

<u>Study</u>	<u>PI</u>	<u>Enrollment Status</u>	<u>Sponsor</u>	<u>Description</u>	<u>TL # enrolled</u>
Acusphere AI-700-33	Dr. Michael Main	just completed close-out visit	Acuphere, Inc.	A Phase 3, International, Multicenter, Open-Label, Dual-Injection, Echocardiographic Imaging and Safety Study of AI-700 in Patients with Suspected Ischemic Heart Disease Undergoing Diagnostic Coronary Angiography	58
CHF QOL	Dr. Michael Main	enrolling	independent	Echocardiographic predictors of quality of life in ambulatory CHF patients	1
Definity DMP 115-412	Dr. Michael Main	open	BMS Medical Imaging	A Multicenter, Phase IV, Study To Evaluate The Ability Of DEFINITY®-Enhanced Versus Unenhanced Echocardiography To Improve The Accuracy And Reproducibility Of Left Ventricular Ejection Fraction When Compared To Cardiac Magnetic Resonance Imaging	18
ICD Clinical Outcomes	Dr. Michael Main	retrospective	independent	Clinical and Echocardiographic Predictors of Clinical Outcomes in Patients with ICDs	297
LV Remodeling	Dr. Michael Main	enrolling	independent	Prediction of Left Ventricular Remodeling after Acute Myocardial Infarction using Myocardial Contrast Echocardiography (Definity)	107
LV Volume	Dr. Michael Main	enrolling	independent	Use Of Contrast Echocardiography To Improve Accuracy In Determination Of Left Ventricular Volumes And Ejection Fraction In Patients With Good Baseline Endocardial Definition. (Definity)	60

POINT PB127-013	Dr. Michael Main	enrolling	POINT Biomedical	A Phase 2 Dose-finding Clinical Trial of CARDIOSphere (PB127) in Normal Volunteers and in Patients with Known or Suspected Coronary Artery Disease	27
					Total: 568

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TRIUMPH	Dr. Spertus	Active/enrolling	NIH	Multi-center study of outcomes related to M.I., incorp. many patient characteristics with hospitalization and procedural data, 1, 6, & 12 month f/u with labs incl. pharmacogenomics.	2749 (as of 6/25/07)
Cholesterol Med Discontinuance	Dr. Decker	Enrollment starts 7/07	Schering-Plough	Acute myocardial infarction - patient's perspective of cholesterol lowering therapy discontinuation. Qualitative interviews with patients stopping cholesterol lowering meds. Evaluating the use of patient-specific risk models embedded in PCI informed consent documents at the 4 SLHS KC metro hospitals.	n/a
PREDICT	Drs. Spertus and Decker	Enrolling	Self-funded		200
					Total: 2949

<u>Study</u>	<u>PI</u>	<u>Enrollment Status</u>	<u>Sponsor</u>
The Diabetes Gemone Project	Dr. Marso	Active enrolling, goal 2000 patients	In House SLH trial
SAGA Cypher Registry Saphenous Vein Graft Study	Dr. Marso	closed to enrollment	Cleveland Clinic
SFA Plaque Trial	Dr. Marso	active enrollment	In House SLH and UMKC
Stent Thrombosis Registry	Dr. Marso	not enrolling yet	In House SLH

<u>Description</u>	<u>TL # enrolled</u>
A multi-phase prospective registry to identify genetic variation among diabetic patients undergoing coronary revascularization	1356
Matching DES in SVG target lesions and comparing this with BMS (Bare metal stents) in SVG lesions Plaque analysis with Raman Spectroscopy and Scanning Acoustic Microscopy	reviewed 300 pt charts, matched 16 pts to Cleveland Clinic 1
DES vs. BMS: 30 pts identified via 4000 chart review, had in stent restenosis of a drug eluting stent	n/a
	Total: 1357

