Neal H. Surasky, MDiv, CCRC

PROFILE:

A Certified Clinical Research Study Coordinator with a range of experience in the pharmaceutical development/clinical research industry, including bioequivalence and first-in-man trials, as well as Phase 2 and Phase 3 testing. Is able to work independently as well as part of a team. Experienced in study coordination, development of study timetables based on sponsor protocols, conducting study initiation meetings, randomization and dosing of study participants. Management skills include training of site staff, scheduling of clinical technicians, document and financial analysis and inventory control. Pays attention to detail, is reliable and dedicated to a quality product.

EXPERIENCE:

2006 - present **CHESAPEAKE RESEARCH GROUP**
8030B Ritchie Highway
Pasadena, Maryland 21122

Director of Compliance:

- Review and become familiar with sponsor protocols.
- Based on sponsor protocols and eCRF systems, design, implement, track and revise site source documents.
- Manage three full- and part-time staff responsible for eCRF data entry.
- Create and maintain all electronic Investigator Site Files for regulatory documentation.
- Complete and submit documents for Institutional Review Board review.
- Review and revise company Standard Operating Procedures as needed.
- Provide oversight for company training programs.
- Interface with Sponsors/monitors during site visits, including site qualification visits, site initiation visits, interim monitoring visits and close-out visits.

Data Manager/Quality Assurance Coordinator:

- Review and become familiar with sponsor protocols.
- Based on sponsor protocols and eCRF systems, design, implement, track and revise site source documents.
- Complete eCRF data entry based on completed site source documents.
- Review all site source documents for completeness and accuracy.
- Interface with monitors from CRO and sponsor during interim monitoring visits.
- Review and complete all study source documentation accurately and completely.

Clinical Research Study Coordinator:
Chesapeake Research Group (CRG) conducts clinical research trials with human study subjects. Responsibilities include:

- Review and become familiar with sponsor protocols.
- Recruit, screen and conduct study visit procedures per protocol.
- Review and complete all study source documentation accurately and completely.
- Transcribe data from source documents to Case Report Forms accurately and completely.
- Design, revise and track original source documents based on sponsor protocols.
- Use various electronic data capture sites to enter study data, review and respond to queries.
- Design and implement Quality Assurance and Quality Control programs

2005 - 2006 **BIOANALYTICAL SYSTEMS, INC.**

Clinical Research Study Coordinator:
Bioanalytical Systems, Inc. (BASi) conducts clinical research trials with human study subjects, primarily in Phase I and Phase IIa of development. Responsibilities included:

- Providing overall coordination for clinical research trials according to GCP.
- Developing study timetables based on sponsor protocols.
- Conducted study initiation meetings.
- Randomized study participants into studies based on inclusion and exclusion criteria.
- Supervised up to 20 phlebotomy technicians, including time management, scheduling and study-specific assignments.

1996 - 2005 **MAXIM HEALTH CARE**

Licensed Practical Nurse, Home Care:
Maxim Health Care provides supplemental health care staffing to health care facilities as well as home care staffing for patients requiring home health nursing. Responsibilities included:

- Providing one-on-one direct patient care to a variety of patients.
- Specialization in pediatric ventilator and tracheotomy care.
- Providing ventilator and tracheotomy care.
- Providing G-tube care and feeding.
- Providing personal hygiene care, intake and output, physical assessment, vital signs, and decubitus ulcer prevention.

2000 - 2004 **THE LEWIS & HARRIET LEDERER FOUNDATION, INC.**

Business/Office Manager:
The Lewis & Harriet Lederer Foundation, Inc. is a non-profit publishing company provided proprietary materials, as well as other resources, via a printed catalog as well as the internet. Responsibilities included:

- Supervising 6-14 personnel in all aspects of daily operations, including Accounts Payable, Accounts Receivable, Inventory, Shipping, Customer Service, and Purchasing.

- Facilitating transition from in-house operations to outsource company.
- Working independently to perform financial analysis for company president.
- Hiring and firing personnel, as well as conducting personnel annual reviews.
- Managing payroll and benefits for up to 14 personnel.
- Maintaining up to 14 Macintosh computers, including both hardware and software.
- Assisting in the planning and organization of multiple bulk mailings of printed materials.

1998 - 2000 **DEATON SPECIALTY HOSPITAL**

Licensed Practical Nurse:
Deaton Specialty Hospital is a long-term care facility. The ventilator unit specialized in the care of both acute and chronic ventilator-dependent patients. Responsibilities included:

- Providing direct patient care for up to 15 medically complex ventilator-dependent patients.
- Facilitating transition from ventilator to T-collar, then decannulation.
- Working with interdisciplinary team to coordinate plans of care.
- Serving as resource person for intravenous catheterization.
- Serving as primary preceptor for newly hired personnel.

