CURRICULUM VITAE

Physicians Research Center, LLC

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Ownership:

June, 2016 to present: Teresa Simon, MPH
November 1, 1992 to July 4, 2015: Henry J. Simon, MD

Research Experience: Over 25 years of clinical trial research experience

Hospital Affiliation: All physicians associated with the Physicians Research Center network are affiliated with: Community Medical Center, Toms River, NJ

Professional Board Certification: All physicians in the Physicians Research Center network are Board Certified

Research Experience:

Research Grants and Contracting Coordinator
Set-up, manage and oversee clinical trial site and a network of investigators
Experience with FDA and Sponsor audits
Recruiting for large (up to 300 subjects studies)
Long term follow-up of study participants
Prepare and submit Regulatory documents if needed
Negotiate study grant budgets
Contracting including master service agreements (MSA) and statement of work (SOW)

Clinical Research Coordinators
All trained in Good Clinical Practices, Safety PAK training; Informed consent training;
Review and implement all procedures according to protocol
Chart review, recruit and schedule potential subjects for screenings and visits
Record visit events in electronic data software, extensive eCRF experience
Ensure compliance with FDA, GCP, GLP guidelines and protocol regulations
Cooperative interaction with study monitors
Creation, completion and verification of source documents

Drug accountability, management on trial supplies
Daily interaction with principal investigator and sub investigators
Submission of regulatory documents and IRB reporting
Oversee and supervise study related support staff and coordinator assistant

Management
Set up and managed Internal Medicine private practice medical laboratory for 20 years
Including all personnel issues: hiring manager
Oversee management of budget negotiation, subject recruitment ideas, HIPAA,laboratory procedures, Safety PAK training and use of electronic medical records for clinical trials
Set up and managed Obstetrics and Gynecology 5 physician practice microbiology laboratory for 20 years
Write and maintain all Standard Operating Procedures

Compliance
- OSHA
- HIPAA guidelines,
- Exposure control plans
- CLIA waived laboratory tests
- Safety PAK
- Informed Consent
- GCP, GLP

Certifications:
CPR
National Certified Phlebotomy Technician
GCP, GLP trained

Clinical Studies Physicians Research Center, LLC Participated in:

Phase	Title (N= number randomized)
Phase II	Vaccine Trial for the Prevention of Lyme Disease in Sero-Positive Subjects (N-21)
Phase II	AII Receptor Antagonist for Hypertension with ABPM (N=16)
Phase II	Glycoprotein for Erythropoiesis in Presurgical Subjects (dose ranging study) (N=10)
Phase II	Safety and Efficacy of Omapatrilat Modified Release Formulation in Subjects with Mild to Moderate Hypertension 2002
Phase II	A double-blind, randomized, placebo and active controlled, parallel group, dose-finding study to evaluate the efficacy and safety of once daily oral administration of 5 mg, 10 mg, 25 mg, and 50 mg of M100240 for 8 weeks in subjects with mild-to-moderate essential hypertension. 2002
Phase IIA	A Study to Assess the Steady-State Trough Serum Concentrations, Safety, and Immunogenicity of Abatacept Administered Subcutaneously in Subjects with Active Rheumatoid Arthritis Who are Receiving Disease Modifying Anti-Rheumatic Drugs (DMARDS). (N=4)
Phase IIB	Comparative Study of Safety and Efficacy of 3 oral doses of ABT-492 for Treatment of Subjects with CAP. 2002
Phase IIB	A 12-Week, Multicenter, Double-blind, Placebo-controlled, Randomized, Dose-finding Study to Evaluate the Safety and Efficacy of GM-611 in Patients with Diabetic Gastroparesis (N-3) 2003
Phase IIB	Comparative Dose Ranging Study of a difluoropyridine in CAP (N-1)
Phase IIB	Dose Ranging Study of HMG-COA Reductase Inhibitor (N= 31)
Phase IIB/III	Dose Ranging Placebo-Controlled Lipid Lowering Efficacy and Safety of a peroxisome proliferators-activated receptor agonist with and without Pravastatin (N= 17)
Phase IIB/III	Dose Ranging, Comparison Controlled of a peroxisome proliferators-activated receptor agonist in Type II Diabetics (N= 18)
Phase IIb/III	A Phase IIb/III Randomized, Placebo-controlled Clinical Trial to Study the Safety and Efficacy of MK-0364 in Obese Patients and in Overweight Patients with Obesity-Related Co-morbitities.
Phase II/III	A multi-center, randomized, double-blind study to evaluate the efficacy and long-term safety of vildagliptin modified release (MR) as monotherapy in patients with type 2 diabetes.
Phase IIb	A multicenter, randomized, double-blind, placebo-controlled, parallel-group, multiple-dose, outpatient study in patients with active FA despite ongoing MTX therapy.
Phase IIb	A Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging, Parallel-Group, Phase 2b Study of LY3009104 in Patients with Active Rheumatoid Arthritis on Background Methotrexate Therapy. (N=2)
Phase III	Glycoprotein for Erythropoiesis in Presurgical Subjects (N=24)
Phase III	Placebo-Controlled Vaccine Trial for the Prevention of Lyme Disease (N=300)
Phase III	Booster Study for the Prevention of Lyme Disease with 2-Year Follow-up (N=240)
Phase III	Lot Consistency Vaccine Trial for the Prevention of Lyme Disease (N=126)
Phase III	Administration of a Fourth Dose of Lyme Vaccine (N=102)
Phase III	Double-Blind All Receptor Antagonist for Hypertension (N=26)
Phase III	Two-Year, Open-Label, Long-Term AII Receptor Antagonist for Hypertension (N=14)
Phase III	Glycoprotein for Erythropoiesis versus Autologous Pre-Deposit in Presurgical Subjects (N=23)
Phase III	AII Receptor Antagonist Comparison for Hypertension with ABPM (N=15)
Phase III	AII Receptor Antagonist in Diabetic, Hypertensive Subjects: IDNT (N=12)
Phase III	AII Receptor Antagonist in Elderly Hypertensive Subjects (N=10)
Phase III	Immunization of the Placebo Group (N=101)

