Julie VanOrsdel Daves, MSHS, CCRP

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Consulting: www.jvdpharma.com

Senior VP / VP, Clinical Development Operations & Outsourcing

Fractional Clinical Development Operations Leadership | Clinical Operations Program Strategy & Execution, Phase 1–4 | CRO/Vendor Selection & Contracting | Vendor Oversight & Quality Assurance | Strategic Relationships | Budgeting & Forecasting | Timelines & Planning | Global Expertise | KOL Relationships

With nearly 27 years of combined sponsor and CRO drug development experience, I am a multifunctional strategic and hands-on leader in clinical development operations and outsourcing, with a proven track record of delivering high-quality, cost-effective clinical trials across multiple therapeutic areas and phases. I have led global teams and vendor relationships, exceeded aggressive timelines and budgets, and ensured compliance with ICH/GCP standards while contributing to the strategic planning and execution of clinical programs. As a Certified Clinical Research Professional, I am passionate about advancing the science and practice of clinical research and improving patient outcomes.

THERAPEUTIC AREAS

Cardiovascular/Renal: LMNA-related Dilated Cardiomyopathy, Calciphylaxis (CUA), PAD, ESRD | **Dermatology**: Wound Healing, Scar Development, Calciphylaxis, Chronic Spontaneous Urticaria | **Endocrine**: Hypoparathyroidism | **Hematology/Oncology**: Relapsed/Refractory Multiple Myeloma, CTCL | **Infectious Disease**: Influenza (Antiviral) | **Neurology**: Becker & Duchenne MD, Acute Ischemic Stroke, Alzheimer's, Parkinson's | **Normal Healthy Volunteers**: Phase 1, FIH, SAD, MAD, FE, PK studies | **Oncology**: Advanced Solid Tumor, Low-grade Serous Ovarian/Fallopian Tube/Peritoneal Cancer, Metastatic CRC | **Ophthalmology**: AMD, Dry Eye | **Pain/Inflammation**: Osteoarthritis of the Knee | **Gastroenterology/GI**: Inflammatory Bowel Disease | **Respiratory**: Asthma

PROFESSIONAL CLINICAL DEVELOPMENT OPERATIONS EXPERIENCE

President & Principal Consultant, JVD Pharma Consulting, LLC

2/2018 – Present

- Fully insured, flexible, hands-on consultant providing clinical operations leadership, strategy and execution, outsourcing/contract negotiation, monitoring, medical writing, and data review across sponsor and CRO engagements. Representative projects listed on consulting website. Note: this practice has run continuously in parallel to the appointments below.

Senior Vice President, Global Head of Clinical Development Operations, DiaMedica Therapeutics, Inc.

06/2022 – 04/2024

- Joined the organization while it was on FDA clinical hold; key contributor to removal of the hold in June 2022 – personally ran a PK and safety clinical trial outside the IND in APAC, providing key human data for the hold-removal package
- Restarted the Phase 2/3 adaptive trial in Acute Ischemic Stroke following the lift of the clinical hold
- Terminated the relationship with the previous CRO, selected a new CRO and vendor network, and negotiated a strategic agreement with the CRO's parent company saving over $8M in the first year alone
- Wrote two protocol amendments incorporating FDA and investigator feedback; had the first site re-opened within 5 weeks of the FDA's 30-day protocol review clock
- Restructured the clinical development operations team and adjusted study management titles/career ladder, with extensive training and zero turnover since joining
- Hired permanent heads of Data Management, Pharmacovigilance, and Clinical Supplies, plus consultants spanning regulatory operations/strategy, medical writing, clinical contracts/budgets/payments, GxP QA, clinical pharmacology, ex-FDA CMC regulatory, and biostatistics/adaptive trial strategy
- Completely revamped all clinical development operations SOPs and departmental infrastructure, including CAPA development for prior work; engaged a Senior CRA SWAT team and locked all previous trial databases within 9 months of hire; transitioned the safety database into Veeva

Vice President, Global Head of Clinical Operations, Sanifit Therapeutics, S.A.

