

The background of the report cover is a photograph of a modern building with red brick and large glass windows. A prominent feature is a large, circular, metallic sculpture with a textured surface, mounted on a tall, rectangular, textured pedestal. The building has multiple stories and a mix of brick and glass facades. The sky is blue with some clouds. The overall aesthetic is professional and academic.

# 2023 ANNUAL REPORT

DEPARTMENT OF  
PHARMACEUTICAL  
OUTCOMES AND  
POLICY

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# LETTER FROM THE CHAIR


Dear POP family and friends,

This has been another great year for the department of pharmaceutical outcomes and policy, but also a year of significant change, particularly in leadership across UF. In 2023, UF installed a new President, Dr. Ben Sasse, as well as a new dean of the College of Pharmacy, Dr. Peter Swaan. As you may know, Dr. Almut Winterstein stepped down as chair at the end of 2022 to focus more on her thriving research program and directing the Center for Drug Evaluation and Safety, or CoDES, and the Consortium for Medical Marijuana Clinical Outcomes Research. I hope you will join me in thanking Almut for her many years of service and leadership to the department, which helped us grow in many remarkable ways. At the start of her service as chair, the POP department had six faculty, and by the time of this writing in fall 2023, the department has grown to 15 full-time faculty, with more to come. We developed four focal areas in the department: pharmacoepidemiology & drug safety science, pharmacoeconomics, health services research, and most recently, artificial intelligence, or AI, for pharmaceutical outcomes research. Further, the department grew in many other important ways: increased graduate training, increased research productivity and funding, incredible growth in research infrastructure (including support staff) through CoDES, a substantial contribution to leadership in the AI community at UF and many more. It has truly been a remarkable period of growth for the POP department, and much of that growth was due to Almut's leadership.



This year, we added a new faculty member, Dr. Mikael Svensson, further strengthening our pharmacoeconomics expertise in the department. He came to us by way of the University of Gothenburg in Sweden. I encourage you to check out his faculty profile on page 7. We also recently added a new faculty member, Dr. Earl Morris, in our pharmacoepidemiology specialization, and have another search open. More to come on these new faculty in next year's annual report. We also welcomed a number of research staff, including postdoctoral fellows, research coordinators, data analysts, and a new administrative support staff member, Gabby Gele.

Both our residential and online graduate programs continue to grow, and we continue logging record numbers of highly competitive candidates. It has been a great joy to watch them excel in our program. Our research focus continues to build around areas of excellence in pharmacoeconomics, pharmacoepidemiology and pharmaceutical



health services research and the most recent emphasis on the application of AI methods in POP research. Our faculty evaluated the safety and effectiveness of drugs, examined the quality of medication use and the impact of regulatory efforts to improve health care quality and designed prediction models that can help guide patient and provider decision-making for more effective and safer use of medications. Our clinical areas of emphasis have retained a focus on the opioid epidemic and mental health, cardiometabolic disease, geriatrics and dementia, infections and cancer, and pregnancy and pediatrics. Our Consortium for Medical Marijuana Clinical Outcomes Research, which involves nine universities in the state, held its third annual conference this year and continues to support innovative research on outcomes related to medical marijuana use. Finally, CoDES has grown to nearly 40 members, sharing a growing data infrastructure that now includes patient-level data on some 350+ million lives. We also added a new center to the department, the Center for Integrative Cardiovascular and Metabolic Disease, or CICMD. The new home for POP, CoDES, CICMD, and the Medical Marijuana Consortium — the Malachowsky Hall for Data Science & Information Technology — had its ribbon cutting ceremony in November 2023, and we moved into the building in December.

I hope you agree that our department continues to make impressive strides, growing to meet the needs of both the state and the broader profession. These are exciting times in pharmaceutical outcomes research, and we continue to lead the way. I also hope you take the opportunity to read about some of these directly from our “POP stars” and continue to stay close to our department. If you have not been in Gator country recently, please consider visiting us, virtually or in person, and taking a visit of our new space in Malachowsky Hall.

Sincerely,



STEVEN SMITH, PHARM.D., M.P.H., FCCP, FAHA  
*Assistant Professor and Interim Chair*

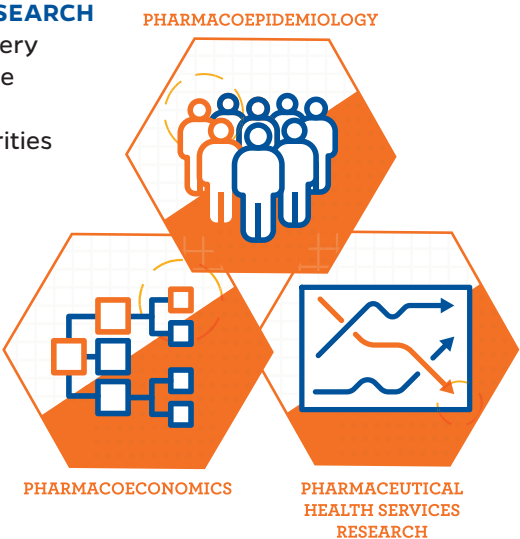
# PUBLIC HEALTH IMPACT SPANNING OVER 30 YEARS OF GRADUATE TRAINING, RESEARCH AND SERVICE

## WHAT IS POP ABOUT?

The department of pharmaceutical outcomes and policy excels in three areas of specialization in both research and training. Each area employs its own set of methodological approaches, but all utilize the vast array of big data sources available in the department.

- 1. PHARMACOEPIDEMIOLOGY AND SAFETY SCIENCES** applies epidemiologic methods and knowledge to the study of uses and effects of drugs in populations after drug approval. Important research areas include causal inference studies on postmarketing drug safety and comparative effectiveness and predictive models of drug outcomes and use.
- 2. PHARMACOECONOMICS AND OUTCOMES RESEARCH** assesses the value (clinical and economic) of pharmaceutical products and related services in the delivery of health care. It aims to provide patients, providers and payers with evidence to inform decision-making. Important research areas include economic evaluations, budget impact analysis, multicriteria decision analysis and policy evaluations related to drug formulary, reimbursement and pricing.
- 3. PHARMACEUTICAL HEALTH SERVICES RESEARCH** examines the quality, accessibility and delivery of pharmaceuticals and related services. The program places emphasis on vulnerable populations, such as children, elderly, minorities and persons with high-burden diseases and disabilities. Examples of research include the development of quality measures or assessment of disparities and determinants of appropriate therapy.

In addition, our new focus area, **Artificial Intelligence in Pharmaceutical Outcomes and Policy Research**, supports the three specialization areas with the goal of employing and tailoring novel AI methodology on automated health care data to answer important questions about clinical outcomes of drug effects, other health care interventions, and the policies governing medication use.



In this report, Dr. Tianze Jiao shines a spotlight on the department's pharmacoepidemiology and drug safety science area of specialization.



## SPOTLIGHT ON

# PHARMACOEPIDEMIOLOGY & DRUG SAFETY RESEARCH AND TRAINING

## PHARMACOEPIDEMIOLOGY AND DRUG SAFETY

Our program in pharmacoepidemiology and drug safety has grown significantly over the last decade. With nine faculty specializing in this area, it is one of the most robust areas of specialization in the POP department. Faculty in this area are actively collaborating on research and shaping the curriculum for pharmacoepidemiology and drug safety research within the POP graduate program, as well as contributing significantly to the training in our Pharm.D. curriculum. Within the POP graduate program, our primary aim is to equip students with the essential knowledge and methodologies crucial for engaging in pharmacoepidemiology and drug safety research across a wide variety of therapeutic areas. Indeed, in this specific track, we offer a range of graduate courses from introductory, intermediate to advanced levels. These courses continuously hone students' critical thinking, reasoning abilities and analytical skills. The emphasis of these courses includes a comprehensive understanding and practical application of observational research methods, particularly in phase IV studies and translational clinical sciences. To continuously demonstrate our departmental leadership in the advanced method and prepare our students with expertise in cutting-edge methods, we have further integrated AI into our existing curriculum via seminars and new courses in the past two years. Alongside these didactic courses, students benefit from hands-on training opportunities. They collaborate with our faculty members in diverse realms such as perinatal, pediatric and geriatric pharmacoepidemiology. This practical engagement allows students to gain invaluable experience in generating real-world evidence.

# WHO WE ARE

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STAFF

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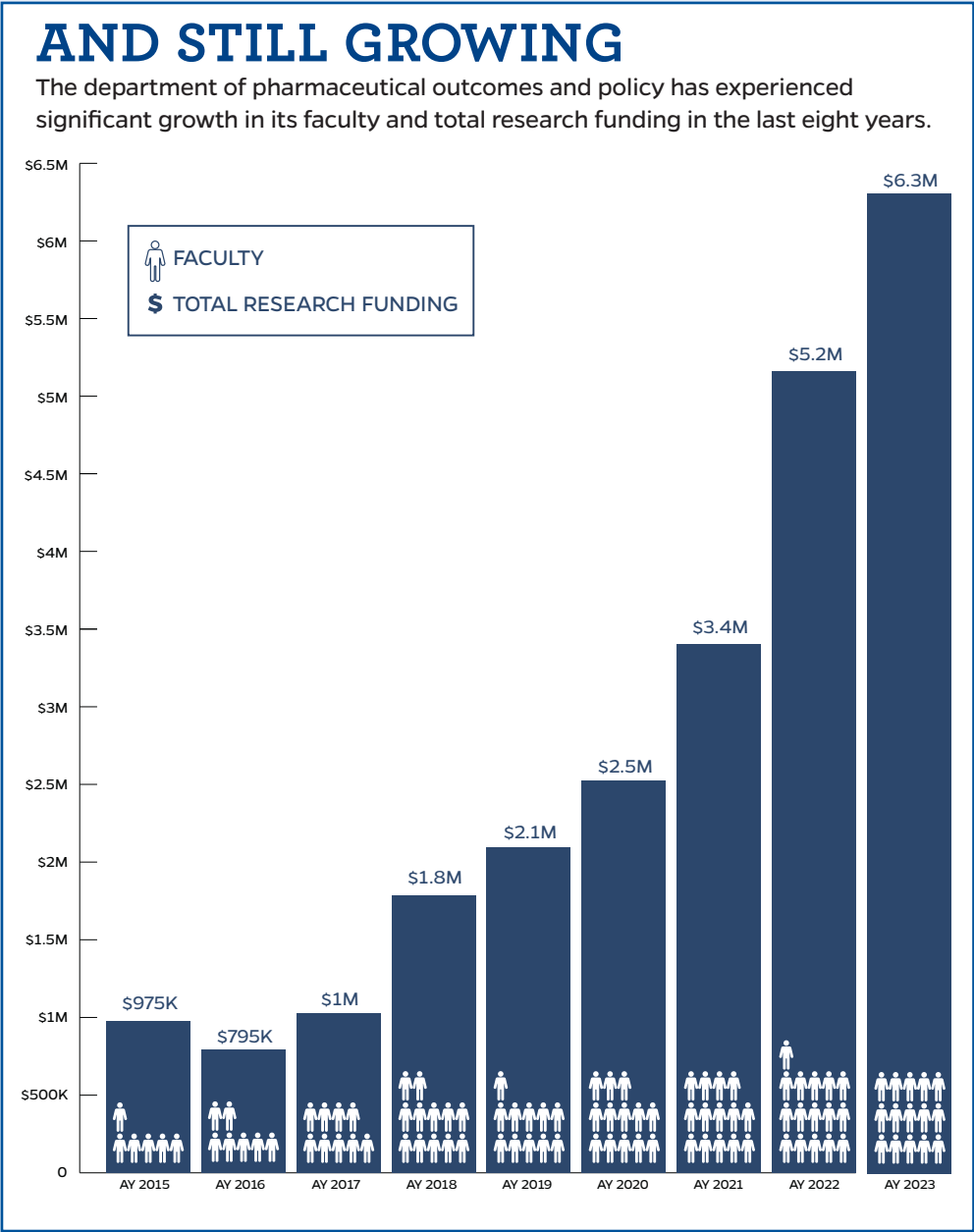
POSTDOC  
FELLOWS &  
RESEARCH  
SCIENTISTS

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RESIDENTIAL  
MASTER'S  
STUDENTS

# RESEARCH & GRADUATE FACULTY

This year, our research funding grew by an impressive 20%, even while our graduate and research faculty group remained relatively stable. This academic year marked seven years of year-on-year growth for our department with a nearly eight-fold increase in research funding between the academic years 2015-16 and 2022-23.