<u>Study</u>	<u>PI</u>	<u>Enrollment Status</u>	<u>Sponsor</u>
EVENT Wave-4 Sapphire WW	Dr. Marso Dr. Laster	Enrolling Enrolling	Sanofi Aventis Cordis
Virtual Histology Intravascular Ultrasound Registry (IVUS)	Dr. Marso	Follow-up	Volcano

<u>Description</u>	<u>TL # enrolled</u>
Registry for evaluation of drug eluting stents and ischemic events	60
Carotid stent trial	1
Evaluates the correlation between the post-processed Virtual Histology IVUS data and patient data such as demographics, clinical presentation, and risk factors for coronary artery disease. SLH the Data Coord. Center for all the 24 sites.	312
	Total: 373

<u>Study</u>	<u>PI</u>	<u>Enrollment Status</u>	<u>Sponsor</u>
ATS Simulus	Dr. Borkon	Enrolling	ATS Medical
ATS OPIA	Dr. Borkon	Enrolling	ATS Medical
Crest	Dr. Laster & Dr. Daon	Enrolling	NIH
Epic	Dr. Borkon	Follow-up	St. Jude Medical
Freedom	Dr. B. Rutherford/Dr. C. Rutherford, & Dr. Borkon	Enrolling	NIH
Intermacs	Dr. Borkon	Enrolling	NIH
Mitroflow	Dr. Borkon	Follow-up	CarboMedics
Omega-3 (Omacor)	Dr. Zorn	Active	Reliant Pharm.
Feasibility (Paracor)	Dr. Kao & Dr. Zorn	Closed	Paracor
Peerless (Paracor)	Dr. Kao & Dr. Zorn	Enrolling	Paracor
Plavix in CABG	Dr. Borkon	Active	AstraZeneca Cobe Cardiovascular/In-house study
Synergy	Dr. T. Sydzyik	Closed	

<u>Description</u>	<u>TL # enrolled</u>
Annuloplasty Ring surgeon survey	9
Post-market patient registry of ATS Open Pivot Heart Valve	1
Carotid Stent vs. Endarterectomy	0
Aortic and Mitral SJM Epic porcine valves with Linx to lessen calcium deposits.	14
CABG vs. Stenting	0
VAD Registry	2
Aortic Pericardial Valve	1
Pre-load CABS/Valve with prescription Omega-3 to decrease incidence of AF	not yet/awaiting drug
Class II-III HF patient A ventricular support device to improve cardiac function.	1
Target class II-III HF patients randomized to device or medical therapy.	0
A RCR study looking at clinical outcomes in ACS pts. Receiving Plavix pre-op.	not enrolling yet
CPB vs. mini-circuit in CABG pts.	50
	Total: 78

<u>Study</u>	<u>PI</u>	<u>Enrollment Status</u>	<u>Sponsor</u>
Crescendo Study	Dr. Alan Forker	Maintenance	Sanofi-Aventis
Merck 003 Study	Dr. Alan Forker	Post study completion	Merck
Merck 008 Study	Dr. Alan Forker	Recruiting	Merck
Merck 011 Study	Dr. Alan Forker	Post study completion	Merck
Merck 015 Study	Dr. Alan Forker	Maintenance	Merck
Merck 022 Study	Dr. Alan Forker	Post study completion	Merck
Merck 024 Study	Dr. Alan Forker	Maintenance	Merck

