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EDUCATION

1978 – 1981 Medical: M.D., Ohio State University, Columbus, Ohio
Clerkship Honors - Medicine, Surgery, OB/GYN, Pediatrics

1974 – 1978 Undergraduate: Biology, BA/MS, Northwestern University, Evanston, Illinois
Honors: Biology Combined BA/MS Program

TRAINING

1984 – 1986 Fellowship: Rush-Presbyterian-St. Luke's Medical Center, Chicago, Illinois
Cardiology

1981 – 1984 Residency: Rush-Presbyterian-St. Luke's Medical Center, Chicago, Illinois
Internal Medicine

MEDICAL EXPERIENCE

2003 – Present Executive Medical Director, Radiant Research, Chicago, Illinois

2001 – Present Associate Professor of Medicine and Director of Preventive
Cardiology, Rush University Medical Center, Chicago, Illinois

1998 – 2003 Executive Medical Director, Protocare Trials

1996 – 2003 President & CEO, Protocare Trials Chicago Center for Clinical
Research, Chicago, Illinois

1986 – Present Academic Appointment, Associate Professor, Department of Medicine,
Rush University Medical Center Chicago, Illinois

1986 – 1996 Medical Director, Chicago Center for Clinical Research Chicago,
Illinois

CERTIFICATION AND LICENSURE

1987 Cardiology

1984 Internal Medicine

Licensure: State of Illinois Physician and Surgeon
Number: 036-065126
Expiration Date: July 31, 2008

PATENT/TRADEMARK

United States Patent Number: 5,279,540 - Michael H. Davidson, M. D., F.A.C.C.
Date of Patent: January 18, 1994

Abstract: A method for reducing the risk of atherosclerosis in a patient at risk of same comprising the steps of removing cholesterol ester transfer protein from blood of the patient to reduce the plasma CETP levels in the patient. In an embodiment, the method includes the step of passing the patient's

plasma through an apheresis machine to remove at least some of the plasma cholesterol ester transfer protein.

BOOKS

Michael Davidson, M.D., F.A.C.C. the Mobile Lipid Clinic: A companion manual. Lippincott and Wilkins, 2002. (First edition 80,000 copies sold.)

Software Development: Developed in the Mobile Lipid Clinic, a Palm OS cardiovascular risk calculation and patient management system for PDA's and the desktop PC. (Over 10,000 copies requested.)

JOURNAL PUBLICATIONS

1. **Davidson MH.** Newer pharmaceutical agents to treat lipid disorders. *Curr Cardiol Rep.* 2003; 5:463-469.
2. **Davidson MH.** Efficacy of simvastatin and ezetimibe in treating hypercholesterolemia. *J Am Coll Cardiol.* 2003;42:298-399. [Letter to the editor]
3. Maki KC, **Davidson MH**, Dicklin MR, Ingram KA, Cyrowski M, Umporowicz DM, Bell M, Elliot JG. Bioavailability of Eicosapentaenoic and Docosahexaenoic n-3 polyunsaturated fatty acids in salmon patties compared with capsules. *J Food Sci.* 2001; 68:761-764.
4. Jones Peter H, **Davidson MH**, Stein EA, Bays HE, McKenney JM, Miller E, Cain VA, Bassetto JW, for the STELLAR Study Group. Comparison of the efficacy and safety of rosuvastatin versus atorvastatin, simvastatin, and pravastatin across doses (STELLAR* trial). *Am J Cardiol.* 2003; 92:152-160.
5. **Davidson MH**, Kurlandsky SB, Kleinpell RM, Maki KC. Lipid management and the elderly. *Prev Cardiol.* 2003; 6:128-135.
6. **Davidson MH.** Combination lipid-lowering therapy in diabetes. *Curr Diabetes Rep.* 2003;3:263-268.
7. **Davidson MH**, Maki K, Umporowicz D, Wheeler A, Rittershaus C, Ryan U. The safety and immunogenicity of a CETP vaccine in healthy adults. *Atherosclerosis.* 2003;169:113-120.
8. Maki KC, **Davidson MH**, Dicklin MR, Ingram KA, Cyrowksi M, Umporowicz DM, Bell M, Elliott JG. Bioavailability of eicosapentaenoic and docosahexaenoic n-3 polyunsaturated fatty acids in salmon patties compared with capsules. *J Food Sci.* 2003;68:761-764.
9. Rader DJ, **Davidson MH**, Caplan RJ, Pears JS. Lipid and apolipoprotein ratios: association with coronary artery disease and effects of rosuvastatin compared with atorvastatin, pravastatin, and simvastatin. *Am J Cardiol.* 2003;91(5A):20C-23C.
10. Ballantyne CM, Corsini A, **Davidson MH**, Holdaas H, Jacobson TA, Leitersdorf E, Marz W, Reckless JP, Stain EA. Risk for myopathy with statin therapy in high-risk patients. *Arch Intern Med.* 2003;163:553-564.
11. Maki KC, Shinnick F, Seeley MA, Veith PE, Quinn LC, Hallissey PJ, Temer A, **Davidson MH.** Food products containing free tall oil-based phytosterols and oat beta-glucan lower serum total and LDL cholesterol in hypercholesterolemic adults. *J Nutr.* 2003;133:808-813.

12. **Davidson MH.** Ezetimibe: a novel option for lowering cholesterol. *Expert Rev Cardiovasc Ther.* 2003;1:89-99.
13. **Davidson MH,** Geohas CT. Efficacy of over-the-counter nutritional supplements. *Curr Atheroscler Rep.* 2003;5:15-21.
14. Isaacsohn J, Hunninghake D, Schrott H, Dujovne CA, Knopp R, Weiss SR, Bays H, Crouse JR III, **Davidson MH,** Keilson LM, McKenney J, Korenman SG, Dobs AS, Stein E, Krauss RM, Maccubbin D, Cho Meehyung, Plotkin DJ, Mitchel YB. Effects of simvastatin, an HMG-CoA reductase inhibitor, in patients with hypertriglyceridemia. *Clin Cardiol.* 2003;26:18-24.
15. Braun LT, **Davidson MH.** Cholesterol-lowering drugs bring benefits to high-risk populations even when LDL is normal. *J Cardiovasc Nurs.* 2003;18:44-49.
16. **Davidson MH,** McGarry T, Bettis R, Melani L, Lipka LJ, LeBeaut AP, Suresh R, Sun S, Veltri EP. Ezetimibe coadministered with simvastatin in patients with primary hypercholesterolemia. *J Am Coll Cardiol.* 2002;40:2125-34.
17. Greenspan SL, Emkey RD, Bone HG, Weiss SR, Bell NH, Downs RW Jr, McKeever C, Miller SS, **Davidson M,** Bolognese MA, Mulloy AL, Heiden N, Wu M, Kaur A, Lombardi A. Significant differential effects of alendronate, estrogen, or combination therapy on the rate of bone loss after discontinuation of treatment of postmenopausal osteoporosis. A randomized, double-blind, placebo-controlled trial. *Ann Intern Med.* 2002;137:875-83.
18. **Davidson, MH.** Combination therapy for dyslipidemia: safety and regulatory considerations. *Am J Cardiol.* 2002;90(suppl):50K-60K.
19. Maki KC, **Davidson MH,** Tsushima R, Matsuo N, Tokimitsu I, Umporowicz DM, Dicklin MR, Foster GS, Ingram KA, Anderson BD, Frost SD, Bell M. Consumption of diacylglycerol oil as part of a reduced-energy diet enhances loss of body weight and fat in comparison with consumption of a triacylglycerol control oil¹⁻³. *Am J Clin Nutr.* 2002;76:1230-6.
20. Maki KC, Dicklin MR, Cyrowski MS, Umporowicz DM, Nagata Y, Moon G, Forusz S, **Davidson MH.** Improved calcium absorption from a newly formulated beverage compared with a calcium carbonate tablet. *Nutr Res.* 2002;22:1163-76.
21. **Davidson MH.** Unidentified multiple risk factor patients: A missed opportunity for primary CHD prevention. *Fam Pract Recertif.* 2002;86:23-32.
22. **Davidson MH.** Controversy surrounding the safety of cerivastatin. *Expert Opin Drug Saf.* 2002;1:207-12.
23. **Davidson MH,** Ma P, Stein EA, Gotto AM Jr, Raza A, Chitra R, Hutchinson H. Comparison of effects on low-density lipoprotein cholesterol and high-density lipoprotein cholesterol with rosuvastatin versus atorvastatin in patients with type IIa or IIb hypercholesterolemia. *Am J Cardiol.* 2002;89:268-75.
24. **Davidson MH.** Rosuvastatin: a highly efficacious statin for the treatment of dyslipidaemia. *Expert Opin Investig Drugs.* 2002;11:125-41.

