



Department of Experimental and Clinical Pharmacology

2021 Annual Report

Department of Experimental and Clinical Pharmacology
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Minneapolis, MN 55455
pharmacy.umn.edu/ecp

Table of Contents

| | |
|---|-----------|
| ABOUT | 2 |
| LETTER FROM THE DEPARTMENT HEAD | 3 |
| NEW FACULTY & PROMOTIONS | 4 |
| DEPARTMENT MEMBERS | 5 |
| FACULTY | 5 |
| ADJUNCT FACULTY | 6 |
| STAFF | 7 |
| POSTDOCS & FELLOWS | 7 |
| NEW & CONTINUING GRADUATE STUDENTS | 8 |
| PhD PROGRAM | 8 |
| MASTERS PROGRAM | 8 |
| RESEARCH | 9 |
| ANNUAL PERFORMANCE AND YEAR-TO-YEAR TRENDS | 9 |
| A RESEARCH-RICH ENVIRONMENT | 10 |
| NEW EXTERNALLY FUNDED PROJECTS WITH ECP FACULTY | 11 |
| NEW INTRAMURAL PROJECTS WITH ECP FACULTY | 12 |
| ONGOING SPONSORED PROJECTS WITH ECP FACULTY | 13 |
| ONGOING INTRAMURAL PROJECTS WITH ECP FACULTY | 17 |
| PUBLICATIONS | 26 |
| TEACHING | 27 |
| SERVICE | 28 |
| ECP GRADUATE PROGRAM | 29 |
| ECP GRADUATE PROGRAM-RELATED METRICS | 29 |
| ECP DOCTORAL GRADUATES | 29 |
| ECP MASTERS GRADUATES | 30 |
| FELLOWSHIPS AND AWARDS FOR GRADUATE STUDENTS | 30 |
| ECP RESEARCH EMPHASIS TRACK GRADUATES | 30 |
| PUBLICATIONS BY GRADUATE STUDENTS & POSTDOCS | 31 |
| PRESENTATIONS BY GRADUATE STUDENTS & POSTDOCS | 34 |
| ECP RESEARCH SEMINAR | 35 |

ABOUT

ECP MISSION

The mission of the Department of Experimental and Clinical Pharmacology (ECP) is to discover, disseminate, and apply new knowledge related to safe, effective, and economical medication use in patients. ECP will educate students of pharmacy, post-graduate trainees, and others for careers in pharmacy and health care with the ultimate goal of improving health. The ECP faculty and staff actively engage in teaching and conduct research pertaining to experimental and clinical pharmacology and patient outcomes to identify and promote the use of the best therapies. Together, ECP strives to advance the science of human pharmacology and therapeutics, while maintaining the highest standards of ethics in research and education.

DATA COLLECTION

Note that financial data is reported by fiscal year (2021: July 2020-June 2021). All other data uses the calendar year. These parameters continue to be the standard since 2019.

UNIVERSITY OF MINNESOTA MISSION

The University of Minnesota, founded in the belief that all people are enriched by understanding, is dedicated to the advancement of learning and the search for truth; to the sharing of this knowledge through education for a diverse community; and to the application of this knowledge to benefit the people of the state, the nation and the world. The University's threefold mission of research and discovery, teaching and learning, and outreach and public service is carried out on multiple campuses and throughout the state.

EQUAL OPPORTUNITY STATEMENT

The University of Minnesota shall provide equal access to and opportunity in its programs, facilities, and employment without regard to race, color, creed, religion, national origin, gender, age, marital status, disability, public assistance status, veteran status, sexual orientation, gender identity, or gender expression.

Inquiries regarding compliance may be directed to the Director, Office of Equal Opportunity and Affirmative Action, University of Minnesota, 274 McNamara Alumni Center, 200 Oak Street S.E., Minneapolis, MN 55455, (612) 624-9547, eoaa@umn.edu. Website: www.eoaa.umn.edu.

This publication/material is available in alternative formats upon request. Please contact Zack McGough, Experimental and Clinical Pharmacology, 612-626-4677.

DISABILITY ACCESS STATEMENT

This publication/material is available in alternative formats upon request. Direct requests to Zack McGough, Experimental and Clinical Pharmacology, 612-626-4677.

LETTER FROM THE DEPARTMENT HEAD

Dear Colleagues and Friends,

In this 2021 annual report, I take pride in sharing a few highlights for the Department of Experimental and Clinical Pharmacology (ECP). Covid-19 persisted as a challenge throughout 2021, however our entire department and college persevered in accomplishing our research, education, and service missions by adapting work with flexibility approaches and in many cases going above and beyond to accommodate unique circumstances.

The efforts and commitments made by ECP faculty, staff and students over the 2021 year are reflected in strong performance research metrics:

- sponsored award expenses consistently over \$3 million for 2021
- a consistent 22% faculty salary offset in 2021
- over 78 peer-reviewed articles published by ECP faculty in 2021
- an increase in new grants received in 2021 to 38 (up from 24 in 2000)

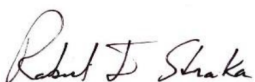
These metrics, along with our strong record of contributions to the teaching and service missions of our college, reflect well on the exceptional dedication of our faculty, staff, and students. Even as we power through the pandemic, our faculty, staff, and students dutifully completed our tasks including our departmental self-study. The findings from this study will inform our department strategic plan, help shape new initiatives our faculty have embraced, and motivate our contributions to re-envisioning our curriculum as we prepare for our next (2023) Collegiate Accreditation visit.

Since our 2020 report, we've had several personnel changes, including the retirement of long time UMN Professor William Oetting, and departure of Lindsay Bork Nichols, our department administrative manager. We wish them all the very best and thank them for their outstanding service and dedication to the department and college. At the same time, we welcome Zack McGough as our new department administrator as of January 2022.

As we emerge from, what we hope, was the worst of the COVID-19-related challenges, I take pride in sharing in this report as testimony to what our faculty, students, and staff have accomplished to advance the science of our discipline and support a new generation of students from our ECP graduate program.

Finally, I wish to acknowledge and thank all alumni, donors, and friends of the department for their continued support, engagement, and ongoing pride for the things we do for our global community.

With warm regards,



Robert J. Straka
Department Head

NEW FACULTY & PROMOTIONS



Dr. Beshay Zordoky, an ECP faculty member since July 2015, was promoted to Associate Professor with tenure in May 2021. Dr. Zordoky received his PhD from the University of Alberta followed by a postdoctoral clinician fellowship in the Department of Pediatrics and the Cardiovascular Research Center at the University of Alberta. His current research focuses on cardio-oncology. Cardio-oncology has emerged as a novel scientific discipline that aims to mitigate the cardiovascular adverse effects of anti-cancer agents. Since the survival of cancer patients has significantly increased over the past two decades, it is very important to improve the quality of life of these cancer survivors.

DEPARTMENT MEMBERS

FACULTY

Mahmoud Al-Kofahi, DDS, PhD

Assistant Professor

Angela K. Birnbaum, PhD, FAES

Professor; Director of Graduate Studies

Jeffrey Bishop, PharmD, MS, BCPP, FCCP

Associate Professor

Richard C. Brundage, PharmD, PhD, FISO, FCP

Professor

Scott A. Chapman, PharmD

Associate Professor

James C. Cloyd, PharmD, FCCP

Professor, Weaver Endowed Chair in Orphan Drug Development

Lisa Coles, PhD

Research Assistant Professor

Jeannine M. Conway, PharmD, BCPS

Associate Professor; Associate Dean for Professional Education

Esam El-Fakahany, PhD

Professor

Elizabeth Hirsch, PharmD, BCPS

Associate Professor

R. Stephanie Huang, PhD

Associate Professor

Pamala A. Jacobson, PharmD, FCCP

Distinguished Professor; Associate Department Head

L'Aurette A. Johnson, PhD

Assistant Professor; Associate Director of Graduate Studies

Reena Kartha, PhD

Research Assistant Professor

Mark N. Kirstein, PharmD

Associate Professor

Michael Kotlyar, PharmD

Associate Professor

Ilo E. Leppik, MD

Professor

Ling Li, PhD, DVM

Professor, VFW Endowed Chair in Pharmacotherapy for the Elderly; Associate Department Head

