



## **Curriculum Vitae**

### **I. Professional Recognition and Certifications**

Diplomate, American Board of Internal Medicine, 1996  
Re-certified 2006, 2016

Fellow, American College of Physicians, 2002

Fellow, American College of Physician Executives, 2002

Certified Principal Investigator, Association of Clinical Research Professionals (ACRP), 2003  
Re-certified 2005, 2007, 2009, 2011, 2013

### **II. Education**

Master of Healthcare Administration (MHA)  
Louisiana State University, 2019

Master of Science, Health Services / Clinical Research (MS)  
George Washington University, 2005

Master of Business Administration (MBA)  
Webster University, 1998

Doctor of Medicine (MD)  
The University of Texas Southwestern Medical School, 1993

Bachelor of Arts, Biochemistry (BA)  
The University of Texas at Austin, 1995

### **III. Work Experience**

Center for Executive Medicine; founder and president; 1999 - present

Dr. Yates and his colleagues at the Center for Executive Medicine provide primary care and consultative medical services. Our physicians and team counsel successful families around the world to coordinate all aspects of their wellness, preventive and acute medical care. A lifelong aviation enthusiast, Dr. Yates is the group's unofficial chief pilot as well, having earned his private pilot license and instrument rating certificate.

Vattaca, LLC; Executive Vice President and Chief Medical Officer; 2014 - 2019

As Chief Medical Officer for Vattaca (d/b/a VerifyItNow), Dr. Yates has been recognized as an expert in the health and human safety aspects of counterfeiting.

Glenview Capital LLC; consultant; 2011 - 2017

Glenview Capital is a privately owned hedge fund sponsor. Glenview engages consultants with subject matter expertise and among Glenview's investments are healthcare affiliated entities.

North Texas Medical Research, Principal Investigator; inpatient/outpatient clinical research, 1999 - 2014

Dr. Yates founded North Texas Medical Research in 1999 to provide patients and colleagues opportunities to participate in clinical trials in various therapeutic areas including vaccines, medical devices and pharmaceuticals. He served as principal investigator for more than 100 clinical trials.

United States Navy, Active Duty; 1996 - 1999

Internal Medicine Staff Physician, Naval Hospital Jacksonville Florida, 1996 - 1999  
Family Medicine Residency Faculty, Naval Hospital Jacksonville Florida, 1996 - 1999  
Chief, Division of General Internal Medicine, Naval Hospital Jacksonville Florida, 1997 - 1999

Methodist Hospital, Memphis Tennessee, Internal Medicine Internship / Residency, 1993 - 1996

#### **IV. Board Memberships**

Genovista Health, LLC Member, Board of Managers: 2019 - present

A joint venture between GPG Holding Company and Innovista Health Solutions (a subsidiary of Health Care Services Corporation, parent entity of Blue Cross, Blue Shield of Illinois and others), Genovista Health was established to champion independent physicians' passion for the profession of medicine and promote affordable quality patient care by creating a culture and infrastructure to support that passion.

Curantis, LLC Member, Board of Managers: 2017 - present  
JDCQ Solutions, LLC Member, Medical Advisory Board: 2015 - present

Curantis Solutions has developed an industry-leading electronic medical record software delivered via software-as-a-service (SaaS) architecture, specifically designed for use in hospice and palliative care environments settings.

CMORE Health / Genesis Accountable Physician Network, LLC  
Member, Board of Managers: 2013 - present  
Chair, Board of Managers: 2013 - present

CMORE Health/Genesis Accountable Physician Network (GAPN), a subsidiary of Genesis Physicians Group, Inc. was initially organized in 2013 to allow independent practicing physicians to participate in Accountable Care network contracts. In a joint effort with Healthways (TVTY), GAPN was able to decrease Medicare expenditures for 16,800 patients by \$11M in CY2014 by focusing on high quality patient care to prevent serious illness.

More recently, CMORE Health has engaged with independent primary care and subspecialty physicians to offer credentialing and other support services and to make sophisticated population health management strategies available to independent physicians and their patients.

Genesis Accountable Care Organization / MSSP Accountable Care Program

Launched in 2018, the Genesis Physicians Group Accountable Care Organization (ACO)

Texas Academy of Internal Medicine Foundation Member, Board of Directors: 2010 - present  
Chair, Board of Directors: 2010 - present

Oil Interests I, LLC Managing Member, 2008 - present

GPG Holding Company, Inc. Member, Board of Directors: 2004 - 2007, 2013 - present  
Genesis Physicians Group, Inc.

GenHealth, LLC Member, Board of Managers: 2014 - 2017

GenHealth was formed as a joint venture between Genesis Physicians Group and Healthways, Inc. to provide wellness, wellbeing and disease management services to patients cared for by physician members of the Genesis Accountable Physician Network. This was accomplished in part by the application of wellbeing principles developed by Healthways.

Texas Academy of Internal Medicine Member, Board of Directors: 2004 - 2011  
Chair, Board of Directors: 2008 - 2009

American College of Physicians Services PAC Member, Board of Directors: 2010 - 2012

Texas Alliance for Patient Access Member, Board of Directors: 2006 - 2010

Genesis Physician Network, Inc. Member, Board of Directors: 2005 - 2007

#### **V. Journal Peer Review**

American Journal of Medicine, Editorial Board, 2009 - present  
Certificate of Excellence in Peer Review, 2013

Hospital Practice, Editorial Board, 2011 - present

American Journal of Men's Health, Editorial Board, 2009 - present

Baylor University Medical Center Proceedings, Editorial Board, 2009 - present

American Journal of Therapeutics, Editorial Board, 2009 - present

Pharmacy and Therapeutics, Editorial Board, 2003 - present

Southern Medical Journal, Editorial Board, 2002 - 2012; Clinical Reviewer, 2002 - present

Texas Health Guide, Editorial Board, 1999 - present

Critical Care Nurse, Peer Reviewer, 2015 - present

Hypertension, Peer Reviewer, 2013 - present

The Journal of General Internal Medicine, Peer Reviewer, 2013 - present

Journal of Cardiovascular Pharmacology, Peer Reviewer, 2013 - present

Journal of Hypertension, Peer Reviewer, 2013 - present

Atherosclerosis, Peer Reviewer, 2013 - present

Journal of Clinical Pharmacology, Peer Reviewer, 2013 - present

Journal of Human Hypertension, Peer Reviewer, 2013 - present

Journal of Cardiovascular Pharmacology and Therapeutics, Peer Reviewer, 2013 - present

Journal of Atrial Fibrillation, Peer Reviewer, 2011 - present

American Journal of Cardiovascular Drugs, Peer Reviewer, 2012 - present

Mayo Clinic Proceedings, Peer Reviewer, 2010 - present

The Journal of Infectious Diseases, Peer Reviewer, 2009 - present

Brain and Cognition, Peer Reviewer, 2009 - present

Journal of Human Hypertension, Peer Reviewer, 2009 - present

Clinical Pharmacology & Therapeutics, Peer Reviewer, 2009 - present

Infection Control & Hospital Epidemiology, Peer Reviewer, 2009 - present

Clinical Infectious Diseases, Peer Reviewer, 1996 – 1998, 2008 - present

Journal of Aging and Age Related Diseases, Editorial Board, 2016 - 2019

Hospital Medicine, Editorial Board, 1999 - 2001

Medical Aspects of Human Sexuality, Editorial Board, 2000 - 2002

Contemporary Internal Medicine, Peer Reviewer, 1996 - 1998

## **VI. Publications**

Wheless C, Yates SW, Schrader MD. Osteoporosis Screening as a Model for Preventive Healthcare. Submitted for consideration.

Yates SW. Physician Stress and Burnout. Am J Med. Sept 2019. doi:10.1016/j.amjmed.2019.08.034

Alexander KP, Brouwer MA, Mulder H, et al. Outcomes of apixaban versus warfarin in patients with atrial fibrillation and multi-morbidity: Insights from the ARISTOTLE trial. Am Heart J. 2019;208:123-131. doi:10.1016/j.ahj.2018.09.017

Nguyen E, Mehta S, Yates SW, Schrader MK, Martin MC. Colon Cancer Screening in Concierge Practice. Southern Medical Journal 2017;110(6): 408-411. <https://doi.org/10.14423/SMJ.0000000000000661>

Ridker PM, Mora S, Rose L; JUPITER Trial Study Group. Percent reduction in LDL cholesterol following high-intensity statin therapy: potential implications for guidelines and for the prescription of emerging lipid-lowering agents. Eur Heart J. 2016;37(17):1373–1379. doi:10.1093/eurheartj/ehw046

Holmqvist F, Guan N, Zhu Z, et al. Impact of obstructive sleep apnea and continuous positive airway pressure therapy on outcomes in patients with atrial fibrillation-Results from the Outcomes Registry for Better Informed Treatment of Atrial Fibrillation (ORBIT-AF). Am Heart J. 2015;169(5):647-654.e2. doi:10.1016/j.ahj.2014.12.024

Yates SW. Interrupting anticoagulation in patients with nonvalvular atrial fibrillation. P&T 2014;39(12) 858-880. PMID: 25516695

McMurray JJ V, Ezekowitz JA, Lewis BS, et al. Left ventricular systolic dysfunction, heart failure, and the risk of stroke and systemic embolism in patients with atrial fibrillation: insights from the ARISTOTLE trial. *Circ Heart Fail.* 2013;6(3):451-460. doi:10.1161/circheartfailure.112.000143

Yates SW. Novel oral anticoagulants for stroke prevention in atrial fibrillation: a focus on the older patient. *Intl J Gen Med* 2013;6:167-180. PMID: 23687449

Easton JD, Lopes RD, Bahit MC, et al. Apixaban compared with warfarin in patients with atrial fibrillation and or transient ischaemic attack: a subgroup analysis of the ARISTOTLE trial. *Lancet Neurol.* 2012;11(6):503-511. doi:10.1016/S1474-4422(12)70092-3

Granger CB, Alexander JH, McMurray JJV, et al. Apixaban versus Warfarin in Patients with Atrial Fibrillation. *N Engl J Med.* 2011;365(11):981-992. doi:10.1056/NEJMoa1107039

Yates SW. Apixaban for stroke prevention in atrial fibrillation: a review of the clinical trial evidence. *Hosp Pract* 2011;39(4):7-16. PMID: 22056819

Ezekowitz MD, Wallentin L, Connolly SJ, et al. Dabigatran and Warfarin in Vitamin K Antagonist-Naive and -Experienced Cohorts With Atrial Fibrillation. *Circulation.* 2010;122(22):2246-2253. doi:10.1161/circulationaha.110.973735

Ridker, PM, Genest, J, Boekholdt, SM, Libby, P, Gotto, AM, Nordestgaard, BG; JUPITER Trial Study Group. HDL cholesterol and residual risk of first cardiovascular events after treatment with potent statin therapy: an analysis from the JUPITER trial. *The Lancet,* 2010;376(9738), 333–339. [https://doi.org/10.1016/S0140-6736\(10\)60713-1](https://doi.org/10.1016/S0140-6736(10)60713-1)

Grimm R, Malik M, Yunis C, Sutradhar S, Kursun A; TOGETHER Investigators. Simultaneous treatment to attain blood pressure and lipid goals and reduced CV risk burden using amlodipine/atorvastatin single-pill therapy in treated hypertensive participants in a randomized controlled trial. *Vasc Health Risk Manag.* 2010;6:261–271. doi:10.2147/vhrm.s7710

Ridker, PM, Danielson, E, Fonseca, FA, Genest, J, Gotto, AM; JUPITER Trial Study Group. Reduction in C-reactive protein and LDL cholesterol and cardiovascular event rates after initiation of rosuvastatin: a prospective study of the JUPITER trial. *The Lancet,* 2009;373(9670), 1175–1182. [https://doi.org/10.1016/S0140-6736\(09\)60447-5](https://doi.org/10.1016/S0140-6736(09)60447-5)

Yates SW. Undisclosed Conflict. American College of Physicians, Texas Chapter Newsletter. Oct. 2009.

