4/6/23

CURRICULUM VITAE

NAME: Hermann, M.D. Mark Christopher | **DATE:** 06/Apr/2023

POSITION TITLE: Investigator

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PROFESSIONAL LICENSURE: Commonwealth of Virginia Board of Medicine #0101045002 USA

EDUCATION/TRAINING:
(Include baccalaureate or other initial professional education such as nursing, postdoctoral training, GCP training.)

INSTITUTION AND LOCATION	DEGREE *(if applicable)*	YEAR(s)	FIELD OF STUDY
Carolinas Medical Center, Charlotte, NC, USA	Residency	1986-1990	Orthopedic Surgery
St. Vincent's Medical Center, Bridgeport, CT, USA	Internship	1985-1986	General Surgery
Georgetown University, Washington, DC,USA	Doctor of Medicine	1981-1985	MD
Emory University, Atlanta, GA, USA	B.A.	1978-1981	B.A. Philosophy/Pre-Medicine

Specialization: Orthopedic Surgery

POSITIONS AND EMPLOYMENT:

1990-present Orthopedic Surgeon, Spectrum Medical, Inc. (formerly Danville Orthopedic Clinic, Inc.), Danville, Virginia, USA

BOARD CERTIFICATIONS, OTHER EXPERIENCE, AND PROFESSIONAL MEMBERSHIPS:

1992-present American Board of Orthopaedic Surgery
Since 1994 Fellow of American Academy of Orthopedic Surgeons
Medical Society of Virginia , Member
Association of Clinical Research Professionals (ACRP), Member
Arthroscopy Association of North America, Member

RESEARCH EDUCATION/CERTIFICATION:

3/8/08-present Certified Physician Investigator (CPI) by APPI's CPI Exam Committee/ACRP
9/29/07-present Good Clinical Practice for Clinical Research Professionals/ ACRP

PUBLICATIONS/PRESENTATIONS:

Ardehali A, Spotnitz WD, Hoffman RW, et al. Evaluation of the safety and efficacy of a new hemostatic powder using a quantitative surface bleeding severity scale. *J Card Surg*. 2019; 34:50–62. https://doi.org/10.1111/jocs.13982

Daniel Del Gaizo, Mark Christopher Hermann & Maximilian Y. Emmert (2019): The SPOT GRADE: A Clinically Validated, Quantitative Bleeding Severity Scale, *Journal of Investigative Surgery*, DOI: 10.1080/08941939.2019.1651430.

Daniel Del Gaizo, Spotnitz WD, Hoffman RW, et al. SPOT GRADE II: Clinical Validation of a New Method for Reproducibly Quantifying Surgical Wound Bleeding, *Clinical and Applied Thrombosis/Hemostasis,* Volume 26: 1-8, DOI: 10.1177/1076029620936340.

Pressure Dynamics of the Anterior and Deep Posterior Compartments During Exercise. Presented at he Eastern Orthopedic Association Meeting, October 1990 in Bermuda and the American Academy of Orthopedic Surgeons, 1991, Anaheim, California.

RESEARCH EXPERIENCE:

A **Phase 3,** Multicenter, randomized, placebo controlled, double-blind, 22 week and 30 week open label study to evaluate the efficacy, safety, and PK of XXX Spray in relief of the pain for subjects with Osteoarthritis of the knee. Role Principal Investigator 10/21- Present

A **Phase 3,** 14-Day, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group Multicenter Study of the Efficacy and Safety of XXX in subjects with pain due to Acute Back Muscle Spasm. (2020-2/2022). Role: Sub-Investigator

A phase 3 Prospective, multicenter, double-blind, randomized, placebo-controlled study to evaluate the efficacy of XXX in in patients with osteoarthritis of the knee.(12/2020-Present) Role: Principal Investigator. Injectable OA knee.

