

PHA5040

Pharmacogenomic Literature Assessment

Fall 2023

1 Credit Hour – [Satisfactory/Unsatisfactory]

Students will further develop the knowledge and skills necessary to appraise peer-reviewed pharmacogenomic literature. This course will provide opportunities to critically evaluate literature focused on both discovery and implementation of gene-drug pairs, become informed about research developments in pharmacogenomics, and further develop presentation skills in a seminar format.

Teaching Partnership Leader

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

- Email: caitrinmcdonough@ufl.edu
- Phone: 352-273-6435

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

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

Course-Level Objectives

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

1. Retrieve published medical literature for use in research, design/planning of a clinical implementation, and clinical decision-making related to pharmacogenomics.
2. Critique a pharmacogenomic journal article by analyzing the purpose, methods, results, and clinical significance of the primary literature article.
3. Evaluate analytical questions during a peer review of a pharmacogenomic article.
4. Use appropriate presentation skills when presenting a journal article to peers.
5. Use appropriate communication skills and professional affective skills when discussing pharmacogenomic journal articles with peer students and faculty.
6. Evaluate pharmacogenomic literature to identify gene-drug pairs that may have sufficient evidence for implementation into clinical practice.

Course Pre-requisites

Successful completion of Blocks 1-12 of the Doctor of Pharmacy curriculum including milestones

Course Co-requisites

None.

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

There are no required textbooks for this course. The following articles are required reading that can be accessed online and will be provided in Canvas:

1. Attia J, et al. How to use an article about genetic association: A: Background concepts. *JAMA*. 2009;301(1):74-81.
2. Attia J, et al. How to use an article about genetic association: B: Are the results of the study valid? *JAMA*. 2009;301(2):191-7.
3. Attia J, et al. How to use an article about genetic association: C: What are the results and will they help me in caring for my patients? *JAMA*. 2009;301(3):304-8.

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

Suggested readings will be posted on Canvas.

Other Required Learning Resources

None

Materials & Supplies Fees

None

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

Assessment Item	Grade Percentage
Scientific Article Presentation (See Appendix C for Rubric)	40%
Quizzes (4 @ 5% each)	20%
Course Participation – <i>Article selection and questions for presenters</i> (See Appendix D for Rubric)	10%
Final Exam (written, in person)	30%
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."

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/>

Artificial Intelligence Use

The use of artificial intelligence (AI) text generators such as ChatGPT on assignments, projects, quizzes, and exams is prohibited in this course. Use of AI text generators is considered evidence of academic dishonesty. If a student is uncertain about the use of AI technology, it is the student's responsibility to ask the instructor prior to beginning the assignment or assessment

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/>

Attendance Policy

Attendance is mandatory for active learning sessions such as team-based learning sessions, case discussions, laboratory sessions, and other activities that the instructor designates as required. This course has 4 required sessions. A student who misses greater than 1 session (>25% of the required active learning sessions/activities) or laboratory sessions for this course will receive an incomplete in the course and will retake the course during the next offering, resulting in delayed graduation.

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

Late assignments may be accepted on a case-by-case basis. Please contact your course leader in advance regarding late assignment submissions.

Accessibility and Belonging Statement

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. It is our intent that students from all diverse backgrounds and perspectives be well served by this course, that students' learning needs be addressed both in and out of class, and that the diversity that students bring to this class be viewed as a resource, strength, and benefit.

We intend to present materials and activities that are 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's effectiveness for you personally or for other students or student groups.

If any of our class meetings conflict with any of your religious events, an excused absence will be provided when requested using the standard UF COP process as detailed in the [UF COP Course policies](#).

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

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):

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

- Email: caitrinmcdonough@ufl.edu
- Phone: 352-273-6435

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

Teaching Assistants:

Jean Malave, Pharm.D.

- Email: jean.malave@ufl.edu

Instructional Designer:

Skylar Johnson, M.A.

