

PHA5780 Oncology Clinical Trials Evaluation

Spring 2023

2 Credit Hours – [A-E Grading]

This course is designed to allow student pharmacists with strong interest in oncology to further develop the skills necessary to make optimal decisions regarding treatment and supportive care pharmacotherapy in patients with cancer. Students will be required to read and evaluate primary oncology literature including study design, methodology, biostatistical analysis, and applicability to clinical practice. Student pharmacists will supplement their current knowledge of oncology and supportive care through an in-depth discussion of clinical trials and debates related to controversies in clinical practice.

Teaching Partnership Leaders

David DeRemer, Pharm.D., BCOP, FCCP, FHOPA

- Email: dderemer@ufl.edu
- Office: HPNP 3308 | Gainesville
- Phone: 352-294-8891

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

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:

3. 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.

5.2 Evaluate the selected monitoring parameters to determine the therapeutic and adverse effects related to the treatment plan

9. Maximize the appropriate use of medications in a population.

11.1 Lead a discussion regarding a recently published research manuscript and its application to patient care.

12.1 Retrieve and analyze scientific literature to make a patient-specific recommendation.

12.2 Retrieve and analyze scientific literature to answer a drug information question.

Course-Level Objectives

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

1. Evaluate scientific manuscripts including study design, methodology, biostatistics, and applicability to clinical practice for an oncology patient population.
2. Apply statistical knowledge and skills to interpret the usefulness of clinical drug studies
3. Develop a formalized journal club review document that summarizes essential criteria of assigned oncology based clinical trial
4. Apply applicability of trial outcomes to clinical practice

Course Pre-requisites

Successful completion of Blocks 1-15 of the Doctor of Pharmacy curriculum including milestones

Course Co-requisites

None required.

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

None required. All required readings will be posted in 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

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
Quizzes (5 total = 4% each)	20%
Mock Online Final Exam	10%
Trial Assessments (9 total = 3.8% each) [group submission] - <i>See Appendix C</i>	35%
Participation in ALS (10 total = 1% each) - <i>See Appendix D</i>	10%
Final Exam	25%
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](#) 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

Trial assessments must be completed and submitted prior to in-class discussion. Any late submissions will not 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. 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):

David DeRemer, Pharm.D., BCOP, FCCP, FHOPA

- Email: dderemer@ufl.edu
- Office: HPNP 3308 | Gainesville
- Phone: 352-294-8891

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:

Brooke Adams, Pharm.D., BCOP

- Email: caada0002@shands.ufl.edu
- Office: Gainesville

Emma Garrison, Pharm.D.

- Email: efgarrison@mdanderson.org
- Office: Gainesville

Mohammed Gbadamosi, Ph.D.

- Email: mgbadamosi@cop.ufl.edu
- Office: Gainesville

Ashley Richards, Pharm.D., BCOP

- Email: ricash@shands.ufl.edu
- Office: Gainesville

Sarah Wheeler, Pharm.D., BCOP

- Email: whees@shands.ufl.edu
- Office: Gainesville

Instructional Designer:

Chris Egan, M.Ed., NRP

- Email: cegan@ufl.edu
- Phone: 352-294-5636

Academic Coordinator Gainesville Campus:

