

ANTHONY J. MARGHERITA, M.D

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EDUCATION

1981-1985	Medical Degree	Georgetown University School of Medicine, Washington, DC
1977-1981	Bachelors Degree	Georgetown University, Washington, DC

TRAINING

1985 - 1989 Resident Physician, University of California, Sacramento, CA

CERTIFICATION AND LICENSURE

Licensure:

State of California	#G057987
State of Missouri	#MO113120

Certification:

National Board of Medical Examiners:	1983 - Part I; 1985 - Part II; 1986 - Part III
American Board of Physical Medicine & Rehab:	1989, Passed Part I; 1990, Passed Part II
American Board of Electrodiagnostic Medicine:	1994-2004

PROFESSIONAL AND ACADEMIC APPOINTMENTS

Professional:

2014-present	Principal Investigator, Clinical Research Professionals, St. Louis, MO
2006-present	Active Medical Staff, St. Luke's Hospital, St. Louis, MO
2009-present	Active Medical Staff, Missouri Baptist Medical Center, St. Louis, MO
1999-present	Medical Director, St. Louis Marathon, St. Louis, MO
2007-2008	Event Physician, NCAA Wrestling Championships, St. Louis MO
2008-2009	Event Physician, Tour of Missouri Professional Cycling Race
2003-2005	Assistant Team Physician, River City Otters Hockey Team, St. Charles, MO
2001-2005	Team Physician, Lafayette High School Athletics, Wildwood, MO
1997-2003	Active medical staff, Barnes-Jewish-Christian Hospital System, St. Louis, MO
1996-1997	Director, Harborview Medical Center Sports Medicine Clinic, Seattle, WA
1992-1995	Associate Director, Harborview Medical Center Sports Medicine clinic, Seattle, WA
1989-1997	Active medical staff, Harborview Medical Center, Seattle, WA
1989-1997	Associate Medical Staff, University of Washington Medical Center, Seattle, WA
1990-1996	WIAA State Championships Tournament Physician, Seattle, WA
1987-1988	Race Physician, Coors International Bicycle Classic, Road Race and Criterium stages

Academic:

2000-2003	Assistant Professor of Physical Medicine and Rehabilitation, Washington University Department of Anesthesiology and Director, Musculoskeletal Health, Wellness, and Rehabilitation.
1997-2000	Associate Professor, Washington University, Departments of Neurology and Orthopedic Surgery

1996	Clinical Information Systems Physician, University of Washington Academic Medical Centers, Seattle, WA
1993-1997	Assistant Professor, University of Washington, Department of Rehabilitation Medicine, University of Washington, Seattle, WA
1989 - 1993	Acting Assistant Professor, Department of Rehabilitation Medicine, University of Washington, Seattle, WA

INSTITUTIONAL AFFILIATIONS

EDITORIAL RESPONSIBILITIES:

- Reviewer, PM&R Journal
- Ad-hoc study section panelist, National Institutes of Health, National Center for Medical Rehabilitation Research
- Ad-hoc reviewer, National Institutes on Disability and Rehabilitation Research
- International Advisory Editor, *The Encyclopedia of Disability*, Sage Publications, Inc.

SPECIAL NATIONAL RESPONSIBILITIES:

2002-2003	Medical Director, Women's Marathon National Championship
2003-2004	Medical Director, Women's Olympic Marathon Trials

CONSULTING ACTIVITIES

1999-present	Founder and Consultant, Magic Wheels, Inc.
2009-present	Founding member and Consultant, Best Doctors Inc. Medical Advisory Board
2010	Janssen Pharmaceutical Canada National Advisory Board
2009	Decile Ten Communications National Advisory Board
2008-2009	NEO Pathways in Pain National Consultant
2002	Armand Scott National Consultant 21 st Century Advances in Arthritis and Pain
2002	Faculty, Pfizer Regional Consultants Meeting
2002	Elan Pharmaceuticals National Consultants Panel
2001	Pharmacia/Pfizer National Consultants Panel

PRESENTATIONS

Pharmaceutical Consulting/Advisory Services, Speaking Services (abbreviated):

2000-present	Pfizer Pharmaceuticals Speakers Bureau
2006-present	Lilly Corporation Speakers Bureau
2007-2011	King Pharmaceuticals Speakers Bureau
2007-present	Endo Pharmaceuticals Speakers Bureau
2009-present	Janssen (Johnson & Johnson Corp.) Speaker's Bureau

National Presentations:

1. Margherita, AJ, Felix, MS, Lieberman, JS, Heterotopic ossification in the absence of neurological or orthopedic injury, (poster session) American Academy of Physical Medicine and Rehabilitation Annual Meeting, 1988.
2. Margherita, AJ, Perkins, P, Johnson, K, Mitsuda, P, Campbell, R, Furuta, G, Baarslag-Benson, R. Access to Microcomputers: assessment and training for adults with high-level spinal cord injuries,(poster session) American Academy of Physical Medicine and Rehabilitation Annual Meeting, 1991.

