IRENE TENNANT, BS, MS
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PROFESSIONAL EXPERIENCE

THERAPEUTIC EXPERIENCE

Oncology, Gene Therapy, Vaccines, Infectious Diseases, Vascular Disease, Cardiovascular Disease, Pain Management, Dermatology, Ophthalmology, Infections/Chronic Wounds, Gastroenterology, Women's Health, Pediatrics, Device

Vice President, Clinical Research Strategy and Operations **Nov 2016 - Present**
GXP FARMA CONSULTING, LLC

- Promote strategy to optimize the development of vaccines, biopharma products, and pharmaceutical "first in class" treatments
- Develop and evaluate clinical programs to support successful FDA and regulatory approvals by identifying potential issues and advising on mitigation strategies to help control these issues with robust and cost effective operational plans
- Focus on growing biopharma and pharmaceutical companies from molecule to clinical product development to successful licensure

Director, Clinical Development **Mar 2017 – Present**
AMERICAN GENE TECHNOLOGIES INT'L INC.

- Lead the planning and implementation of the clinical development strategy and protocol design for company lead program for HIV cure
- Lead and coordinate CMC and regulatory activities for cell product manufacturing
- Responsible for developing and driving clinical development plans, clinical trial protocols, data analyses, clinical study reports, and other related clinical documents
- Partner with internal and external experts and consultants to refine the clinical development plan and protocol and to optimize the scientific integrity of the methodology and ensure that the overall scientific, statistical, and medical content of the clinical program is sound
- Lead and coordinate all submissions activities for Investigational New Drug Application (IND) for HIV cure
- Serve a functional CMC representative on product development and related technical tasks
- Oversee and assist with development of assay development, validation and sample analyses to ensure that material requirements and qualification dates are met
- Work with functional experts to provide review of and input on the CMC section
- Coordinate and lead tasks in drafting responses to FDA questions and feedback
- Communicate and lead resolution of product manufacturing risks and escalate to relevant teams as appropriate
- Support transfer of manufacturing processes and analytical methods from R&D to Clinical
- Assist in the development of release assays and stability protocols for clinical product
- Lead and motivate the clinical science and operations team to effectively and efficiently operationalize the clinical development strategy (i.e. clinical trials management)
- Oversee all activities of the Clinical Operations team to launch company into clinical stage with the first in human clinical trial (Phase I)
- Oversee activities and communications with study committees, Clinical Advisory Board and DSMB
- Oversee vendor selection to support pre-clinical and clinical tasks
- Manage and oversee the vendors in the design, conduct, and management of the projects to ensure on-time delivery and adherence to agreed costs and timelines
- Work closely with Program Management team to integrate resources and to align operational efforts
- Work closely with Translational development lead to support exploratory biomarker strategy
- Work closely with Statistician to develop statistical analysis plan for Phase I protocol

- Provide oversight on quality and compliance for all clinical trial(s) programs
- Develop and maintain excellent and sound working relationships with internal and external functional groups, CMOs, and corporate partners
- Lead by influence within Project Teams to ensure alignment of company strategy and agreed project goals
- Provide leadership and mentorship across functional groups to build up high performing teams
- Responsible for building a small but scalable internal team to support the conduct of early clinical trials in coordination with clinical research organizations

Director, Clinical Development and Global Operations **Dec 2014 – Oct 2016**
ANGES, INC.

