JULIE VANORSDEL DAVES, MSHS, CCRP

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SENIOR CLINICAL OPERATIONS & OUTSOURCING PROFESSIONAL

Clinical Operations Program Strategy & Execution in Phase 1 thru Phase 4 | CRO/Vendor Selection & Contracting | Vendor Oversight & Quality Assurance | Strategic Relationships | Budgeting & Forecasting | Cross-Functional Collaboration & Leadership | Timelines & Planning | Global Expertise | KOL Relationships

With 25 years of combined sponsor and CRO drug development experience, I am a multifunctional strategic and hands-on leader in clinical development operations and outsourcing. I have a proven track record of delivering high-quality, impactful, and cost-effective clinical trials across multiple therapeutic areas and phases. I have successfully managed global teams, vendors, and resources, exceeded aggressive timelines and budgets, and ensuring compliance with ICH/GCP standards. I have also contributed to the strategic planning, execution, and analysis of clinical programs, leveraging my expertise in clinical study management, timeline management, and team leadership. As a Certified Clinical Research Professional and a board member, 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), Peripheral Arterial Disease (PAD), End Stage Renal Disease (ESRD)
- **Dermatology:** Wound Healing, Scar Development, Calciphylaxis
- **Hematology/Oncology:** Relapsed/Refractory Multiple Myeloma, CTCL
- **Infectious Disease:** Uncomplicated, and Hospitalized Influenza (Antiviral, not Vaccine)
- **Neurology:** Becker & Duchenne Muscular Dystrophy, Acute Ischemic Stroke
- **Normal Healthy Volunteers:** Phase 1, First in Human, Differing Formulations, SAD, MAD, PK studies
- **Oncology:** Advanced Solid Tumor, Low-grade Serous Ovarian, Fallopian Tube or Peritoneal Cancer, Metastatic Colorectal Cancer
- **Ophthalmology:** Age-Related Macular Degeneration, Dry Eye
- **Pain/Inflammation:** Osteoarthritis of the Knee
- **Respiratory:** Asthma

PROFESSIONAL EXPERIENCE SUMMARY

JVD Pharma Consulting, LLC
President & Principal Consultant **2/2018 – Present**

- Fully insured, flexible, reliable consultant – clinical operations strategy and execution, outsourcing/contract negotiation, monitoring, medical writing, data review, etc.

Assentia Global
Board Member **02/2023 - Present**

Global clinical trials site/vendor contracting, budgeting and payments functional service provider.

DiaMedica Therapeutics, Inc.
Senior Vice President, Global Head of Clinical Development Operations **06/2022 – 04/2023**

(needed to leave organization when father was in hospice and subsequently passed away to attend to family matters)

- Joined organization when it was on FDA clinical hold; key contributor to removal of hold in June 2022 – personally ran a PK and safety clinical trial outside of the IND in APAC, which provided key human data for hold removal package
- Restarted Phase 2/3 adaptive trial in Acute Ischemic Stroke following the lift of the clinical hold
    - Terminated relationship with previous CRO and selected new CRO and vendors to support the trial; negotiated strategic agreement with CRO's parent company saving over $8M in first year alone
    - Wrote two protocol amendments (and other documents) to incorporate FDA and investigator feedback
    - Had first site re-opened within 5 weeks of FDA 30-day protocol review clock
- Restructured clinical development operations team
    - Adjusted sponsor study management titles / career ladder, and provided extensive training; zero turnover on my team since joining organization
    - Hired permanent heads of Data Management, Pharmacovigilance and Clinical Supplies
    - Hired consultants to manage: regulatory operations and strategy, medical writing, clinical contracts/budgets/payments, GXP QA consultant, clinical pharmacology, focused ex-FDA CMC regulatory consultant, statistics and adaptive trial strategy
- Completely revamped all clin dev ops SOPs and departmental infrastructure, including development of CAPAs for previous work
- Engaged a Sr. CRA SWAT team and locked all previous clinical trial databases within 9 months of hire
- Transitioned safety database into Veeva

Sanifit Therapeutics, S.A.
Vice President, Global Head of Clinical Operations **09/2021 – 08/2022**