Susan E. Marino, PhD

Associate Professor

Melanie R. Nicol, PharmD, PhD

Associate Professor

William S. Oetting, PhD

Professor

Leo J. Sioris, PharmD

Professor

Debra J. Skaar, PharmD, FCCM

Professor

Robert J. Straka, PharmD, FCCP

Professor; Department Head

Lynda Welage, PharmD, FCCP

Professor; Dean

Beshay Zordoky, PhD

Associate Professor

ADJUNCT FACULTY

Kyle Baron, PharmD, PhD

Assistant Professor

Andrew Behm, PharmD, CGP

Assistant Professor

Alexander Berg, PharmD, PhD, FCP

Associate Professor

Ashley Brown, PharmD

Assistant Professor

Samuel Callisto, PhD

Assistant Professor

Jason Chittenden, PhD

Assistant Professor

David Gregornik, PharmD

Associate Professor

John Gualtieri, PharmD

Assistant Professor

Serge Guzy, PhD

Professor

Silvia M Illamola, PharmD, PhD

Assistant Professor

Jeanine Jarnes, PharmD

Assistant Professor

Nitin Kaila, PhD

Assistant Professor

Daniel E. Keyler, PharmD

Professor

Richard Kingston, PharmD

Assistant Professor

Frank N. Konstantinides, MT, MS

Professor

George Konstantinides, PharmD

Assistant Professor

Edris Kosar, PharmD

Assistant Professor

Robert Kriel, MD

Research Professor

Smita Kshirsagar, PhD

Assistant Professor

Marie D. Kuker, RPh

Assistant Professor

Richard L. Lalonde, PharmD, FAAPS, FCP, FCCP

Professor

Stephen H. LeMaster, PharmD

Associate Professor

Ramaiah Muthyala, PhD

Associate Professor

David Parra, PharmD

Associate Professor

Pamela A. Pawloski, PharmD

Assistant Professor

Mark Robbins, PhD, JD

Associate Professor

Samuel Roiko, PhD

Assistant Professor

Ahmed H. Salem, PhD

Associate Professor

Kyriakie Sarafoglou, MD

Associate Professor

Robert J. Schumacher, PhD

Assistant Professor

Catherine Sherwin

Associate Professor

Kelly M. Sioris, PharmD

Assistant Professor

Catherine St. Hill, DVM, PhD

Associate Professor

John V. St. Peter, PharmD

Associate Professor

Sean Stewart, PharmD, BCACP, CLS

Associate professor

Mary A. Ullman, PharmD

Associate Professor

Brian Van Ness, PhD

Professor

Orly Vardeny, PharmD, BCPS, FHFSA

Associate Professor

STAFF

| | |
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| Christopher Barkley, PhD | Research Associate, Marino Research Program |
| Lindsay Bork Nichols, MBA | Administrative Manager, ECP Office |
| Sandra Bowers | Researcher, Birnbaum Research Program |
| Lindsey Collins | Junior Scientist, Nicol Research Program |
| Sheena Dufresne | Study Coordinator, Kotlyar Research Program |
| Lori Endsley | MTRF Administrator |
| James Fisher | Technical Director, CPAS Laboratory |
| Katherine Goffin | Administrative Specialist, ECP Office |
| Andrea Gram | Junior Scientist, Li Research Program |
| Marianne Grant | Lab Manager, Zordoky Research Program |
| Silvia M. Illamola, PharmD, PhD | Research Associate, Birnbaum Research Program |
| Alyssa Johnson | Research Professional, Marino and Jacobson Research Programs |
| Adam M. Lee, PhD | Research Associate, Bishop Research Program |
| Erin McGonagle | Staff, Precision Medicine Grand Challenge |
| Usha Mishra, MS | Assistant Scientist, Center for Orphan Drug Research |
| Rachel Moniz | Researcher, Birnbaum Research Program |
| Becky Palapala | Finance & Communications Specialist, ECP Office |
| Sam Stensgard | Researcher, Birnbaum Research Program |
| Marcia Terluk, PhD | Researcher, Center for Orphan Drug Research |
| Susan Williford | Graduate Program Coordinator, ECP Office |

POSTDOCS & FELLOWS

| | |
|---------------------------|----------------------------------|
| Kevin Agostinucci, PhD | Advisor: Beshay Zordoky, PhD |
| Vasudeva Reddy Dodda, PhD | Advisor: Ramaiah Muthyala, PhD |
| Alex Ling, PhD | Advisor: R. Stephanie Huang, PhD |
| Jaehyeok Roh, PharmD | Advisor: Reena Kartha, PhD |
| Sampreeti Jena, PhD | Advisor: R. Stephanie Huang, PhD |
| Samuel Williams | Advisor: Jeff Bishop, PharmD |

NEW & CONTINUING GRADUATE STUDENTS

PhD PROGRAM

| | |
|--------------------------------|--|
| Ibrahim Abdelgawad, BS | Advisor: Beshay Zordoky, PhD; Ling Li, DVM, PhD |
| Charul Avachat, MS | Advisor: Angela Birnbaum, PhD |
| Cecilia (Cece) Barajas, BS | Advisor: Carolyn Fairbanks, PhD |
| Jessica Barry, BS | Advisor: Angela Birnbaum, PhD |
| Morgan Bixby, BS | Advisor: Elizabeth Hirsch, PharmD, RPh; Pamala Jacobson, PharmD |
| Shen Cheng, MS | Advisor: Richard C. Brundage, PharmD, PhD; Mahmoud Al-Kofahi, DDS, PhD |
| Mohamed Dabour, MS | Advisor: Beshay Zordoky, PhD |
| Yingbo Huang, MS | Advisor: R. Stephanie Huang, PhD |
| Mu'taz Jaber, PharmD | Advisor: Richard C. Brundage, PharmD, PhD; Mahmoud Al-Kofahi, DDS, PhD |
| Angela Jeong, PharmD | Advisor: Ling Li, DVM, PhD |
| Sarah Kim, PharmD | Advisor: Jeanine Jarnes, PharmD; James Cloyd, PharmD |
| Alyssa Lantz, BS | Advisor: Melanie Nicol, PharmD, PhD |
| Chenxu Li, MS | Advisor: Reena Kartha, PhD; Lisa Coles, PhD |
| Yuhan Long, BS | Advisor: Angela Birnbaum, PhD |
| Xintian Lyu, BS | Advisor: Angela Birnbaum, PhD |
| David Margraf, MS, PharmD | Advisor: Scott Chapman, PharmD; Mark Kirstein, PharmD |
| Moataz Mohamed, MS | Advisor: Pamala Jacobson, PharmD |
| Siddhee Anand Sahasrabudhe, MS | Advisor: Reena Kartha, PhD; James Cloyd, PharmD |
| Yuting Shan, PharmD | Advisor: R. Stephanie Huang, PhD |
| Jason Sriwijaya, MD | Advisor: Angela Birnbaum, PhD |
| Mei-Chi (Judy) Su, MS | Advisor: R. Stephanie Huang, PhD; Angela Birnbaum, PhD |
| Boguang Sun, PharmD | Advisor: Robert J. Straka, PharmD |
| Takuto Takahashi, MD | Advisor: Mark Kirstein, PharmD; Mahmoud Al-Kofahi, DDS, PhD |
| Fan Wang, MS | Advisor: Melanie Nicol, PharmD, PhD; Angela Birnbaum, PhD |
| Ya-Feng (Jay) Wen, PharmD | Advisor: Robert J. Straka, PharmD |
| Lusi Zhang, , MHI, PharmD | Advisor: Jeff Bishop, PharmD, MS |
| Rui Zhong, BS | Advisor: Ling Li, DVM, PhD |

MASTERS PROGRAM

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|----------------------|----------------------------------|
| Joshua Mentzer, BS | Advisor: R. Stephanie Huang, PhD |
| Abdelrahman Saqr, BS | Advisor: Pamala Jacobson, PharmD |

RESEARCH

Led by our world-class faculty, research teams conduct groundbreaking and critical research in the Department of Experimental and Clinical Pharmacology. Faculty research programs focus on oncology, transplantation, infectious diseases, pharmacogenomics, geriatrics, critical care, neuroscience, cardiovascular diseases, pediatrics, and psychiatry, among other areas. ECP is home to the Lawrence C. Weaver Endowed Chair in Orphan Drug Development and the VFW Endowed Chair in Pharmacotherapy for the Elderly. In addition, ECP's state-of-the-art, CLIA-certified Clinical Pharmacology Analytical Services Laboratory has provided an important research resource to both University researchers and external customers for more than fifteen years.

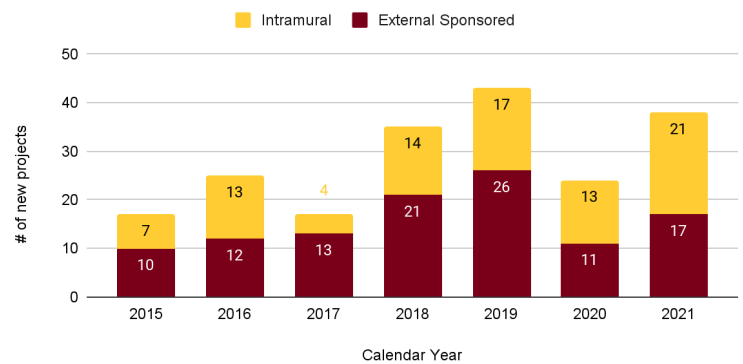
Our faculty routinely present important research at national and international conferences, lecture and collaborate across the country, serve as reviewers and editorial board members of international journals, hold leadership positions in national organizations, and serve on review committees for National Institutes of Health (NIH) and other granting agencies.

ANNUAL PERFORMANCE AND YEAR-TO-YEAR TRENDS

- Funding for research in ECP comes from both intramural and external sources:
 - New Grants Received: 38
 - Intramural: 21
 - External sponsored: 17
- Research endeavors result in various outputs, including:
 - Articles in peer-reviewed publications: 78
 - Books, chapters and other publications: 15

New Projects by Type

2015-2021

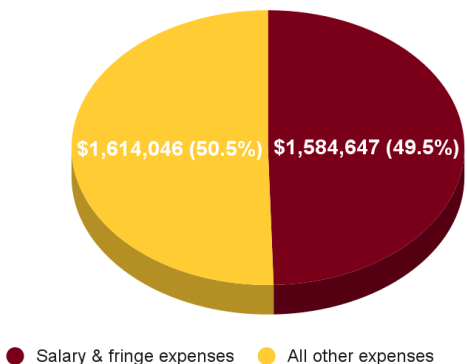


Financials of Sponsored Projects in FY2021

- Expenditures by category
 - Salary and Fringe \$1,584,647
 - Other Expenses \$1,614,046
 - Total \$3,198,693
- Percentage of department faculty salaries supported by sponsored projects: 22.04%
 - Salary offset percentage held steady at 22% for the year (22.77% in FY20).

