CAPABILITIES AND EXPERIENCE

APRIL M. ALLISON

WORK EXPERIENCE

Landrich Group (2019 – Present)

- Assisting clients in development of Regulatory & Development strategies, including budgets & timelines Writing or contributing to study designs, clinical trial reports, protocols, developing and executing monitoring plans, developing case report forms, and other trial-related documents.
- Third-party vendor management selection and oversight
- Clinical trial management.

Director: AM Allison Consulting, LLC (2019 – Present)

- Leading clinical programs and project teams
- Assisting clients in development of Regulatory & Development strategies, including budgets & timelines
- Writing or contributing to study designs, clinical trial reports, protocols, statistical analysis plans, data management plans, case report forms, and other trial-related documents

Director, Clinical Operations: Cerus Corporation (2014 – 2019)

Previous roles within organization: AD, Clin. Ops & Sr. CTM

- Responsible for management of all activities associated with the conduct of clinical trials.
- Oversee or develop protocols, consent forms, monitoring plans, case report forms, SOPs and other clinical documents related to clinical trials.
- Oversee clinical operations staff management of or directly manage investigative sites to ensure compliance with protocol and overall clinical objectives; including traveling to sites to conduct or oversee pre-study, initiation, interim and closeout visits and/or co-monitor with CRO, members of the clinical operations group, or contract associates.
- Oversee contracts and budgets negotiations with clinical investigative sites and other vendors.
- Manage clinical monitoring staff (internal and/or contract)
- Participate in data review, analysis and report writing, regulatory submissions, and safety reviews
- Select and manage CROs and other consultants to ensure adherence to national and international regulations and standards (GCP, MDD, ICH).
- Develop and maintain clinical project timelines, budget and resource management.

Director, Clinical Management: Premier Research (2012 – 2013)

- Directed and supervised Line Managers, Clinical Managers, and other Clinical Trial Management staff
- Developed and implemented departmental policies and procedures
- Provided line management supervision including performance management

Associate Clinical Project Management Director: Quintiles (1998 – 2012)

Previous roles within organization: Clinical Study Mgr., Assoc. Clinical Scientist, Sr. CRA, CRA, Research Associate

- Managed cross-functional project teams, budget & timelines
- Performed Risk Management, developed study plans, and supervised team performance

EXPERIENCE HIGHLIGHTS

Clinical Management professional with more than 20 years of experience in the drug development and medical device industry with a strong background in global project management and clinical operations. She has global trial management and monitoring experience across a wide variety of indications, including hematology, infectious disease, immunology, oncology, ophthalmology, pediatrics, respiratory, and transfusion medicine. She is well-versed in all aspects of phase I-IV studies, from clinical development strategy and planning through closeout and submissions to regulatory authorities. April has developed protocols, consent forms, monitoring plans, case report forms, clinical study reports, SOPs, and other clinical documents related to clinical trials as well as managed a variety of third-party vendors, including CROs, IRTs, central labs, and clinical suppliers.

EDUCATION

B.A., Journalism, San Francisco State University, San Francisco, CA