3. Margherita, AJ, Martin, WR, Amsterdam, E. Phantom angina, a case report, (free communication) American Academy of Physical Medicine and Rehabilitation Annual Meeting, 1991.
4. Margherita, AJ, Edlund, G, Crill, J, Schoene, RB. The effects of cycling position on ventilatory function, (free communication) American College of Sports Medicine Annual Meeting, 1993.
5. Margherita, AJ, , Robinson, LR, . Friedman, AS, Wong, K. Therapeutic electrical reactivation (TER) and the treatment of conversion paralysis (poster session) American Academy of Physical Medicine and Rehabilitation Annual Meeting, 1993.
6. Margherita, AJ, Guthrie, M, Malone, E, Wong, K. The Spine Fracture Outcome Assessment Project (SOAP): Functional status following spine fracture without neurologic injury. (poster session) American Academy of Physical Medicine and Rehabilitation Annual Meeting, 1993.
7. Margherita, AJ, , Robinson, LR Heimbach, DM, Fishfader, VL, Schneider, VA, Jones, D. Timing of Peripheral Polyneuropathy after Burns (platform presentation) American Association of Electrodiagnostic Medicine Annual Meeting, 1993.
8. Chan, S, Margherita, AJ, , Robinson, LR Heimbach, DM, Fishfader, VL, Schneider, VA, Jones, D. Burn associated peripheral polyneuropathy: a search for causative factors (poster session) American Academy of Physical Medicine and Rehabilitation Annual Meeting, 1993.
9. Taylor, S, Margherita, AJ, Sandwith E, Fox C. Aerobic Training Responses in Acute Spinal Cord Injured Patients: Preliminary Results. (poster session) American Academy of Physical Medicine and Rehabilitation Annual Meeting, 1993.
10. Majaess GC, Margherita AJ, Price R, Guthrie MR, Fox C. The kinematics of wheelchair propulsion in acute spinal cord injury. (poster session) American Academy of Physical Medicine and Rehabilitation Annual Meeting, 1993.
11. Willick, S, Sherman, A, Margherita AJ. Medical and rehabilitation outcomes of atlano-occipital dissociation (poster session) American Academy of Physical Medicine and Rehabilitation Annual Meeting, 1996.
12. Cousins, AK, Margherita, AJ, Al-Awadhi, K, Aleshire, A, Livesay, J Woodwell, M. Geared wheelchairs for persons with mobility impairments: design requirements and prototype (poster session) Rehabilitation Engineering Society of North America annual meeting, 1997.

PUBLICATIONS

Thesis:

Margherita, AJ, Physiologic Effects of Endurance Exercise Training: Cardiovascular and Respiratory Responses to Exercise. Georgetown University Press, Washington, DC, 1981.

Referred and in press publications:

1. Martin, WR, Margherita, AJ, Amsterdam, E, Phantom Angina, a case report, Chest, 105:1271-2, 1994.
2. Carter, GT, McDonald CM, Chan TT, Margherita AJ, Isolated femoral mononeuropathy to the vastus lateralis: EMG and MRI findings, Muscle Nerve, 1994;18:341-4.

3. Margherita AJ, Robinson LR, Heimbach DM, Schneider V, Fishfader V, Jones, D, Peripheral neuropathy in burns: a search for causative factors, *Am J Phys Med Rehab*, 1995;74:28-32..
4. Buchner, DM, Cress, ME, deLateur, BJ, Esselman, PE, Margherita, AJ, Price, R, Wagner, EH, The effect of strength and endurance training on gait, balance, fall risk, and health service use in community-living older adults, *J Gerontol A Biol Med Sci*, 52(4):M218-224.
5. Buchner, DM, Cress, ME, Esselman, PE, Margherita, AJ, deLateur, BJ, , Price, R, Wagner, EH, Factors associated with changes in gait speed in older adults. *Am J Gerontol* 1996 51:M297-302
6. Buchner, DM, Cress, ME, deLateur, BJ, Esselman, PE, Margherita, AJ, Price, R, Wagner, EH, A comparison of the effects of three types of endurance training in balance and other fall risk factors in older adults, *Aging Clin Exp Res* 1997;9:112-9.
7. Willick, SW, Margherita AJ, Carter, GT, Isolated superior gluteal nerve injury: a report of two cases, *Muscle Nerve*, 1998; 21:951-3.
8. Rauh MJ, Margherita AJ, Koepsell TD, Rice SG, Rivara FP. High school cross country running injuries: A longitudinal study *Clin J Sport Med* 2000;10:110-116.
9. Lee, E, Margherita AJ. Piriformis syndrome: radiological findings, *Journal of Roentgenology*, 2004;183:63-64
10. Rauh MJ, Koepsell TD, Margherita AJ, Rice SG, Rivara FP, Hildebrandt J. The quadriceps angle and risk of injury among high school cross-country runners. *Journal of Sports Physical Therapy*, 2007: 12:725-733. .

