KATHY LENHARD, RN
301-633-6602
klenhard@panamclinicalresearch.com

PROFESSIONAL SUMMARY

- 28 years in healthcare industry, 4 years as a Critical Care Registered Nurse, and 25 years in Clinical Operations globally for the Pharmaceutical, Biotechnology and Medical Device Industry.
- Major responsibilities have included Directing Clinical Operations for Global trials Phase 1-4 Pharmacovigilance, monitoring out-patient and in-patient clinical trials, managing CRA teams, authoring SOPs for Sponsors and clinical sites, authoring a graduate level program in Clinical Research (accredited by the 2nd largest University in Mexico City, Mexico), and conducting GCP and Safety audits globally.
- Major clinical operations contributor on the licensure team of products.
- Successfully led a clinical trial in Mexico City during the Pandemic H1N1 in the epicenter of the pandemic, enrolling 4550 subjects in 5 months at one clinical site and co-authored a publication in Vaccine Journal.
- CEO, Operations Director of a clinical research site in Mexico City, Mexico.
- Expert in Good Clinical Practices GCP Readiness for FDA inspection.
- International Speaker on Clinical Operations and Regulatory Compliance.
- Served in various Clinical Operation capacities, including as Regulatory Compliance Auditor for GCP including PV Audits. Medical Writer, Clinical Research Associate (CRA) and held the position of Director of Clinical Operations.
- Contributed to IND, NDA and BLA for Pharma and IDE & PMA for Device.
- Successfully participated in 2 NDAs.

PROFESSIONAL EXPERIENCE

PANAM Infusion & Medical Services
Chairman of the Board of Directors &
Investor
Clinical Research Operations
Oct 2012 –present
President/Owner PanAmerican Clinical Research

- Site management for Global sites in Latin America
- Directing Clinical Operations of PanAmerican Clinical Research
- Clinical Operations services to Pharmaceutical Companies specializing in Community based recruitment and retention.

Director Clinical Operations
June 2011 – Jan 2013
Mexico Centre for Clinical Research, Mexico City, Mexico (MCCR)

- Investor in building a clinical research facility for Medical Device and Pharmaceuticals, authoring company intellectual property with SOPs, work practices, Negotiation of Clinical Trial Budgets, training staff, creating tools for source documentation, completing feasibilities assessments, hosting qualification, initiation, routine and close-out visits
- Accomplishments to Date:
  - Secured 40 clinical trials for the center with signed contracts.
  - Submitted 40 regulatory packages to Ethics committee and all were approved as submission to Ethics in Mexico is completed by the clinical sites.

- Educated Clinical Research Professionals in Medical Device and Pharmaceutical Research and assist with the set-up of additional clinical sites.
- Authored a graduate level clinical research course at the 2nd largest University in Mexico City, Mexico. Contributed also as an International Professor. Course content included Medical Device, Pharmaceuticals and Biologic research.
- Established MCCR as the highest enrolling site in a global study for HIV study for BMS with less than 2% screen failure rate.
- Managed a staff of 11 including 4 MDs, 1 PhD, 1 Dietician, 1 RN, 1 CPA and 3 administrative staff.
- Held position on the Board of Directors as Vice President

Director Clinical Operations
April 2008 – April 2011
Novavax Inc., Rockville, Maryland

- Led and managed the Clinical Operations Department
- RSV and Seasonal Vaccine Development
- Conducted training for clinical staff.
- Authored all SOPs, set up Trial Master File, created and negotiated clinical trial budgets, managed clinical trial agreements, identified clinical sites for 5 clinical studies, selected CRO and managed the CRO and oversight of all clinical monitoring and reporting of subject data
- Responsible for clinical portion of regulatory submissions to Mexico for emergency use. Responsible for providing clinical data for Novavax to obtain award from BARDA (US Govt. Agency)
- Delivered presentations to COFEPRIS, Mexican Govt. for vaccine approval.
- Conducted 3rd party vendor audits, GCP compliance audits and co-monitored with CRO/CRAs
- Responsible for Phase I-III, from start to completion, with positive results.
- Co-authored 3 abstracts for industry presentations and co-authored 1 publication in Vaccine Journal; July 2011
- Conducted Due-diligence audit at Cadilla Pharmaceuticals in Ahmedabad, India for joint venture between Novavax and Cadila
- Prepared written reports as required for senior executives

Consultant Vice President Clinical Operations
April 2007 – April 2008
Spinal Kinetics

- Responsible for implementation of Post-marketing study in Germany, (Project Management) including conducting investigator meetings, training and managing German Study Team, qualifying and conducting all monitoring visits, creation of SOP's, US-CRF design, OUS database audits, managing OUS Data Management flow, set-up of IDE feasibility study and investigator qualification.
- Managed 10 direct reports
- Prepared written reports and presentations for Board of Directors.
- Conducted GCP audit of clinical site in Mexico City, Mexico.
- Managed Clinical outsourcing, contract and budget negotiation

