

PHA5223 Pharmacoepidemiology & Drug Safety

Fall 2025 | 2 Credit Hours – [A-E Grading]

The goal of this course is to familiarize students with the concepts and tools of pharmacoepidemiology and drug safety. Students will develop a basic understanding of evaluation of study designs and drug safety programs, how these fields influence regulation and policy of medications and other treatments, and how to use this information to make evidence-based decisions to achieve positive care outcomes for individual patients or populations.

Course Prerequisites: Completion of all Year 2 Pharm.D. program coursework including milestones.

Course Corequisites: PHA5165L Professional Practice Skills Lab V

Course Faculty and Staff		
Course Directors		Instructional Designer
Sebastian Jugl, BSPHarm, RPh, MS, Ph.D. Office: DSIT 6005 Phone: 352-273-6458 Email: s.jugl@ufl.edu	Earl Morris, Pharm.D., MPH, Ph.D. Office: DSIT 6017 Phone: 352-273-6458 Email: earl.morris@ufl.edu	Chris Egan, M.Ed., NRP, PMD, CHSE Email: cegan@ufl.edu
Academic Coordinators		
Ashleigh Langford (GNV) Email: lynn8597@cop.ufl.edu		Jessica Linares (ORL) Email: Jnoriegalinares@ufl.edu
Jaime Welsh (JAX) Email: jaimewelsh@ufl.edu		Nadja Rivera (ORL) Email: nl.riverarivera@ufl.edu
Teaching Faculty		
Tianze Jiao, Ph.D. Email: tianzejiao@cop.ufl.edu POP: DSIT 5 th floor		

[Faculty and Staff: Who to Contact and Questions to Ask](#)

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

Course Objectives and Educational Outcomes	
Course Objectives	Linked Educational Outcome
1. Identify and distinguish the basics of pharmacoepidemiologic study designs, including cohort study and case-control study.	Learner
2. Apply the knowledge of study design to evaluation of drug safety in pharmacoepidemiologic studies.	Problem-solver
3. Analyze the effect bias and confounding may have on the results of a study and understand ways to minimize these threats to validity.	Learner Problem-solver
4. Describe comparative effectiveness research (CER) on treatment options and common pitfalls of CER studies.	Learner
5. Describe how the pharmacoepidemiologic studies and drug safety programs are used to guide federal regulations and other policies for medications and other therapies.	Learner Steward
6. Make evidence-based decisions through critical appraisal of the literature to achieve positive care outcomes for individual patients or patient populations.	Provider Promoter

Course Resources and Fees

Course Outline

See Appendix A. Please routinely check your Google 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 class. Any required readings will be made available on 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](http://www.library.health.ufl.edu/) at this URL:<http://www.library.health.ufl.edu/>

Suggested Textbooks/Readings

Will be posted on Canvas

Other Required Learning Resources

None

Materials & Supplies Fees

None

Evaluation and Grading

Student Evaluation & Grading

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

Assessment Item	Grade Percentage
iRATs (4 @ 2.5% each)	10%
tRATs (4 @ 2.5% each)	10%
Self-Assessments (2 @ 5% each)	10%
Critical Literature Appraisal	10%
Exam 1	30%
Exam 2	30%
Total	100%

Grading Scale

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

University of Florida Honor Pledge and Academic Dishonesty

UF students are bound by The Honor Pledge which states “We, the members of the University of Florida community, pledge to hold ourselves and our peers to the highest standards of honor and integrity by abiding by the Honor Code. On all work submitted for credit by students at the University of Florida, the following pledge is either required or implied: “On my honor, I have neither given nor received unauthorized aid in doing this assignment.”

The Conduct Code specifies a number of behaviors that are in violation of this code and the possible sanctions. Expectations for Artificial Intelligence and when use constitutes academic dishonesty is outlined below.

Tendering information (giving your work to another to be copied, giving someone answers to assessment questions, informing another person in a later section about the questions that appear on an assessment that you have taken, or giving or selling a paper to another student), is considered academic dishonesty.