25. Furberg CD, Vittinghoff E, **Davidson M**, Herrington DM, Simon JA, Wenger NK, Hulley S. Subgroup interactions in the Heart and Estrogen/Progestin Replacement Study. Lessons learned. *Circulation*. 2002;105:917-22.
26. **Davidson MH**, Bittner VA, Deedwania PC. Lipid management in elderly patients: clinical challenges and therapeutic strategies. *Ann Long Term Care*. 2002;10:21-4.
27. **Davidson MH**, Lukacsko P, Sun JX, Phillips G, Walters E, Serman A, Niecestro R, Friedhoff L. A multiple-dose pharmacodynamic, safety, and pharmacokinetic comparison of extended- and immediate-release formulations of lovastatin. *Clin Ther*. 2002;24:112-25.
28. **Davidson MH**. The National Cholesterol Education Program (NCEP) Adult Treatment Panel (ATP) III Guidelines. A look to the future: new treatment guidelines and a perspective on statins. *Am J Med*. 2002;112(Suppl)8A:34S-41S.
29. **Davidson MH**. Strategies to improve Adult Treatment Panel III guideline adherence and patient compliance. *Am J Cardiol*. 2002;89(suppl):8C-22C.
30. **Davidson MH**. A symposium: National Cholesterol Education Program Adult Treatment Panel III: impact and implementation of the new guidelines. Introduction. *Am J Cardiol*. 2002;89:1C-2C.
31. **Davidson MH**, Maki KC, Umporowicz DM, Ingram KA, Dicklin MR, Schaefer E, Lane RW, McNamara JR, Ribabya-Mercado JD, Perrone G, Robins SJ, Franke WC. Safety and tolerability of esterified phytosterols administered in reduced-fat spread and salad dressing to healthy adult men and women. *J Am Coll Nutr*. 2001;20:307-19.
32. **Davidson MH**, Toth P, Weiss S, McKenney J, Hunninghake D, Isaacsohn J, Donovan JM, Burke SK. Low-dose combination therapy with colestevam hydrochloride and lovastatin effectively decreases low-density lipoprotein cholesterol in patients with primary hypercholesterolemia. *Clin Cardiol*. 2001;24:467-74.
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34. Hunninghake D, Insull W, Knopp R, **Davidson M**, Lohrbauer L, Jones P, Kafonek S. Comparison of efficacy of atorvastatin versus cerivastatin in primary hypercholesterolemia. *Am J Cardiol*. 2001;88:635-9.
35. **Davidson MH**. Cardiovascular implications of hormonal therapy. *The Female Patient*. December, 2001:13-19.
36. **Davidson MH**. Treatment of the elderly with 3-hydroxy-3-methylglutaryl coenzyme A reductase inhibitors: focus on drug interactions. *J Cardiovasc Pharmacol Ther*. 2001;6:219-29.
37. **Davidson MH**, Maki KC, Karp SK, Ingram KA. Management of hypercholesterolemia in postmenopausal women. *Drugs Aging*. 2001;19:169-78.

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39. Insull W Jr, Koren M, Davignon J, Sprecher D, Schrott H, Keilson LM, Brown AS, Dujovne CA, **Davidson MH**, McLain R, Heinonen T. Efficacy and short-term safety of a new ACAT inhibitor, avasimibe, on lipids, lipoproteins, and apolipoproteins, in patients with combined hyperlipidemia. *Atherosclerosis.* 2001;157:137-44.
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45. **Davidson MH**. Safety profiles for the HMG-CoA reductase inhibitors: treatment and trust. *Drugs.* 2001;61:197-206.
46. **Davidson MH**. Introduction: utilization of surrogate markers of atherosclerosis for the clinical development of pharmaceutical agents. *Am J Cardiol.* 2001 87:1A-7A.
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49. **Davidson M**, Marwah A, Sawchuk RJ, Maki K, Marwah P, Weeks C, Lardy H. Safety and pharmacokinetic study with escalating doses of 3-acetyl-7-oxo-dehydroepiandrosterone in healthy male volunteers. *Clin Invest Med.* 2000;23:300-10.
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- a large group of patients with hypercholesterolemia. World Wide Expanded Dose Simvastatin Study Group. *Clin Cardiol.* 2000;23:39-46.
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 53. **Davidson MH**, Dicklin MR, Maki KC, Kleinpell RM. Colesevelam hydrochloride: a non-absorbed, polymeric cholesterol-lowering agent. *Expert Opin Investig Drugs.* 2000;9:2663-71.
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 58. Maki KC, **Davidson MH**, Marx P, Cyrowski MS, Maki A. Association between elevated plasma fibrinogen and the small, dense low-density lipoprotein phenotype among postmenopausal women. *Am J Cardiol.* 2000;85:451-6.
 59. Maki KC, **Davidson MH**, Torri S, Ingram KA, O'Mullane J, Daggy BP, Albrecht HH. High-molecular-weight hydroxypropylmethylcellulose (HPMC) taken with or between meals has hypocholesterolemic effects in adult men. *J Nutr.* 2000;130:1705-10.
 60. Hunninghake DB, Maki KC, Kwiterovich PO Jr, **Davidson MH**, Dicklin MR, Kafonek SD. Incorporation of lean red meat into a National Cholesterol Education Program Step I diet: a long-term, randomized clinical trial in free-living persons with hypercholesterolemia. *J Am Coll Nutr.* 2000;19:351-60.
 61. **Davidson MH**. Does differing metabolism by cytochrome P450 have clinical importance? *Curr Atheroscler Rep.* 2000;2:14-9.
 62. Maki KC, **Davidson MH**, Cyrowski MS, Maki AC, Marx P. Low-density lipoprotein subclass distribution pattern and adiposity-associated dyslipidemia in postmenopausal women. *J Am Coll Nutr.* 2000;19:23-30.
 63. Isaacsohn JL, **Davidson MH**, Hunninghake D, Singer R, McLain R, Black DM. Aggressive

- lipid-lowering initiation abates new cardiac events (ALLIANCE) – rationale and design of atorvastatin versus usual care in hypercholesterolemic patients with coronary artery disease. *Am J Cardiol.* 2000; 86:250-2.
64. **Davidson MH.** Efficacy of antiobesity therapies. *Am J Clin Nutr.* 2000;71:844.
 65. **Davidson MH,** Dillon MA, Gordon B, Jones P, Samuels J, Weiss S, Isaacsohn J, Toth P, Burke SK. Colesevelam hydrochloride (cholestagel): a new, potent bile acid sequestrant associated with a low incidence of gastrointestinal side effects. *Arch Intern Med.* 1999;159:1893-900.
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 68. **Davidson MH,** Maki KC. Effects of dietary inulin on serum lipids. *J Nutr.* 1999;129:1474S-7S.
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 71. Schwartz JI, Chan CC, Mukhopadhyay S, McBride KJ, Jones TM, Adcock S, Moritz C, Hedges J, Grasing K, Dobratz D, Cohen RA, **Davidson MH,** Bachmann KA, Gertz BJ. Cyclooxygenase-2 inhibition by rofecoxib reverses naturally occurring fever in humans. *Clin Pharmacol Ther.* 1999;65:653-60.
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80. **Davidson MH**, Maki KC, Kong JC, Dugan LD, Torri SA, Hall HA, Drennan KB, Anderson SM, Fulgoni VL, Saldanha LG, Olson BH. Long-term effects of consuming foods containing psyllium seed husk on serum lipids in subjects with hypercholesterolemia. *Am J Clin Nutr.* 1998;67:367-76.
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82. **Davidson MH**, Maki KC. Conjugate equine estrogens and coronary heart disease risk: serum lipid effects. *Menopause Review.* 1998.
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84. Maki KC, Kritsch K, Foley S, Soneru I, **Davidson MH**. Age-dependence of the relationship between adiposity and serum low density lipoprotein cholesterol in men. *J Am Coll Nutr.* 1997;16:578-83.
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87. **Davidson MH**, Maki KC, Kalkowski J, Schaefer EJ, Torri SA, Drennan KB. Effects of docosahexaenoic acid on serum lipoproteins in patients with combined hyperlipidemia: a randomized, double-blind, placebo-controlled trial. *J Am Coll Nutr.* 1997;16:236-43.
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- effects of marine oil and simvastatin in patients with combined hyperlipidemia. *Am J Cardiol.* 1997;80:797-8.
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ABSTRACTS (Selected):