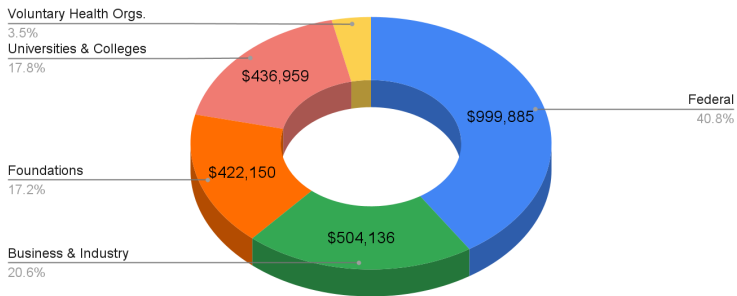
Percent of Expenditures by Category

\$3,198,693 total



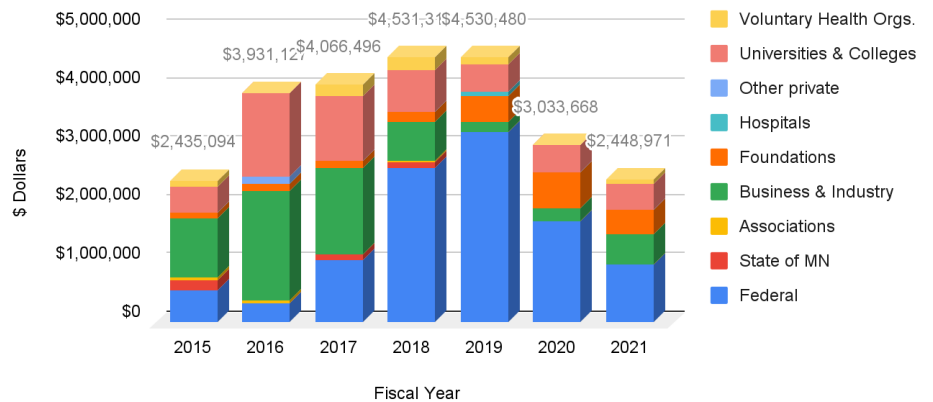
Sponsored Awards by Source (FY21)

Total: \$2,448,971



Sponsored Awards by Source

(FY15-FY20)



A RESEARCH-RICH ENVIRONMENT

The College of Pharmacy is ranked 3rd among outstanding pharmacy education and research institutions in the world. It is located within one of the largest academic health centers in the U.S., with nationally recognized programs in public health, medicine, nursing, dentistry, and veterinary medicine. Major campus research facilities include a Clinical and Translational Science Institute, the Biomedical Genomics Center, and a comprehensive cancer center. In addition, there are numerous partnerships with affiliated healthcare systems that offer exceptional research and educational programs. The Twin Cities also have a large number of cutting-edge biomedical companies eager to collaborate with the academic community.

RESEARCH CENTERS WITHIN ECP

- Center for Orphan Drug Research (Dr. James Cloyd, Director)
- Institute for Personalized Medicine (Dr. Pamala Jacobson, Director)
- Center for Clinical and Cognitive Neuropharmacology (Dr. Susan Marino, Director)

LOCATIONS AND FACILITIES

ECP maintains a total of 25,889 square feet of office and laboratory space within four buildings on the East Bank of the University of Minnesota’s Twin Cities campus:

- Weaver-Densford Hall 7,332 SF
- McGuire Translational Research Facility 7,696 SF
- Phillips Wangensteen Building 6,915 SF
- 717 Delaware Street SE 3,946 SF

NEW EXTERNALLY FUNDED PROJECTS WITH ECP FACULTY

| Faculty | Project Description | Sponsor |
|--|--|--|
| Angela Birnbaum (PI), Stephanie Huang (Co-I) | Physiological-based Pharmacokinetics Approach to Determine the Extent of Drug Exposure of Antiseizure Medications During Pregnancy and Breastfeeding | NIH National Institute of Child Health and Development |
| Richard Brundage (Advisor) | Pharmacometrics Traineeship | Pfizer, Inc. |
| Scott Chapman (Co-I) | Long COVID-RECOVER | NIH NCATS National Covid Cohort Collaborative |
| James C. Cloyd (PI) | Licensing Agreement-IV Topiramate | Ligand Pharmaceuticals |
| R. Stephanie Huang (Mentor) | Understanding the Impact of CD276 and EZH2 on the Immune Microenvironment of Pediatric Central Nervous System Malignancies | Children's Cancer Research Fund (CCRF) 2021 Emerging Scientist Award |
| Elizabeth Hirsch (Co-I) | Optimal vancomycin exposure target for pulmonary exacerbations in CF | Cystic Fibrosis Foundation |
| Pamala Jacobson (PI) | Pharmacogenomics Clinical Training Program for Pharmacists in Rural and Underserved Areas in Minnesota | Minnesota Department of Health (MDH) |
| Reena Kartha (PI) | Dose Optimization of Nervonic Acid-a Potential Therapy to Alleviate Disease Progression in Adrenoleukodystrophy | NIH National Center for Advancing Translational Science |
| Reena Kartha (PI) | Nervonic Acid-a Potential Therapy to Alleviate Disease Progression in Adrenoleukodystrophy | Ligand Pharmaceuticals, Inc. |
| Reena Kartha (PI) | Novel Inflammatory Biomarkers | Sanofi-Genzyme |
| Reena Kartha (PI) | Translational Pharmacology Fellowship (year 2) | Sanofi-Genzyme |
| Ilo Leppik (PI), Angela Birnbaum (Co-I) | Nursing Home Survey Project for Epilepsy | UCB Pharma S.A. |

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| Ling Li (Co-I) | Casual and Integrative Deep Learning for Alzheimer's Disease | NIH National Institute on Aging |
| Melanie Nicol (Mentor) | A toll-free call intervention to improve adverse events reporting among patients being switched to or initiated on Dolutegravir in 3 health centers in Kampala, Uganda | Fogarty Global Health Fellowship Northern Pacific Global Health Fellowship Consortium |
| Melanie Nicol (Advisor) | New Investigator Fellowship | Conference on Retroviruses and Opportunistic Infections |
| Robert Straka (Co-I) | The Long-Life Family Study (LLFS): Pharmacogenetics (PGx) Administrative Supplement | NIH National Institute on Aging |
| Beshay Zordoky (Advisor) | Egyptian Government Scholarship | Egyptian Ministry of Higher Education |

NEW INTRAMURAL PROJECTS WITH ECP FACULTY

| Faculty | Project Description | Sponsor |
|---|--|--|
| Mahmoud Al-Kofahi (Co-PI), Richard Brundage (Co-PI), Lisa Coles (Co-PI) | Drug-delivery Mechanism to Increase Adherence in Patients with Adrenal Insufficiency | UMN Clinical and Translational Science Institute (CTSI) |
| Angela Birnbaum (Co-I) | Neurobehavioral Impacts of Medical Cannabis Treatment in Chronic Pain Patients | University of Minnesota |
| Angela Birnbaum (Co-I) | CanAroma UMN CTRS | University of Minnesota |
| Jeffrey Bishop (Advisor) | ECP Fellowship | College of Pharmacy |
| Richard Brundage (Advisor), Mahmoud Al-Kofahi (Advisor) | Graduate School Doctoral Dissertation Fellowship | University of Minnesota Graduate School |
| James C. Cloyd (PI) | Allopregnanolone (ALLO), A Novel Neurosteroid Drug, for Treatment of Status Epilepticus, A Life-threatening Neurological Emergency | Office of Academic Clinical Affairs (OACA), University of Minnesota |
| Elizabeth Hirsch (Advisor) | Impact of a collaborative OPAT program at UMMC | University of Minnesota College of Pharmacy Melendy Research Scholarship |
| R. Stephanie Huang (Advisor) | Bighley Fellowship | University of Minnesota |

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| Elizabeth Hirsch (Advisor) | Coin Fellowship | College of Pharmacy |
| Pamala Jacobson (PI), Jeffrey Bishop (Co-I) | Pharmacogenomics ECHO | University of Minnesota |
| Pamala Jacobson (PI), Jeffrey Bishop (Co-I) | Toward Pharmacogenomics-Enabled Healthcare at Statewide Scale: Implementing Precision Medicine | University of Minnesota, College of Pharmacy, Strategic Investment Initiative |
| Reena Kartha (Advisor), James Cloyd (Advisor) | James C. Cloyd Neuropharmacology Fellowship | College of Pharmacy |
| Debra Skaar | Efficacy of Self-management of Sedative Therapy by Ventilated ICU Patients | University of Minnesota |
| Robert J. Straka (Advisor) | Robert Straka Fellowship | College of Pharmacy |
| Robert J. Straka (PI) | Assessment of Anticoagulants and Antiplatelets Dosing Requirement in Hmong (A4) Study in Hmong | College of Pharmacy |
| Robert J. Straka (PI) | Microbiome Variation, Gout and Dietary Interactions within the Hmong “Hmong Microbiome And Gout, Obesity, Vitamin C (HMANGO-C) Study” | Minnesota Mayo Partnerships |
| Robert J. Straka (PI) | Very Important Pharmacogenes in Hmong (VIP-HC) Study (California Cohort) | College of Pharmacy |
| Robert J. Straka (PI) | Hmong Individualized Pharmacogene Sequencing (HIPS) Initiative | College of Pharmacy |
| Beshay Zordoky (Advisor) | Pathways to Research Program | UMN Clinical and Translational Science Institute (CTSI) |
| Beshay Zordoky (Advisor) | Summer College of Pharmacy Experiences (SCoPE) Program | College of Pharmacy |
| Beshay Zordoky (Advisor) | Bighley Graduate Fellowship | University of Minnesota |

