CAPABILITIES AND EXPERIENCE

JEROME G. PINKETT

WORK EXPERIENCE

Landrich Group (2020 – Present)

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. Third-party vendor management selection and oversight. Clinical trial management. Lead Pre-Clinical, Phase I-IV studies and team within the US and ROW.
Audit clinical programs for clients intent to implement changes to infrastructure related to US and ROW GCPs.

Senior Director, Clinical Operations: Aimmune Therapeutics Brisbane (2017 – April 2020)
Responsible for strategic oversite of all clinical programs, 17 clinical FTEs and 14 regional CRA consultants. Budgeting of clinical vendors, sites, and clinical department. Preparing the department for FDA/MHRA inspection. Preparing the department for BLA submission.

Director, Clinical Operations: Aimmune Therapeutics Brisbane (2015 – 2017)
Responsible for strategic oversite of all clinical programs, implementation of clinical infrastructure, and mentoring and training of staff and contractors. Financial oversite of the clinical budgets for staff, contractors and vendors. Maintained timelines and reported results as a member of the core team. Presented at investigator meetings, advocacy groups, and site visits.

Director, Clinical Operations: Principia Biopharma (2013 – 2015)
Responsible for initiating the clinical department by initiating SOPs, guidelines, study templates, and infrastructure. Initiated first Phase 1 studies for the company. Tracking of critical path issues including timelines and budgets. Negotiation of CRO and vendor SOWs and budgets. Strategize with KOLs and key departments about compounds to move into the clinic, indications, and portfolio management.

Associate Director, Clinical Operations (consultant): Elan Pharmaceuticals (2010 – 2013)
Responsible for operational over site of Phase Ib and Phase II Multiple Sclerosis trials, Phase II Alzheimer's Disease trial, along with a Phase IV Crohns Disease trial. Assist with strategic long range planning and budgeting for the MS program. Over site of 1 CPM and 2 CTAs along with CRO and vendor management. Tracking of critical path issues including timelines and budgets. Negotiation of CRO and vendor SOWs and budgets.

Director of Clinical Operations: Revance Therapeutics, Inc. (2009 – 2010)
Responsible for hiring appropriate staff of clinical specialist including clinical program managers, clinical research associates and clinical research assistants for dermatology trials. Project management of the clinical programs consisting of timeline management, budget oversight, and vendor management. Assist with strategic decisions for clinical programs and writing protocols. Liaison with both internal and external clients including vendors, QA/QC, purchasing and accounts payable, regulatory, and research development. Strong communication skills to foster relationships with both internal and external clients.

EXPERIENCE HIGHLIGHTS

Over 25 years of extensive experience in clinical operations and a leader with a track record of success in oncology, CNS, HIV, CKD, food allergies, Phase I – IV studies, Authored SOPs, BLA filings, CSRs, and preparation for inspections. Most recently lead the team from Phase 2 to approval for Palforzia.

EDUCATION & ACCREDITATIONS

- MBA, John F. Kennedy University
- Bachelor of Science- Biological Science, Cal. State University Hayward
- Credits toward B.S. Forestry and Wildlife Biology, Virginia Polytechnical Institute
- Associate of Science, Forestry and Wildlife Biology, Tuskegee Institute