1. Maki KC, Bell M, Oldham KM, **Davidson MH**. Is hyperfibrinogenemia a component of the metabolic syndrome? Presented at the American Diabetes Association. December, 2001.
2. **Davidson MH**, Wheeler A, Rittershaus C, Emmett C, Umporowicz D, Maki KC. A phase I trial of an immunotherapeutic approach for managing low plasma HDL-C. Presented at the XIV International Symposium on Drugs Affecting Lipid Metabolism. September, 2001.

3. **Davidson MH**, Lukacsko P, Friedhoff L, Sterman A, Walters E, Sun J, Phillips G. A multi-dose safety, pharmacokinetic and pharmacodynamic study of lovastatin extended-release relative to lovastatin immediate-release. Presented at the XIV International Symposium on Drugs Affecting Lipid Metabolism. September, 2001.
4. **Davidson M**, Scott R, Frohlich J, Cihon F, Kush D, O'Grady L, Vala M, Mitchel Y. Differential effects of simvastatin and atorvastatin on high density lipoprotein cholesterol and apoprotein A-1 in hypercholesterolemic patients: Cohort and subgroup analyses. Presented at the XIV International Symposium on Drugs Affecting Lipid Metabolism. September, 2001.
5. **Davidson MH**, Hutchinson HG, Chitra R, Raza A, Gotto A. ZD4522 is superior to atorvastatin in decreasing LDL-C and increasing HDL-C in patients with type IIa and IIb hypercholesterolemia. Submitted to *American College of Cardiology* annual meeting.
6. Maki KC, **Davidson MH**, Palmisano J, Susmano A, Dobs A, Kerber I, Hunninghake D, Knopp R, Goldberg A, McKenney J, Kakavas P, Walters D, Bittar N. Separate and combined efforts of hormone replacement and simvastatin 10 mg on lipoprotein (a) and lipoprotein subfractions in postmenopausal women with hypercholesterolemia. Submitted to *American College of Cardiology* annual meeting.
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8. **Davidson MH**, Maki KC, Marx PD, Arce J-C, Nanavati N. Effects of low-dose, continuous combined hormone replacement on serum lipids in postmenopausal women. Presented at the *First Conference on Arteriosclerosis, Thrombosis, and Vascular Biology, 2000*.
9. Maki KC **Davidson MH**, Marx PD, Cyrowski M, Arce J-C. Effects of continuous hormone replacement therapy on indicators of carbohydrate metabolism. Presented at the *American Diabetes Association 60th Scientific Sessions, 2000*.
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12. **Davidson MH**, Maki KC, Hunninghake DB, Knopp RH, Goldberg RB, Waters D, Dobs AS, Cyrowski M. Effects of Low Dose Simvastatin and Hormone Replacement Therapy on Serum Lipids in Postmenopausal Women with Hypercholesterolemia. *American College of Cardiology 49th Annual Scientific Session, 2000*.
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 24. LaBelle P, **Davidson MH**, Gazdick L, Liss C. Efficacy of Starting Doses of Simvastatin vs Pravastatin in Elderly and Non-Elderly Patients. Xth International Symposium on Atherosclerosis. Montreal (Canada), October, 1994.
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- Group: Long-term Safety Of Fish Oil In Hyperlipidemic Patients: A New Synthetic HMG-CoA Reductase Inhibitor in Hyperlipidemic Patients Stratified by Genetic Disorder and Gender. XIth International Symposium on Drugs Affecting Lipid Metabolism. Florence (Italy), May, 1992.
27. **Davidson MH**, Dugan LD, Drennan KB, Story K. Combination Marine Oil & Lovastatin Therapy For Familial Combined Hyperlipidemia. Xth International Symposium on Drugs Affecting Lipid Metabolism. Houston, TX, November, 1989.
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 29. **Davidson MH**. Safety of Omega-3 Fatty Acids. Submitted to the *American Journal of Clinical Nutrition*. National Meeting, Las Vegas, NV, March, 1988.
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 35. **Davidson MH**, Billhardt RA. Acute Ventricular Septal Rupture in Myocardial Infarction: Prognostic Factors for Survival. *Clinical Research* 1985, April.
 36. **Davidson MH**, Stang JM. The Clinical Severity of Isolated Disease of the Diagonal Branch Coronary Artery. American Heart Association, National Meeting. Dallas, TX. November, 1981. American College Physicians, Regional Meeting. Dayton, OH, October, 1981.
 37. **Davidson MH**, Stang JM. The Efficacy of Floating Telemetry Unit Within an Ambulatory Cardiac Care Unit. AFCR, Midwest Regional Meeting. Chicago, IL; November, 1981. American College Physicians, Regional Meeting. Dayton, OH, October 1981.

OTHER PUBLICATIONS

1. **Davidson MH**, Maki KC. Cardiovascular Risk Factors: Evaluation and Treatment Goals. In: Kris-Etherton PM Burns J (eds). *Cardiovascular Nutrition: Strategies and Tools for Disease Management and Prevention*. Chicago, IL: American Dietetic Association, 1998;3-16.

2. McDonald A, Maki KC, **Davidson MH**. Management of Dyslipidemia and Hypertension. In: Kris-Etherton PM, Burns J, (eds). *Cardiovascular Nutrition: Strategies and Tools for Disease Management and Prevention*. Chicago, IL: American Dietetic Association, 1998;17-27.

PROFESSIONAL ORGANIZATIONS

1998	American Medical Association, Illinois State Medical Society
1991	American College of Cardiology, Fellow
1991	American College of Chest Physicians, Fellow
1986 – 1989	Young Physician Section Delegate
1984 –1986	Illinois State Medical Society, Vice Chairman, Resident Section Chairman, Resident Section, American College of Physicians Associate, Chicago Heart Association, American Heart Association – Epidemiology, Associate fellow
1984 – 1985	Alternate Delegate to the House of Delegates, State of Illinois Representative
1983 – 1985	American Medical Association, Resident Selection Delegate

CLINICAL RESEARCH EXPERIENCE

Since 1986, Dr. Michael H. Davidson has served as **Principal Investigator in a vast number of studies in the following areas:**

- Hypercholesterolemia
- Claudication
- Food, Nutrition and Diet
- Heart Failure/Myocardial Infarction
- Hypertension
- Obesity
- Diabetes
- Smoking Cessation
- Osteoporosis

The following is a list of selected studies conducted to date:

1. A 4-Year Population-Based, Randomized, Open-Label Study Comparing the Effect of Aggressive Lipid Lowering with XXXXXX Versus Usual Care in Hypercholesterolemic Patients with Coronary Artery Disease at Risk of Adverse Outcomes. **(259)**
Principal Investigator: Michael Davidson, M.D.
2. A Multi-center, Randomized, Double-Blind, Four Arm, Parallel Group Trial to Evaluate the Separate and Combined Effects of XXXXXXXXXXXXXXXX and XXXXXXXXXXXXXXXX. **(304)**

Principal Investigator: Michael Davidson, M. D.
3. A Randomized, Double-Blinded, Parallel Group Evaluation of XXXXXX. **(356)**
Principal Investigator: Michael Davidson, M. D.
4. XXXXXXXXXXXXX as Adjunctive Therapy in Subjects with Type 2 Diabetes Mellitus Not Well Controlled on XXXXXXXXXXXXX: A Three-Month Open-Label, Parallel Comparative Trial with Optional One Year Extension. **(426 & 426 Ext.)**
Principal Investigator: Michael Davidson, M. D.

