Enzo J. Leone, DPM

EMPLOYMENT 2011-present	**FOOT AND ANKLE SPECIALISTS OF THE MID-ATLANTIC, LLC** 8028 Ritchie Highway Suites 100-104 Pasadena, Maryland 21122 (410) 768-5800
09/03-2011	**CHESAPEAKE FOOT AND ANKLE CENTER, PA** 8028 Ritchie Highway Suites 100-104 Pasadena, Maryland 21122 (410) 768-5800
POSTDOCTORAL TRAINING 07/02-present	**WEIL FOOT AND ANKLE INSTITUTE/SURGICAL & RESEARCH** FELLOWSHIP Director: Lowell Scott Weil, Jr., DPM, FACFAS 1955 Golf Road, Suite 131 Golf River Professional Bldg. Des Plaines, IL. 60016 (847) 390-7666
07/00-06/02	**WEST JERSEY PODIATRIC SURGICAL RESIDENCY/PSR 24** Director: Paul R. Quintavalle, DPM 1000 Atlantic Ave. Camden, NJ 08104 (856) 246-3543
07/99-6/00	**WYCKOFF HEIGHTS MEDICAL CENTER/PPMR** Director: Charles M. Lombardi, DPM 374 Stockholm Street Brooklyn, NY 11237
EDUCATION 9/95-5/99	**TEMPLE UNIVERSITY SCHOOL OF PODIATRIC MEDICINE** Philadelphia, Pennsylvania Doctor of Podiatric Medicine
9/88-6/93	**YOUNGSTOWN STATE UNIVERSITY** Youngstown, Ohio Bachelor of Science in Biology, Minor in Chemistry
BOARD QUALIFICATION	AMERICAN BOARD OF PODIATRIC ORTHOPAEDICS AND PRIMARY MEDICINE
PROFESSIONAL LICENSURE	STATE MEDICAL BOARD OF N.Y. LICENSE NO. N005600 STATE MEDICAL BOARD OF IL. LICENSE NO. 016-005071

CHESAPEAKE RESEARCH GROUP, LLC

PROFESSIONAL MEMBERSHIP

AMERICAN COLLEGE OF FOOT & ANKLE SURGEONS
AMERICAN PODIATRIC MEDICAL ASSOCIATION
NEW JERSEY PODIATRIC MEDICAL ASSOCIATION
ILLINOIS PODIATRIC MEDICAL ASSOCIATION

EXPERIENCE

10/02 — **CHICAGO MARATHON**
Assistant Podiatric Medical Director

04/02 — **HEALING THE CHILDREN MEDICAL MISSION–PA CHAPTER**
El Hospital Dr. Humberto Alvarado V.
Masaya, Nicaragua

RESEARCH

02/98 — **TEMPLE UNIVERSITY SCHOOL OF PODIATRIC MEDICINE**
"The Biomechanical Effects of the Triple Arthrodesis: An objective Gait Analysis." Proceedings from the 56th Annual meeting of the American College of Foot and Ankle Surgeons
Orlando, Florida

2003-2004 — **SCIREX CLINICAL RESEARCH CENTER**
10 Warren Road, Suite 333
Cockeysville, MD 21030

2004-present — **CHESAPEAKE RESEARCH GROUP, LLC**
Sub-Investigator
8030B Ritchie Highway
Pasadena, Maryland 21122

CLINICAL RESEARCH

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 MOB015-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 (DSO)

Protocol ESTEVE-SUSA-301
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 INS005-16-062 (2016)
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-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 (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 the 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 4975-MN-202 (2014)
A Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging Study to Evaluate the Efficacy and Safety of CNTX-4975 in Subjects with Painful Intermetatarsal Neuroma (Morton's Neuroma)

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 Post-Operative Pain After Bunionectomy

Protocol 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 vaccine) compared with Menactra

Protocol TCO2-2012-01 (2012)
A Prospective, Randomized, Double-Blind Multicenter Study Comparing (the study device) standard Moist Wound Therapy (MWT) in the Treatment of Diabetic Foot Ulcers

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 15000182-US (2011-2012)
A Phase 3 Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Evaluation of the Safety and Analgesic Efficacy of COV795 ER Tablets in Moderate to Severe Post-Operative Bunionectomy Pain followed by an Open Label Extension

