Claudia P. Jennings, MBA

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Experienced Clinical Trial Professional

Research & Clinical Trial Competencies

- Leadership, Management, Trainer
- Clinical Trial Management - From Start to Finish (i.e., Protocol implementation, execution, completion)
- Analytical Thinking
- Data Management and Integrity
- Medical / Technical Writer
- Problem Solving
- Research and Development (Phase 1 through 4) - ~30 years
- Product positioning (pharma, consumer, OTC)
- Data Capture Design (i.e., Case Report Forms, Training materials)
- Vendor Management (i.e., CRO, SMO, ESP)
- QA/QC, Compliance and Audit Preparedness
- Communications

Career Experience

Trial Management Consulting Group, LLC NJ – New Jersey Clinical Research Center

Sr. Director Clinical R&D and Operation, Montclair, NJ

- *Therapeutic Area(s) or Study*
  - Lipolysis – (New technology) – 2014 – present – Pending IDE submission
  - Skin Quality (Laxity and Tightening) – 2018 – present
  - Skin Quality – (IIT study) - 2018 - present - Pending IRB approval
  - Adiposity - (Ultrasound technology) – 2018- present
  - Skin Quality - (Laser technology) – 2019 – present
  - Nutraceutical – (PK study) – 2019 - present
  - Cellulite – (Exploratory study) – 2019 - present

- *Operational*
  - Implementation of process improvement initiatives for audit readiness
  - Identified outsourcing needs for the study
  - Lead and managed contracting and engagement of required study vendors
  - Collaborated on Investigator and site selection
  - Assign adequate resource(s) to approved projects, and Oversee operational performance and sponsor-site collaboration efficiencies
  - Implement and execute on several clinical trials key deliverables (i.e., for submission and for publication)
  - Deliver key training to sponsor, and site personnel in the absence of sponsor delivery. Training include but is not limited to:
    - Good Documentation Practices (GDP)
    - Good Clinical Practices (GCP)
    - Safety Reporting and Safety Surveillance
    - Protocol Compliance Key elements and Reporting of Deviation
    - Sponsor and Investigator Obligations in accordance with the Regulatory

...continued...

Guidance per ICH E6 (R2)
    - Protocol Deviation reporting, management and oversight
    - Other,
- Directly execute, or provide needed support in the execution, management to completion of Institutional Review Board (IRB) submissions
- Support and develop applicable sections of INDs, INDAs and IDE for assigned products as needed
- Active participant along with the site Medical Officer at NJCRC in FDA scheduled or required submission defense meetings
- Primary liaison between the sponsor and NJCRC in:
    - Handling unexpected, scheduled or for cause FDA inspections as applicable
    - Reporting or Handling quality issues towards Issue/Resolution at the site level alone, or between the sponsor and the site
    - Evaluating risk at all times during the sponsor-site engagement
    - Communicating identified risk and possible issue/resolution strategies towards mitigating risk to the engagement or the project
- Developed supply forecast for the study if not provided by the sponsor
- Support the assigned resource with the development of essential tracking tools (e.g., supplies for dispensation accountability logs, screening and enrollment logs, site visit logs, other as needed) in the absence of sponsor provision thereof
- Support the assigned study resource (i.e., study coordinator, other) in evaluating, managing and communicating all product quality and complaints as provided by the sponsor prior to study start, and during study conduct to study completion including securing the return of all clinical study supplies (used and unused) as specified in the protocol and contract agreement
- Evaluate and participate in protocol development strategies (i.e., Sponsor-TMC group alone or with the collaboration of the NJCRC Medical Officer as needed)
- Develop first draft, or provide input to the budget and contract, and ensure fully executed versions are on file before any study related activities can commence
- Implemented a preparedness strategy at the site level for monitoring visits, recruitment and Regulatory audits.

