Edward M. Tavel, Jr. M.D.

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Education

1981-1985	Davidson College, Davidson, NC Bachelor of Science, Pre-Med
1985-1989	Medical University of South Carolina, Charleston, SC MD

Residency

1989 – 1990	Internship Roanoke Memorial Hospital, Roanoke VA
1990 - 1993	Anesthesiology University of North Carolina, Chapel Hill, NC (Residency)
1992 - 1993	University of North Carolina, Chapel Hill, NC (Chief Resident)

Professional Experience

Pain Specialists of Charleston, PA,
Owner/Medical Director 2009 – Present

Pain Care Physicians of Charleston
Managing Partner, 2006-2009

Medical Executive Committee
Trident Regional Medical Center, 2005-2009

Palmetto Anesthesia of Charleston
Managing Partner, 2003-2009

Trident Anesthesia Group
Member: 1993-2009, Partner: 1996-2009, Managing Partner: 2003-2009

Relevant Affiliations

The Academy of Pharmaceutical Physicians and Investigators (**APPI**), 2010 – Present

Society of Clinical Research Associates (**SOCRA**), 2010 – Present

Drug Information Association (**DIA**), 2010 – Present
Atlanta Center for Clinical Research, Corp., 2008 - Present

International Spinal Intervention Society (ISIS), 2006-Present

American Society of Interventional Pain Management, 2006-Present

American Society of Regional Anesthesia

Licensures and Certifications

South Carolina Board of Medical Examiners, 1993 - Present

Board Certified in Anesthesiology, 1994 – Present

Board Certified in Pain Management, 2009 - Present

Posters and Publications

Tavel, E. "Success Using Neuromodulation with BURST (SUNBURST) Study: Results from a Prospective, Randomized Controlled Trial Using a Novel Burst Waveform" Article Author, Neuromodulation NER12698. August 2017

Tavel, E. "Programming Optimization Strategies for Burst may Improve Outcomes" Poster session presented 2017 NANS Annual Meeting; 2017 January 19-22; Las Vegas Nevada

Tavel, E, Kim, C., Amirdelfan, T., Yearwood, T.,McLeod, C., Phillips, G., Houden, T., Fabi, A., Justiz, R., Wilson, D., Falowski, S., Davis, K., Diaz, R.
"Therapy-Related Healthcare Utilization was Lower during Burst than during Traditional Tonic SCS: SUNBURST Sub-Analysis," Abstract author. December 2016

Tavel, E, Kim, C., Amirdelfan, T., Yearwood, T.,McLeod, C., Phillips, G., Houden, T., Fabi, A., Justiz, R., Wilson, D., Falowski, S., Davis, K., Diaz, R.
"Lower Amplitudes for Burst SCS Programming Associated with Improved Outcomes: SUNBURST Sub-Analysis," Abstract author. December 2016

Tavel, E, Slavin, K., North, R., Deer, T., Staats, P., Kim, C., Amirdelfan, T., Yearwood, T.,McLeod, C., Phillips, G., Houden, T., Fabi, A., Justiz, R., Wilson, D., Falowski, S., Davis, K., Diaz, R.
"Burst Provided Sustained Pain Relief through 1 year: Long-term Outcomes from the SUNBURST Study," Abstract author. December 2016

Tavel E, Amirdelfan K, Phillips G, McLeod C, Fabi A, Justiz R, Falowski S, Fontenot H. Burst Spinal Cord Stimulation Programming Optimization: Interim Clinical Outcomes for Subjects Programmed with a Burst-specific Programming Strategy. Presented at the Annual Meeting of the American Society of Regional Anesthesiologists, November 2016, San Diego CA.

