


**PRECISION RESEARCH INSTITUTE**  
**CURRICULUM VITAE**

**Signature:**  **Date:** 5/11/16

<b>NAME:</b>	Carlton Wayne Thomas, Jr., MD	<b>DATE</b>	May 2016
<b>TITLE:</b>	Investigator	<b>UPDATED:</b>	

**RESEARCH SITE ADDRESS & PHONE:**

<p><b>Main office:</b></p> <p><b>Precision Research Institute, LLC</b> 292 Euclid Ave # 115 San Diego, CA 92114</p> <p><b>Contact Info:</b> Office: (619) 501-0371 Fax: (619) 501-0390 Email: info@prisandiego.com</p>	<p><b>Site:</b></p> <p><b>Precision Research Institute, LLC</b> 292 Euclid Ave # 115 San Diego, CA 92114</p> <p><b>Contact Info:</b> Office: (619) 501-0371 Fax: (619) 501-0390 Email: info@prisandiego.com</p>
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**EDUCATION/TRAINING:**

<b>INSTITUTION AND LOCATION</b>	<b>DEGREE (if applicable)</b>	<b>YEAR(s)</b>	<b>FIELD OF STUDY</b>
Mayo Graduate School of Medicine Rochester, Minnesota		2001-2004	Fellow, Gastroenterology Clinician Investigator Program
Mayo Graduate School of Medicine Rochester, Minnesota		1998-2001	Intern and Resident Internal Medicine
Medical University of South Carolina Charleston, South Carolina	M.D.	1994-1998	Medicine
University of South Carolina Honors College Columbia, South Carolina	B.S.	1980-1984	Biology
GCP Training	Certificate	2011	Good Clinical Practices
Collaborative Institutional Training Initiative (CITI)	Certificate	2012	Good Clinical Practices
National Institute of Health (NIH) Web-based Training	Certificate	2011	Protecting Human Subject Research Participants

**BOARD CERTIFIED:**

<b>BOARD CERTIFIED/ELIGIBLE</b>	<b>YEAR(s)</b>	<b>SPECIALTY</b>
Board Certified	2001	Internal Medicine
Board Certified	2004	Gastroenterology

**POSITIONS AND EMPLOYMENT:**

2011-Present	Investigator-Precision Research Institute, LLC, San Diego, CA
2009-2011	Investigator- Desta Digestive Disease Medical Center, San Diego, CA
2011-Present	Private Practice-Digestive Disease Associates, San Diego, CA
2009-2011	Private Practice-Desta Digestive Disease Medical Center, San Diego, CA
2008-2009	Section Chief of GI, Eisenhower Medical Center, Rancho Mirage, CA
2004-2009	Private Practice, Gastroenterologist, Ranch Mirage, CA

**RESEARCH EXPERIENCE:**

**Principal Investigator**

BI: A phase III, randomized, double-blind, parallel group study to evaluate the efficacy and safety of XXXXXXXXXXXX 5 mg compared to placebo, administered as oral fixed dose combination with XXXXXXXXXXXXXXXXXXXX 10 mg or 25 mg for 24 weeks, in patients with type 2

ManKind: A Phase 3, Multicenter, Open-label, Randomized Clinical Trial to Evaluate the Safety of XXXXXXXXXXXXXXXX Insulin Inhalation Powder in Type 1 or Type 2 Diabetic Subjects with Obstructive Pulmonary Disease (Asthma or Chronic Obstructive Pulmonary Disease) Over a 12-month Treatment Period with a 2-month Follow-up

Intarcia: A Phase 3, Randomized, Active Comparator, Double-Blind, Multi-Center Study to Compare the Efficacy, Safety and Tolerability of XXXX XXX to XXXXXXXXXXXXXXXX as Add-on Therapy to XXXXXXXXXXXXXXXX in Patients with Type 2 Diabetes

VX14-787-103 - A Phase 2b, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group, Multicenter Study of 2 Dose Levels of XXXX Administered as Monotherapy and One Dose Level of XXXX Administered in Combination With XXXX for the Treatment of Acute Uncomplicated Seasonal Influenza A in Adult Subjects