Merck 061 Study Dr. Alan Forker Recruiting Merck

Merck 069 Study Dr. Alan Forker Recruiting Merck

Merck 107 Study Dr. Alan Forker Recruiting Merck

Microbia 201 Study Dr. Alan Forker Maintenance Microbia

Navigator Study Dr. Alan Forker Maintenance Novartis

Novartis 23103 Study Dr. Alan Forker Recruiting Novartis

Novartis 2301 Study Dr. Alan Forker Maintenance Novartis

Novartis 2352 Study	Dr. Alan Forker	Delayed study start	Novartis
Novonordisk 1583 Study	Dr. Alan Forker	Recruiting	Novonordisk
Novonordisk 1640 Study	Dr. Alan Forker	Recruiting	Novonordisk
Phenomix 202 Study	Dr. Alan Forker	Recruiting	Phenomix Corp.
Pfizer Imaging Study	Dr. Alan Forker	Post study completion	Pfizer
Reliant OM5, OM5X, and OM5XX	Dr. Alan Forker	Maintenance	Reliant Pharmaceuticals
Reliant OM6X Extension Study	Dr. Alan Forker	Maintenance	Reliant Pharmaceuticals

Reliant OM9L Study	Dr. Alan Forker	Prestudy	Reliant Pharmaceuticals
Sankyo 304 Study	Dr. Alan Forker	Maintenance	Sankyo
Takeda 022	Dr. Alan Forker	Maintenance	Takeda 022

<u>Description</u>	<u>TL # enrolled</u>
Comprehensive Rimonabant Evaluation Study of Cardiovascular ENDpoints and Outcomes. Randomized, multinational, multicenter, double-blind, placebo-controlled, two-arm parallel group trial of rimonabant 20 mg OD for reducing the risk of major cardiovascular events in abdominally obese patients with clustering risk factors.	22
A multicenter, randomized, double-blind, placebo-controlled study to assess the effects of MK-0524 in patients w/primary hypercholesterolemia or mixed hyperlipidemia	12
A Multicenter, Double-Blind, Randomized, Placebo and Active Comparator Controlled Dose-Range Finding Study of MK-0893 in Patients With Type 2 Diabetes Mellitus Who have Inadequate Glycemic Control	0
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	6
A 2-year study to assess the efficacy, safety, and tolerability of L-000899055 in obese patients	10
A multi-center, randomized, double-blind, factorial design study to evaluate the lipid-altering efficacy and safety of MK-0542B combination tablet in patients with primary hypercholesterolemia or mixed hyperlipidemia	10
A multicenter, randomized study to evaluate the safety and efficacy of the addition of MI-0431 compared with sulfonylurea therapy in patients with type 2 diabetes with inadequate glycemic control on metformin therapy	10

A Phase I Double-Blind, Randomized, Placebo-Controlled Clinical Trial to Study the Safety, Efficacy, and Mechanism of Action of Sitagliptin and Pioglitazone in Patients With Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control on Diet and Exercise	0
A Multicenter, Randomized, Double-Blind, Placebo-Controlled, 36-Week Study to Evaluate the Efficacy and Safety of Extended Release (ER) Niacin/Laropiprant in Patients with Type 2 Diabetes Mellitus	0
A multicenter, randomized, double-blind, parallel arm, 6-week study to evaluate the efficacy and safety of Ezetimibe/Simvastatin vs. Atorvastatin in patients with metabolic syndrome and hypercholesterolemia at high risk for coronary heart disease	0
A phase 2, randomized, multi-center, double-blind, placebo-controlled, parallel-group, dose-range-finding study of the safety and efficacy of orally administered MD-0727 in patients with primary hypercholesterolemia	6
A multinational, randomized, double-blind, placebo-controlled, forced-titration, 2x2 factorial design study of the efficacy and safety of long term administration of nateglinide and valsartan in the prevention of diabetes and cardiovascular outcomes in subjects with impaired glucose tolerance (IGT).	10
A multicenter, double-blind, randomized, parallel-group study to compare the effect of 24 weeks treatment with Vildagliptin 100 mg qd to Placebo as add-on therapy in patients with Type 2 diabetes inadequately controlled with metformin monotherapy	4
A 54-week, open-label, multicenter study to assess the long-term safety of the combination of aliskiren 300 mg/valsartan 320 mg in patients with essential hypertension	4

An 8-week, double-blind, randomized, placebo-controlled, multifactorial, parallel-group, multicenter study to evaluate the efficacy and safety of the fixed-dose combinations of aliskiren and HCTZ (150/12.5, 150/25, 300/12.5, 300/25 mg) in patients with essential hypertension

0

Inhaled mealtime insulin with the AERx iDMS plus Metformin & Glimepiride in type 2 diabetes: A 26-week, open-label, multicentre, randomised, parallel trial to investigate safety and efficacy

0

Inhaled mealtime insulin with the Aerx iDMS plus Pioglitazone vs. Pioglitazone alone in type 2 diabetes: A 26-week, open-label, multicentre, randomised, parallel trial to investigate efficacy and safety.