CERTIFICATIONS

Association of Clinical Research Professionals
Certified Clinical Research Coordinator 2015 - present

Collaborative Institutional Training Initiative
Human Subjects Research for Coordinators 2014 - present
Good Clinical Practice (ICH Focus) 2014 - present
Health Information Privacy and Security 2014 - present

International Air Transport Association
Certified in the transport of Dangerous Goods 2015 - present

QUALIFICATIONS / EDUCATION:

St. Philip's College, San Antonio, Texas
President's Honor Roll, Vocational Nurses Course

Landstuhl Army Medical Center, Landstuhl, Germany
Distinguished Honor Graduate, Medical Proficiency Training Course

Fort Sam Houston, San Antonio, Texas
Honor Graduate, Medical Specialist Course

Talbot School of Theology, La Mirada, California
Master of Divinity, May 2017, Highest Honors

Clinical Trial Experience:

Protocol HTX-011-301 (2017)
A Phase 3, Randomized, Double-Blind, Saline Placebo- and Active-Controlled, Multicenter Study of (the study drug) via Local Administration for Postoperative Analgesia and Decreased Opioid Use Following Unilateral Simple Bunionectomy

Protocol AVE-901-102 (2017)
A Phase 3, Multicenter, Randomized, Double Blind, Three-Arm Study to Evaluate the Efficacy and Safety of (the study drug) versus Placebo in the Management of Postoperative Pain Following Bunionectomy

Protocol CLCT-018 (2017)
A Randomized, Double-Blind, Placebo- and Active-Controlled Study to Determine the Efficacy and Safety of (the study drug) as a Treatment for Moderate-to-Severe Acute Pain and the Prevention of Opioid-Induced Nausea and Vomiting (OINV) Following Orthopedic Surgery

Protocol MOB015B-IV (2017)
A Multi-Centre, Double-Blind, Randomized, Vehicle-Controlled Study of Efficacy and Safety of (the study drug) in the Treatment of Mild to Moderate Distal Subungual Onychomycosis

Protocol ESTEVE-SUSA-01 (2017)
A Randomized, Double-Blind, Active- and Placebo-Controlled, Parallel Groups, Phase 3 Clinical Trial to Establish the Efficacy of (the study drug) for the Management of Moderate to Severe Post-Surgical Pain After Bunionectomy

Protocol AFT-MXIV-07 (2016)
A Phase 3, Randomized, Double-Blind, Multiple-Dose, Parallel-Group and Placebo-Controlled Study of (the study drug) for the Treatment of Acute Postoperative Pain After Bunionectomy

Protocol CP130-3002 (2016)
A Phase 3, Multicenter, Randomized, Double-Blind, Placebo- and Active-Controlled Study of (the study drug) for the Treatment of Moderate to Severe Acute Pain After Abdominoplasty

Protocol CP130-3001 (2016)
A Phase 3, Multicenter, Randomized, Double-Blind, Placebo- and Active-Controlled Study of (the study drug) for the Treatment of Moderate to Severe Acute Pain After Bunionectomy

Protocol HTX-011-C2015-203 (2016)
A Phase 2, Randomized, Controlled Evaluation of the Efficacy and Safety of (the study drug) for Post-Operative Analgesia Following Abdominoplasty Surgery

Protocol HTX-011-C2016-208 (2016)
A Phase 2, Randomized, Controlled, Multicenter, Evaluation of the Efficacy and Safety of Locally Administered (study drug) for Postoperative Analgesia Following Bunionectomy

Protocol REC-15-016 (2016)
A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Evaluation of the Efficacy and Safety of (the study drug) Following Bunionectomy

Protocol INS005-15-062 (2016)
A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Evaluation of the Efficacy and Safety of (the study drug) Following Bunionectomy

Protocol 4975-MN-203 (2015)
An Open-Label, Multiple-Dose Extension Study to Evaluate the Safety and Efficacy of (the study drug) in Subjects with Painful Intermetatarsal Neuroma (Morton's Neuroma)

Protocol TV46763-CNS-30031 (2015)
A Multicenter, Randomized, Double-blind, Placebo-controlled, Phase 3 Study to Evaluate the Analgesic Efficacy and Safety of (the study drug) Every 4 to 6 Hours in Patients with Moderate to Severe Pain Following Bunionectomy

