

Clinical Study Experience

Losartan Intervention for Endpoint Reduction in Hypertension (LIFE) Study, Merck & Company, Inc.

Medtronic Wiktor Coronary Stent Delivery System, Abrupt or Threatened Closure and Failed Intervention Clinical Protocol

Otsuka America Pharmaceutical, Inc., VEST Trial, Protocol Number 22-94-201 A randomized, double-blind, placebo controlled, multiple dose study of the chronic administration of vesnarinone in heart failure

Stent Antithrombotic Regimen "STARS" Study, Johnson and Johnson Interventional Systems

Reduced Anticoagulation after Vein Graft Stenting "RAVES" Pilot Study, Johnson and Johnson Interventional Systems

B Braun "E" PTCA Dilatation Catheter

ACS Multilink Stent Clinical Study, GUIDANT, Inc.

Pacesetter Passive Plus DX Model 1342T/1346T Bipolar Steroid Eluting, Passive Fixation Endocardial Pacing Lead, Pacesetter, Incorporated

Predictors and Outcomes of Stent Thrombosis "POST" Registry, Stanford University Medical Center, Stanford, California

Spectranetics CVX-300 Excimer Laser Systems for Percutaneous Coronary Angioplasty and Percutaneous Peripheral Angioplasty

Guidance by Ultrasound Imaging for Decision Endpoints (GUIDE) Trial - Phase I

Guidance by Ultrasound Imaging for Decision Endpoints (GUIDE) Trial - Phase II

USCI Rapid Flow Perfusion Catheter (RFPC) Protocol No. 3101

Thrombolytic Drugs for Acute MI, Rapid Administration of Activase in Myocardial Infarction (RAAMI), Genentech, Incorporated

Cordis Helix and Helix II PTCA Dilatation Catheters

Cordis Orion and Orion II Steerable PTCA Balloon Catheters

Leocor Perfusion Catheter Clinical Study

SCIMED ACE Percutaneous Transluminal Coronary Angioplasty Catheter - 1 cm. and Flexible (2 cm.) Tip Models

USCI Autoperfusion Catheter - Investigations I & II

Johnson and Johnson Interventional Systems Percutaneous Recanalization of Stenotic Human Saphenous Vein Bypass Grafts with Balloon Expandable Intracoronary Stents

Maxima Oxygenator/Intersept Closed Chest Circuit with Carmeda Bio-Active Surface (CBAS)

Integra I and Integra II Single Lumen Balloon Catheter Clinical Study

GV Medical, Incorporated (GVM) LASTAC System for Treatment of Ischemic Heart Disease

Interventional Technologies, Incorporated, Coronary Atherectomy Clinical Study

Medtronic Elite Pacemaker Model(s) 7074/7075/7076/7077 Clinical Study

Primary Angioplasty in Myocardial Infarction (PAMI) Trial

A Multicenter, Placebo-Controlled, Double-Blind, Randomized, Comparison of Altace (ramipril) with Placebo in Elderly Patients with Mild to Moderate Hypertension, Hoechst-Roussel Pharmaceuticals, Inc.

Medtronic Jewel PCD

TRAC-5 Rotating Atherectomy Device, Down, Corning, Wright, Theratek, Incorporated

GV Med Laser - Peripheral Application, GV Medical, Incorporated

Percutaneous Transluminal Coronary Angioplasty vs. Coronary Stenting of DeNovo Saphenous Vein Bypass Grafts: A Randomized Comparative Trial (SAVED Trial), Johnson and Johnson Interventional Systems, Inc.

Medtronic CapSure SP (Model 5024M and 5542M) Transvenous Tined Steroid Eluting Pacing Leads - Control Study

Laser Thrombolysis Clinical Trial - Phase II, Palomar Medical Technologies, Incorporated

ACS Perfusion Trial, Advanced Cardiovascular Systems

Coronary Ultrasound Selected Invasive Decisions (CUSSID) Trial

Stent Treatment Region (assessed by) Ultrasound Tomography - The "STRUT" Trial, Stanford University, Stanford, California

Medtronic, Incorporated Model 4068 (Steroid-tipped) Pacemaker Lead

Medtronic Thera VDD Pacing System

A Single-Blind Randomized Study of the Safety and Effectiveness of Percutaneous Transluminal Myocardial Revascularization (PTMR) Performed with the Eclipse Holmium Laser as an Adjunct to Percutaneous Coronary Intervention – Study #TMR012-A, Eclipse Surgical Technologies, Inc. – Phase II