0

A Phase 2b, Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study to Evaluate Safety and Efficacy of PHX1149T in Subjects with Type 2 Diabetes Mellitus

6

Phase 3 multi-center, double-blind, randomized, parallel group, carotid B-mode ultrasound evaluation of the anti-atherosclerotic efficacy, safety, and tolerability of fixed combination CP-529, 414/atorvastatin, administered orally, once daily (QD) for 24 months, compared with atorvastatin alone, in subjects with mixed hyperlipidemia.

25

A randomized, double-blind, placebo-controlled, parallel-group, Phase IV study to assess the efficacy and safety of adjunctive Omacor therapy in hypertriglyceridemic subjects treated with Antara

10

A randomized, double-blind, placebo-controlled study to assess the efficacy and safety of combined Omacor and Simvastatin therapy in hypertriglyceridemic subjects

2

A randomized, double-blind, placebo-controlled, forced Titration study to assess the efficacy and safety of Omacor, co-administered with open-label Atorvastatin therapy, in hypertriglyceridemic subjects	0
A multi-center, 52-week, open-label extension study (from Studies WEL-301, WEL-302, WEL-303) to evaluate the long-term safety and tolerability of WELChol in type 2 diabetic patients	10
A double-blind, randomized study to evaluate the efficacy and safety of TAK-475 50 mg, 100 mg or placebo when co-administered with Rosuvastatin 10 mg or 20 mg in subjects with primary hypercholesterolemia	7
Total:	154

<u>Study</u>	<u>PI</u>	<u>Enrollment Status</u>	<u>Sponsor</u>
Attain Model 4196 Left Ventricular Lead Study	Dr. Brian Ramza	Active	Medtronic
Enrhythm MRI Surescan Pacing System	Dr. Brian Ramza	Active	Medtronic
InSync Registry	Dr. Brian Ramza	Enrolling	Medtronic
REFORM Study	Dr. Brian Ramza	Enrolling	Medtronic
RIGHT Study	Dr. Brian Ramza	Enrolling	Guidant/Boston Scientific
System Longevity Study	Dr. Brian Ramza	Enrolling	Medtronic
WIF Registry	Dr. Kao	Ready to enroll	Life Cor.

<u>Description</u>	<u>TL # enrolled</u>
Prospective multicenter clinical trial using objective performance criteria to evaluate the safety and efficacy of the Model 4196 lead. The lead features a proximal ring and distal tip electrode providing the ability to program LV pacing from either of these points therefore giving the physician a non-invasive option for lead revisions post implant due to high thresholds, or diaphragmatic stim etc.	not enrolling yet
Prospective randomized controlled multicenter trial evaluating the safety and efficacy of the EnRhythm MRI SureScan pacing system pre, during and post MRI scans. The key new features to the EnRhythm MRI pacing system is changes in the hardware to optimize its use in an MRI environment.	not enrolling yet
Non randomized, multicenter study to characterize the post market performance of the InSyn Model 8040, Model 8042, and any Medtronic Market released CRT-D system for cardiac resynchronization therapy.. Data from a 2000 patients followed to 3 years will be required to assess the study goals as mandated by the FDA.	75
The registry evaluating functional outcomes of resynchronization management	on hold
Comparing Medtronic and Guidant's rhythm detections to compare if one company's algorithms have fewer inappropriate shocks	5
n/a	96
A registry following defibrillation therapy for VT and VF, compliance with patients wearing the life vest, how long they had to wear the life vest, etc.	n/a
Total:	176

