

KATHRYN GAIL DAVIS, MBA

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SUMMARY

Clinical Operations – Clinical Outsourcing Professional with strong analytical skills, strategic thinker and extensive experience in solving complex problems and building teams. In addition, business minded, excellent interpersonal skills and superior ability to execute strategies to ensure that clinical operations activities are conducted effectively, efficiently and in compliance with all applicable regulations.

Received **Above and Beyond** award from Wyeth for demonstrating exemplary efforts and achievement towards the company values, as well as leading clinical teams to consistently meet department goals on time and within budget.

AREA OF EXPERTISE/ACCOMPLISHMENTS

- Brought investigational products from IND to NDA/BLA submission at Bristol Myers Squibb and Wyeth
- Management of outsourcing process, initiation of investigator grants and management of project finances including financial Forecasting
- Clinical project management leadership
- Clinical Department implementation of electronic tools (EDC,CTMS,IVRS)
- Strategic thinker/problem solver
- Primary Therapeutic areas experience; Oncology and Infectious Disease
- Other Therapeutic areas/disease types: Orthopedics (combination), Hemophilia, Crohn's Disease, Asthma.
- Management of Proof-concept, phase 1, 2, 3 and 4 global clinical trials.
- Monitoring/Management of GCP ICH guidelines
- US and European clinical audits, as well as, vendor audits which assured quality and compliance
- Lead Clinical Department audits
- Planning and timeline management
- Leadership of projects that ultimately increased the profitability of the company
- Strategic thinker, as well as an excellent executor of strategies
- RFP's, contract review and negotiation, budget review/management, as well as management of external service providers/outsourcing vendors including developing business relationships

PROFESSIONAL EXPERIENCE

Consultant

March 2009 – September 16, 2011

(Kelly Services - Sunovion) March 2011 - Present

As a Consultant at Sunovion (Sepracor) I am currently working as a Clinical Monitoring Manager. Responsible for the following:

- Collaborating with and managing CRO
- Informed Consent review to ensure procedures outlined were understandable
- Regulatory document review (North America and outside NA) for initial drug shipment
- Monitoring report review
- Preparation of Study related documents
- Contract Management including obtaining fully executed Clinical Trial Contracts

Consultant

(Clinical Services Consulting) March 2009 - February 2011

As a Consultant at a global Central Laboratory I was Responsible for the following

- Oncology protocol review which resulted in a accurate identification of safety test needed
- Interaction with Clinical Staff at Biotech as necessary
- Interaction with the Director of Business Development

ArQule Inc. Woburn, MA.

May 2007 – October 2008

Head of Clinical Operations, Clinical Department

Arqule is a small biotech company developing Oncology drugs; the company is in phase 1, 2a and 2b development, domestic and international clinical studies. The company obtained a new CEO, was re-organized and down sized in October 2008; as a result of these actions my boss and I were laid off.

- Developed Clinical Drug Development strategy within the clinical team
- Protocol Development
- Provided study specific training at Investigator meetings
- Implementation (clinical) of an EDC system and identification of a IVRS
- Managed a phase 2 global pancreatic cancer study and initiated a phase 2 breast cancer and non small cell lung cancer study
- Expanded, CRAs, Clinical Coordinators and clinical consultants head count, this expansion resulted in goals being met in a timely manner.
- Establish compliance guidelines
- Conducted Clinical Operations and Project Management Leadership meetings
- RFP's, contract review and negotiation, budget review/management
- Actively coordinated resource allocation, financial forecasting and clinical budget review
- Oversight/management of Clinical Research Organizations (CROs) and other external/outsourcing vendors.
- Collaboration with Biostatistician, Regulatory Affairs team and pre-clinical scientists
- Identified problems and implemented corrective action plans, including staff development.
- Promoted efficiencies within the Clinical Department and improved data quality through training and identified subject matter expert consultants. All of the aforementioned tasks resulted in an effective and efficient running of the Clinical Department.
- Managed 4 permanent employees and 5 consultants/contractors

Independent Consultant, AVEO Pharmaceuticals

August 2006 – May 2007

As a Consultant, was acting Director of Clinical Operations reporting to the Chief Medical Officer

AVEO is a small biotech company developing Oncology drugs; that was in phase 1 development