Book Chapters:

1. Margherita, AJ, Issues in Dancers and Gymnasts, in Buschbacher, R, Braddom, RL (eds.), *Sports Medicine and Rehabilitation: A Sport Specific Approach*, 1994, pp.151-169.
2. Margherita, AJ, Sports Medicine and Injury Prevention, in deLateur, BJ, Kraft, GH (eds.), *Physical Medicine and Rehabilitation Clinics of North America*, 5:345-57, 1994
3. Margherita, AJ, Effects of Exercise and Training on Cardiovascular Function, in Halar, E, Kraft, GH (eds.), *Physical Medicine and Rehabilitation Clinics of North America*, 6:225-241, 1994.
4. Kumar, A, Margherita, AJ, Lower Extremity Fractures, in Braddom, R (ed.), *Physical Medicine and Rehabilitation Clinics of North America*, 9:164-171
5. Martin, RW, Margherita, AJ, Wrestling, in Buschbacher, R (ed.), *Physical Medicine and Rehabilitation Clinics of North America*, 10:(117-40).
6. Sadowsky, C, Margherita, AJ, Costs of Spinal Cord Injury, *Spine State of the Art Reviews*, 13(3):593-606, 1999.
7. Margherita, AJ, Acute and Chronic Conditions, *International Encyclopedia of Disability*, 1:31-34, Sage Publications, 2005
8. Margherita, AJ, The Sports Medicine Approach to Musculoskeletal Medicine, in Buschbacher, R, (ed.), *Sports Medicine and Rehabilitation: A Sport Specific Approach*, 2nd edition 2008, pp. 23-30.

ABSTRACTS

1. Margherita, AJ, Edlund, G, Schoene, RB, The effects of aerodynamic cycling positions on ventilatory function in trained athletes, *Med Sci Sports Exerc*, 25(5):245, 1993.
2. Margherita, AJ, Felix, MS, Lieberman, JS, Heterotopic ossification in the absence of neurological or orthopedic injury, *Arch Phys Med Rehabil*, 69(9): 785, 1988.
3. Margherita, AJ, Martin, WR, Amsterdam, E, Phantom Angina, a case report, *Arch Phys Med Rehabil*, 72(9):782, 1991.
4. Margherita, AJ, Perkins, P, Johnson, K, Mitsuda, P, Campbell, R, Furuta, G, Baarslag-Benson, R, Access to Microcomputers: Assessment and Training for Adults with High-Level Spinal Cord Injuries, *Arch Phys Med Rehabil*, 72(9): 837, 1991.
5. Guthrie, M, Margherita, AJ, The UW Spine Fracture Study: ,Phase I, *JAPTA*, 73(6):S30, 1993.
6. Margherita, AJ, Robinson, LR, . Friedman, AS, Wong, K. Therapeutic electrical reactivation (TER) and the treatment of conversion paralysis *Arch Phys Med Rehabil*, 74(11): 1250, 1993
7. Chan, S, Margherita, AJ, , Robinson, LR Heimbach, DM, Fishfader, VL, Schneider, VA, Jones, D. Burn associated peripheral polyneuropathy: a search for causative factors *Arch Phys Med Rehabil*, 74(11): 1250, 1993
8. Margherita, AJ, Guthrie, M, Malone, E, Wong, K. The Spine Fracture Outcome Assessment Project (SOAP): Functional status following spine fracture without neurologic injury. *Arch Phys Med Rehabil*, 74(11): 1256, 1993
9. Majaess GG, Margherita AJ, Price R, Guthrie MR, Fox C. The kinematics of wheelchair propulsion in acute spinal cord injury. *Arch Phys Med Rehabil*, 74(11): 1271, 1993
10. Taylor, S, Margherita, AJ, Sandwith E, Fox C, Aerobic Training Responses in Acute Spinal Cord Injured Patients: Preliminary Results. *Arch Phys Med Rehabil*, 74(11): 1273, 1993
11. Margherita, AJ, , Robinson, LR Heimbach, DM, Fishfader, VL, Schneider, VA, Jones, D. Timing of Peripheral Polyneuropathy after Burns, *Muscle Nerve*, 16(10):1080,1993.
12. Margherita AJ, Rice D, Roberts I, Chou C, Turnbull R, The Rehabilitation Learning Center: A Network Based Learning Environment for People with Disabilities, *Arch Phys Med Rehabil*, 81(11): 865, 2000
13. Margherita AJ, Rauh M, Rice S, Taniguchi J, Koepsell T, High School Soccer Injuries: a 15-Year Injury Surveillance Study, *Arch Phys Med Rehabil*, 81(11): 985, 2000

