RODOLFO NELSON MOLINA

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PROFESSIONAL SUMMARY

Experienced clinical research professional with extensive expertise in trial management, regulatory compliance, and cross-functional coordination. Skilled in overseeing clinical studies and ensuring full adherence to GCP and institutional standards. Demonstrated success in developing and executing trial timelines, enrollment strategies, and risk mitigation plans to ensure efficient study delivery. Proficient in study start-up activities, including protocol and consent development, site training, and regulatory documentation review. Adept at leading process improvement initiatives and building strong collaborations with investigators, coordinators, and hospital personnel to advance clinical research goals effectively and compliantly.

WORK HISTORY

Clinical Research Manager 3, 07/2023 - Current
Yale University, New Haven, CT

- Planned and directed research and development activities for 45+ clinical trials, including device, drug, and investigator-initiated studies.
- Managed budgets, approved expenses, and ensured timely financial reporting.
- Oversaw quality control, assurance, and improvement processes for post-IRB monitoring and sponsor audits.
- Recruited, trained, and supervised exempt and non-exempt staff; assessed staffing needs and guided professional development.
- Developed and implemented research protocols, operational plans, and project timelines to ensure compliance and efficiency.
- Led administrative and operational management, including budgeting, technology needs, facilities, and policy implementation.
- Prepared financial forecasts and performance analyses; ensured compliance with University and federal regulations.
- Coordinated and delivered training on new policies and procedures.
- Built strategic partnerships to expand research visibility and collaboration.
- Conducted study start-up activities, including protocol and consent development, source documentation, and staff training.

Volunteer, Physician-scientist, 06/2016 - Current
Yale University IRB, New Haven, CT

SKILLS

- Detailed oriented Clinical Research Professional with medical education background and Publications.
- Extensive experience working on complex clinical trials.
- Solid knowledge of GCP/ICH guidelines and FDA regulations.
- Certified CPR/AED 2025 and IATA Dangerous Goods, Safe-Pack Training for shipping Hazardous materials
- Ability to work in high volume and high stress setting in clinical research.
- Advance knowledge of federal regulations concerning clinical research, regulatory filling adverse event reporting.
- Proven knowledge of HIPAA, IRB, electronic medical records, EPIC, Yale's Clinical Trials Management System and Advarra e-Regulatory Management System
- Excellent written and verbal communication skills, with eye for detail.
- Proficiency use of variety of software application (E.G., Microsoft Word, Excel,
- CCRP (Certified by SOCRA)

- Human Investigation Committee (HIC 1a and HIC IV)
- Review all biomedical human subject research for its ethical soundness and regulatory compliance.
- Ensure that research design is sound and study hypothesis is reasonable.
- Ensure risks to subjects are minimized, risks to subjects are reasonable in relation to anticipated benefits, selection of subjects is equitable, informed consent is obtained or appropriately waived from all prospective subjects and documented, research protocol includes plan for data and safety monitoring.
- Ensure subject's privacy and confidentiality are protected and appropriate additional safeguards are incorporated for any vulnerable subjects.
- Prepared and presented comprehensive reports to IRB chair and audit team, covering issues and recommendations.
- Interviewed patients concerning physical complaints, discussed symptoms, asked questions, and suggested treatment options

Research Associate II, 01/2014 - 07/2023
Yale, Transplantation Center, YNHTC, New Haven, CT

- Closely worked with various CROs in maintaining site adherence to study drug protocol, FDA regulations, ICH guidelines, Good clinical Practice (GCP) and HIPA
- Managed over 20 clinical trials including observational trials, device and treatment clinical studies.
- Responsible for collection, extraction, and reporting of study-related clinical data
- Monitor study progress daily, generate and present study progress reports to principal investigator.
- Ensure compliance with protocol guidelines and requirements of regulatory agencies: identify problems and/or inconsistencies.
- Coordinate preparation, evaluation, submission, and continuation of all clinical trial protocols to HIC/IRB
- Responsible for resource requirements and financial cost for budged development
- High level of communication with sponsors and contracted monitors on a day-to-day basis
- Manage Cardiac surgery research program, in a dyad relationship with cardiac surgeons
- Holding administrative responsibilities including feasibility, set up and staffing for internally and external funded projects
- Clinical trial budgets (primary internal and external contact for all budget negotiations and invoicing
- Directly train and supervise new study coordinators
- Reviews incoming clinical trials, recommends acceptance of study based on knowledge of university policies
- Organizes regular meetings with section clinical research leadership team.
- Validated incoming data to check information accuracy and integrity while independently locating and correcting concerns.

- Data Analytics
- Laboratory Equipment Functions
- Lab Experiments and Research

- Helped team meet regulatory requirements by coordinating documentation and filings.
- Set up equipment, organized inventory and maintained facilities.
- Evaluated potential subject participants to assess suitability for planned studies.
- Organized participant-informed consent waivers and research scope documentation.
- Collaborated with staff to develop and implement best practices and accomplished all team goals.
- Performed research into study topics to increase knowledge and to provide valuable contributions.
- Collaborated with team members to initiate best practices to achieve organizational goals.
- Worked with principal investigator and sponsors to facilitate daily trial activities and comply with research protocols.
- Screened patient records, databases and physician referrals to identify prospective candidates for research studies.
- Gathered, processed and shipped lab specimens.
- Demonstrated respect, friendliness and willingness to help wherever needed.
- Identifies operational, logistical, and regulatory challenges related to conduct of clinical trials and acts as leader in overseeing their resolution.