Protocol CV154-009-027: A Double-Blind, Randomized, Placebo Controlled Study of the Efficacy and Safety of BMS-207940, A Selective Endothelin_A Receptor Antagonist, In Subjects with Intermittent Claudication, Bristol-Myers Squibb – Phase II

Protocol CV123-231: A Double-Blind Comparison of 80 and 160 mg. Doses of Pravastatin with Placebo in Hypercholesterolemic Subjects, Bristol-Myers Squibb – Phase III

Protocol Number 244: An Open Study, with Blinded Endpoint Assessment, to Assess the Safety, Tolerability and the Effect on Coronary Artery Patency of Intravenous AR-C69931MX as both Monotherapy and Adjunct to Activase in Patients with ST-elevation Myocardial Infarction (STEP AMI) - AstraZeneca LP, Henry Ford Coordinating Center, Duke Clinical Research Institute – Phase II

Protocol CV137-120: Omapatrilat Cardiovascular Treatment Assessment Versus Enalapril (OCTAVE) – Bristol-Myers Squibb, Inc. - Phase III

Study #CO116T31: A Phase III, Randomized, Open-Label Trial Evaluating the Efficacy and Safety of Reopro[®] (Abciximab) in Combination with Reduced Dose Retavase[®]/Rapilysin[™] (Recombinant Plasminogen Activator, Reteplase, r-PA) for the Treatment of Acute Myocardial Infarction (GUSTO IV AMI) – Eli Lilly, Co., Centocor, The Cleveland Clinic Foundation – Phase III

Protocol #EFC7086 - Clopidogrel for Reduction of Events During Observations – A Double-Blind Randomized Trial of Clopidogrel 300 mg. Loading Dose and Aspirin 325 mg. Followed by Clopidogrel 75 mg. and Aspirin Daily Compared with Placebo Loading Dose Followed by Clopidogrel 75 mg. and Aspirin Daily For The Prevention of Vascular Events and All-Cause Mortality in Patients Undergoing Percutaneous Coronary Intervention (CREDO) Trial – Bristol-Myers Squibb/Sanofi Pharmaceuticals, Inc., The Cleveland Clinic Foundation

Protocol CV137-068: Omapatrilat versus Enalapril Randomized Trial of Utility in Reducing Events (OVERTURE) – Bristol-Myers Squibb, Inc. - Phase III

Protocol #100306: A Single Arm Open Label Study of Cerivastatin (Baycol[®]) in Community Based Patients with Hypercholesterolemia at Risk for Cardiovascular Disease and Patients with Cardiovascular Disease (CRISP) – Bayer Corporation and Mayo Physicians Alliance for Clinical Trials (MPACT) – Phase III

Multi-Center InSync Randomized Clinical Evaluation (MIRACLE) Trial – Medtronic, Inc.

Protocol No.: 180-00/ZOC467: A Multicenter, Randomized, Controlled, Double-Blind Trial to Investigate the Clinical Efficacy and Tolerability of Early Treatment with Simvastatin 40 mg. Daily for 30 Days, Followed by Simvastatin 80 mg. Daily Thereafter in Tirofiban-Treated Acute Coronary Syndrome Patients Who Have Been Randomized to Receive Enoxaparin or Unfractionated Heparin in Conjunction with Aspirin (A to Z Trial) – Merck & Co., Inc., The TIMI Study Group, Duke Clinical Research Institute – Phase IV

Occluded Artery Trial (OAT) – National Heart, Lung and Blood Institute, St. Luke's/Roosevelt Hospital Center, Maryland Medical Research Institute and Duke Clinical Research Institute

Multicenter Automatic Defibrillator Implantation Trial II (MADIT) – GUIDANT/CPI

Ventricular Resynchronization Therapy Randomized (VECTOR) Trial – St. Jude Medical, Inc.

The Advanced Elements of Pacing (ADEPT) Trial – Medtronic, Inc.