Protocol REC-15-014 (2015)
A Phase 2, Single-Center, Randomized, Double-Blind Placebo-Controlled, Evaluation of Safety, Efficacy, and Pharmacokinetics of (the study drug) Following Bunionectomy

Protocol ELI-200-003-2014 (2015)
A Multi-Center, Randomized, Multiple-Dose, Double-Blind, Placebo-Controlled, Parallel Group, Phase 3 Study to Evaluate the Efficacy and Safety of (the study drug) for the Treatment of Adults with Moderate to Severe Pain Following Bunionectomy Surgery

Protocol INS-14-026 (2015)
A Phase 3, Randomized, Double-Blind, Multiple-Dose, Parallel-Group, Placebo-Controlled Study of (the study drug) for the Treatment of Moderate to Severe Pain

Protocol 4975-MN-202 (2014)
A Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging Study to Evaluate the Efficacy and Safety of (the study drug) in Subjects with Painful Intermetatarsal Neuroma (Morton's Neuroma)

Protocol TCO2-2012-01 (2014)
A Prospective, Randomized, Double-Blind Multicenter Study Comparing (the study drug) to standard Moist Wound Therapy in the Treatment of Diabetic Foot Ulcer

Protocol CP130-2001 (2014)
A Phase 2, Multicenter, Randomized, Double-blind, Multiple-dose, Adaptive, Placebo- and Active-controlled Study of (the study drug) for the Treatment of Acute Postoperative Pain After Bunionectomy

Protocol 4975-MN-201 (2014)
An Open Label, Ascending Dose Study to Evaluate the Safety and Tolerability of (the study drug) in Subjects with Painful Intermetatarsal Neuroma (Morton's Neuroma)

Protocol JN-NM-002 (2013)
A Phase 2, Randomized, Controlled, Double Blind, Multi-Center Study to Evaluate Safety and Immunogenicity of (the study drug) Compared with Menactra

Protocol COV15010232-US (2012)
A Phase 3 Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Evaluation of the Safety and Analgesic Efficacy of (the study drug) in Moderate to Severe Post-Operative Bunionectomy Pain Followed by an Open-Label Extension

Protocol RBI.2012.003.P.2 (2012)
A Multicenter, Randomized, Sham-Controlled, Double-Blinded Study to Evaluate the Analgesic Efficacy and Safety of (the study device) in Bunionectomy Surgery for the Treatment of Post-Operative Pain

Protocol IND3-10-06 (2012)

A Phase 3, Randomized, Double-Blind, Multiple-Dose, Parallel-Group, Placebo-Controlled Study of (the study drug) for the Treatment of Acute Postoperative Pain After Bunionectomy

Protocol IND3-08-04b (2011-2012)
A Phase 3, Randomized, Double-Blind, Multiple-Dose, Parallel-Group, Active- and Placebo-Controlled Study of (the study drug) for the Treatment of Acute Postoperative Pain After Bunionectomy

Protocol COV795 (2011)
A Phase 3 Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Evaluation of the Safety and Analgesic Efficacy of (the study drug) in Moderate to Severe Post-Operative Bunionectomy Pain Followed by an Open-Label Extension

Protocol DIC3-08-04 (2011)
A Phase 3, Randomized, Double-Blind, Multiple-Dose, Parallel-Group, Active- and Placebo-Controlled Study of (the study drug) for the Treatment of Acute Postoperative Pain After Bunionectomy

Protocol Q8003-021 (2008)
A Double-Blind, Randomized, Multi-Center, Repeat-Dose Comparison of the Analgesic Efficacy and Safety of (the study drug) to each of the Individual Milligram Components in the Management of Acute Moderate to Severe Pain Following Bunionectomy Surgery

Protocol M10-277 (2008)
A Phase 3, Open-Label Period Followed by a Randomized, Double-Blind, Placebo-Controlled Study of the Analgesic Efficacy of (the study drug) Compared to Placebo in Subjects with Chronic Low Back Pain

Protocol KET-017 (2008)
A Randomized, Multiple-Center, Double-Blind, Placebo-Controlled Study of the Safety and Analgesic Efficacy of Repeated Dosing of (the study drug) to Treat Acute Post-Operative Pain Following Orthopedic Trauma, Injury or Surgery

Protocol DFC-005 (2008)
A Randomized, Double-Blind, Active- and Placebo-Controlled Study of the Analgesic Efficacy and Safety of Repeated Dosing of (the study drug) Relative to Parenteral Ketorolac and Placebo in Patients With Acute Moderate to Severe Post-surgical Pain Following Mixed Elective General Orthopedic Surgery