# NEW FACULTY IN 2022-23



**MIKAEL SVENSSON, PH.D.**

Professor

Dr. Svensson is a health economist and pharmacoeconomist specializing in comparative- and cost-effectiveness analyses, causal inference and policy evaluation. Svensson received his Ph.D. in Economics from Örebro University (Sweden) in 2007 and also participated in the International Ph.D. Program in Health Economics & Policy at the Swiss School of Public Health (hosted by the University of Lausanne).

Svensson joined the department of pharmaceutical outcomes and policy in the fall of 2022. Before joining the University of Florida, he was a professor of applied health economics at the University of Gothenburg (Sweden). He has also had visiting positions at the Centre for Health Economics (York, UK), Toulouse School of Economics (France) and Williams College (U.S.).

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# CURRENT FACULTY IN 2022-23



**STEVEN SMITH, PHARM.D., M.P.H.**

Interim Chair & Assistant Professor

Dr. Smith's research is in the area of cardiovascular pharmacotherapy and hypertension and is funded by the National Heart, Lung, and Blood Institute of the National Institutes of Health, the Patient-Centered Research Outcomes Institute, and the U.S. Department of Defense. He is a member of the American Heart Association, American College of Cardiology, American College of Clinical Pharmacy, and the International Society for Pharmacoepidemiology. He is an Assistant Professor in the Department of Pharmaceutical Outcomes and Policy, with a joint appointment in the Division of Cardiovascular Medicine in the UF College of Medicine.



**AMIE GOODIN, PH.D., M.P.P.**

Assistant Professor

Dr. Goodin's research focuses on policy evaluation through the lens of health services research, incorporating mixed-method approaches to assess the impact of policy changes on populations that face health disparities. Specific interests include substance use disorders, particularly opioids and tobacco cessation during pregnancy.

# CURRENT FACULTY IN 2022-23



**JINGCHUAN "SERENA" GUO, M.D., PH.D.**  
Assistant Professor

Dr. Guo's research is built at the intersection of epidemiology and pharmaceutical health services and outcomes research, with focus on diabetes, cardiovascular health and social determinants of health. She uses large health care databases and advanced methods (e.g., machine learning, causal mediation analysis) to study the equitable delivery of high-quality care, individualized effectiveness and safety of treatment and interventions, and fairness and bias in algorithmic decision-making.



**LAURA E HAPPE, PHARM.D., M.S.**  
Clinical Professor, Director of The POP Online M.S. Program

Dr. Happe is an editor, professor and author who specializes in using data to aid in decision-making. Happe leads the online master's degree program with approximately 150 students and 50 graduates annually. She is also the editor-in-chief of the Journal of Managed Care and Specialty Pharmacy, the official peer-reviewed journal of the Academy of Managed Care Pharmacy. Her first book, If You Give an Ox an Oxy, is an educational resource for parents to teach their adolescents about the hazards of opioid use.



**MD MAHMUDUL HASAN, PH.D.**  
Assistant Professor

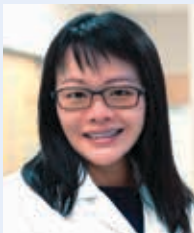
Dr. Hassan's research focuses on leveraging advanced artificial intelligence/machine learning, and management science techniques to contribute to health care decision-making, policy and management. He conducts data-driven interdisciplinary research in pharmaceutical outcomes and health service utilization with a focus on substance use and mental health disorder, opioid-related adverse drug events and chronic diseases.



**TIANZE JIAO, PH.D.**  
Assistant Professor

Dr. Jiao's research focuses on investigating and applying innovative and rigorous epidemiologic, economic and comparative effectiveness research methods to identify and apply the precision medicine approach that will result in optimal outcomes for each patient in a resource-efficient manner.

# CURRENT FACULTY IN 2022-23



**WEI-HSUAN “JENNY” LO-CIGANIC, PH.D., M.S., M.S. PHARM.**  
Associate Professor

Dr. Lo-Ciganic’s research program focuses on the evaluation of treatment effectiveness and safety, the application of advanced predictive analytics, and the improvement of prescribing quality and health disparity, especially among vulnerable populations. Areas of research interests include medication adherence, prescription drug abuse, treatment for substance use disorders, chronic diseases management and oncology.



**HAESUK PARK, PH.D.**  
Associate Professor

Dr. Park’s research program focuses on the evaluation of economic and health outcomes of medication and pharmaceutical care services, as well as policy associated with the use of pharmaceuticals.



**RACHEL REISE, PHARM.D., M.S.**  
Clinical Assistant Professor

Dr. Reise’s research focuses on evaluations of outcomes relating to transitions of care, access to care and medication safety. She is also involved with a number of projects aimed at improving quality within UF Health Physicians outpatient practices.



**MASOUD ROUHIZADEH, PH.D., M.SC., M.A.**  
Assistant Professor

Dr. Rouhizadeh’s research focuses on applying machine learning and natural language processing methods for identifying clinical concepts from unstructured text and converting them into structured data. Another major part of his research has been developing clinical ontologies and lexical resources, as well as computational models for identifying social and behavioral determinants of health.



**RICHARD SEGAL, R.PH., PH.D., M.S.**  
Professor

Dr. Segal’s research focuses on improving the quality and safety of the medicines use process, with a particular emphasis on improving prescribing practices and in creating collaborative practice models to improve medication use by patients.

# CURRENT FACULTY IN 2022-23



**HUI SHAO, M.D., PH.D.**  
Assistant Professor

Dr. Shao’s research interests include predictive modeling, using advanced machine learning, microsimulation, and econometrics method to build valid predictive models to resolve real-world issues. He is one of the original developers of the Building, Relating, Assessing, and Validating Outcomes diabetes model, which is the first person-level microsimulation model predicting the progression of diabetes based on individuals’ characteristics and treatment regimen, in the U.S. Shao is currently working with the Centers for Disease Control and Prevention on multiple projects, oversees the development process of several national diabetes/ prediabetes predictive models.



**SCOTT MARTIN VOURI, PHARM.D., PH.D., BCGP**  
Assistant Professor and Assistant Director of Pharmacy Services–  
UF Health Physicians

Dr. Vouri’s research interests include pharmacoepidemiology and pharmaceutical health services research related to the fields of inappropriate medication prescribing/deprescribing, geriatrics, urology and medication utilization following bariatric surgery.



**ALMUT WINTERSTEIN, R.PH., PH.D., FISPE**  
Dr. Robert and Barbara Crisafi Chair and Distinguished Professor

Dr. Winterstein’s research program focuses on the evaluation and prediction of drug safety and effectiveness in real-world populations and on devising ways to improve medication use. Clinical areas of interest include pediatrics and pregnancy, psychopharmacology and treatment and prevention of infectious disease. She also serves as director of CoDES.

# POSTDOCTORAL FELLOWS & RESEARCH FACULTY



**ADENIYI JEREMIAH IDIGO, B.PHARM., PH.D., M.P.H.**

Postdoctoral Fellow

Dr. Idigo is a postdoctoral fellow and works with Dr. Winterstein.



**HYERIM KANG, PH.D.**

Postdoctoral Fellow

Dr. Kang is a postdoctoral fellow and works with Dr. Park.



**KELLY MA, PHARM.D.**

Postdoctoral Fellow

Dr. Ma is a postdoctoral fellow and works with Dr. Reise.



**MUNAZA RIAZ, PH.D.**

Postdoctoral Associate

Dr. Riaz is a postdoctoral associate and works with Dr. Park.



**HYUN JIN SONG, PH.D.**

Postdoctoral Fellow

Dr. Song is a postdoctoral fellow and works with Dr. Park.



**THUY THAI, PH.D., M.P.H.**

Assistant Scientist

Dr. Thai is an assistant scientist and works with Dr. Winterstein.



**DEBBIE WILSON, PH.D.**

Research Assistant Professor

Dr. Wilson is a research assistant professor and works with Dr. Lo Ciganic.

# AWARDS, HONORS & APPOINTMENTS

## CONGRATULATIONS



CONGRATULATIONS TO DR. LAURA HAPPE,  
PHARM.D., M.P.H., FOR PROMOTION TO  
CLINICAL PROFESSOR!

### **AMIE GOODIN, PH.D.**

Assistant Professor

- Appointed as Fellow for Center for Public Health Law Research, 2022-2024
- Editorial Board member for the Journal Pain Medicine, 2022-2023
- Editorial Board member for the Journal Medical Cannabis & Cannabinoids, 2022-2023

### **JINGCHUAN “SERENA” GUO, M.D., PH.D.**

Assistant Professor

- Award for Excellence, Journal of Managed Care and Specialty Pharmacy, 2022
- Career Development Award, University of Florida, College of Pharmacy, 2022
- Distinguished Reviewer, Diabetes Care, 2022
- Advisor, Public Health & Epidemiology, Interest Group Leadership Team, American Diabetes Association, 2022-2024

### **LAURA HAPPE, PHARM.D., M.P.H.**

Clinical Professor; Director of the POP Online M.S. Program

- Exemplary Online Award for Inclusive Teaching Strategies, University of Florida, 2022

### **MD MAHMUDUL HASAN, PH.D.**

Assistant Professor

- Academy of Management, Best Accepted Papers in the 83rd Annual Meeting of the Academy of Management

### **HAESUK PARK, PH.D.**

Associate Professor

- UF College of Pharmacy Outstanding Publication in Clinical Science Research Award, 2023

### **STEVEN SMITH, PHARM.D., M.P.H., FCCP, FAHA**

Assistant Professor and Interim Chair

- Elected Fellow of the American Heart Association, 2023

### **ALMUT WINTERSTEIN, R.PH., PH.D., FISPE**

Distinguished Professor

- Member, Academy of Science, Engineering and Medicine in Florida, 2022

# POP RESEARCH

GUIDING CLINICAL CARE AND POLICY DECISIONS  
WITH REAL-WORLD EVIDENCE

## UF COLLEGE OF PHARMACY RESEARCHERS AIM TO IMPROVE HEALTH EQUITY IN DIABETES CARE

New glucose-lowering drugs are reducing the risk of cardiovascular disease and renal complications as well as lowering mortality rates, however, the high costs associated with these medications are leading to significant equality concerns in diabetes care. Socially disadvantaged patients with lower income and education levels often struggle to access these newer treatments and social barriers can lead to disparities in diabetes care.