Students are required to report any condition that facilitates academic misconduct to appropriate personnel. Failure to report is also considered academic dishonesty. If you have any questions or concerns, please consult the course’s Teaching Partnership Leader/Course Director or Assistant Dean for Curricular Affairs.

See the [UF Conduct Code website](#) for more information. If you have any questions or concerns, please consult with the instructor or TAs in this class.

Assignment Descriptions

Please note that this course does *not* require assignments to be completed in a proctored environment. However, if any assessments are designated as proctored (e.g., quizzes or exams administered through a testing center or virtual proctoring service), students will be clearly notified in advance. In such cases, students must comply with all applicable exam policies, including academic integrity guidelines, permitted materials, and conduct expectations. If no proctoring is specified, students are expected to complete assignments independently, adhering to the University’s academic honesty policy.

Course-Related Policies

UF Resources and Policies

University of Florida resources and policies can be found at this URL: <https://go.ufl.edu/syllabuspolicies>

PharmD Course Policies

The Policies in the following link apply to this course. Review the General [Pharm.D. 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 (ALS sessions). A student who misses greater than 1 session(s) 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 or it results in a zero.

Late Assignments

Late assignments **unrelated to absences** up to one week will receive a 20% grade reduction. Assignments submitted more than one week late will receive a zero grade.

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 (AI) Use for Assessments

The use of generative AI in assessments is prohibited, unless explicitly allowed by the course instructor. Assessments include any submitted work, graded or ungraded, that will be evaluated. These include, but are not limited to, quizzes, exams, assignments, writing projects, etc. 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.

When authorized by the course director/course instructors, students may use AI technologies in the completion of an assessment if they acknowledge all use by naming the technology, describing how it was employed, and adhering to any other requirement stipulated in the assessment's instructions. Failure to acknowledge the use of AI technology or disregarding instructions related to the use of AI for assessments is considered academic misconduct. Students must disclose the use of AI and AI-assisted technologies by following the instructions below.

Application of AI technology must be done with human oversight and control, and students should carefully review and edit the result, as AI can generate outputs that can be incorrect, incomplete, or biased. **Students assume full responsibility for all content, including errors and omissions, if AI is employed.** Additionally, privacy is a concern with AI-generated content. Most commercially available AI systems are not compliant with [HIPAA](#) or FERPA protections, inputting patient or student information is prohibited by federal law.

Instructions to acknowledge the use of AI:

Statement: During the preparation of this assignment I/we, [INSERT NAME/S], used [INSERT TOOL / SERVICE] in order to [INSERT REASON OR PURPOSE]. After using this tool/service, I/we reviewed and edited the content as needed and take full responsibility for the content of the submission.

Penalties for unauthorized use:

Unauthorized use of AI text generators for assessments is considered evidence of academic dishonesty (see [policy on academic dishonesty](#)).

Disability Resource Center

Students with disabilities who experience learning barriers and would like to request academic accommodations should connect with the Disability Resource Center. See the [Get Started with the DRC webpage](#) on the Disability Resource Center site. It is important for students to share their accommodation letter with their instructor and discuss their access needs, as early as possible in the semester.

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. Students can complete evaluations in three ways:

1. The email they receive from GatorEvals,
2. Their Canvas course menu under GatorEvals, or
3. The central portal at <https://my-ufl.bluera.com>

Guidance on how to provide constructive feedback is available at <https://gatorevals.ua.ufl.edu/students/>. Students will be notified when the evaluation period opens. Summaries of course evaluation results are available to students at <https://gatorevals.ua.ufl.edu/public-results/>