- *Authorship / Medical Writing*

    - Synopsis/concept sheet
    - Protocol and amendments (when applicable)
    - IND, NDAs, IDEs, other
    - Informed consent form (s) and amendments (if applicable)
    - Case Report Form Design (prototype)
    - Study Management/Monitoring Plan (SMP) applicable to the investigator, sponsor and external resource (CRO/Consultant) roles and responsibilities
    - Study specific plans and manuals as needed (Consenting, IMP handling, PD reporting, Communications, Start-Up, other as needed)
    - Task Ownership Matrix (TOM)
    - Training Tools and forms
    - Training materials and power point presentations for investigator/site initiation activities
    - Recruitment strategy and associated advertisement materials
    - Standard Operating Procedures (SOPs) and Guidance documents

- Safety Narratives
- Clinical Study Report and Sections thereof

- *Strategy and Project Implementation*

  - Develop baseline timelines for new projects and forecasted on ongoing trials
  - Develop recruitment strategy and study implementation plan
  - Secured study and sponsor personnel prior to study start and in support of the sponsor planned SIV
  - Key collaborator to the database development plan including review and approving of edit checks/edit specifications,
  - Data Integrity and security oversight via query issuance and resolution, data reconciliation, quality assurance and quality control activities
  - Lead the database management, clean-up and closure of an external resource to secure a scheduled FDA submission package

- *Regulatory*
  - Responsible for all CT.Gov reporting requirements (when applicable)
  - Reviewer and approver of the Clinical Study Report (CSR) – by request only
  - Key supporter to the FDA submission of study results – by request only
  - Key handler of Regulatory Inspections with sponsor support (when applicable)

- *Quality and Compliance*
  - Establish and implement good practice for a clinical research department to secure quality and compliance of clinical trials at all times
  - Established the sponsor and investigator regulatory document filing system/governance, investigator selection process for sponsored trials versus Investigator Initiated Trials (ITTS)
  - Key contributor to the audit preparedness, audit management, and Corrective Action Preventive Action (CAPA) plans and strategies

Shionogi, US/Japan
Clinical Trial Manager/Lead*, (Syneos)* 9/2018 – 10/2019

- *Therapeutic Area(s)*
  - Infectious Diseases Program
  - HIV Program
- *Operations*
  - **Lead the cross-functional team** as the regional lead in the planning and delivery of a defined clinical project to scope, quality, budget, time, managing resource and risk
  - Manage and oversee projects as assigned, including the development and maintenance of study plans, timelines and budget.
  - Lead the selection, manage and oversight of CRO and other external service providers
  - Review and ensure alignment between the final approved protocol and all corresponding and associated documents (i.e., inform consent form, CRFs, edit specifications and checks, tracking forms, monitoring plan, other)
  - Provide input into study feasibility, study specifications, vendor/partner contracts
  - Author, or provide input to clinical study protocols, informed consents, CSRs, and other essential documents as appropriate.

- Act as operational interface with external (e.g. CRO) partners. Ensure successful delivery of all study lifecycle deliverables (RFP through completion of the Trial Master File).
- Review and approve contracts, work orders and invoices prior to submission to senior management for approval.
- Lead the development and presentations at investigator meetings or other key project meetings as assigned.
- Establish and maintain effective communication and collaboration with functional area peers, in order to meet program objectives and support achievement of goals.

Novartis, New Jersey

Expert Clinical Trial Manager *(Vivos)*, 10/2017 – August/2018

- *Therapeutic Area(s)*
  - Gastrointestinal Solid Tumor (GIST)
- *Operations*
  - Lead the cross-functional study team responsible for clinical trial deliverables
  - Management and Oversight of one Oncology Global Clinical Trial in the area of Gastrointestinal Solid Tumors (GIST)
  - Data Review and Clean-up in preparation for LPLV and Study Close-Out
  - Safety data review and planning for safety narrative preparations
  - Reconciliation of safety data, regulatory filing system, listings versus electronic data capture
  - Review and collaborate on the Clinical Study Report (CSR) development
  - Clinical supply oversight
  - Lead the collaborations related to a Manage Access Program (MAP)/Post Trial Access (PTA) initiative for patients wishing to transition from a clinical trial to physician only care using the product under investigation.
- *Quality and Compliance*
  - Perform and qualified data management activities respective to remote data capture and database clean-up in preparation for database lock
  - Performed 100% quality assurance review of data listings against the electronic data capture tool to ensure accuracy and completeness of information prior to regulatory submission.
  - Supporting resource to a second trial in the area of pediatric oncology. Primary responsibilities include, but are not limited to review of safety narrative reports, source record (eCRF) against respective listings, QA/QC activities associated with the CSR development, IRB allocation by investigational site.
  - Executed on the reconciliation of the regulatory filing system, review of safety narratives, for a second study (ad hoc assignment) in preparation for database lock.