- Lead and develop Clinical Team in advancing and developing asset level program for gene therapy product in PAD in multiple studies
- Assume responsibilities of the vice president in the clinical development activities
- Serve as member of Leadership team to advise on company objectives and product development
- Supervise the development of Phase III protocol to position asset for submission and market approval
- Provide leadership, strategic planning, direction and implementation of clinical operations
- Collaborate with project team members (regulatory, CMC, pharmacovigilance, etc.) in planning, conducting and evaluating clinical trials
- Develop annual and study-specific operating budgets for clinical affairs to meet long-term company and departmental objectives; creates detailed study budgets and communicates closely with finance on study budgets and changes in scope
- Responsible for management of timelines, cost, and quality of projects in accordance with company goals
- Manage and track project timelines to ensure milestones and deliverables are met on time
- Evaluate, select, and manage Contract Research Organizations (CRO) to supplement the department. Creation of RFP, solicitation of bids, evaluation of all aspects of clinical trial needs
- Establishes timelines and plans proactively to complete clinical studies on time. Monitors progress and drives enrollment at sites. Ensures collection of high quality data, monitoring plan.
- Oversee planning and lead Advisory boards, Joint Committee Meetings, Steering Committee meetings, Investigator Meetings, and other external meetings as required
- Provide cross-functional leadership and governance to help advance company objectives
- Represent company and presented to external opinion leaders and at conferences
- Prepare and author protocols, SAPs, safety plans, TLFs, and related project documents to support the development of the projects
- Review and monitor the study data for clinical trends and contribute to its analysis
- Provide clinical input to manufacturing team to support optimal development, release, and management of drug product in clinical setting
- Manage global clinical operations team. Establish and maintain an adequate and quality organizational team structure
  Responsible for resource management and development of the clinical team as well as company structure (hiring of new staff members permanent and contractor)
- Establish clear goals for the department that tie in to the broader company objectives
- Lead process and SOP development and improvement within operations as well as cross-functionally
- Develops and mentors team members within department and cross-functionally
- Lead line managers in development of a quality clinical operations team to meet project deliverables as well as coaching and training individual team members
- Encourages continuous improvement and provides training to keep department current on best practices, regulatory requirements, etc.
- Travel to investigational centers to meet with investigators to help ensure study success: establishing rapport with investigators, reinforcing importance of timely, high quality data, overseeing monitors, etc.
- Responsible for ethical and scientific integrity of studies and clinical plans
- Responsible for other duties as assigned by president of company

Associate Director **Aug 2013 – Dec 2014**
PFIZER PHARMACEUTICALS

- Team Lead for two Phase III Oncology studies in NSCLC
- Manage operational activities, such as project planning, metrics, budgets, and resourcing, to ensure successful execution of submission activities and deliverables
- Responsible for the on-time delivery of submission activities and reporting of a Phase III NSCLC study
- Lead activities and planning for Compassionate Use Strategy for post study transition of active patients
- Lead study team to ensure alignment with overall asset objectives and strategy
  Provide operational review updates and recommendations to senior leadership team
- Provide guidance and leadership to project team members across functional lines
- Lead regular project team meetings
- Ensure project costs are within scope and drive cost reduction activities when possible
- Manage critical changes and/or variance in financial forecast and schedule
- Lead project priorities and communicate key study and asset level objectives to team members
- Identify risk and propose mitigation plans to ensure project remains within timelines and budget
- Maintain and ensure quality is upheld in all aspects of the project (reporting, data, training, adherence to GCPs, audit readiness, etc.)
- Drive standardization of process and alignment of study execution across program
- Lead study team and Alliance Partners to ensure study deliverables are met through internal (within Development Operations, business unit and other platform lines) and external resources
- Manage study timelines, and as needed, regulatory defense activities, to ensure timelines for CSR activities are met
- Leads cross-functional integration of various components of a submission by working with study team members (Study Managers, Data Managers, C&O, Clinical Programmers, etc.) on data mapping, harmonization, and reporting
- Liaise with functional teams (Translational Medicine, CAG, HEOR, etc.) to ensure all relevant activities are included in the data cleaning and submission activities used to support final reporting
- Manage changes in scope of work and deliverables
- Lead the team in managing issues and problem solving
- Lead study team in Inspection Readiness preparation and coordination

Clinical Manager **Nov 2012 – July 2013**
NOVARTIS PHARMA AG

- Manage and lead all operational activities for two global Phase III psoriasis trials
- Ensure that deliverables are met according to timelines, budget, and quality standards
- Write synopses and clinical study protocols
- Develop Informed Consent Form, study tools, and training materials
- Manage all study start-up activities (e.g., trial budget, country submissions, vendor selection, and investigator meeting planning and presentations, etc.)
- Prepare clinical outsourcing specifications and manage vendors
- Collaborate with Informatics and data management on development of electronic Case Report Form and Interactive Voice and Web Response Systems
- Manage trial allocation and coordination of activities leading to site initiation
- Develop, manage, and track trial budget
- Participate in the on-boarding, mentoring and training of new staff

Senior Global Project Manager, Lead **Apr 2008 - Oct 2012**
PFIZER PHARMACEUTICALS

Responsible for the day-to-day operational aspects to the Project Team as Lead Global Manager in support of domestic and Global Phase I, II, and III Oncology programs, from protocol feasibility and development to database release and study reporting

