Lee Ann Morgan**

Regional Clinical Monitor

****Simply Working Smarter: Endpoint-Focused Clinical Project Success.**

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12 Years of Calm, Cool, Collected & Collegial Research Site Monitoring (Surgical, Device, and Pharma)

Allergy / Immunology / Asthma
Anesthesia - Reversal
Anti-infectives – Skin, Lung, Abdominal.
Cardiology – Pacing
Cosmetic Surgical – Implantables
CNS – Insomnia
Cardiovascular: CHF, CAD, CABG
Gastroenterology
Hematology – Anemia / Chemo
Neurology – Peripheral Neuropathy
Orthopedics – Spine, Knee
Pediatrics – Immunology, Cardiology
Endoscopic Surgery: CT, GI, Gyn, Urology

Clinical Monitoring / Writing / Data Project Skill Sets

- **Study Initiation, Interim, and Close-out monitoring of Western U.S./Canadian regional sites.**
- **In-patient and out-patient record review.**
- **Phase I-IV, prospective, randomized, blinded, comparative, open-label, & post-marketing studies.**
- **Writing/Editing: Concise, accurate site visit reports, SOPs, training/operations manuals.**
- **Regulatory: writing/editing of clinical protocols, consents, case report forms, interim/final reports.**
- **Business Process / Site Monitoring Improvement Practices per FDAMA 1997 Industry Guidance.**
- **21 CFR, ICH, FDA, F.D.A.M.A. Compliance.**
- **Electronic Data Capture (EDC), Continuous Data Flow, Paper CRF data models.**
- **Timely, efficient, customer-relations approach in study monitoring and compliance.**
- **Databases: Oracle Clinical, E-Clinical, Documentum, Lotus, Access, Vista Care, VPN Remote Networking, Citrix, Windows, EDC: Third Phase, InForm, E-Track, Open Clinica, & Web-based Document Management Platforms.**

INDUSTRY EXPERIENCE: 1998-Present (by Project)

2004-Present:
A Multi-Center, Multi-national, Phase II, U.S.- Canada – United Kingdom - New Zealand Study of Device XXX for prevention of sustained lumbar spinal compression syndrome during physical activity.

2009 : National Heart, Lung and Blood Institute: Regional Site Monitor: National Heart, Lung and Blood Institute / University of Utah – A Multi-Center, Long-Term Outcome Study of the Effects of Therapeutic Hypothermia After Pediatric Cardiac Arrest. (THAPCA). Manage site visit schedule for assigned Sites; Conduct Interim Site Visits: Provide Ongoing GCP Training to Site Staff; Manage Study Documentation for Project Leads at Sponsor, CRO, and Monitoring Lead.

2006-2008: Medimmune, Inc. Western Regional Clinical Research Associate
A Phase IV Pediatric Respiratory Syncitial Virus (RSV) Vaccine Study Comparing Immune Reactivity Between Liquid and Lyophilized Formulations of Substance XXX.

2007: Western Regional CRA – Asthma / Allergy Inhaler Therapy Comparison Study During Allergy Season (Sept.-December 2007)

2006:Cmed Inc. Western Regional CRA Phase III – Anesthesia Reversal Study. Conducted Site Initiation and Interim Monitoring Visits. Consent review, Study site training, Site Management.

2006: Neurology Associates: A Prospective Phase I Study of the Application of TOS/MPR-P Transdermal Gel in Conjunction with Sonophoresis and Physical Therapy for the Treatment of Peripheral Neuropathy. Study Design, Protocol , Consent, Case Report Form Development..

2005: Norwich Clinical Research Associates New York
Independent Third Party Clinical Auditor for PMA Implantable Orthopedic Device. Conduct final audit of Clinical Data for QA and Regulatory Compliance, reporting results to FDA prior to Market approval.

2005: Valle Verde Skilled Nursing Center (Santa Barbara, CA)
Health Information Systems and Quality Assurance Officer
Management and organization of In-patient Health Information Systems Database and Records/Charting system for 80-bed skilled nursing facility. Conducted QA Audits of in-patient records, maintained resident medical files, managed health information correspondence and documentation per HIPAA and State regulations.

2004: Clinical Cardiovascular Research, LLC:
Regional Clinical Research Associate
Conducted interim field monitoring visits for client companies in 3 cardiology trials at **9** study sites per FDA/ICH guidelines for Good Clinical Practices and Corporate SOPs. Assured proper informed consent and reporting/tracking of adverse events, verified protocol data to source records, monitored concomitant medications, noted protocol deviations, resolved data queries. Developed framework for regional monitoring training program modules. Revised corporate standard operating procedures for field monitoring.