5. A Randomized, Double-Blind, Active-Controlled Evaluation of the Dose-Response of XXXX in Patients with Intermittent Claudication. **(510)**
Principal Investigator: Michael Davidson, M. D.
6. A Randomized, Double-Blind, Placebo-Controlled, Escalating Dose and Pharmacokinetic Study to Evaluate the Safety of the XXXXXXXXXXXXX. **(608)**
Principal Investigator: Michael Davidson, M. D.
7. A Randomized, Double-Blind, Parallel Group Evaluation of XXXXXXXXXXXXX. **(650)**
Principal Investigator: Michael Davidson, M. D.
8. The Efficacy and Safety of XXXX for the Treatment of Mild to Moderate Obesity: A Randomized, Double-Blind, Placebo-Controlled Trial. **(659)**
Principal Investigator: Michael Davidson, M. D.
9. A Randomized, Double-Blind, Placebo-Controlled Trial of the Effect of XXXXX. **(667)**
Principal Investigator: Michael Davidson, M. D.
10. A Randomized Study to Evaluate the Effect of XXXXXXXXXXXXX. **(669)**
Principal Investigator: Michael Davidson, M. D.
11. A Multi-center, Randomized, Open-Label, Parallel Study to Evaluate XXXXXXXX. **(683)**
Principal Investigator: Michael Davidson, M. D.
12. A Twenty-eight Week, Double-Blind and Observer-Blind to Lipid Values, Active-Controlled, Randomized, Parallel-Group, Multi-center Study to Assess the Safety and Efficacy of XXXXXXXXXXXX Administered Once Daily at Bedtime in Patients with Primary Hypercholesterolemia Compared to XXXXX. **(685)**
Principal Investigator: Michael Davidson, M.D.
13. A Twenty-eight Week, Open-Label, Multi-Center, Extension Study to F351-E00 to Prospectively Evaluate the Long-Term Safety and Efficacy of XXXXXXXX XX Mg Slow Release (SR) Monotherapy in Patients With Primary Hypercholesterolemia **(685X)**
Principal Investigator: Michael Davidson, M.D.
14. A Randomized, Double-Blind, Trial of XXXXXXXX vs. Placebo in Patients With Primary Hypercholesterolemia **(693)**
Principal Investigator: Michael Davidson, M.D.
15. Phase II Double-Blind, Placebo-Controlled, 4-Week Multiple Dose Evaluation of XXXXX For Its Safety, Toleration and Efficacy for Increasing XXXX in Older Men and Women. **(695)**
Principal Investigator: Michael Davidson, M.D.
16. A Multi-Center, Double-Blind, Randomized, Placebo-Controlled Study Evaluating XXXXXXXX XXXXXXXX Daily for the Treatment of Episodic Heartburn. **(701)**
Principal Investigator: Michael Davidson, M.D.
17. A Multiple-Dose Safety, Pharmacokinetic and Pharmacodynamic Study of XXXX Relative to XXXX
Principal Investigator: Michael Davidson, M.D.
18. Collection of Normal Human Plasma. **(711)**

- Principal Investigator: Michael Davidson, M.D.
19. The Efficacy and Safety of XXXXX for the Treatment of Constipation: A Randomized, Double-Blind, Placebo Controlled Pilot Trial. **(712)**
Principal Investigator: Michael Davidson, M.D.
 20. A Randomized, Double-Blind, Parallel, Placebo-Controlled, Multi-center Study to Evaluate the Efficacy of XXXXX Therapy in Patients with Hypertryglyceridemia. **(720)**
Principal Investigator: Michael Davidson, M.D.
 21. Randomized, Double-Blind, Placebo-Controlled Re-challenge Test of XXXXX. **(722)**
Principal Investigator: Michael Davidson, M.D.
 22. Phase I Double-Blind, Placebo-Controlled, Multiple Dose Evaluation of XXXXX, For It's Safety, Toleration and Efficacy in Calorically Restricted Men and Women. **(728)**
Principal Investigator: Michael Davidson, M.D.
 23. A 1-Year Randomized, Double-Blind, Placebo-Controlled, Multi-center Study Comparing the Efficacy of XX and XX XXXXXX in Patients with Peripheral Vascular Disease **(740)**
Principal Investigator: Michael Davidson, M.D.
 24. The Effect of LDL-cholesterol Lowering Beyond Currently Recommended Minimum Targets on Coronary Heart Disease (CHD) Recurrence in Patients With Pre-Existing CHD **(744)**
Principal Investigator: Michael Davidson, M.D.
 25. A Double-Blind, Randomized Placebo Controlled Trial of Three Doses of XXXXXX and XXXXX for the Prevention of Postmenopausal Osteoporosis. **(761)**
Principal Investigator: Michael Davidson, M.D.
 26. Comparison of the Prevalence of Cardiac Valvular Abnormalities in Patients Treated with XXXXX and XXXX in Combination for at Least Three Consecutive Months Versus Untreated Controls, as Assessed by Echocardiogram. **(769)**
Principal Investigator: Michael Davidson, M.D.
 27. A Multi-center, Double-Blind, Completed-Block, 3-Period, Crossover Study to Evaluate the Effect of XXXXX on Postprandial Hyperlipidemia in Patients with Combined Hyperlipidemia. **(800)**
Principal Investigator: Michael Davidson, M.D.
 28. A Long-Term, Open-Label, Multi-Center Trial of the Safety and Efficacy of XXXXXX in Patients With Dyslipidemia. **(938)**
Principal Investigator: Michael Davidson, M.D.
 29. A Multi-center, Randomized, Parallel Group Study to Evaluate the Effect of Dosing Time on Efficacy and Safety of XXXXX in Patients with Primary Hypercholesterolemia. **(939)**
Principal Investigator: Michael Davidson, M.D.
 30. A Double-Blind, Randomized Comparison of the Efficacy and Safety of 52 Weeks of XXXXXX Therapy Plus Diet in the Treatment of Obesity in Peri and Post-Menopausal Women at Cardiovascular Risk **(980)**
Principal Investigator: Michael Davidson, M.D.