AWARDS AND PRIZES

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|--------------|---|
| 1998-present | Best Doctors in the US, Midwest Region |
| 1996-1997 | Best Doctors in the US, Pacific Region |
| 1985 | Margaret D. Kenrick Award in Physical Medicine and Rehabilitation |

PROFESSIONAL ORGANIZATIONS

American Academy of Physical Medicine and Rehabilitation
American College of Sports Medicine
North American Spine Society

CLINICAL RESEARCH EXPERIENCE

- 1989-1992 Principal Investigator, "Preliminary Evaluation of an Innovative Wheelchair Propulsion System," Paralyzed Veterans of America, \$2000
- 1990-1997 Associate Investigator, (.10 FTE), "Northwest Regional Spinal Cord Injury System," National Institute on Disability and Rehabilitation Research , \$350,000
- 1992 Principle Investigator, " A Study of Peripheral Nerve Lesions in Burns," Northwest Burn Foundation, \$5800
- 1993 Co-Principle Investigator, " A Study of Peripheral Nerve Lesions in Burns," Graduate School Fund, \$5000
- 1993 Investigator, (.05FTE), "Spasticity: Evaluation of Management: Comparison of Selected Electrophysiological to Mechanical Measurement Systems", Brain Injury Research and Training Center Project 13, National Institute on Disability and Rehabilitation Research, \$539,273
- 1993 Co-Principle Investigator, "Early Intervention Wheelchair Exercise Studies," Graduate School Fund, \$3000.
- 1994 Principle Investigator, "The Burn Neuropathy Project, Phase II," Northwest Burn Foundation, \$10,000.
- 1995 Investigator, (.05FTE), "Spasticity: Evaluation of Management: Comparison of Selected Electrophysiological to Mechanical Measurement Systems", Northwest Regional Spinal Cord Injury System, National Institute on Disability and Rehabilitation Research , \$350,000
- 1997 Principle Investigator, "The Harborview Medical Center Rehabilitation Learning Center," various private sources, \$170,000.
- 1997 Investigator (.05FTE), "Mobility, Disabilities, Participation and Environment", Centers for Disease Control, \$547,950
- 1997 Investigator (.10FTE), "Determinants of Disability", Social Security Administration subcontract, \$300,000
- 1998 Clinical Investigator (\$10,000 subcontract), "2-Speed Manual Wheelchair", National Institutes of Health, Phase I Small Business Innovative Research Grant, \$100,000
- 1998 Clinical Director (\$250,000 research budget), "2-Speed Manual Wheelchair", National Institutes of Health, Phase II Small Business Innovative Research Grant, \$700,000.
- 2001-2003 Investigator, Spine Patient Outcome Research Trial (Washington University), National Institutes of Health (\$14,000,000 total funding)

CLINICAL RESEARCH EXPERIENCE

Principle Investigator

1. A Randomized, Multicentered, Double-Blind, Placebo-Controlled Study to Assess the Safety and Efficacy of XXX in Subjects with Muscle Strain.
2. A Multi-Center, Standard of Care-Controlled Study to Evaluate the Long-Term Safety of XXX for the Treatment of Chronic Low Back Pain.