09/2021 – 08/2022

- Provided clinical operations leadership through due diligence and acquisition activities as Sanifit was acquired by Vifor Pharma (closed January 2022), with Vifor/Sanifit subsequently acquired by CSL in 2H 2022; maintained consultant status post-close
- Restructured vendor governance and engaged directly with CRO leadership, completing the initial enrollment target on a global Phase 3 registrational study 2.5 months early despite COVID-related challenges
- Set up a rigorous data cleaning process, including remediation of monitoring data missed during the pandemic
- Initiated startup, protocol development, and CRO/vendor selection for a second global Phase 3 study at the time of acquisition, and contributed to resourcing/insourcing/outsourcing planning and a $100MM+ trial budget for the combined organization

Vice President, Outsourcing & Vendor Management (05/2021–08/2021); Executive Director and Head of Clinical Operations (04/2020–05/2021), Edgewise Therapeutics, Inc.; Boulder, Colorado

04/2020 – 08/2021

- Built the clinical operations function from the ground up – strategy, trial execution, staffing, and the corporate Quality Management System including all SOPs, working instructions, and guidelines
- Led vendor contract proposal/budget review and final selection decisions cross-functionally with finance and legal; developed CRO RFPs and managed bid defenses
- Owned drafting and finalization of clinical protocols, study documents, MSAs, work orders, change orders, and consulting agreements; drove vendor governance meetings on KPIs, budgets, staffing, and deliverables
- Achieved RFP through kickoff in under 4 weeks for a new unit, contributed to a successful IND filing, and significantly beat timeline and data goals despite COVID challenges – providing strong clinical data in support of a successful IPO
- Departed when the incoming CMO brought her own clinical operations and outsourcing leadership team

Senior Director, Clinical Operations & Head of Outsourcing, miRagen Therapeutics, Inc.; Boulder, Colorado

02/2018 – 04/2020

- Initially contracted for short-term clinical operations support, protocol design/medical writing, and site visits; subsequently hired full time. Led business, financial, and operational aspects of all clinical outsourcing relationships
- Served as Clinical Operations Program Director for one of three lead assets, and Co-Lead on two global Phase 2 Oncology trials including CRO/vendor management and in-house activities
- Member of the company's Operating Committee and developer of essential infrastructure processes (e.g., SOPs); remained through an 80% staff reduction in 2019 to support transition before departing

Global Head / Senior Director, Clinical Vendor Management (02/2016–02/2018); Director, Clinical Operations (11/2015–02/2016), Chiltern International Inc.; North Carolina

11/2015 – 02/2018

- Accountable for corporate-level relationships with 330+ approved/active and 500+ inactive vendors; managed 70 direct reports across Vendor Management, Clinical Supplies/IMP, Medical Monitoring Call Center, and Study Start-Up Support
- Led 50+ new vendor capability evaluations per year and strategic vendor partnerships across Oncology, Biopharma, Device, and Clinical Analytics segments; closely collaborated with Legal on vendor MSAs
- Drove vendor oversight process improvements and SOP revisions for ICH E6(R2); resulting department processes were audited by a regulatory agency in 2016 with zero findings. Served as executive escalation point on 100+ clinical trials per year. Stayed on through LabCorp/Covance acquisition (Sept 2017) for integration before departing

Director (10/2014–11/2015); Associate Director (10/2011–10/2014); Principal Clinical Research Manager (01/2011–10/2011), Array Biopharma, Inc.; North Carolina & Colorado

01/2011 – 11/2015

- Transitioned 40 global Novartis studies and 1,400+ vendor/investigator contracts into Array, leading insourcing and outsourcing for clinical operations; fully responsible for all clinical trial budgets and outsourcing strategy.

