

# Provident Clinical Research

**Andrea Lawless, MD**

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## **PROFESSIONAL EXPERIENCE:**

2008-Present	Clinical Investigator Provident Clinical Research Addison, Illinois
2002-2008	Housecall Physician, Medical Director Housecall Services of Greater Chicago Db a MD at Home Rockford, Illinois
2000-2002	Housecall Physician, Associate Medical Director Housecall Services of Greater Chicago Rockford, Illinois
1993-2000	Medical Director of Clinical Management Services and Quality Assessment First Health (previously Healthcare Compare) Downers Grove, Illinois
1992-1996	Medical Consultant Research & Data Consulting, Inc Bloomington, Illinois
1988	Employee Physician Fermilab Batavia, Illinois
1989-2001	Physician Volunteer DuPage Community Clinic Wheaton, Illinois
1986-1987	Employee Physician AT&T Bell Laboratory Naperville, Illinois

**Andrea Lawless, MD – Curriculum Vitae**  
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1985-1993                      Director of Urgent Care Department  
   Glen Ellyn Clinic  
   Glen Ellyn, Illinois

1983-1985                      Staff Physician, Urgent Care Department  
   Glen Ellyn Clinic  
   Glen Ellyn, Illinois

**EDUCATION:**

1980-1983                      Internal Medicine Residency Program  
   Rush Presbyterian- St. Luke's Medical Center  
   Chicago, Illinois

1976-1980                      Doctor of Medicine  
   Rush Medical College  
   Chicago, Illinois

1969-1973                      Bachelor of Arts, Music  
   Clarke College  
   Dubuque, Iowa

**CERTIFICATION:**

Current                              Illinois State License

1987                                 American Board of Internal Medicine

1981                                 National Board of Medical Examiners

**PROFESSIONAL SOCIETIES:**

2008-Present                      National Lipid Association

**KEY ACCOMPLISHMENTS:**

- Managed and grew the Glen Ellyn Clinic Urgent Care Department from approximately 10,000 patient visits to over 27,000 patient visits per year
- Developed guidelines for Healthcare Compare/ First Health nurse case managers for the management of HIV/AIDS related patient care
- Developed Healthcare Compare/ First Health transplant guidelines for assessing appropriateness of patient care for nurse case managers.
- Oversaw the development of the strategic plan for DuPage Community Clinic's Medical Advisory Committee, and was Chairman of the Medical Advisory Committee for a free clinic serving residents without insurance in DuPage County
- Participated in End of Life Care Physician Educator training program and educated all physician associates at Housecall Services of Greater Chicago
- Developed the Clinical Guidelines Manual for Housecall Services of Greater Chicago

**PUBLICATIONS (peer reviewed journals):**

1. Maki KC, Rubin MR, Wong LG, McManus JF, Jensen CD, Marshall JW, **Lawless A.** Serum 25-Hydroxyvitamin D is an Independent Predictor of High Density Lipoprotein Cholesterol and Metabolic Syndrome in Men and Women. *National Lipid Association Annual Scientific Session.* May, 2009.
2. Maki KC, Lubin BC, Reeves MS, **Lawless A,** Dicklin MR, Harris WS. Prescription omega-3 acid ethyl esters plus Simvastatin 20 and 80 mg: Effects in mixed dyslipidemia. *J Clin Lipidol.*