Phase 2, Randomized, Double-Blind, Placebo Controlled study of the safety and efficacy of XXX for the treatment of adhesive Capsulitis of the Shoulder (2020-2022.) Role: Sub-Investigator

A Randomized, Double-Blind, Placebo-Controlled, Multi-center Pilot Study of a Single Injection XXX Combined with YYY to Provide Symptomatic Relief of OA of the Knee. Phase 2. (2020-2022)
Role: Principal Investigator

A Randomized, Double-Blind, Placebo Controlled, Parallel group study to evaluate the efficacy and safety of XXX in patients with Hip Osteoarthritis. (2019-2020). Role: Sub Investigator

A Randomized, Double-Blind, Placebo controlled, 2-injection, 52 week study to evaluate the efficacy and safety of Intra-articular injections of XXX in subjects with chronic, Moderate-to Severe osteoarthritis knee pain. (Jan 2019-2021). Role: Principal Investigator

A Randomized, Multicenter, Open-label, Parallel Group Study in Postmenopausal Women with Osteoporosis to Evaluate the Non-inferiority of subjects administered XXX via auto injector/pen vs. Healthcare provider administered XXX via prefilled syringe. (Jan 2018-2019). Role: Sub-Investigator.

A Phase 4, Randomized, Double-Blind, Multicenter, Placebo Controlled Study to Evaluate the Safety and Efficacy of XXX in combination with XOI compared with XOI alone, in subjects with Gout and Estimated Creatinine Clearance 30 to <60 mL/min who have not achieved target serum uric acid levels on an XOI Alone. (Aug 2017-Feb 2019). Role: Sub-Investigator.

A **Phase 3**, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study of the analgesic efficacy and safety of a dose titration regiment for the subcutaneous administration of XXX in subjects with osteoarthritis of the hip of knee. (2016-2018). Role: Principal Investigator.

A **Phase 2A**, Randomized, Double-Blind, Placebo Controlled crossover study of the Safety and Efficacy of XXX in subjects with Osteoarthritis of the knee. (2016-2016). Role: Principal Investigator.

Prospective, Multicenter, Single Arm Pilot Clinical Investigation Evaluating the use of a Surface Bleeding Severity Scale and the Safety and Efficacy of a new hemostatic device in abdominal and orthopedic lower extremity surgeries. (2015-2016). Role: Principal Investigator. **Device Study.**

Prospective, Multi-Center, Randomized, Three–Arm, Parallel group, clinical study to evaluate the superiority of 3 weekly intra-articular doses of 2ml of Investigational Product as compared to Placebo and XXXX injected into the target knee for the treatment of pain in subjects with Osteoarthritis.
(2015) Role: Sub-Investigator. **Device Study.**

Double Blind, Placebo-controlled, Randomized, Parallel–group Study to Determine the Safety and Efficacy of a Topical Patch (XXXX) Following Daily Administration for 2 Weeks in Patients with Chronic Low Back Pain. **Phase 2.** (2015-2015) Role: Sub Investigator

A Randomized, Sham-Controlled Pilot Study of XXXX Therapy in the Treatment of Persistent Post-Operative Pain following a Total Knee Arthroplasty (**Device Study**). (2015-2016). Role: Sub-Investigator

A **Phase 3**, Randomized, Double-Blind, Multicenter, Placebo Controlled Study to Evaluate the Efficacy and Safety of XXX , XXX, XXX, XXX in Subjects with Gout. (2014-2016).
Role: Sub-Investigator

A Randomized, Placebo-controlled, Double-Blind Study to Evaluate the Efficacy and Safety of a single intra-articular injection of XXX in adults with pain due to osteoarthritis of the knee. (1/2014- 10/2014). **Phase 3.** Role- Principal-Investigator.

A Randomized, Double-Blind, Placebo Controlled Study of the Safety and Efficacy of XXX for the Treatment of Adhesive Capsulitis of the Shoulder. **Phase 2b.** (12/2013-11/2014) Role: Principal Investigator.

A, Double-blind, Randomized, Parallel Group, Dose-Ranging Study to Assess the Safety and Efficacy of XXXX for the Treatment of Pain in Patients with Osteoarthritis of the Knee. (2014-2015). Role: Sub-Investigator.