Tavel, E., K. Slavin, K. Amirdelfan, T. Yearwood, C. Kim, G. Phillips, J. Pope, C. McLeod, A. Fabi, T. Houden, R. Justiz, P. Staats, R. North, S. Falowski, D. Wilson, B. Edmiston, A. Taghva, D. Paicius, T. Deer
Understanding Bust Stimulation: Insights into Mechanism of Action and Programming Optimization from the SUNBURST Study

Tavel, E., Rosenberg, J., Jackson, A., Ghodsi, A., Saranita, J., Davis, M.
Comparison of SCS Treatment With and Without Prior Surgery. Poster – to be presented at World Institute of Pain (WIP) Congress; 2014 May 7-10;
Maastricht, Netherlands

Tavel, E. Dunteman, D. Sweeney, M.
Safety and Efficacy of Gastroretentive Gabapentin in Real-World Clinical Practice for Treatment of Patients with Postherpetic Neuralgia (PHN). Poster session presented at: The American Academy of Pain Medicine's 29th Annual Conference; 2013 April 9-14;
Ft. Lauderdale, Florida

Tavel, E. Brownlow, C. Howes, G. Haley, T. Creamer, M. Ghodsi, A. Rosenberg, J. Washburn, S.
The validation of a multi sensor on-body monitoring system to objectively measure changes in physical function and sleep, in patients undergoing a spinal cord stimulation trial; Interim results. Poster session presented at: From Innovation to Reality. 16th Annual North American Neuromodulation Society; 2012 December 6-9; Las Vegas Nevada

Research-Specific Training

DIA Annual Conference
Good Clinical Practice Training
SOCRA Annual Conference
NIH Online Training in the Protection of Human Research Subjects
CITI Course for Human Subjects Research

Clinical Research Experience

- RVT-901-3003: An International Phase 3, Randomized, Double-Blind, Placebo- and Active (Tolterodine)-Controlled Multicenter Study to Evaluate the Safety and Efficacy of XXX in Patients with Symptoms of Overactive Bladder
  Principal Investigator

- RVT-901-3004: An International Phase 3, Randomized, Double-Blind, Active (Tolterodine)-Controlled Multicenter Extension Study to Evaluate the Long-Term Safety and Efficacy of XXX in Patients with Symptoms of Overactive Bladder
  Principal Investigator

- A 12-week, Randomized, Double-blind, Placebo-controlled, Phase 3 Trial with a 4-week Randomized-withdrawal Period to Evaluate the Safety and Efficacy of XXX in Participants with Diabetic Gastroparesis
  Principal Investigator

- A double-blind, placebo-controlled, randomized dose ranging trial to determine the safety and efficacy of three dose levels of XXX in reducing 24-hour average pain intensity score in patients with post-herpetic neuralgia
  Principal Investigator

- A Double-blind, Placebo-controlled, Crossover Study to Evaluate the Efficacy and Tolerability of XXX Cream for the Treatment of Pain Associated with Post-Herpetic Neuralgia: A Proof of Concept Study November 2017-present
  Principal Investigator

- A Phase 3, Multicenter, Observational Long-term Study Evaluating the Safety, Tolerability, and Efficacy of Treatment of XXX or Placebo Previously Injected in the Target Knee Joint of Subjects with Moderately to Severely Symptomatic Osteoarthritis November 2017- present
  Principal Investigator

- An International Phase 3 Randomized, Double-Blind, Placebo-Controlled Efficacy and Safety Study to Evaluate XXX Co-Administered with and without XXX in Women with Heavy Menstrual Bleeding Associated with Uterine Fibroids October 2017- Present
  Sub-Investigator

- "A Phase 1, Open-label Study of the Safety, Tolerability, and Pharmacokinetics of XXX Following Single Intradiscal Injection in Subjects with Degenerative Disc Disease" May 2017- Present
  Principal Investigator

- A Double-blind, Placebo-controlled, Randomized Study to Assess the Safety and Efficacy of XXX Cream for the Treatment of Chronic Pain caused by Osteoarthritis of the Knee: A Dose-Ranging Study
  Principal Investigator

- A Phase 2, 24-Week, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Safety and Efficacy of XXX for the Treatment of Moderately to Severely Symptomatic Knee Osteoarthritis April 2017- Present
  Principal Investigator

- "Multi-center, open-label, uncontrolled study to assess contraceptive efficacy and safety of XXX during extended use beyond 5 years in women 18 to 35 years of age including a subgroup evaluation of treatment effect on heavy menstrual bleeding"
  January 2017- Present
  Sub-Investigator