last updated 7/07
MCR

<u>Study</u>	<u>PI</u>	<u>Enrollment Status</u>	<u>Sponsor</u>
n/a	Dr. Timothy Bateman	Open	Molecular Insight Pharmaceuticals
n/a	Dr. Timothy Bateman	Open	Duke University/NIH
n/a	Dr. Timothy Bateman	Retrospective Chart Review	Bracco Diagnostics
n/a	Dr. Timothy Bateman	Open	GE Healthcare

last updated 7/07
MCR

<u>Description</u>	<u>TL # enrolled</u>
Development of a normal database and criteria for abnormality for B-Methy-P [123I]-Iodophenyl-Pentadecanoic Acid (Iodofiltic Acid I 123) for quantitative imaging	18
HF-action ancillary nuclear study "Effects of exercise training on ventricular function dyssynchrony, resting myocardial perfusion and clinical outcomes in HF patients"	20
The prognostic value of left ventricular ejection fraction from cardiac PET myocardial perfusion imaging in patients with known or suspected coronary artery disease	2,000
An open-label, multicentre, Phase 3 study evaluating the prognostic usefulness of I123-Mibg scintigraphy for identifying subjects with heart failure who will experience an adverse cardiac event	14
Total:	2052

<u>Study</u>	<u>PI</u>	<u>Enrollment Status</u>	<u>Sponsor</u>
BARI 2D	James O'Keefe & Alan Forker	Maintenance phase	NIH
CEPT	Steven Marso	In process of close-out, with 1 year safety f/u expected	Pfizer, Inc.
COURAGE Trial	James O'Keefe	In process of close-out	NIH

<u>Description</u>	<u>TL # enrolled</u>
Revascularization Investigation 2 Diabetes	18
A Phase 3, Multi-Center, Double-Blind, Randomized, Parallel Group, Coronary Artery Intravascular Ultrasound Evaluation of the Anti-Atherosclerotic Efficacy, Safety, and Tolerability of Fixed Combination CP-529/414/Atrovastatin, Administered Orally, Once Daily (QD) for 24 Months, Compared with Atrovastatin Alone in Subjects with Angiographically Documented Coronary Heart Disease (CEPT)	2
Specialized medication and revascularization therapy - Randomized comparison of PTCA vs Medical Therapy for the Treatment of Coronary Artery Disease	29
	Total: 49

<u>Study</u>	<u>PI</u>	<u>Enrollment Status</u>	<u>Sponsor</u>	<u>Description</u>	<u>TL # enrolled</u>
CHF Outcomes Study	Dr. Magalski & Felicia Menefee	Closed	Medtronic	QOL study The Chronicle Implantable Hemodynamic Monitor is an implantable hemodynamic monitor which measures multiple pressure-related hemodynamic parameters through a lead implanted in the right ventricle.	40
Chronicle Phase I/II Study	Dr. Magalski & Felicia Menefee	Closed, but open for long term enrollment	Medtronic	This is a multicenter, randomized, single blind, parallel controlled clinical study of patients diagnosed with moderate to severe Congestive Heart Failure (CHF). It will involve 635 subject and will run for approximately 3 years or until 3356 months of total subject randomized data has been collected .	24
Compass HF HF Action	Dr. Maglaski & Felicia Menefee	Closed, but open for long term enrollment	Medtronic	HF/Exercise Study	24
	Dr. Kao	Recruiting and enrolling	Duke University	Targets HF patients class II-III, involves getting a device called a ventricular support system. In an attempt to help reduce the signs and symptoms of HF, and improve overall cardiac function.	33
PARACOR Feasibility Study	Dr. Kao	Closed, but doing follow-up	Paracor Medical, Inc.	Targets the same patient population as the PARACOR study, but patients are randomized to a treatment group, where they receive the device, or a control group, where they are treated with the best medical therapy.	1
PEERLESS HF	Dr. Kao	Enrollment open	Paracor Medical, Inc.	Darbepoetin alfa vs placebo	0
RED HF: Anemia Trial	Dr. Magalski	Enrollment open	Medtronic	Single chamber ICD w/Chronicle Guided Care technology	0
Reduce HF: Chronicle ICD Study	Dr. Magalski	Enrollment open	Medtronic		0
Total:					122