31. A Randomized, Double-Blind, Placebo-Controlled Trial of XXXXXX XXXXXX and XXXXXX Alone and in Combination in Patients with Primary Hypercholesterolemia. **(993)**
Principal Investigator: Michael Davidson, M.D.
32. A Pilot Double-Blind, Placebo-Controlled, Randomized Crossover Study of XXXXX in Patients with Stable Intermittent Claudication. **(A112)**
Principal Investigator: Michael Davidson, M.D.
33. Efficacy and Safety of XXXX compared with Subcutaneous Human Insulin Therapy in Subjects with Type 1 Diabetes Mellitus: A Six-Month, Outpatient, Parallel Comparative Trial **(1001)**
Principal Investigator: Michael Davidson, M.D.
34. A Double-Blind Investigation of the Efficacy and Safety of Morning vs. Evening Dosing of Two Doses of XXXXX Compared to Placebo in Subjects with Primary Hypercholesterolemia **(1034)**
Principal Investigator: Michael Davidson, M.D.
35. A Multicenter, Double-Blind, Randomized, Parallel, 36-Week, Dose Escalation Study to Evaluate the Efficacy and Safety of XXXXXX 40 and 80mg/day Versus XXXXXX 20, 40 and 80mg/day in Patients with Hypercholesterolemia **(1058)**
Principal Investigator: Michael Davidson, M.D.
36. A Multicenter Six Week Randomized Open-Label Parallel Arm Study comparing the Efficacy of Once Daily XXXXXX to XXXXXX in Hypercholesterolemic Patients (The Challenge Study). **(1061)**
Principal Investigator: Michael Davidson, M.D.
37. A Study to Evaluate the Degree of Correlation Between XXXX Ultrasound, XXXXXX XXXXXX, and XXXXXX as Methods to Detect Potential Fat Infiltration of the Liver Following 80 and 160 mg XXXX, or Placebo dosed Once Daily for 38 Days in Hypercholesterolemic Patients. **(1077)**
Principal Investigator: Michael Davidson, M.D.
38. Efficacy and Safety of Inhaled Compared with Subcutaneous Human Insulin Therapy in Subjects with Type 2 Diabetes Mellitus: A Six-Month, Outpatient, Parallel Comparative Trial.**(1090)**
Principal Investigator: Michael Davidson, M.D.
39. Efficacy and Safety of Inhaled Human Insulin Therapy in Subjects with Type 2 Diabetes Mellitus Not Well Controlled with Combination Oral Agents: A Three-Month, Outpatient, Parallel Comparative Trial **(1093)**
Principal Investigator: Michael Davidson, M.D.
40. Protein XXXX Inhibitor-Diabetic Peripheral Arterial Disease **(1097)**
Principal Investigator: Michael Davidson, M.D.
41. A Twenty-Four Week, Randomized, Double-Blind Study of the Effects of XXXXX Versus XXXX and Placebo Administered Orally to Patients With Intermittent Claudication Secondary to Peripheral Arterial Disease **(1104)**
Principal Investigator: Michael Davidson, M.D.
42. An Open-Label, Fixed Dose, Safety Trial of XXXXXX XXXXXX Tablets in Normal Volunteers **(1244)**
Principal Investigator: Michael Davidson, M.D.

43. A Randomized, Double-Blind Controlled Evaluation of the Lipid-Altering Effects of XXXXXX XXXXXX XXXXXX and XXXXXX in Postmenopausal Women with Hypercholesterolemia **(1251)**
Principal Investigator: Michael Davidson, M.D.
44. A Randomized, Double-Blind, Active and Placebo-Controlled, Parallel Group, Multicenter Study Assessing the Effect of XXXXX XXXX Plus XXXX XXXXXX on Lipids in Postmenopausal Women **(1256)**
Principal Investigator: Michael Davidson, M.D.
45. A Multicenter, Randomized, Double-Blind, Placebo Controlled Study to Compare the Efficacy and Safety of XXXXXX 0.4mg and 0.8mg Versus Placebo Once Saily in the Treatment of patients with Hypertriglyceridemia **(1260)**
Principal Investigator: Michael Davidson, M.D.
46. Phase II Double-Blind, Parallel Design, Placebo and Active comparator-Controlled Trial of the Effects of XXXXXX on Lipoprotein Metabolism, Cardiovascular Reactivity and Cognitive Function in Postmenopausal Women **(1263)**
Principal Investigator: Michael Davidson, M.D.
47. Multiple Dose Trial of Safety and Pharmacokinetics of XXXXXX Administered in Patients with Hypercholesterolemia on Background Statins **(1391)**
Principal Investigator: Michael Davidson, M.D.
48. Evaluation of the Safety and Efficacy of XXXXXX: A Dose-Ranging Study **(1409)**
Principal Investigator: Michael Davidson, M.D.
49. A Multi-Center, Randomized, Double-Blind, 2 Period, Complete Block, Crossover Study to Evaluate the Efficacy of XXXXXX and XXXXX in Patients with Hypercholesterolemia **(1419)**
Principal Investigator: Michael Davidson, M.D. **(North Shore)**
50. A 12 week Randomized double-blind Placebo-controlled Multicenter Trial to Evaluate the Efficacy and Safety of XXXXXX and XXXXX in the Treatment of Subjects with Hypercholesterolemia **(1436)**
Principal Investigator: Michael Davidson, M.D.
51. A Phase I Safety and Immunogenicity Study of the XXXX Vaccine in Healthy Adults **(1454)**
Principal Investigator: Michael Davidson, M.D.
52. A Randomized Double-Blind Multicenter Trial to Compare the Short-term and Long-term Efficacy and Safety of XXXXX, XXXXX, and XXXX in the Treatment of Subjects with Hypercholesterolemia **(1567)**
Principal Investigator: Michael Davidson, M.D.
53. A Multi-Center, Double-Blind, Randomized, Single-Dose, Placebo-Controlled Study to Investigate the Efficacy and Safety of 20.6mg and 10.3mg XXXXXX XXXXXX in Treating Heartburn Symptoms Following a provocative Meal **(1602)**
Principal Investigator: Michael Davidson, M.D.
54. A Randomized, Double-Blind, Placebo Controlled Trial of XXXXXX Alone and in combination with XXXXX in Patients with Primary Hypercholesterolemia **(2267)**

- Principal Investigator: Michael Davidson, M.D.
55. A 24-week Randomized Double-Blind Multicenter Multinational Trial to Evaluate the Efficacy and Safety of XXXXX and XXXXX in the Treatment of Subjects with Heterozygous Familial Hypercholesterolemia **(2295)**
Principal Investigator: Michael Davidson, M.D.
 56. Long-Term, Open Label, Safety and Tolerability Study of XXXXX in Addition to XXXXX in Subjects with Primary Hypercholesterolemia Who Have Previously Completed the 12-Week Double-Blind Study (Protocol Nos. P00679 or P00680) **(3512)**
Principal Investigator: Michael Davidson, M.D.
 57. Long-Term, Safety and Tolerability Study of XXXXX or Placebo in Addition to XXXXX in Subjects With Primary Hypercholesterolemia **(3585)**
Principal Investigator: Michael Davidson, M.D.
 58. A Multi-Center, Randomized, Double-Blind, Placebo-Controlled and Open-Label Evaluation of the Safety and Efficacy of Dual Therapy with XXXXX Plus XXXXX When Compared to Either Therapy Alone in the Treatment of Patients with Simultaneous Hyperlipidemia and Hypertension (The AVALON Study) **(3244)**
Principal Investigator: Michael Davidson, M.D.
 59. A Randomized, Placebo Controlled, Double-Blind, Parallels Design Phase III Trial of the Efficacy and safety of XXXXXX in Male Patients with Mild to Moderate Erectile Dysfunction **(3322)**
Principal Investigator: Michael Davidson, M.D.
 60. A 6-Week, Open-Label, Dose-Comparison Study to Evaluate the Safety and Efficacy of XXXXX Versus XXXXX, XXXXX, XXXXX, and XXXXX in Subjects With Hypercholesterolemia **(3682)**
Principal Investigator: Michael Davidson, M.D.
 61. Clinical Protocol for a Randomized, Double-Blind, Placebo-Controlled Study of XXXXX as Monotherapy in Patients with Primary Hypercholesterolemia **(3616)**
Principal Investigator: Michael Davidson, M.D.
 62. An Open-label, Randomized, Multi-center, Phase IIIb, Parallel Group Switching Study to Compare the Efficacy and Safety of Lipid Lowering Agents XXXXX and XXXXX with XXXXX in High Risk Subjects with Type IIa and IIb Hypercholesterolemia **(4094)**
Principal Investigator: Michael Davidson, M.D.
 63. Clinical Protocol for a Randomized, Double-Blind, Placebo-Controlled Study of XXXXX as Monotherapy in Patients with Primary Hypercholesterolemia **(3636)**
Principal Investigator: Michael Davidson, M.D.
 64. A Phase III, Double-Blind, Randomized, Placebo Controlled Study of XXXXX in Severely Obese Subjects **(3696)**
Principal Investigator: Michael Davidson, M.D.
 65. Double-Blind, Placebo-Controlled, Dose Ranging Trial To Evaluate The Efficacy Of XXXXX On Bone Mineral Density And Markers For Bone Turnover In Postmenopausal Women With Dyslipidemia And At Risk For Osteoporosis **(3763)**