Phase III	Safety and Efficacy of a Benzofuran in Patients with Chronic Constipation (N=18)
Phase III	Long-tern Tolerability of a Benzofuran in Patients with Chronic Constipation (N=12)
Phase III	Vasopeptidase inhibitors in Elderly Hypertensive Subjects.
Phase III	Vasopeptidase inhibitors in Isolated Systolic Hypertensive Subjects: OPERA
Phase III	Safety and Efficacy of a Vasopeptidase Inhibitor and ACE in Hypertensives: OCTAVE
Phase III	Metformin/Glyburide in Type II Diabetes (N= 8)
Phase III	Rosiglitazone and Metformin/Glyburide in Type II Diabetes (N=10)
Phase III	A Dose-Ranging Study of Metformin/Glyburide in Type II Diabetes (N=5)
Phase III	A Fixed Combination of Metformin/Glyburide in Type II Diabetes (N=8)
Phase III	Modified Release Formulation of a HMG-Co Reductase in Hypercholesterolemia (N=37 screened; study terminated during screening)
Phase III	Single Dose Darbepoetin Alfa or Placebo and PAD before Noncardiac, Nonvascular Surgery (N-7)
Phase III	Single Dose Darbepoetin Alfa or Placebo before bilateral hip or knee surgery (N-8)
Phase III	Multi-Center, Randomized, Double-Blind, Placebo-Controlled Clinical Use Study to Evaluate the Safety and Tolerability of BMS-188667 Administered Intravenously to Subjects with Active Rheumatoid Arthritis (RA) With or Without Medical Co-Morbidities Receiving Disease Modifying Anti-Rheumatic Drugs (DMARDs) and/or Biologics Approved for RA (N-7)
Phase III	Randomized, Double-Blind, Placebo Controlled, Multicenter Trial to Evaluate the Safety and Efficacy of BMS-298585 as Monotherapy in Subjects with Type 2 Diabetes Who Have Inadequate Glycemic Control (N-3)
Phase III	Randomized, Double-Blind, Placebo Controlled, Multicenter Trial to Evaluate the Safety and Efficacy of BMS-298585 in Combination with Metformin Therapy in Subjects with Type 2 Diabetes Who Have Inadequate Glycemic Control on Metformin Therapy Alone (N-4)
Phase III	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. (2005-06)
Phase III	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. (2005-06)
Phase III	An 18-Month Study to Assess the Efficacy, Safety, and Tolerability of L-000899055 in Obese Patients. (2005) (N=15)
Phase III	A Multicenter Randomized, Double-Blind Study to Evaluate the Safety and Efficacy of MK-0431 Monotherapy in Patients with Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control. (2005) (N=6)
Phase III	A Multicenter, Double-Blind, Randomized Study to Evaluate the Safety and Efficacy of the Addition of MK-0431 Compared With Sulfonylurea Therapy in Patients With Type 2 Diabetes With Inadequate Glycemic Control on Metformin Monotherapy. (2005) (N=8)
Phase III	A Multicetner, Randomized, Double-Blind, Factorial Study of the Co-Administration of MK-0431 and Metformin in Patients with Type 2 Diabetes Mellitus Who Have Inadequate Glycemic Control. (2005) (N=6)
Phase III	A Multicenter, Randomized, Double-Blind, Parallel-Group, Placebo-Controlled Study to Asses the Efficacy and Safety of 12 Week Treatment with Vildagliptin (LAF237) 50 mg QD in Subjects with Impaired Glucose Tolerance IGT). (2005-06)
Phase III	A Multicenter, Randomized, Double-Blind, Parallel Group, 6-Week Study to Evaluate the Efficacy and Safety of Ezetimibe/Simvastatin Combination Tablet Versus Atorvastatin in Patients with Type 2 Diabetes Mellitus (T2DM) and Hypercholesterolemia. (2005) (N=6)