**RESEARCH PARTICIPATION (CONFIDENTIAL INFORMATION REPRESENTED WITH XXX):**

1. A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Phase III Study to Assess Efficacy and safety of XXX Therapy in Subjects with Severe Hypertriglyceridemia. 2010, (Clinical Investigator)
2. A RANDOMIZED, DOUBLE-BLIND, ACTIVE-CONTROLLED, PARALLEL-GROUP STUDY OF XXX VS. XXX IN PATIENTS WITH PRIMARY HYPERLIPIDEMIA OR MIXED DYSLIPIDEMIA. (2010, Clinical Investigator)
3. A Randomized, Double-Blind, Controlled, Crossover Trial to assess the Acute Effects of Two Doses of XXX on Endothelial Function in Women (2010, Principal Investigator) Sponsor: Welch Foods Inc., a Cooperative
4. A Randomized, Controlled, Double-blind Crossover Study to Assess the Effects of a XXX Ingredient, at Two Doses, on Insulin Sensitivity (2010, Clinical Investigator) Sponsor: National Starch LLC
5. A Randomized, Controlled, Crossover Trial to Assess the Effects of XXX on Exercise Performance at Two Intensities in Healthy Men (2010, Clinical Investigator) Sponsor: The Coca-Cola Company
6. A Study to Determine Eligibility for a Randomized, Double-Blind, Placebo-Controlled, Parallel Group Trial Designed to Assess the Effects of XXX on Lactate Threshold in Trained Cyclists (2010, Clinical Investigator) Sponsor: PepsiCo Global Long Term Research
7. A Single-blind Pilot Study to Assess XXX from a Softgel Capsule Compared to a Standard Tablet (2010, Clinical Investigator) Sponsor: Pharmavite, LLC
8. A Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study of the Effects of XXX on Oxidized LDL (2010, Clinical Investigator) Sponsor: KitoZyme, Inc.
9. Evaluation of an Oral Nutritional Supplement Containing XXX in Malnourished and Frail Subjects (2010, Clinical Investigator) Sponsor: Abbott Nutrition, Abbott Laboratories
10. A Randomized, Controlled Trial to Assess the Effects of XXX on Eicosapentaenoic Acid Levels of Red Blood Cells and the Omega-3 Index (2010, Clinical Investigator) Sponsor: Monsanto/The Solae Company
11. A Double-Blind, Randomized, Controlled, Crossover Trial to Assess the Effects of XXX on Urinary Anti-Adhesion Activity in Healthy Men and Women (2010, Clinical Investigator) Sponsor: Ocean Spray Cranberries, Inc.

12. Effect of XXX on Metabolic Parameters in Subjects with Type 2 Diabetes (2010, Clinical Investigator) Sponsor: Abbott Nutrition, Abbott Laboratories
13. A Double-blind, Randomized, Placebo-controlled, Crossover Trial to Assess the Effects of 4 g/d XXX on Indices of Glucose Homeostasis and Lipoprotein Lipids in Subjects with Hypertriglyceridemia (2010, Clinical Investigator) Sponsor: Provident Clinical Research & Consulting, Inc.
14. Evaluation of XXX Containing a Slowly Digestible Carbohydrate on Energy Intake and Satiety (2010, Clinical Investigator) Sponsor: GlaxoSmithKline Consumer Healthcare
15. A Randomized, Placebo-Controlled, Double-Blind, Crossover Study to Evaluate the Effects of Three Doses of XXX, on Alertness, Attention and Concentration in Healthy Men and Women (2010, Clinical Investigator) Sponsor: DSM Nutritional Products Ltd
16. A Randomized, Double-blind, Placebo-controlled, Crossover Study Evaluating the Effects of XXX on Physical Performance in Healthy Male Volunteers (2010, Clinical Investigator) Sponsor: PepsiCo, Inc.
17. Randomized, double-blind, placebo controlled Phase II study to examine the effects of XXX in healthy adult subjects with laboratory confirmed influenza (2010, Principal Investigator) Sponsor: NexBio, Inc.
18. A Double-blind, Randomized, Placebo-controlled, Two-period Crossover Trial to Assess the Effects of 4g/d XXX on Low-density Lipoprotein Cholesterol and Other Aspects of the Fasting Lipid Profile in Subjects with Primary Hypercholesterolemia (2010, Clinical Investigator) Sponsor: Provident Clinical Research and Consulting, Inc.
19. A Randomized, Controlled, Double-blind Crossover Study to Assess the Effects of a XXX, at Two Doses, on Insulin Sensitivity (2009, Principal Investigator) Sponsor: National Starch LLC
20. A Randomized, Controlled, Crossover Trial to Assess the Effects of XXX on Work Capacity During Exercise in Trained Male Athletes (2009, Clinical Investigator) Sponsor: The Coca-Cola Company
21. A Randomized, Controlled, Parallel Trial to Evaluate the Effects of XXX on Cognitive Processes in Children 8-12 Years of Age (2009, Clinical Investigator) Sponsor: Kellogg Company
22. A Phase 3, Multi-Center, Placebo-Controlled, Randomized, Double-Blind, 12-Week Study to Evaluate the Effects of Two Doses of XXX on Fasting Serum Triglyceride Levels, in Patients With Persistent High Triglyceride Levels ( $\geq 200$  mg/dL and  $< 500$  mg/dL) Despite Statin Therapy (2009, Principal Investigator) Sponsor: Amarin Pharma Inc.
23. A Randomized, Double-Blind, Placebo-Controlled Study of the Efficacy and Safety of XXX Added to Antihypertensive Treatment with Lisinopril or Losartan in Patients with Hypertension (2009, Principal Investigator) Sponsor: Forest Research Institute
24. "A Phase 3, Multi-Center, Placebo-Controlled, Randomized, Double-Blind, 12-Week Study With an Open-Label Extension to Evaluate the Efficacy and Safety of XXX in Patients With Fasting Triglyceride Levels  $\geq 500$  mg/dL and  $\leq 2000$  mg/dL: The XXX MARINE Study (2009, Principal Investigator) Sponsor: Amarin Pharma Inc.
25. A Phase II, Randomized, Double-Blind, Placebo-Controlled, Multi-Center, Parallel Group Study Evaluating the Efficacy, Safety and Pharmacokinetics of XXX Administered for 12