A Multicenter, Randomized, Double-Blind, Parallel, Active Controlled Non-Inferiority Clinical Trial Comparing Three Weekly Intra-Articular Injections of XXXX Versus Three Weekly Intra-Articular Injections of XXX for the Treatment of Osteoarthritis Pain of the Knee. (2014-2015). Role: Principal Investigator. (**Device Study**)

Placebo Controlled, Double Blind Evaluation of the Efficacy and Safety of XXX for the treatment of Ankle Sprain. (Nov. 2013-2015). **Phase 3**. Role: Sub Investigator.

A Randomized, Placebo-controlled, Double-Blind Study to Evaluate the Efficacy and Safety of Two Doses of intra-articular injection of XXX in adults with pain due to osteoarthritis of the knee. (April 2013-August 2013). **Phase 2**. Role- Principal-Investigator.

A Randomized, Double-Blind, Double Dummy, Placebo Controlled, Active Controlled, Parallel Group, Multicenter Trial of XXX to Assess the Analgesic Efficacy and the Management of Opioid Induced Constipation in Subjects with Moderate to Severe Chronic Low Back Pain and a history of OIC. (November 2012-2015). **Phase 3**. Sub Investigator

Placebo Controlled, Double Blind Evaluation of the Efficacy and Safety of XXX for the treatment of Ankle Sprain. (Nov. 2013-2015). **Phase 3**. Role: Sub Investigator.

A Randomized, Placebo-controlled, Double-Blind Study to Evaluate the Efficacy and Safety of Two Doses of intra-articular injection of XXX in adults with pain due to osteoarthritis of the knee. (April 2013-August 2013). **Phase 2**. Role- Principal-Investigator.

A Randomized, Double-Blind, Double Dummy, Placebo Controlled, Active Controlled, Parallel Group, Multicenter Trial of XXX to Assess the Analgesic Efficacy and the Management of Opioid Induced Constipation in Subjects with Moderate to Severe Chronic Low Back Pain and a history of OIC. (November 2012-2015). **Phase 3**. Sub Investigator

A Randomized, Double-Blind, Multicenter, Placebo Controlled, Combination Study to Evaluate the Efficacy and Safety of XXX and YYY compared to YYY Alone in Lowering Serum Uric Acid and Resolving Tophi in Subjects with Tophaceous Gout.(March 2012- 2015). **Phase 3**. Role- Sub-Investigator

A Randomized, Double-Blind, Multicenter, Placebo Controlled, Combination Study to Evaluate the Efficacy and Safety of XXX and YYY compared to YYY Alone in Subjects with Gout who had an inadequate hypouricemic response to Standard of Care YYY.(March 2012- 2015). **Phase 3**. Role- Sub-Investigator

A Randomized, double Blind, active controlled study of XXX prefilled syringes or XXX reconstituted lyophilizate or YYY for treating acute gouty arthritis flares in frequently flaring patients. **Phase 3**. (5/2011- 2014). Role: Sub Investigator

A Multicenter, Randomized, Double-Blind, Phase 2 Study to Evaluate the Effect of XXX vs placebo on Renal Function in Gout Subjects with Hyperuricemia and Moderate to Severe Renal Impairment. **Phase 2**. (4/2011-2012). Role: Sub Investigator

A Multicenter, Randomized, Active Control, Phase 3B Study to Evaluate the Cardiovascular Safety of XXX and YYY in Subjects with Gout and cardiovascular Co-morbidities. **Phase 3B.** (3/2011-2017).Role: Sub-Investigator

A Randomized, Multicenter, Double-Blind, Placebo-Controlled **Phase III** trial to evaluate the Efficacy, Tolerability, and Safety of XXX in the Treatment of Tendonitis and Bursitis of the shoulder. (2010-2011).Role: Principal Investigator

A Randomized, Multi-center, Double-Blind, Factorial, Comparator and Placebo-Controlled **Phase III** trial to Evaluate the Efficacy, Tolerability, and Safety of XXX in the Treatment of Ankle Sprains.