- Lead and manage a group of study managers and clinical trial assistants in a global Phase III Oncology registration study and a Phase II Oncology study
- Oversee activities and deliverables of cross-functional project team including Study Managers, U.S. and Global Regional Offices, Clinicians, Data Management, Pharm Sci, Contract & Outsourcing, and Vendors

- Ensure operational activities meet expected timelines, enrollment targets, and costs
- Lead internal operational meetings and cross-functional project team meetings
- Report and update on project management activities during project team meetings
- Liaise with finance to develop study start-up budget and clinical trial budget
- Manage protocol budget; determine appropriate revenue forecasting/recognition based on project deliverables; approve study invoices and payments
- Initiate and track budget and scope changes, obtain necessary approvals for change in scope work; ensure trial costs stay within study budget and are effectively managed within budget expectations
- Responsible for project management components of inspection readiness for the study
- Develop project plans, contingency plans, and implement resource and risk mitigation strategies to ensure successful delivery of project goals
- Liaise with data management in the design of data capture tools (Oracle Clinical), review and approve database design, data transfer activities, data acquisition timelines, and data quality requirements to support DSMB, interim analyses and/or database lock
- Conduct country and site level feasibility and site selection; oversee country allocation and subject recruitment plans/strategies
- Oversee US and Global Country Offices to ensure timely site selection, regulatory approvals, and overall site readiness for site initiation
- Support team in developing submissions and regulatory applications
- Create and forecast enrollment targets throughout study; develop recruitment tools/strategies
- Organize global investigator meetings and other project and therapeutic training venues
- Work with supply chain coordinator to ensure clinical drug and supplies are labeled and supplied to all US and ROW sites, including coordination of translations
- Liaise with Contract and Outsourcing to develop vendor RFPs, contracts, and budgets
- Work with internal functional groups and country offices to track metrics and actively manage and report on the delivery of project goals and milestones and to ensure project compliance
- Provide ongoing project training to country offices and clinical monitors
- Work with cross-functional group leads to determine and manage project resource needs and utilization
- Manages CROs and Vendors to ensure quality of deliverables
- Serve as Subject Matter Expert (SME) on Pfizer Data Quality Focus Group eCRF Completion Requirements Workstream and Interactive Response Systems
- Directs project team initiatives and ensures adherence to study specific guidelines, company SOPs, GCPs, and ICH guidelines
- Assist program leads in implementing an Integrated Quality Management process to ensure GCP compliance and to provide robust risk mitigation plans throughout the study's life cycle
- Effectively promotes collaboration and success in a team-based matrix organization across a TK Inhibitor Program

Project Manager **Dec 2007 - Apr 2008**
OMNICARE CLINICAL RESEARCH

- Project Lead for a Phase I Vaccine study
- Project Manager of a Phase III Hepatic Encephalopathy trial
- Primary liaison between client, third party vendors and internal project team for project issues, including initiation, planning, execution and close-out of studies
- Manage and develop day-to-day operations, project metrics, timelines and deliverables
- Communicate to internal senior management, client, and third-party vendors as needed about project progress, potential issues and recommendations for issues resolution
- Lead internal team, client, and other project related teleconferences and meetings
- Communicate expectations for roles and responsibilities to assigned project team members and ensure that those expectations are fulfilled
- Lead project team training sessions
- Review, follow-up on, and approve project invoices
- Manage and determine appropriate revenue forecasting and revenue recognition based on project plan, budget and contract deliverables
- Track budget and scope changes and obtain necessary client approvals for change in scope work. Initiate and follow-up on change order/contract amendment activities
- Work with internal functional department leads, determine and manage project resource

needs and utilization according to project contract and contract amendments
- Communicate and coordinate project timelines for all required project functional service areas, client, and third-party vendors
- Participate in business development activities and bid defenses
- Manage, lead, and motivate in a matrix environment the assigned cross-functional project team to facilitate the team's ability to fulfill responsibilities in accordance with project contract, contract amendments, and internal policies and procedures
- Develop and maintain close working relationship with client's study management team to ensure client satisfaction, operational, and customer excellence
- Ensure successful design, implementation, tracking and maintenance of project plans

