

PHA5012: Clinical Applications of Personalized Medicine

Spring 2023

2 Credit Hours – [A-E Grading]

Personalized medicine involves the use of an individual's genetic profile to guide decisions about the prevention, diagnosis, and treatment of disease. This course will focus on how pharmacogenomic and genomic data can be used in patient care to provide students with the knowledge and skills to use a personalized medicine approach in their future clinical practice. Students can opt to participate in personal genotyping and use their own genetic data for class assignments or work with a de-identified genotype dataset. This course will use a combination of lectures, patient cases, assignments, and case-based discussions of clinical pharmacogenetic guidelines and primary literature

Teaching Partnership Leaders

Julio Duarte, Pharm.D., Ph.D.

- Email: juliod@cop.ufl.edu
- Office: PG-21
- Phone: 352 – 273 - 8132

Office Hours: See Canvas

See Appendix A. for Course Directory of Faculty and Staff Contact Information.

Entrustable Professional Activities

This course will prepare you to perform the following activities which the public entrusts a Pharmacist to perform:

- Collect information to identify a patient's medication-related problems and health-related needs.
- Analyze information to determine the effects of medication therapy, identify medication-related problems, and prioritize health-related needs.
- Establish patient-centered goals and create a care plan for a patient in collaboration with the patient, caregiver(s), and other health professionals that is evidence-based and cost-effective.
- Follow-up and monitor a care plan.
- Identify patients at risk for prevalent diseases in a population.
- Minimize adverse drug events and medication errors.
- Maximize the appropriate use of medications in a population.
- Use evidence-based information to advance patient care.

Course-Level Objectives

Upon completion of this course, the student will be able to:

1. Explain potential risks and benefits of pharmacogenetic testing.
2. Interpret and apply evidence for clinical pharmacogenetics and genomic medicine to patient care.
3. Apply genetic information to patient cases for clinically actionable gene-drug pairs.
4. Demonstrate best practices for returning pharmacogenetic test results to patients, including legal and ethical concerns and communication strategies.
5. Apply family history and pedigree information to clinical decision-making and disease risk prediction.
6. Apply theoretical genetic information to clinical decision-making and disease risk prediction for the following types of diseases:
 - Complex Diseases: Cardiovascular Disease Risk
 - Somatic Genomics: Genomic Medicine in Breast Cancer
7. Demonstrate the contributions and roles of other health care professionals in the clinical application of pharmacogenetic information to patient care.
8. Summarize challenges and opportunities in integrating pharmacogenetic data into the clinical process of patient care, including informatics and clinical laboratory considerations.

Course Pre-requisites

1. Completion of all Year 1 Pharm.D. program coursework including milestones
2. Satisfactory completion of blocks 5 through 11

Course Co-requisites

1. Completion of all Year 2 Pharm.D. program coursework including milestones.
2. Satisfactory completion of blocks 5 through 11

Course Outline

See Appendix. Please routinely check your campus calendar and the Canvas course site for any messages about changes in the schedule including meeting dates/times, deadlines, and room changes.

Required Textbooks/Readings

Arwood MJ, Chumnumwat S, Cavallari LH, Nutescu EA, Duarte JD. Implementing pharmacogenomics at your institution: establishment and overcoming implementation challenges. Clin Tranl Sci (2016) 00, 1-14. Available via Canvas.

Use [UF VPN to access UF Libraries Resources](#) when off-campus.

The UF HSC library staff can assist you with questions or issues related to accessing online library materials. For assistance contact your College of Pharmacy librarian or visit the [HSC Library Website](#) at this URL: <http://www.library.health.ufl.edu/>

Suggested Textbooks/Readings

N/A. Suggested readings will be posted on Canvas.

Other Required Learning Resources

N/A

Materials & Supplies Fees

N/A

Student Evaluation & Grading

Evaluation Methods and How Grades are calculated.

[The Canvas® gradebook will be set-up using the percentages below to compute the grade.]

Table 1.1 Evaluation and Grading Above

Assessment Item	Grade Percentage
Genomic Medicine Application Assignment (Module 3)	7.5%
Pain Management Application Assignment (Module 6)	7.5%
iRAT (4 @ 5% each)	20%
Case Worksheets (4 @ 7.5% each)	30%
Final Exam	35%
Total	100%

Table 1.2 grading scale

Percentage	Letter Grade
92.50-100%	A
89.50-92.49%	A-
86.50-89.49%	B+
82.50-86.49%	B
79.50-82.49%	B-
76.50-79.49%	C+
72.50-76.49%	C
69.50-72.49%	C-
66.50-69.49%	D+
62.50-66.49%	D
59.50-62.49%	D-
< 59.50%	E

Rounding of grades:

Final grades in Canvas will be rounded to the 2nd decimal place. If the decimal is X.495 or higher, Canvas will round the grade to X.50. The above scale depicts this policy and grades are determined accordingly. Grade assignment is made using this policy and NO EXCEPTIONS will be made in situations where a student's grade is "close."

