Research trials conducted at Community Hospital Clinical Research Center

Cardiology

Amgen, Protocol 2005002. A Double-blind, Randomized, Placebo-controlled, Multicenter, Phase III 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. Dr. Bournique, Dr. Lee, Dr. Jetty

ARYx Protocol ATI 5923 CLN 505: A Randomized, Double Blind Comparison of ATI 5923, a Novel Vitamin K Antagonist, with Warfarin in Patients Requiring Chronic Anticoagulation, Embrace, Phase II. Dr. Jetty, Sheri Lantz, FNP

Astrazeneca. Protocol: 4522US/0001. A 12-Week, Randomized, Open-Label, 3-Arm, Parallel Group, Multicenter, Phase IIIB Study Comparing the Efficacy and Safety of Rosuvastatin 20mg and 40mg with that of Atorvastatin 80 mg in Patients with Acute Coronary Syndromes. Dr. Bournique, Dr. Lee, Dr. Jetty. 2005

Bayer: BAY 59-7939/12839: Phase III, MAGELLaN – Multicenter, rAndomized, paralleIGroup Efficacy and safety study for the prevention of venous thromboembolism in hospitalized medically iLL patients comparing rivaroxabaN with enoxaparin – Dr. Kabir, Dr. Malik, Dr. Blankenship, Dr. Rocco, Dr. Jetty, Dr. Ghumman, Sheri Hughel (Lantz), FNP 2009-2011

Brigham and Women’s Hospital: PRE-DETERMINE: Biologic Markers and MRI SCD Cohort Study. Dr. Jetty, Dr. Alexander, Dr. Oscherwitz, Dr. Williams. 2012-

Bristol Myers Squibb: CV185030 (Aristotle) A Phase III, Active (Warfarin) Controlled, Randomized, Double-Blind, Parallel Arm Study To Evaluate Efficacy And Safety Of Apixaban In Preventing Stroke And Systematic Embolism In Subjects With Nonvalvular Atrial Fibrillation. Dr. Bournique, Dr. Lee, Dr. Jetty, Sheri Lantz, FNP. 2007-2011

Cogentus, Protocol CG104. A Randomized, Double-Blind, Double-Dummy, Parallel Group, Phase III Efficacy And Safety Study Of CGT-2168 Compared With Clopidogrel To Reduce Upper Gastrointestinal Events Including Bleeding And Symptomatic Ulcer Disease. Dr. Bournique, Dr. Lee, Dr. Jetty, Sheri Lantz, FNP

Hoffman La Roche Protocol NC20971. A phase III, double-blind, randomized placebo-controlled study, to evaluate the effects of RO4607381 on cardiovascular (CV) risk in stable CHD patients, with adocumented recent Acute Coronary Syndrome (ACS). dal-OUTCOMES. Dr. Jetty, Sheri Lantz, FNP.

Iverson Protocol IG-0109. Warfarin Adverse Event Reduction For Adults Receiving Genetic Testing at Therapy Initiation (WARFARIN). Dr. Jetty, Dr. Tahir Naqvi, Dr. Oscherwitz, Dr. Patel 2012-

Johnson & Johnson. A Prospective, Randomized, Double-Blind, Double-Dummy, Parallel-Group, Multicenter, Event-Driven, Non-Inferiority Study Comparing the Efficacy and Study Drug With Adjusted-Dose Oral Warfarin for the Prevention of Stroke and Non-Central Nervous System Systemic Embolism in Subjects With Non-Valvular Atrial Fibrillation. ROCKET. Phase III Dr. Jetty
Lilly H7T-MC-TABY(b).  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. Phase III. Dr. Jetty, Sheri Lantz, FNP

Merck Protocol: MK-4448 Protocol 006: A Phase II, Open-Label, Dose Exposure Confirmation Study to Evaluate the Pharmacokinetics and Safety and Tolerability of Betrixaban (MK-4448) in Adult Patients with Non-Valvular Atrial Fibrillation or Atrial Flutter. Dr. Jetty, Sheri Lantz, FNP

Merck/University of Oxford: CTSUREVEAL1; HPS 3 / TIMI 55: REVEAL (Randomized EValuation of the Effects of Anacetrapib through Lipid-modification): A large-scale, randomized placebo-controlled trial of the clinical effects of anacetrapib among people with established vascular disease. Phase III. Dr. Jetty, Dr. Oscherwitz, Dr. Patel

