KATHRYN GAIL DAVIS, MBA

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CLINICAL OPERATIONS PROFESSIONAL SUMMARY

Over 20 years of clinical operations experience in the management of global multi-center clinical trials with thorough knowledge of GCP ICH guidelines. Broad exposure within several therapeutic areas such as Oncology, (breast, lung, renal cell carcinoma, pancreatic, prostate), Infectious disease, (COVID), vaccines, and central nervous system (CNS). Excellent ability to successfully lead cross-functional team, CRO and Central Laboratory management. Experience with timeline management, clinical trial budget management, problem identification and resolution. Ability to work independently, to execute strategies ensuring that clinical operational activities supporting clinical trial management are conducted effectively, efficiently, quality driven, and in compliance with all applicable regulations.

NOTED CAREER HIGHLIGHTS

Supported investigational products through their respective submission life cycle, ie, from investigational new drug/biologics to new drug application/biologics license application.

Clinical trials fully enrolled, completed on time and on budget through problem identification, resolution, oversight of outsourced clinical activities such as clinical research organization (CRO), management of cross-functional teams from first subject enrolled through completion of clinical study report, oversight of data safety boards, timeline management from study feasibility to study completion.

PROFESSIONAL EXPERIENCE

Global Clinical Operations Lead Consultant, Novavax Pharmaceuticals August 2021 – Dec. 2023

- Provided Clinical Operations leadership for 3 COVID vaccine studies (1 Phase 3 UK Study, 1 Phase 3 US study, 1 Phase 2 US and Australia) encompassing 100 sites, with approximately 16,000 subjects enrolled
- Provided Clinical Operational expertise and support to Novavax Core Study Team
- Collaborated extensively with QA, Legal, eTMF Specialists, Regulatory managers, Outsourcing, and internal labs
- Vendor Oversight (CRO, Specialty labs) for Study Maintenance and Study Close out
- Fulfilled the role as unblinded CPM for 5 Clinical Studies
- Review and approve site invoices, review, and approve CRO Change Orders/ Con Mods

Clinical Operations Lead Consultant, Kintor Pharmaceuticals, April 2021 – July 2021

- Provided Clinical Operations leadership Infectious Disease (COVID) vaccine Phase 2/3 study
- Collaborated with global clinical colleagues in providing Clinical Operational performance, expertise, and support
- CROs RFPs review and approval
- Provided Regulatory support for Study approval outside the US
- Vendor Oversight (CRO, Clinical Supplies, Central labs)

Global Clinical Operations Lead Consultant, Seqirus Sept 2020 – Feb. 2021

- Provided Clinical Operations leadership Infectious Disease vaccine Phase 2 study
- Collaborated with clinical colleagues to manage patient recruitment and vendor Oversight

Clinical Operations Consultant, Magenta Therapeutics, Cambridge, MA Dec. 2019 – June 2020

- Provided clinical project management of a Phase 2 Rare disease (Gene Therapy) study
- Collaborated with clinical colleagues in Patient recruitment, vendor Oversight (primary contact), CRO management (primary contact), Informed Consent review and approval

Clinical Operations Consultant, Tarveda Therapeutics, Watertown, MA Feb.2019 – Sept 2019

- Provided clinical management of a Phase 1/2a Oncology (solid tumor) Clinical Trial in- patient study
- Provided CRO oversight/management
- Collaborate with internal supply team to manage Investigator Product supply/resupply
- Vendor Management - CRO and Central lab
- Reviewed study related plans, including reviewing monitoring reports, and project team minutes

Sr Clinical Operations Lead, Radius Pharmaceutical, Waltham, MA Sept. 2017-Feb. 2019

- provided Clinical Operations management to a phase 1 Breast Cancer studies, involved in study start-up/initiation, and maintenance to ensure quality and timely execution of clinical trial
- CROs RFP review with cross functional team
- Managed study timelines
- Managed 3 phase 1 Breast Cancer studies, involved in study maintenance and close-out, focused on patient engagement efforts, patient recruitment and retention in collaboration with CRO
- Managed vendors - CRO, IVRS, Central Laboratory, imaging, Cardiac and PK (primary contact)
- Reviewed regulatory documents for initial drug supply to clinical sites
- Collaborated closely with Data Management, Biostats, and Regulatory to oversee query resolution and protocol deviation management
- Manage Cross Functional Team
- Mentored Junior staff assigned to Clinical Trial
- Reviewed data listings, patient profiles and SAE reports

Consultant, Clinical Trials/Clinical Operations Lead- Merck, New Jersey Nov 2015 – Sept. 2017

- Provided Clinical Operations Management to a phase I (solid tumor) Oncology global clinical trial – Clinical Operations focus
- Lead and directed cross functional team in key study planning, development, and execution elements (e.g., data management and regulatory) deliverables, protocol level plans/timelines, country/site selection, Investigator Meeting planning.
- Provided training to CRO, Central lab, IVRS, and CRA training
- Successfully managed external vendors (Central labs, IVRS - Subject Randomization vendor)
- Facilitated and collaborate with key internal/external stakeholders in support of clinical trial objectives
- Focus on patient recruitment

Consultant, Head of Clinical Operations, Accellient Partners, Waltham, MA July 2014 – June 2015

- As Head of Clinical Operations provide clinical operations-clinical project management expertise for phase I/II CNS (movement disorders, Tardive dyskinesis) clinical trials
- Work with CEO to champion Clinical Operational excellence, Provided Clinical Operational expertise
- Instrumental in the management of the assigned CRO
- Implemented electronic data system in collaboration with CRO and eVendor
- Managed eVendor, ensured TMF is audit ready, and responsible for reviewing monitoring reports

EDUCATION

Masters of Business Administration, California Coast University, Santa Ana, CA

Bachelor of Science, Biology, Greensboro College, Greensboro, NC

Volunteer Services

Pro Bono/Healthcare Businesswomen's Association (Volunteer) **March 2010 - April 2014**

- Marketing/ Social media event posting for Healthcare Businesswomen's Association (HBA)
    - Chairperson, HBA Communication Marketing Sub-Committee
    - Chairperson, HBA Editorial Marketing Sub-Committee

Board Member, Community Day Center of Waltham (non-profit organization) April 2009 – Sept 2015

- Successfully liaised with the executive director to provide leadership and fundraising strategies
- Successfully collaborate and partner with other members of the board to set strategies regarding the vision, mission, and goals of the organization