“There is an urgent need to improve the quality of care and health equity among the millions of Americans living with type 2 diabetes,” said Hui Shao, M.D., Ph.D., an assistant professor of pharmaceutical outcomes and policy in the University of Florida College of Pharmacy. “Equity should be at the forefront of diabetes care to ensure people can access the lifesaving treatments they need.”

Shao said given the high costs of the medications, it is infeasible to implement broad programs and policies that increase the use of these newer glucose-lowering drugs universally. Not all patients will benefit from the newer glucose-lowering drugs equally. Instead, previous studies have shown that targeting patients in certain populations can have many clinical benefits and improve health equity.

“The proliferation of big real-world data, such as electronic health records and administrative claims, and recent advancements in machine learning and artificial intelligence methods, offers unique opportunities to identify individuals who will receive high clinical benefits from the newer glucose-lowering drugs,” said Serena Guo, M.D., Ph.D., an assistant professor of pharmaceutical outcomes and policy in the UF College of Pharmacy. “Thus, it is feasible to develop an algorithm to be used in health systems or health plans to stratify their patients based on the expected clinical benefit from the newer treatment. A policy-level intervention can then be designed precisely targeting the high-benefit patient subgroups to improve their drug access.”

A four-year project led by researchers in the UF College of Pharmacy, Tulane University and Cornell University aims to identify the patient groups who would benefit most from newer GLDs. Researchers will use artificial intelligence to develop an algorithm to accurately identify these patients and then target the population with policy-level interventions to increase the use of newer glucose-lowering drugs. The project will also explore ways to design health insurance plans that could potentially lead to healthier outcomes and billions of dollars in health care savings.

The National Institute of Diabetes and Digestive and Kidney Diseases is providing \$2.5 million in funding for the project through an R01 grant. Shao and Guo are the co-principal investigators leading the study, while Almut Winterstein, Ph.D., R.Ph., a distinguished professor in the UF College of Pharmacy and director of the Center for Drug Evaluation and Safety, is involved with the study.



## STUDY: ELECTION STRESS MIGHT IMPACT HEALTH

Presidential politics, research suggests, can threaten good health. In an atmosphere of debate and disagreement, fed by an unrelenting 24-hour news cycle, a presidential campaign seems tailored to produce in abundance something our hearts could do without — stress.

And that, scientists say, can be deadly.

A recent study by a University of Florida Health researcher and his collaborators suggests population-level blood pressure, particularly among racial and ethnic minorities, might have increased following the 2016 presidential election.

The study, published in the *American Journal of Human Biology*, analyzed blood pressure readings from 4,660 people who participated in the federal National Health and Nutrition Examination Survey. Measurements were taken from May to October in the two years before and after Election Day.

Researchers noted a “significant” 3.4 millimeters of mercury increase of systolic blood pressure after the election in non-Hispanic Asians, which was not seen in other racial and ethnic groups. Black participants in the study, however, saw an increase of 2.3 mmHg in diastolic pressure, while a 2.9 mmHg diastolic hike was measured in the Hispanic group. (Systolic is the top number of a blood pressure reading and measures the pressure exerted on blood vessels during circulation. Diastolic is the bottom number, measuring pressure as the heart rests between beats.)

The trend appears to be driven by a rise in blood pressure among women, researchers noted in the paper. No significant change in blood pressure was seen in non-Hispanic whites.

Researchers warn, however, against drawing any conclusions on the party affiliation of those seeing their blood pressure climb. The health and nutrition survey didn’t ask about political leanings and study authors do not believe results correlate with party affiliation.

The study’s senior author, Steven M. Smith, Pharm.D, M.P.H., an assistant professor in the UF College of Pharmacy and the UF College of Medicine and a member of the UF Center for Integrative Cardiovascular and Metabolic Disease, believes stress from a presidential campaign impacts folks across the political spectrum.

“I think we’ve shown stressors of an election may have a clinically important population-level effect on cardiovascular risk factors,” Smith said. “An increase of several millimeters of mercury correlates with an up to 10% increase in risk of death due to stroke and heart disease. So, these are not trivial differences in blood pressure we’re seeing.”



The health implications of electoral politics are getting increased scrutiny. Last year, a study by different researchers used data from implanted heart devices to show a 77% increase in heart arrhythmias in the weeks after the 2016 election compared with the weeks before. Researchers pointed to “sociopolitical stress” as a potential culprit. (Arrhythmias include instances when the heart beats too slow, too fast or irregularly.)

That study used data from implanted defibrillators or pacemakers in a population of 2,400 older adults in North Carolina.

Researchers did not see a higher rate of arrhythmias in those who voted for the losing candidate.

Smith said even election winners face heightened stress from a bitter campaign.

“I don’t think it’s as simple as, your side wins, your blood pressure stays the same or goes down. Your side loses, it goes up,” he said. “It’s more complex than that. Certainly, no matter what side you were on, it was a contentious election.”

To Smith, it’s all a reminder that the stress in our lives, whether it originates from a political campaign or worries about paying the bills, ultimately impacts health.

“I’m not sure how feasible it is to lower the temperature of these elections going forward,” he said. “But I think it’s an important reminder that we need to take care of ourselves and that we, as health care providers, need to be cognizant of what may be going on with patients who are struggling with some of those stressors.”



## UF MODEL INVESTIGATES HOW DRUG INTERACTIONS LEAD TO CONTRACEPTIVE FAILURE

More than 900 million women and their partners worldwide use contraceptive products to prevent pregnancies. However, many contraceptive users may not realize taking additional medications can reduce the effectiveness of birth control — leading to unintended pregnancies.

In a study published in the journal *Clinical Pharmacology & Therapeutics*, University of Florida College of Pharmacy researchers describe how they developed a computer model and validated the findings in real-world data to compare hormonal contraceptive drug products when given alone or in combination with other medications. The model will help regulators, as well as the pharmaceutical industry, evaluate the best- and worst-case scenarios when hormonal contraceptives are prescribed with new drug candidates.

“There is an urgent public health need to understand how drug interactions are leading to unplanned pregnancies,” said Stephan Schmidt, Ph.D., the Certara Endowed Professor in the UF College of Pharmacy and director of the Center for Pharmacometrics and Systems Pharmacology. “We have more than 300 million women worldwide who are susceptible to these drug interactions, and the evidence suggests up to a 50 percent failure rate in low- and middle-income countries.”

Contraceptive failure rates are lower in the United States than in Sub-Saharan Africa and countries where widespread diseases, such as HIV and tuberculosis, require multiple medications. Women taking these drugs are susceptible to unintended pregnancies because HIV and tuberculosis medications induce CYP3A4, an enzyme that helps release the progestins found in hormonal contraceptives into the bloodstream.

“It’s the scenario where one drug has the potential to change the speed at which the body gets rid of the other drug,” Schmidt said. “If drug concentration levels drop faster than intended, then birth control medications are at an increased risk of being ineffective at preventing pregnancy.”

UF researchers examined multiple hormonal contraceptives — formulated with different ingredients — to identify the risk of drug interactions causing unplanned pregnancies. In the best-case scenario, they found oral hormonal contraceptives to be 100% effective, however, this efficacy rate can diminish due to various factors without the use of secondary protection.


The upper and lower boundaries were established using a computer-aided modeling approach called pharmacokinetic bracketing. UF researchers developed the model to simulate and evaluate drug interactions that may not be frequently studied in the real world. Using real-world data, the researchers compared the rate of unintended pregnancy among women using different hormonal contraceptives who were exposed to drug interactions



“Our main goal was to provide a developmental framework for drug regulators and the pharmaceutical industry to use when they evaluate and develop new drug products,” said Brian Cicali, Ph.D., M.S., a research assistant professor of pharmaceuticals in the UF College of Pharmacy and the co-lead author of the study along with Amir Sarayani, Ph.D., M.P.H., and Lais Da Silva, Ph.D. “The thresholds defined for these hormonal contraceptives will help develop novel formulations to improve medication access and use in low- and middle-income countries. The combined computational and pharmacoepidemiological approaches of this multidisciplinary team strengthen the study findings and provide an example for future collaborative research.”

The latest research supports ongoing global drug development and regulatory evaluation efforts led by the departments of pharmaceuticals and pharmaceutical outcomes and policy in the UF College of Pharmacy and supported by the Bill & Melinda Gates Foundation. To date, the foundation has awarded \$2.5 million to study hormonal contraceptive drug interactions that lead to unintended pregnancies. In addition, Bayer has served as an industry collaborator on the research and guided modeling efforts and clinical pharmacology of their compounds.

In addition to Schmidt, Cicali, Sarayani and Da Silva, the following UF College of Pharmacy faculty were involved in the study: Joshua Brown, Pharm.D., Ph.D., M.S., Rodrigo Cristofolletti, Ph.D., Valvanera Vozmediano, Ph.D., and Almut Winterstein, Ph.D., R.Ph.



## GOVERNMENT-MANDATED DRUG SAFETY PROGRAM EFFECTIVE IN REDUCING PRENATAL EXPOSURE TO WEIGHT-LOSS DRUG PHENTERMINE-TOPIRAMATE

A study of nationwide automated health care records found that prenatal exposure to phentermine and topiramate extended-release capsules (phentermine-topiramate) was generally low under the Food and Drug Administration Risk Evaluation and Mitigation Strategy, or REMS, compared to using topiramate or other antiobesity medications. The findings were published March 21 in the *Annals of Internal Medicine* journal. The study's lead authors were Almut Winterstein, Ph.D., R.Ph., a distinguished professor of pharmaceutical outcomes and policy in the UF College of Pharmacy and director for the Center for Drug Evaluation and Safety, and Amir Sarayani, Pharm.D., Ph.D., M.P.H., a 2022 graduate of the UF College of Pharmacy.