3. “An Open-Label, 12-Month Study to Evaluate the Safety, Tolerability, and Efficacy of XXX Fentanyl Citrate for the Management of Breakthrough Pain in Opioid-Tolerant Patients with Chronic Noncancer Pain.”
4. A Phase III, 12 week, Multicentre, Double-blind, Double-dummy, Randomized, Placebo and Active Comparator-Controlled, Parallel Group study to investigate the Efficacy and Safety of XXX 1mg, 5mg, 10mg, 25mg, and 50mg administered orally once daily, in adults with Osteoarthritis of the knee.
5. An Open-Label Study Evaluating the Safety and Tolerability of Long Term Administration of Hydrocodone/Acetaminophen Extended Release Tablets (Vicodin® CR) in Subjects with Moderate to Severe Chronic Non-Malignant Pain.
6. A Phase 3 study of the Analgesic Efficacy and Safety of HCT 3012: a Parallel, Randomized, Double-Blind, 13-week Placebo- and Naproxen-Controlled, Multicenter Study of XXX (375 mg bid and 750 mg bid) in Patients with Osteoarthritis of the Knee.
7. A Phase 3, Randomized, Multicenter, Double-Blind Study Comparing the Analgesic Efficacy of Extended Release Hydrocodone/Acetaminophen Tablets (XXX) to Placebo in Subjects with Osteoarthritis.
8. A Double-Blind, Placebo-Controlled, Multicenter Study to Assess the Safety and Efficacy of Dextromethorphan and Quinidine at Two Dose Levels in the Treatment of the Pain of Diabetic Neuropathy.
9. A Randomized Parallel Arm, Placebo Controlled, Double Blind, Multiple Dose Study of the Safety and Efficacy of XXX in Adults with Moderate to Severe Pain due to Osteoarthritis of the Knee.
10. A Phase II, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled, Multicenter Study to Evaluate the Safety and Efficacy of Rituximab (MabThera®/Rituxan®) in Adults with Relapsing-Remitting Multiple Sclerosis.
11. A Randomized, Double-Blind, Placebo-Controlled, Parallel Group Phase III Study of the Efficacy, Tolerability and Safety of Ketoprofen Topical Patch (KTP) in the Treatment of Pain Associated with Tendonitis or Bursitis of the Shoulder, Elbow or Knee.
12. Gastrointestinal (GI) Randomized Event and Safety Open-Label NSAID Study (XXX): A Randomized, Open-label, Blinded Endpoint Parallel-group Trial of GI Safety of Celecoxib Compared with Non-selective NSAIDS in Osteoarthritis Patients.
13. A Multi-Center, Double-Blind, Randomized, Placebo-Controlled, Multiple Dose, Parallel Design, Dose Ranging Study of the Safety and Efficacy of XXX in Patients with Painful Diabetic Peripheral Neuropathy.
14. Open-Label, Multiple-Dose Study of the Safety and Efficacy of XXX in Adults with Pain due to Osteoarthritis of the Knee.
15. A Phase 3, 53 Weeks Study on XXX Efficacy and Safety of XXX: 26 Week , Randomized, Parallel-Group, Double-Blind, Placebo (13 Weeks)-and XXX (26 Weeks)-Controlled, Multicenter

Study of XXX (375 mg bid and 750 mg bid) with a 26 Week XXX Controlled Safety Follow-Up in Subjects with Osteoarthritis of the Knee, and a 1-Week Post-Treatment Safety Follow-Up.

16. Phase II Randomized, Double-Blind, Placebo-and Positive Controlled, Multicenter, Parallel, Group Proof of Concept Study of the Analgesic Effects of XXX in Adult Patients with Chronic Low Back Pain.
17. A 12-Week, Dose-ranging, Double-blind, Randomized, Placebo-controlled, Parallel-group Study to Assess the Safety and Efficacy of XXX in Obese Patients.
18. Safety and Tolerability of the Japanese Encephalitis Vaccine XXX (JE-PIV). Double Blind, Randomized, Placebo Controlled Phase 3 Study.
19. A Long-Term, Open-Label, Safety Study of XXX (Morphine Sulfate Plus Naltrexone Hydrochloride Extended-Release) Capsules in Subjects with Chronic Moderate to Severe Nonmalignant Pain. A Randomized, Double-Blind, Phase 3 Study of the Efficacy and Safety of XXX in Subjects Requiring NSAID Treatment.
20. A randomized, double-blind, placebo-controlled multicenter Phase II / III study to evaluate the efficacy and safety of XXX and placebo given orally for 12 weeks for the treatment of opioid-induced constipation (OIC) in patients with chronic non-cancer pain.
21. A 2 Week, Randomized, Double Blind, Placebo and Positive Controlled, Parallel Group, Multicenter Study to Assess the Efficacy and Tolerability of XXX in Patients with Moderate to Severe Pain due to Osteoarthritis.
22. A Randomized-Withdrawal Phase III Study Evaluating the Safety and Efficacy of XXXX Extended-Release (ER) in Subjects with Painful Diabetic Peripheral Neuropathy (DPN)
23. Phase II Randomized, Double Blind, Placebo and Active Controlled, Multicenter, Parallel Group Proof of Concept Study of the Analgesic Effects of XXX in Adult Patients with Chronic Low Back Pain.