- Principal Investigator: Michael Davidson, M.D.
66. A Single-Center, Randomized, Single-Blind, Placebo-Controlled, Phase II Study to Assess the Safety and Effects on HDL Cholesterol of XXXXX Vaccine in Subjects with Low HDL-Cholesterol **(3755)**
Principal Investigator: Michael Davidson, M.D.
 67. Measurement of the Glycemic Index of a Liquid Meal Replacement **(4009)**
Principal Investigator: Michael Davidson, M.D.
 68. A Multicenter, Double-Blind, Randomized, Placebo-and Active-Controlled, Parallel Study to Evaluate the Lipid Altering Efficacy and Safety of XXXXX in Patients with Metabolic Syndrome and Dyslipidemia **(4011)**
Principal Investigator: Michael Davidson, M.D.
 69. A Comparison of Treatment with XXXXX and XXXXX Coadministration Versus XXXXX in Attaining the National Cholesterol Education Program (NCEP) Adult Treatment Panel (ATP) III Coronary Heart Disease (CHD) or CHD Risk Equivalent Strata Low-Density Lipoprotein Cholesterol (LDL-C) Target Level **(4203)**
Principal Investigator: Michael Davidson, M.D.
 70. A Randomized, Double-Blind, Placebo-Controlled Study Of The Efficacy And Safety Of XXXXX Tablets In Patients With Primary Hypercholesterolemia **(3713)**
Principal Investigator: Michael Davidson, M.D.
 71. A Six Week, Randomized, Open-Label, Comparative Study to Evaluate the Efficacy and Safety of Rosuvastatin and Atorvastatin in the Treatment of Hypercholesterolemia in African American Subjects **(4206)**
Principal Investigator: Michael Davidson, M.D.
 72. A Multicenter, Double-Blind, Randomized, Parallel Group, 28 week Study to Evaluate the Efficacy and Safety of XXXXX and XXXXX Co-administration Versus XXXXX in Patients with Hypercholesterolemia **(4223)**
Principal Investigator: Michael Davidson, M.D.
 73. An Open Label Study of Topical XXXXX Gel Applied 2 Times per Week for 3 Weeks for Each Recurrence of Herpes Genitalis over 52 Weeks **(4347)**
Principal Investigator: Michael Davidson, M.D.
 74. An Eight-Week, Parallel Group, Double-blind, Randomized, placebo- and Active-controlled, Multicenter Study to Evaluate the Efficacy, Safety and Tolerability of Two Formulations of XXXXX, Each at Two Different Doses, in Obese Subjects **(4317)**
Principal Investigator: Michael Davidson, M.D.
 75. A Phase II, Randomized, Double Blind, Placebo-Controlled, Study of the Safety and Activity of XXXXX in Patients with Dyslipidemia **(4628)**
Principal Investigator: Michael Davidson, M.D.
 76. A Dose Range-Finding, Double-Blind, Randomized, Placebo-Controlled, Multicenter Study to Assess the Safety, Tolerability, and Efficacy of XXXXX in Obese Subjects **(4690)**
Principal Investigator: Michael Davidson, M.D.
 77. A Randomized, Double-Blind, Placebo-Controlled, Multi-Center Parallel Group Phase III Study Measuring Effects on Intima Media Thickness: An Evaluation Of XXXXX **(4523)**
Principal Investigator: Michael Davidson, M.D.

78. Efficacy of XXXXX as an Add-on to Simvastatin Therapy **(4927)**
Principal Investigator: Michael Davidson, M.D.
79. The Effects of XXXX Juice on Carotid Intima-Media Thickness. **(202528)**
Principal Investigator: Michael Davidson, M.D.
80. A Parallel, Six-Month, Double-blind, Randomized, Placebo-Controlled, Multicenter, Dose-Ranging Study to Evaluate the Efficacy, Safety and Tolerability of Orally Administered XXXX on Weight Loss in Overweight and Obese Subjects. **(202574)**
Principal Investigator: Michael Davidson, M.D.
81. Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Effectiveness and Tolerability of XXXX™ for Lowering LDL and Total Cholesterol, and Improving the LDL/HDL Ratio. **(202849)**
Principal Investigator: Michael Davidson, M.D.
82. A Double-Blind, Randomized, Placebo-Controlled, Multicenter Study to Assess the Safety, Tolerability, and Efficacy of XXXX in Obese Patients. **(202959)**
Principal Investigator: Michael Davidson, M.D.
83. A Randomized Clinical Trial to Evaluate the Effect of XXXX versus Placebo by Ultrasound Measurement of Breast Volume in Healthy Pre-Menopausal Women (203172)
Principal Investigator: Michael Davidson, M.D.
84. A Multicenter, Randomized, Double-Blind Study to Evaluate the Lipid-Altering Efficacy and Safety of XXXX Versus XXXX in Patients with Primary Hypercholesterolemia. (203391)
Principal Investigator: Michael Davidson, MD.
85. A Multicenter, Randomized, Double-Blind, Prospective, Parallel Study to Compare the Safety and Efficacy of XXXX or XXXX as Add-On Therapy to XXXX in Subjects with Combined Hyperlipidemia, Typical of the Metabolic Syndrome. (203225)
Principal Investigator: Michael Davidson, MD.
86. A Phase 3, Double-Blind, Placebo-Controlled, Randomized, Parallel Group, Multicenter Study of the Efficacy, Safety, and Tolerability of Fixed Combination XXXX Administered Orally, Once Daily for 6 Months, Compared to XXXX Alone or Placebo, in Subjects With Mixed Dyslipidemia (Fredrickson Types IIa and IIb). (203840)
Principal Investigator: Michael Davidson, MD.
87. Parallel-Group Study of the Efficacy and Safety of XXXX for Reducing the Progression of Atherosclerosis in Subjects with Heterozygous Familial Hypercholesterolemia and Carotid Atherosclerosis Using Carotid Ultrasound (CUS). (203832)
Principal Investigator: Michael Davidson, MD.
88. Part A: A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Effects of XXXX Compared to Placebo; Part B: A Dose-Ranging Study to Evaluate the Tolerability of XXXX and its Effects on Niacin-Induced Flushing in Lipid Clinic Patients. (204236).
Principal Investigator: Michael Davidson, MD.
89. A Randomized, Double-Blind, Placebo-Controlled Endpoint Selection and Questionnaire Validation Study to Assess the Niacin Induced Flushing Caused by XXXX. (204235).
Principal Investigator: Michael Davidson, MD.