Managed operational aspects of programs including encorafenib and binimetinib (BRAFTOVI™ and MEKTOVI™), FDA-approved in 2018, and developed strategic/preferred partnerships with performance-based pricing

- Reduced program expenses by $22M over 12 months through vendor selection and agreement negotiations, achieved a 24% reduction in patient grants via benchmarking, and mobilized a cross-departmental team to lock an EDC database 90% faster than prior practice

Senior Manager, Clinical Development, BioCryst Pharmaceuticals, Inc.; North Carolina

04/2007 – 01/2011

- Clinical operations lead for a high-intensity global pandemic parenteral antiviral program (300+ sites, 37 countries); following a $180M+ HHS/BARDA award, led extensive outsourcing and vendor management including risk-share CRO contract language enabling the program to exceed start-up timelines. Managed FTEs/consultants with rapid seasonal scaling, exceeded First Patient In and database lock timelines, handled Emergency IND investigator requests, and contributed to CSR/SOP medical writing

Study Manager & Senior CRA (07/2006–04/2007); Clinical Project Manager (02/2005–07/2006); CRA (12/2002–02/2005), Cellgate Pharmaceuticals, Inc. / Inveresk-Charles River Clinical/Kendle; North Carolina

12/2002 – 04/2007

- Independently managed and monitored international and first-in-man studies under funding constraints, selecting and managing regional CROs across North America, Latin America, and Eastern Europe. PM for two global studies ($30M direct / $20M indirect budgets) including monitoring oversight; led international patient recruitment/retention strategy and founded a new In-House Clinical Support Center (protocol helpdesk, CRA support, patient call center)

EDUCATION

- **Executive Program, Artificial Intelligence in Pharma and Biotech** – MIT Sloan School of Management (in progress, completion July 2026)
- **MSHS, Health Sciences, Clinical Research Concentration** – The George Washington University School of Medicine & Health Sciences. Received two scholarships for Clinical Development Plan creation & Outsourcing Modeling
- **BS (cum laude), Zoology, Genetics Concentration** – North Carolina State University. Symphonic Musician; year-long exchange student in Applied Physiology, UK

AWARDS

- Team Leader, Gold Medal (First Place), "Clinical Research Team of the Year," PharmaTimes US Competition, 2016
- CEO's discretionary "Award of Excellence" for global study execution, three consecutive years
- Discretionary "Critical Employee" stock awards for team leadership, six consecutive years

BOARD APPOINTMENTS

- **Advisory Board Member, DataCompass** (08/2024 – Present) – Start-up service provider focused on AI-built software for global clinical supplies management, resource/labor optimization, and custom AI tools for clinical operations at CROs and biotechs
- **Board Member, Assentia** (02/2023 – 08/2024) – Global clinical trials technology company/FSP focused on expediting site/vendor contracting, budgeting, and payments; company successfully acquired August 2024, concluding board responsibilities post-deal

REPRESENTATIVE VENDOR OVERSIGHT CATEGORIES

Advertising; Archivists & Document/Data Storage; Bioanalytical, Biomarker, Central, Companion Diagnostic, Core, PK & Specialty Labs; Biologics Couriers; Biostatistics FSP; Central Cardiac Safety; Central Efficacy Reviews; Central Imaging & Reading Centers (e.g., Ophthalmology); Central IRBs; Central Photography; Clinical Trial Insurance; CMC Consultants; Comparator Sourcing; Consultants; Contract CRAs and PMs; CRO Oversight Monitoring FSP; Full Service & Regional CROs; Customs Brokers; Data Management FSPs; Data Monitoring Committee; Disease Surveillance/Epidemiology; Drug Depots/Labeling; Drug Import/Export; Early Phase Units; eCTD Publishing; eCOA/ePRO; Endpoint Adjudication; Specialized Equipment Sourcing; eTMF; Feasibility Vendors; GDPR Consultants; Home Nursing/Infusion FSP; Investigator Meeting Planners; Investigator Sponsored Trials (IST); IRT/IXRS/RTSM; Legal/Investigator Contracting & Payments FSP; Local Legal Representation (EU & AUS); Linguistic Validation; Medical Writing FSP; Patient Advocacy Group Partnerships; Patient Concierge/Travel FSP; Patient Expense