Trial Management Consulting Group, LLC NJ working for Thermigen, LLC, Irvine, TX

Clinical Research Lead, 1/2016 – 1/2018 (two year contract)

- *Therapeutic Area(s)*
  - OBGYN / Women's Health - vaginal laxity, sexual dysfunction and Stress urinary

incontinence
    - Dermatology and Aesthetic Medicine and Plastic Surgery – Skin Laxity and Hyperhidrosis

- *Operational*
    - Implementation of process improvement initiatives for audit readiness
    - Identified outsourcing needs for the study
    - Lead and managed contracting and engagement of required study vendors
    - Collaborated on Investigator and site selection
    - Implemented and executed on several clinical trials (i.e., for submission and for publication)
    - Delivered project training to sponsor, and site personnel via investigator meeting/site initiation
    - Executed on all Institutional Review Board (IRB) regulatory submissions for approval prior to study start and during the conduct of the study to close-out)
    - Evaluated risk and identified risk mitigation strategies at the study level
    - Developed the clinical supply forecast, developed the clinical supply accountability logs and reconciliation documentation and managed Investigational product availability, labeling and handling (i.e., shipping and return)
    - Managed all product quality and complaints during the conduct of the study and secure timely reporting of any safety concerns with association
    - Provided input to the budget development and management thereof
    - Implemented a "conflict of interest" strategy for investigators directly contracted by the sponsor as key opinion leaders (KOL)
    - Training plan development of junior personnel including site personnel first engaging in formal research activities. Training included GCP/ICH-E6, Consenting process, Good documentation practices, and equipment training if required by the protocol.
    - Implemented a preparedness strategy at the site level for monitoring visits, recruitment and Regulatory audits.

- *Authorship / Medical Writing*

    - Synopsis/concept sheet
    - Protocol and amendments (when applicable) for several Phase II and Phase III aesthetic medicine indications using a 510K Approved Medical Device
    - Informed consent form (s) and amendments (if applicable)
    - Case Report Form Design (prototype)
    - Study Management/Monitoring Plan (SMP) applicable to the investigator, sponsor and external resource (CRO/Consultant) roles and responsibilities
    - Task Ownership Matrix (TOM)
    - Training Tools and forms
    - Training materials and power point presentations for investigator/site initiation activities
    - Recruitment strategy and associated advertisement materials
    - Standard Operating Procedures (SOPs) and Guidance documents
    - Safety Narratives
    - Clinical Study Report and Sections thereof

- *Strategy and Project Implementation*

    - Developed the baseline timelines for new projects and forecasted on ongoing trials
    - Developed recruitment strategy and study implementation plan for a domestic single

center study
    - Secured study and sponsor personnel training for study requirements, Good clinical Practices (GCPs), Food and Drug Administration (FDA) Guidance for medical devices.
    - Key collaborator to the database development plan including review and approving of edit checks/edit specifications,
    - Data Integrity and security oversight via query issuance and resolution, data reconciliation, quality assurance and quality control activities
    - Lead the database management, clean-up and closure of an external resource to secure a scheduled FDA submission package

- *Regulatory*
    - Responsible for all CT.Gov reporting requirements
    - Reviewer and approver of the Clinical Study Report (CSR)
    - Key supporter to the FDA submission of study results

- *Quality and Compliance*
    - Established and implemented good practice for a clinical research department to secure quality and compliance of clinical trials at all times
    - Established the sponsor and investigator regulatory document filing system/governance, investigator selection process for sponsored trials versus Investigator Initiated Trials (ITTS)
    - Key contributor to the audit preparedness, audit management, and Corrective Action Preventive Action (CAPA) plans and strategies