90. A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Assess the Efficacy and Safety of XXXX Monotherapy in Patients with Type 2 Diabetes Mellitus and Metabolic Syndrome. (203839)
Principal Investigator: Michael Davidson, MD.
91. A Multicenter, Double-Blind, Randomized, Placebo-Controlled, Parallel Study of the Safety and Efficacy of a Combination of XXXX and Metformin Compared to Placebo and Metformin in the Treatment of Patients with Type 2 Diabetes Mellitus. (204473)
Principal Investigator: Michael H. Davidson, M.D.
92. A Phase II Randomized, Double-Blind, Placebo-Controlled, Multicenter, Pharmacokinetic, Pharmacodynamic and Tolerability Study of XXXX In Patients With Stable Atherosclerosis. (204781) Principal Investigator: Michael H. Davidson, M.D.
93. A Randomized, Double-Blind, Placebo Controlled, Multicenter, Phase III Study of XXXX 20 mg in the Primary Prevention of Cardiovascular Events Among Subjects with Low Levels of LDL-Cholesterol and Elevated Levels of C-Reactive Protein. (203617)
Principal Investigator: Michael H. Davidson, M.D.
94. A Multicenter, Randomized, Parallel, Double-Blind, Placebo-Controlled Study to Assess the Safety, Tolerability, Pharmacokinetics, and Pharmacodynamics of PAI-749 in Subjects With Peripheral Arterial Disease (PAD). (204846)
Principal Investigator: Michael H. Davidson, M.D.
95. A Randomized, Placebo-Control, Parallel Trial to Assess the Effects of XXXX and XXXX Plus Sterols on Blood Lipids in Men and Women with Moderate Primary Hypercholesterolemia. (204406)
Principal Investigator: Michael H. Davidson, M.D.
96. Phase 3, Multi-Site, Double-Blind, Randomized, Forced Titration, Parallel Group Evaluation of the Efficacy, Safety, and Tolerability of Fixed Combination XXXX Administered Orally, Once Daily (QD) for Eighteen Weeks, Compared with XXXX Alone, in Subjects with Fredrickson Type IV Hypertriglyceridemia. (204753)
Principal Investigator: Michael H. Davidson, M.D.
97. Assessment of Lipoprotein Profiles with XXXX. (203616)
Principal Investigator: Michael H. Davidson, M.D.
98. Phase 3, Multi-Center, Double-Blind, Randomized, Parallel Group Study of the Efficacy, Safety, and Tolerability of Fixed Combination XXXX/XXXX Administered Orally, Once Daily (QD) for Six Months, Compared with Maximally Tolerated XXXX Therapy Alone, in Subjects with Heterozygous Familial Hypercholesterolemia. (205083)
Principal Investigator: Michael H. Davidson, M.D.
99. A Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of the Addition of XXXX to Patients With Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control on Glimepiride Alone or in Combination With Metformin. (205215)
Principal Investigator: Michael H. Davidson, M.D.
100. A Multicenter, Randomized, Double-Blind, Parallel Group, 6-Week Study to Evaluate the Efficacy and Safety of XXXX Combination Tablet Versus Atorvastatin in

- Patients With Type 2 Diabetes Mellitus (T2DM) and Hypercholesterolemia. (205093)
Principal Investigator: Michael H. Davidson, MD
101. Randomized, multicenter, double-blind, placebo-controlled, two-arm parallel group trial of XXXX 20 mg od, for inhibition of atherosclerosis progression assessed by carotid artery intima-media thickness (CIMT), in overweight patients with additional risk factors. (205311)
PI: Michael H. Davidson, MD
 102. An 18-Week, Randomized, Double Blind, Placebo-Controlled Parallel Group Study to Assess the Safety, Tolerability and Bioefficacy of XXXX to Reduce C-Reactive Protein in Patients With a History of Atherosclerotic Coronary Artery Disease, Elevated C-Reactive Protein and Concurrent Treatment with a Statin. (205371)
PI: Michael H. Davidson, MD
 103. A Double-Blind, Randomized, Placebo-Controlled Trial Measuring the Effects of XXXX on C-Reactive Protein Levels in Patients with Risk Factors for Cardiovascular Disease. (205542)
PI: Michael H. Davidson, MD
 104. A Two Year Study to Assess the Efficacy, Safety, and Tolerability of XXXX in Obese Patients. (205592)
PI: Michael H. Davidson, MD
 105. An 18-Month Study to Assess the Efficacy, Safety, and Tolerability of XXXX in Obese Patients. (205943)
PI: Michael H. Davidson, MD
 106. Predictor of Advanced Sub-Clinical Atherosclerosis (PASA) (205765)
PI: Michael H. Davidson, MD
 107. A Phase 3, Open-Label, Multistate, Randomized, Parallel Group Study of the Efficacy and Safety of Fixed Combination XXXX Administered Once Daily (QD) Compared to Simvastatin for 6 Weeks in Subjects With Hypercholesterolemia. (205669)
PI: Michael H. Davidson, MD
 108. A Double-Blind, Randomized Study to Evaluate the Efficacy and Safety of XXXX Versus Placebo in Subjects with Primary Hypercholesterolemia. (205988)
PI: Michael H. Davidson, MD
 109. A Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Efficacy and Safety of XXXX when Co-Administered with XXXX in subjects with Primary Hypercholesterolemia. (206001)
PI: Michael H. Davidson, MD
 110. A Multicenter, randomized, double-blind, placebo-controlled, parallel-group, dose-ranging study of XXXX, and oral lipoprotein-associated phospholipase A2 (Lp-PLA2) inhibitor, in subjects with stable coronary heart disease (CHD) or CHD-risk equivalent to examine chronic inhibition of Lp-PLA2, effects on circulating biomarkers associated with cardiovascular risk, safety and tolerability over 12 Weeks. (205780)
PI: Michael H. Davidson, MD

111. An Open-Label Extension Study to Evaluate the Safety and Tolerability of XXXX in Subjects with Primary Hypercholesterolemia or Combined Hyperlipidemia. (206000)
PI: Michael H. Davidson, MD
112. A Worldwide, Multicenter, Double – Blind, Randomized, Parallel, Placebo – Controlled Study to Evaluate the Lipid – Altering Efficacy, Safety and Tolerability of MK – 0524A in Patients With Primary Hypercholesterolemia or Mixed Hyperlipidemia. (206241)
PI: Michael H. Davidson, MD
113. A Multicenter, Randomized, Double-Blind, Parallel Group, 12 Week Study to Evaluate the Efficacy and Safety of MK-0524B Versus XXXX in Patients With Mixed Hyperlipidemia. (206370)
PI: Michael H. Davidson, MD
114. A Multicenter, Randomized, Double-Blind, Prospective Study Comparing the Safety and Efficacy of XXXX and XXXX Combination Therapy to XXXX and XXXX Monotherapy in Subjects with Mixed Dyslipidemia. (205743)
PI: Michael H. Davidson, MD
115. A Long-Term, Open-Label, Safety Extension Study of the Combination of XXXX and Statin Therapy for Subjects with Mixed Dyslipidemia. (206221)
PI: Michael H. Davidson, MD
116. A Double-Blind, Randomized, Placebo-Controlled Factorial Study to Evaluate the Efficacy and Safety of XXXX and XXXX Alone and in Combination in Subjects With Hypercholesterolemia. (206464)
PI: Michael H. Davidson, MD
117. A Double-Blind, Randomized Study to Evaluate the Efficacy and Safety of XXXX or Placebo When Co-Administered With XXXX in Subjects With Combined Hyperlipidemia. (206517)
PI: Michael H. Davidson, MD
118. ALPs PLUS - Assessment of Lipoprotein Profiles with XXXX PLUS Statin. (206591)
PI: Michael H. Davidson, MD
119. A Randomized, Placebo-Controlled, Parallel Group, Double-Blind Study of the Efficacy and Safety of XXXX in Abdominally Obese Subjects With Multiple Cardiovascular and Metabolic Risk Factors and With LDL-Cholesterol at NCEP ATP III Treatment Goal. (206599)
PI: Michael H. Davidson, MD
120. A Randomized, Double-Blind, Active-Controlled, Parallel-Group Study to Evaluate the Safety and Efficacy of the Combination XXXX and XXXX VS. Monotherapy in Subjects With Moderate Hypercholesterolemia. (206669)
PI: Michael H. Davidson, MD
121. A Phase II, Double-Blind, Randomized, Placebo-controlled, Parallel Group Study, Evaluating the Efficacy and Safety of XXXX over a 24-week period in Patients with CHD or a CHD Risk Equivalent. (206366)
PI: Michael H. Davidson, MD
122. An 18-Month Study to Assess the Efficacy, Safety and Tolerability of XXX in Obese