Description of Assignments

Application Assignments

Application assignments will be completed in Canvas and have no time limit for completion (as long as completed before the assigned deadline). These assignments are designed for students to apply the knowledge acquired after completion of the corresponding module as well as individually research additional information regarding the topic.

Pre-ALS Worksheets

Pre-ALS worksheets will be uploaded to Canvas and include the case(s) to be discussed during the corresponding ALS. ***These worksheets are due at the beginning of the ALS.*** The questions prompt students to review the case(s) and answer questions related to the case that will assist in analysis of the clinical and biological topics to be discussed in the ALS.

Educational Technology Use

The following technology below will be used during the course and the student must have the appropriate technology and software.

1. ExamSoft™ Testing Platform
2. Canvas™ Learning Management System

For technical support, navigate to [Educational Technology and IT Support Contact Information](http://curriculum.pharmacy.ufl.edu/current-students/technical-help/) at this URL: <http://curriculum.pharmacy.ufl.edu/current-students/technical-help/>

Pharm.D. Course Policies

The Policies in the following link apply to this course. Review the General [Pharm.D. Course Policies](http://curriculum.pharmacy.ufl.edu/current-students/course-policies/) carefully, at this URL: <http://curriculum.pharmacy.ufl.edu/current-students/course-policies/>

Makeup Assignments

Makeup assignments may be required for excused absences from all Active Learning Sessions. Students will be required to complete the makeup assignment within one week of the missed session.

Late Assignments

All quizzes and assignment submissions will be completed in Canvas. Quizzes may include questions on any materials covered since the previous active learning session. Case questions for ALS are also due in Canvas before the session begins. Technology such as Lock-down browser and Turn-it-in may be used to encourage the individual completion of these materials.

All course materials are due by the deadlines posted in Canvas and the course outline. Late submissions will be accepted in Canvas (with a 50% grade reduction) **up to 2 days after the deadline**. Once the submission link closes in Canvas, submissions will no longer be accepted.

Respect for Diversity

The University of Florida College of Pharmacy strives to stimulate a culture that promotes diversity and inclusion within an exceptional community of students, faculty, and staff. We intend that students from all diverse backgrounds and perspectives be well served by this course/rotation, that students' learning needs be addressed both in and out of course/rotation, and that the diversity that students bring to this course/rotation be viewed as a resource, strength, and benefit.

We intend to present materials and activities respectful of diversity: gender, sexuality, disability, age, socioeconomic status, ethnicity, race, and culture. Your suggestions are encouraged and appreciated. Please let us know ways to improve the course/rotation effectiveness for you personally or for other students or student groups.

Regarding special consideration for any religious events, please review the standard UF COP process as detailed in the [UF COP Course policies](#) for classroom requests. For experiential requests, please review the [Experiential Time and Attendance Policy](#).

If you feel that you have experienced or witnessed any bias/treatment that falls short of these expectations, you may submit a report through either the UF COP [Student Mistreatment Report](#) (for classroom concerns) or the [Experiential Confidential Form](#) (for rotation concerns).

Course Evaluation Process

Students are expected to provide professional and respectful feedback on the quality of instruction in this course by completing course evaluations online via GatorEvals. Guidance on how to give feedback in a professional and respectful manner is available at <https://gatorevals.aa.ufl.edu/students/>. Students will be notified when the evaluation period opens, and can complete evaluations through the email they receive from GatorEvals, in their Canvas course menu under GatorEvals, or via <https://ufl.bluer.com/ufl/>. Summaries of course evaluation results are available to students at <https://gatorevals.aa.ufl.edu/public-results/>.

Appendix A. Course Directory

Teaching Partnership Leader/Course Director(s):

Julio Duarte, Pharm.D., Ph.D.

- Email: juliod@cop.ufl.edu
- Office: PG-21
- Phone: 352 – 273 - 8132

Office Hours: Please see the Canvas course site for posted office hours

Questions to Ask:

- Concerns about performance
- Guidance when there are performance problems (failing grades)
- General questions about content

Other Teaching Partnership Faculty Members:

Larisa Cavallari, Pharm.D., BCPS, FCCP

- Email: lcavallari@cop.ufl.edu
- Office: GNV
- Phone: 352 – 273 - 8245

Emily Cicali, Pharm.D

- Email: Emily.cicali@cop.ufl.edu
- Office: GNV
- Phone: 352 – 273 – 7919

Eda Eken, PharmD

- Email: edaeken@ufl.edu
- Phone: 352 – 284 - 6595

Brian Gawronski, Pharm.D.

- Email: briangaw@ufl.edu

Christelle Lteif, Pharm.D

- Email: christelle.lteif@ufl.edu

Caitrin McDonough, Ph.D., M.S.

