KATHRYN GAIL DAVIS, MBA

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CLINICAL OPERATIONS PROFESSIONAL

Strategic, tactical and hand-on experience in the management of global multi-center clinical trials with thorough knowledge of GCP ICH guidelines. Primary therapeutic area experience is oncology; tumor types include breast, lung, renal cell carcinoma, pancreatic, prostate. Other therapeutic area/disease types, combination drug, oncology vaccine, hemophilia, asthma, and CNS. Excellent ability to successfully lead cross-functional teams including 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 operations activities supporting clinical trial management are conducted effectively, efficiently, quality driven, and in compliance with all applicable regulations.

ACCOMPLISHMENTS

- Instrumental in the leadership and execution of proof of concept, phase 1, 2, 3 and 4 global multi-center clinical trials
- Assisted in bringing 4 investigational products from IND to NDA/BLA submission at Bristol Myers Squibb, Genetics Institute, and GI/Wyeth
- Managed and assisted in authoring clinical protocol, clinical section of the investigator brochure, development and review of Final Study Report , as well as development and review of the clinical section of the IND Safety Report and SAE/AE narratives developed
- Collaborated/Managed vendors such as, CROs, central laboratories and EDC, as well as, had responsibility for Clinical Operational planning and performance. In addition, reviewed and had oversight regarding budgets, forecasts, and accruals for clinical studies
- Successfully provided timeline management and budget management from study feasibility to study completion
- Clinical Trial Management, Management of cross functional teams (regulatory, legal, pre-clinical, data management, marketing, business development) from clinical protocol development through database lock

PROFESSIONAL EXPERIENCE

Consultant, 2009 – Present

Global Clinical Operations Lead Consultant, Seqirus, Remote **September 2020 – February 2021**

Worked on an Infectious Disease vaccine Phase 2 study

- Provided Clinical Operational performance, expertise and support
- Collaborated with clinical colleagues in Patient recruitment
- Responsible for Vendor Oversight
- Developed Study Newsletter
- Countries: UK, Germany, Italy, France, Philippines, Honduras

Clinical Operations Consultant, Magenta Therapeutics, Cambridge, MA **December 2019 – June 2020**

- Provided Clinical Operational performance/expertise and support
- Assisted clinical colleagues in managing Patient recruitment activities
- Vendor Oversight (primary contact)
- Assisted in clinical site budget review and approval
- Assisted in Change Order review and approval

- Manage Informed Consent review and approval
- Management of CRO regarding the continued execution and maintenance of the Clinical Trial (primary contact)
- Collaborated with clinical colleagues in the Management of a Phase 2 Rare Disease (Pediatric Patients Population) Clinical Trial
- Collaborate on an ongoing basis with Data management, Biostatistics, Regulatory, and legal
- Provided Oversight in communication with Data Monitoring Board
- Multi-tasking to complete tasks on time per established timelines

Clinical Operations Consultant, Tarveda Therapeutics ,Watertown, MA February 2019 – September 2019

- Collaborated with (or did she Lead) ? clinical colleagues in the Management of a Phase 1/2a Oncology (solid tumor) Clinical Trial in collaboration with CRO, additionally, assisted in the involved in study maintenance to ensure quality and timely execution of clinical trial activities.
- Ongoing focus on Patient recruitment in collaboration with CRO
- Collaborated with clinical colleagues in the Management of the dose escalation process in the Phase 1 portion of the study
- Collaborate with internal supply team to manage Investigator Product supply/resupply
- Vendor Management - CRO and Central lab
- Assisted in development of a Protocol Amendment
- Reviewed study related plans, including reviewing monitoring reports, and project team minutes
- Multi-Tasking to address project planning and oversight of project timelines

Sr Clinical Operations Lead, Radius Pharmaceutical, Waltham, MA September 2017-February 2019

- Managed phase 1 Breast Cancer studies, involved in study start-up/initiation, and maintenance to ensure quality and timely execution of clinical trial
- 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)
- Responsible for reviewing data captured via EDC (RAVE)
- Reviewed documents for initial drug supply
- Collaborated closely with Data Management, Biostats, and Regulatory to oversee query resolution and protocol deviation management
- Assist in the development of a Protocol Amendment
- Assist in the revision of IB and IND annual Report
- Manage Cross Functional Team
- Mentored Junior staff assigned to Clinical Trial
- Reviewed data listings, patient profiles and SAE reports
- Provided financial oversite, for example, review and approve site and vendor invoices, as well as negotiate, review and approve Vendor Change Orders and collaborated with Finance for program budget and Vendor budgets
- Multi- task in order to meet timelines requested

Consultant, Clinical Trials/Clinical Operations Lead- Merck, New Jersey facility November 2015 – September 2017