- "Open-label safety trial of intravenous XXX in subjects with complex regional pain syndrome (CRPS)"
  January 2017-present
  Principal Investigator

- "A Phase 3, Multicenter, Randomized, Double-blind Study of a Single Dose of XXX Compared with Placebo or XXX Twice Daily for 5 Days in Otherwise Healthy Patients with Influenza"
  January 2017-Present
  Principal Investigator

- "A Phase 3, Multicenter, Randomized, Double-blind Study of a Single Dose of XXX Compared with Placebo or XXX Twice Daily for 5 Days in Patients with Influenza at High Risk of Influenza Complications"
  January 2017-Present
  Principal Investigator

- A Randomized, Placebo-controlled, Double-blinded, Multicenter Study of the Efficacy and Safety of XXX in Adult Subjects with Chronic Idiopathic Constipation
  January 2017- Present
  Principal Investigator

- "A Randomized, Double-Blind, Placebo-Controlled, Titration-to-Effect Study of Orally Administered XXX in Patients with Osteoarthritis of the Hip or Knee"
  September 2016-present
  Principal Investigator
  Recognized for screening TWO patients on day of site initiation

- "A Study of Three Doses of XXX Compared to Placebo in the Acute Treatment of Migraine: A randomized, double-blind, placebo-controlled parallel group study"
  August 2016- Present
  Sub-Investigator
  Exceeded enrollment goal by TWENTY subjects

- "An Open-label, Long-term, Safety Study of XXX in the Acute Treatment Of Migraine"
  September 2016-present
  Sub-Investigator

- "A 12-Week, Randomized, Double-Blind, Placebo-Controlled Study with a 4-Week Randomized Withdrawal Period to Evaluate the Efficacy and Safety of XXX for the Treatment of Constipation-Predominant Irritable Bowel Syndrome (IBS-C)"
  June 2016- present
  Sub-Investigator

- "Multicenter, randomized, double-blind, placebo-controlled, Phase 2 study comparing 3 mg and 12 mg of XXX with placebo over 52 weeks in approximately 500 patients with mild Alzheimer's disease dementia."
  September 2016- present
  Sub-Investigator
  Top Five Site for Enrollment Nationwide

- "A Safety and Efficacy Evaluation of XXX Laxative in Adults Experiencing Non-Idiopathic Constipation."
  May 2016-Present
  Sub-Investigator

- "A Randomized Withdrawal, Double-blind, Placebo-controlled Phase 3 Trial to Evaluate the Efficacy and Safety of XXX in Patients with Moderate-to-Severe Chronic Low Back Pain"
  May 2016- Present
  Principal Investigator
  First Site to ENROLL Studywide (across 88 sites)
  Recognized for highest enrollment and highest screening STUDYWIDE
  Recognized for HIGHEST RANDOMIZATION studywide
  Exceeded contracted enrollment goal by 600% (original goal of 6, completed goal of 40)

- "A Phase 3, multisite, randomized, double-blind, placebo-controlled, 6-month study to compare the efficacy and safety of two doses of XXX with placebo in preventing migraine headaches in patients with episodic migraine (with or without aura)"
  November 2015-Present
  Sub-Investigator
  Received Top Tier Enrollment Performance Award from Sponsor
  Enrollment goal met - Amended enrollment goal exceeded (doubled original)
  Randomized goal met - Amended enrollment goal exceeded (doubled original)

- "A Phase 3, multisite, double-blind, randomized, placebo-controlled, 3-month study to compare the efficacy and safety of two doses of XXX in preventing migraine headaches in patients suffering from chronic migraine. Patients may continue into a 9-month open-label extension following the double-blind treatment period."
  November 2015-Present
  Sub-Investigator
  Received Top Tier Enrollment Performance Award from Sponsor
  Fourth Highest Site for Enrollment (of 57 sites)