- Weeks in Untreated or Metformin-treated Type 2 Diabetic Patients (BALANCE) (2009, Principal Investigator) Sponsor: Akros Pharma Inc.
26. A Randomized, Double-Blind, Active-Comparator, 8-Week Forced-Titration Study of the Efficacy and Safety of XXX Versus XXX in Hypertensive Subjects (2009, Principal Investigator) Sponsor: Daiichi Sankyo, Inc.
  27. A Randomized, Controlled Crossover Study to Assess the Effects of Consuming XXX as Part of a Typical American Diet on the Plasma Lipid Profile in Men and Women with Primary Hypercholesterolemia (2009, Clinical Investigator) Sponsor: Almond Board of California
  28. Evaluation of the Relationships of Time and Dose of XXX and XXX to Changes in XXX of Red Blood Cells (2009, Principal Investigator) Sponsor: Monsanto Company/The Solae Company
  29. A Randomized, Placebo-Controlled, Crossover Trial to Assess the Effects XXX on Fasting Lipoprotein Lipids in Men and Women with Primary Hypercholesterolemia (Protocol A) (2009, Principal Investigator) Sponsor: Pharmavite, LLC
  30. A Randomized, Placebo-Controlled, Crossover Trial to Assess the Effects of XXX on Fasting Lipoprotein Lipids in Men and Women with Primary Hypercholesterolemia (Protocol B) (2009, Principal Investigator) Sponsor: Pharmavite, LLC
  31. A Randomized, Double-Blind, Placebo-Controlled, Parallel Arm Trial to Assess the Effects of XXX on High-Density Lipoprotein Cholesterol and Other Cardiovascular Disease Risk Markers (2009, Principal Investigator) Sponsor: Shaklee Corporation
  32. A Multicenter, Randomized, Double-Blind, Active Controlled, Parallel Group, Phase 3 Trial to Evaluate the Safety and Efficacy of XXX in Combination with Metformin as Initial Therapy as Compared with XXX Monotherapy and Metformin Monotherapy in Subjects with Type 2 Diabetes Who Have Inadequate Glycemic Control (2009, Principal Investigator) Sponsor: Bristol-Myers Squibb
  33. A Multicenter, Randomized, Double-Blind, Active-Controlled Study to Evaluate the Durability of the Efficacy and Safety of XXX Compared to Glipizide When Used in Combination with Metformin in Subjects with Type 2 Diabetes (2009, Principal Investigator) Sponsor: Takeda
  34. A Pilot Study to Assess Adherence XXX in Men and Women with Type 2 Diabetes Mellitus (2009, Clinical Investigator) Sponsor: Kraft
  35. A Randomized, double-blind, placebo-controlled, 2-arm parallel-group, multicenter study with a 24-week main treatment period and an extension assessing the efficacy and safety of XXX on top of pioglitazone in patients with type 2 diabetes not adequately controlled with pioglitazone (2009, Principal Investigator) Sponsor: Sanofi-Aventis
  36. A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Safety and Efficacy of XXX in Combination with Metformin in Subjects with Type 2 Diabetes (2009, Principal Investigator) Sponsor: Surface Logix, Inc.
  37. A Double-blind, Randomized, Controlled Crossover Trial to Assess the Digestive and Physiological Effects of XXX in Healthy Men and Women (2009, Principal Investigator) Sponsor: Kellogg Company