(2010-2011). Role: Principal Investigator

Phase III, Randomized, controlled study of XXX on the treatment and prevention of gout flares in patients with frequent flares for whom NSAIDS and/or colchicine are contraindicated, not tolerated or ineffective. (2010) Role: Sub Investigator

Multinational, prospective, Observational Study to characterize and assess the burden of refractory gouty arthritis on patients over one year. (2010-2011) Role: Sub Investigator

A Randomized, Double blind, placebo controlled study to determine the efficacy of XXX in the treatment of pain caused by osteoarthritis of the knee. (2009) **Phase III**. Role: Principal Investigator

A randomized, Multicenter, Double-Blind, Placebo controlled study to evaluate the Efficacy and Safety of XXX in the treatment of pain associated with mild to moderate ankle sprain. **Phase III.** (2009-2010). Role: Principal Investigator

Observational Registry of Patients Using Prescription Medications Containing XXX for the treatment of pain. **Phase 4.** (2009) .Role: Sub-Investigator

Phase III, Open Label, Randomized, Referred Care-Controlled, Clinical Trial to Evaluate the Efficacy and Safety of XXX on Vitamin D Adequacy in the Treatment of Osteoporosis in Postmenopausal Women. (2008-2010). Role: Sub Investigator

Study for the validation of XXX for Assessing Opioid-Induced Constipation/ **Device Study** (2008-2009) Role: Sub Investigator

A Multicenter, Randomized, Double-Blind, Placebo Controlled Trial of three injections of XXX For the treatment of Chronic Shoulder Pain Associated with Glenohumeral Osteoarthritis. (2008-2009). Role: Sub Investigator

A **Phase III**, Flexible-Dose Titration Followed by a Randomized Double Blind Study of Controlled Release XXX Compared to Placebo in Patients with Osteoarthritis Pain (2008). Role: Sub Investigator

A Randomized, Open Label, Blinded-Endpoint, Parallel Group Trial of GI Safety of XXX compared with NSAIDS in Osteoarthritis Patients. (2007-2009).Role: Principal Investigator

Open Label Extension, Single Arm, Flexible Dosing, **Phase III** Trial with XXX in Subjects with Moderate to Severe Chronic Pain. (2008-2009). Opioid Study.
Role: Sub Investigator

A Randomized, Double-Blind, Active- And Placebo Controlled, Parallel-Group, Multicenter Study to Evaluate the Efficacy and Safety of Multiple Doses of XXX In Subjects Awaiting Primary Joint Replacement Surgery for End-Stage Joint Disease. (2007). Opioid Study Role: Sub Investigator

A Randomized, Double Blind, Parallel-Group Study of Cardiovascular Safety in Osteoarthritis or Rheumatoid Arthritis Patients with or at High Risk for Cardiovascular Disease. **Phase 4.** Comparing XXX with YYY and ZZZ. (2006-present). Role: Principal-Investigator.

A Six week Double-blind, Randomized, Multi-center comparison Study of the analgesic effectiveness of XXX compared to YYY in Subjects with Chronic Low Back Pain. (2006)
Role: Principal-Investigator.

Observational study of men and women with osteoporosis who have been prescribed XXX. (2004- 2010). Role: Sub-Investigator.

Multinational, Multi-center, Double-blind, Randomized, Placebo-controlled, Parallel group study assessing the efficacy of intravenous XXX in preventing subsequent osteoporotic fractures after a hip fracture. (2002-2007). Role: Principal-Investigator.

Multi-center, double-blind, placebo controlled, Randomized, Parallel Group study to compare the efficacy and tolerability of XXX vs. YYY in treatment of acute ankle sprains. (2002-2003).
Role: Principal-Investigator.

A Randomized, Double-Blind, Active-comparator controlled, Parallel Group study to evaluate the safety of XXX in patients with Osteoarthritis or Rheumatoid Arthritis. (2002-2006).
Role: Sub-Investigator.

Virginia Department of Health Professions
License Lookup

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License Information

License Number	0101045002
Occupation	Medicine
Name	Mark C Hermann
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Initial License Date	03/30/1990
Expire Date	10/31/2024
License Status	Current Active
Additional Public Information*	No

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