- Acquisition of Sanifit by Vifor Pharma closed in January 2022; Vifor/Sanifit was acquired again by CSL in 2H 2022
- Served as clinical operations leadership through due diligence activities and in acquisition meetings and throughout planned consolidation activities and maintained consultant status after close
- Following assumption of this role, restructured vendor governance, met face to face with President of CRO and got very "hands on." Result: completed initial enrollment target on global Ph 3 registrational study 2.5 months early, despite COVID challenges
- Set up rigorous data cleaning process - including monitoring data missed during pandemic with CRO
- Began startup, protocol development, CRO and vendor selection activities for a 2nd global Ph 3 registrational study at the time of acquisition
- Post-acquisition, contributed to resourcing / insourcing / outsourcing planning of joint organization, and developed $100MM+ trial budget

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

- Departed company when new CMO decided to bring her previous clinical operations/outsourcing team and leadership with her when she was hired
- Built the clinical operations function from the ground up, including strategy, execution of trials, hiring staff, the corporate Quality Management System inclusive of all SOPs, working instructions and guidelines
- Work cross-functionally with all clinical trial functional areas, finance and legal to define, solicit and review vendor contract proposals and budgets, with final decisions on vendor selection
- Develop RFPs for CRO bids, liase with CROs to ensure proposals and bid defenses are accurate
- Own and drive the drafting, editing, and finalization process for clinical protocols and other study documents, MSAs, work orders, change orders, consulting agreements, etc.
- Drive vendor governance meetings to review key performance indicators, budgets, planning, staffing and deliverables.
- Contributed sections and strategies towards successfully filing an IND
- Achieved RFP, vendor selection, MSA and kick off meeting in less than 4 weeks, and tightened timelines with new unit to enable more data available for IPO

- Significantly beat timeline and data goals for opening and conducting clinical trials despite COVID challenges
- Provided strong clinical data in support of a successful IPO

miRagen Therapeutics, Inc.; Boulder, Colorado
Senior Director, Clinical Operations & Head of Outsourcing **02/2018 - 04/2020**

- Contracted for two months to provide **s**hort term clinical operations support, protocol design/medical writing, site visits. Was then hired full time by miRagen. Due to funding challenges, miRagen laid off 80% of its staff by end of 2019; I stayed on to help transition and then departed
- Clinical Outsourcing: Lead on business, financial, and operational aspects of all clinical operations relationships for the organization
- Clinical Operations Program Director for one of three lead assets. Managed all operational aspects of studies
- Clinical Operations Co-Lead on two global Phase 2 Oncology trials, including CRO and vendor management and all in house activities
- Leader and general member on company's Operating Committee, and developer of essential infrastructure processes and systems (e.g., SOPs)

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

- Chiltern was acquired by LabCorp/Covance in Sept 2017; I stayed on to provide leadership during integration and then departed
- Responsible for clinical operations study start up business and process optimization initiatives.
- Accountable for corporate-level relationships with 330+ approved and active vendors, and 500+ inactive vendors
- Managed 70 direct reports across 4 departments (Vendor Management, Clinical Supplies/IMP, Medical Monitoring Call Center, and Study Start Up Support)
- Closely collaborated with Legal to conceive and implement vendor Master Services Agreements
- Led new vendor capability evaluations (50+ per year), and accountable for strategic vendor partnerships across the Oncology, Biopharma, Device and Clinical Analytics business segments
- Managed vendor oversight process improvements and SOP revisions for ICH E6 r2 – following this, my department processes were audited by a regulatory agency in 2016 – zero findings (critical, major or minor)
- Served as executive escalation point for Project Managers and Project Directors, facilitating resolution of complex vendor issues on 100+ clinical trials per year

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

- Transitioned 40 global Novartis studies and 1,400+ vendor and investigator contracts into Array, leading both insource and outsource activities for clinical operations and clinical outsourcing
- Planned and managed all operational aspects of clinical trials within clinical programs. Encorafenib and binimetinib (BRAFTOVI™ and MEKTOVI™) were FDA approved in mid-2018.
- Developed strategic and preferred partnership relationships and implemented performance-based contract pricing
- Provided outsourcing strategy, sourcing, timeline and cost/cash flow modeling scenarios for existing and new indications/patient populations. Fully responsible for all clinical trial budgets
- Facilitated a trial conduct shift (following 20% reduction in force) from insourced to outsourced model
- Reduced company's program expenses by $22M over 12 months through tactical approaches in vendor selection and material agreement negotiations (optimization of fee rates, KPIs, unit costs, etc.)
- Achieved a 24% reduction in patient grants over prior agreements using benchmarking tools
- Mobilized cross-departmental team to lock EDC database 90% faster than had been done previously