Pozen 32540-302. A 6-Month, Phase III, Randomized, Double-Blind, Parallel-Group, Controlled, Multi-Center Study to Evaluate the Incidence of Gastric Ulcers Following Administration of Either PA32540 or Enteric Coated Aspirin 325 mg in Subjects Who Are at Risk for Developing Aspirin-Associated Ulcers. Dr. Jetty, Dr. Nowak, Sheri Lantz, FNP, Dr. Maier 2009

Reliant Pharmaceuticals, Inc AFFECTS (Atrial Fibrillation: Focus on Effective Clinical Treatment Strategies) Registry. Dr. Bournique, Dr. Lee

Sanofi Protocol: EFC11319 - A randomized, double-blind, placebo-controlled, parallel-group, multicenter phase III study to evaluate cardiovascular outcomes during treatment with lixisenatide in type 2 diabetic patients after an Acute Coronary Syndrome. Dr.Jetty, Dr. Afia Naqvi

Schering-Plough Protocol P04736. A Multi-center, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Safety and Efficacy of SCH 530348 in Addition to Standard of Care in Subjects With Acute Coronary Syndrome: Thrombin Receptor Antagonist for Clinical Event Reduction in Acute Coronary Syndrome (TRA-CER). Phase III. Dr. Jetty, Sheri Lantz, FNP

Scios, Protocol A093. Double-Blind, Placebo-Controlled, Multicenter Acute Study of Clinical Effectiveness of Nesiritide in Subjects With Decompensated Heart Failure (ASCEND-HF). Phase III. Dr. Bournique, Dr. Lee, Dr. Jetty, Sheri Lantz, FNP

Zealand Pharma Protocol: 05-025 A Phase II, Multicenter, Randomized, Flexible Dose Study of ZP120 Administered as I.V. Infusion as Add-On Therapy in Patients with Acute or Sub-Acute Decompensated Chronic Heart Failure NYHA Class III-IV Treated with Furosemid.. Dr. Bournique, Dr. Lee, Dr. Jetty. 2005-2007

Neurology

GlaxoSmithKline. Study TXA107977, a Long-Term Safety Phase III Study of a Combination Product Containing Sumatriptan Succinate and Naproxen Sodium for the Treatment of Migraine in Adolescents. Dr. Blankenship, Dr. Rocco, Dr. Jetty 2007-2009
GlaxoSmithKline. TXA107979. A Randomized, Multicenter, Placebo-Controlled, Parallel Group Phase III Study to Evaluate the Efficacy and Safety of a Combination Product Containing Sumatriptan and Naproxen Sodium for the Acute Treatment of Migraine in Adolescents. Dr. Blankenship, Dr. Rocco, Dr. Jetty 2008-2009


MAP Pharmaceuticals, MAP0004-CL-P301-01 A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Phase III Study of MAP0004 in Adult Migraineurs for a Single Migraine Followed by Open-Label Extensions to 26/52 Weeks. Dr. Blankenship, Dr. Rocco 2008-2010

Merck MK-031-00. A Multi-Center, Double-Blind, Placebo-Controlled, Parallel Group Multiple Attacks Phase III Study to Compare the Efficacy and Safety of Oral MK-0974 With Placebo for the Acute Treatment of Migraine With or Without Aura. Dr. Blankenship, Dr. Rocco 2008-2009

MERCK - MK0974-065 - A Six Month Phase II/III, Randomized, Double-Blind, Placebo-Controlled Clinical Trial to Evaluate the Safety, Tolerability, and Efficacy of Telcagepant (MK-0974) for Prevention of Menstrually Related Migraine in Female Patients with Episodic Migraine. Dr. Blankenship, Dr. Rocco, Sheri Lantz, FNP 2008-2011

Novartis Protocol No.: CFTY720DUS01: A Phase IV, 6-month, Randomized, Active Comparator, Open-label, Multi-Center Study to Evaluate Patient OutComes, Safety and Tolerability of Fingolimod 0.5 mg/day in Patients with Relapsing Forms of Multiple Sclerosis who are candidates for MS therapy change from Previous Disease Modifying Therapy (EPOC). Dr. Blankenship, Dr. Rocco, Dr. Yang. 2010-2012

