CAPABILITIES AND EXPERIENCE
APRIL M. ALLISON

WORK EXPERIENCE

Landrich Group (2019 – Present)

- Provide strategic and operational leadership for clinical programs, including regulatory and development planning, timelines, and budgets
- Manage cross-functional teams, vendors, and global study execution
- Develop study protocols, operational plans, and clinical documentation
- Oversee CRO/site management, enrollment, quality initiatives, and risk mitigation strategies
- Devise strategic and tactical plans for executing pivotal clinical studies
- Manage program timelines, department budgets, key objectives, and manage and develop the Clinical Operations team
- Provide clinical study operations leadership for large-scale, fast enrolling, and biospecimen centered clinical trials for IVD development
- Manage operational plans and timelines to achieve on-time enrollment and study completion
- CRO management, site operations/monitoring, and data delivery milestones in line with corporate goals
- Identify barriers to timely and successful study execution and propose solutions, with regular reporting of program performance metrics
- Manage a Clinical Operations team, ensuring development, engagement, and training opportunities
- Lead initiatives to improve systems, processes, procedures to drive quality into Clinical operations, including GCP training programs, SOP gap-assessments/overhaul projects, and rigorous internal audit plans
- Develop communication strategies to work cross-functionally effectively in project team situations to influence, collaborate, and meet the needs of internal and external stakeholders
- Collaborate with senior management to develop project timelines, study budgets, and report periodically on project status to all stakeholders
- Oversee and manage all operational aspects at the Clinical Program level, including investigator selection, analysis, and KOL collaborator engagement
- Prepare study-related documentation, including protocols, case report forms, consent documents, clinical trial agreements, project management plans, etc.
- Collaborate with internal cross-functional teams on assay development activities

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.

EXPERIENCE HIGHLIGHTS

Clinical Management professional with over 20 years of experience in drug development, in vitro diagnostics, and the medical device industry, with expertise in global clinical operations, project management, and regulatory strategy. Directed clinical operations at both sponsor and CRO companies, overseeing global Phase I–IV trials across various indications, including oncology, ophthalmology, infectious disease, immunology, and pediatrics. Skilled in protocol development, vendor oversight, regulatory submissions (FDA, MHRA), and cross-functional team leadership. Experience includes line management, SOP development, and managing BARDA-funded studies. Led a global clinical training program in Japan, integrating systems and teams into a global framework to ensure high-quality, compliant study execution worldwide.

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