Phase III	An eight week, randomized, double-blind, parallel-group, multicenter study to evaluate the efficacy and safety of the combination of Aliskiren/valsartan/HCTX (300/320/25 mg), compared to the combinations of Aliskiren/HCTX (300/25 mg) and valsartan/HCTX(320/25 mg) in patients with essential hypertension not adequately responsive to HCTZ 25 mg. (2005-06)
Phase III	A Phase II, Multicenter, Randomized, Double-blind, placebo-controlled study to Evaluate the Efficacy and Safety of Subcutaneous LY2127399 in Patients with Systemic Lupus Erythematosus (SLE)
Phase III	A Phase III, Multicenter, Double-Blind, Crossover Design Study to Evaluate Lipid-Altering Efficacy and Safety of Extended-Release Niacin/Laropiprant/Simvastatin Combination Tablet in Patients with Primary Hypercholesterolemia or Mixed Dyslipidemia.
Phase III	A Phase III, Multi-Center, Randomized, Placebo-Controlled Study to Evaluate the Clinical Efficacy and Safety of Induction and Maintenance Therapy with Abatacept in Subjects With Active Ulcerative Colitis (UC) who have had an Inadequate Clinical Response and/or Intolerance to Medical Therapy. (2007) (N=1)
Phase III	A Phase III, Multi-Center, Randomized, Placebo-Controlled Study to Evaluate the Clinical Efficacy and Safety of Induction and Maintenance Therapy with Abatacept in Subjects with Active Crohn's Disease (CD) who have had an Inadequate Clinical Response and/or Intolerance to Medical Treatment (2007) (N=1)
Phase III	A Multi-center, Double-Blind, Prospective Study Comparing Safety and Efficacy of Fenofibrate Acid and Simvastatin in Dyslipidemia. (2006)
Phase III	A Long-Term Open-Label, Safety Extension Study of the Combination of Fenofibric Acid and Statin Therapy for Subjects with Mixed Dyslipidemia. (N=3) (2007-2008).
Phase III	Duloxetine 60 to 120 mg versus Placebo in the Treatment of Patients with Osteoarthritis Knee Pain (2007) (N=8)
Phase III	Part A: A randomized, double-blind, placebo-controlled study to determine the efficacy and safety of 5 dose regimens of RO4402257 in patients with active rheumatoid arthritis (RA) on stable methotrexate (MTX) therapy. Part B: A randomized, double-blind, placebo-controlled study to determine the efficacy and safety of 1 dose of RO4402257 in patients with active rheumatoid arthritis (RA) on stable methotrexate (MTX) therapy. (2007) (N=2)
Phase III	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. (2008)
Phase III	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. (2008)
Phase III	The PERSISTENT Trial: A Prospective Randomized Trial Comparing Insulin Lispro Protamine Suspension to Insulin Glargine in Patients with Type 2 Diabetes on Anti-hyperglycemic Medications (2008)
Phase III	A Phase 3, Randomized, Active-Controlled, Open-label, Multi-center Study of the Safety and Efficacy of AF37702 Injection for the Correction of Anemia in Patients with Chronic Renal Failure (CRF) not on Dialysis and not on Erythopoiesis Stimulating Agent (ESA) Treatment. (2008)
Phase III	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 (N= 10)
Phase III	A Phase 3, Randomized, Active-Controlled, Open-label, Multi-center Study of the Safety and Efficacy of AF37702 Injection for the Correction of Anemia in Patients with Chronic Renal Failure (CRF) not on Dialysis and not on Erythropoiesis Stimulating Agent (ESA) treatment. (N=5)
Phase III	A Randomised, active-controlled, double-blind, double-dummy, parallel group design, multi-center trial to compare the efficacy and safety of 2.5 ug and 5 ug Tiotropium Inhalation Solution delivered by the Respimat® Inhaler with Tiotropium inhalation capsules 18 ug delivered by the Handihaler®. (N=6)