Protocol PRD R331333-PAI-3018 (2008)
A Randomized, Double-Blind, Active- and Placebo-Controlled, Parallel-Group, Multicenter Study to Evaluate the Efficacy and Safety of (the study drug) in the Treatment of Acute Pain From Bunionectomy

Protocol INN-TOP-002 (2008)
A Phase II, Randomized, Parallel, Double-blind, Placebo-controlled Study to Assess Prevention of Infection Using (the study drug) in Diabetic Patients with Uninfected Lower Extremity Skin Ulcers

Protocol SKY2028-1-003 (2008)
A Randomized, Double-Blind, Placebo- and Active-Controlled, Parallel Group, 6-Week Study to Evaluate the Effect of Multiple Doses of (the study drug) twice daily, Prednisone and Placebo on the Hypothalamic-Pituitary-Adrenal Axis in Adult Subjects with Mild to Moderate Asthma

Protocol INN-TOP-001 (2007)
A Randomized, Controlled, Open-Label Study to Investigate the Safety and Efficacy of (the study drug) Compared to Levofloxacin in Diabetic Patients with a Mild Infection of a lower Extremity Skin Ulcer

Protocol Q8003-010 (2007)
A Double-Blind, Multi-Center Extension Study to Evaluate the Safety and Efficacy of (the study drug) in Patients with Acute Moderate to Severe Pain

Protocol Q8003-007 (2007)
A Placebo-Controlled, Randomized, Double-blind Study of the Safety and Efficacy of (the study drug) in the Management of Post-Bunionectomy Pain

Protocol KF5503/37 (2007)
A Randomized, Double-blind, Parallel-Group, Multi-Center, Active- and Placebo-Controlled Trial to Evaluate the Analgesic Efficacy and Safety of Multiple Doses of (the study drug) for Postoperative Pain Following Bunionectomy

Protocol M04-697 (2006)
A Phase 3, Randomized, Multicenter, Double-Blind Study Comparing the Analgesic Efficacy of (the study drug) to Placebo in Subjects With Osteoarthritis

Protocol M05-790 (2006)
A Phase 3, Open-Label Period Followed by a Randomized, Double-Blind, Placebo-Controlled Study of the Analgesic Efficacy and Safety of (the study drug) Compared to Placebo in Subjects with Chronic Low Back Pain

Protocol H7U-MC-IDAW (2006)
A Phase 3, Open-Label, Parallel Group Treatment Concordance Study to Compare Insulin Use and Its Effect on Glycemic Control in Patients with Type 2 Diabetes Mellitus: Two Populations with Different Insulin Treatment Options

Protocol R331333-PAI-3003 (2006)
A Randomized, Double-Blind, Active- and Placebo-Controlled, Parallel-Group, Multicenter Study to Evaluate the Efficacy and Safety of Multiple Doses of (the study drug) Immediate-Release Formulation in the Treatment of Acute Pain from Bunionectomy Followed by a Voluntary Open-Label Extension

Protocol XP21L-301 (2006)
Multicenter, Randomized, Double-Blind, Parallel Group, Placebo-Controlled Study of the Analgesic Efficacy of (the study drug) in Subjects with Pain Following Bunionectomy Surgery

Protocol VGF3554g (2006)
A Phase II, Double-Blind, Randomized, Placebo-Controlled Study to Assess the Effect of (the study drug) for Induction of Healing of Diabetic Foot Ulcers

Protocol EN3269-301 (2006)
A Randomized, Double Blind, Placebo Controlled Parallel Group Phase III Study of the Efficacy, Tolerability and Safety of (the study drug) in the Treatment of Pain Associated With Grade 1 or Grade 2 Ankle Sprain or Strain

Protocol 2005-005 (2006)
A Phase III, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Safety and Efficacy of (the study drug) for Sedation During Monitored Anesthesia Care

Protocol 2005-008 (2006)
Determination Study of (the study drug) Administered by a Patient-Controlled Analgesia (PCA) Pump for the Treatment of Postoperative Pain Following Elective Bunionectomy Surgery

Protocol 3000-0523 (2006)
A Phase 3 Open-Label, Single Arm Study to Assess the Safety of (the study drug) For Minimal-To-Moderate Sedation in Patients Undergoing Minor Surgical Procedures

Protocol M03-666 (2005)
An Open Label Study Evaluating the Safety and Tolerability of Long Term Administration of (the study drug) in Subjects with Moderate to Severe Chronic Non-Malignant Pain

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