Ridker PM, MacFadyen JG, Fonseca FAH, et al. Number Needed to Treat With Rosuvastatin to Prevent First Cardiovascular Events and Death Among Men and Women With Low Low-Density Lipoprotein Cholesterol and Elevated High-Sensitivity C-Reactive Protein. *Circ Cardiovasc Qual Outcomes.* 2009;2(6):616-623. doi:10.1161/CIRCOUTCOMES.109.848473

Raskin P, Lewin A, Reinhardt R, Lyness W. for the Repaglinide/Metformin Fixed-Dose Combination Study Group. Twice-daily dosing of a repaglinide/metformin fixed-dose combination tablet provides glycaemic control comparable to rosiglitazone/metformin tablet. *Diabetes, Obes Metab.* 2009;11(9):865-873. doi:10.1111/j.1463-1326.2009.01062.x

Rosenstock J, Aguilar-Salinas C, Klein E, Nepal S, List J, Chen R. Effect of saxagliptin monotherapy in treatment-naïve patients with type 2 diabetes. *Curr Med Res Opin.* 2009;25(10):2401-2411. doi:10.1185/03007990903178735

Yates SW. Medicine is Fun! American College of Physicians, Texas Chapter Newsletter June 2009.

- Connolly SJ, Ezekowitz MD, Yusuf S, et al. Dabigatran versus Warfarin in Patients with Atrial Fibrillation. N Engl J Med. 2009;361(12):1139-1151. doi:10.1056/NEJMoa0905561
- Raskin P, Lewin A, Reinhardt R, Lyness W. for the Repaglinide/Metformin Fixed-Dose Combination Study Group. Twice-daily and three-times-daily dosing of a repaglinide/metformin fixed-dose combination tablet provide similar glycaemic control. Diabetes, Obes Metab. 2009;11(10):947-952. doi:10.1111/j.1463-1326.2009.01069.x
- Littlejohn III TW, Majul CR, Olvera R, et al. Results of treatment with Telmisartan-Amlodipine in hypertensive patients. J Clin Hypertens. 2009;11(4). doi:10.1111/j.1751-7176.2009.00098.x
- Yates SW. First Things First – duties of the internist. American College of Physicians, Texas Chapter Newsletter February 2009.
- Ridker PM, Danielson E, Fonseca FAH, et al. Rosuvastatin to Prevent Vascular Events in Men and Women with Elevated C-Reactive Protein. N Engl J Med. 2008;359(21):2195-2207. doi:10.1056/nejma0807646
- Yates SW. Obesity: Where's The Beef? (Editorial) South Med J 2008;101(4):349-50. PMID: 18360336
- Ridker PM, Fonseca FAH, Genest J, et al. Baseline Characteristics of Participants in the JUPITER Trial. A Randomized Placebo-Controlled Primary Prevention Trial of Statin Therapy Among Individuals With Low Low-Density Lipoprotein Cholesterol and Elevated High-Sensitivity C-Reactive Protein. Am J Cardiol. 2007;100:1659-1664. doi:10.1016/j.amjcard.2007.09.072
- Bakris GL, Fonseca V, Katholi RE, et al. Differential Effects of  $\beta$ -Blockers on Albuminuria in Patients With Type 2 Diabetes. Hypertension. 2005;46(6):1309-1315. doi:10.1161/01.HYP.0000190585.54734.48
- Yates SW. Comparative effects of available thiazolidinediones: a review of the literature. P&T 2004; 29(9):584-8.
- Bond M and Yates SW. Is the future bright for diabetes? (Editorial) South Med J 2004;97(11):1027-8. PMID: 15586587
- Bakris GL, Fonseca V, Katholi RE, et al. Metabolic effects of carvedilol vs metoprolol in patients with type 2 diabetes mellitus and hypertension: a randomized controlled trial. JAMA. 2004;292(18):2227-2236. doi:10.1001/jama.292.18.2227
- Buse JB, Henry RR, Han J, Kim DD, Fineman MS, Baron AD. Effects of Exenatide (Exendin-4) on Glycemic Control Over 30 Weeks in Sulfonylurea-Treated Patients With Type 2 Diabetes. Diabetes Care. 2004;27(11):2628-2635. doi:10.2337/diacare.27.11.2628
- Viera A, Bond M, and Yates SW. Diagnosing night sweats. Am Fam Physician 2003;67:1019-24. PMID: 12643362
- Lieberman P, Yates SW and Welk K. Pulmonary remodeling in asthma. J Investig Allergol Clin Immunol 2001;11(4):220-234. PMID: 11908810
- Yates SW. PDA's take paperwork out of medical practice. Texas Internist Oct. 2001.
- Yates SW, Annis L, Pippins J, and Walden S. Does a lipid clinic increase compliance with NCEP guidelines? Report of a case-matched controlled study. South Med J 2001;94(4):907-9.
- Yates SW. Smoking cessation efforts in primary care practice. Cancer & Me June / July 2000.

Yates SW. Automation facilitates communication in primary care. TIPAA TIPS on Managed Care May/ June 2000, pp.14 – 16.

Yates SW and Viera A. Physostigmine in the treatment of gamma-hydroxybutyric acid overdose. Mayo Clin Proc 2000;75:401-402. PMID: 10761496

Bond M and Yates SW. Sexually transmitted disease screening and reporting practices in a military medical center. Mil Med 2000;165(6):470-472. PMID: 10870366

Viera A, Bond M, and Yates SW. Troponin-I: a specific marker of myocardial damage. Emerg Med 2000;32(1):22-25.

Wentworth M and Yates SW. The new approach to rheumatoid arthritis therapy. Hosp Med 1999;35(8):13-20.

Yates SW. Androgen abuse: the price of growth and performance. Hosp Pract 1999;34(5):113-114,119.

Bond M, Viera A, and Yates SW. The role of the CT scan in the evaluation of minor head injury. Emer Med 1999;31(4):48-64.

Viera AJ and Yates SW. Toxic ingestion of gamma-hydroxybutyric acid. South Med J 1999;92(4):404-405. PMID: 10219359

Carter P, Heinly T, Yates SW, and Lieberman P. Asthma: the irreversible airways disease. J Investig Allergol Clin Immunol 1997(6):566-71. PMID: 9491196

Yates SW, Gelfand M, and Handorf P. Spontaneous pyomyositis due to Staphylococcus epidermitis. Clin Infect Dis 1997;24(5):1016. PMID: 9142821

Yates SW, Heinly T, Carter P, and Lieberman P. Accelerated irreversible decline in lung function in asthmatics. J Allergy and Clin Immun 1996;99(1+2):S417 (Abstract).

Yates SW, Barnett T, and Peterson WJ. The effect of enteric coated charcoal on stool color and ranitidine absorption: a randomized, double blind, crossover study. Amer J Gastro 1992;87(8):981.

Siriwardhana, Yates SW, et. al. Oxygen mediated complement activation: an in-vitro study. Can J Anesth 1990;37(4.IISuppl),S116.

## **VII. Volunteer and Community Activities and Recognition**

Volunteer Faculty, Texas General Internal Medicine Statewide Preceptorship Program, 2000 - present

Texas Monthly "Super Doctor" 2005, 2006, 2007, 2012, 2013, 2014

Advocate of the Year Award, Texas Chapter of the American College of Physicians, 2011

Decade of Service Award, Texas General Internal Medicine Student Preceptorship Program, 2011

Volunteer Consulting Physician, Metrocrest Family Medical Clinic, 2002 - 2008

Dallas Business Journal "Health Care Hero" Award, 2000

## **VIII. Hospital Committee Memberships and Governance**

Clinical Practice Committee / Committee on Evidence Based Practice  
Texas Health Presbyterian Hospital Plano                      Member: 2008 - present  
   Chair: 2008 - present

Member, Credentials Committee, Texas Health Center for Diagnostics & Surgery - Plano, 2017 - present

Governing Board, Trinity Medical Center                      Chair: 2005 - 2006  
   Board Member: 2004 - 2006

Member, Governing Board, Select Specialty Hospital Dallas, 2003 - 2007

Chair, Pharmacy and Therapeutics Committee, Texas Health Presbyterian Hospital Plano, 2002 – 2008

Chief of Staff, Trinity Medical Center, 2004 – 2006

Chair, Department of Internal Medicine, Trinity Medical Center, 2001 - 2003

Chair, Quality and Utilization Management Committee, Select Specialty Hospital, 2005 - 2007

Chair, Pharmacy and Therapeutics Committee, Naval Hospital Jacksonville Florida, 1996 - 1998

Chair, Infection Control Committee, Naval Hospital Jacksonville Florida, 1997 - 1998

Internal Medicine Peer Review Committee, Texas Health Presbyterian Hospital Plano  
   Member: 2001 - 2009, 2011 - 2016

Member, Medical Executive Committee, Select Specialty Hospital Dallas, 2003 - 2007

Member, Medical Executive Committee, Trinity Medical Center, 2001 – 2006

Member, Credentials Committee, Texas Health Presbyterian Hospital Plano, 2002 - 2004, 2005 - 2006

Member, Quality Assurance Committee, Trinity Medical Center, 2000 - 2001

Member, Utilization Management Committee, Trinity Medical Center, 2000 - 2001

Member, Institutional Review Committee, Trinity Medical Center, 2000 - 2001

Member, Pharmacy and Therapeutics Committee, Trinity Medical Center, 2003 - 2004

Member, Credentials Committee, Trinity Medical Center, 2002 - 2003

Member, Pharmacy and Therapeutics Committee, RHD Medical Center, 2000 - 2001

Member, Utilization Management Committee, Naval Hospital Jacksonville Florida, 1996 - 1997

Medical Director, Lipid Disorders Clinic, Naval Hospital Jacksonville Florida, 1997 – 1999

Medical Director, HIV Management Program, Naval Hospital Jacksonville Florida, 1996 - 1999

Member, Quality Assurance Committee, Naval Hospital Jacksonville Florida, 1996 – 1997

## **IX. Professional Society Memberships**



American College of Physicians, 1994 - present

American Association for Physician Leadership, 1999 - present (Life Member)  
(Formerly American College of Physician Executives)

Texas Medical Association, 1999 - present

National Association of Corporate Directors, 2012 - 2015; Governance Fellow, 2012 - 2015

Association of Clinical Research Professionals, 1999 - 2013

Academy of Pharmaceutical Physicians and Investigators / Association of Physicians in Clinical Research, 2004 - 2013

Southern Medical Association, 1997 - 2013

American Association for the Advancement of Science, 1995 - 2012

American Society of Hypertension, 2005 - 2008

Drug Information Association, 2000 - 2006

American Medical Association, 1990 - 2004

American Medical Directors Association, 2003 - 2004

American Diabetes Association, 1999 - 2004, 2013 - 2014

#### **X. Professional Society Committee Memberships and Governance**

Texas Academy of Internal Medicine (Texas Chapter of the American College of Physicians)	Member: 1998 - present Board Member: 2004 - 2011 President: 2008 – 2009
--	---