Protocol #50-0045: Cooling as an Adjunctive Therapy to Percutaneous Intervention in Patients with Acute Myocardial Infarction – COOL MI, Radiant Medical

Protocol #4522US/0013: National Cholesterol Education Program Evaluation Project Utilizing Novel E-Technology (NEPTUNE II), AstraZeneca Pharmaceuticals, Radiant Research Development

Protocol ENO.GMA-401 – A Prospective, Randomized, Open-Label, Multicenter Study in Patients Presenting with Acute Coronary Syndromes (SYNERGY Trial), Aventis Pharmaceuticals, Duke Clinical Research Institute – Phase IV

Protocol A3841003: A Multinational Prospective, Randomized, Double-Blind, Multi-Center, Placebo-Controlled Study to Evaluate Efficacy and Safety of a Fixed Combination Therapy of Amlodipine and Atorvastatin in the Treatment of Concurrent Hypertension and Hyperlipidemia (RESPOND) Study, Pfizer Pharmaceuticals, Integrated Research – Phase III

Protocol #VAA489A2201: A randomized, double-blind, multicenter, multifunctional, placebo-controlled, parallel group study to evaluate the safety and efficacy of valsartan and amlodipine alone and in combination in hypertensive patients, Novartis Pharmaceuticals Corporation – Phase II/III

Organized Program to Initiate Life-Saving Treatment in Hospitalized Patients with Heart Failure – OPTIMIZE-HF Registry, GlaxoSmithKline

Inhibition of Unnecessary RV Pacing with AV Search Hysteresis in ICDs – INTRINSIC RV Study, GUIDANT Corporation

Protocol #50-0045: Cooling as an Adjunctive Therapy to Percutaneous Intervention in Patients with Acute Myocardial Infarction – COOL MI II, Radiant Medical

Protocol #50-0212: Cooling to Prevent Radiocontrast Nephropathy in Patients Undergoing Coronary Catheterization – COOL RCN – Pilot Study, Radiant Medical

Protocol #XRP4563/4001: Safety and Efficacy of Enoxaparin in PCI patients, an international randomized Evaluation – STEEPLE Trial, Aventis Pharmaceuticals - Phase II-III

ADHERE Longitudinal Module – Registry of Severe Heart Failure Patients at High Risk for Rehospitalization, Scios, Inc.

Protocol #EFC3197: An international, randomized, double-blind study evaluating the efficacy and safety of fondaparinux versus enoxaparin in the acute treatment of unstable angina or non ST-segment elevation myocardial infarction acute coronary syndromes – Michelangelo – OASIS 5, Sanofi-Synthelabo, Inc., Duke Clinical Research Institute, The University of Chicago and the Canadian Cardiovascular Collaboration Population Health Research Institute – Phase III

Protocol #2003141: A Multicenter, Randomized, Double-Blind, Parallel-group, Placebo-Controlled Study of 2 mg/kg Bolus plus 24-hour 0.05 mg/kg/hr Infusion of Pexelizumab in Patients Undergoing Coronary Artery Bypass Grafting with Cardiopulmonary Bypass (PRIMO-CABG II), Proctor & Gamble Pharmaceuticals and Alexion Pharmaceuticals, Inc. – Phase III

Protocol #EFC4505: Clopidogrel for High Atherothrombotic Risk and Ischemic Stabilization, Management and Avoidance (CHARISMA) Study, Sanofi-Synthelabo, Bristol Myers Squibb Pharmaceuticals, Cleveland Clinic Coordinating Center (C⁵) – Phase III

Protocol #156-03-246: Multicenter, Randomized, Double-blind, Placebo-controlled Study to Evaluate the Long Term Efficacy and Safety of Oral Tolvaptan Tablets in Subjects Hospitalized with Worsening Congestive Heart Failure – EVEREST Trial, Otsuka Maryland Research Institute, Inc. – Phase III

Reduction of Atherothrombotics for Continued Health Registry – The Reach Registry, Sanofi/Synthelabo and Bristol Myers Squibb

Protocol #2003056: A Multicenter, Randomized, Double-Blind, Parallel-group, Placebo Controlled Study of Pexelizumab in Patients with Acute Myocardial Infarction Undergoing Primary Percutaneous Coronary Intervention – (APEX – AMI), Proctor & Gamble Pharmaceuticals and Alexion Pharmaceuticals, Inc. – Phase III

Protocol #4522US/0001: A 12-Week, Randomized, Open-Label, 3-Arm, Parallel Group, Multicenter, Phase IIIb Study Comparing the Efficacy and Safety of Rosuvastatin 20 mg. and 40 mg. with that of Atorvastatin 80 mg. in Subjects with Acute Coronary Syndromes (LUNAR) Study, AstraZeneca, ICON Clinical Research – Phase IIIb