Novartis, New Jersey
Expert Clinical Trial Manager *(Vivos)*, 10/2015 – 4/2016 (6 month contract)

- *Therapeutic Area(s)*
    - Renal Cell Carcinoma
    - Multiple Myeloma

- *Operations*
    - Management and Oversight of study close-out and database lock activities for three Oncology Global Clinical Trials

- *Quality and Compliance*
    - Perform and qualified data management activities respective to remote data capture and database clean-up activities in preparation for database lock?
    - Performed quality assurance reviews of data listings for errors and omissions
    - Supporting resource to the clinical, CSR and regulatory submission teams
    - Secured query resolution for open queries pending response.

NJPS Clinical Research, New Jersey
Trial Coordinator Supporter & Clinical Research Lead, 10/2012 – 10/2014

- *Therapeutic Area(s)*
    - Aesthetic Medicine and Plastic Surgery in the areas of skin tightening, skin lift, fat reduction technologies, and scar repair.

- *Operations*
    - At the site level, lead the implementation and execution of several device clinical trials by acting as a research coordinator
    - Liaise with the sponsoring company on all study issues/resolution
    - Responsible for IRB submissions and renewals
    - Training of investigator and study personnel on study requirements
    - Developed, managed and implemented recruitment strategies based on IRB approval
    - Secure adherence to timelines and worked within budget
    - Implemented the consenting process with each interested candidate in accordance to FDA and GCP guidance and sponsor requirements
    - Patient consenter and assistant to the principal investigator
    - Supported the sponsor database clean-up and lock for several studies.

- *Quality and Compliance*
    - Managed and secured accuracy of source data collection and transcription thereof onto paper case report form (CRF)
    - Handled query / resolution in a timely manner
    - Performed quality assurance reviews for errors and omissions
    - Supporting resource to the medical teams
    - Delivered audit preparedness training and ensured appropriate measures were taken (i.e., locks on medical record rooms, secure filing of patient's source records in lock-n-key cabinets, secure storage locations for clinical supplies, etc.) to secure patient source records and clinical supply storage.

- *Inspections*
    - *Recipient of an FDA scheduled inspection resulting in the investigator and practice being in good standings. No warning letters issued.*

Trial Management Consulting Group, LLC NJ working for E-Lux Medical, San Diego, CA
Clinical Research Lead, 10/2013 – 10/2014 (one year contract – A start-up company)

- *Therapeutic Area(s)*
    - Aesthetic Medicine - Reduction of Adipose Tissue Technology (new device)

- Project
    - Investigational Device Exemptions (IDEs) for Early Feasibility Medical Device Clinical Study - First in Human (FIH)

- *Operational*
    - Collaborator with key opinion leaders (KOL) towards the development of a concept sheet and a clinical development program

- Developed source data collection tools for transcription onto the planned study data collection tool(s)
- Supported cross functional teams in the preparation and submission of the IDE
- Delivered audit preparedness training and ensured appropriate measures were taken (i.e., locks on medical record rooms, secure filing of patient's source records in lock-n-key cabinets, secure storage locations for clinical supplies, etc.) to secure patient source records and clinical supply storage.
- Forecasted investigational product needs and managed the clinical supplies representatives to ensure labeling and testing (toxicological, PK, stability) were initiated and managed as appropriate
- Establishment of the sponsor and site(s) regulatory document filing systems in accordance with ICH-E6 requirements
- Selection and management of external study resources (i.e., Statistics and Data Management vendor)
- IRB/EC selection in preparation for IRB submissions
- Provided input into the budget development and management thereof
- Implemented a "conflict of interest" strategy for investigators directly contracted by the sponsor as key opinion leaders (KOL)
- Established the training plan for sponsor and site personnel. Training included GCP/ICH-E6, Consenting process, Good documentation practices, and equipment training if required by the protocol.
- Implemented a preparedness strategy at the site level for monitoring visits, recruitment and Regulatory audits.