- Email: skylarjohnson@cop.ufl.edu
- Phone: 352-273-5719

Academic Coordinator Gainesville Campus:

Hanna Stallard

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

[Absence Ticket 3PD](#)

Educational Coordinators

Katie Orben

- Email: korben06@ufl.edu
- Office: Jacksonville Campus
- Phone: (904) 244 - 9590

Jessica Linares

- Email: jnoriegalinares@ufl.edu
- Office: Orlando Campus
- Phone: (407) 313 - 7007

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
11/29/23		Video Other	Welcome to the course			Caitrin McDonough
	1	Module	Critical Appraisal of Pharmacogenomic Literature			Caitrin McDonough
11/29/23	1.1	Lecture Video	Watch: Pharmacogenomic Research	1-2, 6	0.5	Caitrin McDonough
11/29/23	1	Reading	How to Use an Article About Genetic Association: A: Background and Concepts (Attia J, et al. 2009)		0.5	Caitrin McDonough
11/29/23	1	Reading	How to Use an Article About Genetic Association: B: Are the Results of the Study Valid? (Attia J, et al. 2009)		0.5	Caitrin McDonough
11/29/23	1	Reading	How to Use an Article About Genetic Association: C: What are the Results and Will They Help Me in Caring for my Patients? (Attia J, et al. 2009)		0.5	Caitrin McDonough
11/30/23 from 3- 5pm		Active Learning Session -- Zoom	Active Learning Session 1: Pharmacogenomic Journal Club	1-6	2	Caitrin McDonough
11/30/23		Quiz (In Class)	Quiz 1			Caitrin McDonough
12/04/23	1.2	Lecture Video	Watch: Journal Club Presentation and Considerations in Pharmacogenomic Research		0.75	Caitrin McDonough
12/06/23 at 11:59pm		Assignme nt (Graded)	Submit journal club article for approval via discussion board	1, 5		Caitrin McDonough
12/08/23		Reading	Selected Readings for Article Presentations	1-6	2	Caitrin McDonough
12/11/23 from 3- 5pm		Active Learning Session -- Zoom	Active Learning Session 2: Pharmacogenomic Journal Club	1-6	2	Caitrin McDonough
12/11/23		Quiz (In Class)	Quiz 2			Caitrin McDonough
12/11/23		Reading	Selected Readings for Article Presentations	1-6	2	Caitrin McDonough
12/12/23 from 3- 5pm		Active Learning Session -- Zoom	Active Learning Session 3: Pharmacogenomic Journal Club	1-6	2	Caitrin McDonough
12/12/23		Quiz (In Class)	Quiz 3			Caitrin McDonough

Date / Time [Recommended for Independent Study]	Mod #	Activity	Activity Title	Objectives	Contact Time (hr)	Responsible
12/12/23		Reading	Selected Readings for Article Presentations	1-6	2	Caitrin McDonough
12/13/23 from 3- 5pm		Active Learning Session -- Zoom	Active Learning Session 4: Pharmacogenomic Journal Club	1-6	2	Caitrin McDonough
12/13/23		Quiz (In Class)	Quiz 4			Caitrin McDonough
12/15/23 from 1pm- 4pm		Exam	Exam: Written Appraisal of an Article	1-6		Caitrin McDonough
			Total Contact Hours:		16.75	

Appendix C: Rubric for Assessing Student Presentation of Scientific Articles

Key:

24 points = 100%; 23 = 97%; 22 = 94%; 21 = 91%; 20 = 88%; 19 = 85%; 18 = 82%; 17 = 79%; 16 = 77%; 15 = 74%; 14 = 71%; 13 = 68%; 12 = 65%; 11 = 62%; 10 = 59%; 9 = 56%; 8 = 46%; 7 = 36%; 6 = 26%; 5 = 16%; 4 = 6%; 3 = 3%; <2 = 0%

Study Overview				
Introduction	Accurately and completely reported ALL of the relevant intro components (2 points)	Accurately and completely reported MOST of the relevant intro components (1 point)	Did not accurately and completely report MOST of the relevant intro components (0 points)	___/ 2
Authors' affiliation/study support				
Study objective(s) and rationale				
Quality of journal				
Methods				
Methods- Design	Accurately and completely reported ALL of the relevant study design and patient/subject components (2 points)	Accurately and completely reported MOST of the relevant study design and patient/subject components (1 point)	Did not accurately and completely report MOST of the relevant study design and patient/subject components (0 points)	___/ 2
Case-control, cohort, controlled exp, etc.				
Type of Design (cross-over, parallel, etc.)				
Type of assignment use				
Blinding				
Methods- Patients/Subjects				
How enrolled/from where?				
Inclusion/exclusion criteria				
# enrolled per group				
Methods- Treatment Regimens				___/ 4

