KATHRYN GAIL DAVIS, MBA

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CLINICAL OPERATIONS PROFESSIONAL SUMMARY

Over 19 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 teams, 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, i.e., from investigational new drug/biologics to new drug application/biologics license application.

Clinical trials from study initiation to fully enrolled, database lock 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 4 COVID vaccine studies (1 Phase 3 UK Study, 1 Phase 3 US study (from site selection to study initiation), 1 Phase 2 US and Australia) encompassing one hundred sites, with approximately 16,000 subjects enrolled in the Phase 3 clinical trials
- Protocol review, ICF review and approval, protocol deviation review
- Worked with data management (CRO and Novavax) to lock database, and with medical writing to complete the Clinical Study reports
- Unblinded CPM for 5 Phase 2 and randomized, placebo controlled clinical studies
- Provided Clinical Operational expertise and support to Novavax Core/cross functional Study Teams
- Collaborated extensively with QA, Legal, eTMF Specialists, Regulatory, Outsourcing, and clinical supplies
- Vendor Oversight (CRO, Specialty labs) for Study Maintenance and Study Close out
- 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
- Performed site selection, study initiation in the US and outside of the US
- 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 of study start-up from site selection, investigator meeting planning/delivery, study initiation for an Infectious Disease vaccine Phase 2 study
- Collaborated with clinical colleagues to manage patient recruitment and provide 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) pediatric study
- Collaborated with clinical colleagues in patient recruitment, vendor Oversight (primary contact), CRO management (primary contact), ICF 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
- Study started as Open Label, at Phase 2a, study was level Placebo control
- 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 I Breast Cancer study, involved in RFP/Bid Defense, study start-up/initiation, and maintenance to ensure quality and timely execution of clinical trial
- Managed 3 Phase I Breast Cancer studies, involved in study maintenance and close-out, focused on patient engagement efforts, patient recruitment and retention in collaboration with CRO
- Managed study timelines
- 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
- Managed 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
- 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 study 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 provided 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, provided TMF oversight, monitoring report review

Consultant, Study Lead Idenix Pharmaceuticals, Cambridge, MA
February 2014 - July 2014

- Managed a Phase I ID global clinical trial in collaboration with the CRO
- Managed/lead cross functional team meetings, safety meetings and ad-hoc meetings as necessary
- Managed the review and finalization of Informed Consent forms
- Timeline management in collaboration with the CRO
- Collaborated closely with regulatory, clinical supplies, and managed external vendors

Audit Readiness, Genzyme (a Sanofi Co.), Cambridge, MA
April 2012 - December 2012

- Effectively communicated with senior management to provide status updates regarding inspection activities
- Focused on GCP-ICH guidelines
- Managed clinical trial master files
- Assisted in the leadership of pre-approval inspection readiness activities for Phase 3 MS clinical studies
- Assisting in the implementation and management of mock FDA inspection
- Provided mentorship to develop junior staff

Previous Oncology Experience (Phase 1-3)

- Bristol Myers Squibb (phase 1-all tumor types)
- Wyeth/Pfizer (Breast cancer)
- Therion Biologics (Prostate, Pancreatic cancer)
- ArQule (Renal cell carcinoma) Pediatric Study

EDUCATION

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

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