In 2012, the FDA approved the use of the combination product phentermine-topiramate for long-term obesity management. Single-ingredient topiramate product, approved for treatment of epilepsy in 1996, is now used for a variety of indications, including weight loss. Its association with risks for birth defects is well established. Because of specific focus on weight loss for the new combination product, representing many persons of child-bearing age, phentermine-topiramate was approved with the requirement of a REMS aimed at preventing prenatal exposure. REMS is an FDA-mandated drug safety program implemented by the manufacturer to ensure that prescribers, pharmacists and patients are informed about certain drug safety risks.

Researchers from the University of Florida College of Pharmacy studied insurance claim data for 156,280 treatment episodes among women aged 12 to 55 to evaluate the rate of prenatal exposure, contraceptive use and pregnancy testing among patients initiating phentermine-topiramate compared to those who started topiramate (with birth defect risk) or other antiobesity medications (without birth defect risk).

The authors found that the use of phentermine-topiramate was associated with half the risk for exposure during pregnancy compared to either of the control groups. They also found that only 1 in 5 patients used contraceptives before and during treatment overall, and only 1 in 20 patients had pregnancy tests before medication initiation. The authors note that younger patients used more contraceptives and pregnancy tests than their older counterparts, but the absolute risk for prenatal exposures was also higher. The authors note that the effectiveness of the REMS in reducing prenatal exposure is promising, but also emphasize the need for further clinical vigilance and risk mitigation, including topiramate products which do not have a REMS and exhibited higher prenatal exposure rates.

This summary was provided courtesy of the *Annals of Internal Medicine* journal. The research study was conducted as part of Dr. Sarayani's Ph.D. dissertation project.

# GRANTS

DEPARTMENT FACULTY ARE STEADILY INCREASING THEIR EXTRAMURALLY FUNDED RESEARCH PORTFOLIO AND ARE LEADING, OR ACTIVELY INVOLVED, IN OVER 50 GRANTS AND CONTRACTS

## Advancing Personalized Hypertension Care through Big Data Science

NHLBI/NIH (K01HL138172) Research Scientist Development Award  
PI: Steven Smith  
Mentor: Almut Winterstein  
07/2018-06/2023

This project seeks to use large-scale EHR data to better understand current prescribing patterns for new antihypertensive use, to identify treatment effect modifiers of antihypertensive response, and ultimately to develop prediction models for optimal antihypertensive selection following hypertension diagnosis.

## Applying Big Data to Improve Mental Health Outcomes with Restless Legs Syndrome Treatment

National Institute of Mental Health (NIMH) R36  
PI: Brianna Costales  
Mentor: Amie Goodin  
08/2021-08/2022

This dissertation grant examined pharmacotherapies prescribed for the treatment of restless legs syndrome and evaluated mental health and safety outcomes resulting in those treated with gabapentinoids versus dopamine agonists.

## Artificial Intelligence And Counterfactually Actionable Response to End HIV (AI-CARE HIV)

NIH R01AI172875  
PI: Mattia Proserpi  
Co-Investigator:  
Jingchuan “Serena” Guo  
04/2023-03/2027

This study aims to develop a causal artificial intelligence framework that uses integrated electronic health records and social determinants of health to improve HIV care in Florida.

## Assessing Barriers and Facilitators for Participating Structured Lifestyle Intervention and Its Real-world Effectiveness and Cost-Effectiveness Among US Veterans

CDC U18DP006711  
PI: Hui Shao  
Co-Investigator: Masoud Rouhizadeh, Tianze Jiao, Jingchuan “Serena” Guo  
07/2022-06/2027

This project aims to identify barriers and facilitators to the enrollment and completion of the National Diabetes Prevention Program, or NDPP, and evaluate its long-term effectiveness and cost-effectiveness

## Assessing Prevalence, Maternal Perceptions, and Fetal Development Outcomes of Perinatal Marijuana Use

University of Florida Research Opportunity Seed Fund  
PIs: Amie Goodin, Dikea Roussos-Ross, Deepthi Varma, Bruce Goldberger  
06/2022-05/2024

This study examines cannabis use behaviors and perceptions of health risk among women of reproductive age and those who are currently pregnant or lactating, and initiates development of a home test for screening for the presence of detectable tetrahydrocannabinol and cannabidiol in breastmilk.

## Application of Physiologically Based Pharmacokinetic Models to Inform Dosing Recommendations for Hormonal Contraceptives Co-administered with Other Medications

Bill & Melina Gates Foundation (OPP118545)  
PI: Stephan Schmidt  
Co-Investigators: Almut Winterstein  
11/2017-10/2022

This project aims to develop pharmacological and pharmacoepidemiological evidence to inform treatment decisions for hormonal contraceptives and interacting medications by integrating real-world outcomes research, model-based meta-analytic approaches and physiologically based pharmacokinetic modeling and simulations.

## Big data approaches for Safe Therapeutics in Healthy Pregnancies (BOOST-HP)

NICHD R01HD110107  
PIs: Judy Maro, Almut Winterstein  
08/2022-04/2026

This project is a joint effort between the University of Florida, Harvard Pilgrim Health Care, and Johns Hopkins University. BOOST-HP combines innovative data-mining techniques with formal assessments of prioritized

safety signals to accelerate evidence on drug risk-benefit during pregnancy.

## Building Equity Improvement into Quality Improvement in the use of New Glucose-lowering Drugs (GLDs) through Individualized Drug Value Assessment in People with Diabetes

NHI R01DK133465  
PIs: Jingchuan “Serena” Guo, Hui Shao  
02/022-06/2026

This project aims to identify clinically high-benefit type 2 diabetes, or T2D, patient subgroups for newer GLDs, and generate empirical economic evidence for designing policy-level interventions to improve the quality of care and health equity in T2D care.

## Collaboration on Joint Research to Train the Next Generation of Pharmacoepidemiologists

Merck and Company Inc  
PI: Almut Winterstein  
12/2019-12/2023

In collaboration with Merck epidemiologists, UF will nominate senior graduate students to conduct pharmacoepidemiologic research on specific topics identified by Merck.

## Consortium for Medical Marijuana Clinical Outcomes Research

Florida State University System Board of Governors  
PI: Almut Winterstein  
Co-Investigators: Amie Goodin  
07/2019-06/2024

This state appropriation funds the consortium for medical marijuana clinical outcomes research, charged to generate and disseminate evidence on the outcomes of the medical use of marijuana to inform clinical and policy decisions. The consortium includes nine Florida universities.

## COVID-19 Pandemic and Atrial Fibrillation Care

NIH/NHLBI R01HL15705  
PI: Inmaculada Hernandez  
Co-Investigator: Jingchuan “Serena” Guo  
07/2021-06/2025

This study aims to quantify changes in the incidence rate of new atrial fibrillation, or AF, diagnoses, determine whether the COVID-19 pandemic was associated with decreased oral

anticoagulation, or OAC, initiation among newly diagnosed AF patients, quantify changes in adherence and monitoring of OAC therapy among established AF patients and in the incidence rates of stroke, bleeding, cardiovascular hospitalization, and death among established AF patients.

**Developing and Evaluating a Machine-Learning Opioid Prediction & Risk-Stratification E-Platform (DEMONSTRATE)**

National Institute of Drug Abuse  
(1R01DA050676 - 01A1)  
PI: Wei-Hsuan “Jenny” Lo-Ciganic  
Co-Investigator: Masoud Rouhizadeh  
07/2021-04/2026

The study aims to predict opioid overdose and opioid use disorder, or OUD. The study’s authors propose to “develop and evaluate a machine-learning opioid prediction & risk- stratification e-platform (DEMONSTRATE)” that can be used by health care systems to identify patients at high risk for opioid overdose and OUD.

**Identification and Characterization of Blood Pressure Control and Racial Impacts on Alzheimer’s Disease and Related Dementias Risk**

1Florida Alzheimer’s Disease Research Center Development Grant  
PI: Caitrin McDonough  
Co-Investigator: Masoud Rouhizadeh  
06/2022-05/2024

This project will validate Alzheimer’s disease and related dementias models in African Americans and Hispanics and provide an improved understanding of the role of blood pressure control in risk for Alzheimer’s disease and related dementias, allowing high-risk patients to be identified sooner and targeted to precision treatment regimens.

**Diagnosing Suicidal Behaviors in Postpartum Mothers Using Natural Language Processing**

University of Florida Informatics Institute  
PI: Masoud Rouhizadeh  
06/2022-05/2024

This study aims to develop natural language processing algorithms to identify suicidal behaviors in postpartum mothers to better understand the epidemiology of these behaviors and inform future interventions.

**Emerging Infections and Treatment in Pregnancy (EI-TIP)**

Centers for Disease Control and Prevention 75D30122C15503  
PI: Almut Winterstein  
09/2022-09/2024

This project addresses one of CDC’s research priorities, which aims to address critical knowledge gaps related to emerging and re-emerging infectious diseases during pregnancy and the risk, benefits and acceptance of prevention and treatment strategies.

**Epidemiology and Cost of RSV Infections in Infants and Toddlers**

Merk and Company Inc  
PI: Almut Winterstein  
05/2020-09/2022

This study will estimate the number and proportion of children less than five years of age with RSV-associated inpatient admissions or outpatient visits, and estimate RSV-related costs, considering relative contributions of RSV infections to the overall burden of lower-respiratory tract infections and variation in disease incidence and cost across strata defined by chronological and gestational age, key risk conditions, plan type, and RSV season and geographic region.

**The External Exposome and COVID-19 Severity and Mortality**

NIH/NIEHS R21ES032762  
PIs: Hui Hu  
Co-Investigator: Jingchuan “Serena” Guo  
12/2021-07/2024

This study leverages OneFlorida and builds upon our prior work on the external exposome to (1) identify novel environmental factors associated with severe COVID-19, (2) examine whether the external exposome contributes to racial and ethnic disparities in severe COVID-19, and (3) develop predictive models of high-risk patients with external exposome factors.

**High-throughput Screening for Antihypertensive Prescribing Cascades**

NIH/NHLBI R21 HL159576  
PI: Steven Smith  
08/2022-07/2024

The major goals of this project are to apply high-throughput sequence symmetry analysis to detect antihypertensive-related prescribing cascade signals in the U.S. Medicare population, to evaluate such signals for biologic plausibility and to prioritize probable prescribing cascades for future evaluation.

**Identifying Suicidal Behaviors Using Natural Language Processing in Patients with Alzheimer’s Disease and Related Dementias**

OneFlorida Alzheimer’s Disease Research Consortium  
PIs: Masoud Rouhizadeh  
06/2022-05/2024

This project aims to develop natural language processing algorithms to identify suicidal behaviors in people with dementia to better understand the epidemiology of these behaviors and inform future interventions.

**Implementing Prediction Models to Improve Opioid Risk**

Richard King Mellon Foundation  
PI: Walid Gellad  
Co-Investigator: Wei-Hsuan “Jenny” Lo-Ciganic  
07/2020-12/2023

This study aims to implement and pilot test our previously developed machine learning risk models to predict opioid overdose to identify individuals at high risk of opioid overdose in the residents in Allegheny County in Pittsburgh for target interventions.