- Led key organizational process improvement initiatives, including the development of process standards, policies and SOPs, departmental infrastructure and staffing

BioCryst Pharmaceuticals, Inc.; North Carolina
Senior Manager, Clinical Development **04/2007 – 01/2011**

- Clinical Operations lead accountable for high intensity, global pandemic parenteral antiviral program with multiple studies, 300+ sites in 37 countries
- After a $180M+ award from HHS/BARDA, I also led extensive outsourcing and vendor management activities
- Built in risk share language to the CRO contract prior to award enabling us to exceed start up timelines
- Handled Emergency IND drug request calls from investigators
- Line and functional management of FTEs and consultants, scaling up and down rapidly for seasonal indication
- Exceeded First Patient In and database lock timelines
- Medical writing responsibilities (CSR, SOPs, etc.)
- Participated on branding/marketing committee for asset

Cellgate Pharmaceuticals, Inc.; North Carolina
Study Manager & Senior Clinical Research Associate **07/2006 – 04/2007**

- Independently managed and monitored all aspects of international and first-in-man studies; with funding difficulties
- Selected and managed regional CROs (North America, Latin America and Eastern Europe)
- Responsible for certain medical writing components of the studies.

Inveresk/Charles River Clinical/Kendle; North Carolina
Clinical Project Manager **02/2005 – 07/2006**
Clinical Research Associate **12/2002 – 02/2005**

- PM for two global studies with $30M direct and $20M indirect budgets; PM role included monitoring oversight.
- Corporate lead on international patient recruitment and retention program strategy and execution.
- Field CRA on registrational multicenter trials.
- Formed and developed new "In House Clinical Support Center" department/profit center (e.g., protocol helpdesk, CRA support, patient call center, etc.).
- Business development responsibilities, proposal development and pricing.

EDUCATION

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
North Carolina State University
Genetics Concentration, Symphonic Musician, Year-Long Exchange Student in Applied Physiology in UK

AWARDS

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

REPRESENTATIVE VENDOR OVERSIGHT CATEGORIES

Advertising, Archivists and Document/Data Storage, Bioanalytical Labs, Biomarker Labs, Biologics Couriers, Biostatistics FSP, Central Cardiac Safety, Central Efficacy Reviews, Central Imaging, Central IRBs, Central Labs, Clinical Trial Insurance, CMC Consultants, Companion Diagnostic Labs, Comparator Sourcing, Consultants, Contract CRAs and PMs, Core Labs, CRO Oversight Monitoring FSP, Full Service CROs, Regional CROs, Customs Brokers, Data Management FSPs, Data Monitoring Committee, Disease Surveillance/Epidemiology, Drug Depots/Labeling, Drug Import/Export, Early Phase Units, eCTD Publishing, Electronic Clinical Assessments (eCOA), Electronic Patient Reported Outcomes (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 and Payments FSP, Local Legal Representation (EU and AUS), Linguistic Validation, Medical Writing FSP, Patient Advocacy Group Partnerships, Patient Concierge/Travel FSP, Patient Expenses Reimbursement, Patient Recruitment & Retention FSP, Central Photography, PK Labs, QA Auditors, Reading Centers (e.g., Ophthalmology), Regulatory Consultants, Safety/Pharmacovigilance FSPs and Databases, SMOs, Specialty Labs, 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 and Session Chair – "Clinical Project Management & Communication"), Session Chair – "Hidden Costs for Sites and Sponsors"), ClinBiz Panelist on "Reducing and Controlling Clinical Trial Costs," "Innovation in Study Startup," Panel Leader on "Clinical Operations Pain Points – Addressed", and Presenter "Vendor Selection, Contracting and Oversight for Biotech", Outsourcing in Clinical Trials East Speaker on "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 (Infectious Disease), 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, Northeast Cerebrovascular Consortium Summit

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 Writing, 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)

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

REFERENCES

Specific professional and personal references can be provided on request.

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