Protocol #M-INTG03-062 (Millennium); PO3684 (Schering-Plough): Early Glycoprotein IIb/IIIa Inhibition in Non-ST-segment Elevation Acute Coronary Syndrome: A Randomized, Placebo-Controlled Trial Evaluating the Clinical Benefits of Early Front-loaded Eptifibatide in the Treatment of Patients with Non-ST-Segment Elevation Acute Coronary Syndrome (EARLY ACS) – Phase IIIb

Ventricular Automatic Capture Assessment (ULTRA) Study, GUIDANT Corporation

Protocol A034: Follow-Up Serial Infusions of Natrecor (nesiritide) for the Management of Patients with Heart Failure – FUSION II, SCIOS, Inc. – Phase IIb

Protocol #EFC5555: A Placebo-Controlled, Double Blind, Parallel Arm Trial to Assess the Efficacy of Dronedarone 400 mg bid for the Prevention of Cardiovascular Hospitalization or Death From Any Cause in Patients with Atrial Fibrillation/Atrial Flutter (AF/AFL) – The ATHENA Trial, Sanofi-Synthelabo Research, a division of Sanofi-aventis – Phase II-III

Protocol #H7T-MC-TAAL: A Comparison of CS-747 and Clopidogrel in Acute Coronary Syndrome Patients who are to Undergo Percutaneous Coronary Intervention – TRITON-TIMI 38, Eli Lilly and Company, Sankyo Company Limited, Japan – Phase III

Pacing Evaluation – Atrial Support Study in Cardiac Resynchronization Therapy – PEGASUS CRT, GUIDANT Corporation

Protocol #20050222: A Double-blind, Randomized Placebo-controlled, Multicenter study to Assess the Efficacy and Safety of Darbepoetin Alfa Treatment on Mortality and Morbidity in Heart Failure (HF) Subjects with Symptomatic Left Ventricular Systolic Dysfunction and Anemia – RED HF Trial, Amgen, Inc. – Phase III

Protocol # D5130C05262: A Randomized, Double-blind, Parallel Group, Phase Efficacy and Safety of AZD6140 Compared with Clopidogrel for Prevention of Vascular Events in Patients with Non-ST or ST Elevation Acute Coronary Syndromes (ACS) – PLATO Trial – AstraZeneca – Phase III

Protocol #P04103: **IM**proved **R**eduction of **O**utcomes: **V**ytorin **E**fficacy **I**nternational **T**rial (IMPROVE IT) – A Multicenter, Double Blind, Randomized Study to Establish the Clinical Benefit and Safety of Vytorin (ezetimibe/simvastatin) vs. Simvastatin Monotherapy in High Risk Patients Presenting with Acute Coronary Syndrome, Merck/Schering-Plough Pharmaceuticals the developer of Vytorin®, and Merck & Co. – Phase IV

Protocol #EFC5965: CURRENT / OASIS 7 - Clopidogrel optimal loading dose Usage to Reduce Recurrent Events/ Optimal Antiplatelet Strategy for Interventions - Randomized, multinational, double-blind study, comparing a high loading dose regimen of clopidogrel versus standard dose in patients with unstable angina or non-ST segment elevation myocardial infarction managed with an early invasive strategy – Sanofi-Aventis – Phase III

InSync Registry – Medtronic, Inc.

Protocol #CG104: A Randomized, Double-Blind, Double-Dummy, Parallel Group, Phase 3 Efficacy and Safety study of CGT-2168 Compared with clopidogrel to Reduce Upper Gastrointestinal Events including Bleeding and Symptomatic Ulcer Disease – Cogentus Pharmaceuticals – Phase III

Protocol # E5555-G000-201: A Randomized, Double-Blind, Placebo-Controlled Study of the Safety and Tolerability of E5555, and its Effects on Markers of Intravascular Inflammation in Subjects with Coronary Artery Disease – Eisai Limited – Phase II

Protocol #NC20971: A phase III, double-blind, randomized placebo-controlled study, to evaluate the effects of RO4607381 – Hoffman, LaRoche, Inc. – Phase III

The TIMI 38 Coronary Stent Registry (CRS): Long-Term Follow-Up of Subjects with PCI and Stenting for ACS – Brigham and Women's Hospital, TIMI Study Group and Harvard Medical School

Protocol # H7T-MC-TABY(a): A Comparison of Prasugrel and Clopidogrel in Acute Coronary Syndrome (ACS) Subjects with Unstable Angina/Non-ST-Elevation Myocardial Infarction (UA/NSTEMI) Who are Medically Managed – The TRILOGY ACS Study – Eli Lilly and Company – Phase Addendum H7T-MC-TABY(1) – Phase III