- "A Double-blind Placebo-controlled, Randomized Study to Assess to Safety and Efficacy of XXXX Cream for the Treatment of Chronic Pain caused by Osteoarthritis of the Knee: A Proof of Concept Study"
  December 2015- May 2016
  Principal Investigator

- "A Phase 2, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of Topically Applied XXX in Patients with Postherpetic Neuralgia.
  November 2015-Present
  Principal Investigator

- "A Randomized, Placebo-Controlled, Double-Blind Study to Evaluate the Efficacy and Safety of an Intra-Articular Injection of XXX in Adults With Pain Due to Osteoarthritis of the Knee"
  October 2015-January 2016
  Principal Investigator
  Contract goal of 35 patients met and exceeded – 53 subjects randomized into study

- "Long-term, prospective, multinational, parallel-cohort study monitoring safety in patients with MS newly started on XXX once daily or treated with another approved disease-modifying therapy"
  August 2015-Present
  Sub-Investigator

- "A Multicenter, Open-label Study of XXXX in Patients with Lumbar Disc Herniation"
  July 2015-Present
  Principal Investigator

- "Randomized, 16-Week, Multi-Phase, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy, Safety, and Tolerability of XXX as Monotherapy in Subjects with Signs and Symptoms of Osteoarthritis of the Hip or Knee"
  August 2015-Present
  Principal Investigator

- "A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study of the Efficacy and Safety of a Single Dose of XXXX in Women Undergoing Transvaginal Pipelle-Directed Endometrial Biopsy"
  May 2015-Present
  Principal Investigator

- "A phase 3, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of XXX as an Induction and Maintenance Treatment for Patients with Moderately to Severely Active Crohn's Disease"
  May 2015- Present
  Principal Investigator

- "A Phase 3 Randomized, Double-Blind, Placebo-Controlled Study of XXXX in Patients with Episodic Cluster Headaches"
  February 2015-Present
  Sub-Investigator
  Top Five Site for Enrollment Nationwide

- "A Prospective, Multicenter, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Efficacy and Safety of a Single Injection of XXX Alone or Combined with XXX in Subjects with Chronic Discogenic Lumbar Back Pain Through 12 Months"
  February 2015-Present
  Principal Investigator
  SECOND PLACE for randomization studywide

- "Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multicenter Study to Evaluate the Efficacy and Safety of XXX Compared with XXX and Placebo in Patients with Moderate to Severe Ulcertive Colitis Who Are Naïve to TNF Inhibitors"
  January 2015-Present
  Sub-Investigator

- "A Randomized Double-blind, Placebo-controlled, Parallel-group, Multicenter, Phase 3 Study to Evaluate the Long-term Safety of XXX for the Treatment of Opioid-induced Constipation in Subjects with Nonmalignant Chronic Pain Receiving Opioid Therapy"
  October 2014 – Present
  Principal Investigator
  Two Screens On The Day Of Site Activation

- "A Phase 3 Multi-Center Actual-Use Study on the Safety of XXX for the Treatment of Moderate to Severe Acute Pain Associated with Osteoarthritis of the Knee or Hip"
  September 2014-Present
  Principal Investigator
  Two Screens On The Day of Site Activation

- "A Phase 2 Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Group Trial of XXX Administered Orally for 8 Weeks to Adult Outpatients with Opioid-Induced Constipation Receiving Chronic Opioid Treatment for Non-Cancer Pain"
  September 2014 - Present
  Principal Investigator

- "An interventional Phase II/III randomized, double-blind trial investigating the efficacy and safety of intravenous XXX in subjects with complex regional pain syndrome type I (CRPS-I)"
  August 2014-Present
  Principal Investigator

- "A Phase 2, Randomized, Double-Blind, Placebo and Active-Controlled Trial of XXX In Patients with Mild to Moderate Osteoarthritis Pain of the Knee"
  June 2014 – Present
  Principal Investigator
  Two Screens On The Day Of Site Activation

- "A Phase 3 Multicenter, Randomized, Double-blind, Controlled, Comparative Study of XXX in Patients with Lumbar Disc Herniation"
  January 2014-Present
  Principal Investigator