**Improving Medication Adherence with Telehealthcare Medication Therapy Management to Change Health Outcomes in Adolescents and Young Adults with Asthma (MATCH)**

NIH/NHLBI R01HL136945 (R01)  
Research Project Grant Award  
PI: Kathryn Blake (Nemours Children’s Clinic)  
Co-Investigators: Haesuk Park, Almut Winterstein  
05/2018-03/2024

This project aims to develop a tailored, effective, and sustainable Medication Therapy Management video telehealth care intervention plus electronic adherence self-management to improve medication adherence and health outcomes for adolescents and young adults with asthma and evaluate cost-benefit of this intervention.

**Individualized Risk-Benefit Trade-off Prescribing Strategy for Antihypertensive Drugs in People with Concomitant Hypertension and Type 2 Diabetes**

PROSPER Research Seed Award  
PI: Tianze Jiao  
04/2023-04/2024

The objective of this project is to 1) investigate the risks (hyperglycemic effects) of antihypertensive drugs for people with hypertension and type 2 diabetes; 2) investigate the benefits (cardioprotective effects) of antihypertensive drugs for people with hypertension and type 2 diabetes using claims (Medicare) database.

**Linking VA and Non-VA Data to Study the Risk of Suicide in Chronic Pain Patients**

*Voices of Hope National Institute of Mental Health/Cornell University*  
*PIs: Jyotishman Pathak, David W Oslin*  
*Co-Investigator: Wei-Hsuan “Jenny” Lo-Ciganic*  
*09/2020-05/2025*

The study aims to integrate large-scale VA and non-VA data to study the risk of deaths (suicide and accidental opioid overdose), and suicidal ideation and attempts in veterans on chronic opioid therapy using innovative machine learning and data mining approaches.

**Machine-Learning Prediction and Reducing Overdoses with EHR Nudges (mPROVEN)**

*NIDA 1R01AG075280-01*  
*PIs: Walid Gellad*  
*Co-Investigator: Wei-Hsuan “Jenny” Lo-Ciganic, Jingchuan “Serena” Guo*  
*07/2022-06/2027*

This study aims to reduce opioid overdose risk by bringing together overdose risk prediction and behavioral nudges through a scalable electronic health record intervention to improve clinician prescribing behavior.

**Medicaid Prior Authorization Policies for Chronic Hepatitis C Treatment in Vulnerable Populations**

*NIH/NIDA K01DA045618 (K01)*  
*Research Scientist Development Award*  
*PI: Haesuk Park*  
*Mentor: Almut Winterstein*  
*05/2018-04/2023*

This award supports the principal investigator’s career development in viral hepatitis and health policy for individuals with substance use disorders and HIV co-infection. The project will advance the understanding of the consequences of Medicaid policies for hepatitis C treatment on accessibility, quality of care, and clinical outcomes critical to improving access to care and health equality in underserved and vulnerable populations.

**Medical Literature and Data on Cannabis Use**

*Food and Drug Administration via the Sentinel Initiative*  
*PI: Amie Goodin*  
*Co-Investigators: Almut Winterstein, Jingchuan “Serena” Guo, Yan Wang*  
*01/2023-08/2023*

These projects identify, synthesize, and evaluate evidence regarding the effectiveness and safety of medical cannabis for seven indications, as well as evaluate potential harms associated with non-medical cannabis use or use of uncertain intent. This research supports the FDA’s eight-factor analysis to examine federal classification (Scheduling) of cannabis as a controlled substance.

**Opioid Prescribing Practices and Health Outcomes Among Patients with Alzheimer’s Disease and Related Dementia**

*NIH R01AG073442*  
*PI: Yu-Jung “Jenny” Wei*  
*Co-Investigator: Almut Winterstein*  
*09/2022-05/2026*

This study proposes a longitudinal study to assess the effects of opioid prescribing practices on outcomes of patients with Alzheimer’s disease and related dementia (ADRD).

**Pandemic Disruptions of Atrial Fibrillation Care**

*NIH Subaward R01HL157051*  
*PI: Inmaculada Hernandez*  
*Co-Investigator: Jingchuan “Serena” Guo*  
*07/2021-06/2025*

This project aims to develop extraction plans to create analytical data sets for analyses in the Optum cohort.

**A Patient-Focused Collaborative Hospital Repository Uniting Standards for Equitable AI (CHoRUS)**

*NIH Bridge2AI OT2OD032701*  
*PI: Eric Rosenthal*  
*Co-Investigator: Jingchuan “Serena” Guo*  
*09/2022-08/2026*

This study aims to create a network of university health systems that will support a comprehensive repository of data for AI research from more than 100,000 critically ill patients.

**Precision Antiplatelet Therapy after Percutaneous Coronary Intervention**

*NIH/NHLBI R01HL149752*  
*PI: Larisa Cavallari, Craig Lee*  
*Co-Investigator: Almut Winterstein*  
*07/2020-06/30/2025*

This study aims to establish optimal strategies for individualized antiplatelet therapy prescribing decisions that improve outcomes and can be feasibly applied in a diverse, real-world population.

**Program Evaluation and Analytic Support Services for a Substance Use Disorders Recovery Community Center**

*Voices of Hope, Inc.*  
*PI: Amie Goodin*  
*01/2019-12/2022*

This project creates a measurement framework consisting of clinical and process outcomes measures used by a network of substance use disorder recovery community centers.

**Quality Assessment of Electronic Prior Authorization (ePA) and Real-Time Pharmacy Benefits (RTPB) and Program Expansion**

*Shands Quasi-Endowment Funds*  
*PIs: Rachel Reise*  
*07/2021-12/2022*

This study aims to assess the utilization of the Real-Time Pharmacy Benefit tool within the electronic health record, which allows a provider to see estimates for a patient’s out-of-pocket cost for a medication based on their insurance plan, as well as therapeutic alternatives that may result in cost savings for patients at the pharmacy.

**Reducing Maternal Morbidity and Mortality: Phase II**

*Florida Department of Health*  
*PI: Dikea Roussos-Ross*  
*Co-Investigator: Amie Goodin, Deepthi Varma, Tony Wen-Soo*  
*07/2022-06/2023*

This study develops and examines care outcomes resulting from use of a smartphone-based application (app) known as “MOMitor” to monitor maternal physical and mental health symptoms in the six weeks following hospital discharge for childbirth.

**Sentinel FDA Tast Order**

Harvard Pilgrim Healthcare  
Co-Investigator: Almut Winterstein  
12/2020-09/2023

This study aims to assess the performance of the TreeScan method to identify signals for maternal and obstetric adverse outcomes occurring from 20 weeks of gestation to 30 days after delivery among women with live births exposed to oral macrolides compared to oral penicillins.

**Social Determinants Underlying Heart Failure Treatment and Outcomes**

PhRMA Foundation  
PI: Jingchuan “Serena” Guo  
07/2022-06/2024

This study aims to identify key contextual and person-level social determinants of health, or SDoH, associated with novel treatment initiation and adherence, and clinical outcomes of Heart Failure. We will then develop a polysocial risk score and quantify SDoH causal pathways driving disparities in heart failure.

**Social Determinants Underlying and Heart Failure Management**

UF Research Opportunity Seed Fund Competition  
PI: Jingchuan “Serena” Guo  
07/2022-06/2024

This study aims to identify key contextual and person-level SDoH associated with novel treatment initiation and adherence, and clinical outcomes of Heart Failure. We will then develop a polysocial risk score and quantify SDoH causal pathways driving disparities in heart failure.

**Sparking Advancements in Genomic Medicine**

NIH/NHGRI U01HG007269 (U01) Research Project-Cooperative Agreements Grant Award  
PI: Julie Johnson  
Co-Investigators: Almut Winterstein, Haesuk Park  
07/2020-06/2024

This project aims to evaluate the effect of genotype-guided therapy on patients with pain or depression on health outcomes, well-being, health care utilization and cost.

**Teratogenic Risk Impact and Mitigation (TRIM): An Evidence-based Decision Framework**

Food and Drug Administration  
PI: Almut Winterstein  
09/2021-09/2023

This study aims to provide FDA with comprehensive evidence on prenatal exposure to teratogenic drugs to evaluate the current public health impact and the need for enhanced risk mitigation

**Trajectories of Apixaban for Extended Treatment of Recurrent Venous Thromboembolism: a Retrospective Cohort Study**

American Thrombosis Investigator Initiated Research Program (ARISTA)  
PI: Haesuk Park  
Co-Investigators:  
Wei-Hsuan “Jenny” Lo-Ciganic  
06/2020-04/2023

To investigate the effects of extended use of apixaban or warfarin beyond six months of initial treatment on the risk of recurrent venous thromboembolism and major bleeding events among patients with a history of venous thromboembolism.

**Using Community Healthcare Workers to Improve Blood Pressure Control Among Food Insecure Hypertensive Adults (ReCLaiMeD)**

UF CTSI Precision Public Health Pilot Program  
PI: Stephanie Staras  
Co-Investigator: Steven Smith  
05/2023-04/2024

The major goal of ReCLaiMeD is to conduct a randomized trial testing the use of community health care workers (utilizing community resources) versus a standardized education program to improve short-term hypertension control among Gainesville-area hypertensive adults with food insecurity.

**Using Physiologically-Based Pharmacokinetic to Inform Dosing of Hormonal Contraceptives — The Real-World Evidence of Drug-Drug Interactions and Breakthrough Bleeding**

Bill & Melinda Gates Foundation  
PIs: Stephan Schmidt, Tianze Jiao  
12/2022-12/2024

The objective of this project is to 1) evaluate drug-drug interactions associated with various progestins used via various routes of

administration including oral, implant, and injectable products; 2) compare and identify the progestins with the minimum drug-drug interactions; 3) generate real-world evidence by developing algorithms and conducting analyses for breakthrough bleeding using claims (MarketScan) database.

**Utilizing Artificial Intelligence to Identify Bleeding Risk Predictors with Newer P2Y12 Receptor Inhibitors**

UF Informatics Institute  
PIs: Larisa Cavallari, Catrin McDonough  
Co-Investigator: Masoud Rouhizadeh  
2022-2023

This project aims to identify patient-specific factors predictive of bleeding risk with prasugrel or ticagrelor after PCI through AI approaches; and to derive a novel score for predicting bleeding risk with prasugrel and ticagrelor that could be integrated into the electronic health record to provide point-of-care risk assessment.

**VA IPA**

Veterans Affairs  
PIs: Jingchuan “Serena” Guo  
10/2022-09/2023

This project aims to determine racial and ethnic disparities in home dialysis use and the receipt of pre-end-stage kidney disease, or ESKD, education.

**Women’s Ischemia Trial to Reduce Events in Non-Obstructive CAD (WARRIOR)**

Department of Defense  
PI: Carl J Pepine  
Co-Investigator: Steven Smith  
09/2017-09/2024

The aim of this study is to conduct a prospective randomized open-label blinded-endpoint (PROBE) trial testing intensive medical therapy (high-intensity renin angiotensin system inhibitor + statin) versus usual care in women with evidence of ischemia but no obstructive coronary artery disease.