Texas Academy of Internal Medicine Foundation	President: 2010 - present
---	---------------------------

Committee on Quality, Texas Academy of Internal Medicine Services	Chair: 2013 - 2015 Member: 2006 – present
---	--

Health and Public Policy Committee, Texas Academy of Internal Medicine Services	Chair: 2007 – 2010 Member: 2002 – present
---	--

Nominations Committee, Texas Academy of Internal Medicine	Chair: 2008 – 2010 Member: 2008 - 2010
---	---

Medical Services Committee, Texas Academy of Internal Medicine Services	Chair: 2006 – 2007 Member: 2005 – 2010
---	---

Advisory Committee for Leadership, Southern Medical Association

Member: 2010 – 2013

Committee on Quality for Professional Development, Southern Medical Association  
Member: 2010 – 2013

Professional Development Content Review and Validation Board, Southern Medical Association  
Member: 2010 – 2013

Consultant to Health Information Technology Committee, Texas Medical Association 2008 – 2013  
Committee Member: 2005 - 2008

Ad Hoc Committee on Managed Care and Insurance, Texas Medical Association  
Member: 2008 – 2010

Communications Committee, Texas Academy of Internal Medicine  
Member: 2000 – 2002, 2005 - 2010

Administration Committee, Texas Academy of Internal Medicine  
Member: 2007 – 2011

Executive Committee, Texas Academy of Internal Medicine  
Member: 2006 – 2010

Texas Academy of Internal Medicine Services                      President: 2006 – 2007

#### **XI. Other Memberships and Governance**

Credentials Committee, Genesis Physicians Group                      Chair: 2016 – present  
Member: 2016 – present

Expert Panelist, Texas Medical Board, 2009 – present

Member, Texas Medical Foundation, 2004 - present

Member, Medical Advisory Committee, United HealthCare, 2002 - present

Member, Hewlett Packard Enterprise Services Global Healthcare Group Advisory Board, 2011 - present

Member, Medical Quality Committee, Aetna, 2012 - 2014

Utilization and Quality Review Physician, Texas Medical Foundation (Medicare QIO), 2006 – 2014

Member, General Electric Medical Quality Improvement Consortium Advisory Board, 2000 - 2011

Member, Physician Advisory Committee (P&T), Blue Cross/Blue Shield Texas, 2007 - 2010

Member, Aetna Medicare Provider Collaboration Advisory Council, 2012 - 2014

Member, Finance Committee, Genesis Physicians Group, Inc. (IPA), 2004 - 2007

#### **XII. Human Research Studies**

Abbott M03-599: A Phase 3b, Randomized, Open-Label, Active-Controlled Study to Compare the Effects of Tarka and Lotrel on Albuminuria in Hypertensive, Type 2 Diabetic Subjects with Diabetic Nephropathy.

NCT00234871

Abbott M04-697: A Phase 3, Randomized, Multicenter, Double-Blind Study Comparing the Analgesic Efficacy of Extended Release Hydrocodone/Acetaminophen Tablets (Vicodin® CR) to Placebo in Subjects with Osteoarthritis. NCT00404183

Abbott M10-011 SUCCEED (Kos 016-09-06-CR): A Study Evaluating the Co-Administration of Niaspan® (niacin extended-release) Caplets in Combination with Aspirin to Minimize Flush with Placebo Control and Double Blinding.

Cefali, EA, Simmons, PD, Stanek, EJ, McGovern, ME, & Kissling, CJ Aspirin reduces cutaneous flushing after administration of an optimized extended-release niacin formulation. 2007; 45: 78-88.  
doi: 10.5414/CP45078.

Abbott MA-01-010401 (Kos) IMPACT: A Phase 4, Open Label Study for the Impact of Medical Subspecialty on Patient Compliance to Treatment with Lovastatin-Niacin combination tablets.

Acambis H-400-009: The Safety, Tolerability, and Immunogenicity of ACAM2000 in Adults Without Previous Smallpox Vaccination. A Randomized, Double-Blind, Fixed Dose, Phase III Comparison Between ACAM2000 and Dryvax® Smallpox Vaccines.

Acambis, Inc. (2007). ACAM2000 smallpox vaccine. Vaccines and Related Biological Products Advisory Committee (VRBPAC) Briefing Document. Apr 18 2007.

Acambis H-400-012: The Safety, Tolerability, and Immunogenicity of ACAM2000 in Adults With Previous Smallpox Vaccination. A Randomized, Double-Blind, Fixed Dose, Phase III Comparison Between ACAM2000 and Dryvax® Smallpox Vaccines.

Rosenthal, S, Merchlinsky, M, Chowdhury, M (2007). ACAM2000 (Live Vaccinia Virus Smallpox Vaccine). VRBPAC Background Document. May 17, 2007 VRBPAC Meeting.

Akros Pharma Inc. AT302-U-06-003: A Phase 2, Randomized, Double-blind, Placebo-controlled, Parallel Group Study Evaluating the Efficacy and Safety of JTT-302 Administered Daily for Four Weeks in Subjects with Low HDL-C Levels. NCT00749788

Akros Pharma Inc. AT302-U-06-004: An Eight Week, Open-label Extension Study Evaluating the Safety of JTT-302 Administered Once Daily in Subjects with Low HDL-C Levels Who Have Completed the Treatment Phase of Study AT302-U-06-003. NCT00748852

Alba CLIN 1001-006 A Phase IIb, Randomized, Placebo Controlled, Dose Ranging, Multicenter Study to Determine the Safety, Tolerance, and Efficacy of AT-1001 in Celiac Disease Subjects during a Gluten Challenge. NCT00492960

Kelly, CP, Green, PH, Murray, JA, DiMarino, A, Colatrella, A, Leffler, DA, Alexander, T, Arsenescu, R, Leon, F, Jiang, JG, Arterburn, LA, Paterson, BM, Fedorak, RN, et al. for the Larazotide Acetate Celiac Disease Study Group. Larazotide acetate in patients with coeliac disease undergoing a gluten challenge: a randomised placebo-controlled study. Aliment Pharmacol Ther, 2013;37(2): 252-262.  
doi:10.1111/apt.12147

Auxilium AUX-TG-219: Evaluation of the Effect of Transdermal Testosterone Supplementation on Glycemic Control, Body Composition, and Lipid Concentrations in Hypogonadal Men with Non-Insulin-Dependent Diabetes Mellitus.

AstraZeneca Pharmaceuticals 4522US/0011 JUPITER: A Randomized, Double-Blind, Placebo-Controlled, Multicenter, Phase III Study of Rosuvastatin in the Primary Prevention of Cardiovascular Events Among Subjects with Low Levels of LDL-Cholesterol and Elevated Levels of C-Reactive Protein. NCT00239681

Ridker PM, Danielson E, Fonseca FAH, et al. Rosuvastatin to Prevent Vascular Events in Men and Women with Elevated C-Reactive Protein. N Engl J Med. 2008;359(21):2195-2207. doi:10.1056/nejma0807646

Ridker, PM, Danielson, E, Fonseca, FA, Genest, J, Gotto, AM; JUPITER Trial Study Group. Reduction in C-reactive protein and LDL cholesterol and cardiovascular event rates after initiation of rosuvastatin: a prospective study of the JUPITER trial. The Lancet, 2009;373(9670), 1175–1182. [https://doi.org/10.1016/S0140-6736\(09\)60447-5](https://doi.org/10.1016/S0140-6736(09)60447-5)

Ridker PM, MacFadyen JG, Fonseca FAH, et al. Number Needed to Treat With Rosuvastatin to Prevent First Cardiovascular Events and Death Among Men and Women With Low Low-Density Lipoprotein Cholesterol and Elevated High-Sensitivity C-Reactive Protein. Circ Cardiovasc Qual Outcomes. 2009;2(6):616-623. doi:10.1161/CIRCOUTCOMES.109.848473

Ridker, PM, Genest, J, Boekholdt, SM, Libby, P, Gotto, AM, Nordestgaard, BG; JUPITER Trial Study Group. HDL cholesterol and residual risk of first cardiovascular events after treatment with potent statin therapy: an analysis from the JUPITER trial. The Lancet, 2010;376(9738), 333–339. [https://doi.org/10.1016/S0140-6736\(10\)60713-1](https://doi.org/10.1016/S0140-6736(10)60713-1)

Ridker PM, Pradhan A, MacFadyen JG, Libby P, Glynn RJ; JUPITER Trial Study Group. Cardiovascular benefits and diabetes risks of statin therapy in primary prevention: an analysis from the JUPITER trial. Lancet. 2012;380(9841):565–571. doi:10.1016/S0140-6736(12)61190-8

Ridker PM, Mora S, Rose L; JUPITER Trial Study Group. Percent reduction in LDL cholesterol following high-intensity statin therapy: potential implications for guidelines and for the prescription of emerging lipid-lowering agents. Eur Heart J. 2016;37(17):1373–1379. doi:10.1093/eurheartj/ehw046

Ridker PM, Fonseca FAH, Genest J, et al. Baseline Characteristics of Participants in the JUPITER Trial, A Randomized Placebo-Controlled Primary Prevention Trial of Statin Therapy Among Individuals With Low Low-Density Lipoprotein Cholesterol and Elevated High-Sensitivity C-Reactive Protein. Am J Cardiol. 2007;100:1659-1664. doi:10.1016/j.amjcard.2007.09.072

Boehringer Ingelheim Pharma GmbH & Co. 1160.26 RE-LY: Randomized Evaluation of Long term anticoagulant therapy (RE-LY) comparing the efficacy and safety of two blinded doses of dabigatran etexilate with open label warfarin for the prevention of stroke and systemic embolism in patients with non-valvular atrial fibrillation: prospective, multi-center, parallel-group, non-inferiority trial (RE-LY STUDY). NCT00262600

Connolly SJ, Ezekowitz MD, Yusuf S, et al. Dabigatran versus Warfarin in Patients with Atrial Fibrillation. N Engl J Med. 2009;361(12):1139-1151. doi:10.1056/nejmoa0905561

Ezekowitz MD, Wallentin L, Connolly SJ, et al. Dabigatran and Warfarin in Vitamin K Antagonist–Naive and –Experienced Cohorts With Atrial Fibrillation. Circulation. 2010;122(22):2246-2253. doi:10.1161/circulationaha.110.973735

Hijazi Z, Oldgren J, Lindbäck J, et al. A biomarker-based risk score to predict death in patients with atrial fibrillation: the ABC (age, biomarkers, clinical history) death risk score. Eur Heart J. 2018;39(6):477-485. doi:10.1093/eurheartj/ehx584

Boehringer Ingelheim Pharma GmbH & Co. 1235.1: A randomized, double-blind, double-dummy, placebo-controlled, 4x4 factorial design trial to evaluate telmisartan 20, 40 and 80 mg tablets in combination with amlodipine 2.5, 5 and 10 mg capsules after eight weeks of treatment in patients with Stage I or II hypertension, with an ABPM sub-study.