<u>Study</u>	<u>PI</u>	<u>Enrollment Status</u>	<u>Sponsor</u>	<u>Description</u>	<u>TL # enrolled</u>
Max 2	Dr. Alan Forker	Closed	LifeScan, Inc.	Product involved designed to check home blood glucose levels by fingerstick. Study evaluates whether revised handbook instructions are understandable, "off the shelf" without formal training, and able to be translated into action. Two study visits separated by 2-3 days of home testing. Eligible subjects are Type 1 or 2 Diabetes, or gestational diabetes, who currently test blood glucose at home. Evaluation includes open-book questions, opinion questions, and direct observation of skills related to testing.	45
					Total: 45

<u>Study</u>	<u>PI</u>	<u>Enrollment Status</u>	<u>Sponsor</u>	<u>Description</u>	<u>TL # enrolled</u>
Across Cypher	BDR	Follow-up	Cordis	CTO with Cypher DES	14
Amethyst	BDR	Enrolling	Medtronic	Interceptor vs. FDA approved Ant AMI within 6 hours of onset 90 mins	15
AMIHOT II	BDR	Closed	TherOx	aqueous O2 after PCI	0
Beach	SBL	Follow-up	BSCI	Carotid stenting	1
	SBL	Enrolling	Guidant	Carotid stenting	37
Choice	SBL	Enrolling	Abbott	Carotid stenting	1
CREST	SBL	Enrolling	NIH	Carotid stent vs endarterectomy	23
CURRENT OASIS 7	DS	Enrolling	Sanofi Aventis	Plavix dosing regimen comparison trial	1
Endeavor III	BDR	Follow-up	Medtronic	Endeavor DES vs Cypher	17
Endeavor IV	BDR	Follow-up	Medtronic	Endeavor DES vs Taxus	23
EVENT Wave 4	SPM	Enrolling 5/14/07	Schering-Plough Corp.	Registry of practice and outcomes of contemporary PCI in the DES era	60
Exact	SBL	Follow-up	Abbott	Carotid stenting	1
Freedom	BDR	Enrolling	NIH	CABG vs stenting MV DM, No LM	0
Horizons	BDR	Enrolling	CRF	AMI DES vs Bare Metal and	15
Maveric II	SBL	Follow-up	Medtronic	Carotid stenting	3
Prospect	BDR	Follow-up	Guidant	non-Stemi with VH and biomarkers LAA occluder vs Coumadin for patients with AF	40
PROTECT AF	KCH	Enrolling	Atritech		17
RISE	JAG	Follow-up	Abbott	Femoral closure early ambulation	2
Sapphire WW	SBL	Enrolling	Cordis	Carotid stenting	0
SISR	BDR	Follow-up	Cordis	Cypher vs Brachytherapy for ISR	16
Spirit III	JAG	Follow-up	Guidant	Xience vs Taxus	16
Spirit IV	JAG	Enrolling	Abbott/Guidant	Xience DES vs Taxus Denovo	15
Symbiot III	WLJ	Follow-up	BSCI	Symbiot stent in SVG's	20
Taxus IV	BDR	Follow-up	BSCI	Taxus DES vs BMS	13
Taxus V	BDR	Follow-up	BSCI	Taxus DES vs BMS(Express)	17
Taxus ISR	BDR	Follow-up	BSCI	Taxus DES vs Brachytherapy for ISR	11

Total: 312