Appendix A: Course Outline

Date / Time	Mod #	Activity	Activity Title	Contact Time (min)	Responsible
	1	Module	Module 1: Pharmacoepidemiology Study Design		Earl Morris
09/08/25	1.1	Lecture Video	Intro to Course	8	Earl Morris
09/08/25	1.2	Lecture Video	Biostatistics, Epidemiological, or Pharmaco-economic Measures: NAPLEX prep	69	Earl Morris
09/09/25	1.3	Lecture Video	What is a Pharmacoepidemiology Study?	32	Earl Morris
09/09/25	1.4	Lecture Video	Cohort Studies	79	Earl Morris
09/09/25	1.5	Lecture Video	Case-Control Studies	47	Earl Morris
09/09/25		Reading (PDF)	Tramadol Use and the Risk of Hospitalization for Hypoglycemia Patients with Non-cancer Pain	75	
09/10/2025 at 1-2:50pm		Active Learning Session	Active Learning Session 1: Cohort vs Case-Control Studies	100	Earl Morris
09/10/25		Quiz (iRAT/tRAT)	iRAT & tRAT 1		Earl Morris
	2	Module	Module 2: Bias & Confounding		Earl Morris
09/11/25	2.1	Lecture Video	Bias	51	Earl Morris
09/11/25	2.2	Lecture Video	Confounding	52	Earl Morris
09/11/25		Reading (PDF)	Association Between Medication Adherence and the Outcomes of Heart Failure	25	
09/15/25		Assignment (Graded)	Assignment: Study Critique Practice (Bias)		Earl Morris
09/15/25		Assignment (Graded)	Assignment: Study Critique Practice (Confounding)		Earl Morris
	3	Module	Module 3: Real-World Evidence and Real-World Data		Sebastian Jugl
09/12/25	3.1	Lecture Video	What is Real-World Evidence?	39	Sebastian Jugl
09/12/25		Reading (PDF)	FDA RWE Framework (Chapters 1-3)	25	
		Optional/Supplemental	Real-World Evidence to Inform Regulatory Decision Making: A Scoping Review		
		Optional/Supplemental	The Role of Real-World Evidence in FDA-Approved New Drug and Biologics License Applications		
		Optional/Supplemental	Real-World Evidence — Where Are We Now?		
09/15/25	3.2	Lecture Video	What is Real-World Data?	51	Sebastian Jugl
09/15/25		Reading (PDF)	eBook Chapter 8 – Selection of Data Sources (pp. 109-116) (Canvas)	25	
09/15/25		Reading (PDF)	FDA: Real-World Data: Assessing EHR and Medical Claims Data to Support Regulatory Decision-Making for Drug and Biological Products (Chapter IV)	25	
		Optional/Supplemental	When can Real-World data generate Real-World evidence ?		
		Optional/Supplemental	Trial Designs RWE		

Date / Time	Mod #	Activity	Activity Title	Contact Time (min)	Responsible
09/16/2025 at 1-2:50pm		Active Learning Session	Active Learning Session 2: Bias and Confounding & RWE and RWD	100	Earl Morris, Sebastian Jugl
09/16/25		Quiz (iRAT/tRAT)	iRAT & tRAT 2		Earl Morris, Sebastian Jugl
	4	Module	Module 4: FDA Drug Policy and Role of Pharmacoepidemiology		Earl Morris
09/17/25	4.1	Lecture Video	Drug Safety	42	Earl Morris
09/18/25	4.2	Lecture Video	Risk Evaluation and Mitigation Systems (REMS)	37	Earl Morris
09/22/2025 at 9-10:30am		Exam	Exam 1: Modules 1-4	90	
	5	Module	Module 5: Outcomes, Endpoints, and Exposures in Pharmacoepidemiology		Sebastian Jugl
09/24/25	5.1	Lecture Video	Definitions, Measures, and Applications of Outcomes and Endpoints in Pharmacoepidemiology	42	Sebastian Jugl
09/24/25		Reading (PDF)	eBook Chapter 6 – Outcome Definition and Measurement (Canvas)	25	
		Optional/Supplemental	SPIRIT Statement - Item 12 (Outcomes)		
09/24/25	5.2	Lecture Video	Evaluation of Outcomes and Endpoints in Pharmacoepidemiology	57	Sebastian Jugl
09/24/25		Reading (PDF)	FDA: Real-World Data: Assessing EHR and Medical Claims Data to Support Regulatory Decision-Making for Drug and Biological Products (Chapter V: Outcome Ascertainment and Validation)	12	
		Optional/Supplemental	Core concepts in pharmacoepidemiology: Validation of health outcomes of interest within real-world healthcare databases		
09/25/25	5.3	Lecture Video	Exposure Measurement, Applications and Challenges in Pharmacoepidemiology	57	Sebastian Jugl
09/25/25		Reading (PDF)	eBook Chapter 4 – Exposure Definition and Measurement (Canvas)	25	
		Optional/Supplemental	Core concepts in pharmacoepidemiology: Measurement of medication exposure in routinely collected healthcare data for causal inference studies in pharmacoepidemiology		
09/25/25		Reading (PDF)	Hormone Replacement Therapy and Adverse Outcomes in Women with Atrial Fibrillation	12	
09/25/25		Reading (PDF)	Ectopic Pregnancy Risk in Users of Levonorgestrel-Releasing Intrauterine Systems With 52, 19.5, and 13.5 mg of Hormone	12	
09/26/2025 at 10-11:50am		Active Learning Session	Active Learning Session 3: Measuring Exposures & Outcomes	100	Earl Morris, Sebastian Jugl
09/25/25		Reading	Results Section only of the journal article Evolocumab Clinical Outcomes in Patients with Cardiovascular Disease (ALS Prep)	25	
09/26/25		Quiz (iRAT/tRAT)	iRAT & tRAT 3		Earl Morris, Sebastian Jugl

