The Institute for Advanced Medical Research at Mercer University: Translational and Clinical Research Opportunities for Students

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INTRODUCTION

The Mercer University College of Pharmacy has partnered with the Institute for Advanced Medical Research, a privately-held clinical research organization, to provide translational and clinical research opportunities to PharmD and other healthcare students. The Institute for Advanced Medical Research at Mercer University (IAMR-MU) conducts phase II-IV clinical trials at the College of Pharmacy's Center for Clinical Research, located on the Atlanta campus.

Through this collaboration, PharmD students engage in patient care and clinical research studies in a variety of CNS-centric disease states including depression, anxiety, migraine headaches, insomnia, binge eating disorder, ADHD, as well as civilian and veteran PTSD.

Herein, we describe the different research opportunities that are available to students, examples of the projects on which they work on, as well as student expectations, during the first 12-months of the partnership.

RESULTS

Examples of Pharm.D. Student Projects

Project Title	Sponsor
A Phase 3b Efficacy and Safety Study of Adjunctive ALKS 5461 in Treatment Refractory Major Depressive Disorder.	Alkermes
A 12-week, Randomized, Double-blind, Parallel-group, Placebo-controlled, Fixed-dosed, Multicenter Study to Evaluate the Efficacy, Safety, and Tolerability of Dasotraline in Adults with Moderate to Severe Binge Eating Disorder.	Sunovion Pharmaceuticals
A Phase 3, Double-blind, Randomized, Multicenter, Placebo-controlled, study to Evaluate the Efficacy and Safety of TNX-102 SL Taken Daily at Bedtime in Patients with Military-related PTSD.	Tonix Pharmaceuticals
A Phase 2, Multicenter, Randomized, Double-blind, Placebo- and Active-controlled Trial of Brexpiprazole (1-3mg/day) as Monotherapy or as Combination Therapy in the Treatment of Adults with Post-traumatic Stress Disorder.	Otsuka Pharmaceuticals
A Randomized, Double-blind, Placebo-controlled, Multicenter Study of Rapastinel as Adjunctive Therapy in Major Depressive Disorder.	Naurex
A Phase 2/3 Multicenter, Randomized, Double-blind, Placebo-controlled, Parallel-group Study to Evaluate the Efficacy, Safety, and Tolerability of Multiple Dosing Regimens of Oral AGN-241689 in Episodic Migraine Prevention.	Allergan Pharmaceuticals
A Randomized, Double-blind, Active-controlled Trial to Assess the Efficacy and Safety of AXS-05 Administered Orally to Subjects with Treatment Resistant Major Depressive Disorder.	Axsome Therapeutics

Examples of Required Syllabus Activities for P4 APPE Rotations

Students are provided human ethics training, International Air Transport Association Training, and Good Clinical Practice Training.
Students are assigned a clinical and a scientific project that must be completed prior to the completion of the APPE.
Based on chart review, observation, and clinical interviews: 1) Develop a medication and treatment outcome review history of assigned patients; 2) Differentiate between Major Depressive Disorder and Generalized Anxiety Disorder; 3) Differentiate between cognitive symptoms of ADHD vs GAD vs MDD; 4) Determine treatment outcomes and differentiate between treatment resistant and intolerant patients as well as adequate dose and/or duration versus inadequate dose and/or duration patients.
For each investigational product (IP) under study at the clinic, explain: 1) The MOA; 2) The most common predicted ADE and most common ADE in the Informed Consent Document (ICD); 3) The incidence of these versus placebo; and develop your own version of the ADE section of the ICD and how best to present ADEs for each IP to study volunteers.
For each IP, prepare an ADME overview and explain the PK profile, including $t_{1/2}$, T_{max}, and C_{max}. Explain how each IP is cleared from the body, including organs, enzyme systems, and predicted drug-interactions.
What are most common drug interactions with each IP. Describe the basis of excluded study medications related to drug-drug interactions, CNS effects, organ effects, diagnostic and ratings interference.
Design a trial and describe the clinical and/or scientific rationale that you would perform to assist with developing a better understanding of the IP.
Perform a mock Informed Consent discussion with a staff member.

IAMR-MU Pharm.D. Student Research Opportunities

Opportunity	# of Students (2017-2018)	Structure
Fall/Spring Semester Elective	12	16 weeks; 2 cr hr
P4 APPE	14	5 weeks; 5 cr hr
Shadowing/Volunteering	4	16 weeks; No course credit
Summer Research Program	New for 2018-2019	

CONCLUSIONS

The IAMR-MU affords students the opportunity to be integrated into a clinical research team to conduct Phase II-IV human studies on investigational agents. Through this experience, students gain unique insight into pharmaceutical industry, sponsored research, Contract Research Organizations (CRO), and regulatory affairs. Overall, it is anticipated that the collaboration would enhance student respect for, and engagement in, clinical and translational research and provide insight into career opportunities in clinical research within the pharmaceutical and biotechnology industries, regulatory agencies, as well as CROs.