Littlejohn, T. W., Majul, C. R., Olvera, R., Seeber, M., Kobe, M., Guthrie, R., Oigman, W. and on Behalf of the study investigators. Results of Treatment With Telmisartan-Amlodipine in Hypertensive Patients. J Clin Hypertension, 2009;11: 207–213. doi: 10.1111/j.1751-7176.2009.00098.x

Littlejohn, T. W., Majul, C. R., Olvera, R., Seeber, M., Kobe, M., & Guthrie, R. Telmisartan plus Amlodipine in Patients with Moderate or Severe Hypertension: Results from a Subgroup Analysis of a Randomized, Placebo-Controlled, Parallel-Group, 4 x 4 Factorial Study. J Postgrad Med, 2015;121(2): 5 - 14. doi: 10.3810/pgm.2009.03.1972

Boehringer Ingelheim Pharma GmbH & Co. 1236.1: A randomized, double-blind, double-dummy, placebo- controlled, 3x4 factorial design trial to evaluate telmisartan 20, and 80 mg tablets in combination with ramipril 1.25, 10, and 20 mg capsules after eight weeks of treatment in patients with Stage I or II hypertension with an ABPM sub-study.

Boehringer Ingelheim Pharma GmbH & Co. 1245.25: A Phase III, multicentre, international, randomised, parallel group, double blind cardiovascular safety study of BI 10773 (10 mg and 25 mg administered orally once daily) compared to usual care in type 2 diabetes mellitus patients with increased cardiovascular risk.

Boehringer Ingelheim Pharma GmbH & Co. 1160.94: Registry to Evaluate Anticoagulation in Atrial Fibrillation (REAL-AF).

Matchar D, Garcia D, Smasa G, et al. The Registry to Evaluate Anticoagulation in Atrial Fibrillation (REAL-AF). Circulation. 2010;122(A13111).

BioCryst Pharmaceuticals, Inc. BCX1812-304: A Phase III, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Intravenous Peramivir in Adolescents and Adults with Uncomplicated Acute Influenza. NCT01224795

BioCryst Pharmaceuticals, Inc. BCX1812-311: THE IMPROVE 1 STUDY: A phase 3 multicenter, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of intramuscular peramivir in subjects with uncomplicated acute influenza. NCT00610935

Bristol-Myers Squibb / Pfizer CV185-030 : A Phase3, Active (Warfarin) Controlled, Randomized, Double-Blind, Parallel Arm Study to Evaluate Efficacy and Safety of Apixaban in Preventing Stroke and Systemic Embolism in Subjects with Nonvalvular Atrial Fibrillation. NCT00412984

Alexander KP, Brouwer MA, Mulder H, et al. Outcomes of apixaban versus warfarin in patients with atrial fibrillation and multi-morbidity: Insights from the ARISTOTLE trial. Am Heart J. 2019;208:123-131. doi:10.1016/j.ahj.2018.09.017

Hijazi Z, Siegbahn A, Andersson U, et al. High-sensitivity troponin I for risk assessment in patients with atrial fibrillation: insights from the Apixaban for Reduction in Stroke and other Thromboembolic Events in Atrial Fibrillation (ARISTOTLE) trial. Circulation. 2014;129(6):625-634. doi:10.1161/CIRCULATIONAHA.113.006286

Hijazi Z, Oldgren J, Lindbäck J, et al. A biomarker-based risk score to predict death in patients with atrial fibrillation: the ABC (age, biomarkers, clinical history) death risk score. Eur Heart J. 2018;39(6):477-485. doi:10.1093/eurheartj/ehx584

Rao MP, Vinereanu D, Wojdyla DM, et al. Clinical Outcomes and History of Fall in Patients with Atrial Fibrillation Treated with Oral Anticoagulation: Insights From the ARISTOTLE Trial. Am J Med. 2018;131(3):269-275.e2. doi:10.1016/j.amjmed.2017.10.036

Vinereanu D, Lopes RD, Mulder H, et al. Echocardiographic Risk Factors for Stroke and Outcomes in Patients With Atrial Fibrillation Anticoagulated With Apixaban or Warfarin. Stroke. 2017;48(12):3266-3273. doi:10.1161/strokeaha.117.017574

Alexander JH, Andersson U, Lopes RD, et al. Apixaban 5 mg Twice Daily and Clinical Outcomes in Patients With Atrial Fibrillation and Advanced Age, Low Body Weight, or High Creatinine: A Secondary Analysis of a Randomized Clinical Trial. JAMA Cardiol. 2016;1(6):673-681. doi:10.1001/jamacardio.2016.1829

Horowitz JD, De Caterina R, Heresztyn T, et al. Asymmetric and Symmetric Dimethylarginine Predict Outcomes in Patients With Atrial Fibrillation: An ARISTOTLE Substudy. J Am Coll Cardiol. 2018;72(7):721-733. doi:10.1016/j.jacc.2018.05.058

De Caterina R, Andersson U, Alexander JH, et al. History of bleeding and outcomes with apixaban versus warfarin in patients with atrial fibrillation in the Apixaban for Reduction in Stroke and Other Thromboembolic Events in Atrial Fibrillation trial. Am Heart J. 2016;175:175-183. doi:10.1016/j.ahj.2016.01.005

Hijazi Z, Aulin J, Andersson U, et al. Biomarkers of inflammation and risk of cardiovascular events in anticoagulated patients with atrial fibrillation. Heart. 2016;102(7):508-517. doi:10.1136/heartjnl-2015-308887

Hijazi Z, Lindbäck J, Alexander JH, et al. The ABC (age, biomarkers, clinical history) stroke risk score: a biomarker-based risk score for predicting stroke in atrial fibrillation. Eur Heart J. 2016;37(20):1582-1590. doi:10.1093/eurheartj/ehw054

Rao MP, Halvorsen S, Wojdyla D, et al. Blood pressure control and risk of stroke or systemic embolism in patients with atrial fibrillation: Results from the apixaban for reduction in stroke and other thromboembolic events in atrial fibrillation (ARISTOTLE) trial. J Am Heart Assoc. 2015;4(12). doi:10.1161/JAHA.115.002015

Washam JB, Hohnloser SH, Lopes RD, et al. Interacting medication use and the treatment effects of apixaban versus warfarin: results from the ARISTOTLE Trial. J Thromb Thrombolysis. 2019;47(3):345-352. doi:10.1007/s11239-019-01823-y

Flaker G, Lopes RD, Hylek E, et al. Amiodarone, Anticoagulation, and Clinical Events in Patients With Atrial Fibrillation. J Am Coll Cardiol. 2014;64(15):1541-1550. doi:10.1016/j.jacc.2014.07.967

Flaker G, Lopes RD, Al-Khatib SM, et al. Efficacy and Safety of Apixaban in Patients After Cardioversion for Atrial Fibrillation. J Am Coll Cardiol. 2014;63(11):1082-1087. doi:10.1016/j.jacc.2013.09.062

Wallentin L, Lopes RD, Hanna M, et al. Efficacy and Safety of Apixaban Compared With Warfarin at Different Levels of Predicted International Normalized Ratio Control for Stroke Prevention in Atrial Fibrillation. Circulation. 2013;127(22):2166-2176. doi:10.1161/circulationaha.112.142158

Easton JD, Lopes RD, Bahit MC, et al. Apixaban compared with warfarin in patients with atrial fibrillation and previous stroke or transient ischaemic attack: a subgroup analysis of the ARISTOTLE trial. Lancet Neurol. 2012;11(6):503-511. doi:10.1016/S1474-4422(12)70092-3

Granger CB, Alexander JH, McMurray JJV, et al. Apixaban versus Warfarin in Patients with Atrial Fibrillation. N Engl J Med. 2011;365(11):981-992. doi:10.1056/NEJMoa1107039

Wallentin L, Hijazi Z, Andersson U, et al. Growth differentiation factor 15, a marker of oxidative stress and inflammation, for risk assessment in patients with atrial fibrillation: insights from the Apixaban for Reduction in Stroke and Other Thromboembolic Events in Atrial Fibrillation (ARISTOTLE) trial. Circulation. 2014;130(21):1847-1858. doi:10.1161/CIRCULATIONAHA.114.011204

Bristol-Myers Squibb CV181-014: A Multicenter, Randomized, Double-blind, Placebo-controlled, Phase 3 Trial to Evaluate the Efficacy and Safety of Saxagliptin (BMS-477118) in Combination with Metformin in Subjects with Type 2 Diabetes Who Have Inadequate Glycemic Control on Metformin Alone. NCT00121667

DeFronzo RA, Hissa MN, Garber AJ, et al. The Efficacy and Safety of Saxagliptin When Added to Metformin Therapy in Patients With Inadequately Controlled Type 2 Diabetes With Metformin Alone. Diabetes Care. 2009;32(9):1649-1655. doi:10.2337/dc08-1984

Bristol-Myers Squibb CV181-008: A Multicenter Randomized, Double-Blind, Placebo-Controlled Phase II Trial to Evaluate the Safety and Efficacy of Saxagliptin as Monotherapy in Subjects with Type II Diabetes Mellitus Who Have Inadequate Glycemic Control. NCT00950599

Rosenstock J, Sankoh S, List JF. Glucose-lowering activity of the dipeptidyl peptidase-4 inhibitor saxagliptin in drug-naïve patients with type 2 diabetes. Diabetes, Obes Metab. 2008;10(5):376-386. doi:10.1111/j.1463-1326.2008.00876.x

Bristol-Myers Squibb CV168-021: A Phase III Randomized, Double-Blind, Placebo-Controlled Multicenter Trial to Evaluate the Safety and Efficacy of Muraglitazar in Combination with Glyburide Therapy in Subjects with Type II Diabetes Mellitus Who Have Inadequate Glycemic Control on Sulfonylurea Therapy Alone. NCT00162175

Rubin CJ, De Pril V, Fiedorek FT. Coadministration of muraglitazar plus glyburide: Improvement of glycaemic and lipid profiles in patients with type 2 diabetes. Diabetes Vasc Dis Res. 2009;6(2):120-132. doi:10.1177/1479164109336049

Bristol-Myers Squibb MB102-030: A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Phase 3 Trial to Evaluate the Safety and Efficacy of Dapagliflozin in Combination with Thiazolidinedione Therapy in Subjects with Type 2 Diabetes who have Inadequate Glycemic Control on Thiazolidinedione Therapy Alone. NCT00683878

Rosenstock J, Vico M, Wei L, Salsali A, List JF. Effects of Dapagliflozin, an SGLT2 Inhibitor, on HbA1c, Body Weight, and Hypoglycemia Risk in Patients With Type 2 Diabetes Inadequately Controlled on Pioglitazone Monotherapy. Diabetes Care. 2012;35(7):1473-1478. doi:10.2337/dc11-1693

Bristol-Myers Squibb CV131-176: The Efficacy and Safety of Irbesartan/HCTZ Combination Therapy as First Line Treatment for Severe Hypertension. NCT00095394

Bristol-Myers Squibb CV181-011: A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase 3 Trial to Evaluate the Efficacy and Safety of Saxagliptin (BMS-477118) as Monotherapy in Subjects with Type 2 Diabetes Who Have Inadequate Glycemic Control with Diet and Exercise. NCT00121641

Rosenstock J, Aguilar-Salinas C, Klein E, Nepal S, List J, Chen R. Effect of saxagliptin monotherapy in treatment-naïve patients with type 2 diabetes. *Curr Med Res Opin*. 2009;25(10):2401-2411. doi:10.1185/03007990903178735

Bristol-Myers Squibb CV137-120: Omapatrilat Cardiovascular Treatment vs. Enalapril (OCTAVE).