ONGOING SPONSORED PROJECTS WITH ECP FACULTY

| Faculty | Project Description | Sponsor |
|---|---|--|
| Angela Birnbaum (Co-I) | Phase 1a/1b Clinical Trials of Multivalent Opioid Vaccine Components | NIH National Institute on Drug Abuse |
| Angela K. Birnbaum (Co-I), Richard C. Brundage (Co-I) | Maternal Outcomes and Neurodevelopmental Effects of Antiepileptic Drugs | NIH National Institute of Neurological Disorders and Stroke |
| Angela Birnbaum (Co-I) | Vaccines for Fentanyl and Its Derivatives: A strategy to reduce illicit use and overdose | NIH National Institute on Drug Abuse |
| Angela Birnbaum (Co-I) | Novel Nanovaccines Against Opioid Use Disorder | NIH National Institute on Drug Abuse |
| Angela K. Birnbaum (PI) | Pharsight-University of Minnesota Pharmacometrics Collaboration | Pharsight Corporation |
| Jeffrey Bishop (Co-I) | An Informatics Framework for Discovery and Ascertainment of Drug-Supplement Interactions | NIH National Center for Complementary and Integrative Health |
| Jeffrey Bishop (Mentor) | Comorbidity: Substance Use Disorders and Other Psychiatric Conditions | NIH National Institute on Drug Abuse |
| Richard Brundage (PI) | Pharmacometrics Traineeship | Pfizer Pharmaceuticals, Inc. |
| Richard Brundage (PI) | Ph2a SQ HC Infusion Pump in Congenital Adrenal Hyperplasia IND125,640 | DHHS Food and Drug Administration |
| James C. Cloyd (PI), Lisa Coles (Co-I) | An Exploratory, Open-label Study of the Pharmacokinetics and Pharmacodynamics of Diazepam after Intranasal Administration of a Single Dose of Valtoco to Healthy Volunteers | Neurelis, Inc. |
| James C. Cloyd (PI), Lisa Coles (Co-I) | Phase I Study of Midazolam Pharmacokinetics, Pharmacodynamics and Adverse Effect following Intramuscular Injection in Dogs | Mesagreen Pharmaceutical Company |
| James C. Cloyd (Co-I), Lisa Coles (Co-I), Reena Kartha (Co-I) | Identifying Biological Signatures of N-acetylcysteine for Non-Suicidal Self-Injury in Adolescents | NIH National Center for Complementary and Integrative Health |
| James C. Cloyd (Co-I), Lisa Coles (Co-I) | Epilepsy Bioinformatics Study for Antiepileptogenic Therapy (EpiBioS4Rx), | NIH National Institute of Neurological Disorders and Stroke |

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| James C. Cloyd (PI), Lisa Coles (Co-I) | Established Status Epilepticus Treatment Trial (ESETT) | NIH National Institute of Neurological Disorders and Stroke |
| James C. Cloyd (Co-PI), Reena Kartha (Co-I) | Lysosomal Disease Network | NIH National Institute of Neurological Disorders and Stroke |
| James C. Cloyd (Co-PI) | Development of Intravenous Baclofen | Allaysis Pharmaceuticals |
| Lisa Coles (PI) | The Role of Beta-Catenin in the Pathophysiology of Infantile Spasms | Tufts University |
| Lisa Coles (Co-I) | Hypoglycemia After Exercise in Type 1 Diabetes: Intranasal Naloxone as a Novel Therapy to Preserve Hypoglycemia Counterregulation | Juvenile Diabetes Research Fdn. |
| Esam El-Fakahany (Co-I) | University of Minnesota Clinical and Translational Science Institute (UMN CTSI) | NIH National Center for Advancing Translational Science |
| R. Stephanie Huang (PI) | Drug Repurposing in Breast Cancer | NIH National Cancer Institute |
| R. Stephanie Huang (PI) | Genetic Mechanisms Underlying Sexual Dimorphism in Cancer and Response to Therapy | NIH National Cancer Institute |
| Pamala Jacobson (Mentor) | Variants Associated with Tacrolimus Metabolism in Kidney Transplant Recipients in Hepatic Cells | NIH National Institute of Allergy and Infectious Disease |
| Pamala Jacobson (PI) | Gut Microbiota and Effect on Immune Suppressants in Transplantation | NIH National Institute of Allergy and Infectious Disease |
| Reena Kartha (PI) | Translational Pharmacology Research Fellowship (year 1) | Sanofi-Genzyme |
| Reena Kartha (PI), James C. Cloyd (Co-I) | Use of Antioxidant or Anti-inflammatory Medications to Mitigate Oxidative Stress and Inflammation in Type1 Gaucher Disease (GD1) | Pfizer, Inc. |
| Mark N. Kirstein (Co-I) | Novel targeted Chemo/Immunotherapy Approach for Localized and Metastatic CaP | NIH National Cancer Institute |
| Mark N. Kirstein (Co-I) | Development of Mutation Suppression Therapy in a Swine Model of NF1 | Recombinetics, Inc. |

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| Mark N. Kirstein (Co-I) | Cancer Center Support Grant | NIH National Cancer Institute |
| Michael Kotlyar (Co-PI) | Cigarette Smoking as a Risk Factor for Greater Psychiatric Symptom Severity across Serious Mental Illnesses: A Secondary Analysis of Three Nationally-Representative NIH Data-sets | NIH National Institute on Drug Abuse |
| Michael Kotlyar (Co-PI) | Feasibility of Using Wearable Technology for Just-in-Time Prediction of Smoking Lapses | NIH National Institute on Drug Abuse |
| Michael Kotlyar (Co-I) | Bupropion for the Prevention of Postpartum Smoking Relapse | NIH National Institute on Drug Abuse |
| Michael Kotlyar (Co-I) | AI-DCL: Addressing Sociotechnical Challenges of Conversational Agents and Interventions in the Context of Elderly Care | The National Science Foundation |
| Ilo Leppik (PI) | A Randomized, Double-Blind, Placebo-Controlled Study of the Safety and Efficacy of Intranasal Midazolam (USL261) in the Outpatient Treatment of Subjects with Seizure Clusters | PharmaNet, Inc. |
| Ilo Leppik (PI) | A Randomized, Double-Blind, Placebo-Controlled Study to Evaluate the Efficacy and Safety of Sage-547 Injection in the Treatment of Subjects with Super-refractory Status Epilepticus | Sage Therapeutics, Inc. |
| Ling Li (Co-I) | Deep Learning with Neuroimaging Genetic Data for Alzheimer's Disease | NIH National Institute on Aging |
| Ling Li (Co-I) | Integrating Alzheimer's Disease GWAS with Proteomic and Metabolomic QTL Data | NIH National Institute on Aging |
| Ling Li (Co-I) | Macrophage Inflammasome Activation and the Mechanism of Lipolysis Resistance in Aged Adipose | NIH National Institute on Aging |
| Ling Li (PI) | HDL Mimetic Peptide-Mediated Enhancement of Neurovascular Function to Mitigate Cerebral Amyloid Angiopathy and Alzheimer's Disease | NIH National Institute on Aging |
| Ling Li (PI) | Dysregulation of Protein Prenylation in the Pathogenesis of Alzheimer's Disease | NIH National Institute on Aging |

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| Ling Li (Co-I) | Generating Exogenic Hippocampa | NIH National Institute on Aging |
| Melanie Nicol (PI) | Evaluating Antiretroviral Pharmacology in the Female Genital Tract to Optimize HIV Prevention | NIH National Institute of Allergy and Infectious Diseases |
| Melanie Nicol (PI) | Pharmacology of Antiretrovirals in Anatomical Brain Tissue among Persons with Chronic HIV Infection | NIH National Institute of Neurological Disorders and Stroke |
| Melanie Nicol (Co-I) | Midwest Integration of the National HIV Curriculum (MINHC) | University of Illinois--Chicago |
| Melanie Nicol (Co-I) | Improving Diagnostics and Neurocognitive Outcomes in HIV/AIDS-related Meningitis | NIH National Institute of Neurological Disorders and Stroke |
| Melanie Nicol (Co-I) | Encochleated Oral Amphotericin for Cryptococcal Meningitis Trial | National Institutes of Health (NIH) |
| Melanie Nicol (Co-I) | Role of CNS Co-infections in HIV Viral Reservoirs | National Institutes of Health (NIH) |
| Melanie Nicol (Co-I) | Cryptococcal Antigen Screening Plus Sertraline (C-ASSERT) | NIH National Institute of Allergy and Infectious Disease |
| Debra Skaar (Co-I) | Efficacy of Self-Management of Sedative Therapy by Ventilated ICU Patients | NIH National Heart, Lung, and Blood Institute |
| Beshay Zordoky (PI) | Psychosocial Stress Exacerbates Doxorubicin-induced Cardiovascular Aging | NIH National Heart, Lung, and Blood Institute |

ONGOING INTRAMURAL PROJECTS WITH ECP FACULTY

| Faculty | Full Project Name | Sponsor |
|---|--|--|
| Mahmoud Al-Kofahi (Co-PI), Richard Brundage (Co-PI), Lisa Coles (Co-PI) | Intranasal Delivery of Cortisol Stress Dosing in Patients with Adrenal Insufficiency | The Pediatric Device Innovation Consortium (PDIC), University of Minnesota |
| Jeffrey Bishop (PI) | Medication therapy management and pharmacogenetic evaluation in mental health | University of Minnesota |
| Jeffrey Bishop (Mentor) | Cardiovascular Disease Genetics and Medications and Brain structure in Psychosis | Melendy/Peters Fdn., University of Minnesota College of Pharmacy |

