5323 South McColl Rd.
Edinburg, Texas 78539

EDUCATION

1983

John Rodriguez

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Doctor of Medicine
Universidad de Monterrey
Facultad de Ciencias de la Salud Monterrey, N. L., Mex.

Office: 956-362-2378

1974

Pre-Medical Curriculum
Pan American
University/Texas A&I/UANL

Edinburg, TX,
USA/Monterrey, N.L., Mex.

PROFESSIONAL EXPERIENCE

Oct 2014 to Present Clinical Research Study Coordinator
Doctors Hospital at Renaissance
Edinburg, Texas, USA

- Oversee the Clinical activities for a large complex study involving multiple sites.
- Ensure the adherence of controlled clinical trial protocols.
- Serve as liaison between the study Investigators , nurses, coordinators, pharmacists and assistance for numerous institutions.
- Provide performance management for staff.
- Accompany sponsor personnel on pre-site and clinical site initiation visits with the Principal Investigators.
- Obtain human subject consents and enroll in clinical study as appropriate.
- Ensure that all clinical aspects of studies are being carried out in accordance with local, state and federal regulation, guidelines and policies.
- Ensure appropriate transmission of clinical case data to the sponsor data management centers.

PROFESSIONAL EXPERIENCE, CONTINUED

- Reviews case report queries and problems, and clarifies and/or obtains changes to data as appropriate.
- Coordinate the maintenance of record on study medication and study devices dispensation and inventory usage during the course of the study.
- Ensure Confidentiality of subject records.
- Monitor and record patient response to treatment and communicates study data and results to investigators.
- Maintain and complete source documentation and oversee the preparation of study activity reports for sponsors and investigators as appropriate. Prepare regulatory and ethical submissions and procedures to the Institutional Review Boards and study sponsors.
- Responsible for the set-up and maintenance of the administrative structure and the infrastructure of the project(s).
- Responsible for the management of study budget. Conduct the financial and contract negotiations at the appropriate management level.
- Negotiate contract terms, pricing and payment schedule, ensuring that the agreements with the vendors/suppliers are commercially advantageous.
- Establish, revise and implement SOP's.

Apr 2013 to Sep 2015 — Consultant
Houston, Texas, USA

- Provided consulting services to Houston, Texas area Site Management Organizations (SMO's), including, but not limited to, addition of new research specialties/investigators to existing SMO, Standard Operating Procedures SOP)/Compliance reviews and updates/recommendations. Identify areas requiring quality and improvements and implement as needed.

May 2010 to Mar 2013 Clinical Research Coordinator III
US Oncology Research, Inc.
The Woodlands, Texas, USA

= Under minimal supervision of a physician and nurse (if applicable), was responsible for enlisting, maintaining, and assuring protocol compliance for patients on oncology trials.

CJ Collaborated with physicians in determining eligibility of patients for oncology trials.

c:::i Ensured site research quality, patient safety and privacy by practicing in compliance with US Oncology Research, Inc. Standard Operating Procedures (SOP), principles of Good Clinical Practice (GCP), International Conference on Harmonization (ICH), Health Insurance Portability and Accountability Act (HIPPA), Code of Federal Regulations (CFR) and other applicable federal,

== state, and local regulations.

Screened/reviewed patient medical charts for protocol eligibility.

Presented trial concepts and details to the patients, participated in the informed consent process, and enrolled patients on protocol.

e:, Disbursed investigational product (IP) and

= provided patient teaching regarding administration. Maintained IP accountability (received, inventory, and returns).

In collaboration with the physician, interviewed patients for changes in conditions, adverse events (AE), concomitant medication use, protocol cqmpliance, response to study drug and thoroughly document all findings.

E.::::I Participated and presented in required training and

= educational programs.

= Identified quality and performance improvement opportunities (if applicable) and implemented at sites.

= Worked independently while at sites and communicated effectively with site research staff to ensure completion of assignments.

= Verified and confirmed the preparation of orders by physicians to assure protocol compliance was maintained.

Communicated/trained, as required, physicians and site research staff regarding study

- requirements and changes needed for dose modification/adjustment, AE, and deviation reporting.
- Trained, mentored, and provided guidance to newly hired research staff with respect to the research process and systems (paper/electronic) used by US Oncology, Inc. and Texas Oncology.

Feb 2009 to Apr 2010
Contract Clinical Research Coordinator

RID Clinical Research, Inc.

Houston, Texas, USA

1:5 Coordinated under contract status various Phase II-IV clinical trials including but not limited to: cardiovascular, endocrine/metabolic, musculoskeletal, and psychiatric disorders and infectious diseases.
Additional responsibilities included Investigational Review Board (IRB)/sponsor submissions (site feasibility, interim, closeout visit and study progress reports) and vendor negotiations.