Treatments used	Accurately and completely reported ALL of the relevant treatment regimens, outcome measures, data handling and statistics components (4 points)	Accurately and completely reported MOST of the relevant treatment regimens, outcome measures, data handling and statistics components (3 point)	Did not accurately and completely report MOST of the relevant treatment regimens, outcome, data handling and statistics components (1 point)	
Dosages/administration				
Therapy duration				
Methods- Outcome Measures				
Primary Measure				
Secondary Measures				
Methods- Data Handling				
Intention to Treat, per protocol, etc.				
# lost to follow up				
Reasons for dropouts				
Methods- Statistics				
Tests Used				
Power of study				
Results				
Results	Accurately and completely reported ALL of the relevant results and conclusion components (2 points)	Accurately and completely reported MOST of the relevant results and conclusion components (1 point)	Did not accurately and completely report MOST of the results and conclusion components (0 points)	___/2
Results for each outcome measure				
Confidence intervals				
P-values				
Compliance				
Adverse events				
Conclusion				
Authors' conclusion(s)				

Study Conclusion					
Clear, Concise Conclusion Stated	Conclusion summarized accurately and completely all of the following key points to be taken from study (which reflected study limitations); drug's role in therapy or clinical practice implications; AND need for any further research in area (3 points)	Conclusion not summarized accurately and completely ONE of the following key points to be taken from study; drug's role in therapy or clinical practice implications; or the need for any further research in area (2 points)	Conclusion did not summarized accurately and completely TWO of the following key points to be taken from study; drug's role in therapy or clinical practice implications; or the need for any further research in area (1 point)	Failed to give conclusion OR conclusion completely inaccurate (0 points)	___ / 3

Applicability				
List strengths and limitations of study	Multiple strengths and limitations of the study were addressed, including the most significant strengths and limitations (2 points)	Strengths and limitations of the study addressed, but did not emphasize the most significant strengths or limitations (1 point)	Strengths and limitations of the study not addressed (0 points)	___/ 2
Student recommends how study and results should change current pharmacy practice	Student appropriately recommends how study will change practice and provides thorough explanation of why or why not (3 points)	Student recommends how study will change practice but doesn't thoroughly explain why or why not (2 points)	Student does not discuss how the study results will change their practice nor provide an appropriate recommendation for change in practice (0 points)	___/ 3
<i>Examples of questions to address include: How will I change my practice based on results?</i>				
<i>If not, why? E.g. poorly designed study, results showed no difference to standard of care, etc</i>				

Presentation Skills				
Speaking Style, Distractors (um, like...), Eye Contact	Spoke clearly, easy to understand, very few distractors, maintained good eye contact throughout (3 points)	Difficult to hear some of the presentation, some distractors used, occasionally made eye contact (2 points)	Difficult to hear/understand, distractors used throughout, read presentation from notes (1 point)	___/ 3
Timing (not including questions)	16 to 20 minutes (3 points)	<16 min or >20 mins (1 point)		___/ 3
Total Score				
				___/ 24 pts

Adapted from Abate MA, Blommel ML 2007 | Created 8/2016 by Smith KJ, Patel P and Hatton R| Edited by C McDonough 10/2023

Appendix D: Rubric for Assessing Student Questions for Scientific Article Presenters

Key: 3 points = 100%; 2 = 75%; 1 = 50%; 0 = 0%;

Question				
Original and indicative of depth of understanding of concepts presented in the article; does not cover topic already required in presentation or already asked (3 points)	Original and indicative of familiarity with article; does not cover topic already required in presentation or already asked (2 points)	Generic question or question is similar to a previously asked question (1 point)	Does not ask a question or question is not appropriate (0 points)	___ / 3
Examples				
<i>Do you think the results of this study could be applied to the treatment with X drug (similar drug), as they are analogs of each other? Or would you recommend certain follow-up studies?</i>	<i>The results show that perhaps additional evidence to bring this to clinical practice, what other studies would you recommend? (Would need to add why or a little more detail to not be a 2pt ?)</i>	<i>What follow-up studies would you recommend based on the results? (Would need to have more specific details to not be a 1pt ?).</i> <i>How do you think the results could apply in other populations? (Would need to have more specific details to not be a 1pt ?).</i>	<i>No question</i> <i>Why did you pick this paper?</i> <i>What's your favorite color?</i>	
<i>I noticed that the main population in this study was primarily of European ancestry. Could you comment on the generalizability of the results to other populations, and if the variant studied is present in those populations, and if the lack of diversity would have created any bias in the study?</i>	<i>Why is the main study population primarily of European ancestry? (Would need to add why this is important and a little more detail to not be a 2pt?)</i>			