- "A Prospective, Randomized, Multi-Center, Controlled Clinical Trial to Assess the Safety and Efficacy of the XXX Neurostimulator System in the Treatment of Chronic Pain."
  January 2014-Present
  Principal Investigator

- "A Phase 2b Randomized, Double-Blind, Vehicle-Controlled, Repeat-Dose, Multi-Center, Efficacy and Safety Clinical Trial of Topically Applied XXX Gel in Subjects with Moderate to Severe Pain associated with Osteoarthritis of the Knee following Cessation of Pain Therapy."
  December 2013-Present
  Principal Investigator

- "A Phase 3, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of XXX Compared to Placebo as Add-on to Preexisting Antihyperglycemic Therapy over 16 Weeks with 36-week Extension in Type 2 Diabetic Subjects with Chronic Kidney Disease Stage 4 or Stage 5 on Dialysis" \
  December 2013-Present
  Principal Investigator

- "The SUNBURST Study is a Randomized, Prospective, Multicenter, Clinical Study Designed to Demonstrate the Safety and Efficacy of the XXX Neurostimulation System Using XXX and XXX Stimulation Therapy to Manage Patients with Chronic Intractable Pain"
  November 2013-present
  Principal Investigator

- "A Randomized, Double-blind, Placebo-controlled, Parallel-group Study of XXX in the Treatment of Opioid-induced Constipation in Subjects with Non-malignant Chronic Pain Receiving Opioid Therapy."
  September 2013- Present
  Principal Investigator

- "A Phase 3b, Randomized, Double-Blind, Placebocontrolled, Parallel-Treatment Group, Multicenter Efficacy And Safety Study Of Topical XXX In Subjects With Anal Fissure,"
  May 2013 - Present
  Principal Investigator

- "Cardiovascular Safety & Renal Microvascular Outcome with XXX in Patients with Type 2 Diabetes Mellitus at High Cardiovascular Risk,"
  April 2013 – Present
  Principal Investigator

- "A Phase 3, Open-Label, Long-Term Study to Evaluate the Safety, Tolerability and Analgesic Efficacy of XXX in Subjects with Moderate to Severe Chronic Pain Requiring Continuous Around-the-Clock Opioid Analgesia for an Extended Period of Time,"
  January 2013 - Present
  Principal Investigator

- "A Phase 2, A Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel-group Study of the Safety and Efficacy of a Single Treatment of XXX in Patients With Postherpetic Neuralgia,"
  January 2013 – Present
  Principal Investigator

- "A Phase 2, Double-Blind, Randomized, Placebo-Controlled, Parallel Group Study to Evaluate the Efficacy, Tolerability, and Safety of XXX in Patients with Post-Herpetic Neuralgia (PHN),"
  January 2013 – Present
  Principal Investigator

- "A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study to Evaluate the Long-term Safety and Tolerability of XXX for the Treatment of Opioid-induced Constipation in Adults Taking Opioid Therapy for Chronic Non-Cancer Pain,"
  January 2013 - Present
  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 Opioid-experienced Subjects with Controlled Moderate to Severe Chronic Low Back Pain and a History of Opioid-induced Constipation who Require Around-the-clock Opioid Therapy,"
  October 2012-Present
  Principal Investigator

- "A Multicenter, 12-Week, Double-Blind, Placebo-Controlled, Randomized Withdrawal Study To Determine The Efficacy And Safety Of XXX Extended-Release Capsules In Subjects With Moderate To Severe Chronic Low Back Pain","
  June 2012- Present
  Principal Investigator

- "A Phase 3 , Multi-Center, Randomized, Double-Blind, Placebo-Controlled, Safety, Tolerability and Efficacy Study of XXX Versus Placebo in Opioid-Experienced and Opioid-Naïve Subjects with Moderate-to-Severe Chronis Low Bank Pain,"
  August 2012 - Present
  Principal Investigator

- "A Phase 3, Open Label Safety Study of XXX in Subjects with Osteoarthritis or Chronic Low Back Pain,"
  May 2012 – Present
  Principal Investigator
  Recognized as top enrollers nationwide