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| Elizabeth Hirsch (Co-I) | Program to Improve Quality and Safety of Outpatient Parenteral Antibiotic Treatment (OPAT) at UMMC | UMN Medical School Academic Investment Clinical Program |
| R. Stephanie Huang (PI) | Repurposing Drugs to Treat Androgen Receptor Independent Prostate Cancer | University of Minnesota Office of Academic Clinical Affairs (OACA) Faculty Research Development grant |
| Pamala Jacobson (PI), Jeffrey Bishop (Co-I), R. Stephanie Huang (Co-I) | Grand Challenge 3: Statewide Implementation of Pharmacogenomics | UMN Provost's Office |
| Pamala Jacobson (Co-I) | Treatment of Microbiome Dysbiosis after HCT with Activated Charcoal | UMN CTSI |
| Pamala Jacobson (PI) | Microbiome and Immunosuppressants in Hematopoietic Cell Transplantation | UMN Masonic Cancer Center Chainbreaker |
| Michael Kotlyar (Co-I) | Improving Health and Well-Being with Personalized, Pervasive Technology | UMN Provost's Office |
| Ling Li (PI) | Modeling and Reversing Alzheimer's Pathology via Human Brain Organoids | Faculty Research Development Grant Program, OACA, UMN |
| Melanie Nicol (PI) | The Role of Inflammation in Antiretroviral Concentrations in Genital and Central Nervous System Compartments | UMN CTSI K-R01 Transition to Independence Grant |
| Debra Skaar (Co-PI) | Creating a 21 st Century Precision Medicine Intensive Care Unit (ICU) | UMN College of Pharmacy |
| Robert J. Straka (PI) | Assessment of Anticoagulants and Antiplatelets Dosing Requirement in Hmong (A4) Study in Hmong | UMN College of Pharmacy |
| Robert J. Straka (Advisor) | Reducing Health Disparities in Cardiovascular Diseases through Individualized Approaches | University of Minnesota Graduate Program (DDF Fellowship) |
| Beshay Zordoky (PI) | Hypertension Exacerbates Doxorubicin-induced Vascular Aging | UMN CTSI K-R01 Transition to Independence Grant |

PUBLICATIONS

JOURNAL ARTICLES BY ECP FACULTY

(Key: **ECP Faculty**, **ECP Graduate Students**, **Postdocs and Staff**)

2021 Journal Articles

Abdelgawad, I. Y., Grant MKO, Popescu, F. E., Largaespada, D. A., & **Zordoky, B. N.** (2021). Doxorubicin Paradoxically Ameliorates Tumor-Induced Inflammation in Young Mice. *International journal of molecular sciences*, 22(16). 10.3390/ijms22169023

Abdelgawad, I. Y., Sadak, K. T., Lone, D. W., **Dabour, M. S.**, Niedernhofer, L. J., & **Zordoky, B. N.** (2021). Molecular mechanisms and cardiovascular implications of cancer therapy-induced senescence. *Pharmacology & therapeutics*, 221, 107751. 10.1016/j.pharmthera.2020.107751

Al-Kofahi, M., Oetting, W. S., Schladt, D. P., Rimmel, R. P., Guan, W., Wu, B., Dorr, C. R., Mannon, R. B., Matas, A. J., Israni, A. K., & **Jacobson, P. A.** (2021). Precision Dosing for Tacrolimus Using Genotypes and Clinical Factors in Kidney Transplant Recipients of European Ancestry. *Journal of clinical pharmacology*, 61(8), 1035–1044. <https://doi.org/10.1002/jcph.1823>

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Bishop, J. R. (2021). Pharmacists as facilitators of pharmacogenomic guidance for antidepressant drug selection and dosing. *Clinical and Translational Science*, 14(4), 1206-1209. 10.1111/cts.13057

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Jaber, M. M., **Cheng, S.**, & **Brundage, R. C.** (2021). Evaluation of bias in weighted residual calculations when handling below the limit of quantification data using Beal's M3 method. *CPT: pharmacometrics & systems pharmacology*, 10(4), 275-278. 10.1002/psp4.12616

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Keating, B. J., Mukhtar, E. H., Elftmann, E. D., Eweje, F. R., Gao, H., Ibrahim, L. I., Kathawate, R. G., Lee, A. C., Li, E. H., Moore, K. A., Nair, N., Chaluvadi, V., Reason, J., Zanoni, F., Honkala, A. T., Al-Ali, A. K., F., Ahmad **Jacobson, P. A.** ... Snyder, M. P. (2021). Early detection of SARS-CoV-2 and other infections in solid organ transplant recipients and household members using wearable devices. *Transplant international : official journal of the European Society for Organ Transplantation*, 34(6), 1019–1031. <https://doi.org/10.1111/tri.13860>

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Osum, S. H., Coutts, A. W., Duerre, D. J., Tschida, B. R., **Kirstein, M. N.**, **Fisher, J.**, Bell, W. R., Delpuech, O., Smith, P. D., Widemann, B. C., Moertel, C. L., Largaespada, D. A., & Watson, A. L. (2021). Selumetinib normalizes Ras/MAPK signaling in clinically relevant neurofibromatosis type 1 minipig tissues in vivo. *Neuro-oncology advances*, 3(1), vdab020. <https://doi.org/10.1093/oaajnl/vdab020>

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Singkhom, N., Avihingsanon, A., **Brundage, R. C.**, **Birnbaum, A. K.**, Thammajaruk, N., Ruxrungtham, K., Bunupuradah, T., Kiertiburanakul, S., Chetchotisakd, P., Punyawudho, B., & LASA study team (2021). Pharmacogenetics-based population pharmacokinetic analysis for dose optimization of ritonavir-boosted atazanavir in Thai adult HIV-infected patients. *Expert review of clinical pharmacology*, 1–10. Advance online publication. <https://doi.org/10.1080/17512433.2022.2000858>

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Suazo, K. F., **Jeong, A.**, Ahmadi, M., Brown, C., Qu, W., **Li, L.**, & Distefano, M. D. (2021). Metabolic labeling with an alkyne probe reveals similarities and differences in the prenylomes of several brain-derived cell lines and primary cells. *Scientific reports*, 11(1), 4367. [10.1038/s41598-021-83666-3](https://doi.org/10.1038/s41598-021-83666-3)

Takahashi, T., **Jaber, M. M.**, Smith, A. R., **Jacobson, P. A.**, **Fisher, J.**, & **Kirstein, M. N.** (2021). Predictive Value of C-Reactive Protein and Albumin for Temporal Within-Individual Pharmacokinetic Variability of Voriconazole in Pediatric Hematopoietic Cell Transplant Patients. *Journal of clinical pharmacology*. [10.1002/jcph.2024](https://doi.org/10.1002/jcph.2024)

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Takahashi, T., Mohamud, M. A., Smith, A. R., Jacobson, P. A., Jaber, M. M., Alharbi, A. F., Fisher, J., & Kirstein, M. N. (2021). CYP2C19 Phenotype and Body Weight-Guided Voriconazole Initial Dose in Infants and Children after Hematopoietic Cell Transplantation. *Antimicrobial agents and chemotherapy*, 65(9), e0062321. <https://doi.org/10.1128/AAC.00623-21>

Takahashi, T., Scheibner, A., Cao, Q., Pearson, R., Sanghavi, K., Weisdorf, D. J., Brunstein, C. G., Rogosheske, J., Bachanova, V., Warlick, E. D., Wiseman, A., & Jacobson, P. A. (2021). Higher Fludarabine and Cyclophosphamide Exposures Lead to Worse Outcomes in Reduced-Intensity Conditioning Hematopoietic Cell Transplantation for Adult Hematologic Malignancy. *Transplantation and cellular therapy*, 27(9), 773.e1–773.e8. <https://doi.org/10.1016/j.jtct.2021.05.013>

Takahashi, T., Smith, A. R., Jacobson, P. A., Alharbi, A. F., Fisher, J., Rubin, N. T., & Kirstein, M. N. (2021). CYP51A1 polymorphism and voriconazole-associated hepatotoxicity in children undergoing hematopoietic cell transplant. *INTERNATIONAL JOURNAL OF CLINICAL PHARMACOLOGY AND THERAPEUTICS*, 59(6), 442-446. 10.5414/CP203920

Tamma, C. A., Clementz, B. A., Pearlson, G., Keshavan, M., Gershon, E. S., Ivleva, E. I., McDowell, J., Meda, S. A., Keedy, S., Calhoun, V. D., Lizano, P., Bishop, J. R., Hudgens-Haney, M., Alliey-Rodriguez, N., Asif, H., & Gibbons, R. (2021). Biotyping in psychosis: using multiple computational approaches with one data set. *Neuropsychopharmacology : official publication of the American College of Neuropsychopharmacology*, 46(1), 143–155. <https://doi.org/10.1038/s41386-020-00849-8>

Tieu, J. H., Sahasrabudhe, S. A., Orchard, P. J., Cloyd, J. C., & Kartha, R. V. (2021). Translational and clinical pharmacology considerations in drug repurposing for X-linked adrenoleukodystrophy-A rare peroxisomal disorder. *British journal of clinical pharmacology*. 10.1111/bcp.15090

Tuteja, S., Salloum, R. G., Elchynski, A. L., Smith, D. M., Rowe, E., Blake, K. V., Limdi, N. A., Aquilante, C. L., Bates, J., Beitelshes, A. L., Cipriani, A., Duong, B. Q., Empey, P. E., Formea, C. M., Hicks, J. K., Mroz, P., Oslin, D., Pasternak, A. L., Petry, N., Ramsey, L. B., ... IGNITE Pharmacogenetics Working Group (2022). Multisite evaluation of institutional processes and implementation determinants for pharmacogenetic testing to guide antidepressant therapy. *Clinical and translational science*, 15(2), 371–383. <https://doi.org/10.1111/cts.13154>