Protocol IND3-08-04b (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 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 Q8003-022 (2011)
A Randomized, Double-Blind, Multicenter, Repeat-Dose Comparison of the Effects of Q8003 to the Morphine-Equivalent Doses of Oxycodone and of Morphine on the Opioid-Related Adverse Events of Moderate to Severe Nausea, Emesis, and Dizziness in Subjects with Acute Moderate-to-Severe Postoperative Pain Following Bunionectomy

Protocol KD-PV01 (2010)
A multi-Center, Randomized, Double-Blinded, Pivotal Study of the Safety, Local Tolerability and Efficacy of XXX for the Treatment of Onychomycosis

Protocol BK15 (2009)
Evaluation of a Medical Food for Chronic Wounds

Protocol Q8003-008 (2009)
A Randomized, Double-Blind, Multicenter, Repeat-dose Comparison of Analgesic Efficacy and Safety of Q8003 with Oxycodone and Morphine for the Management of Acute Moderate to Severe Postoperative Pain Following Bunionectomy Surgery

Protocol Q8003-021 (2009)
A Double-Blind, Randomized, Multi-Center, Repeat Dose, Comparison of the Analgesic Efficacy and Safety of the (the study drug) to each of the Individual Milligram Components (Oxycodone and Morphine) in the Management of Acute Moderate to Severe Pain Following Bunionectomy Surgery

Protocol DFC-005 (2008)
A randomized, double-blind, active- and placebo-controlled study of the analgesic efficacy and safety of repeated dosing of DIC075V relative to parenteral ketorolac and placebo in patients with acute moderate to severe post-surgical pain following mixed elective general orthopedic surgery

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 INN-TOP-001 (2008)
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 M10-421 (2008)
A Randomized, Multicenter, double-blind Study comparing the Analgesic Efficacy and Safety of (the study drug) to Placebo in Subjects with Acute Pain Following Bunionectomy

Protocol HKT-500-US10 (2008)
A Randomized, Multicenter, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of HKT-500 in the Treatment of Pain Associated with Grade I or Grade II Ankle Sprain

Protocol KET-017 (2008)
A randomized, multiple-center, double-blind, placebo-controlled study of the safety and analgesic efficacy of repeated dosing of PMI-150 to treat acute post-operative pain following orthopedic trauma, injury or surgery

Protocol R331333PAI3018 (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 Q8003-010 (2007)
A Double-Blind, Multi-Center Extenstion Study to Evaluate the Safety and Efficacy of Q8003 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 Q8003 in the Management of Post-Bunionectomy Pain

Protocol M06-850 (2007)
A Global, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study Comparing the Safety and Efficacy of ABT-894, Duloxetine and Placebo in Subjects with Diabetic Neuropathic Pain

Protocol KF5503/37 (2007)
A Phase 3, 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 R331333PAI3003 (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)
A 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 3000-0523 (2006)
A Phase 3 Open-Label, Single Arm Study to Assess the Safety of (study drug) For Minimal-To-Moderate Sedation in Patients Undergoing Minor Surgical Procedures

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

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

Protocol M03-666 (2005) Sub-Investigator
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.

Protocol 3000-0412 (2005) Sub-Investigator
A Phase III, Randomized, Open Label Study to Assess the Safety and Efficacy of (Study drug) Versus Midazolam HCL for Sedation in Patients Undergoing Minor Surgical Procedures.

Protocol M03-643 (2004) Sub-Investigator
A Randomized, Multi-Center, Double-Blind Study Comparing the Analgesic Efficacy of (the study medicine) Extended Release and Placebo in Subjects with Osteoarthritis.

Protocol 4975-2-003-1 (2004) Sub-Investigator
Randomized, Double-Blind, Placebo-Controlled Dose Ranging Trial of (the study drug) in Subjects Undergoing Bunionectomy with First Metatarsal Osteotomy Surgery.

Protocol M03-609 (Nov03-Mar04) Sub-Investigator
A Randomized, Double-Blind, Placebo-Controlled Study Comparing the Analgesic Activity of (the study medicine) Extended Release and Placebo in Subjects with Pain Following Bunionectomy Surgery

Protocol SCIREX 0005 (Sep03) Sub-Investigator
Clinical Protocol For A Multi-Center, Single Dose, Double-Blind, Placebo-Controlled, Randomized, Pilot Study To Investigate the Assay Sensitivity of Single Digit Hammertoe Surgery As A Model For The Study Of Analgesic Drugs In Acute Pain.