# TRANSLATING BIG DATA INTO EVEN **BIGGER, HEALTHIER AND SAFER OUTCOMES**

## RATE OF HALLUCINATIONS AND HOSPITALIZATIONS IN PARKINSON'S DISEASE: WHICH MEDICATION IS THE BEST?

Hallucinations and delusions from psychosis are not uncommon for people living with Parkinson's disease, or PD. According to the Parkinson's Foundation, between 20-40% of people living with PD report hallucinations with the likelihood increasing as someone living with PD ages.

The only FDA-approved medication for hallucinations in Parkinson disease is pimavanserin (commonly sold under the name Nuplazid), a medication that the U.S. Food and Drug Administration) approved in 2016. After its approval, concerns were raised that pimavanserin might increase the risk of death in people using it. The FDA investigated and found no new or unexpected safety risks associated with using pimavanserin. Concerns have remained about pimavanserin safety.

The other most commonly used medication for hallucinations in PD, an older medication called quetiapine (commonly sold under the name Seroquel), is not FDA-approved for the management of hallucinations. How much quetiapine helps hallucinations is also uncertain. Recent research compared the risks of using pimavanserin in people living with PD and hallucinations to people using no medication for hallucinations at all. These results don't necessarily help clinicians though.

"Sometimes hallucinations are mild, and we don't need to treat them. But when hallucinations are a problem, the question isn't whether or not to treat the hallucinations, but rather what medication to use," said Melissa Armstrong, M.D., M.Sc., FAAN, an associate professor in the department of neurology and a movement disorders specialist at the Norman Fixel Institute for Neurological Diseases.

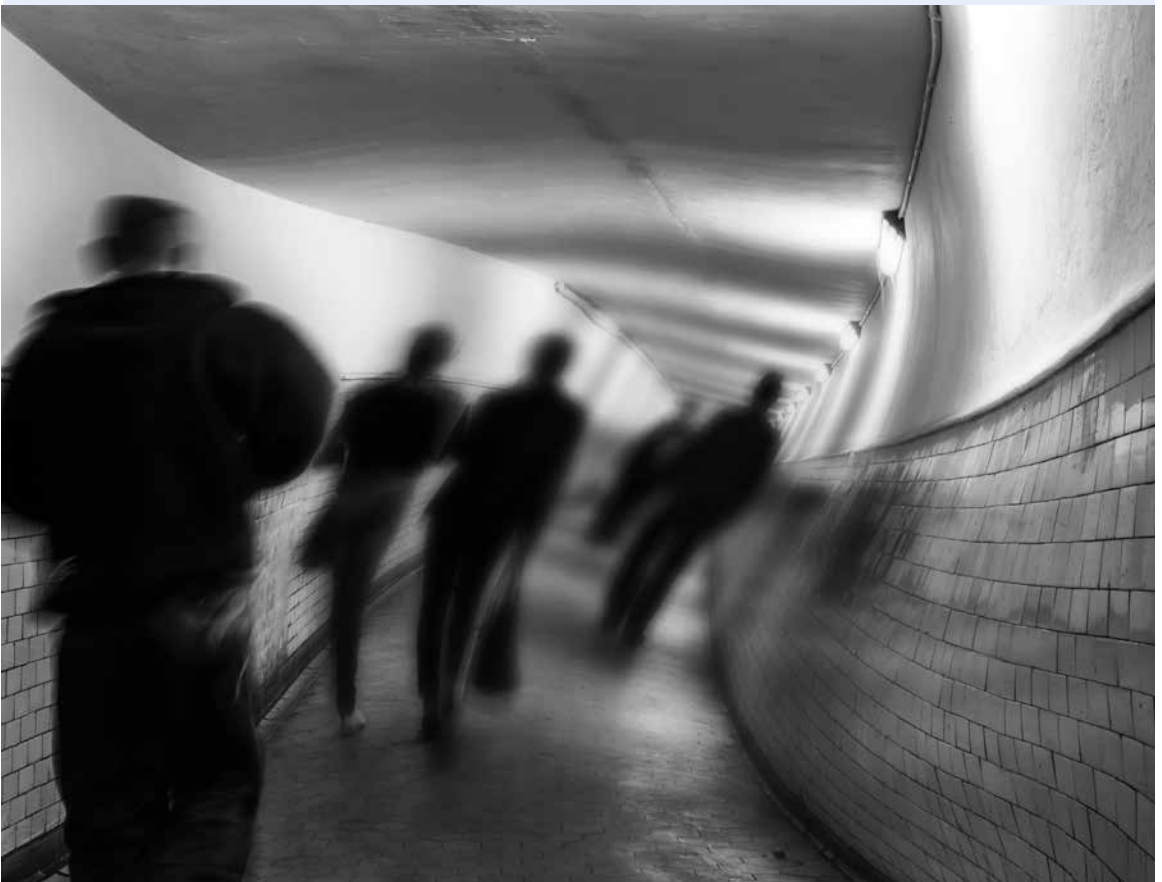
To better understand the safety considerations, researchers at the Norman Fixel Institute for Neurological Diseases at UF Health and the Center for Drug Evaluation and Safety at the University of Florida College of Pharmacy conducted a study comparing the occurrence of hospitalization and death between pimavanserin and quetiapine.

Led by Golnoosh Alipour-Haris, Pharm.D., M.S., a graduate research assistant in the Center for Drug Evaluation and Safety, the research study identified new users of pimavanserin and quetiapine between 2016 and 2018. Data collected for comparison included the occurrence of hospitalization and mortality (death) between users of pimavanserin and quetiapine.

“We found that the risk of hospitalization was lower among people with Parkinson’s disease psychosis who were prescribed pimavanserin compared to those who were prescribed quetiapine. The study did not find a significant difference in mortality between the two groups,” said Alipour-Haris. “We hope this study will advance the field by providing clinically relevant information for patients and physicians about the relative safety of pimavanserin and quetiapine for the treatment of Parkinson’s disease psychosis.”

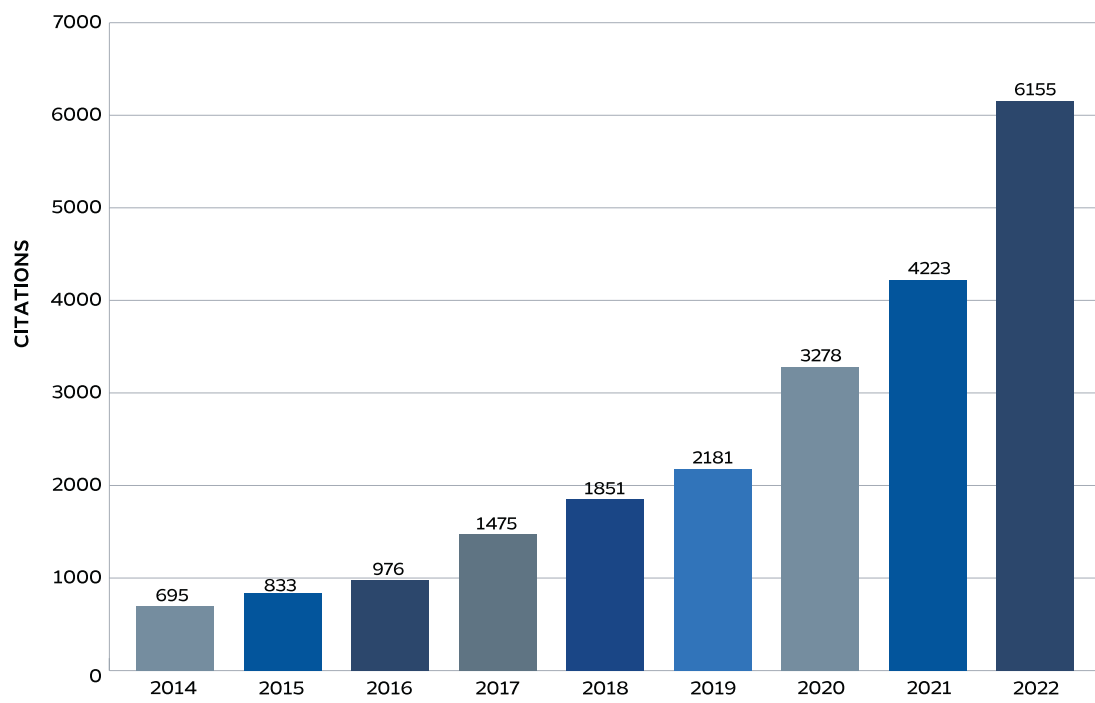
“This research takes the important step of comparing the two most commonly used medications for hallucinations in Parkinson’s disease. It is reassuring to know that when we need to treat hallucinations, the current study using data from people on Medicare found no increased risk of death in people prescribed pimavanserin,” said Armstrong, co-author on the study. “More research is needed to understand why hospitalization was lower in the group receiving pimavanserin.”

The research team included Golnoosh Alipour-Haris, Pharm.D., M.S., a graduate research assistant in the Center for Drug Evaluation and Safety in the department of pharmaceutical outcomes and policy in the University of Florida College of Pharmacy; Melissa Armstrong, M.D., M.Sc., FAAN, an associate professor in the department of neurology and movement disorders specialist at the Norman Fixel Institute for Neurological Diseases at UF Health; Joshua Brown, Pharm.D., Ph.D., M.S., a former associate professor in the department of pharmaceutical outcomes and policy at the University of Florida College of Pharmacy, and Michael Okun, M.D., director of the Norman Fixel Institute for Neurological Diseases and chair and professor of the department of neurology.