Genentech: A Phase III, Double-Blinded, Placebo-Controlled, Multicenter Study of the Efficacy and Safety of XXXXXXXXXXXXXXXX During Induction and Maintenance in Patients with Moderate to Severe Active Ulcerative Colitis who Are Refractory to or Intolerant of TNF Inhibitors

**Sub-Investigator**

MannKind XXX-XX-XXXX: A Phase 3, Multicenter, Open-label, Randomized Clinical Trial to Evaluate the Safety of XXXXXXXXXXXXXXXX Insulin Inhalation Powder in Type 1 or Type 2 Diabetic Subjects with

Obstructive Pulmonary Disease (Asthma or Chronic Obstructive Pulmonary Disease) Over a 12-month Treatment Period with a 2-month Follow-up

Intarcia ITCA XXX-CLP-XXX: A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study to Evaluate the Efficacy, Safety and Tolerability of ITCA 650 in Patients with Type 2 Diabetes

Functional Dyspepsia Reduction Evaluation and Safety Trial (FDREST) A randomized, double-blind, placebo-controlled study to assess the safety and efficacy of XXXX, a medical food, in the dietary management of patients with functional dyspepsia

Actavis: An Open-label, Long-term Study to Assess the Immunogenicity of XXXX Administered Orally to Adult Patients with Irritable Bowel Syndrome with Constipation or Chronic Idiopathic Constipation

Merck: A Phase II, Randomized, Open-Label Clinical Trial to Study the Efficacy and Safety of the Combination Regimen of XXXX and XXXX with Either XXXX or XXXX in Subjects with Chronic HCV GT1 and GT2 Infection

Merck: A Long-term Follow-up Study to Evaluate the Durability of Virologic Response and/or Viral Resistance Patterns of Subjects With Chronic Hepatitis C Who Have Been Previously Treated with XXXX in a Prior Clinical Trial

Paion: A Phase III Study Evaluating the Efficacy and Safety of XXXX Compared to Placebo and Midazolam in Patients Undergoing Colonoscopy.

Stason: A PHASE 1, SINGLE DOSE PK AND SAFETY STUDY WITH XXXX FOLLOWED BY A PHASE 2, RANDOMIZED, DOUBLE-BLIND, PARALLEL GROUP DOSE-RANGING STUDY TO EVALUATE THE SAFETY AND EFFICACY OF XXXX COMPARED TO PLACEBO IN SUBJECTS WITH CHRONIC PANCREATITIS

Evoke: A Phase 3, Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Clinical Study to Evaluate the Efficacy and Safety of XXXXXXXXXXXX Nasal Spray solution in Women with Symptoms Associated with Diabetic Gastroparesis.

Evoke: A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Clinical Study to Evaluate the Efficacy and Safety of XXXXXXXXXXXX Nasal Spray solution in Men with Symptoms Associated with Diabetic Gastroparesis.

Janssen: A Phase 2a Open-label Study to Evaluate Prediction of Response to XXXXXXXXXXXX Using a Transcriptomic Profile in Subjects with Moderately to Severely Active Ulcerative Colitis

Synergy: A Randomized, 12-Week, Double-Blind, Placebo-Controlled Study to Assess the Safety and Efficacy of XXXXXXXXXXXX (3.0 and 6.0 mg) in Patients with Chronic Idiopathic Constipation

gICare: A Randomized, Double-Blind, Placebo-Controlled Phase IIa Proof-Of-Concept Study of XXX-XXXX in the Management of Visceral Pain in Subjects Undergoing Sedation-Free Full Colonoscopy

BMS: A Phase 3 Evaluation of XXXXXXXXXXXX Plus XXXXXXXXXXXX in Treatment-naïve and Treatment experienced Chronic Hepatitis C (Genotype 1, 2, 3, 4, 5, or 6) Subjects Coinfected with Human Immunodeficiency Virus (HIV)