Ashleigh Langford

- Email: lynn8597@cop.ufl.edu
- Office: HPNP 4309
- Phone: 352-273-6284

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	Mod #	Activity	Activity Title	Contact Time (hr)	Responsible
	0	Other	Course Introduction	0.33	David DeRemer
04/26/23	1	Module	Surrogate Endpoints		David DeRemer
04/26/23	1.1	Lecture Video	Surrogate Endpoints in Oncology Clinical Trials	0.68	David DeRemer
04/26/23	1.2	Reading	Irreconcilable Differences: The Divorce Between Response Rates, Progression-Free Survival, and Overall Survival JCO March 17 online ahead of print	0.5	David DeRemer
04/26/23 at 2:00 - 3:00pm	1.3	Active Learning Session	ALS 1: Orientation to course and class discussion of Trial 1 (no team presentation) - (Room 1320)	1	
04/27/23	2	Module	Precision Medicine Trial Design Umbrella vs. Basket Trials		David DeRemer
04/27/23	2.1	Lecture Video	Precision Oncology – Contemporary Trial Designs	0.8	David DeRemer
04/27/23	2.2	Reading	Phase II Study of Copanlisib in Patients With Tumors With PIK3CA Mutations: Results From the NCI-MATCH ECOG-ACRIN Trial (EAY131) Subprotocol Z1F	0.5	David DeRemer
04/27/23	2	Assignment (Graded)	Trial 1 Assessment - Module 2	0.5	
04/27/23 at 2:00 - 3:00pm	2	Active Learning Session	ALS 2 (Room 1320)	1	
04/27/23	2	Quiz (iRAT/tRAT)	Quiz 1		
04/27/23	2	Other	Team Primary Literature Presentation (During ALS)		
04/28/23	3	Module	Anticoagulation in Cancer Patients		David DeRemer
04/28/23	3.1	Lecture Video	Anticoagulation in Cancer Patients	0.84	David DeRemer
04/28/23	3.2	Reading	Apixaban for the Treatment of VTE Associated with Cancer	0.5	David DeRemer
04/28/23	3	Assignment (Graded)	Trial 2 Assessment - Module 3	0.5	
04/28/23 at 2:00 - 3:00pm	3	Active Learning Session	ALS 3 (Room 1320)	1	
04/28/23	3	Quiz (iRAT/tRAT)	Quiz 2		
05/01/23	4	Module	Metastatic Melanoma		Emma Garrison
05/01/23	4.1	Lecture Video	Clinical Trials in Metastatic Melanoma	0.7	Emma Garrison
05/01/23	4.2	Reading	Combination Dabrafenib and Trametinib Versus Combination Nivolumab and Ipilimumab for Patients With Advanced BRAF-Mutant Melanoma: The DREAMseq Trial—ECOG-ACRIN EA6134	0.5	Emma Garrison

Date / Time	Mod #	Activity	Activity Title	Contact Time (hr)	Responsible
05/01/23	4	Assignment (Graded)	Trial 3 Assessment - Module 4	0.5	
05/01/23 at 2:00 - 3:00pm	4	Active Learning Session	ALS 4 (Room 1320)	1	
05/01/23	4	Quiz (iRAT/tRAT)	Quiz 3		
05/01/23	4	Other	Team Primary Literature Presentation		
05/02/23	5	Module	Triple Negative Breast Cancer		Mohammed Gbadamosi
05/02/23	5.1	Lecture Video	Triple Negative Breast Cancer	0.64	Mohammed Gbadamosi
05/02/23	5.2	Reading	Pembrolizumab plus Chemotherapy in Advanced Triple-Negative Breast Cancer. N Eng J Med 2022;387:217-26.	0.5	Mohammed Gbadamosi
05/02/23	5	Assignment (Graded)	Trial 4 Assessment - Module 5	0.5	
05/02/23 at 2:00 - 3:00pm	5	Active Learning Session	ALS 5 (Room 1320)	1	
05/02/23	5	Other	Team Primary Literature Presentation		
05/03/23		Assignment (Graded)	Online Mock Final Exam		
05/03/23	6	Module	Small Molecule Inhibitors to Treat Leukemias CML		David DeRemer
05/03/23	6.1	Lecture Video	Chronic Myeloid Leukemia - Inhibiting BCR-ABL	0.8	David DeRemer
05/03/23	6.2	Reading	(Team Checkpoints): ENESTnd – Nilotinib versus imatinib for newly diagnosed chronic myeloid leukemia. N Engl J Med 2010 Jun 17;362(24):2251-9; (Team Seek and Destroy): DASISION Study – Dasatinib versus imatinib in newly diagnosed chronic phase CML. N Eng J Med 2010; 2260-2270.	0.5	David DeRemer
05/03/23	6	Assignment (Graded)	Trial 5 Assessment	0.5	
05/03/23 at 2:00 - 3:00pm	6	Active Learning Session	ALS 6 (Room 1320)	1	
05/03/23		Quiz (iRAT/tRAT)	Quiz 4		
05/03/23		Other	Team Debate: Which frontline BCR-ABL inhibitor is the best front line therapy?		
05/04/23	7	Module	Lymphomas		Sarah Wheeler
05/04/23	7.1	Lecture Video	Introduction to Lymphoma	0.6	Sarah Wheeler
05/04/23	7.2	Reading	Polatuzumab Vedotin in Previously Untreated Diffuse Large B-Cell Lymphoma. N Eng J Med 2022. Jan 27;386(4):351-363	0.5	Sarah Wheeler
05/04/23		Assignment (Graded)	Trial 6 Assessment - Module 7	0.5	