- Assisted in increasing Clinical and Regulatory staff.
- Assisted in developing clinical strategy
- Management of outsourcing process including RFPs and contract negotiation
- Development of Standard Operating Procedures
- RFP's, contract review and negotiation, budget review/management

Therion Biologics Corp. Cambridge, MA

April 2005 - June 2006

Head of Clinical Operations, Clinical Affairs Department

Therion Biologics is a privately owned Cancer Vaccine Company with Phase 2 Prostate Cancer and Phase 3 Pancreatic Cancer Clinical Trials. Company did not meet the primary endpoint of progression free survival in the Pancreatic Cancer clinical trial and as a result, the company closed and no longer exists

- Primary focus was oversight of all Clinical Operations activities involving study start/activation, maintenance; this oversight resulted in a systematic organized process and timely completion of tasks
- RFP's, contract review, negotiation contracts, budget review including review of change orders
- Managed phase 3 pancreatic cancer clinical trial and phase 2 Prostate cancer clinical trial
- Went on co-monitoring visit as necessary
- Development and Oversight of mock FDA inspection audit at CROs and Sponsor which prepared parties for an FDA audit.
- Closely collaborated with Program Executives to track and plan global clinical studies including life cycle planning.
- Provided leadership to junior clinical staff; managed 4 professionals
- Interacted with several Departments such as Regulatory Affairs, Finance, Program Management and Quality Assurance in an effort to develop and meet metrics, as well as enhanced communication, collaboration and teamwork.

Genetics Institute/Wyeth, Cambridge, MA

May 1994 – March 2005

Head of Clinical Operations, Experimental Medicine 2001 – 2005

Director, Clinical Operations, Clinical Research and Development 1998 – 2001

Associate Director, Clinical Operations, Clinical Research and Development 1996 – 1998

Manager, Clinical Research 1994 – 1996

- Managed proof-of-concept, phase 1, 2 and 3 global clinical trials.
- Protocol Development
- Had oversight for phase 3 / 4 clinical studies; I-L11, BMP and Hemophilia
- Implementation (clinical) of an CTMS system
- Assessed the capabilities and ultimately identified external vendors to process clinical samples for gene expression profiling (PGx) and Proteomics. In addition, involved in study planning, (phase 1-3), as well as provided oversight and leadership in the area of specimen/sample management at external and internal laboratories which resulted in Departmental goals being met (Experimental Medicine)
- RFP's, (outsourcing process) contract review and negotiation, budget review/management, as well as management of external service providers/outsourcing vendors.
- Managed 20 professionals (Direct and indirect) while at Wyeth

Bristol Myers Squibb, Wallingford, CT

March 1989 – May 1994

Senior Clinical Scientist (CRA) 1992 – 1994

Clinical Scientist/ Associate (CRA) 1989 – 1992

Responsible for providing supervision, training, and guidance to assigned clinical scientists.

- Assisted with Protocol Development
- Assisted in the approval (phase 3) and post-marketed (phase 4) clinical studies for DDI & D4T
- Responsible for providing Clinical Research Associate training in the U.S. and Europe for d4T Phase III studies which allowed the company Clinical Research Associates to perform their tasks competently, accurately and correctly.
- Responsible for visiting clinical sites in order to review the progress of studies and to address unusual or complex problems when necessary.

EDUCATION/ PROFESSIONAL DEVELOPMENT

MBA, UC-Coast, Santa Anna, CA

BS, Biology Greensboro College, Greensboro, NC

Webinars: Risk Management, Regulatory Landscape-Clinical Trials, FDA guidance in Clinical Trials, Leadership during challenging times and Adaptive clinical design
Bio – IT World; Recognizing the key role of IT in empowering Translational Research

PROFESSIONAL ACTIVITIES

Healthcare Business Women's Association (HBA)
Women Entrepreneur in Science & Technology (WEST)

Drug Information Association (DIA)
Society of Professional Consultants (SPC)

VOLUNTEER/COMMUNITY SERVICE

St Matthew's Food Pantry
Winchester Hospital, Breast Care Center
Waltham Day Community, Board of Directors
HBA Marketing Editorial Chairperson
WEST Program Committee
SPC Development Chairperson