Ian John Valencia
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SUMMARY:

- Clinical Research Professional with over 10 years of experience
- Diverse therapeutic experience includes Virology, Oncology, Cardiovascular, Immunology, Infectious Diseases, Inflammation, Oncology, and Ophthalmology
- Clinical Operations experience includes Study Lead, study start-up, vendor management, site and trial management for global studies for Phase 2 and 3 trials

EDUCATION

University of California Extension, Santa Cruz
Certificate Program in Clinical Trials Design and Management, July 2011

California Polytechnic State University, San Luis Obispo
Bachelor of Science in General Engineering: Biomedical Concentration, August 2008

WORK EXPERIENCE

Senior Clinical Trial Manager (Sr. CTM) *Gilead Sciences Inc, Oct 2021-Present*
ClinOps Lead for Ph2 and Ph3 Hepatitis Delta Studies

- People Leader managing 2 direct reports
- Support integration from a company acquisition
- Lead multiple interim analysis
- Navigate the Ukraine/Russia Geopolitical situation that impacted ClinOps
- Accountable for audits and inspection readiness
- Provide guidance and oversight to assigned ClinOps team members to ensure successful management of all aspects of studies within budget and timelines

Global Study Manager (GSM) *Genentech/Roche, Aug2018 - Oct2021*
As a GSM, I seek to understand different stakeholder perspectives and think about the impact on sites and patients. I am an agile team member with a curious and solution-focused mindset with a human touch. I create a collaborative environment based on shared purpose and common ground.

- CCO Partnership Lead to provide country oversight
- Drive operational excellence with organizing and problem-solving skills to plan and run efficient operational aspects of studies
- Manage vendors and stakeholders
- Lead and influence; including motivating others to deliver against commitments, including leadership of global teams across diverse cultures and time zones, embracing diversity and creating a culture of inclusion to ensure successful collaboration
- Manage risk and compliance
- Apply good knowledge of drug development process and respective regulations, including ICH and GCP guidelines

Country Study Specialist (CSS) *Genentech/Roche, Jul 2016-Aug 2018*

- Develop Operational Elements at a Country Level
- Provide proactive co-ordination and study oversight actively involving respective internal and external Local Study Team members
- Project Management and Effective Communication skills
- Compliance- Focused on cleaning up CTMS and providing additional guidance to CRAs
- Relationship Management with Global and Local Study Teams

Clinical Trial Management Associate (CTMA) *Gilead Sciences Inc, Nov 2014-Jul 2016* Core values: Teamwork, Accountability, Excellence, and Integrity
A Combined Phase 2/3, Double-Blind, Randomized, Placebo-Controlled, Induction and Maintenance Study Evaluating the Safety and Efficacy of GS-5745 in Subjects With Moderately

to Severely Active Ulcerative Colitis:

Study Start-up activities

- Manage study start-up activities including CDA, feasibility, review of site regulatory packets, and site activation in CTMS and IWRS
- Coordinate with CRO SSU team and internal team on site contracts, non-IMP supply planning, and site initiation visits
- Create country template ICFs and review/approve Central IRB ICFs along with Clinical Research, Biomarkers, and Legal routing as needed

Clinical Operations

- Led cross-functional collaboration in the development of a protocol amendment to include a long term open-label treatment extension phase
- Communicate with sites regarding recruitment and discussions as needed when escalated
- QC review of site payments to ensure procedures completed and aligned with study budget/fully executed CTA

ePro Vendor Management

- One of the SMEs on the technical aspects of the ePro vendor
- Manage device inventory, request initial shipments, and collaborate with vendor/provisioning partner on Import/Export Licenses and proforma review
- Obtain License agreements for Quality of Life (QOL) questionnaires along with translations from respective QOL vendors
- Troubleshooting, CRO training, and obtaining screen shots for global submissions
- Facilitate the eConversion review and Full Linguistic Validation of patient materials for global re-submission
- Conduct specification review and UAT for reports and vendor system
- Provide feedback for governance meetings and vendor CAPA

North America Region Site Management

- Develop Global Newsletter with input from Study Management Team
- Co-monitor sites during site initiation visits and developed slide presentation materials
- Create monitoring reports and site report review

Global Study ClinOps team member

- Collaborate cross-functionally on a Place Mat/ Instructions for Use (IFU) manual ・ Develop and update Site Regulatory Package instructions for internal use and guidelines for CRO transfer of responsibility.
- Establish Master ICF templates for country and site adaptation along with ICF version control system globally
- Conduct site training as well as CRO/CRA training

Global Phase 3 JAK1-selective inhibitor Filgotinib for inflammatory disease indication:

- SSU activities- IXRS vendor lead and ePro vendor lead across two Phase 3 studies as well as Americas regional lead (US/CAN/Brazil)
- Assist in the vendor selection process from RFP to awarding bid

Clinical Research Assistant/ Study Coordinator *Stanford University, May 2011-Oct 2014*
(Reclassified from Clinical Research Assistant to Study Coordinator, August 2012)
Stanford School of Medicine, Division of Infectious Diseases and Geographic Medicine
The Synergy Trial (Clinical trial sponsored by K-PAX Pharmaceuticals)