- Email: cmcdonough@cop.ufl.edu
- Office: GNV
- Phone: 352 – 273 – 6435

Khoa Nguyen, Pharm.D.

- Email: khoanguyen@cop.ufl.edu
- Office: GNV
- Phone: 352 – 273 - 9418

Nathan Seligson, Pharm.D.

- Email: nseligson@cop.ufl.edu
- Office: JAX
- Phone: 904 – 244 - 9590

Cameron Thomas, Pharm.D

- Email: cameronthomas@ufl.edu

Instructional Designer:

Skylar Johnson, M.A.

- Email: skylarjohnson@cop.ufl.edu
- Office: HPNP 4309
- Phone: 352 – 273 - 5719

Academic Coordinator Gainesville Campus:

Hanna Stallard

- Email: hstallard@ufl.edu
- Office: HPNP 4309
- Phone: (352) – 273 - 6312

[2PD Absence/Tardy Ticket](#)

[3PD Absence/Tardy Ticket](#)

Educational Coordinators

Katie Orben

Email: korben06@ufl.edu

Office: Jacksonville Campus

Andrea M Arredondo

Email: aarredondo1@cop.ufl.edu

Office: Orlando Campus

Phone: (407) 313 - 4087

Questions to Ask:

- Issues related to course policies (absences, make up exams, missed attendance)
- Absence/tardy requests (Only the Academic Coordinator handles absence requests)
- Questions about dates, deadlines, meeting place
- Availability of handouts and other course materials

- Assignment directions
- Questions about grade entries in gradebook (missing grades, incorrect grade)
- Assistance with ExamSoft® (Distance campus students may contact the Educational Coordinator for use of Exemplify and assistance during exams. The Academic Coordinator is the contact person for issues related to grading and posting of ExamSoft grades.)

Appendix B: Course Outline

Date / Time [Recommended for Independent Study]	Mod#	Activity	Activity Title	Objectives	Contact Time (hr)	Responsible
04/26/23	1	Module	Module 1: PGx review and Bioethics			Julio Duarte
04/26/23	1.1	Lecture Video	Watch: Course Introduction		0.25	Julio Duarte
04/26/23	1.2	Lecture Video	Watch: Understanding and Applying Your Genotype Results	2, 6	0.75	Caitrin McDonough
04/27/23	2	Module	Module 2: Evidence Evaluation			Julio Duarte
04/27/23	2.1	Lecture Video	Watch: Evidence Evaluation in Clinical Pharmacogenetics	2, 4	1	Julio Duarte
04/27/23	2.2	Lecture Video	Watch: Drug-Drug-Gene Interactions/Phenoconversion	1, 3-4	0.5	Emily Cicali
4/27/23 @ 12pm-1:50pm	1	Active Learning Session	Active Learning Session 1: Evidence Evaluation Activity	1-4, 6	2	Christelle Lteif, Julio Duarte
04/27/23	1	Quiz (In Class)	In-class Quiz 1			Julio Duarte
04/27/23 at 12pm	1	Assignment (Graded)	Case Worksheet DUE at class start		0.75	
04/28/23	3	Module	Module 3: Population Genetics, Genomic Medicine, and Testing			Caitrin McDonough
04/28/23	3.1	Lecture Video	Watch: Clinical Relevance of Population Genetics/Ancestry	2, 5-6	0.5	Caitrin McDonough
04/28/23	3.2	Lecture Video	Watch: Monogenic and Complex Disease Genomic Medicine	6	0.75	Caitrin McDonough
04/28/23	3.3	Lecture Video	Watch: Consumer-Based Genetic Testing	3-4	0.5	Cameron Thomas
04/28/23	3.4	Lecture Video	Watch: Clinical Laboratory Testing	3-4	0.5	Julio Duarte
05/01/23 at 11:59pm	1-2	Assignment (Graded)	Assess: Genomic Medicine Assignment	2, 5-7	1	Julio Duarte
05/01/23	4	Module	Module 4: Cardiology			Larisa Cavallari
05/01/23	4.1	Lecture Video	Watch: Cardiology: CYP2C19-clopidogrel	1-3, 7-8	1	Larisa Cavallari
05/01/23	4.2	Lecture Video	Watch: Cardiology: CYP2C9/VKORC1-warfarin; SLCO1B1-simvastatin	1-3, 7-9	0.5	Julio Duarte
5/2/23 @ 12pm-1:50pm	1-3	Active Learning Session	Active Learning Session 2: Cardiology Pharmacogenetics	1-4, 6	2	Cameron Thomas, Julio Duarte