BMS: A Phase 3 Evaluation of XXXXXXXXXXXX and XXXXXXXXXXXX in Treatment Naïve and Treatment Experienced Subjects with Genotype 3 Chronic Hepatitis C Infection

Merck: A Phase II/III Randomized Clinical Trial to Study the Efficacy and Safety of the Combination Regimen of XX-XXXX and XX-XXXX in Subjects with Chronic Hepatitis C Virus Infection and Chronic Kidney Disease

Ferring: A Double-blind, Randomised, Placebo-controlled, Phase 3 Trial in Patients with Chronic Idiopathic Constipation to Demonstrate the Efficacy and Safety of XXXXXXXXXXXX 5 mg and 10 mg for 12 Weeks Followed by a 4-week Withdrawal Period

Ferring: A Multicenter, Open-label, Safety and Tolerability Extension Trial of 5 mg and 10 mg XXXXXXXXXXXX Daily in the Treatment of Chronic Idiopathic Constipation

BI: Safety, antiviral effect and pharmacokinetics of BI XXXXXXXX in combination with XXXXXXXXXXXX and with or without XXXXXXXXXXXX for 4, 16, 24, 28 or 40 weeks in patients with chronic HCV genotype 1 infection (randomized Phase Ib/II)

BI: A phase III randomised, double-blind and placebo-controlled study of XXXXXXXXXXXX in combination with XXXXXXXXXXXXXXXX and XXXXXXXXXXXX in patients with moderate hepatic impairment (Child-Pugh B) with genotype 1b chronic hepatitis C infection

BI: A phase III randomised, partially double-blind and placebo-controlled study of XXXXXXXXXXXX in combination with XXXXXXXXXXXXXXXX and XXXXXXXXXXXX for chronic genotype 1 hepatitis C infection in an extended population of treatment naïve patients that includes those ineligible to receive XXXXXXXXXXXXXXXX

BMS: A Long-Term Follow-up Study of Subjects Who Participated in a Clinical Trial in Which XXXXXXXXXXXXXXXX (XXX-XXXXXX) and/or XXXXXXXXXXXXXXXX (XXX-XXXXXX) Was Administered for the Treatment of Chronic Hepatitis C

Salix: A Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging, Multicenter Study To Assess the Efficacy and Safety of XXXXXXXXXXXX Soluble Solid Dispersion (SSD) Tablets for the Prevention of Complications in Subjects with Early Decompensated Liver Cirrhosis

Sanofi: A randomized, double-blind, placebo-controlled, multicenter study evaluating efficacy and safety of XXXXXXXXXXXX in patients with active moderate to severe Ulcerative Colitis (UC).

Sanofi: A single-arm open label extension study evaluating the long term safety and tolerability of XXXXXXXXXXXX in patients with Ulcerative Colitis (UC)

Cubist: A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study to Evaluate the Long-Term Safety and Tolerability of XX-XXXX for the Treatment of Opioid-Induced Constipation in Adults Taking Opioid Therapy for Chronic Non Cancer Pain

Cubist: A Randomized, Double-Blind, Placebo controlled, Phase 3 Study to Evaluate the Efficacy and Safety of XX-XXXX for the Treatment of Opioid-Induced Constipation in Adults Taking Opioid Therapy for Chronic Non-Cancer Pain

Abbvie: A Long-Term Non-Interventional Registry to Assess Safety and Effectiveness of XXXXXXXX® (XXXXXXXXXXXX) in Patients with Moderately to Severely Active Ulcerative Colitis (UC)

Novartis: A randomized, multicenter, double-blind, placebo-controlled, parallel-group, 24-week pilot study to assess the efficacy, safety and tolerability of XXXXXXXX in patients with non-alcoholic fatty liver disease

Astra Zeneca: A Longitudinal Study of Patients with Opioid-Induced Constipation

Salix: A Phase 3, Open Label, Multicenter Study to Assess the Safety and Tolerability of XXXXXX in Subjects with Active Ulcerative Proctitis or Proctosigmoiditis

BMS XXX: A Phase 2 study of BMS- in combination with Peg-Interferon Alfa-2a and Ribavirin in Treatment Naïve Subjects with Chronic Hepatitis C Genotype 1 and 4 Infection (what BMS are you referring to 014 or 017).