Research Assistant, 02/2011 - 11/2013
Pfizer Clinical Research Unit, New Haven, CT
Professional Experience

- Provided specialized support in the execution of more than 50 Phase I and II clinical studies, assessing safety, establishing dosage ranges, and identifying potential side effects.
- Performed comprehensive statistical, qualitative, and quantitative analyses to support study outcomes.
- Collected, validated, and organized research data, preparing accurate charts, graphs, and reports for presentations and regulatory submissions.
- Drafted clear, detailed correspondence and technical reports demonstrating strong scientific writing skills.
- Collaborated with leadership to define study objectives, develop data collection methods, and optimize research design.
- Planned, modified, and executed research methodologies, procedures, and testing protocols to ensure data integrity and compliance.
- Reviewed and validated incoming data to ensure accuracy, resolving discrepancies independently.
- Managed informed consent documentation and maintained compliance with research scope and ethical standards.
- Screened and evaluated potential study participants to confirm eligibility and protocol alignment.
- Designed and implemented surveys and questionnaires to support data collection and analysis.

- Partnered with cross-functional research teams to develop and refine study strategies and workflows.
- Led and contributed to process improvement initiatives, including the development and revision of standard operating procedures (SOPs).

Referral Testing Representative, 04/2008 - 01/2011
Quest Diagnostic, Wallingford, CT

- General microbiology and basic cell culture; media preparation; culturing techniques; culture maintenance
- Responsible for specimen processing, verification of specimen compliance, and operation of centrifuges, aliquoting specimens and preparing and shipping all labs per protocol requirements
- Perform laboratory specimen processing consisting of receiving, identifying, assigning accession numbers, sorting, preparation and internal laboratory distributing of blood, urine, and other biological specimens
- Perform data processing distribution of laboratory reports to 120 patient units throughout Lab; perform clerical duties such as filing, recording, and charting patient results; prepare and/or send data for computer processing; perform filing related to storage of computed data
- Perform semi-technical procedures such as collecting and measuring samples, recording data, weighing specimens, etc.
- Order supplies from established sources and assist in inventories of supplies and equipment, Ensure integrity of specimens sent to other facilities meet criteria necessary to provide accurate and timely results
- Follow compliance policies related to test ordering, research test ordering information on translation tables, computer system, and directory of services.

EDUCATION

M.D., General Physician, 2004
Fundación Universitaria San Martín - Barranquilla, Colombia, Colombia

- Research Project: Quality of life in patients with Chronic Renal Insufficiency who are in dialysis in the renal unit.
- Awarded Gold Altruist Award Issued by Hospital Seguro de los Andes · Dec 2004

CURRENT AND PAST CLINICAL TRIALS

- STIMIT Activator I Pivotal Study
- Terumo Aortic Global Endovascular Registry
- A prospective, multicenter, nonblinded, nonrandomized study of the RelayPro Thoracic Stent Graft in subjects with acute, complicated type B aortic dissections
- Pulse Biosciences' CellFX® nanosecond Pulsed Field Ablation (nsPFA)™ Cardiac Surgery Clamp System for treatment of Atrial Fibrillation (AF) during concomitant cardiac surgery

- BOX-NoAF Trial: A Prospective, Randomized, Controlled Study to Evaluate the Safety and Effectiveness of the AtriCure CryoICE Cryoablation System for the Prophylactic Treatment of New-Onset Atrial Fibrillation in Cardiac Surgery Patients
- CORMATRIX® COR™ TRICUSPID ECM® Valve Replacement Study
- A Prospective, Single Arm, Multi-center Clinical Investigation to Evaluate the Safety and Effectiveness of AMDS in the Treatment of Acute DeBakey Type I Dissection: PERSEVERE
- FREEZE-AFIB Post-Market Study Outcomes of Surgical AF ablation using CryoICE cryoablation system
- PRECISE: A Post-market, Real-World Experience: Expanding Access to Care by Incorporating the Symani System and Enabling Surgeons
- A Phase 3 Randomised, Double-blind, Placebo-controlled Study to Assess the Safety and Efficacy of S-888711 (Lusutrombopag) for the Treatment of Thrombocytopenia in Patientswith Chronic Liver Disease Undergoing Elective Invasive Procedures (L-PLUS 2) PI Dr Manuel Rodriguez-Davalos
- A Prospective, Single-blind, Randomized, Phase III Study to Evaluate the Safety and Efficacyof Fibrin Sealant Grifols (FS Grifols) as an Adjunct to Hemostasis During Parenchymous
- Tissue Open Surgeries.;Sponsor: Grifols
- Open, Prospective, Historic-Controlled, Multicenter Study to Evaluate the Safety and Efficacyof Infusion of Liver Cell Suspension (HHLivC) in Children With Urea Cycle Disorders
- A Multi-Center Trial to Study Acute Liver Failure: Data and Specimen Collection Protocol Acute Liver Injury (ALI)
- A Randomized, Double-blind, Placebo-controlled, Phase 2b study to Evaluate Safety and Efficacy of DUR-928 in Subjects with Alcoholic Hepatitis
- A Phase 2, Multi-Center, Randomized, Double-Blind, Placebo-Controlled,
- Dose-Ranging Study to Evaluate the Efficacy and Safety of Botulinum Toxin Type A
- (AGN-151607) Injections into the Epicardial Fat Pads to Prevent Post-Operative Atrial
- Fibrillation in Patients Undergoing Open-Chest Cardiac Surgery

CERTIFICATIONS

- Certified Clinical Research Professional (CCRP)

LANGUAGES

Spanish

Native or Bilingual

English

Native or Bilingual