Novartis Protocol NO: CFTY720DUS09: A Phase IV, 12-month, Prospective, Randomized, active-controlled, open-label study to Evaluate the patient retention of Fingolimod vs. approved first-line disease modifying therapies in adults who are in Early stages of treatment for Relapsing remitting multiple sclerosis (PREFER). Dr. Blankenship, Dr. Stevens, Kathy Glass, Dr. Yang 2012-

**Pulmonology**

AstraZeneca D5896C00027: A 26 week, randomized, double-blind, parallel-group, active controlled, multicenter, multinational safety study evaluating the risk of serious asthma-related events during treatment with Symbicort®, a fixed combination of inhaled corticosteroid (ICS) (budesonide) and a long acting β2-agonist (LABA) (formoterol) as compared to treatment with ICS (budesonide) alone in adult and adolescent (≥12 years of age) patients with asthma. Principal Investigator. Phase III/IV.

Chiesi, US/PR/033009/001/05 Phase II A Randomized, Controlled, 14-Treatment Day, Multicenter Study To Determine The Optimal Efficacious And Safe Dose Of Chf 4226 In A Metered Dose Inhaler In Treating Patients With Chronic Obstructive Pulmonary Disease. Dr. Kabir, Dr. Gatewood, Dr. Bakdash 2006-2007

Forest Protocol: LAS-MD-38. A Randomized, Double-blind, Placebo-Controlled Phase III Study Evaluating the Efficacy, Safety, and Tolerability of 2 Doses of Aclidinium 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 2 Aclidinium Bromide Doses – Dr. Kabir, Dr. Malik, Sheri Lantz 2009-2010

Novartis. CQAB149B2335S Phase II A 26-week Treatment, Multicenter, Randomized, Double Blind, Double Dummy, Placebo-controlled, Adaptive, Seamless, Parallel-group Study to Assess the Efficacy, Safety and Tolerability of Two Doses of Indacaterol (Selected From 75, 150, 300 & 600 µg o.d.) in Patients With Chronic Obstructive Pulmonary Disease Using Blinded Formoterol (12 µg b.i.d.) and Open Label Tiotropium (18 µg o.d.) as Active Controls. Dr. Kabir, Dr. Bakdash, Dr. Gatewood 2007-2008

SkyePharma, SKY2028-3-004 Phase III, A Randomized, Double-blind, Placebo-controlled, Parallel Group, Stratified, Multi-center, 12-Week Study Comparing the Safety and Efficacy of Fluticasone and Formoterol Combination (FlutiForm(tm) 100/10 µg or 250/10 µg Twice Daily) in a Single Inhaler (SkyePharma HFA pMDI) With the Administration of Placebo or Fluticasone (250 µg Twice Daily) and Formoterol (10 µg Twice Daily) Alone in Adolescent and Adult Patients With Moderate to Severe Asthma. Dr. Kabir, Dr. Bakdash, Dr. Gatewood 2006-2007

**Oncology**

BioDelivery FEN-201 A Phase III double-blind, placebo controlled evaluation of the efficacy, safety and tolerability of BEMA™ Fentanyl in the treatment of breakthrough pain in cancer subjects. Dr. Tharp, Dr. Tahir Naqvi 2006

BioDelivery FEN-202 An open label, long-term treatment evaluation of the safety of BEMA™ Fentanyl use for breakthrough pain in cancer subjects on chronic opioid therapy. Phase III. Dr. Tharp, Dr. Tahir Naqvi 2006
Generon: GC-627-02: A Phase II, Randomized, Multi-Centre, Open-Label, Active-Controlled, Dose-Finding Trial of F-627 in Women with Breast Cancer Receiving Myelotoxic Chemotherapy. Dr. Tahir Naqvi, Dr. Preetham Jetty. 2012-

Merck 130-00 Phase III Randomized, double blind, parallel group study conducted in house blinding conditions to determine the efficacy and tolerability of Aprepitant for the prevention of chemotherapy induced nausea and vomiting associated with moderately emetogenic chemotherapy. Dr. Tahir Naqvi

Merck V212-011. A Phase III Randomized, Placebo-Controlled, Clinical Trial to Study the Safety and Efficacy of V212 in Adult Patients with Solid Tumor or Hematologic Malignancy. Dr. Tahir Naqvi, Dr. Jetty, Dr. Elsaharty. 2011-