BMS XXX: A Phase 3, Randomized, Double-Blind, Controlled Study Evaluating the Efficacy and Safety of Peginterferon Lambda-1a, with and without Declatasvir, Compared to Peginterferon Alfa-2a, Each in Combination with Ribavirin, in the Treatment of Naïve Genotype 2 and 3 Chronic Hepatitis C Subjects.

BI XXXX.XX: A phase III randomized, partially double-blind and placebo-controlled study of BI 207127 in combination with faldaprevir and ribavirin for chronic genotype 1 hepatitis C infection in an extended population of treatment naïve that includes those ineligible to receive peginterferon.

Novartis: A Randomized, open-label trial of the safety and efficacy of DEBXXX-Alsiporivir in combination with Peg-Interferon and Ribavirin and boceprevir in combination with Peg-INF/RBV in African-American treatment naïve subjects with Chronic Hepatitis C genotype 1.

Novum: A Double-Blind, Randomized, Placebo-Controlled, Parallel Group, Multi-Site Study to Evaluate the Clinical Equivalence of Lubiprostone 24mcg Capsules with AMITIZA in the Treatment of Chronic Idiopathic Constipation.

Pharmasset: A Multicenter, Open-Labe;, Randomized, Duration finding study to Investigate the Safety, Tolerability, Pharmokinetics and Pharmacodynamics following oral administration of PSI-XXXX in combination with Peg-Interferon and Ribavirin in treatment Naïve Patients with Chronic hepatitis C genotype 1,4,5 or 6.

Purdue 04 Randomized, Double-Blind, Double-Dummy, Placebo controlled, Active controlled parallel group, Multicenter trial of Oxycodone/Naloxone Controlled release tablets to Assess the Analgesic Efficacy and management of opioid induced constipation compared to Oxycodone Controlled release Tablets in Uncontrolled moderate/ severe Chronic Low back pain.

Purdue 05 Randomized, Double-Blind, Double-Dummy, Placebo controlled, Active controlled parallel group, Multicenter trial of Oxycodone/Naloxone Controlled release tablets to Assess the Analgesic Efficacy and management of opioid induced constipation compared to Oxycodone Controlled release Tablets in Controlled moderate/ severe Chronic Low back pain.

Sanofi-Aventis: A Phase 3 randomized, double blind, placebo controlled, parallel group, multicentered study to evaluate cardiovascular outcomes during treatment with lixisenatide in Type 2 Diabetic patients after an Acute Coronary Syndrome Event.

Santarus: Randomized, Double-Blind, Placebo controlled study to evaluate the Efficacy and Safety of oral Budesonide MMX Extended Release tablets as Add-on therapy in patients with Active, mild-moderate Ulcerative Colitis not adequately controlled on a background Oral 5-ASA Regimen.

Prometheus: Study to Evaluate The Utilization Of Testing for Infliximab And Antibodies to Infliximab in Patients Treated with Infliximab.

Salix XXXX : A Phase 3, Randomized, Double Blind, Placebo-Controlled, Multicenter Study to Assess The Efficacy and Safety of Budesonide versus Placebo in Subjects with Active Mild to Moderate Ulcerative.

Proctitis or Proctosigmoiditis.Salix XXXX: A Study to Assess Repeat Treatment Efficacy and Safety of Rifaximin in Subjects with Irritable Bowel Syndrome with Diarrhea.

Sanofi ACTXXXX: A randomized, double-blind, placebo-controlled, multicenter study evaluating efficacy and safety of SAR 339658 in patients with active moderate to severe Ulcerative Colitis (UC).

BI XXX.XX: A 24-Week, randomized, Double-blind, active-controlled, parallel group trial to assess the superiority of oral linagliptin and metformin compared to linagliptin monotherapy in newly diagnosed, treatment naïve, uncontrolled Type 2 Diabetes Mellitus patients

Takeda ) A Multicenter, Randomized, Double-Blind, Placebo- and Active-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of TAK-XXX 25 mg and 50 mg Compared to Placebo and Sitagliptin 100 mg When Used in Combination with Metformin in Subjects with Type 2 Diabetes.