Reimbursement; Patient Recruitment & Retention FSP; QA Auditors; Safety/Pharmacovigilance FSPs & Databases; SMOs; Spirometry; Training Video Production for Investigators; Translators; Web Design

GLOBAL EXPERIENCE

Argentina, Australia, Austria, Belgium, Bosnia, Brazil, Bulgaria, Canada, Chile, China (Start-Up Only), Croatia, Czech Republic, Egypt, France, Georgia (Start-Up Only), Germany, Hungary, India (Start-Up Only), Israel, Italy, Latvia, Lebanon, Mexico, Netherlands, New Zealand, Peru, Poland, Russia, Serbia, Slovak Republic, South Africa, Spain, UK, Ukraine, US

PROFESSIONAL ORGANIZATIONS & CONFERENCES

Summit for Clinical Operations Executives (Outsourcing Panel & Study Start-Up Roundtable Facilitator); Linking Leaders (Clinical Outsourcing Roundtable); Partnerships in Clinical Trials; MAGI (Speaker & Session Chair, "Clinical Project Management & Communication" and "Hidden Costs for Sites and Sponsors"); ClinBiz Panelist ("Reducing and Controlling Clinical Trial Costs," "Innovation in Study Startup"), Panel Leader ("Clinical Operations Pain Points – Addressed"), Presenter ("Vendor Selection, Contracting and Oversight for Biotech"); Outsourcing in Clinical Trials East (Speaker, "Third Party Vendor Management"); ACRP, DIA, SoCRA, Marcus Evans Evolutions Summit, Association for Research in Vision and Ophthalmology, Interscience Conference on Antimicrobial Agents and Chemotherapy, American Academy of Ophthalmology, Prevent Blindness America, American Pain Society, American Society of Hematology, American College of Rheumatology, American Society of Clinical Oncology, World Stroke Congress, International Stroke Conference, Northeast Cerebrovascular Consortium Summit, STAIR, American Academy of Neurology, European Stroke Organisation Conference, Society of NeuroInterventional Surgery (Faculty, "Prioritizing Safety in Clinical Trials: The Impact of Culture on Operational Success"), Catalyst Flex Webinar, Society of Vascular and Interventional Neurology, Web Panelist ("AI in Clinical Trial Operations"), BIO

TRAINING

Leadership; Technical Public Speaking; Essential Skills for Personnel Managers; Clinical Research Financial Management; Research Proposal Development & Negotiation; Best Recruitment Practices; Clinical Research Foundation; Project Manager Seminars; Effective Line Management; Technical & Medical Writing in Clinical Research; Mastering Business Development; ICH/GCP; Biostatistics for Clinical Researchers; Partnership with Human Subjects; Health Care Enterprise Management; Critical Data Analysis in Clinical Research; Outsourcing Models and Techniques for Clinical Programs; Clinical Monitoring Management and Methods; Contracts for Non-Lawyers; prior Certified Clinical Research Professional (CCRP) certification

PUBLICATION

Kivitz, A., Christensen, S., Agaiby, J., Spierings, E., Daves, J., Aitchison, R., Miller, S., Witt, K., & Gimbel, J. (2012). A Randomized, Placebo-Controlled Phase 2 Study of ARRY-797 in Patients with Osteoarthritis Pain Refractory to NSAID Treatment Showed Statistically Significant Improvements in WOMAC Pain and in Biomarkers of Bone and Cartilage Degradation. American College of Rheumatology Annual Meeting Poster Presentation, November 2012.

Specific professional and personal references can be provided on request.