38. A Randomized, Controlled Parallel Study to Evaluate the Effects of XXX on Fecal Bile Acids and Blood Lipids in Men and Women with Mild to Moderate Hypercholesterolemia (2009, Principal Investigator) Sponsor: The Solae Company
39. A Randomized, Double-Blind, Placebo-Controlled, Parallel-Group Study to Evaluate the Safety and Efficacy of Different Doses of XXX in Combination With a Statin vs. Statin Mono-Therapy in Patients With Hyperlipidemia (2009, Principal Investigator) Sponsor: Surface Logix, Inc.
40. A Randomized, Double-Blind, Placebo-Controlled, Dose-Ranging, Exploratory, 28-Day Study to Examine the Effects of XXX on Blood Pressure and Glucose Tolerance in Patients With Mild to Moderate Hypertension and Impaired Glucose Tolerance (2009, Principal Investigator) Sponsor: Arete Therapeutics
41. A Multicenter, Double-Blind, Randomized, 12-Month, Placebo-Controlled Study to Evaluate the Lipid-Lowering Effect, Safety and Tolerability of XXX 25 mg/day and 50mg/day When Added to Ongoing Stable Statin Therapy (HMG-CoA Reductase Inhibitors) in Patients with Primary Hypercholesterolemia (2008, Principal Investigator) Sponsor: Sanofi Aventis
42. Efficacy and Safety of New Oral XXX Extended Release Tablet Formulations In Patients with Mild or Moderate, Active Ulcerative Colitis. A Multicenter, Randomized, Double-Blind, Double Dummy Comparative Study Versus Placebo, with an Additional Reference Arm Evaluating XXX (2008, Clinical Investigator) Sponsor: COSMO Pharmaceuticals
43. A Phase II, Randomized, Double-Blind, Placebo And Active Controlled, Parallel Group, Multi-Center, Dose Ranging Study to Evaluate the Efficacy and Safety of XXX Compared to Placebo after 8 Weeks Treatment In Patients with Resistant Hypertension (2008, Principal Investigator) Sponsor: Great Lakes Drug Development/Novartis
44. A Double-blind, Randomized, Controlled, Crossover Study to Assess the Effects of Consuming a Beverage Containing XXX on Cognitive Function in Healthy Men and Women (2008, Principal Investigator) Sponsor: The Beverage Institute for Health & Wellness, LLC The Coca-Cola Company
45. A Prospective, Open-Label, Titration Study to Evaluate the Efficacy and Safety of XXX in Multiple Subgroups of Hypertensive Subjects Who Are Non-Responders to Anti-Hypertensive Monotherapy (2008, Principal Investigator) Sponsor: Daiichi Sankyo, Inc.
46. A Double-blind, Randomized, Placebo-controlled, Two-period Crossover Trial to Assess the Effects of XXX on Low-density Lipoprotein Cholesterol and Other Aspects of the Fasting Lipid Profile in Subjects with Primary Hypercholesterolemia (2008, Clinical Investigator) Sponsor: Provident Clinical Research & Consulting, Inc.
47. A Multicenter, Double-Blind, Randomized, Placebo-Controlled Study to Evaluate the Efficacy, Safety and Tolerability of XXX when Added to Ongoing Stable Statin Therapy at High Doses in Patients with Severe Primary Hypercholesterolemia (2008, Principal Investigator) Sponsor: Sanofi Aventis
48. A Phase III, Double-blind, Randomized, Multi-Center, Prospective, Placebo-Controlled Comparative Study to Evaluate XXX on Carotid Intima-Media Thickness (cIMT) in Subjects with Type IIb Dyslipidemia with Residual Risk in Addition to Atorvastatin Therapy Trial. (2008, Principal Investigator) Sponsor: Abbott Laboratories
49. A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study of the Long-Term Safety and Efficacy of XXX for the Treatment of Hypoactive Sexual Desire

- Disorder in Postmenopausal Women (2008, Principal Investigator) Sponsor: BioSante Pharmaceuticals, Inc.
50. A Phase III, Randomized, Double-Blind, Placebo-Controlled, Multi-Center Study of the Safety and Efficacy of XXX for the Treatment of Hypoactive Sexual Desire Disorder in Surgically Menopausal Women (2008, Principal Investigator) Sponsor: BioSante Pharmaceuticals, Inc.
  51. A Double-blinded, Randomized, Controlled Crossover Trial to Assess the Effects of XXX on Postprandial Hunger and Satiety in Men and Women. (2008, Clinical Investigator) Sponsor: Dairy Management, Inc. / National Dairy Council
  52. A Double-blind, Randomized, 12-month, Placebo-controlled, Parallel Group, Fixed-dose Study to Evaluate the Efficacy and Safety of XXX in Patients with Primary Hypercholesterolemia. (2008, Principal Investigator) Sponsor: Sanofi Aventis
  53. XXX Status and Risk for Cardiovascular Disease. (2008, Principal Investigator) Sponsor: Shaklee Corporation