Investigator

24. Long Term Immunogenicity of the Japanese Encephalitis Vaccine IC51 (JE-PIV). An Open Uncontrolled Phase 3 Follow-up Study.
25. Efficacy and Safety of 10 mg XXX for Treating Heartburn in Frequent Sufferers.
26. A randomized, double-blind, multi-center, placebo-controlled, cross-over study to determine the consistency of response for XXX (sumatriptan 85mg/naproxen sodium 500mg) administered during the mild pain phase for the acute treatment of multiple migraine attacks.
27. A double blind, placebo controlled, randomized, parallel group study of the efficacy and safety of oral doses of 20 mg XXX when used on-demand for up to 7 episodes over a period of 6 weeks for the treatment of occasional episodes of self-reported abdominal pain, cramping and discomfort in an OTC-like study population.

28. A US Randomized Questionnaire-Based Trial Assessing the Impact of the Availability of Inhaled Insulin on Therapeutic Choice in Patients with Suboptimally Controlled Type 2 Diabetes.
29. A Multicenter, Randomized, Double-Blind, Prospective Study Comparing the Safety and Efficacy of Fenofibric Acid and Rosuvastatin Calcium Combination Therapy to Fenofibric Acid and Rosuvastatin Calcium Monotherapy in Subjects with Mixed Dyslipidemia.
30. A Multicenter, Double-Blind, Placebo-Controlled Study of the Safety, Tolerability, and Efficacy of XXX Trap in Subjects with CIAS1 Associated Periodic Syndromes (CAPS) Using Both Parallel Group and Randomized Withdrawal Designs.
31. A randomized, double-blind, multi-center, placebo-controlled, cross-over study to determine the consistency of response for XXX (sumatriptan 85mg/naproxen sodium 500mg) administered during the mild pain phase for the acute treatment of multiple migraine attacks.
32. A Multicenter, Randomized, Double-Blind, Placebo Controlled Study to Evaluate Safety and Efficacy of XXX XXX in Patients with Mild to Moderate Alzheimer's Disease.
33. A Double-Blind, Randomized, 6-Month Evaluation of the Safety and Efficacy of Topical Alprostadil in Hysterectomized Women with Female Sexual Arousal Disorder (FSAD).
34. A Multicenter, Randomized, Double-blind, Parallel-group, Placebo-controlled, Active-controlled Study of the Efficacy and Safety of Sustained-release Quetiapine Fumarate (XXX) Compared with Placebo in the Treatment of Generalized Anxiety Disorder (Gold Study), XXX.
35. A Multicenter, Double-blind, Randomized, Parallel-group, Placebo-controlled and Active-controlled Phase III Study of the Efficacy and Safety of Quetiapine Fumarate Sustained-release (XXX) as Monotherapy in the Treatment of Patients with Major Depressive Disorder (Diamond Study), XXX.
36. A Double-Blind, Randomized, Placebo-Controlled Study of the Efficacy, Safety and Tolerability of 8 Week Treatment of XXX 8 mg (QHS) in Sleep Disturbed, Community Dwelling, Mild to Moderately Severe Alzheimer's Disease Subjects.
37. A Forty-Eight Week, Randomized Discontinuation Trial of Flibanserin in Women With Hypoactive Sexual Desire Disorder Containing an Open-Label, Flexible Dose Period Followed by an Double-Blind, Randomized, Placebo-Controlled Period.
38. A Long-Term, Open-Label, Safety Extension Study of the Combination of Fenofibric Acid and Statin Therapy for Subjects with Mixed Dyslipidemia.
39. Long Term, Open-Label Safety Study of Oral Almotriptan Malate 12.5 mg in the Treatment of Migraine in Adolescents.
40. The Rembrandt study: A Randomized, Double-blind, Placebo Controlled Parallel-group Fixed and Flexible XXX Dose Arm Study to Assess Efficacy and Safety of XXX Monotherapy in the Treatment of Patients with Early Stage Parkinson's Disease.