Date / Time	Mod #	Activity	Activity Title	Contact Time (hr)	Responsible
05/04/23 at 2:00 - 3:00pm		Active Learning Session	ALS 7 (MDL)	1	
05/04/23		Other	Team Primary Literature Presentation		
05/05/23	8	Module	Acute Lymphoblastic Leukemia (ALL)		Brooke Adams
05/05/23	8.1	Lecture Video	Adult Acute Lymphoblastic Leukemia	0.7	Brooke Adams
05/05/23	8.2	Reading	(Team Checkpoints): Inotuzumab ozogamicin versus standard therapy for ALL (2016) (Team Seek and Destroy): Bilinatumomab versus Chemotherapy for advanced ALL (2017)	0.5	Brooke Adams
05/05/23	8	Assignment (Graded)	Trial 7 Assessment - Module 8	0.5	
05/05/23 at 2:00 - 3:00pm		Active Learning Session	ALS 8 (Room 1320)	1	
05/05/23	8	Other	Team Debate: Which agent is better in heavily pretreated ALL?		
05/08/23	9	Module	Multiple Myeloma (MM)		Ashley Richards
05/08/23	9.1	Lecture Video	Myeloma Treatment	0.75	Ashley Richards
05/08/23	9.2	Reading	Belantamab mafodotin for relapsed or refractory multiple myeloma (DREAMM-2): a two-arm, randomised, open-label, phase 2 study. Lancet Oncol 2020 Feb;21:207-221	0.5	Ashley Richards
05/08/23		Assignment (Graded)	Trial 8 Assessment - Module 9	0.5	
05/08/23 at 2:00 - 3:00pm	9	Active Learning Session	ALS 9 (Room 1320)	1	
05/08/23	9	Quiz (iRAT/tRAT)	Quiz 5		
05/08/23	9	Other	Team Primary Literature Presentation		
05/09/23	10	Module	Chimeric Antigen Receptor T Cell Therapy (CAR T)		Sarah Wheeler
05/09/23	10.1	Lecture Video	Chimeric Antigen Receptor (CAR) T-Cell Therapy	0.4	Sarah Wheeler
05/09/23	10.2	Reading	Axicabtagene Ciloleucel CAR T-Cell Therapy in Refractory Large B-Cell Lymphoma (2017)	0.5	Sarah Wheeler
05/09/23	10	Assignment (Graded)	Trial 9 Assessment - Module 10	0.5	
05/09/23 at 2:00 - 3:00pm	10	Active Learning Session	ALS 10 (Room 1320)	1	
05/09/23		Other	Team Primary Literature Presentation		

Date / Time	Mod #	Activity	Activity Title	Contact Time (hr)	Responsible
05/11/23 at 12:00 2:00pm	1 10	Exam	Final Exam		
			Total Contact Hours	26.74	

Appendix C: Trial Assessment

Group Name:				
Article Title:				
5 Accomplished	4 Developing	3 Acceptable, but Needs Development	2 Needs Significant Development	1 Unacceptable
ALL parts appropriately critiqued, accurately and completely reported, summarized well	MOST parts appropriately critiqued, some relevant information was not provided	SOME parts appropriately critiqued, several key components of discussion were omitted	Did not accurately and/or completely report relevant trial components	Failed to appropriately critique, inaccurate information and conclusions presented
Outcome		Points	Comment	
Relevance: <ul style="list-style-type: none"> Provides sufficient background information Identifies trial purpose/importance Identifies study question/objective(s) 		1 2 3 4 5		
Methodology: <ul style="list-style-type: none"> Appropriately explains: <ul style="list-style-type: none"> Study design Selection bias? Exclusion/inclusion criteria Endpoints Study groups Baseline characteristics 		1 2 3 4 5		
Complete Explanation of Discussion & Analysis: <ul style="list-style-type: none"> Appropriately explains: <ul style="list-style-type: none"> Data and Statistical Analysis Results Discussion Conclusions 		1 2 3 4 5		
Clinical Trial Evaluation & Practice Application <ul style="list-style-type: none"> Critique of: <ul style="list-style-type: none"> Strengths & Limitations Statistics Addressed author's conclusion, but formulates own conclusion as well Explains impact and/ or application to current clinical practice Future studies needed? 		1 2 3 4 5		
Written Presentation <ul style="list-style-type: none"> Organization and Preparedness <ul style="list-style-type: none"> Handout: accurate, concise, organized, grammatically correct Information delivered logically 		1 2 3 4 5		