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# FAST FACTS FOR 2023

43

ACTIVE  
FUNDED  
PROJECTS

\$4.8M

EXTRAMURAL  
FUNDING IN AY 23  
LED BY DEPT.  
FACULTY

127

PEER-REVIEWED  
MANUSCRIPTS

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PUBLICATIONS  
FIRST AUTHORED  
BY GRADUATE  
STUDENTS


165

TOTAL NUMBER  
OF TRAINEES

53

NEW  
GRADUATES

85.  Sarayani A\*, Albogami Y, Thai TN, Smolinski NE, Patel P, Wang Y, et al. Prenatal exposure to teratogenic medications in the era of Risk Evaluation and Mitigation Strategies. *Am J Obstet Gynecol*. 2022 Aug;227(2):263. e1-263.e38.
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# CONGRATULATIONS

## TO OUR GRADUATES IN ACADEMIC YEAR 2022-23

### PH.D. GRADUATES



**MOHANNAD ELKHIDER, PH.D., M.S., B.S.PHARM.**

**DISSERTATION:** Real-World Performance of Sacubitril-Valsartan in the Management of Heart Failure

**ADVISOR:** Vakaramo Diaby

**FIRST POSITION AFTER GRADUATION:** Senior Pharmacist at the Drug Control Department — Ministry of Health, Oman



**EARL J. MORRIS, PHARM.D., M.P.H., PH.D.**

**DISSERTATION:** Treatment Patterns and Cardiorenal Outcomes Associated with Xanthine Oxidase Inhibitor Use in Older Adults

**ADVISOR:** Steven Smith

**FIRST POSITION AFTER GRADUATION:** Research Assistant Professor, Department of Pharmaceutical Outcomes and Policy, UF



**MUNAZA RIAZ, PHARM.D., PH.D.**

**DISSERTATION:** Pharmacotherapy in Heart Failure with Preserved Ejection Fraction: Trends, Costs, Effectiveness, and Safety

**ADVISOR:** Haesuk Park

**FIRST POSITION AFTER GRADUATION:** Postdoctoral Associate, Department of Pharmaceutical Outcomes and Policy, UF



**PHUONG "PHOENIX" TAN TRAN, PH.D., M.P.H., B.S.PHARM.**

**DISSERTATION:** Advancing Evidence on Antibiotic Use, their Safety, and Methodology to Deal with Unmeasured Confounding

**ADVISOR:** Almut Winterstein

**FIRST POSITION AFTER GRADUATION:** Associate Director, RWD & Analytics, Boehringer Ingelheim

### M.S. GRADUATES



**KHALID ALKHUZAM, M.S.**

**THESIS TITLE:** Long-term Health Benefit and Economic Return of Time in Range (TIR) Improvement in Individuals with Type 2 Diabetes

**ADVISOR:** Hui Shao

**FIRST POSITION AFTER GRADUATION:** TBD



**WENXI HUANG, M.S.**

**THESIS TITLE:** Trajectories of Sacubitril/Valsartan Adherence Among Medicare Beneficiaries with Heart Failure

**ADVISOR:** Jingchuan "Serena" Guo

**FIRST POSITION AFTER GRADUATION:** Ph.D. Program in POP



**SHU NIU, B.E.**

**THESIS TITLE:** Five-year simulation of Diabetes Related Complications in People Treated with Tirzepatide or Semaglutide vs Insulin Glargine

**ADVISOR:** Hui Shao

**FIRST POSITION AFTER GRADUATION:** Ph.D. Program in POP

# TRAINING THE NEXT GENERATION OF SCIENTISTS

## CURRENT PH.D. STUDENTS



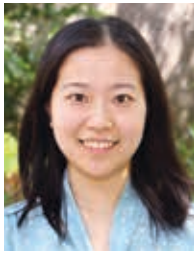
Sumaya Abuloha,  
M.Sc.



Farzana Islam Adiba,  
M.Sc.



Hung-Kai "Henry"  
Chen, B.Pharm., M.S.



Fanxing Du, M.P.H.



Celeste Ewig,  
Pharm.D.



Dawei Guan, M.D.,  
M.S.



Golnoosh  
Alipour-Haris,  
Pharm.D., M.S.



Maria Pilar  
Hernandez-Con, M.D.



Shu Huang, M.S.,  
M.P.H.



Yushi Huang,  
Pharm.D.



Sebastian Jugl, M.S.,  
R.Ph.



Shailina Keshwani,  
M.S.



Priyanka Kulkarni,  
M.P.H., B.Pharm.



Piaopiao Li, M.S.



Motomori Lewis, B.S.



Matthew Muschett,  
Pharm.D.



Asinamai Ndai, M.S.



Yun Shen, M.P.H.



Kayla Smith, Pharm.D.



Nistha Shrestha,  
M.P.H., B.S.Pharm.

CURRENT PH.D. STUDENTS



Nicole Smolinski,  
Pharm.D.



Huilin Tang, M.Sc.



Ikenna Francis  
Unigwe, B.S.,  
Pharm.D., M.S.



Hsin-Ming "Grace"  
Wang, M.S.



Yanning Wang, M.S.



Yehua Wang, M.S.P.H.



Seonkyeong Yang,  
M.S., B.S.Pharm.



Kimia Zandbiglari,  
M.Sc.

THESIS M.S. STUDENTS



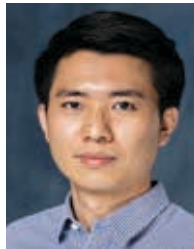
Alaa Abdullah  
Alshehri, Pharm.D.



Khalid Alkhuzam,  
M.S.Pharm.



Rupal Aroza,  
Pharm.D.



Shao Husan  
"Brendan" Chang,  
B.Pharm.



Wei-Han "William"  
Chen, B.S.



Wenxi Huang, M.S.



Pareeta Kotecha,  
Pharm.D.



Hsin-Yueh "Shawn"  
Lin, B.S.



Shu Niu, B.E



Julia Yang, B.S.

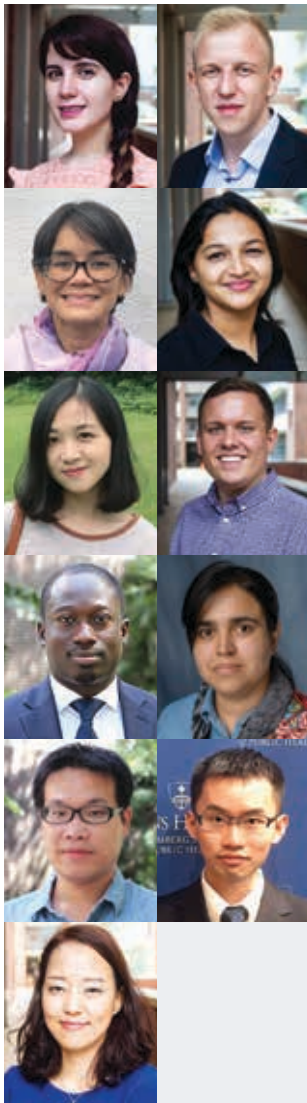
# STUDENT AWARDS

## POPstar AWARDS

Each year the department recognizes the hard work of our graduate students. We announced the winners of our 5th annual POP Star Awards at our POP Winter Reception in February 2023.

Three different awards were presented to graduate students:

- **POPSTAR GRADUATE STUDENT PUBLISHING AWARD** recognizes a graduate student for contributions to the department and science through demonstrated excellence in publishing research and scholarly work for either a single research article or a body of work
- **POPSTAR LEADERSHIP SERVICE AWARD** recognizes a graduate student who stands out in Leadership Service to the department, college and profession
- **POP PROGRAMMER HALL OF FAME AWARD** recognizes a graduate student for contributions to the department and science through developing a novel computer program/tool that can assist in improving the efficiency and quality of conducting research



**GOLNOOSH ALIPOUR-HARIS**

- Cluff Aging Research Award, UF, 2023

**SEBASTIAN JUGL**

- Certificate of Outstanding Merit, UF International Center, 2022

**MARIA PILAR HERNANDEZ-CON**

- POPStar Leadership Service Award, 2023

**SHAILINA KESHWANI**

- Certificate of Outstanding Merit, UF International Center, 2022
- 1st Place for Clinical/Population Poster Presentation, Annual CICMD Early Career Showcase and Mixer, 2023

**PIAOPIAO LI**

- Research Showcase Poster Winner, UF College of Pharmacy, 2023

**EARL MORRIS**

- Top Teaching Assistant Award, UF College of Pharmacy, 2022

- Predoctoral Fellowship, American Heart Association, 2023

**ASINAMAI NDAI**

- POPStar Leadership Service Award Runner-Up, 2023

**MUNAZA RIAZ**

- Finalist Oral Competition, Julie A. Johnson Senior Graduate Student Clinical Science Research, 36th Annual Research Showcase, 2023

**HUILIN TANG**

- POPStar Graduate Student Publishing, 2023

**YEHUA WANG**

- POPStar Programming Hall of Fame, 2023

**SEONKYEONG YANG**

- Frontiers in Headache Research Award, American Headache Society, 2022
- Stanley A. Edlavitch Award, International Society for Pharmacoepidemiology, 2022
- Certificate of Outstanding Merit, UF International Center, 2022

# ONLINE GRADUATE PROGRAMS

POP'S RESIDENTIAL GRADUATE PROGRAM is complemented by its online graduate program focused on working professionals. The program includes graduate certificates and a non-thesis M.S. degree in five areas of specialization.



## APPLIED PHARMACOECONOMICS

Applied pharmacoeconomics centers on the conversion of pharmacoeconomic principles, methods and theories into practice to assess the value of pharmaceutical products and services used in real-world settings. Pharmacoeconomic studies provide scientifically grounded data to inform the optimal allocation of health care resources.

## MANAGED CARE PHARMACY SYSTEMS

Managed care is a defined structure and process of designing and delivering covered health care benefits that balances clinical outcomes with access and costs. When applied to pharmacy, the result is optimized pharmaceutical treatments at a price that patients can afford. The curriculum in this program is an in-depth analysis of the structure, set-up, management and delivery of benefit coverage for medicines, as well as current innovations such as risk-sharing, drug pricing reform, and coverage of digital therapeutics.

## PHARMACEUTICAL REGULATION

Pharmaceutical regulation is an essential, global and diverse field that is tasked with ensuring safe, effective, and high-quality health care through regulatory compliance. The curriculum in the pharmaceutical regulation track is designed to give students a firm grounding in the regulatory framework around the manufacturing, distribution, dispensing and use of pharmaceutical products, and to place pharmaceuticals in a large context of health care.

## PHARMACEUTICAL VALUE ASSESSMENT AND COMMUNICATION

In the Pharmaceutical Value Assessment and Communications program, students develop applied skills to translate clinical, economic and patient-reported data into accurate and compelling communication tools to improve decision-making and health outcomes. Students combine a scientific approach to pharmaceutical evidence assessment with effective communications for specific stakeholders.

# EXCELLENCE IN ONLINE EDUCATION



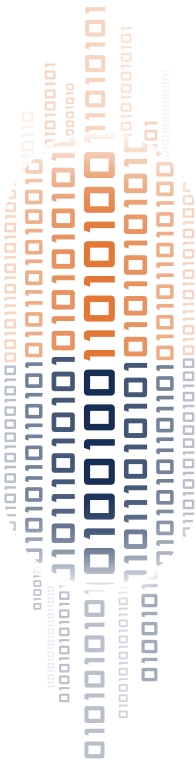
Several courses in the online POP graduate program earned an Exemplary Rating by the University of Florida + Quality Matters review process. Exemplary is the highest designation of quality for online courses.

- PHA6187 POP Foundations I
- PHA6276 Pharmacy Benefit Design & Management
- PHA6283 Introduction to Pharmacoeconomics
- PHA6213 Advanced Case Studies in Managed Care Pharmacy

In addition, the University for Florida Center of Teaching Excellence selected two online POP faculty for its top online teaching awards. Laura Happe, Pharm.D., M.P.H., a clinical professor, and Randy Hatton, Pharm.D., a clinical professor, were named 2022 Exemplary Online Award winners. Happe was honored in the Inclusive Teaching Strategies category, while Hatton was recognized in the Large Enrollment Strategies category.