Phase III	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 (N=0)
Phase III	The PERSISTENT Trial: A Prospective Randomized Trial Comparing Insulin Lispro Protamine Suspension to Insulin Glargine in Patients with Type 2 Diabetes on Anti-hyperglycemic Medications (N=5)
Phase III	A multi-center, randomized, placebo-controlled, "factorial" design, 12-month study to evaluate the efficacy and safety of AVE5530 25 mg/day and 50 mg/day co-administered with all registered atorvastatin strengths ranging from 10 mg to 80 mg in patients with primary hypercholesterolemia. (N=70)
Phase III	Design Validation Study of the 5mm and 8mm BD Auto Shield ™ Pen Needles (N=70)
Phase III	Validation of user acceptability of the BD Emerald® PRO (ReUse prevention)Syringe. (N=100)
PhaseIII	Effect of liraglutide on body weight in overweight or obese subjects with type 2 diabetes. A 56 week randomized, double-blind, placebo-controlled, three armed parallel group, multi-centre, multinational trial with a 12 week observational follow-up period.(N=5)
Phase III	Begin: VICTOZA ADD-ON: A trial comparing the efficacy and safety of adding liraglutide versus addition of insulin aspart with the largest meal to insulin degludec, both in combination with metformin, in subjects with type 2 diabetes qualifying for treatment intensification. (N=5)
Phase III	A Phase 3, Multicenter, Randomised, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Subcutaneous LY2127399 in Patients with Systemic Lupus Erythematosus (SLE) (Illuminate-1). (N=2)
Phase III	DUAL II: A trial comparing the efficacy and safety on insulin degludec/liraglutide and insulin degludec in subjects with type 2 diabetes. (N=0)
Phase III	BEGIN: COMPARE: A trial comparing the efficacy and safety of insulin degludec 200U/mL and insulin degludec 100U/mL in subjects with type 2 diabetes mellitus. (N=10)
Phase III	A Phase III Multicenter, Double-Blind, Crossover Design Study to Evaluate Lipid-Altering Efficacy and Safety of Extended-Release Niacin/Laropoprant/Simvastatin Combination Tablet in Patients with Primary Hypercholesterolemia or Mixed Dyslipidemia.(N=5)
Phase III	A 12-week, Multi-Center, Randomized Double-Blind, Active Control Parallel Group Study to Evaluate the Efficacy and Safety of the Combination of Valturna and Amlodipine or Valturna and Chlorthalidone Versus Valturna Alone in Patients with Stage 2 Hypertension and Diabetes. (N=0)
Phase III	START-CKD:Strategies Using Darbepoetin alfa to Avoid Transfusions in Chronic Kidney Disease(N=1)
Phase III	6-Month, Multicenter, Randomised, Open-label, Parallel-group Study Comparing the Efficacy and Safety of a New Formulation of Insulin Glargine and Lantus both in combination with oral antihyperglycemic drug(s) in Patients with Type 2 Diabetes Mellitus with a 6-month Safety Extension Period (N=3)
Phase III	6-Month, Multicenter, Randomized, Open-label, Parallel-group Study Comparing the Efficacy and Safety of a New Formulation of Insluin Glargine and Lantus both plus Mealtime Insulin in Patients with Type 2 Diabetes Mellitus with a 6-month Safety Extension Period (N=1)
Phase III	Assessment of Clincial Effects of Cholesteryl Ester Transfer Protein Inhibition with Evacetrapib in Patients at a High-Risk for Vascular Outcomes-the ACCELERATE study(N=5)
Phase III	Clinical Evaluation of the BD Next (Extra Thin Wall Pen Needles) Compared to the Currently Marketed Pen Needles
Phase IIIa	A 26 week randomized, parallel three-arm, open-label, multi-centre, multinational treat-to-target trial comparing fixed ratio combination of insulin degludec and liraglutide