Clinical Trial Manager **Feb 2007 - Dec 2007**
OMNICARE CLINICAL RESEARCH

- Project Lead for a Phase I TB vaccine study
- Project Lead for a Phase IV registry study in chronic kidney disease and anemia
- Project Manager of a Phase III Hepatic Encephalopathy trial
- Plan and attend study start-up meetings with Sponsors
- Manage study budget and timelines; prepare monthly projections
- Effectively work with other internal departments to assure project success
- Lead weekly project status and CRA meetings
- Provide oversight and management of regulatory documents; provide input to IDP
- Maintain clinical trackers and weekly/monthly project status reports
- Track and approve investigator payments
- Propose appropriate investigators and review and approve recruitment list prior to submission of the sponsor
- Project Lead for weekly Data Management meetings to discuss trends, edit specifications, data capture issues, DCF management, and ensure adherence to the protocol, Data Management Plan, Statistical Analysis Plan, and the Protocol Deviation Plan
- Update, distribute, and ensure the accuracy of the investigator and CRA assignment list
- GPMP updates and review for allocated tasks
- Revenue recognition and forecasting tasks for Clinical Operations/Management activities
- Manage Coordinating Center Help Desk
- Effectively manage and provide support to CRAs in the conduct of the clinical trial
- Track, approve, and ensure timeliness of CRA time and expense and site visit reports
- Routinely manage the clinical trial budget by ensuring visits and hours are in accordance to contract. Take immediate action when excessive charges of time are observed to bring them back to scope
- Track visits to ensure that timelines are being met
- Provide input for annual performance reviews of CRA employees assigned to the project
- Arrange for therapeutic area training as needed to CRAs on project
- Review CRAs planned visit schedule, ensuring adherence to contract and timeliness of trips
- Review and approve monitoring reports
- Arrange for or perform periodic quality control visits with the CRAs as specified in the contract and/or as require by Omnicare Clinical Research's standard operating procedures to ensure CRAs adherence to Good Clinical Practices
- Review and approve CRA responses to quality assurance audits to ensure responses are appropriately addressing the issues
- Update guidelines as needed throughout the conduct of the study
- Initiate change order when required
- Participate in client and project team meetings/presentations/Kick-Off Meetings
- Develop and write monitoring guidelines and protocol deviation plans
- Establish and maintain positive client interactions/communications with sponsors regarding clinical issues and project goals. Ensure the delivery of quality services to the sponsor
- Coordinate investigator meetings if required
- Communicate with investigators and site personnel as needed to ensure a smooth study flow
- Participate in bid-defense

Manager, Clinical Operations **Aug 2005 - Dec 2006**
GENVEC INC.

- Managed an international Phase II/III gene therapy study in locally advanced pancreatic cancer, an international Phase IIB gene therapy study in severe coronary artery disease, and a Phase I gene therapy study in macular degeneration
- Managed a rectal cancer study and head and neck cancer study
- Evaluate and select international and domestic investigators and study sites
- Supervise the set-up of international and domestic clinical sites
- Manage, collect, and review regulatory and study essential documents
- Prepare study-related documents, e.g., study manuals, monitoring tools, project specific procedures**,** monitoring plans, and training tools
- Authored pharmacy manual for a Melanoma trial and a Head & Neck cancer trial
- Manage operational budget; track invoices; oversee investigator and vendor payments
- Assist in the development of Letters of Intent, Clinical Study Agreements, site budgets, and vendor proposals
- Manage domestic and international CROs to ensure adherence to company's procedures, SOPs, ICH-GCP guidelines, and country specific regulatory requirements
- Oversee protocol specific database generation and production
- Train clinical team, monitors, and vendors on protocol specifications and Standard Operating Procedures
- Write standard operating procedures and work practice documents for clinical operations
- Coordinate timely site initiation, patient enrollment, and data collection; establish tools to track and report study status
- Manage and maintain study metrics and timelines
- Oversee local and international distribution of clinical IP and supplies
- Participate in the selection of clinical research organizations and study vendors
- Monitored all sites for Phase I ophthalmology study
- Collected and reviewed regulatory documents
- Reviewed and collaborated on validation checks and edit specifications
- Assisted with protocol and case report form designs and amendments
- Earned certification on Phase Forward electronic data capture system

Manager, Clinical Development **Jan 2002 - Jun 2002**
ANTEX BIOLOGICS INC.