## FAST FACTS FOR 2023

|   |   |   |   |   |
|---|---|---|---|---|
|  |  |  |  |  |
| <b>84</b>   | <b>578</b>  | <b>61</b>   | <b>26</b>   | <b>51</b>   |
| matriculated students   | course enrollments  | certificates awarded  | faculty taught courses  | M.S. graduates  |



# INTRODUCING CoDES

## CENTER FOR DRUG EVALUATION & SAFETY

Established in 2019, the University of Florida Center for Drug Evaluation and Safety, or CoDES, aims to improve public health by enhancing and disseminating evidence on the safety and value of medications in real-world populations. CoDES unites a multidisciplinary group of big data researchers in epidemiology, health economics, health services research and decision-sciences who evaluate and project drug outcomes to guide policy and clinical and personal decision-making. In addition to delivering new actionable evidence, CoDES fosters the development of new methods and analytic tools to enhance drug evaluation and regulatory science.

### FOCUS

CoDES develops and integrates resources on the assessment and improvement of drug use locally, nationally and internationally through five distinct research programs:

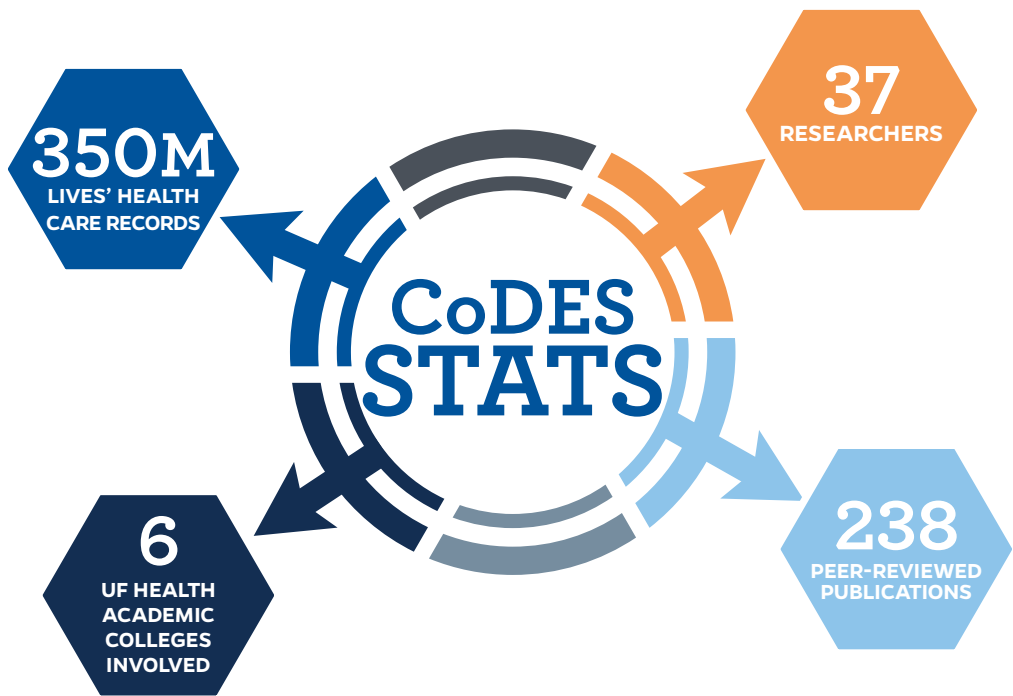
- **PHASE IV STUDIES** evaluate drug safety and effectiveness in real-world populations to enhance pre-approval evidence.
- **PHARMACOECONOMIC STUDIES** assess the value of drugs and related programs to guide the investment of personal, payer and societal resources.
- **MEDICATION USE QUALITY STUDIES** evaluate the quality and determinants of medication use to direct the allocation of programmatic resources and policy.
- **PHARMACEUTICAL PREDICTIVE ANALYTICS STUDIES** develop predictive tools for drug response and adverse events to support clinical care and related policy.
- **PHARMACEUTICAL POLICY STUDIES** evaluate policy surrounding medication use to enhance programmatic efforts aimed to improve access and quality of drug therapy.



## CoDES FEATURES

Activities at CoDES aim to build a foundation for real-world data research.

- **BIG DATA INFRASTRUCTURE** — CoDES has access to health care records for more than 350 million lives.
- **BIG DRUG DATA ANALYTICAL SUPPORT**— CoDES provides expertise in the measurement of drug exposure and outcomes/phenotypes, causal inference and predictive design and analysis.
- **RESEARCH EXCHANGE** — CoDES maintains an email listserv, website, X, formerly known as Twitter, account and seminar series.
- **POSTDOCTORAL FELLOWSHIP PROGRAM** — CoDES has introduced a postdoctoral fellowship program that capitalizes on the interdisciplinary nature of its researchers, with the goal of training the next generation of researchers.



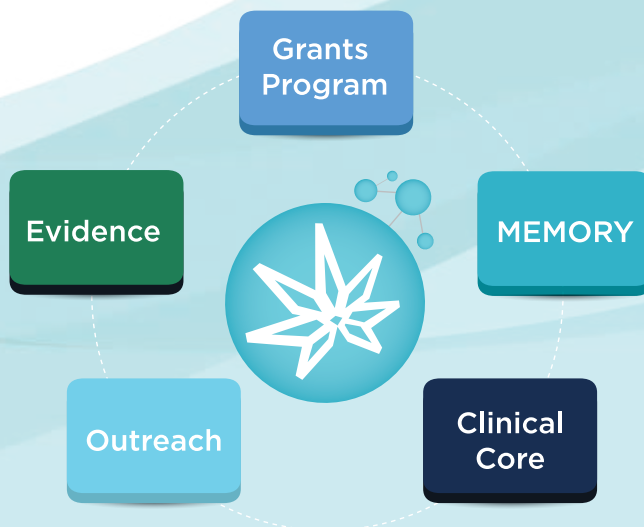
FOLLOW CoDES ON TWITTER  
[@UFCODES](#)



## Consortium for Medical Marijuana Clinical Outcomes Research

The Consortium for Medical Marijuana Clinical Outcomes was founded by the state of Florida in June 2019 to conduct, disseminate, and support research on the use and effects of medical marijuana on patient outcomes.

The Consortium’s efforts and programs support medical marijuana clinical outcomes research through five pillars aimed at establishing an effective infrastructure for research and evidence dissemination: a Grants Program, the Medical Marijuana Clinical Outcomes Repository, or MEMORY, which links medical marijuana dispensing data with existing data resources, a clinical research core which supports and conducts prospective studies, an evidence core, and an outreach core.



AMIE GOODIN,  
PH.D., M.P.P.  
CCORC Chair and  
Scientific Program  
Committee Chair

The Consortium engages public and private universities across Florida, including Florida Atlantic University, Florida A&M University, Florida Gulf Coast University, Florida International University, Florida Memorial University, Florida State University, the University of Central Florida, and the University of Miami, with leadership housed in the University of Florida.

POP Distinguished Professor Almut Winterstein serves as the consortium director, and Robert Cook, from the UF College of Medicine and College of Public Health and Health Professions, department of epidemiology, serves as the consortium associate director. Other UF faculty members with consortium leadership roles include Yan Wang (epidemiology department) as the assistant director of the clinical core and Amie Goodin (POP department) as the assistant director of evidence.

Now in its fifth year of existence, the consortium has funded 46 pilot grants, which have resulted in 41 peer-reviewed publications, 1 patent and 22 new extramural grant applications, seven of which have been awarded. Noteworthy, 86 trainees, including 18 identifying as underrepresented minorities, have been involved in or supported by consortium-funded research grants.

In addition, UF core faculty led by Goodin secured federal funding for cannabis research addressing cannabis outcomes from the Food and Drug Administration (FDA) and has submitted its findings. For the latest news and information about the consortium, see [www.mmjoutcomes.org](http://www.mmjoutcomes.org), where you can also access a host of resources about medical marijuana clinical outcomes research as well as opportunities for research involvement for patients, practitioners, researchers and industry.



## 3RD ANNUAL CANNABIS CLINICAL OUTCOMES RESEARCH CONFERENCE (CCORC)

In May of 2023 the Consortium for Medical Marijuana Clinical Outcomes Research hosted the 3rd annual Cannabis Clinical Outcomes Research Conference, or CCORC. This year's conference was held in a hybrid format. CCORC 2023 was organized as a scientific meeting to foster and disseminate research on medical marijuana clinical outcomes, while promoting engagement among medical marijuana researchers, trainees, clinicians, policymakers and industry partners.

Key conference themes included:

- Disentangling conflicting evidence in research studying the relationship between medical cannabis and public health.
- Seeking solutions to address barriers faced when conducting clinical cannabis research.
- Unpacking the data behind cannabis use, mental health and cognition.

### CCORC HIGHLIGHTS INCLUDE:

**133** registrants | **47** abstracts presented as posters or oral presentations

Three keynote speaker presentations from internationally renowned cannabis researchers:

- Dr. Jodi Gilman • Dr. Kelly Young-Wolff • Dr. Shanna Babalonis

## SAVE THE DATE

CCORC 2024 is planned for May 2024 and we hope to see you there!  
For the latest updates and for more information about  
the scientific program of previous CCORC meetings.

**[www.ccorc.mmjoutcomes.org](http://www.ccorc.mmjoutcomes.org)**

# POP'S NEW HOME




Construction is complete on the Malachowsky Hall for Data Science and Information Technology building, POP's new research home. The sixth floor houses POP, CoDES and the Consortium for Medical Marijuana Clinical Outcomes Research.

For more information, visit us at <https://pharmacy.ufl.edu/malachowsky-hall/>

## WE ARE HIRING

POP IS HIRING A NEW DEPARTMENT CHAIR, ADDITIONAL FACULTY, POSTDOCTORAL FELLOWS AND ANALYSTS. PLEASE SPREAD THE WORD AND CONTACT US IF INTERESTED!



# WE TRANSLATE BIG DATA INTO EVEN BIGGER, HEALTHIER and SAFER OUTCOMES

It's no secret drugs can do amazing, positive things for your health. But real-life medical miracles can turn into health threats. Many drugs have raised serious safety concerns after FDA approval, often because they were tested on only small samples or patients different than you.

At the University of Florida College of Pharmacy, we are working hard to gather and translate literally millions of real-life results into effective knowledge that can catch harmful side effects before they hurt you or your family. For us, this isn't just a numbers game. It's an opportunity to combine comprehensive data and proven expertise into a whole new way for pharmacists to improve and save patients' lives.

To learn more about how you can invest in our efforts to make drugs safer for you and your loved ones, please contact Christie Priddy at (352) 273-6605 or [christiepriddy@ufl.edu](mailto:christiepriddy@ufl.edu).



Department of Pharmaceutical  
Outcomes & Policy  
UNIVERSITY of FLORIDA