Walters, K., Stornetta, A., Jacobs, F., Villalta, P. W., Razzoli, M., Grant, M., Zordoky, B., Bartolomucci, A., Borgatti, A., & Balbo, S. (2021). Identification of new candidate biomarkers to support doxorubicin treatments in canine cancer patients. *BMC veterinary research*, 17(1), 378. <https://doi.org/10.1186/s12917-021-03062-x>

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Zheng, D., Bergen, P. J., Landersdorfer, C. B., & Hirsch, E. B. (2021). Differences in fosfomycin resistance mechanisms between *Pseudomonas aeruginosa* and Enterobacterales. *Antimicrobial Agents and Chemotherapy*, AAC0144621. 10.1128/AAC.01446-21

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Zhou, J., **Terluk, M. R.**, Orchard, P. J., **Cloyd, J. C.**, & **Kartha, R. V.** (2021). N-Acetylcysteine Reverses the Mitochondrial Dysfunction Induced by Very Long-Chain Fatty Acids in Murine Oligodendrocyte Model of Adrenoleukodystrophy. *Biomedicines*, 9(12), 1826. <http://dx.doi.org/10.3390/biomedicines9121826>

Zhu, X. H., Lee, B. Y., Tuite, P., **Coles, L.**, Sathe, A. G., Chen, C., **Cloyd, J.**, Low, W. C., Steer, C. J., & Chen, W. (2021). Quantitative Assessment of Occipital Metabolic and Energetic Changes in Parkinson's Patients, Using In Vivo 31P MRS-Based Metabolic Imaging at 7T. *Metabolites*, 11(3), 145. <https://doi.org/10.3390/metabo11030145>

Zylla, D. M., Eklund, J., Gilmore, G., Gavenda, A., Guggisberg, J., VazquezBenitez, G., Pawloski, P. A., Arneson, T., Richter, S., **Birnbaum, A. K.**, Dahmer, S., Tracy, M., & Dudek, A. (2021). A randomized trial of medical cannabis in patients with stage IV cancers to assess feasibility, dose requirements, impact on pain and opioid use, safety, and overall patient satisfaction. *Supportive care in cancer : official journal of the Multinational Association of Supportive Care in Cancer*, 29(12), 7471–7478. <https://doi.org/10.1007/s00520-021-06301-x>

OTHER PUBLICATIONS BY ECP FACULTY

2020 Other Publications by ECP Faculty

Birnbaum, A. (2021). Progress Toward Obtaining Seizure Freedom With New Medications in Older Adults 4th ed., vol. 21, 267-269. *EPILEPSY CURRENTS*. 10.1177/15357597211015659

Nicol, M. R., Boulware, D. R., & Rajasingham, R. (2021). Reply to Neves. 7th ed., vol. 73, e1772-e1774. *Clinical infectious diseases : an official publication of the Infectious Diseases Society of America*. 10.1093/cid/ciaa1809

Nicol, M. R., Cicali, E. J., Seo, S. K., & Rao, G. G. (2021). The Complex Roadmap to Infectious Disease Innovation: The Intersection of Bugs, Drugs, and Special Populations. 4th ed., vol. 109, 793-796. *Clinical pharmacology and therapeutics*. 10.1002/cpt.2208

TEACHING

The College of Pharmacy consistently ranks among the top three pharmacy schools in the country for the quality of its PharmD program. Faculty fill a variety of roles in the educational process, including course director, lecturer, discussant, seminar participant, and others. In addition to these classroom roles, faculty also serve as mentors and advisors to students, providing them with one-on-one training and counsel as they prepare for their careers.

In 2021, ECP faculty contributed significant, didactic education to PharmD classes. This instruction included teaching and directing the required pharmacotherapy series and the pharmaceutical care skills course sequence, as well as teaching elective courses. Instruction to pharmacy students also included experiential education in acute care, geriatric patient care, pediatric infectious disease, and clinical toxicology. The department also offers a research emphasis track for PharmD students which pairs students with an advisor(s) in the Clinical Pharmacology Research Emphasis program. In addition to coursework, students choose a research topic in experimental, translational, or clinical pharmacology for their PharmD paper project.

ECP faculty also teach graduate program classes. While these are primarily designed to support the department's own graduate students, the courses also include students in nursing, public health, geriatrics, and genetics, as well as graduate students in other College of Pharmacy programs.

TEACHING-RELATED METRICS IN ECP

- (unspecified) Students mentored by ECP faculty 9
- Undergraduate students mentored or advised by ECP faculty 2
- Graduate/Professional students mentored or advised by ECP faculty 69

Reported Student Credit Hours by Course Level

| Course level | Credit hours | # of sections |
|--------------|--------------|---------------|
| 1000 | 57 | 1 |
| 4000 | 76 | 4 |
| 5000 | 91 | 5 |
| 6000 | 3645 | 49 |
| 7000 | 5516 | 31 |
| 8000 | 183 | 27 |

SERVICE

ECP faculty discover opportunities for service both within and outside the University. The hours spent offering expertise and guidance are a way to give back to students, the community, and the field. In 2021, faculty members served on boards of directors or advisory councils of research organizations and others reviewed grant proposals and/or faculty promotion documents for institutions across the country. While much of the service performed by ECP faculty is performed on behalf of the department, college, and university in which they work, they also support their colleagues and their profession.

SERVICE-RELATED METRICS IN ECP

| | |
|---|-----|
| Service commitments to the discipline or profession | 136 |
| Service commitments to the university, college, or department | 21 |
| External and public service commitments | 30 |
| Professional memberships | 45 |
| Professional development activities | 13 |
| Licensures & certifications | 1 |
| Peer mentorship relationships | 2 |

ECP GRADUATE PROGRAM

The ECP Graduate Program provides individualized, hands-on learning experiences to those who will become tomorrow's leaders in experimental and clinical pharmacology research and teaching.

The ECP Graduate Program is an innovative, interdisciplinary program that trains students to conduct research utilizing methodology from basic and clinical pharmacology perspectives. Designed specifically for students interested in clinical research, the goal of the program is to advance the science of human pharmacology and therapeutics to improve the safe, effective, and economical use of drugs by patients. Students study such topics as experimental pharmacotherapy, drug metabolism, infectious disease, pharmacometrics, neuropharmacology/neuroscience, and pharmacogenomics. Graduates are prepared for distinguished careers in clinical research.

ECP GRADUATE PROGRAM-RELATED METRICS

| | |
|------------------------------------|----|
| ● PhD degrees completed | 37 |
| ● MS degrees completed | 6 |
| ● ECP program graduates | 5 |
| ● Students in ECP graduate program | 26 |

ECP DOCTORAL GRADUATES

| Name | Advisor | Thesis Title |
|---------------------------|---|--|
| Shen Cheng, PhD | Richard Brundage, PharmD, PhD; Mahmoud Al-Kofahi, DDS, PhD | Understanding the Impact of Pharmacogenetic Differences in Drug-Drug Interactions (DDIs): A Model-Based Approach to Predict Differences in Drug Exposure |
| Angela Jeong, PhD | Ling Li, PhD | Protein prenylation in the pathogenesis of Alzheimer's Disease and its therapeutic potential |
| Sarah Kim, PhD | Jeanine Jarnes, PhD; James Cloyd, PharmD | Improving Delivery of Therapeutics to Targeted Tissues in Lysosomal Diseases |
| David Margraf, PhD | Scott Chapman, PharmD; Mark Kirstein, PharmD | Quantitative Methods for Evidence Building in Clinical Pharmacology and Pharmaceutical Outcomes Research |

ECP MASTERS GRADUATES

| Name | Advisor | Project Title |
|--------------------|-------------------------|--|
| Joshua Mentzer, MS | R. Stephanie Huang, PhD | Using Machine Learning in High Throughput Drug Screening of In-Vitro Drug Response Data to predict In-Vivo Clinical Response for Metastatic Castration-Resistant Prostate Cancer |

FELLOWSHIPS AND AWARDS FOR GRADUATE STUDENTS

| Name | Fellowships/Awards |
|----------------------|--|
| Ibrahim Abdelgawad | Bighley Fellowship, Honorable Mention Poster Award Rho Chi Research Day College of Pharmacy, UMN |
| Charul Avachat | Student Co-investigator on Women's Health Research Program Seed Grant, Medical School, UMN |
| Jessica Barry | CTSI APReP Summer Scholar, Teaching Assistant Recognition Award 2021 |
| Morgan Bixby | Coin Fellowship |
| Shen Cheng | University of Minnesota Doctoral Dissertation Fellowship, Honorable Mention Poster Award Rho Chi Research Day College of Pharmacy, UMN |
| Yingbo Huang | Bighley Fellowship, 3M Science and Technology Fellowship |
| Xintian Lyu | CTSI APReP Summer Scholar, ICRS Braude Foundation Award, 2021 ICRS Trainee Award |
| Siddhee Sahasrabudhe | Cloyd Fellowship, Rare Disease Scholar, COGS Career Advancement Award, Riverton Community Housing Civic Leadership Award |
| Yuting Shan | Izaak M. Kolthoff Rho Chi Research Award |
| Boguang Sun | Straka Fellowship, Teaching Assistant of the Year 2021, College of Pharmacy, UMN |
| Fan Wang | New Investigator Fellowship, Conf on Retroviruses and Opportunistic Infections |
| Lusi Zhang | ECP Fellowship |
| Rui Zhong | First Place Poster Award Rho Chi Research Day College of Pharmacy, UMN |

ECP RESEARCH EMPHASIS TRACK GRADUATES

ECP also provides professional students in the PharmD program an opportunity to specialize in research by participating in the ECP Research Emphasis Track.

