & Diagnostic Evaluations: Directed negotiations for clinical tools, biowearables, and decentralized platforms with partners like Google, Fitbit, LabCorp, and Quest Diagnostics.
Licensing & Biomarker Expertise: Oversaw multiple biomarker deals, IP licenses, and strategic partnerships, driving innovation and growth.
Postdoctoral Research Fellow – Vanderbilt University
Designed and conducted in vitro and animal studies on CM-101, an anti-neovascularization drug for solid tumors. Focused on signal transduction pathways and their physiological implications, advancing knowledge of tumor vascularization and its disruption through targeted therapies.

EDUCATION & CERTIFICATION

Doctor of Medicine Degree, 2000
VANDERBILT UNIVERSITY, Nashville, Tennessee

Bachelor of Science in Biochemistry, 1995
DAVID LIPSCOMB UNIVERSITY – Nashville, Tennessee

PROFESSIONAL AFFILIATIONS

American Association for Cancer Research
Licensing Executive Society
Certified Project Management Professional
Lean Six Sigma Yellow Belt – Novartis, January 2008
Certified Member of the Association of Clinical Research Professionals