Kostis J. Omapatrilat and enalapril in patients with hypertension: the Omapatrilat Cardiovascular Treatment vs. Enalapril (OCTAVE) trial. *Am J Hypertens*. 2004;17(2):103-111. doi:10.1016/j.amjhyper.2003.09.014

Bristol-Myers Squibb 800-01-01: A Multicenter Randomized, Double-Blind, Placebo-Controlled Parallel Study to Determine the Effect of Pravastatin 20 mg on LDL-C when Administered Once Daily to Subjects with Moderately Elevated Primary Hypercholesterolemia.

Cubist Pharmaceuticals DAP-00-05: A Randomized, Double-Blind, Phase III, Comparative Study of Cidecin™ (Daptomycin) to Rocephin® (Ceftriaxone) in the Treatment of Moderate to Severe Community-Acquired Acute Bacterial Pneumonia Due to *S. Pneumoniae*. NCT00538694

DOV Pharmaceuticals, Inc. DOV-075-021-US: A Phase III, Multi-Center, Double-blind, Placebo-Controlled, Randomized Study of Bicifadine 200 mg BID, Bicifadine 400mg BID, and Bicifadine 400 mg TID in the Treatment of Chronic Back Pain. NCT00295724

Eli Lilly / Amylin Pharmaceuticals H8O-MC-GWAP: Safety and Efficacy of Exenatide in Patients with Type 2 Diabetes Using Thiazolidinediones or Thiazolidinediones and Metformin. NCT00099320

Zinman B, Hoogwerf BJ, Durán García S, et al. The Effect of Adding Exenatide to a Thiazolidinedione in Suboptimally Controlled Type 2 Diabetes. *Ann Intern Med*. 2007;146(7):477. doi:10.7326/0003-4819-146-7-200704030-00003

Eli Lilly / Amylin Pharmaceuticals 2993-113: A Phase 3, Randomized, Triple-Blind, Parallel-Group, Long-Term, Placebo-Controlled, Multicenter Study to Examine the Effect on Glucose Control (HbA1c) of AC2993 Given Two Times a Day in Subjects With Type 2 Diabetes Mellitus Treated With a Sulfonylurea Alone. NCT00039026

Buse JB, Henry RR, Han J, Kim DD, Fineman MS, Baron AD. Effects of Exenatide (Exendin-4) on Glycemic Control Over 30 Weeks in Sulfonylurea-Treated Patients With Type 2 Diabetes. *Diabetes Care*. 2004;27(11):2628-2635. doi:10.2337/diacare.27.11.2628

Eli Lilly I4L-MC-ABEC: A Prospective, Randomized, Double-Blind Comparison of Long-Active Basal Insulin Analog LY2963016 to Lantus in Adult Patients with Type 2 Diabetes Mellitus: The ELEMENT 2 Study. NCT01421459

Pollom RK, Costigan T, Lacaya LB, Ilag LL, Hollander PA. Similar Efficacy and Safety of Basaglar® and Lantus® in Patients with Type 2 Diabetes in Age Groups (< 65 Years, ≥ 65 Years): A Post Hoc Analysis from the ELEMENT-2 Study. *Diabetes Ther*. 2018;9(2):827-837. doi:10.1007/s13300-018-0405-5

Eli Lilly I3P-MC-GKBC: A 12-Week, Phase 2, Randomized, Double-Blind, Active-Controlled Study of LY2608204 Given as Monotherapy or in Combination with Metformin in Patients with Type 2 Diabetes Mellitus. NCT01408095

Forest Research Institute GK1-MD-201: A Phase 2a, Multicenter, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Dose-Ranging, 28-Day Study to Evaluate the Safety, Tolerability, and Efficacy



of Orally Administered GK1-399 in Patients with Type 2 Diabetes Mellitus Inadequately Controlled on Metformin.

Forest Research Institute LAS-MD-38: A Randomized, Double-Blind, Placebo-Controlled Study Evaluating the Efficacy, Safety and Tolerability of 2 Doses of Acridinium Bromide Compared with Placebo for 12 Weeks in Patients With Moderate to Severe, Stable Chronic Obstructive Pulmonary Disease Followed by a 40-Week Evaluation of the Higher Acridinium Bromide Dose. NCT01045161

Rennard SI, Scanlon PD, Ferguson GT, et al. ACCORD COPD II: A Randomized Clinical Trial to Evaluate the 12-Week Efficacy and Safety of Twice-Daily Acridinium Bromide in Chronic Obstructive Pulmonary Disease Patients. Clin Drug Investig. 2013;33(12):893-904. doi:10.1007/s40261-013-0138-1

Forest Research Institute DUT-MD-303: A Phase III, Randomized, Double-Blind, Active-Controlled, Multicenter Safety Study to Evaluate Cardiovascular Outcomes in Patients With Type 2 Diabetes Mellitus Treated with Dutogliptin Compared to Glimepiride. NCT00947557

Forest / Janssen Pharmaceutica NEB-203: A Double Blind, Randomized, Multi-Center, Active-Comparator, Five Treatment Study of the Effects of Nebivolol Compared to Metoprolol on Cardiovascular Hemodynamics and Exercise Capacity in Patients with Mild to Moderate Hypertension. NCT00200421

Genomics Collaborative 99-302: A Multi-center, Multinational open clinical study to explore relationships between genotypic and serologic findings and phenotypic manifestations in a large cohort of participants.

Gilead Sciences GS-US-259-0147: A Phase 3, Randomized, Double-blind, Placebo-controlled, Parallel group Study to Evaluate the Efficacy and Safety of Ranolazine When Added to Metformin in Subjects with Type 2 Diabetes Mellitus. NCT01555164

Gilead Sciences (Myogen) DAR-312 and 312-E (Extension of DAR-312): A Double-Blind, Active-Controlled, Long-Term Safety Extension Study of Optimized Doses of Darusentan in Subjects with Resistant Hypertension Despite Receiving Combination Therapy with Three or More Antihypertensive Drugs, Including a Diuretic, as Compared to Guanfacine. NCT00389779 and NCT00389675

Bakris GL, Lindholm LH, Black HR, et al. Divergent Results Using Clinic and Ambulatory Blood Pressures. Hypertension. 2010;56(5):824-830. doi:10.1161/hypertensionaha.110.156976

General Electric Medical Systems Information Technology: Using Electronic Health Records (EHR) – Based Disease Management Tools to Improve Management of Depression in Primary Care.

GlaxoSmithKline plc RRL104025: Evaluation of Restless Legs Syndrome Awareness and Quality of Care in the Primary Care Setting.

GlaxoSmithKline plc: 105517/367: A Randomized, Double-Blind, Multi-Center Study Comparing the Effects of Administration of Controlled Release Carvedilol or Placebo on Blood Pressure in Essential Hypertension Patients.

GlaxoSmithKline plc GEMINI 105517/346: A Randomized, Double-Blind, Multicenter Study Comparing the Glycemic Control Characteristics of Carvedilol and Metoprolol in Hypertensive Patients with Type II Diabetes Mellitus. NCT00060931

Messerli FH, Bell DSH, Fonseca V, et al. Body Weight Changes with  $\beta$ -Blocker Use: Results from GEMINI. Am J Med. 2007;120(7):610-615. doi:10.1016/j.amjmed.2006.10.017

Fonseca V, Bakris GL, Bell DSH, et al. Differential effect of  $\beta$ -blocker therapy on insulin resistance as a function of insulin sensitizer use: results from GEMINI. *Diabet Med*. 2007;24(7):759-763. doi:10.1111/j.1464-5491.2007.02151.x

Bakris GL, Fonseca V, Katholi RE, et al. Differential Effects of  $\beta$ -Blockers on Albuminuria in Patients With Type 2 Diabetes. *Hypertension*. 2005;46(6):1309-1315. doi:10.1161/01.HYP.0000190585.54734.48

Bakris GL, Bell DSH, Fonseca V, et al. The rationale and design of the Glycemic Effects in Diabetes Mellitus. *J Diabetes Complications*. 2005;19(2):74-79. doi:10.1016/j.jdiacomp.2004.07.003

Bakris GL, Fonseca V, Katholi RE, et al. Metabolic effects of carvedilol vs metoprolol in patients with type 2 diabetes mellitus and hypertension: a randomized controlled trial. *JAMA*. 2004;292(18):2227-2236. doi:10.1001/jama.292.18.2227

GlaxoSmithKline plc ADC 111116: Assessment of the Prevalence of Chronic Airway Obstruction in subjects with a history of Cigarette Smoking in a Primary Care Setting.

Genentech / Hoffman-La Roche Inc. BM18248: A multi-center phase 2 randomized, double-blind, placebo-controlled dose-ranging study to determine the efficacy, safety, tolerability and pharmacokinetics of RO4389620 in patients with type 2 diabetes mellitus. NCT00266240

Genentech / Hoffman-La Roche Inc. NV22155: A randomized, multicenter trial of oseltamivir [Tamiflu] doses of 75 mg for 5 or 10 days versus 150 mg for 5 or 10 days to evaluate the effect on the duration of viral shedding in influenza patients with pandemic (H1N1) 2009. NCT01032837

Ingenix, Inc. 94117: Outcomes of Antibiotic Therapy for Respiratory-Related Infections.

Johnson & Johnson RIVAROX-AFL-4001 ORBIT-AF: Outcomes Registry for Better Informed Treatment of Atrial Fibrillation. NCT01165710

Madhavan M, Holmes DN, Piccini JP, et al. Association of frailty and cognitive impairment with benefits of oral anticoagulation in patients with atrial fibrillation. *Am Heart J*. 2019;211:77-89. doi:10.1016/j.ahj.2019.01.005

Thind M, Holmes DN, Badri M, et al. Embolic and Other Adverse Outcomes in Symptomatic Versus Asymptomatic Patients With Atrial Fibrillation (from the ORBIT-AF Registry). *Am J Cardiol*. 2018;122(10):1677-1683. doi:10.1016/j.amjcard.2018.07.045

Steinberg BA, Gao H, Shrader P, et al. International trends in clinical characteristics and oral anticoagulation treatment for patients with atrial fibrillation: Results from the GARFIELD-AF, ORBIT-AF I, and ORBIT-AF II registries. *Am Heart J*. 2017;194:132-140. doi:10.1016/j.ahj.2017.08.011

Gundlund A, Fosbøl EL, Kim S, et al. Family history of atrial fibrillation is associated with earlier-onset and more symptomatic atrial fibrillation: Results from the Outcomes Registry for Better Informed Treatment of Atrial Fibrillation (ORBIT-AF) registry. *Am Heart J*. 2016;175:28-35. doi:10.1016/j.ahj.2016.01.020

Piccini JP, Simon DN, Steinberg BA, et al. Differences in Clinical and Functional Outcomes of Atrial Fibrillation in Women and Men. JAMA Cardiol. 2016;1(3):282. doi:10.1001/jamacardio.2016.0529

Golwala H, Jackson LR, Simon DN, et al. Racial/ethnic differences in atrial fibrillation symptoms, treatment patterns, and outcomes: Insights from Outcomes Registry for Better Informed Treatment for Atrial Fibrillation Registry. Am Heart J. 2016;174:29-36. doi:10.1016/j.ahj.2015.10.028