| Name | Advisor |
|---------------------|---------------------------------|
| Danielle Armbruster | Jacob Brown and Sarah Schweiss |
| Brooke Carlson | Pamala Jacobson |
| Patricia Maglalang | Lisa Coles and James Cloyd |
| Maryam Mohamud | Mark Kirstein |
| Jennifer Nelson | Robert Straka |
| Tam Nguyen | Pamala Jacobson and Debra Skaar |
| Rachael Pearson | Pamala Jacobson |
| Yuting Shan | R. Stephanie Huang |
| Lusi Zhang | Jeffrey Bishop |

PUBLICATIONS BY GRADUATE STUDENTS & POSTDOCS

2021 Journal Articles

Abdelgawad, I. Y., Grant MKO, Popescu, F. E., Largaespada, D. A., & **Zordoky, B. N.** (2021). Doxorubicin Paradoxically Ameliorates Tumor-Induced Inflammation in Young Mice. *International journal of molecular sciences*, 22(16). 10.3390/ijms22169023

Abdelgawad, I. Y., Sadak, K. T., Lone, D. W., **Dabour, M. S.,** Niedernhofer, L. J., & **Zordoky, B. N.** (2021). Molecular mechanisms and cardiovascular implications of cancer therapy-induced senescence. *Pharmacology & therapeutics*, 221, 107751. 10.1016/j.pharmthera.2020.107751

Al-Kofahi, M., Ahmed, M.A., **Jaber, Mutaz M.,** Tran, T.N., Willis, B.A., Zimmerman, C.L., Gonzalez-Bolanos, M.T., **Brundage, R.C.,** and Sarafoglou, K. "An integrated PK-PD model for cortisol and the 17-hydroxyprogesterone and androstenedione biomarkers in children with congenital adrenal hyperplasia". en. In: *Br J Clin Pharmacol* 87.3 (Mar. 2021), pp. 1098–1110. issn: 0306-5251, 1365- 2125. doi: 10.1111/bcp.14470. url: <https://onlinelibrary.wiley.com/doi/10.1111/bcp.14470> (visited on 05/02/2021)

Al-Rayess, H., Addo, O.Y., Palzer, E., **Jaber, Mutaz,** Fleissner, K., Hodges, J., **Brundage, R.,** Miller, B.S., and Sarafoglou, K. "Hydrocortisone Suspension Provides Similar Growth Outcomes as Hydrocortisone Tablets in Young Children With Congenital Adrenal Hyperplasia: A Cross Sectional Study". In: *Journal of the Endocrine Society* 5 (2021).

Barry, J. M., Birnbaum, A. K., Jasin, L. R., & **Sherwin, C. M.** (2021). Maternal Exposure and Neonatal Effects of Drugs of Abuse. *Journal of clinical pharmacology*, 61 Suppl 2, S142-S155. 10.1002/jcph.1928

Bishop JR, Zhang L, Lizano P. Inflammation subtyping and translating inflammation-related findings from genome-wide association studies for treatment stratification and novel therapies in psychosis. *Harvard Review of Psychiatry*, 30(1):59-70.

Che, M., Chaturvedi, A., Munro, S. A., Pitzen, S. P., **Ling, A.,** Zhang, W., **Mentzer, J.,** Ku, S. Y., Puca, L., Zhu, Y., Bergman, A. M., Severson, T. M., Forster, C., Liu, Y., Hildebrand, J., Daniel, M., Wang, T. Y., Selth, L. A., Hickey, T., Zoubeidi, A., ... Dehm, S. M. (2021). Opposing transcriptional programs of KLF5 and AR emerge during therapy for advanced prostate cancer. *Nature communications*, 12(1), 6377. <https://doi.org/10.1038/s41467-021-26612-1>

Cheng S., Bo Z., Hollenberg P.F., Osawa Y., and Zhang H., Amphipol-facilitated Elucidation of the Functional Tetrameric Complex of Full-length Cytochrome P450 CYP2B4 and NADPH-Cytochrome-P450 Oxidoreductase. *J Biol Chem*, 100645; 10.1016/j.jbc.2021.100645

Cheng S., Nethi S.K. **Al-Kofahi M.,** Prabha S. Pharmacokinetic-Pharmacodynamic (PK-PD) Modeling of Tumor Targeted Drug Delivery using Nano-engineered Mesenchymal Stem Cells (Nano-MSCs). *Pharmaceutics*, 13(1), 92; 10.3390/pharmaceutics13010092

Holzer, K., Culhane-Pera, K. A., **Straka, R. J.,** **Wen, Y. F.,** Lo, M., Lee, K., Xiong, T., Peng, K., Bishop, J., Thyagarajan, B., & Zierhut, H. A. (2021). Hmong participants' reactions to return of individual and community pharmacogenetic research results: "A positive light for our community". *Journal of community genetics*, 12(1), 53–65. <https://doi.org/10.1007/s12687-020-00475-3>

Huang, Y., Ling, A., Pareek, S., & **Huang, R. S.** (2021). Oncogene or tumor suppressor? Long noncoding RNAs role in patient's prognosis varies depending on disease type. *Translational Research*, 230, 98-110.

Jaber, M. M., Cheng, S., & Brundage, R. C. (2021). Evaluation of bias in weighted residual calculations when handling below the limit of quantification data using Beal's M3 method. *CPT: pharmacometrics & systems pharmacology*, 10(4), 275-278. 10.1002/psp4.12616

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Jeong A, Cheng S, Zhong R, Bennett DA, Bergö MO, Li L. Protein farnesylation is upregulated in Alzheimer's human brains and neuron-specific suppression of farnesyltransferase mitigates pathogenic processes in Alzheimer's model mice. 2021. Biorxiv. <https://www.biorxiv.org/content/10.1101/2021.05.19.444846v2>

Li, Y-X; Wei, Y; Zhong, R; Li, Ling; Pang, H-B. Transportan Peptide Stimulates the Nanomaterial Internalization into Mammalian Cells in the Bystander Manner through Macropinocytosis. *Pharmaceutics* 2021, 13(4), 552. <https://doi.org/10.3390/pharmaceutics13040552>

Okoef G, Weisdorf DJ, Wagner EJ, Blazar BR, MacMillan ML, DeFor T, Lazaryan A, Jurdi NE, Holtan SG, Brunstein CG, Betts BC, Takahashi T, Bachanova V, Warlick ED, Rashidi A, Arora M, Outcomes of chronic graft-versus-host disease following matched sibling donor versus umbilical cord blood transplant, *Bone Marrow Transplant*, 2021 Jan. PMID: 33420387. DOI: 10.1038/s41409-020-01195-5

Salian, V. S., Wright, J. A., Vedell, P. T., Nair, S., Li, C., Kandimalla, M., Tang, X., Carmona Porquera, E. M., Kalari, K. R., & Kandimalla, K. K. (2021). COVID-19 Transmission, Current Treatment, and Future Therapeutic Strategies. *Molecular pharmaceutics*, 18(3), 754–771. <https://doi.org/10.1021/acs.molpharmaceut.0c00608>

Sahasrabudhe SA, Kartha RV, Ng M, Orchard PJ, Cloyd JC, Brundage RC, Coles LD, Population Pharmacokinetic Analysis of N-acetylcysteine in Pediatric Patients with Inherited Metabolic Disorders Undergoing Hematopoietic Stem Cell Transplant 2021 Jul 18. doi: 10.1002/jcph.1943. Epub ahead of print. PMID: 34275158.

Shan Y, Huang Y, Lee AM, Mentzer J, Ling A, Huang RS. A Long Noncoding RNA, GAS5 Can Be a Biomarker for Docetaxel Response in Castration Resistant Prostate Cancer. *Front Oncol*. 2021;11:675215. Published 2021 May 21. doi:10.3389/fonc.2021.675215

Suazo, K. F., Jeong, A., Ahmadi, M., Brown, C., Qu, W., Li, L., & Distefano, M. D. (2021). Metabolic labeling with an alkyne probe reveals similarities and differences in the prenylomes of several brain-derived cell lines and primary cells. *Scientific reports*, 11(1), 4367. 10.1038/s41598-021-83666-3

Takahashi T, Arora M, Okoef G, DeFor TE, Weisdorf DJ, MacMillan ML, Late-onset Acute and Chronic Graft-Versus-Host Disease in Children: Clinical features and Response to Therapy, *Transplantation and Cellular Therapy*, 2021 May. PMID: 34077812. DOI: 10.1016/j.jtct.2021.05.022

Takahashi T, Illamola SM, Jennissen CA, Long SE, Lung TC, Orchard PJ, Gupta AO, Long-Boyle JR, Busulfan dose recommendation in inherited metabolic disorders: Population pharmacokinetic analysis, *Transplantation and Cellular Therapy*, 2021 December. DOI: <https://doi.org/10.1016/j.jtct.2021.11.018>

Takahashi T, Jaber, M. M., Smith, A. R., Jacobson, P. A., Fisher, J., & Kirstein, M. N. (2021). Predictive Value of C-Reactive Protein and Albumin for Temporal Within-Individual Pharmacokinetic Variability of Voriconazole in Pediatric Hematopoietic Cell Transplant Patients. *Journal of clinical pharmacology*. 10.1002/jcph.2024

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Takahashi T, Smith AR, Jacobson PA, Alharbi AF, Fisher J, Rubin NT, Kirstein MN, CYP51A1 polymorphism and voriconazole-associated hepatotoxicity in children undergoing hematopoietic cell transplant, *International Journal of Clinical Pharmacology and Therapeutics*, 2021 Feb. PMID: 33560212. DOI: 10.5414/CP203920