Total Score = ____ Conversion to a percentage grade

Appendix D: Rubric for Assessing Student Participation in Class

This document will be used to provide an assessment of the student's overall participation at the end of the course. Instructors will keep track of student participation during each session.

	Exemplary (Score = 5)	Proficient (Score = 4)	Developing (Score = 3)	Unacceptable (Score = 0)
Frequency of participation in class	Student initiates contributions more than once in each recitation.	Student initiates contribution once in each recitation.	Student initiates contribution at least in half of the recitations	Student does not initiate contribution and needs instructor to solicit input.
Quality of	Comments always insightful and constructive; uses appropriate terminology. Comments balanced between general impressions, opinions and specific, thoughtful criticisms or contributions.	Comments mostly insightful and constructive; mostly uses appropriate terminology. Occasionally comments are too general	Comments are sometimes constructive, with occasional signs of insight. Student does not use	Comments are uninformative, lacking in appropriate terminology. Heavy reliance on opinion and personal taste, e.g., "I love it", "I hate it", "It's bad" etc.

comments		or not relevant to the discussion.	appropriate terminology; comments not always relevant to the discussion.	
Listening Skills	<p>Student listens attentively when</p> <p>others present materials,</p> <p>perspectives, as indicated by</p> <p>comments that build on others'</p> <p>remarks, i.e., student hears what others say and contributes to the dialogue.</p>	<p>Student is mostly attentive</p> <p>when others present ideas,</p> <p>materials, as indicated by</p> <p>comments that reflect and</p> <p>build on others' remarks.</p> <p>Occasionally needs encouragement or reminder from T.A of focus of comment.</p>	<p>Student is often</p> <p>inattentive and</p> <p>needs reminder of</p> <p>focus of class.</p> <p>Occasionally makes disruptive</p> <p>comments while others are speaking.</p>	<p>Does not listen to others; regularly talks while others speak or does not pay attention while others speak; detracts from discussion; sleeps, etc.</p>

Total Score = ____ Conversion to a percentage grade:

15 = 100%, 14 = 93.3%, 13 = 86.6%, 12 = 80%, 11 = 73.3%, 10 = 66%, 9 = 60%, 8 = 53.3%, 7 = 46.6%, 6 = 40%, 5 = 33.3% , 4 = 26%, 3 = 15%

Appendix E: Rubric for Classroom Debate

Criteria	4 points	3 points	2 points	1 points	Total Points
Respect for other team	All statements and body language were respectful to others	Most statements and body language were respectful to others, some sarcasm	Borderline inappropriate statements or responses, some sarcasm	Statements and responses were not respectful of others	
Information	Clear, accurate, and thorough information	Most information was clear and accurate.	Some information was accurate, but there were some minor inaccuracies	Information had some major inaccuracies	
Rebuttal	Counter-arguments are strong, relevant	Most counter-arguments were accurate and relevant, but several were weak	Some counter-arguments were weak and irrelevant	Counter-arguments were not accurate and/or relevant	
Factual	Major points supported with relevant facts	Most points were supported by facts, relevance on some questionable	Some points were supported well, others were not	Points not supported by facts	
Delivery	Communicated clearly and confidently, maintained eye contact, excellent voice inflection and delivery	Communicated clearly, frequent eye contact, good voice	Lacked self-confidence, poor eye contact	Failed to communicate clearly, no eye contact	

Understanding of Topic	Team understood topic in depth and presented info very well	Team seemed to understand the main points of the topic and presented well	Team understood main points but didn't present topic	Team lacked understanding of topic	
Total Points= __/24 (conversion to a percentage grade)					
Commentary:					