**Endocrinology**

GlaxoSmithKline Protocol GLP110125: A 16-week, Parallel-Group, Double-Blind, Randomized, Placebo-Controlled, Multicenter, Dose-Ranging Phase II Study to Evaluate the Efficacy, Safety and Tolerability of Multiple Doses and Multiple treatment Regimens of GSK716155, with Byetta as an Open-Label Active Reference, in Subjects with Type 2 Diabetes Mellitus. Dr. Tharp, Dr. Bakdash, Erin Snyder

**Orthopedics**


Endo EN3269-301 A Randomized, Double-Blind, Placebo-Controlled, Parallel Group Phase III Study of the Efficacy, Tolerability and Safety of Ketoprofen Topical Patch, 20% (KTP) in the Treatment of Pain Associated with Grade 1 or Grade 2 Ankle Sprain or Strain. Dr. Mines, Dr. Krepps 2006

OrthoLogic OLADRFX03 A Double-Blind, Randomized, Placebo-Controlled Phase 2b Study To Establish the Effective Dose Range and To Evaluate The Safety of XXXX In Adult Subjects With A Fractured Distal Radius. Dr. Mines, Dr. Krepps 2005

**Gastroenterology**

Genzyme: Protocol:GD3-170-301. A Randomized, Double-Blind Phase III Study of GT267-004 Versus Vancomycin and GT267004 Versus Metronidazole, in Patients with C.Difficile-Associated Diarrhea. Dr. Nowak, Dr. Foster, Dr. Nisi, Dr. Maier. 2005
Ironwood MCP-103-302. A Phase III, Randomized, Double-blind, Placebo-controlled, Parallel-group Trial of Linaclotide Administered Orally 26 weeks in Patients with Irritable Bowel Syndrome with Constipation. Dr. Maier, Dr. Nowak, Sheri Lantz, FNP 2009-2010

Ironwood MCP-103-303. A Phase III, Randomized, Double-blind, Placebo-controlled, Parallel-group Trial of Linaclotide Administered Orally for 12 Weeks Followed by a 4-Week Randomized Withdrawal Period in Patients with Chronic Constipation. Dr. Maier, Sheri Lantz, FNP 2009-2009

Ironwood MCP-103-305. An Open-label, Long-term Safety Study of Oral Linaclotide Administered to Patients with Chronic Constipation or Irritable Bowel Syndrome with Constipation. Phase III. Dr. Maier, Dr. Nowak, Sheri Lantz, FNP 2009-2011

Salix: Protocol: BZUC3003: A Phase III, Multicenter, Randomized, Double-Blind, Actively Controlled Trial To Evaluate The Safety And Efficacy Of A New Tablet Formulation And Dosing Regimen Of Balsalazide Disodium 3.3 G Bid Versus Mesalamine (5-Asa) As Asacol® 0.8 G Tid In Mildly To Moderately Active Ulcerative Colitis. Dr. Nowak, Dr. Foster, Dr. Maier, Dr. Nisi 2005-2008

Salix. Protocol: BZUC3005: A Phase III, Multicenter, Open-Label Trial To Evaluate The Long-Term Safety And Tolerability Of A New Balsalazide Disodium Tablet Formulation In Patients With Ulcerative Colitis, Dr. Nowak, Dr. Foster, Dr. Maier, Dr. Nisi 2006-2008

Salix: RFIB2001: A Phase II, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study To Assess The Efficacy And Safety Of Three Different Doses (275, 550 And 1100 Mg) Of Rifaximin Administered Bid For Either Two Or Four Weeks In The Treatment Of Patients With Diarrhea-Associated Irritable Bowel Syndrome. Dr. Nowak, Dr. Foster, Dr. Nisi, Dr. Maier. 2005-2008

Outpatient Surgery

GlaxoSmithKline, Protocol NKT102553: A Phase III, Multicenter, Randomized, Double-blind, Parallel Group Study to Evaluate the Safety and Efficacy of 50mg Oral Dosing with the Neurokinin-1 Receptor Antagonist GW679769 for the Prevention of Postoperative Nausea and Vomiting in Female Subjects at High Risk for Emesis. Dr. Tharp 2006