Takahashi T, Turcotte LM, Gordon PM, Johnson AD, Rubin N, Spector LG, Therapeutic Leukapheresis in Pediatric Leukemia: Utilization Trend and Early Outcomes in a US Nationwide Cohort, *Journal of Pediatric Hematology/Oncology*, 2021 May. PMID: 33735152. DOI: 10.1097/MPH.0000000000002140

Tieu, J. H., **Sahasrabudhe, S. A.**, Orchard, P. J., **Cloyd, J. C.**, & **Kartha, R. V.** (2021). Translational and clinical pharmacology considerations in drug repurposing for X-linked adrenoleukodystrophy-A rare peroxisomal disorder. *British journal of clinical pharmacology*. 10.1111/bcp.15090

Zhang L, Hill SK, Guo B, Wu B, Alliey-Rodriguez N, Eum S, Lizano P, Ivleva EI, Reilly JL, Keefe RSE, Keedy SK, Tamminga CA, Pearlson GD, Clementz BA, Keshavan MS, Gershon ES, Sweeney JA, **Bishop JR**. Polygenic risk for coronary artery disease, cardiovascular medication burden and cognitive performance in psychotic disorders. *Progress in Neuro-Psychopharmacology and Biological Psychiatry* (2021): 110464

PRESENTATIONS BY GRADUATE STUDENTS & POSTDOCS

2021 Abstracts, Posters, and Presentations

Abdelgawad IY, Biesdorf C, and Nader AM. Evaluation of CYP3A Maturation Functions Using Population Pharmacokinetics and Physiologically-Based Pharmacokinetic Modeling to Inform Dose Selection of CYP3A Substrates in Pediatrics. Presented in ASCPT 2021 virtual annual meeting. March 12, 2021.

Abdelgawad IY, **Grant MKO**, and **Zordoky BN**. Metformin Modulates Doxorubicin-induced Senescence Phenotype in Endothelial Cells. Presented at Experimental Biology 2021 virtual conference. April 27, 2021.

Abdelgawad IY, **Grant MKO**, and **Zordoky BN**. Metformin modulates doxorubicin-induced senescence phenotype in endothelial cells. Presented at American Aging Association (AGE) annual meeting, Madison, Wisconsin. July 21, 2021.

Bishop JR, **Zhang L**, Guo B, Xu Y, Rubin LH, Alliey-Rodriguez N, Keedy SK, Wu B, Tamminga CA, Pearlson GD, Clementz BA, Keshavan MS, Gershon ES, Sweeney JA, Lizano P. Polygenic risk for cardiometabolic disorders and peripheral inflammation in psychosis. Presented at 2021 Society of Biological Psychiatry (SOBP) Annual Meeting. Poster/Abstract

Grant MKO, **Abdelgawad IY**, and **Zordoky BN**. Induction of multiple senescence markers by tumor inoculation in young C57BL/6 mice. Presented at American Aging Association (AGE) annual meeting, Madison, Wisconsin. July 21, 2021.

Huang, Yingbo; Feng, L; Weijie, Z; **Yuting, S**; Lee, C; Barbara.E, S; **Huang, R.Stephanie**. Sex differences in the expression and genetic regulation of drug metabolism and transporter genes in human liver. *American Society of Human Genetics Annual Meeting*, 2021.

Huang, Yingbo; Feng, L; Weijie, Z; **Yuting, S**; Lee, C; Barbara.E, S; **Huang, R.Stephanie**. Sex differences in the expression and genetic regulation of drug metabolism and transporter genes in human liver. *Pharmacogenomics Global Research Network Annual Meeting*, 2021.

Li, Chenxu "Effects of Anti-A β Antibody on A β Peptide Trafficking at the Blood-Brain Barrier" at the 2021 AAPS PharmSci 360 Conference in Philadelphia

Lyu, X, **Illamola, S**, **Dahmer, S**, Lehfeldt, P, **Leppik, IE**, **Birnbaum, AK**. Dosage and formulations received by patients within a US state cannabis program. International Cannabinoid Research Society (ICRS).

Lyu X, **Remmel RP**, Turesky R, **Illamola SM**, **Stensgard S**, **Birnbaum AK**, **Leppik, IE**. Simultaneous Quantification of Parent and Metabolite Cannabinoids in Human Plasma. Advanced Pathways to Research Program Clinical and Translational Science Institute (CTSI).

Sun, B. et al. Assessment of warfarin management and outcomes in Minnesota Hmong versus East Asians within an integrated Healthcare System. 2021 ACCP Annual Meeting: October 26-29, 2021. Presented at: ACCP Annual Virtual Scientific Poster Session

Varughese LA, **Zhang L**, Lee YM, Ho T, Brown JT, Lee JC. 2021 Accomplishments and Future Perspectives of the ACCP Pharmacokinetics/Pharmacodynamics/Pharmacogenomics Practice and Research Network (PRN). Presented at American College of Clinical Pharmacy (ACCP) 2021 Annual Meeting. Poster/Abstract.

Wang F, **Karanam A**, **Al-Kofahi M**, **Collins L**, **Fisher J**, Boulware DR, **Birnbaum KA**, **Jacobson PA**, Rajasingham R, **Nicol MR**. A clinical and in silico analysis of the exposure response relationship between hydroxychloroquine and SARS-CoV-2 prevention. 2021 annual meeting of the American Society of Clinical Pharmacology & Therapeutics (ASCPT), Feb 8-19, 2021, Online.

Zhong, Rui, Dustin Chernick, David Hottman, **Ling Li**. "The HDL Mimetic Peptide 4F Attenuates Neuropathology and Cognitive Deficits in a Transgenic Mouse Model of Alzheimer's Disease". March 9-14, 2021. International Conference on Alzheimer's and Parkinson's Diseases (AD/PDTM). Virtual conference.

ECP RESEARCH SEMINAR (ECP 8100)

Both graduate students and postdoctoral associates present at the weekly research seminar.

| Date - Spring 2021 | Title | Presenter |
|--------------------|--|---|
| January 27 | Pharmacokinetics of levetiracetam in women of childbearing age | Charul Avachat, ECP Graduate student, Dr. Angela Birnbaum's Lab |
| February 3 | Leveraging Two-Hit Mouse Models to Understand the Mechanisms of Latent Doxorubicin Cardiotoxicity | Beshay Zordoky, MSc, PhD, Assistant Professor ECP |
| February 17 | Adeno-associated virus as a gene therapy for opioid use disorder | Cecilia Barajas, ECP Graduate student, Dr. Carolyn Fairbanks Lab |
| February 24 | Predicting cancer drug sensitivity and resistance in multiple myeloma | Brian Van Ness, PhD, Adjunct Professor ECP |
| March 17 | Opioid-dependency: Treatment options for mothers and their neonates | Jessica Barry, ECP Graduate student, Dr. Angela Birnbaum's Lab |
| March 24 | Application of deep neural networks in pharmacokinetic analyses | Mu'taz Jaber, ECP Graduate student, Dr. Richard Brundage's Lab |
| March 31 | Patient Use of Medical Cannabis | Xintian Lyu, ECP Graduate student, Dr. Angela Birnbaum's Lab |
| April 14 | Differences in predicted warfarin dosing requirements between Hmong and East Asians using genotype-based dosing algorithms | Boguang Sun, ECP Graduate student, Dr. Robert Straka's Lab |
| April 21 | Is there an ultrarapid CYP3A metabolism phenotype? Using tacrolimus genomics as a probe for discovery | Abdelrahman Saqr, ECP Graduate student, Dr. Pamala Jacobson's Lab |
| April 28 | An Introduction to Clinical Trial Simulation, with a Case Study in Vaccine Development | Jason Chittenden, PhD, Adjunct Assistant Professor ECP |
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| Date - Fall 2021 | Title | Presenter |
|---------------------|--|--|
| September 15 | Lab Safety Presentation | DEHS: Nancy Rolstad, Jodi Ogilvie, Rebecca Cuellar |
| September 22 | Towards precision medicine in stem cell transplantation: Pharmacogenomics-pharmacokinetics- pharmacodynamic analysis of a conditioning regimen | Takuto Takahashi, Graduate student ECP |
| September 29 | Integrating Big Data into Drug Discovery | R.Stephanie Huang, PhD, AssociateProfessor |
| October 6 | Developing a Pharmacogenomics Enterprise at the University of Minnesota | Pamala Jacobson, PharmD, FCCP, Distinguished Professor |
| October 13 | Dietary Supplement Use in Lysosomal Storage Diseases and Neuropsychiatry | Jaehyeok Roh, PharmD, Post-Doctoral Associate |
| October 20 | Lamotrigine Pharmacokinetics During Pregnancy, Postpartum, and Breastfeeding | Angela Birnbaum, PhD, FAES, Professor ECP, Director of Graduate Studies |
| November 3 | Real-world G-CSF Utilization: The Biologics and Biosimilars Collective Intelligence Consortium (BBCIC) Experience | Pamala Pawloski, PharmD, Research Investigator, HealthPartners Institute |
| November 10 | Beyond the drug-gene pair: polygenic approaches to study disease genetic risks and drug relationships with cognition in psychotic disorders | Lusi Zhang, ECP graduate student |
| November 17 | Pioneering Prescription Digital Therapeutics in Pharmaceutical Care | Denise Wolff, PharmD, Executive Director at Pear Therapeutics |
| November 24 | Investigating the contributions of residual unexplained variability components in nonlinear mixed-effect approach | Mu'taz Jaber, ECP graduate student |
| December 1 | Development of a novel preclinical model that captures tumor heterogeneity for successful drug screening in Prostate Cancer | Sampreeti Jena, PhD, Post-Doctoral Associate |