Date / Time	Mod #	Activity	Activity Title	Contact Time (min)	Responsible
	6	Module	Module 6: Comparative Effectiveness Research (CER)		Tianze Jiao
09/29/25	6.1	Lecture Video	Introduction to Comparative Effectiveness Research (CER)	17	Tianze Jiao
		Optional/Supplemental	eBook Chapter 1 – Study Objectives and Questions (Canvas)		
09/29/25	6.2	Lecture Video	What Makes an Appropriate Comparator?	30	Tianze Jiao
09/30/25	6.3	Lecture Video	Heterogeneity of Treatment Effects	28	Tianze Jiao
		Optional/Supplemental	eBook Chapter 3 – Estimation and Reporting of Heterogeneity of Treatment Effects (Canvas)		
		Optional/Supplemental	eBook Chapter 11 – Sensitivity Analysis (pp. 146-150) (Canvas)		
09/30/25	6.4	Lecture Video	Pragmatic Clinical Trials	29	Tianze Jiao
09/30/2025 at 2:50pm		Course Evaluation	Course Evaluation		
	7	Module	Module 7: Critiquing Pharmacoepidemiology and Drug Safety Literature for Decision-Making		Earl Morris
10/01/25		Reading (PDF)	Relationship Between Selective Cyclooxygenase-2 Inhibitors and Acute Myocardial Infarction in Older Adults	12	
10/01/25		Other	STROBE Checklists	5	
10/01/25	7.1	Lecture Video	Critical Evaluation of the Literature for Pharmacists	74	Earl Morris
10/01/25		Reading (PDF)	A Questionnaire to Assess the Relevance and Credibility of Observational Studies to Inform Health Care Decision Making: An ISPOR-AMCP-NPC Good Practice Task Force Report	12	
10/01/25		Reading (PDF)	Proton Pump Inhibitors and Risk of Dementia (for Critical Literature Appraisal assignment)	12	
10/01/25		Reading (PDF)	When and How Can Real World Data Analyses Substitute for Randomized Controlled Trials?	12	
10/02/2025 at 1-2:50pm		Active Learning Session	Active Learning Session 4: Selecting Comparator Groups in Pharmacoepidemiological Studies	100	Earl Morris, Tianze Jiao
10/02/25		Quiz (iRAT/tRAT)	iRAT & tRAT 4		Earl Morris, Tianze Jiao
10/06/2025 at 1-3pm		Exam	Exam 2: Modules 5-7		
10/10/25		Assignment (Graded)	Assignment: Critical appraisal of a pharmacoepidemiology study		Earl Morris, Sebastian Jugl
			Total Course Contact Hours	33.5	