- Patients (205943).
Principal Investigator: Michael H. Davidson, MD
123. A Double-Blind, Randomized, Parallel Group Study to Evaluate the Safety, Tolerability and Efficacy of XXXX Alone or Co-administered with Atorvastatin in Patients with Primary Dyslipidemia. (204516)
PI: Michael H. Davidson, MD
 124. A Phase II, Double-Blind, Randomized Placebo-controlled Parallel Group Study, Evaluating the Efficacy and Safety of Three Doses of XXXX Combined with Pravastatin over a 12-week period in Patients with low or Average HDL-C Levels. (205404)
PI: Michael H. Davidson, MD
 125. A Randomized, Double-Blind, Placebo-Controlled, 1-Year Extension of the Phase IIA Endpoint Validation Study to Assess the Tolerability of XXXX/XXXX Combination Tablet. (205170)
PI: Michael H. Davidson, MD
 126. A Phase III Randomized, Placebo-Controlled Clinical Trial to Study the Safety and Efficacy of the Addition of XXXX in Patients With Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control on Combination Therapy with Metformin and a PPAR γ Agonist. (206766)
PI: Michael H. Davidson, MD
 127. A Phase 2, Double-Blind, Placebo Controlled, Dose Escalation Study to Assess the Safety, Efficacy, and Pharmacokinetics of XXXX as Add-On Therapy in Heterozygous Familial Hypercholesterolemia Subjects. (207111)
PI: Michael H. Davidson, MD
 128. A Worldwide, Multicenter, Double-Blind, Parallel Study to Evaluate the Tolerability of XXXX versus Niacin Extended-Release. (207063)
PI: Michael H. Davidson, MD
 129. A Two-Year, Randomized, Double-Blind, Placebo-Controlled Phase 3 Study to Evaluate The long-Term Efficacy And Safety of XXXXXXXX In The Treatment Of Obese Subjects. (207184)
PI: Michael H. Davidson, MD
 130. A Four-Week Dose-Ranging Study of Evaluate Antidyslipidemic Effects, Other Pharmacodynamic Effects, Safety and Tolerability of XXXXXX with Concomitant Open-Label Simvastatin Therapy in Patients with Elevated Triglycerides, Elevated Low Density Lipid Cholesterol and Abdominal Obesity: a Randomized, Double-Blind, Placebo-Controlled, Multi-Centre, Parallel-Group Study with Fenofibrate as Reference Treatment. (207276)
PI: Michael H. Davidson, MD

131. A Randomized, Double-Blind, Placebo-Controlled Study of XXXXXX for Men with Rising Prostate-Specific Antigen Levels Following Surgery or Radiations for Prostate. (205232)
PI: Michael H. Davidson, MD
132. A Phase 2, Randomized, Multi-Center, Double-Blind, Placebo-Controlled, Parallel-Group, Dose-range-Finding study Of the Safety and Efficacy of XXXX Administered XXXXX in Patients with Primary Hypercholesterolemia. (207332)
PI: Michael H. Davidson, MD
133. A Phase II, Placebo-Controlled, Double-Blind Extension Study of XXXX Assessing Long Term Safety and Efficacy of XXXXXX. (207620)
PI: Michael H. Davidson, MD
134. A Phase 2, Open-Lavel, Dose Escalation Study to Assess the Safety and Efficacy of XXXXXXXX as Add-on Therapy in XXXXXXX Hypercholesterolemia subjects. (207173)
PI: Michael H. Davidson, MD
135. A Two-Year, Randomized, Double-Blind, Placebo-Controlled Phase 3 Study to Evaluate The long-Term Efficacy And Safety of XXXXXXXX In The Treatment Of Obese Subjects. (207184)
PI: Michael H. Davidson, MD
136. An Open Label, Phase 2, Long Term Safety Study of XXXXX An up to Four Year Extension of Therapy in Subjects with Type 1 or Type 2 Diavetes Mellitus Participating in Extension Protocols 217-102, 103, or 104. (5049)
PI: Michael H. Davidson, MD
137. A randomized, double-blind, parallel-group, placebo-controlled, multicenter study evaluating the efficacy and safety of three doses of XXXXX in abdominally obese patients with atherogenic dyslipidemia. (206612)
PI: Michael H. Davidson, MD
138. A 12-Week, Multicenter, Randomized, Double-Blind, Parallel-Group Study of the Combination of XXXXX and XXXXX compared to XXXX and XXXXX Monotherapy in Subjects with Type IIa and IIb Dyslipidemia (207591)
PI: Michael H. Davidson, MD
139. The Effect of Dairy Drinks from Several Production Routes on Daytime Blood Pressure. (207714)
PI: Michael H. Davidson, MD
140. An Open-Label Extension Study to Assess the Long-term Safety and Efficacy of XXXXXXXXXXXX in Subjects with Familial Hypercholesterolemia. (208050)
PI: Michael H. Davidson, MD

141. A Double-Blind Randomized Study to Evaluate the Efficacy and Safety of XXXXXX 100 mg in the Morning vs XXXXXX 100 mg in the Evening vs XXXXXX 50 mg Twice Daily vs Placebo in Subjects with Hypercholesterolemia (208073)
PI: Michael H. Davidson, MD
142. A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate low doses of the XXXXXXXX XXXXXXXX on Hepatic fat accumulation as measured by magnetic resonance spectroscopy (208038)
PI: Michael H. Davidson, MD
143. A Randomized, Double-Blind, Placebo-Controlled Study to Assess Safety, Exposure, and Efficacy of XXXXXX as Add-on Therapy in Low to Moderately-High Risk Hypercholesterolemic Subjects (207860)
PI: Michael H. Davidson, MD
144. A Phase III Randomized, Double-Blind, Placebo Controlled Multicenter study to Determine the Safety and Efficacy of XXXXXX ion the Treatment of Obesity in Adults with Obesity-Related Co-Morbid Conditions (208380)
PI: Michael H. Davidson, MD
145. A Phase III Randomized, Double-Blind, Placebo Controlled Multicenter study to Determine the Safety and Efficacy of XXXXXX ion the Treatment of Obesity in Adults with Obesity-Related Co-Morbid Conditions (208379)
PI: Michael H. Davidson, MD
146. XXXXXX Reverse Cholesterol Transport (RCT) Pilot Study (207396)
PI: Michael H. Davidson, MD
147. XXXXXX Reverse Cholesterol Transport (RCT) Pilot Study (207525)
PI: Michael H. Davidson, MD
148. A Randomized, Double-Blind, Parallel, Multicenter Placebo-Controlled Prospective Study to Evaluate the Functionality of the Flushing Assessment Tool (FAST) in Subjects Administered XXXXXXXX® Plus Acetylsalicylic Acid (ASA) XXXXXXXX® Plus ASA Placebo or XXXXXXXX® Placebo Plus ASA Placebo Daily for Six Weeks (208600)
PI: Michael H. Davidson, MD
149. A Multicenter, Randomized, Double-Blind, Parallel Group, 12-Weeks Study to Evaluate the Efficacy and Safety of (ER) XXXXXX Added to Statin Versus Doubling the Dose of Statin in Patients With Primary Hypercholesterolemia or Mixed Dyslipidemia (208584)
PI: Michael H. Davidson, MD
150. A Multicenter, Randomized, Double-Blind, Prospective Study Comparing the Safety and Efficacy of XXXXXX in Combination with Atorvastatin and Ezetimibe to

- Atorvastatin in Combination with Ezetimibe in Subjects with Combined (Atherogenic) Dyslipidemia (208697)
PI: Michael H. Davidson, MD
151. A 76-Week, Worldwide, Multicenter, Double-Blind, Randomized, Placebo-Controlled Study to Assess the Tolerability and Efficacy of Anacetrapib When Added to Ongoing Therapy With a Statin in Patients With Hypercholesterolemia or Mixed Hyperlipidemia (208577)
PI: Michael H. Davidson, MD
152. A Randomized, Double-Blind, Placebo-Controlled Study to Assess Efficacy and Safety of XXXXXXXX as Add-on Therapy in Heterozygous Familial HyperCHOLesteroemia Subjects with Coronary Artery Disease (207134)
PI: Michael H. Davidson, MD
153. Home Test Kit Pre-Screening for a Study of Subjects with Dyslipidemia (208705)
PI: Michael H. Davidson, MD
154. A double-blind, randomized, 12-month, placebo-controlled, parallel group, fixed-dose study to evaluate the efficacy and safety of XXXXXXXX 25mg/day and XXXXXXXX 50 mg/day in patients with primary hypercholesterolemia (208594)
PI: Michael H. Davidson, MD