Holmqvist F, Simon D, Steinberg BA, et al. Catheter Ablation of Atrial Fibrillation in U.S. Community Practice - Results From Outcomes Registry for Better Informed Treatment of Atrial Fibrillation (ORBIT-AF). J Am Heart Assoc. 2015;4(5). doi:10.1161/JAHA.115.001901

Allen LA, Fonarow GC, Simon DN, et al. Digoxin Use and Subsequent Outcomes Among Patients in a Contemporary Atrial Fibrillation Cohort. J Am Coll Cardiol. 2015;65(25):2691-2698. doi:10.1016/j.jacc.2015.04.045

Holmqvist F, Guan N, Zhu Z, et al. Impact of obstructive sleep apnea and continuous positive airway pressure therapy on outcomes in patients with atrial fibrillation—Results from the Outcomes Registry for Better Informed Treatment of Atrial Fibrillation (ORBIT-AF). Amer Heart J 2015;169(5): 647-654.e2. doi 10.1016/J.AHJ.2014.12.024

Steinberg BA, Kim S, Thomas L, et al. Increased Heart Rate Is Associated With Higher Mortality in Patients With Atrial Fibrillation (AF): Results From the Outcomes Registry for Better Informed Treatment of AF (ORBIT-AF). J Am Heart Assoc. 2015;4(9). doi:10.1161/JAHA.115.002031

Steinberg BA, Holmes DN, Piccini JP, et al. Early Adoption of Dabigatran and Its Dosing in US Patients With Atrial Fibrillation: Results From the Outcomes Registry for Better Informed Treatment of Atrial Fibrillation. J Am Heart Assoc. 2013;2(6). doi:10.1161/JAHA.113.000535

Cullen MW, Kim S, Piccini JP, et al. Risks and Benefits of Anticoagulation in Atrial Fibrillation. Circ Cardiovasc Qual Outcomes. 2013;6(4):461-469. doi:10.1161/circoutcomes.113.000127

Steinberg BA, Kim S, Piccini JP, et al. Use and Associated Risks of Concomitant Aspirin Therapy With Oral Anticoagulation in Patients With Atrial Fibrillation. Circulation. 2013;128(7):721-728. doi:10.1161/CIRCULATIONAHA.113.002927

Johnson & Johnson NRGMON-CON-3001: A Randomized, Double-Blind, Two-Part, Parallel-Group, Comparative Study to Evaluate Blood Folate Levels in Women Taking an Oral Contraceptive With and Without Folic Acid.

Johnson & Johnson 39039039-AFL-3001 ROCKET-AFib: A Prospective, Randomized, Double-Blind, Double-Dummy, Parallel-Group, Multicenter, Event-Driven, Non-inferiority Study Comparing the Efficacy and Safety of Once-Daily Oral Rivaroxaban (BAY 59-7939) With Adjusted-Dose Oral Warfarin for the Prevention of Stroke and Non-Central Nervous System Systemic Embolism in Subjects With Non-Valvular Atrial Fibrillation. NCT00403767

Fordyce CB, Hellkamp AS, Lokhnygina Y, et al. On-Treatment Outcomes in Patients With Worsening Renal Function With Rivaroxaban Compared With Warfarin. Circulation. 2016;134(1):37-47. doi:10.1161/CIRCULATIONAHA.116.021890

Goodman SG, Wojdyla DM, Piccini JP, et al. Factors Associated With Major Bleeding Events. J Am Coll Cardiol. 2014;63(9):891-900. doi:10.1016/j.jacc.2013.11.013

Hankey GJ, Patel MR, Stevens SR, et al. Rivaroxaban compared with warfarin in patients with atrial fibrillation and previous stroke or transient ischaemic attack: a subgroup analysis of ROCKET AF. *Lancet Neurol*. 2012;11(4):315-322. doi:10.1016/S1474-4422(12)70042-X

Patel MR, Mahaffey KW, Garg J, et al. Rivaroxaban versus Warfarin in Nonvalvular Atrial Fibrillation. *N Engl J Med*. 2011;365(10):883-891. doi:10.1056/NEJMoa1009638

Piccini JP, Stevens SR, Chang Y, et al. Renal dysfunction as a predictor of stroke and systemic embolism in patients with nonvalvular atrial fibrillation: Validation of the R2CHADS2 index in the ROCKET AF. *Circulation*. 2013;127(2):224-232. doi:10.1161/circulationaha.112.107128

Piccini JP, Stevens SR, Lokhnygina Y, et al. Outcomes after cardioversion and atrial fibrillation ablation in patients treated with rivaroxaban and warfarin in the ROCKET AF Trial. *J Am Coll Cardiol*. 2013;61(19):1998-2006. doi:10.1016/j.jacc.2013.02.025

Pokorney SD, Piccini JP, Stevens SR, et al. Cause of Death and Predictors of All-Cause Mortality in Anticoagulated Patients With Nonvalvular Atrial Fibrillation: Data From ROCKET AF. *J Am Heart Assoc*. 2016;5(3). doi:10.1161/JAHA.115.002197

Sherwood MW, Douketis JD, Patel MR, et al. Outcomes of Temporary Interruption of Rivaroxaban Compared With Warfarin in Patients With Nonvalvular Atrial Fibrillation. *Circulation*. 2014;129(18):1850-1859. doi:10.1161/circulationaha.113.005754

Singer DE, Hellkamp AS, Piccini JP, et al. Impact of Global Geographic Region on Time in Therapeutic Range on Warfarin Anticoagulant Therapy: Data From the ROCKET AF Clinical Trial. *J Am Heart Assoc*. 2013;2(1). doi:10.1161/JAHA.112.000067

Singer DE, Hellkamp AS, Yuan Z, et al. Alternative Calculations of Individual Patient Time in Therapeutic Range While Taking Warfarin: Results From the ROCKET AF Trial. *J Am Heart Assoc* 2015;4(3):e001349 doi:10.1161/JAHA.114.001349

The Executive Steering Committee on Behalf of the ROCKET AF Study Investigators. Rivaroxaban - Once daily, oral, direct factor Xa inhibition Compared with vitamin K antagonism for prevention of stroke and Embolism Trial in Atrial Fibrillation: Rationale and Design of the ROCKET AF study. *Am Heart J*. 2010;159(3):340-347.e1. doi:10.1016/j.ahj.2009.11.025

Washam JB, Stevens SR, Lokhnygina Y, et al. Digoxin use in patients with atrial fibrillation and adverse cardiovascular outcomes: a retrospective analysis of the Rivaroxaban Once Daily Oral Direct Factor Xa Inhibition Compared with Vitamin K Antagonism for Prevention of Stroke and Embolism Trial. *Lancet*. 2015;385(9985):2363-2370. doi:10.1016/S0140-6736(14)61836-5

Bansilal S, Bloomgarden Z, Halperin JL, et al. Efficacy and safety of rivaroxaban in patients with diabetes and nonvalvular atrial fibrillation: The Rivaroxaban Once-daily, Oral, Direct Factor Xa Inhibition Compared with Vitamin K Antagonism for Prevention of Stroke and Embolism Trial in Atrial Fibrillation. *Am Heart J*. 2015;170(4):675-682.e8. doi:10.1016/j.ahj.2015.07.006

Kowa K604-2.01US: A Phase II multi-center, randomized, double-blind, placebo controlled, parallel evaluation of the efficacy and safety of K-604 by High Resolution Magnetic Resonance Imaging (MRI) in carotid atherosclerotic plaque. NCT00851500

MannKind Corporation: MKC-TI-126: A 2-Month Safety Follow Up of Subjects from Mannkind Protocols MKC-TI-009, MKC-TI-102, MKC-TI-103, and MKC-TI-030. NCT00741429

MannKind Corporation: MKC-TI-030: Pulmonary Outcomes within a 2-year Period in Subjects with Diabetes Mellitus Treated with Technosphere®/Insulin or Usual Antidiabetic Treatment and in Subjects without Abnormalities in Glucose Control. NCT00741429

Merck MK-0524A-015-01: A Randomized, Double-Blind, Placebo-Controlled Endpoint Selection and Questionnaire Validation Study to Assess the Niacin-Induced Flushing Caused by NIASPAN™. NCT00533676

Merck MK-0524A-015-10: A Randomized, Double-Blind, Placebo-Controlled 1-Year Extension of the Phase IIA Endpoint Validation Study (015-01) to Assess the Tolerability of the MK-0524/Niacin Combination Tablet.

Merck MK-0524A-011-00: Part A: A Randomized, Double-Blind, Placebo-Controlled Study to Assess the Effects of MK-0524 Compared to Placebo. Part B: A Dose-Ranging Study to Evaluate the Tolerability of MK-0524 and its Effects on Niacin-Induced Flushing in Lipid Clinic Patients. NCT00536237 and NCT00479882

Paolini JF, Mitchel YB, Reyes R, et al. Effects of Laropiprant on Nicotinic Acid-Induced Flushing in Patients With Dyslipidemia. Am J Cardiol. 2008;101(5):625-630. doi:10.1016/j.amjcard.2007.10.023

Paolini JF, Mitchel YB, Reyes R, et al. Measuring flushing symptoms with extended-release niacin using the flushing symptom questionnaire©: results from a randomised placebo-controlled clinical trial. Int J Clin Pract. 2008;62(6):896-904. doi:10.1111/j.1742-1241.2008.01739.x

Norquist JM, Watson DJ, Yu Q, Paolini JF, McQuarrie K, Santanello NC. Validation of a questionnaire to assess niacin-induced cutaneous flushing. Curr Med Res Opin. 2007;23(7):1549-1560. doi:10.1185/030079907X199637

Merck MK-0524A-011-10: A Randomized, Double-Blind, Placebo-Controlled 1-Year Extension of the Phase IIB Dose Selection Study to Assess the Tolerability of MK-0524/Niacin Combination Tablet.

Merck MK-201-01 ViP Study: A Double-Blind, Randomized, Placebo-Controlled, Multicenter Study to Evaluate the Effects of Rofecoxib in Decreasing the Risk of Prostate Cancer. NCT00060476

van Adelsberg J, Gann P, Ko AT, et al. The VIOXX in prostate cancer prevention study: cardiovascular events observed in the rofecoxib 25 mg and placebo treatment groups. Curr Med Res Opin. 2007;23(9):2063-2070. doi:10.1185/030079907X219526

Merck MK-0663-066-00: A Randomized, Double-Blind, Active-Comparator-Controlled, Parallel-Group Study to Evaluate the Safety of Etoricoxib in Patients with Osteoarthritis or Rheumatoid Arthritis. NCT00250445

Laine L, Curtis SP, Cryer B, Kaur A, Cannon CP. Assessment of upper gastrointestinal safety of etoricoxib and diclofenac in patients with osteoarthritis and rheumatoid arthritis in the Multinational Etoricoxib and Diclofenac Arthritis Long-term (MEDAL) programme: a randomised comparison. Lancet. 2007;369(9560):465-473. doi:10.1016/S0140-6736(07)60234-7

Cannon CP, Curtis SP, FitzGerald GA, et al. Cardiovascular outcomes with etoricoxib and diclofenac in patients with osteoarthritis and rheumatoid arthritis in the Multinational Etoricoxib and Diclofenac Arthritis Long-term (MEDAL) programme: a randomised comparison. Lancet. 2006;368(9549):1771-1781. doi:10.1016/S0140-6736(06)69666-9

Novartis Pharma AG CCIB0021-I2301 ACCOMPLISH: A Prospective, Multinational, Multicenter, Double-Blind, Randomized, Active-Controlled Trial to Compare the Effects of Amlodipine-Benazepril to Benazepril

and Hydrochlorothiazide on the Reduction of Cardiovascular Morbidity and Mortality in Patients with High Risk Hypertension (Avoiding Cardiovascular Events through COMbination Therapy in Patients Living with Systolic Hypertension). NCT00170950

Bakris GL, Sarafidis PA, Weir MR, et al. Renal outcomes with different fixed-dose combination therapies in patients with hypertension at high risk for cardiovascular events (ACCOMPLISH): a prespecified secondary analysis of a randomised controlled trial. Lancet. 2010;375(9721):1173-1181. doi:10.1016/S0140-6736(09)62100-0

Jamerson K, Weber MA, Bakris GL, et al. Benazepril plus Amlodipine or Hydrochlorothiazide for Hypertension in High-Risk Patients. NEJM. 2008;359(23):2417-2428. doi:10.1056/NEJMoa0806182

Novartis Pharma AG CCIB002-K2301: A Randomized- Double-Blind, Multicenter, Positive Controlled, Parallel Group Study to Evaluate the Safety and Efficacy of Amlodipine-Benazepril compared to Lisinopril-Hydrochlorothiazide in hypertensive patients (high dose combinations).