Date / Time [Recommended for Independent Study]	Mod#	Activity	Activity Title	Objectives	Contact Time (hr)	Responsible
05/02/23	1-3	Quiz (In Class)	In-class Quiz 2			Julio Duarte
05/02/23 at 12pm	1	Assignment (Graded)	Case Worksheet DUE at class start		0.75	
05/02/23	5	Module	Module 5: Adverse Drug Reactions			Julio Duarte
05/02/23	5.1	Lecture Video	Watch: Adverse Drug Reactions/Hypersensitivity: abacavir, allopurinol, carbamazepine, phenytoin	1-3, 7-8	0.5	Julio Duarte
05/03/23	6	Module	Module 6: Pain Management			Emily Cicali
05/03/23	6.1	Lecture Video	Watch: Pain Management: CYP2D6-opiates; CYP2C9- NSAIDs	1-3, 7-8	1	Emily Cicali
05/03/23 at 11:59pm	6	Assignment (Graded)	Assess: Pain Management Assignment	1-3, 7-8	1	Julio Duarte
05/04/23	7	Module	Module 7: Oncology			Nathan Seligson
05/04/23	7.1	Lecture Video	Watch: Introduction to Cancer Biology	2,3,6	0.5	Nathan Seligson
05/04/23	7.2	Lecture Video	Watch: Germline and Somatic Genomic Testing in Cancer	1-3, 5-8	1	Nathan Seligson
05/04/23	7.3	Lecture Video	Watch: Tissue Agnostic Therapy	3,5,6	0.25	Nathan Seligson
05/04/23	7.4	Lecture Video	Watch: Molecular Tumor Boards	6-8	0.25	Nathan Seligson
5/5/23 @ 12pm- 1:50pm	1-7	Active Learning Session	Active Learning Session 3: Oncology Pharmacogenetics	1-3, 6-8	2	Nathan Seligson
05/05/23	1-7	Quiz (In Class)	In-class Quiz 3			
5/05/23 at 12pm		Assignment (Graded)	Case Worksheet DUE at class start		0.75	
05/05/23	8	Module	Module 8: Gastroenterology and Transplant			Emily Cicali
05/05/23	8.1	Lecture Video	Watch: Gastroenterology: TPMT-thiopurines; CYP2C19- PPIs; CYP2D6- ondansetron	1-3, 7-8	0.5	Emily Cicali
05/05/23	8.2	Lecture Video	Transplant: CYP3A5- tacrolimus; CYP2C19- voriconazole;	1-3, 7-8	0.5	Christelle Lteif
05/08/23	9	Module	Module 9: Psychiatry			Emily Cicali
05/08/23	9.2	Lecture Video	Watch: Psychiatry: CYP2D6/CYP2C19-TCAs and SSRIs	1-3, 7-8	1	Hana Al Alshaykh

Date / Time [Recommended for Independent Study]	Mod#	Activity	Activity Title	Objectives	Contact Time (hr)	Responsible
5/9/23 @ 12pm- 1:50pm	1-9	Active Learning Session	Active Learning Session 4: Psychiatry Pharmacogenetics	1-4, 7-8	2	Eda Eken, Emily Cicali
05/09/23	1-9	Quiz (In Class)	In-class Quiz 4			Emily Cicali
05/09/23 at 12pm		Assignment (Graded)	Case Worksheet DUE at class start		0.75	
05/09/23	10	Module	Module 10: Clinical Informatics in Pharmacogenetics			Julio Duarte
05/09/23	10.1	Lecture Video	Clinical Informatics in Pharmacogenetics	1-4, 8	0.5	Khoa Nguyen
05/09/23	10.1	Lecture Video	Beyond the CPIC Guidelines: Emerging Gene-Drug Pairs and Clinical Implementation	8	0.5	Brian Gawronski
05/09/23	10.1	Reading	Implementing pharmacogenomics at your institution: establishment and overcoming implementation challenges	4, 7-8	2	Julio Duarte
5/11/23 @ 9am- 11am	1-11	Exam	Final Exam	All		Julio Duarte
			Contact Hours		28	

Appendix C: Rubric for Assessing Active Learning Session Cases and Assignments

Grade Determination (each question is worth a total of 6 points):

Proficiency Level	Accomplished(2 Points)	Meets Expectations(1 Point)	Deficits Exist(0 Points)
Quality of Information	Interprets information in accurate and highly insightful ways. Cites data sources and explains how these references extend and refine insights.	Information is summarized and not a reiteration of information provided by the instructor or in readings. References are sometimes made. Interpretation of information are mostly precise and clear.	Responses are descriptive: a reiteration of what was presented by instructor or read. Serious misinterpretations or no interpretation of the information is evident.
Organization	Information is very well organized with well-organized complete sentences and paragraph form.	Information is logically organized and most sentences/paragraphs are well organized.	Information is disorganized.
Mechanics	No grammatical, spelling or punctuation errors.	1-2 grammatical, spelling or punctuation errors.	Three or more grammatical, spelling or punctuation errors.