PanAmerican Clinical Research

Clinical Research Consultant
April 1992 – April 2007
Lenhard Clinical Research Consulting

- CRA, conducting study site qualification, initiation, routine and close-out visits Critical Care in-patient studies (Risk based monitoring) and out-patient
- Proficient in EDC, monitoring in-patient and out-patient studies, Phase I-IV
- Auditing clinical sites for compliance with ICH GCPs and US Federal
- Regulatory and safety audits both for Device and Drug Trials, including IRB's and Third Party Vendor audits, databases, protocols, CSRs and IB's. in US, Canada, India, Latin America specifically Mexico and EU.
- Medical writer for IB, Protocols, CSR, IND's.
- Managed CRA monitoring teams
- Safety Surveillance activities, SAE database reconciliation, SAE narratives, assemble safety data into medical summaries, Medical Safety Review Nurse
- Assisted with development of systems to streamline data queries related to drug safety and medical safety review
- Developed regional drug safety program including implementation of systems and tools exported Internationally for the facilitation of reporting drug and medical safety data
- International Speaker at Investigator meetings on Clinical Operations including Safety reporting in the following cities, Paris, Madrid, Rome, London.
- Developed SOPs for small biotech companies

Registered Nurse
May 1988 – April 1992
Good Shepard Hospital

EDUCATION

Elgin College
Nursing

- Registered Nurse (RN), 1988

PanAmerican Clinical Research

THERAPEUTIC AREA EXPERIENCE

Pharmaceuticals:

- Anesthesia
- Respiratory
- Allergy
- Cardiac
- Chronic Pain
- CNS
- Dermatology
- Diabetic
- Gastrointestinal
- Nephrology
- Oncology
- Ophthalmology
- Rheumatology
- Respiratory
- Vaccines
- Infectious Disease

Device:

AAA Stents
Carotid Stents
Spinal Cord Implants
Hip Replacements
Interventional Radiology
Heart Valve
Knee Replacement
Renal Stents

PROFESSIONAL MEMBERSHIPS AND ACCREDITATION

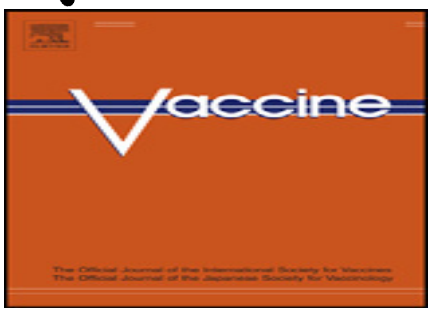
- MEMBER DIA
- MEMBER RAPS (Regulatory Professionals)
- MEMBER SQA (Society of Quality Assurance)
- CERTIFIED INSTRUCTOR – Nursing Program
- RN NURSING LICENURE- ILLINOIS (current)
- COPYRIGHT – MCCR CLINICAL RESEARCH GRADUATE LEVEL PROGRAM
- (POLITECHNICAL INSTITUTE OF MEXICO) Mexico City, Mexico

PUBLICATIONS

Nursing Journal Article (Nursing Spectrum 1994)
(From the Bedside to the Boardroom)

Vaccine Journal July 2011
Vaccine 29 (2011) 7826–7834

PanAmerican Clinical Research



Contents lists available at ScienceDirect Vaccine journal homepage: www.elsevier.com/locate/vaccine Safety and immunogenicity of a virus-like particle pandemic influenza A (H1N1) 2009 vaccine in a blinded, randomized, placebo-controlled trial of adults in Mexico

Constantino López-Macías,*, Eduardo Ferat-Osorio, Alejandra Tenorio-Calvo, Armando Isibasi, Juan Talavera, Oscar Arteaga-Ruiza, Lourdes Arriaga-Pizanoa, Somia P. Hickman, María Allende, Kathy Lenhard, Steven Pincus, Kevin Connolly, Ramadevi Raghunandan, Gale Smith, Gregory Glenn,**

[a] Medical Research Unit on Immunochemistry, Specialities Hospital of the National Medical Centre "Siglo XXI" Mexican Social Security Institute (IMSS), Mexico City, Mexico [b] Epidemiology Research Unit, Specialities Hospital of the National Medical Centre "Siglo XXI" IMSS, Mexico City, Mexico [c] Biomedicine and Molecular Biotechnology Program, Biochemistry Department, National School of Biological Sciences, National Polytechnic Institute, Mexico City, Mexico [d] Novavax, Inc., 9920 Belward Campus Drive, Rockville, MD 20850, USA

GCP Audits including PV/Safety Audits

DataBase Audit for 43,000 patient study including reconciliation of clinical and safety database

GCP and Safety Audit and corrective action to assist client to get off Data integrity hold by FDA. Clinical data was released off "Hold" and the product is approved.

GCP audits globally (23) for PDE- 4 inhibitor for COPD, German company and product is now approved in EU and USA

GCP audits Latin America on vaccine studies, Infectious Disease (HIV) CNS and endocrinology indications.

•