GSK-HZC(Summit): A Clinical Outcomes Study to compare the effect of Fluticasone Furoate/Vilanterol Inhalation Powder 100/25mcg with placebo on Survival in Subjects with moderate Chronic Obstructive Pulmonary Disease (COPD) and a history of or at increased risk for cardiovascular disease.

ITCA-XXX-CLP-XXX: A Randomized, Multicenter Study to Evaluate Cardiovascular Outcomes in Patients Treated with Standard of Care for Type 2 Diabetes.

ITCA-XXX-CLP-XXX: An Open-Label, Multi-Center, Sub-Study to Evaluate the Efficacy, Safety and Tolerability of ITCA 650 In Patients with Type 2 Diabetes with High Baseline HbA1c.

Cephalon: A 16-Week, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Reslizumab (3.0 mg/kg) Treatment in Patients with Moderate to Severe Asthma

Forest NAC-MD-XX : A Multicenter, Randomized, Double-Blind, Placebo-Controlled, 8-Week Study to Evaluate the Safety and Efficacy of Nebivolol and Valsartan Given as a Fixed-Dose combination in Patients With Stage 1 or 2 Essential Hypertension.

Dey XXX-XXX(Open): A 12-week Randomized, Multiple-Dose, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate Nebulized Fluticasone Propionate (FP) Dose Response in Adult Subjects with Partly Controlled and Uncontrolled Asthma.

Lilly-FXZ-M: A Multinational Observational Study Assessing Insulin use: understanding the challenges associated with progression of therapy - The MOSAic Type 2 Diabetes Study.

Amarin: A Multi-Center, Prospective, Randomized, Double-Blind, Placebo-Control, Parallel-Group Study to Evaluate the Effect of AMR XXX on Cardiovascular Health and Mortality in Hypertriglyceridemic Patients with Cardiovascular Disease or High Risk for Cardiovascular Disease.

FuriexXXX: A Randomized, Double-blind, Placebo-controlled, Phase 3 Study to Evaluate the Efficacy, Safety, and Tolerability of JNJ-XXXXXXX in the Treatment of Patients With Diarrhea-Predominant Irritable Bowel Syndrome.

BI XXXX.XX: A phase III, randomized, double-blind, parallel group study to evaluate the efficacy and safety of linagliptin 5 mg compared to placebo, administered as oral fixed dose combination with empagliflozin 10 mg or 25 mg for 24 weeks, in patients with type 2 diabetes mellitus and insufficient glycemic control after 16 weeks of treatment with empagliflozin 10 mg or 25 mg on metformin background therapy

Astra-Zeneca XXXXX: A Randomized, Double Blind, Placebo-Controlled Study of a fixed Dose of Subcutaneous MNTX in Adults With Advanced Illness and OIC\*Open Label Extension Study to Assess the Safety of a Fixed Dose of Subcutaneous MNTX in Subjects With Advanced Illness and OIC

Ferring XXXXXX: A Double-blind, Randomised, Placebo-controlled, Phase 3 Trial in Patients with Chronic Idiopathic Constipation to Demonstrate the Efficacy and Safety of XXXXXXXXXXXX 5 mg and 10 mg for 12 Weeks Followed by a 4-week Withdrawal Period

Ferring XXXXXX: A Multicenter, Open-label, Safety and Tolerability Extension Trial of 5 mg and 10 mg XXXXXXXXXXXX Daily in the Treatment of Chronic Idiopathic Constipation

Cubist XXXX-OIC-XX-XX: A Multicenter, Randomized, Double-Blind Placebo-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of XX-XXXX for the Treatment of Opioid-Induced Constipation in Adults Taking Opioid Therapy for Chronic Non-Cancer Pain

AbbVie XXX-XXX: A Long-Term Non-Interventional Registry to Assess Safety and Effectiveness of XXXXXX (Adalimumab) in Patients with Moderately to Severely Active Ulcerative Colitis (UC)