Novartis Pharma AG / Shering-Plough CFOR258-D2307: A randomized, multicenter, placebo-controlled parallel group study of four months duration per patient to evaluate the safety and efficacy of treatment with 24 µg b.i.d. and 12 µg b.i.d. formoterol, double-blind, and 12 µg b.i.d. formoterol with additional on-demand formoterol doses, open-label, in adolescent and adult patients with persistent stable asthma. NCT01845025

Novartis Pharma AG CHTF919-A2306: A Randomized, Double-Blind, Placebo-Controlled, Parallel Group, Multicenter Study to Assess the Efficacy and Safety of Repeated Treatment with Tegaserod b.i.d. and Placebo in Female Patients With Irritable Bowel Syndrome with Constipation (IBS-C). NCT00142987

Novartis Pharma AG CLAF237-A2303: Efficacy and Safety of Vildagliptin in Combination With Metformin in Patients With Type 2 Diabetes. NCT00099892

Bosi E, Camisasca RP, Collober C, Rochotte E, Garber AJ. Effects of Vildagliptin on Glucose Control Over 24 Weeks in Patients With Type 2 Diabetes Inadequately Controlled With Metformin. Diabetes Care. 2007;30(4):890-895. doi:10.2337/dc06-1732

Novartis Pharma AG CLAF237-A2303/CLAF237-A2303-E1: A 28-Week Extension to A Multicenter, Randomized, Parallel- Group Study to Compare the Effect of 24 Weeks Treatment with LAF237 (50 mg daily or twice daily) to Placebo as Add-On Therapy in patients with Type 2 Diabetes Inadequately Controlled with Metformin Monotherapy. NCT00099892 and NCT00138515

Ligueros-Saylan M, Foley JE, Schweizer A, Couturier A, Kothny W. An assessment of adverse effects of vildagliptin versus comparators on the liver, the pancreas, the immune system, the skin and in patients with impaired renal function from a large pooled database of Phase II and III clinical trials. Diabetes, Obes Metab. 2010;12(6):495-509. doi:10.1111/j.1463-1326.2010.01214.x

Bosi E, Camisasca RP, Collober C, Rochotte E, Garber AJ. Effects of Vildagliptin on Glucose Control Over 24 Weeks in Patients With Type 2 Diabetes Inadequately Controlled With Metformin. Diabetes Care. 2007;30(4):890-895. doi:10.2337/dc06-1732

Novartis Pharma AG CLAF237-A2304: A Multicenter, Randomized, Parallel-Group Study to Compare the Effect of 24 Weeks Treatment with LAF237 (50 mg daily or twice daily) to Placebo as Add-On Therapy in Patients with Type 2 Diabetes Inadequately Controlled with Pioglitazone Monotherapy. NCT00099853

Garber AJ, Schweizer A, Baron MA, Rochotte E, Dejager S. Vildagliptin in combination with pioglitazone improves glycaemic control in patients with type 2 diabetes failing thiazolidinedione

monotherapy: a randomized, placebo-controlled study. Diabetes. Obes Metab. 2007;9(2):166-174.  
doi:10.1111/j.1463-1326.2006.00684.x

Novartis Pharma AG CLAF237-A2304-E1: A 28-Week Extension to A Multicenter, Randomized, Parallel-Group Study to Compare the Effect of 24 Weeks Treatment with LAF237 (50 mg daily or twice daily) to Placebo as Add-On Therapy in Patients with Type 2 Diabetes Inadequately Controlled with Pioglitazone Monotherapy.

Novartis Pharma AG CLAF237-A2305: A Multicenter, Randomized, Parallel-Group Study to Compare the Effect of 24 Weeks Treatment with LAF237 (50 mg qd or bid) to placebo as Add-On Therapy in Patients with Type 2 Diabetes Inadequately Controlled with Glimepiride Monotherapy.

Novartis Pharma AG CLAF237-A2305-E1: A 28-Week Extension to A Multicenter, Randomized, Parallel-Group Study to Compare the Effect of 24 Weeks Treatment with LAF237 (50 mg daily or twice daily) to placebo as Add-On Therapy in Patients with Type 2 Diabetes Inadequately Controlled with Glimepiride Monotherapy.

Novartis Pharma AG CLAF237-A2327: A Multicenter, Randomized, Double-Blind, Active Controlled Study to Compare the Effect of 24 Weeks Treatment with LAF237 50 mg bid to Rosiglitazone 8 mg qd in drug naïve patients with type 2 Diabetes.

Novartis Pharma AG CLAF237-A2327-E1: A 28-Week Extension to A Multicenter, Randomized, Double-Blind, Active Controlled Study to Compare the Effect of 24 Weeks Treatment with LAF237 50 mg bid to Rosiglitazone 8 mg daily in drug naïve patients with type 2 Diabetes.

Novartis Pharma AG CLAF237-A2355: A Multicenter, Randomized, Double-Blind, Active Controlled Study to Compare the Effect of 24 Weeks Treatment with Combination Therapy of LAF237 and Pioglitazone to LAF237 Monotherapy or Pioglitazone Monotherapy in Drug Naïve Patients with type 2 Diabetes.

Novartis Pharma AG CLAF237-A2384: A Multicenter, Randomized, Double-Blind Study to Compare the Effects of 24 Weeks Treatment with LAF237 (50 mg qd, 50 mg bid or 100 mg qd) to Placebo in Drug Naïve Patients with Type 2 Diabetes.

Novartis Pharma AG CLAF237-A23119 GALIANT: A multi-center, randomized, open-label, active controlled, parallel arm study to compare the efficacy of 12 weeks of treatment with Vildagliptin 100mg, qd to thiazolidinedione as add-on therapy in patients with type 2 diabetes inadequately controlled with metformin monotherapy in a community-based practice setting.

Novartis Pharma AG CVAH631-C2301: A Randomized, Double-Blind, Multicenter, Multifactorial, Placebo-Controlled, Parallel Group Study to Evaluate the Efficacy and Safety of Valsartan 160 and 320 mg and Hydrochlorothiazide (12.5 and 25 mg) Combined and Alone in Hypertensive Patients.

Novartis Pharma AG CVAH631-C2301-S1: Pharmacogenetic sub-study for: A Randomized, Double-Blind, Multicenter, Multifactorial, Placebo-Controlled, Parallel Group Study to Evaluate the Efficacy and Safety of Valsartan 160 and 320 mg and Hydrochlorothiazide (12.5 and 25 mg) Combined and Alone in Hypertensive Patients (CVAH631-C2301).

Novartis Pharma AG CVAH631-C2301-E1: A 54-week open-label extension to a randomized, double-blind, multicenter, placebo-controlled, parallel group study to evaluate the efficacy and safety of valsartan (320mg) and hydrochlorothiazide (12.5 and 25mg) combined and alone, valsartan 160mg and valsartan 160mg/ hydrochlorothiazide 12.5mg in hypertensive patients (extension of CVAH631-C2301).

Novartis Pharma AG PRSW-GN-305: A phase III, multi-center, randomized, double-blind, placebo-controlled, parallel group trial of fourteen day treatment with lansoprazole 15 mg or 30 mg once a day in frequent nighttime heartburn.

Novo Nordisk NN304-1720: Impact of a Self-Adjusted Titration guideline in Subjects with Type 2 Diabetes Mellitus: A 6-Month, Multicenter, Open-label, Randomized, Parallel-Group, Treat-to-Target of the Efficacy and Safety of Levemir® (insulin detemir injection).

Novo Nordisk NN4440-1794: Repaglinide and Metformin Combination Tablet (NN4440) in a T1D Regimen Compared to a BID Regimen and BID Avandamet in Subjects with Type 2 Diabetes: A Twenty-Six Week, Open-Label, Multicenter, Randomized, Parallel Group Trial to Investigate Efficacy and Safety.

Raskin, P., Lewin, A., Reinhardt, R., Lyness, W. and for the Repaglinide/Metformin Fixed-Dose Combination Study Group (2009), Twice-daily and three-times-daily dosing of a repaglinide/metformin fixed-dose combination tablet provide similar glycaemic control. *Diabetes, Obesity and Metabolism*, 11: 947–952. doi: 10.1111/j.1463-1326.2009.01069.x

Raskin, P., Lewin, A., Reinhardt, R., Lyness, W. and for the Repaglinide/Metformin Fixed-Dose Combination Study Group (2009), Twice-daily dosing of a repaglinide/metformin fixed-dose combination tablet provides glycaemic control comparable to rosiglitazone/metformin tablet. *Diabetes, Obesity and Metabolism*, 11: 865–873. doi: 10.1111/j.1463-1326.2009.01062.x

Novo Nordisk BIAsp-1714: Effects of NovoLog® Mix 70/30 (biphasic insulin aspart 70/30) BID and QD vs. Byetta™ (exenatide) BID on Glycemic Control: A Multicenter, 24-Week, Open-Label, Parallel Group Study in Patients with Type 2 Diabetes Mellitus not Achieving Glycemic Targets with Metformin and a Sulfonylurea.

Novo Nordisk BIAsp-2191: NovoLog Mix 70/30 (biphasic insulin aspart 70/30) bid vs. Once Daily Lantus (insulin glargine) in Subjects with Type 2 Diabetes and Inadequate Glycemic Control on Basal Insulin Plus Oral Antidiabetic Therapy: A Multicenter, Randomized, Open-Label, Parallel Group Study.

Novo Nordisk NN304-2175: A 26-week, Multi-Center, Open-Label, Parallel, 2:1 Randomized Treat-to-Target Trial Comparing Efficacy and Safety of Insulin Detemir Versus Insulin Glargine Using a Basal-Bolus Regimen with Insulin Aspart as Mealtime Insulin in Subjects with Type 2 Diabetes.

Novo Nordisk NN1998-1683: Inhaled Mealtime Insulin with the AERx® iDMS plus Pioglitazone versus Pioglitazone alone in Type 2 Diabetes: A 26-Week, Open-Label, Multicentre, Randomised, Parallel Trial to Investigate Efficacy and Safety.