Aug 2005 to Dec 2008

Sub-Investigator/Regulatory Associate Fein-Jennings Clinic, Inc.

PROFESSIONAL EXPERIENCE, CONTINUED

Houston, Texas, USA

= Sub-Investigator/Regulatory Associate responsible for Phase II-IV central nervous systems (CNS) clinical trials.

e, Was responsible for the proper conduct and execution of clinical trials were done by investigators in accordance and in compliance with SOP, CFR, GCP, ICH, HIPPA and other

= applicable regulatory agency guidelines.

As a Regulatory Associate was responsible for completion, submissions, revisions and filing of all project related critical documents to local and/or central IRB and sponsor.

C3 Performed internal audit/quality assurance of site study files and source documentation to assure compliance.

e:'I Was responsible for creation and submission of study budgets.

Jun 2005 to Aug 2005

Jun 1991 to Jun 2005

In-house Monitoring/Quality Assurance Therapeutic Concepts, Inc.

PROFESSIONAL EXPERIENCE, CONTINUED

Houston, Texas, USA

Adverse Events reported by the

e=, Was responsible for in-house monitoring (verified source data documents against case report form (CRF) entries for accuracy and completeness) of all infectious diseases and HIV/AIDS clinical research studies conducted by six full-time clinical research coordinators (CRC). Performed quality assurance/edit checks to ensure that all trials were conducted as per protocol and in compliance with SOP, CFR, GCP, ICH, and other regulatory agency guidelines.

= Was responsible for the initial writing of, follow up, and submission of all Serious

CRC's.

Sub-Investigator/Inpatient Facility SupeNisor/Co- Monitor
Fabre Research Clinics, Inc./Research Testing, Inc./Fabre-Kramer Pharmaceuticals
Houston, Texas, USA

ei Sub-Investigator, inpatient facility supeNisor and trial coordinator for Phase I-IV CNS, generic formulation, cardiovascular, infectious, oncology

= and pharmacokinetic clinical trials. Supervised and managed 36 bed inpatient facility supported by 4-8 full-time staff (licensed nurses, paramedics, CRC's, and research assistants) and up to 18 contract staff members during Phase I trials and normal healthy male studies.

C::::i Trained, mentored, and provided guidance and continuing education for all supervised staff in new and existing protocols (amendments,) GCP's, SOP's, and policies.

e.::i Assisted or was solely responsible for the development/design of CRF's , study budgets, and study analysis.

PROFESSIONAL EXPERIENCE, CONTINUED

- In-house monitoring of studies conducted by CRC's as well as time permitting co-monitoring visits (site selection, site initiation, interim, and closeout visit reports) with field Clinical Research Associate.
- Assisted under Principle Investigator's Texas License to provide direct supervision of patient care and management.
- Was trained and certified to administer psychiatric and neurocognitive rating scales.
- Translated, Spanish to English, medical articles, journals, and clinical trial findings for pharmaceutical division of the corporation.

Aug 1987 to Dec 1990

Assistant to Physician/Liaison/Instructor

Bellaire Physical Medicine & Family Practice Houston, Texas, USA

PROFESSIONAL EXPERIENCE, CONTINUED

- Was responsible for assisting physician in the reports and narratives for insurance companies.
- Prepared insurance

for assisting physician in the evaluation and examination of clients involved in work related injuries and/or motor vehicle accidents.

- Acted as liaison between physician, patient, and attorney as well as preparing preliminary medical

- Prepared insurance claims and/or assisted accident victims in obtaining workers

compensation.

Was part-time teaching instructor of anatomy, physiology, pharmacology, and laboratory procedures for teaching institute.

Apr 1986 to Aug 1987

Assistant to Physician

Physicians Plaza OB-Gyn Clinic
Corpus Christi,
Texas, USA

PROFESSIONAL EXPERIENCE, CONTINUED

- Assisted clinic physician with the diagnosis and •

- Was second surgical assistant during scheduled hospital based

treatment of obstetrical/gynecological patients and family planning.

surgeries.

Jan 1985 to Apr 1986

FOREIGN LANGUAGES

Language

Medical Doctor/Director

United States of Mexico Health Ministry Northeast Medical Division, N. L., Mex.

a Managed other health care professionals including but not limited to: medical doctors, dentists, nurses, and nutritionists

a Director of medical services and practicing physician responsible for all facets of government owned and operated emergency clinic.

a Provided emergency care, primary patient care, minor surgeries, obstetrics, primary and secondary preventive care to the indigent.

dentists, nurses, and nutritionists.

e:i Developed and implemented protocol involving antiviral medications for purposes of pharmaceutical research under the Health Ministry's guidelines and regulations.

Fluent in Spanish, speak, read, and write.