2003:Covance, Inc.:
Regional Clinical Research Associate
Conducted interim field monitoring visits at **15** sites in California per FDA/ICH guidelines, Corporate SOPs and study Monitoring Plans in 3 therapeutic areas: Anemia, Chronic Insomnia, Anti-infectives. Assured proper consent, patient eligibility, protocol adherence, verified CRF data to source, resolved queries, assured proper reporting of adverse events. Provided guidance to sites for patient recruiting.

2001-2003 Medtronic, Inc.:
Regional Clinical Research Associate
Conducted interim and close-out monitoring visits at **17** sites in the Western U.S. and Canada. for Phase II Implantable Bi-ventricular pacemaker for Class II-IV Congestive Heart Failure. Verified patient eligibility and consent. In-patient and out-patient record review. Prepared sites for FDA audits. Collected adverse events, monitored concomitant medications, recorded protocol deviations, administered corrective action procedures to secure protocol compliance.

2000-2001 Inamed Medical Corporation: (Santa Barbara, CA)
Clinical Research Associate III
Conducted field research monitoring visits at **20** sites across U.S. for Phase II implantable silicone device. Reviewed and verified data with medical records, verified study documentation to be current and valid. Trained site staff when indicated. Assured compliance with regulatory requirements, wrote site inspection reports, entered visit findings into central database. Revised Clinical Monitoring standard operating procedures.

1998-2000: Computer Motion, Inc.: (Santa Barbara, CA)
Clinical Research Associate I and II
Coordinated multiple pilot research studies per FDA requirements for endoscopic cardiovascular surgical device. Assisted in study design and strategy, literature review, writing/editing of FDA submissions. Initiation of investigational sites, conducted monitoring visits at sites for compliance with study protocol, verified data with source documentation. Review and tracking of subject data, database creation, validation, data entry and analysis. Writing/editing/compiling of clinical interim and summary reports and regulatory documentation. Developed GLP procedures and data collection. Created and organized company's internal research data files and filing systems.

Relevant Prior Experience: Value-Added.

Medical Coding: 7 years
Sansum Clinic Multi-specialty CPT/ICD9-CM Medical Coder, Medical Records Reviewer, Computer Systems Operator. **Ability to leap into new therapeutic areas in a single bound.**

Training / Post-Secondary Education: 11 years
Santa Barbara Community College District / California Two-Year College System Instructor, English Composition - Preparatory & Transfer-level Composition, Literature, and Interdisciplinary Academic Research Writing Programs. Institutional Committee Service, Curriculum Designer and Presenter of District and Statewide Instructor Training Seminars. Co-Director of Honors Program and Coordinator of Adult Education Pharmacy and Medical Records Technician Programs.

CLINICAL TRIALS

1. **Device: Phase I and II** Multi-Center Prospective Inpatient Safety and Efficacy Study of a Videoscopic Robotic-assisted Surgical Platform for Coronary Artery Bypass Grafting (CABG) in Adults with Coronary Artery Disease.
2. **Device: Phase I and II** Multi-Center Prospective Inpatient Safety and Efficacy Study of a Videoscopic Robotic-assisted Surgical Platform for Laparoscopic Cholecystectomy in Adults with Acute Gall Bladder Disease.
3. **Device: Phase I** Single-Center Inpatient Efficacy Study of a Videoscopic Robotic-assisted Surgical Platform in the Re-anastomosis of Previous Fallopian Tube Ligation in Women of Childbearing Age.
4. **Device: Phase II** Multi-Center Prospective Long-term Safety and Efficacy Study of Implantable Silicone Device in Post-Mastectomy Breast Reconstruction and Augmentation.
5. **Device / Pharma: Phase II** Multi-Center, Randomized, Double-Blind Safety and Efficacy Study of Implantable Bi-Ventricular Pacemaker Comparison With Medical Therapy in Adults with Class II-IV Heart Failure.
6. **Pharma: Phase III**, Randomized, Double-Blind, Placebo-Controlled, Outpatient, Two-Arm Safety and Efficacy Study of XXX in Adults and Elderly Adults over 65 with Chronic Insomnia.
7. **Pharma:** Randomized, Open-Label, Multi-Center Study of XXX Administered Once Every 2 Weeks (Q2W) Compared with YYY Administered Once Every Week (QW) for the Treatment of Anemia in Subjects with Non-Myeloid Malignancies Receiving Multi-cycle Chemotherapy.
8. **Pharma: Phase III**, Multi-Center, Double-Blind, Randomized (3:1) Study Evaluating XXX and YYY for the Treatment of Selected Serious Infections In Subjects With Vancomycin-Resistant Enterococcus and Evaluating XXX and ZZZ for the Treatment of Selected Serious Infections in Subjects with Methicillin-Resistant Staphylococcus Aureus.