	versus insulin degludec or liraglutide alone, in subjects with type 2 diabetes trated with 1-2 oral anti-diabetic drugs (OADs) (N=0)
Phase IIIa	A long-term, randomized, double-blind, placebo-controlled, multinational, multi-centre trial to evaluate cardiovascular and other long-term outcomes with semaglutide in subjects with type 2 diabetes. (SUSTAIN 6-Long-term Outcomes)
Phase IIIa	BEGIN: ONCE: A trial comparing efficacy and safety of insulin degludec and insulin glargine in insulin naïve subjects with type 2 diabetes
Phase IIIa	Efficacy and Safety in FIAsp compared to Insulin Aspart in combination with insulin Glargine and Metformin in Adults with type 2 diabetes(Onset 2)
Phase IIIa	Efficacy and safety of semaglutide once weekly versus insulin glargine once daily as add on to metformin with or without sulphonylurea in insulin-naïve subjects with type 2 DM.
Phase IIIB	Caring for Hypertension on Initiation: Costs and Effectiveness (CHOICE Pilot) (N=80)
Phase IIIB	Clopidogrel for High Altherothrombotic Risk and Ischemic Stabilization, Management And Avoidance (CHARISMA) (N-20)
Phase IIIB	A Double-Blind, Randomized, Placebo-Controlled, Multicenter Study to Evaluate the Effects of Rofecoxib in Decreasing the Risk of Prostate Cancer (ViP Study) (N-7)
Phase IIIB	A multi-center, randomized, open-label, active controlled, parallel arm study to compare the efficacy of 12 weeks of treatment with Vildagliptin 100 mg, qd to thiazolidinedione (TZD) as add-on therapy in patients with type 2 diabetes inadequately controlled with metformin monotherapy in a community-based practice setting. (2006-07) (N=3)
Phase IIIB	A Phase 3b, Multicenter, Open-Label Study to Evaluate the Long-Term Safety and Efficacy of Subcutaneous LY2127399 in Patients with Systemic Lupus Erythmeatosus (SLE) (ILLUMINATE-X) (N=2)
Phase IIIB	The effect of insulin degludec in combination with liraglutide and metformin in subjects with type 2 diabetes qualifying for treatment intensification (N=2)(BEGIN:Add to GLP-1)
Phase IIIB	A trial comparing the efficacy and safety of two different titration algorithms for insulin degludec/insulin aspart in subjects with type 2 diabetes mellitus previously treated with insulin glargine (N=5)(BOOST:Simple Vs. Stepwise)
Phase IIIB	A randomized trial comparing efficacy and safety after intensification with either insulin aspart once daily as add-on or changing to basal bolus treatment with insulin degludec and insulin aspart in subjects with type 2 diabetes previously treated with insulin degludec/insulin aspart twice daily(N=2)(Boost: Intensify BID)
Phase IIIB	A 26-week trial comparing efficacy and safety of insulin degludec/insulin aspart BID and insulin degludec OD plus insulin aspart in subjects with type 2 Diabetes Mellitus treated with basal insulin in need of treatment intensification with mealtime insulin (N=2)
Phase IV	An 8-week randomized, double-blind, parallel-group, multi-center, active-controlled dose escalation study to evaluate the efficacy and safety of aliskiren HCTZ (300/25 mg) compared too HCTZ (25 mg) in older patients wityh stage 2 systolic hypertension.
Phase IV	A Multicenter, Randomized, Double-Blind, Parallel Design Trial to Evaluate the Blood Pressure Loering Efficacy Comparing Moderate Versus Aggressive Treatment Regimen of Exforge in patients Uncontrolled on ARB Monotherapy. (N=12)
Phase IV	A 12-week, Multi-center, Randomized Double-Blind, Active control parallel group study to Evaluate the Efficacy and Safety of the Combination of Valturna an Amlodipine or Valturna and Chlorthalidone Versus Valturna Alone in patients with Stage 2 Hypertension and Diabetes
Phase IV	The effect of Sulodexide in patients with type 2 diabetes and Microalbuminuria. (2006)
Phase IV	The Effect of Sulodexide in Overt Type 2 Diabetic Nephropathy. (2006)
Phase IV	Beta Blocker for Hypertension (N=12)
Phase IV	Vasodilator for Hypertension (N=16)
Phase IV	Calcium Channel Blocker for Hypertension (N=16)
Phase IV	Comparison Trial of Two Benzodiazepines for Insomnia (N=14)

Phase IV	An 8-Week randomized, double-blind, parallel-group, multi-center, active-controlled dose escalation study to evaluate the efficacy and safety of aliskiren HCTZ (300/25 mg) compared to HCT (25 mg) in older patients with stage 2 systolic hypertension.
Outcomes	Validation of Arithmetic Physical Performance Measures in the Elderly (N=30)
Device	Wearability and Form Factor Assessment of Non-Functional On-Body-Sensor(OBS) Units With Needle In Adult and Pediatric Subjects(N=35)
Device	Patient assessment of auto-injector technologies