- Managed phase l (solid tumor) Oncology global (*Switzerland, Italy*)clinical trials – 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 manage external vendors (Central labs, IVRS - Subject Randomization vendor)
- Facilitate 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 l/ll 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
- Responsible for reviewing monitoring reports
- Responsible for reviewing data captured via EDC
- Ensured TMF is audit ready

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

- Managed a phase l ID global (*Switzerland)*, clinical trial/clinical project management in collaboration with the CRO
- Managed/lead cross functional team meetings, safety meetings and ad-hoc meetings as necessary
- Manage 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 leadership to junior staff

Consultant, Clinical Operations, Sunovion (Sepracor), Marlboro, MA **March 2011 - September 2011**

- Managed the CRO involved in a Multi-National (*Germany, Poland, Romania, Spain*) Epilepsy phase 3 clinical trial.
- Managed aggressive study timeline in collaboration with CRO,
- Effectively communicated with all functional areas to ensure alignment
- Regulatory document review (North America and outside NA) for initial drug shipment
- Reviewed monitoring reports
- Collaborated closely with regulatory and quality assurance departments to ensure successful submission of regulatory documents.

Senior Level, Clinical Operations, Consultant, Global Central Laboratory, Rochester, February 2009 - March 2011

- Oncology protocol review which resulted in an accurate identification of safety tests needed
- Interacted with clinical staff at biotech companies to better understand clinical study goals
- Interacted/collaborated with the Director of Business Development

ArQule Inc., Woburn, MA. **May 2007 – October 2008**

Head, Clinical Operations, Clinical Department

Arqule is a small biotech company developing oncology drugs.

- Provided clinical operations leadership, strong organizational skills, and the execution of quality systems within the Department
- Instrumental in planning Clinical Trials for the Clinical Operations Department
- Conducted ongoing Study endpoint quality checks/adjudication

- Reviewed and approved Clinical Study Reports
- Assisted in authoring clinical protocols and relevant clinical sections of regulatory documents
- Primary contact for Medical inquiries from clinical sites, CRO and CRAs (triaged as necessary and appropriate)
- Responsible for reviewing data captured via EDC (RAVE)
- Clinical Project Management/oversight of the initiation, maintenance, and completion of phase I and 2 global clinical trial; clinical trials in Pediatric population
- Managed clinical trial budget in collaboration with the finance department
- Provided oversight in the development and updating of clinical SOPs and ensured adherence to GCP ICH guidelines

15 direct reports, mixture of employees, consultants and contractors

AVEO Pharmaceuticals, Cambridge, MA **September 2006 – May 2007**

- Managed outsourcing process for external vendors including RFP review and contract negotiation.
- Authored Standard Operating Procedure (SOPs)
- Effectively communicated with senior management to provide an overview of clinical operations

Therion Biologics Corp., Cambridge, MA **April 2005 - June 2006**
Head, Clinical Operations, Clinical Affairs Department
Therion Biologics is a privately-owned cancer vaccine company.

- Instrumental in managing Clinical Research Organizations (CROs) and other external/outsourcing vendors. Primary point of contact.
- Managed cancer vaccine clinical trials (Prostate Cancer and Pancreatic Cancer)
- Facilitated knowledge sharing to enhance clinical operational compliance
- Collaborated with DM Vendor to manage- Oversee endpoint adjudication team
- Liaised with several departments (internal and external) such as Data Management, Marketing/Business Development, Regulatory Affairs, Finance, Pre-clinical and Quality Assurance to enhance communication cross functionally and optimize clinical trial execution
- Focused on patient recruitment
- Mentored/managed Junior Staff
- Reviewed SAE reports and Safety Narratives

5 direct reports

Previous Experience

GI/Wyeth/Pfizer, Cambridge, MA. **March 1995 – April 2005**
CPM – Head of Clinical Operations

- Managed Investigator Sponsored Clinical Trials,
- Developed clinical section of IND Annual Safety Report
- Review Investigator Brochure
- Reviewed and approved Clinical Study Reports
- Managed Phase 1, 2, 3 Global (*Italy, France, Germany, UK)* Clinical Trials, from study initiation to Study close out
- Collaborated closely with Regulatory, Data management, Cross Functional Teams
- Managed Vendors, such as CROs, Central and Specialty labs
- Negotiated Vendor contracts
- Approved site budgets

Bristol Myers Squibb, Wallingford, CT **January 1990 – February 1995**
CRA-Sr. CRA

- Reviewed Clinical Site Data
- Developed monitor reports
- Addressed patient recruitment and patient retention
- Addressed Quality issues and Protocol Compliance issues at the Investigative Site level
- Reviewed investigational Drug Safety Site process
- Reviewed Regulatory Documents
- Ensured investigational drug safety reports were submitted/reported per IRB and agency established timelines

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 – September 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 organized