9. **Pharma: Phase III** Multi-Center, Open-Label, Non-comparative Study of XXX for the Treatment of Subjects with Selected Serious Infections due to Resistant Gram-Negative Organisms e.g. Enterobacter Species, Acinetobacter baumannii, and Klebsiella pneumoniae.
10. **Pharma: Phase III** Multi-Center , Randomized, Double-Blind Comparison Study of the Safety and Efficacy of XXX as Broad-Spectrum Agent with YYY to Treat Complicated Skin and Skin Structure Infections.
11. **Pharma: Phase III** Multi-center, Double-Blind, Randomized, Comparison Study of the Efficacy and Safety of XXX to YYY/ZZZ to Treat Complicated Intra-Abdominal Infections in Hospitalized Subjects.
12. **Pharma: Phase III**, Open-Label, Multi-Center Long-Term Prospective Safety and Pharmacokinetic Study of Positive Oral Inotrope XXX in Patients with Class III-IV Congestive Heart Failure.
13. **Device: Phase II** Multi-Center, Controlled Safety and Efficacy Study of Left Ventricular Assist Device in the Treatment of Acute Decompensated Heart Failure in Patients Requiring Hospitalization and Intravenous Pharmacologic Intervention.
14. **Pharma: Phase II**, Multi-Center, Dose-Escalation Study to Evaluate the Safety, Tolerability, Pharmacokinetics and Efficacy of XXX (a biologic agent) Administered by Intra-myocardial Injection to Induce Angiogenesis for the Treatment of Coronary Artery Disease.
15. **Device: Phase II**, Multicenter, Prospective, Randomized, Safety and Effectiveness Study of an Implantable Bovine Collagen Meniscal Replacement Through Arthroscopic or Open Approach in Patients with Grade I-III Meniscal Degeneration and Reparable Meniscal Injury.
16. **Pharma**: **Phase I**: A Prospective Study of the Application of TOS/MPR-P Transdermal Gel in Conjunction with Sonophoresis and Physical Therapy for the Treatment of Peripheral Neuropathy in Patients Failed Under Conventional Medical Therapies. Protocol, Consent, CRF development, Data Collection, Compilation, Analysis, Preparation of abstract for peer review and publication, Journal of the American Academy of Neurology.
17. **Pharma / Device**: Phase **IIIa** – Anesthesia Reversal Study. A Multicenter, Randomized, Parallel group, Active Controlled, Blinded Study, Comparing Recovery from Deep Neuromuscular Block using Rocuronium followed by XXX with Recovery from Deep Neuromuscular Block using Succinylcholine, with Train of Four Device for Neuromuscular Monitoring.
18. **Pharma / Biologic**: A Phase **IV** Multi-Center Pediatric Respiratory Syncitial Virus (RSV) Vaccine Study Comparing Immune Reactivity Between Liquid and Lyophilized Formulations of Substance XXX.
19. **Device – Phase II Orthopedic: March 2008 - Present**
    Project Manager: A Multi-Center Phase I U.S., Canadian, and New Zealand Study of Device XXX for prevention of sustained lumbar spinal compression syndrome during physical activity as compared with Device YYY. Protocol Development, Consent, CRF Design, Site Qualification, Initiation, Interim and Closeout Monitoring, Data Review, SAE reporting.
20. **Device** – University of Utah & National Heart, Lung and Blood Institute: A Long-Term Outcome Study – Therapeutic Hypothermia After Pediatric Cardiac Arrest.
21. **Device** – Ideal Implant Incorporated, Dallas, Texas: Long Term Safety / Efficacy Study, Dual-Shell Saline Breast Implant.

EDUCATION

University of California, Riverside, CA
Post Graduate Coursework*: Instructional Theory in Post-Secondary and Adult Education.

University of California, Santa Barbara, CA
M.A.* English: Literature, Composition Theory, Academic Research Writing. Minor: Biology

University of California, Santa Barbara, CA
B.A.** English & American Literature