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. My Primary therapeutic area experience is oncology; tumor types include breast, lung, renal cell carcinoma, pancreatic, prostate. Other therapeutic area/disease types I have experience in, combination drug, oncology vaccine, hemophilia, asthma, and CNS. Excellent ability to successfully lead cross-functional teams including CRO management. Experience with timeline management, clinical trial budget management, problem identification and resolution. Demonstrated ability 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 clinical protocol development and review, investigator brochure development and review, Final Study Report development and review and the clinical section of the IND Safety Report and SAE/AE narratives developed
- Instrumental in providing Program Management support
- Successfully collaborated cross functionally to lead clinical project teams with the goals & objectives to meet regulatory submissions by 100%
- Collaborated/Managed vendors such as, CROs, central laboratories, EDC, IVRS to manage the clinical development process, saving companies (clinical budget) ~20%. In addition, I 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
- Managed cross functional teams (regulatory, legal, pre-clinical, data management, marketing, business development) from clinical protocol development through database lock

PROFESSIONAL EXPERIENCE

Consultant, Merck New Jersey **November 2015 – present**

- Managed phase l (solid tumor) Oncology global 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, as well as CRA training
- Successfully manage external vendors (Central labs, Subject Randomization vendor)
- Facilitate and collaborate with key internal/external stakeholders in support of clinical trial objectives

Consultant, Accellient Partners, Waltham **July 2014 – June 2015**

- Provide clinical operations-clinical project management expertise for phase l/ll CNS (movement disorders) clinical trials
- Instrumental in the management of the assigned CRO
- Implemented electronic system in collaboration with CRO and eVendor
- Managed eVendor
- Responsible for reviewing monitoring reports
- Responsible for reviewing data captured via EDC

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

- Managed a phase l ID global clinical trial/clinical project management in collaboration with the CRO
- Managed clinical team meetings, safety meetings and ad-hoc meetings as necessary
- Manage the review and finalization of Informed Consent forms
- Manage project timeline in collaboration with the CRO
- Work with regulatory, clinical supplies and external vendors

Consultant, Genzyme (a Sanofi Co.), Cambridge, MA **April 2012 - December 2012**

- Effectively communicated with senior management to provide status updates regarding inspection activities.
- 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, Sunovion (Sepracor), Marlboro, MA **March 2011 - September 2011**

- Managed the CRO involved in a Multi-National 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 back log of monitoring reports
- Collaborated with regulatory and quality assurance departments to ensure successful submission of regulatory documents

Consultant, Global Central Laboratory, Rochester, NY **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 and the execution of quality systems within the Department
- Created a culture of clinical project management and study planning
- Reviewed and approved Clinical Study Reports
- Assisted in authoring clinical protocols and relevant clinical sections of regulatory documents
- Clinical Project Management/oversight of the initiation, maintenance, and completion of phase l and 2 global clinical trial.
- Managed clinical trial budget in conjunction with the finance department
- Provided oversight in the development and updating of clinical SOPs

15 direct reports, mixture of employees, consultants and contractors

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

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

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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
- Facilitated knowledge sharing to enhance clinical operational compliance
- 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
- Mentored/managed Junior Staff
- Provided leadership in the development of clinical timelines
  5 direct reports

Genetics Institute/Wyeth, Cambridge, MA
Head of Clinical Operations, Experimental Medicine **2001 – 2005**

- Managed proof of concept, phase 1 and 2 Oncology global clinical trials implemented by Experimental Medicine
- Assisted in resource planning
- Successfully provided clinical project management support for clinical trial activities including timeline management
- Collaborated with budget manager to review clinical operations budget
- Successfully managed external vendors (CROs, Central labs, Subject Randomization vendor)
  7 direct reports (direct reports had 2-3 direct reports)

Wyeth, Cambridge, MA
Director, Clinical Operations, Clinical Research and Development **1998-2000**

- Manage external vendors (CROs, Central labs, and IVRS vendor)
- Managed phase 1, 2 and phase 3 global clinical trials
- Collaborated with data management, regulatory affairs and quality assurance to ensure appropriate execution of global clinical trials, phase 1-3
- Provided program management support as necessary
  7 direct reports

Genetics Institute/Wyeth, Cambridge, MA
Associate Director, Clinical Operations, Clinical Research and Development **1996 – 1998**

- Successfully wrote clinical protocols
- Provided management of clinical project activities including timeline management for phase 1, 2 and 3 clinical studies
- Reviewed data with data management and the Medical Director.
- Provided guidance to clinical staff for GCP/ICH guidelines

Genetics Institute, Cambridge, MA
Manager, Clinical Research **1994 – 1996**

- Managed proof- of-concept, phase 1and 2 global clinical trials
- Successfully reviewed data with data management and the Medical Director
- Provided guidance to clinical staff for GCP/ICH guidelines and 21 part 11

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Bristol Myers Squibb, Wallingford, CT
Senior Clinical Scientist (CRA) **1989 – 1994**

- Mentored junior CRAs
- Responsible for on-site monitoring of multiple investigative sites involved in anti-infective clinical trials

EDUCATION

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

Bachelors of Science, Biology, Greensboro College, Greensboro, NC

Pro Bono 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) **2009 - 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

Board Member, Cambridge Children and Family Services (non-profit organization) **2001 -2008**

- Partnered with other members of the board to set strategies regarding the vision, mission and goals of the organization
- Worked with executive director and board members on fundraising activities