Astra-Zeneca XXXXXXXXXXXX: A Phase 2a Study to Evaluate the Efficacy and Safety of XXXXXXXX in Subjects with Moderate to Severe Crohn's Disease

Ono Pharma ONO-XXXXXXXXXX: A Phase 2, Multicenter, Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of ONO-XXXX in Female Subjects With Diarrhea-Predominant Irritable Bowel Syndrome (IBS-D)

TAK-XXX-XXX: A Phase 3, Multicenter, Randomized, Double-Blind, PlaceboControlled, 24-Week Study to Evaluate the Efficacy and Safety of Daily Oral TAK-XXX 50 mg Compared With Placebo as an Add-On to Glimepiride in Subjects With Type 2 Diabetes

ITCA XXX-CLP-XXX: A Randomized, Multicenter Study to Evaluate Cardiovascular Outcomes with ITCA XXX in Patients Treated with Standard of Care for Type 2 Diabetes

Euclid XXXXXXXXXXXX: A randomized, double-blind, parallel group, multicentre phase IIIb study to compare ticagrelor with clopidogrel treatment on the risk of cardiovascular death, myocardial infarction and ischemic stroke in patients with established Peripheral Artery Disease. EUCLID (Examining Use of tiCagreLor In paD)

TAK-XXX\_XXX: A Multicenter, Randomized, Double-Blind, Placebo-Controlled, Phase 3 Study to Evaluate Cardiovascular Outcomes of TAK-875, 50 mg in Addition to Standard of Care in Subjects with Type 2 Diabetes and with Cardiovascular Disease or Multiple Risk Factors for Cardiovascular Events

BAYER XXXXX: A prospective, randomized, open-label, parallel-group, active-controlled, multicenter study exploring the efficacy and safety of once-daily oral rivaroxaban (BAY XX-XXXX) compared with that of dose-adjusted oral vitamin K antagonists (VKA) for the prevention of cardiovascular events in Subjects with nonvalvular atrial fibrillation scheduled for cardioversion

ITCA XXX-CLP-XXX: A Randomized, Multicenter Study to Evaluate Cardiovascular Outcomes with ITCA XXX in Patients Treated with Standard of Care for Type 2 Diabetes

TAK-XXX-XXX: A Multicenter, Randomized, Double-Blind, Placebo- and Active-Controlled, Phase 3 Study to Evaluate the Efficacy and Safety of TAK-875 25 mg and 50 mg Compared to Placebo and Sitagliptin 100 mg When Used in Combination with Metformin in Subjects with Type 2 Diabetes

**Sub-Investigator**

Logical Therapeutics, Osteoarthritis, XX-XX001-003

Sangamo, Diabetic Neuropathy XXXX

TAP Pharmaceutical, GERD X-XXX4-082

Novartis, Hypertension, XXXX100XXX03

Merck, Hypertension/Diabetes Mellitus II, XX0736-007-00

Merck, Weight Loss, 015-XX

Luitpold Pharmaceutical, Iron Deficiency Anemia, 1XXX07017

Merck, Diabetes, XX-0431-024

Pfizer, Diabetes/Asthma, X2171028

Pfizer, Diabetes/COPD, X2171030

Merck, Obesity, XXX-0364

Mylan Bertek Pharmaceutical, Inc, Hypertension, XXX-324

Mylan Bertek Pharmaceutical, Inc, Hypertension, XXX-310

Pfizer, Hypertension, XXXX1001

Takeda, Diabetes, 01-04-XX-XXX-525

Alteon, Hypertension, XX-711

Merck, Diabetic, XX-043

Merck & Co Inc, Weight Loss XXXXX

Endo, LBP EN-3261-001

Tap Pharmaceuticals, Gout X-XX06-153

Pfizer, Tibia Fractured X3241002

Millennium, Crohn's X13007

Millennium, Ulcerative Colitis X13006

Millennium, Rollover X13008

Eisai, Colonoscopy Sedation, X408