Ono Pharma USA, Inc. ONO-5129POU006: Randomized, Double-Blind, Placebo-Controlled, Pharmacodynamic Evaluation of ONO-5129 in Patients with Treatment Naïve Type 2 Diabetes Mellitus.

Perlegen 2005111: Pharmacogenomic Sample Collection From Subjects with Type 2 Diabetes Treated with Pioglitazone or Rosiglitazone.

Pfizer A0531063 ADHERE: A Multi-Center, Randomized, Double-Blind, Double-Dummy Study Evaluating the Safety and Efficacy of the Addition of Amlodipine to Quinapril or Losartan in the treatment of diabetic hypertensive subjects.

Pfizer A2581049 BONES: Double-blind, placebo-controlled, dose ranging trial to evaluate the efficacy of Atorvastatin on bone mineral density and markers for bone turnover in postmenopausal women with dyslipidemia and at risk for osteoporosis.



Pfizer A3071026: Phase 2 multi-center, double blind placebo-controlled, randomized, parallel group, dose ranging study of the efficacy, safety, tolerability and pharmacokinetics of Torcetrapib and open-label Atorvastatin when concurrently administered orally once daily (QD) for 12 weeks to subjects with elevated low-density lipoprotein cholesterol and without overt cardiovascular disease.

Pfizer A3071027: Phase 2 multi-center, double blind placebo-controlled, randomized, parallel group, dose ranging study of the efficacy, safety, tolerability and pharmacokinetics of Torcetrapib and open-label Atorvastatin when concurrently administered orally twice daily (BID) for 12 weeks to subjects with elevated low-density lipoprotein cholesterol and without overt cardiovascular disease.

Pfizer A3191053: Study of the efficacy and tolerability of once daily Celebrex® (celecoxib) and twice daily naproxen vs. placebo in the treatment of Hispanic subjects with osteoarthritis of the knee.

Pfizer A3191069: Efficacy and Safety of Celebrex® (celecoxib) Versus Placebo in the Treatment of Patients With Osteoarthritis of the Knee Who Were Unresponsive to Naproxen and Ibuprofen.

Pfizer A3191082: A Double-Blind, Placebo Controlled Study of the Efficacy and Tolerability of Once Daily Celebrex® (celecoxib) vs. Placebo in the Treatment of Subjects with Osteoarthritis of the Knee Non-Responsive to Naproxen and Ibuprofen.

Pfizer A3191172 PRECISION: Prospective Randomized Evaluation of Celecoxib Integrated Safety vs. Ibuprofen or Naproxen.

Pfizer A3191331 GI-REASONS: Gastrointestinal (GI) Randomized Event and Safety Open-label NSAID Study (GI-REASONS): A Randomized, Open-Label, Blinded-Endpoint, Parallel-Group Trial of GI Safety of Celecoxib Compared with Non-Selective Nonsteroidal Anti-inflammatory Drugs (NSAIDs) in Osteoarthritis Patients.

Pfizer A3841045 TOGETHER: A 6-Week, Prospective, Randomized, Double-Blind, Double-Dummy Phase IV Clinical Trial Designed to Evaluate the Efficacy of an Aggressive Multi-Risk Factor Management Strategy with Caduet (A3841045) versus a Guideline-Based Approach in Achieving Blood Pressure and Lipid Goals in Hypertensive Subjects with Additional Risk Factors.

Pfizer A4141001-4033 GEM Study: An 8-Week, Double-Blind, Randomized, Placebo-Controlled, Dose Ranging Study of the Efficacy and Safety Gemcabine Administered in Combination With Atorvastatin or Alone to Hypercholesterolemic Patients.

Pfizer A5091018: A Phase 3, Double-Blind, Placebo-Controlled, Randomized, Parallel Group, Multicenter Study of the Efficacy, Safety, and Tolerability of Fixed Combination Torcetrapib/Atorvastatin Administered Orally, Once Daily for 6 Months, Compared to Atorvastatin Alone or Placebo, in Subjects with Mixed Dyslipidemia (Fredrickson Types IIa and IIb).

Pfizer A5091043: Phase 3 Multicenter, Double-Blind, Randomized, Parallel Group Evaluation of the Fixed Combination Torcetrapib/Atorvastatin, Administered Orally, Once Daily (QD), Compared with Atorvastatin Alone, on the Occurrence of Major Cardiovascular Events in Subjects with Coronary Heart Disease or Risk Equivalents.

Sankyo CS0917-A-U204: A Randomized, Double-Blind, Placebo-Controlled 12-Week Efficacy and Safety Study of CS-917 200 mg BID and 400 mg QHS in Subjects with Type 2 Diabetes.

sanofi-aventis ACT11308: Randomized, double-blind, placebo-controlled study of the effect of a single injection of SAR164877 (REGN475) on reduction of pain from vertebral fracture associated with osteoporosis.

sanofi aventis EFC5107 Rimonabant (SR141716) RAPSODI: A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter study to assess the efficacy and safety of long-term administration of rimonabant in the Prevention of Type 2 Diabetes in patients with prediabetic status (i.e., Impaired Fasting Glucose (IFG), Impaired Glucose Tolerance (IGT) or both).

sanofi-aventis EFC10781: A randomized, placebo-controlled, 2-arm parallel-group, multicenter study with a 24-week double-blind treatment period assessing the efficacy and safety of lixisenatide in patients with Type 2 diabetes insufficiently controlled with insulin glargine and metformin.

sanofi aventis H901-4033 GOAL A1c: Impact of Point-of-Care vs. Laboratory Testing of Hemoglobin A1c (HBA1c), and Intense vs. Standard Monitoring of Titration Algorithm Adherence on Glycemic Control in Type 2 Diabetes Subjects, who are Inadequately Controlled on Oral Anti-Hyperglycemic Therapy, and Starting Lantus: A 2 x 2, Randomized, Open-Label Trial.

sanofi-aventis HMR1964A/3515: All To Target Trial Lantus® (insulin glargine) with stepwise addition of APIDRA (insulin glulisine) or Lantus with one injection of Apidra ®vs. a twice-daily premixed insulin regimen (Novolog® Mix 70/30) in adult subjects with type 2 diabetes failing dual or triple therapy with oral agents: a 64-week, multi-center, randomized, parallel, open label clinical study.

sanofi aventis L8890: Prospective, Observational Registry and Patient Survey of the Management of Men with Symptomatic Benign Prostatic Hypertrophy (BPH): BPH Registry and Patient Survey.

sanofi-aventis LACE-EMR: A Retrospective Clinical Practice Evaluation of Lantus Cost-Effectiveness Compared to Levemir in Insulin-Naïve Type 2 Diabetes Patients.

sanofi-aventis TREAT: The Telithromycin Respiratory Effectiveness Trial. An Open Label Multicenter Comparative Trial of Telithromycin in Community Acquired Upper Airway Infections.

Takeda 01-04-TL-475-002: A Double-Blind, Randomized Parallel Group Study to Evaluate the Safety, Tolerability and Efficacy of TAK-475 Alone or Co-Administered with Atorvastatin in Patients with Primary Dyslipidemia.

Takeda 01-06-TL-322OPI-004: A Multicenter, Randomized, Double-Blind Study to Determine the Efficacy and Safety of the Addition of SYR-322 25 mg versus Dose Titration from 30 mg to 45 mg of ACTOS Pioglitazone HCl in Subjects with Type 2 Diabetes Mellitus Who Have Inadequate Control on a Combination of Metformin and 30 mg of Pioglitazone HCl Therapy.

Takeda 01-04-TL-475-009: A Double-Blind, Randomized Placebo-Controlled Study to Evaluate the Efficacy and Safety of TAK-475 (50 MG or 100 MG) when Co-Administered with Atorvastatin (10 MG to 40 MG) in Subjects with Primary Hypercholesterolemia.

Takeda 01-04-TL-475-010: An Open-Label Extension Study to Evaluate the Safety and Tolerability of TAK-475 in Subjects with Hypercholesterolemia.

Wyeth Research 3151A1-4415-NA (B2061006): A Multicenter, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate Functional Outcome in Outpatients with Major Depressive Disorder Treated with Desvenlafaxine Succinate Sustained Release.

Wyeth Research 0600B-416-US: Patients Outcomes With Education, Drug Therapy, and Support (POETS) - A Multi-Center, Open-Label, Randomized, Study to Evaluate Depressed Patients Treated With Venlafaxine Extended-Release Vs. Venlafaxine Extended-Release Plus Dialogues Time to Talk Program in a Primary Care Setting.

Wyeth Research 0600B-100470: An Open-Label, Randomized, Rater-Blinded Study to Compare Rate of Remission in Patients with Major Depressive Disorder Treated With Venlafaxine Extended-Release Versus Selective Serotonin Reuptake Inhibitors Using Treatment Algorithms.

Wyeth Research 0600B-101334: A Randomized, Double-Blind, Placebo-Controlled, Pilot Study to Evaluate the Efficacy and Safety of Venlafaxine XR in Depressed and Anxious Patients With Multiple, Unexplained Somatic Symptoms in Primary Care.

(Investigator Initiated): A Study of the Effect of Treatment with Salmeterol and Prednisone on Reversal of Decline in Lung Function in Asthmatics (see publication above).

(Investigator Initiated): A Retrospective Review of Compliance with NCEP Guidelines, Treatment Efficacy and Outcomes in a Case Managed Lipid Treatment Clinic (see publication above).

(Investigator Initiated): A Study of the Effect of Enteric Coated Charcoal on the Absorption of a H-2 Receptor Antagonist, Gastric pH, and Stool Color (see publication above).

### **XIII. Conflict of Interest Disclosure**

Dr. Yates has current professional advisory relationships with Curantis Solutions LLC, Vattaca LLC, Hewlett Packard Enterprise Services Group, United HealthCare and several law firms (primarily related to expert witness activity in medical administration and medical malpractice litigation, both plaintiff and defense).

He has had prior professional advisory or other economic relationships with Glenview Capital LLC, Gerson Lehrman Group, General Electric Medical Systems Information Technology Division, Select Specialty Hospitals, iHeart Imaging, Aetna, Blue Cross / Blue Shield, BravoHealth, HealthSpring, Humana, Superior Health Plan, and other payors.

Dr. Yates has performed consulting work and/or human clinical trials in association with or sponsored by pharmaceutical and health care improvement organizations including: Ingenix, Inc., General Electric Medical Systems Information Technology Division, Gilead Sciences, Inc., Boehringer Ingelheim Pharma GmbH & Co., Eli Lilly and Company, Forest Research Institute, BioCryst Pharmaceuticals, sanofi-aventis, Wyeth Research Institute, Bristol-Myers Squibb, GlaxoSmithKline plc, Kowa Pharmaceuticals, DOV Pharmaceutical, Inc., Pfizer Pharmaceuticals, Takeda Pharmaceuticals North America, Myogen Pharmaceuticals, Akros Pharma, Inc., Novo Nordisk, Johnson & Johnson Clinical Research, Novartis, Alba Pharmaceuticals, Genentech, Hoffman-La Roche Inc., MannKind Corporation, Auxilium, ONO Pharma USA, Inc., Merck, Amylin Pharmaceuticals, Acambis, AstraZeneca Pharmaceuticals, Janssen Pharmaceutica, Schering-Plough, Perlegen, Kos Pharmaceuticals, Cubist Pharmaceuticals and Genomics Collaborative, Inc.