- "A Phase 2 Enriched Enrollment, Randomized-Withdrawal, Double-Blind, Placebo-Controlled, Multi-Center Study to Assess the Efficacy, Tolerability and Safety of XXX in Opioid-Naïve Subjects with Moderate to Severe Chronic Pain Due to Osteoarthritis of the Knee,"
  June 2012 – Present
  Principal Investigator
  Recognized as top enrollers nationwide (2012)
  Recognized for first place titration and randomization of study subjects
  Recognized as second highest screening study-wide

- "An Open-Label 52-week Study to Assess the Long-Term Safety of XXX in Patients with Opioid-Induced Constipation,"
  May 2011- January 2013
  Principal Investigator
  Recognized for exceptional strategies in identifying, pre-screening and screening patients
  Recognized as high enroller 1st month of enrollment
  Recognized for highest enroller in our region

- "A Phase 3, Multicenter, Randomized, Double-blind, Placebo-controlled Study with an Open-label Run to Assess the Efficacy and Safety of XXX Tablets 20 to 120 mg Once-daily in Subjects with Moderate to Severe Chronic Low Back Pain," 2011-present
  Principal Investigator
  Recognized as high enroller

- "A Phase 4, Open Label, Study of Safety and Effectiveness of XXX Tablets in the Treatment of Patients with Post-herpetic Neuralgia in Clinical Practice," 2011-present
  Principal Investigator
  Enrollment goal reached in 10 days
  Highest enroller overall to date

- "A Phase 2b, Double-Blind, Randomized, Placebo-Controlled, Parallel-Group Study to Assess the Safety and Efficacy of XXX in Subjects With Opioid-Induced Constipation,"
  December 2011-2012
  Principal Investigator
  Recognized as top three in screening and enrollment in the United States

- "A Multi-Centered Evaluation of Patients with Chronic Pain of the Trunk and/or Limbs using XXX(s).
  November 2011 - Present
  Principal Investigator
  Recognized as top enrollers nationwide (2012)
  Reached sponsor enrollment goal within 4 months
  Enrollment goal doubled by sponsor

- "A Multi-Centered Evaluation of Patients with Chronic Pain of the Trunk and/or Links using Paddle Lead(s); Validation of a Multi-Sensor On-Body Monitoring System to Objectively Measure Changes in Physical Function and Sleep in Patients Undergoing XXXX,"
  June 2012 – Present
  Principal Investigator
  Selected as one of five sites nationwide
  Selected for sub-trial based on stellar performance, outcomes and data within primary study

- "A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of XXX in Patients with Non-Cancer-Related Pain and Opioid-Induced Constipation (OIC)"
  Principal Investigator

- "A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of XXX in Patients with Non-Cancer-Related Pain and Opioid-Induced Constipation (OIC)"
  2011-December 2012
  Principal Investigator

- "An Evaluation of the Burden of Illness among Adults in the United States with Peripheral and Central Neuropathic Pain", Oct. 2011
  Principal Investigator
  Enrollment goal reached within 3 weeks
  Tripled enrollment goal set by sponsor

- "A Multi-center, Randomized, Placebo-controlled, Double-blinded Study of the Efficacy and Safety of XXX in Subjects with Opioid-Induced Bowel Dysfunction"
  2010-2011
  Principal Investigator
  Recognized as high enroller

- "A Multicenter, Randomized, Double Blind, Parallel-Group Study of Cardiovascular Safety in Osteoarthritis or Rheumatoid Arthritis Patients With or at High Risk for Cardiovascular Disease Comparing Three XXX Medications",
  2010-present
  Principal Investigator
  Recognized as high enroller - Second highest enroller WORLD WIDE for August 2011
  Recognized as having high level of subject retention

- "A Multi-center, Randomized, Double-blind, Placebo-controlled Study an Open-label Run-in to Assess the Efficacy, Tolerability, and Safety XXXX or XXXX Compared to Placebo in Opioid-Naïve Subjects with Moderate to Severe Chronic Pain due to Osteoarthritis of the Knee", 2008-2009
  Principal Investigator