- *Authorship / Medical Writing*

  - Synopsis/concept sheet for a two-part proof of concept study
  - Protocol for several Phase II and Phase III aesthetic medicine indications
  - Informed consent form (s) and amendments (if applicable)
  - Case Report Form Design (prototype)
  - Study Management/Monitoring Plan (SMP) applicable to the investigator, sponsor and external resource (CRO/Consultant) roles and responsibilities
  - Training Tools and forms
  - Training materials and power point presentations for investigator/site initiation activities
  - Recruitment strategy and associated advertisement materials
  - Standard Operating Procedures (SOPs)

- *Strategy and Project Implementation*

  - Development of Timelines in accordance with the clinical development plan
  - Developed the recruitment strategy and study implementation plan for a domestic single center study

- *Regulatory*
  - Key collaborator to the development and submission of the IDE

Mela Sciences, New York

Senior Trial Manager, 10/2013 – 10/2014

- *Therapeutic Area(s)*
    - Oncology – Melanoma Diagnostic Technology (new device)
- Project
    - Post Market Application
- *Operational*
    - Investigator, site and vendor management
    - Establishment of a sponsor and site regulatory document filing system
    - Implemented a process for securing the study database
    - IRB/EC submissions
    - Budget, contract and timeline management

Prior Positions and Therapeutic Areas

- Associate Director Clinical Research *(Pain, Allergy, Dermatology)* - Johnson & Johnson Group of Consumer Companies, Inc. *(12/2006 – 10/2012)*
- Manager/Senior Manager Clinical Research *(Rx-to-OTC switches, Pain, CNS, Dermatology, Infectious Disease, OBGYN-Female Health, Sleep Deprivation)* - Pfizer Consumer Healthcare *(05/2002-12/2006)*
- Manager Clinical Research *(Rx-to-OTC switches, Cardiovascular)* - Warner-Lambert Company *(07/1999- 05/2002)*
- Senior Clinical Research Associate (*Oncology, CNS, Infectious Diseases*) - Schering-Plough Research Institute *(09/1997-07/1999)*
- Regional Clinical Research Associate-North East Region (*Oncology, CNS, Infectious Diseases, Dermatology, Transplant*) - RCR Consultants Corporation *(10/1995 - 08/1997)*
- Clinical Research Associate (*Sepsis*) - Knoll Pharmaceutical Company *(07/1995 – 10/1995)*
- Clinical Research Associate II (*Immunology, Infectious Disease*) - Sandoz Pharmaceutical Corporation *(10/1989 - 07/1995)*

Direct Involvement in Product Approval

Direct involvement in several Investigational New Drug (IND), New Drug Application (NDA), Investigational Device Exemption (IDE) and approvals for the following products:

- Gabapentin
- Lipitor
- Tylenol (various formulations)
- Zyrtec (various formulations)
- Nanoparticles (IDE)
- Radiofrequency technologies (various projects – Label extension and

claim support)
- Trojan
- Bengay formulation Expansion
- 510K approvals on several technologies

Corporate Strategic Planning

- Due Diligence - reviewers of key elements for a product or a service, or combination of both during planned product acquisition or company merger and acquisitions
- Lead SOP and best practice harmonization efforts and prioritize key activities to secure business continuity
- Implementer of consolidated based practice to minimize learning curve between two entities merging to one.

Education and Credentials

Master of Business Administration
University of Phoenix
Bachelor of Arts in Biology, minor in Chemistry
Caldwell College/University, Caldwell, NJ

Professional Training & Certification

A course in Clinical Research for CRAs
A course in Advance Human Physiology
Clinical Research Writing for Protocols
Clinical Research Monitoring Assessment
Professional Excellence Program-Management Series
Statistics for Non-Statisticians
Polysomnography (PSG) Certified
Regulations for Medical Devices
Cambridge "Who is Who Amongst Professionals"
A course in Dealing with Emotional Behavior
Project Management Series workshop
Clinical Research Training System
Foundations of Leadership
Making the Leap: The Innovation White Belt
Technical Writing
Vectra 3D photography Certified
Life Style/Weight Management Coach
CPR certified
Introduction to Pharmacology (PERI) course in Clinical Research for CRAs