- Screen, recruit, obtain informed consent and enroll patients for protocol eligibility
- Arrange and schedule study visits for 12-week study
- Assist with submission of regulatory documents and create NTF's as needed
- Maintain source documents and collect data via outcome measurements tools
- Ensure protocol adherence and research billing charges, send invoice to Sponsor
- Create Banking Sample protocol for future testing, manage sample inventory

Gene Expression and Immune System Dynamics Study for Chronic Fatigue Syndrome (CFS)

- Large study analyzing Genetic, Immune, and Pathogenic testing of CFS patients and comparing to healthy controls to further understand the disease
- Conducted phone interviews and completed the enrollment of 780 patients on the study
- Managed scheduling and logistics, recruited participants, screened participants, assisted in patient visits, and organized and developed study forms.
- Performed patient recruitment and conducted patient study visits involving consenting and administering questionnaires to patients
- Facilitated in the entry and verification of the data and updated the Redcap Database
- Performed quality control and data management while collaborating with Statistics team
- Created a Sample Inventory to record the various test and organize thousands of samples
- Coordinate various Research projects (r10k project, Dr. Robinson lab, Dr. Quake lab)

XMRV and MLV Study-National Institutes of Health (NIH) sponsored multi-site research study

- Assisted in recruiting 25 Cases and 25 Controls
- Administered comprehensive questionnaire to study participants and created patient files

Quantitative EEG (qEEG) Research Study

- Recruited 50 Cases and 50 Controls matched by age, sex, and education
- Coordinated and planned clinical operations of the study recruitment process
- Assisted Neuropsychologist with eligibility requirements and adhered to regulations
- Maintained database including creating new fields, quality control, & troubleshooting

Cardiovascular-Exercise Research Study

- Assisted in phone interviews and recruiting of cases and controls

Cytof and HLA testing- Department Of Defense Grant

- Facilitate in creating timelines and ensuring scope of work being completed
- Oversee and collaborate with different labs regarding testing, budget, and logistics
- Establish and locate the samples needed for testing
- Communicate with DOD representative to ensure human subjects protection
- Organize and monitor research in preparation for testing started 2013

Clinical Data Coordinator *ClinOps, January 2010-January 2011*
Specialized Contract Research Organization with a core service offering and combining, expert data management, biostatistics and specialized clinical services.

- Efficiently performed all aspects of Data Management as it relates to processing & QC of the data by following the client specific Data Management Data Quality (DMDQ) Plan
- Processed, resolved and wrote queries for multiple projects with minimum supervision
- Ensured accurate monthly study status updates and communicated with clients as needed
- Maintained clinical databases, updated data, and generated/reviewed listings
- Reliably validated over 100 edit checks with dummy data to ensure quality assurance
- Cleaned data for study close out and performed database lock procedures
- Involved with Phase I, II,& III Clinical Trials in Neurology, Ophthalmology, & Oncology

Clinical Trials Intern *Stanford University, September 2010-December 2010*
Stanford University Medical Center, Infectious Disease Unit

- Completed the Human Subject Protection Training for Stanford University
- Independently conducted Telephone-Screening Interviews for patient's study eligibility
- Assisted in Informed Consent process, patient questionnaires and study visits

Research Engineer *Biomedical Forensics, December 2008-August 2009*
Technical consulting firm established in 1983 specializing in areas of Mechanics and Kinematics of Trauma, Impact Biomechanics, and Accident Reconstruction.

- Prepared data from a variety of sources for engineering analysis
- Gathered data for biological tolerances, epidemiological studies, & medical research
- Efficiently created case file, protocol and framework within budget restrictions
- Provided value with calculations, mechanisms of injury, & biomedical assessments

TECHNICAL PROJECTS AND COURSEWORK

Relevant coursework includes:
Project Management, GCP, Drug Development Process, CRF Development, Site Monitoring,

Stanford Courses:
Accomplishing More with Less, Web Basics: Drupal Site and Overview of Web Languages, HIPAA Fundamentals Certification and HIPAA Awareness, and Business Fundamentals

LEADERSHIP EXPERIENCE AND INVOLVEMENT

- President(06-07), Internal Vice President(05-06) *Omega Xi Delta Fraternity*
- Culturefest Chairman *Culturefest*, 2007
- Student Leader *Student Quality Advisory Committee*,Winter2005-2006
- Mainstage Manager *Cal Poly's 12th Annual Open House,* Spring 2005
- Biomedical Engineering Society *Member*
- Stanford Research Volunteer *Aware for All- Clinical Research Education Day*
- Gene Academy Tutor

ADDITIONAL DATA MANAGEMENT TRAINING

SQL Programming, Good Documentation Standards, Data Receipt, Tracking & Entry, Data Reconciliation & Instructions, CRF Annotations, Conventional Database Design, Screen Development, Database Build & Validation, DMDQ Design & Maintenance, Edit Check Programming, Transfers & Data Load Procedure, Conventional Edit Check Validations, QC Discrepancy Management Series, Audit Procedure & Guidelines, EDC Edit Checks

CERTIFICATES AND AWARDS

- Certificate of Completion in ICH E6: Good Clinical Practices Guidelines
- Completion of Mission Valley Regional Occupational Program in Programming C++
- Fraternity received the 2009 President's Diversity Award
- Multiple G. Thanks awards from Gilead peers and Manager
- 2021-2022: Received multiple Values at Work (VAW) awards at Gilead and received Outstanding rating given to top ~15% of Operations Department