- Managed a Phase I and Phase II vaccine study for gastrointestinal disease
- Managed overall conduct of clinical trials, including management of clinical research organizations and clinical research associates
- Wrote the protocol for the Phase II GI study and authored the clinical section in protocol for a topical antimicrobial study
- Worked with the Department of Defense in the supervision and conduct of a vaccine trial
- Prepared and assisted in the writing of an investigational new drug application and investigator's brochure
- Assisted in product development plans, clinical trial design, and timeline development (moved product from laboratory to Phase I clinical trials)
- Responsible for regulatory issues such as filings to USFDA, release criteria for products used in clinical trials and safety reviews
- Designed and developed case report forms and subject diaries
- Assisted in clinical trial contracting and budgeting
- Executed quality control and quality assurance procedures in all aspects of trial development

Consultant, Quality Assurance **Sep 2001- Dec 2001**
HEART OF AMERICA RESEARCH INSTITUTE

- Developed and wrote standard operating procedures for Phase I/II clinical unit
- Audited study files and onsite clinical activities
- Trained clinical staff on internal SOPs and Good Clinical Practices (GCP)

Senior Clinical Research Associate **Dec 1997- Aug 1998**
OXFORD RESEARCH INTERNATIONAL CORPORATION

- Assisted in the recruitment strategies and screening of subjects for a Phase III study involving patients with renal function in type II diabetes and overt diabetic nephropathy
- Managed a Phase I device trial on chronic wounds of patients with skin disease
- Managed a Phase III crossover study in women's health
- Managed a Phase III open-label study in diabetic patients with symptomatic corneal erosion or ulcer
- Managed a Phase IV pain management study
- Assisted in the protocol writing for a device study for an antibacterial product for infectious wounds
- Conducted investigational site training for medical investigators and clinical staff on proper protocol execution, data collection and completion of study objectives within the established timelines
- Worked on the data resolution and preparation for listings and coding of a pediatric acute otitis media study and a dental device study
- Developed informed consents and case report forms
- Assisted in the preparation of a New Drug Application (NDA) for a pediatric acute otitis media study and a dental device study

Clinical Research Associate **Jul 1995 - Dec 1997**
OXFORD RESEARCH INTERNATIONAL CORPORATION

- Independently monitored clinical studies in Phases I–IV at multiple investigational sites for various therapeutic areas, which included diabetes, infections, women's health, cardiology, ophthalmology, dermatology, vaccines, pain management, devices, and biologics
- Performed initiation, monitoring, and close-out visits to ensure accurate and verifiable data entries in case report forms, study files, and drug accountability logs
- Collaborated in the development of an investigational device exemption protocol of a skin graft
- Trained clinical research staff at study sites on protocol objectives and procedures
- Developed tracking tools and processes to successfully monitor a clinical study
- Assisted in the data management, data analysis, coding, and statistical verification of an acute otitis media study in pediatric patients

OTHER PROFESSIONAL EXPERIENCE

Computer Specialist, Information Systems Center **Feb 2005 - Jun 2005**
UNITED STATES MISSION TO THE NORTH ATLANTIC TREATY ORGANIZATION
Brussels, Belgium

- Worked on and maintained Windows 2000 Server, XP Client, XP Office 2003 Professional
- Maintained Windows 2000 Active Directory
- Installed security patches (Patch Management) to OpenNet workstations for 100% compliance
- Performed back-ups for OpenNet LAN
- Upgraded all OpenNet workstations to XP Office 2003 Professional
- Provided first-tier support and problem-solving for the IT help desk

Management Assistant, Office of the Administrative Advisor **May 2004 - Jan 2005**
UNITED STATES MISSION TO THE NORTH ATLANTIC TREATY ORGANIZATION
Brussels, Belgium

- Assisted in the management of the integrated State and Defense U.S. Mission Office
- Assistant to the Deputy Chief of Mission
- Responsible for all Consular issues
- Advised NATO employees on U.S. Visa and Passport matters
- Published and maintained general administrative instructions on management policy and files

- Authored and published the weekly U.S. Mission Bulletin
- Assisted in official and VIP (Presidential, Secretary of State, Secretary and Defense) visits
- Worked with the U.S. State Department on organizing and reviewing employee evaluations

EDUCATION

Master of Science, Neurobiology and Endocrinology
NEW YORK UNIVERSITY, *New York City, New York* **1995-1998**

Bachelor of Science, Biology
CORNELL UNIVERSITY, *Ithaca, New York* **1987-1991**

AFFILIATIONS / MEMBERSHIPS

Board of Advisors
LIFT, Women's Action Focus Organization

Board of Directors, Vice President of Operations
MSTA, Non-Profit Community Recreational Facility

Select Member
NEXT HORIZONS, Enterprise incubator for multidisciplinary (science, technology, educational, etc.) engagement and advancement