41. A Phase IIa Study Evaluating the Efficacy and Safety of a Unique Intravenous Iron Preparation in the Treatment of Restless Leg Syndrome (RSL).
42. A validation study of the COPD-PS in a community-based sample.
43. A Randomized, Open-Label, Multicenter, Comparator-Controlled Study to Examine the Effects of Exenatide Long-Acting Release on Glucose Control (HbA1c) and Safety in Subjects with Type 2 Diabetes Mellitus Managed with Diet Modification and Exercise and/or Oral Antidiabetic Medications.
44. A Phase 3 Multicenter, Randomized, Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of XXX Extended Release (G-ER) Tablets in the Treatment of Patients with Postherpetic Neuralgia.
45. A Phase 2, Randomized, Double Blind, Placebo Controlled Study to Evaluate the Safety, Tolerability, and Pharmacodynamics of Multiple Doses and Dose Levels of DDP225 in Female Patients with Irritable Bowel Syndrome with Diarrhea.
46. A Phase 3, 24-Week, Multi-Center, Open-Label, Randomized, Controlled Trial Comparing the Efficacy and Safety of Prandial Inhalation of Technosphere[®]/Insulin in Combination with Metformin or Technosphere[®]/Insulin Alone Versus 2 Oral Anti-Diabetic Agents (Metformin and a Secretagogue) in Subjects With Type 2 Diabetes Mellitus Sub-Optimally Controlled on Combination Metformin and a Secretagogue.
47. A randomized, double-blind, active-controlled, vehicle-controlled, subject initiated study comparing efficacy and safety of XXX versus acyclovir cream for treatment of recurrent herpes simplex labialis. A multinational, multicenter, phase III study.
48. A 24-Week, Randomized, Double-Blind, Placebo Controlled, Safety and Efficacy Trial of XXX 50 and 100 Milligrams Each Evening in Premenopausal Women With Hypoactive Sexual Desire Disorder.
49. A multicenter, randomized, 1-week, double-blind, placebo-controlled study to evaluate the safety and tolerability of abrupt discontinuation of saredutant in outpatients with major depressive disorder who completed 8 weeks of open-label treatment with XXX 100 mg once daily."
50. A multi-center, double-blind, parallel group, fixed dose, 4-arm, placebo and paroxetine controlled 8-week efficacy study of 2 oral doses of XXX (175mg or 350mg, bid) in adult outpatients with Major Depression Disorder.
51. A 104-Week, Double-blind, Randomized, Placebo-controlled, Parallel-group Study to Assess the Safety and Efficacy of Lorcaserin Hydrochloride in Obese Patients.
52. Effect of Septal Closure of Atrial PFO on Events of Migraine with the XXX Device.
53. "A phase IIIb, prospective, observer-blind, randomized, controlled multicenter study to evaluate immunogenicity and safety of GlaxoSmithKline (GSK) Biologicals' tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine, adsorbed [Tdap Boostrix[®]] compared to Sanofi

- Pasteur's tetanus toxoid, reduced diphtheria toxoid and acellular pertussis vaccine, adsorbed [Adacel™], when administered as a booster vaccination in adults aged 19 to 64 years of age."
54. A Multicenter, Open-Label Study of the Safety and Efficacy of Long Term Use of XXX Extended Release (G-ER) Tablets in the Treatment of Patients with Postherpetic Neuralgia.
 55. A Multi-Center, Randomized, Double-blind, Placebo-controlled Study of the Efficacy and Safety of XXX in Adult Subjects with type 2 diabetes Mellitus.
 56. Safety and Immunogenicity of Tetanus Toxoid, Reduced Diphtheria Toxoid and Acellular Pertussis Vaccine Adsorbed (XXX) in Persons > 65 Years of Age.
 57. A Clinical Study to Evaluate the Safety and Efficacy of XXX 12-Hour 5 mg Loratadine Tablet BID vs. Placebo Tablet in the Treatment of Allergic Rhinitis.
 58. A phase III, multi-center, randomized, double-blind, placebo-controlled, parallel group trial of fourteen day treatment with XXX 15 mg or 30 mg once a day in frequent nighttime heartburn.
 59. A Randomized, Double-Blind, Placebo-Controlled, Dose-Titration Study to Assess the Safety, Tolerability, and Efficacy of XXX in Persons with Multiple Sclerosis with Cognitive Impairment.
 60. A Double-Blind, Multi-Center, Randomized, Parallel-Group, Yearlong Study to Assess the Efficacy and Safety of XXX, or XXX of XXX Administered Orally Once Daily with a Reduced Calorie Diet in Obese Males and Females.
 61. Efficacy and Safety of XXX of XXX on Sleep Maintenance Insomnia with a sub study of the effect of XXX on stable Type II Diabetes Mellitus: a 12-week, multi-center, randomized, double-blind, placebo-controlled study.
 62. A Multicenter, Placebo Controlled, Randomized, Double Blind, Subject Initiated Study of the Safety and Efficacy of the Electrokinetic Transdermal System with XXX for the Episodic Treatment of Recurrent Herpes Labialis.
 63. Double-Blind, Parallel-Group Comparison of 23 mg XXX Sustained Release to 10 mg XXX Immediate Release in Patients with Moderate to Severe Alzheimer's Disease.
 64. Efficacy and safety of 2mg/day of XXX on Sleep Maintenance Insomnia with a sub-study of the effect of XXX on stable Type II Diabetes Mellitus: a 12-week, multi-center, randomized, double-blind, placebo-controlled study.
 65. Open Label Study of the Effect of Daily Treatment with XXX in Subjects with Dementia of the Alzheimer's Type.
 66. A Phase II, Multicenter, Randomized, Double-Mask, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Intramuscular Peramivir in Subjects with Uncomplicated Acute Influenza.
 67. A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Effects of DHA on Cognitive Functions in the Elderly.

68. A Phase 3, Randomized, Multicenter, Double-Blind, Allopurinol-Controlled Study Assessing the Efficacy and Safety of Oral XXX in Subjects with Gout.
69. A Randomized, Double Blind, Placebo-Controlled, Parallel Group, Multi-Center Study Investigating the Efficacy and Safety of a Fast-Dissolving (“XXX”) Formulation of XXX for the Treatment of Nocturia in Adults.
70. A Phase 3, Randomized, Active-Controlled, Modified Double Blind Trial Evaluating the Safety, Tolerability and Immunogenicity of a 15-Valent Pneumococcal Conjugate Vaccine Compared to a 23-Valent Polysaccharide Vaccine in Adults 60-64 Years Old who are Naive to 23-Valent Polysaccharide Vaccine
71. A Randomized-Withdrawal Phase III Study Evaluating the Safety and Efficacy of XXX Extended-Release (ER) in Subjects with Painful Diabetic Peripheral Neuropathy (DPN).
72. A Phase III, Flexible-Dose Titration Followed by a Randomized Double-Blind Study of Controlled-Release XXXX Compared to Placebo in Patients with Osteoarthritis Patients
73. A 2 Week, Randomized, Double Blind, Placebo and Positive Controlled, Parallel Group, Multicenter Study to Assess the Efficacy and Tolerability of XXX in Patients with Moderate to Severe Pain Due to Osteoarthritis.
74. A Multicenter, Randomized, Double Blind, Placebo Controlled Study Comparing the Safety and Efficacy of Multiple Doses of XXX Sustained Release (SR)/XXX Sustained Release (SR) and Placebo in Obese Subjects with Type 2 Diabetes Mellitus.
75. A Randomized, Multicenter, Double-blind, Placebo-controlled, Dose-range-finding, Parallel-design, Phase 2 Trial of Oral XXX Administered to Patients with Irritable Bowel Syndrome with Constipation.
76. A Multicenter, Randomized, Double-Blinded, “Crossover” Design Study to Evaluate the Lipid-Altering Efficacy and Safety XXX Combination Tablet Compared to XXX+Simvastatin Coadministration in Patients With Primary Hypercholesterolemia and Mixed Dyslipidemia.
77. A Double-Blind Randomized Study to Evaluate the Efficacy and Safety of XXX 50 mg or Placebo When Coadministered With Statins in Subjects With Hypercholesterolemia, With an Optional Open-Label Extension.
78. A phase IIIb, controlled, multicenter study to evaluate antibody persistence at 1, 3, 5 and 10 years following administration of a single dose of Tdap vaccine to healthy subjects, 19 years of age and older in the study XXX (XXX).
79. A Phase 3, Randomized, Double-Blind Trial To Evaluate the Safety, Tolerability, And Immunogenicity of A 13-Valent Pneumococcal Conjugate Vaccine (13vpnc) When Administered Concomitantly With Trivalent Inactivated Influenza Vaccine In Healthy Adults 50-59 Years of Age Who Are Naive to 23-Valent Pneumococcal Polysaccharide Vaccine and to Evaluate the Immune Response of a Second Dose of 13vpnc Administered 5 Years After Initial 13vpnc Vaccination.

80. A phase IIb, multi-center, randomized, double-blind, placebo-controlled study, with open-label follow on, to evaluate the efficacy, safety and tolerability of PSD502 in subjects with Premature Ejaculation (PE).
81. A Randomized, Double-Blind, Parallel-Group, Multicenter Study to Compare the Glycemic Effects, Safety, and Tolerability of XXXX Long-Acting Release to Those of XXXX and XXXX in Subjects with Type 2 Diabetes Mellitus Treated with XXXX
82. A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Dose Response of XXXX Compared to Open-Label XXXX in Patients with Hypercholesterolemia
83. A Phase III, Randomized, Double-Blind, Parallel-Design Study Comparing Multiple Doses Of XXX to Placebo and Their Single-Agent XXX and XXX Constituents for the Treatment of Obesity in Adults.
84. Evaluation of XXXX on Carotid Intima-Media Thickness (cIMT) in Subjects with Type IIa and IIb Dyslipidemia with Residual Risk in Addition to Atorvastatin Therapy (FIRST) Trial
85. A Phase 3, observer-blind, randomized, placebo-controlled, multi-center trial to evaluate the safety and immunogenicity of a two-dose series of XXXX vaccine antigen in association with AS03 adjuvant in adults aged ≥ 18 years.