

PHA5933 Oncology Clinical Trial Evaluation

Spring 2021

2 Semester Credit Hours Block 18 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 Leader

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

- Email: dderemer@ufl.edu
- Office: HPNP 3308/GNV
- 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

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:

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

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

<i>Date</i>	<i>Mod #</i>	<i>Activity</i>	<i>Conta ct hours</i>	<i>Learning Objectives Covered</i>	<i>Faculty Module Leader</i>
4/20	1	Watch: Course Introduction Video	0.10 hr	NA	DeRemer
4/21 1100-1200	1	Module 1: Biosimiliars and Their Role in Cancer Therapy		1,2,3,4	DeRemer
	1.1	WATCH: Biosimiliars in Oncology Practice	1 hr		DeRemer
		READ: A Comparison of Proposed Biosimilar LA-EP2006 and Reference Pegfilgrastim for the Prevention of Neutropenia in Patients With Early-Stage Breast Cancer Receiving Myelosuppressive Adjuvant or Neoadjuvant Chemotherapy: Pegfilgrastim Randomized Oncology (Supportive Care) Trial to Evaluate Comparative Treatment (PROTECT-2), a Phase III, Randomized, Double-Blind	0.5 hr		

		Trial. Oncologist 2016 Jul;21(7):789-94			
	1.2	PREPARE: Trial #1 Assessment	0.5 hr		
	1.3	Active Learning Session 1: Orientation to course and class discussion of Trial #1 (no team presentation)	1 hr		
4/22 0900-1000	2	Module 2: Vaccine Recommendations in the Cancer Population		1,2,3,4	DeRemer
	2.1	WATCH: Overview of Vaccines in Cancer Populations	1 hr		DeRemer
	2.2	READ: Influenza Vaccine Effectiveness Among Patients with Cancer. J Clin Oncol 2019 Oct 20;37(30):2795-2804	0.5 hr		
	2.3	PREPARE: Trial #2 Assessment	0.5 hr		
	2.4	Active Learning Session 2: - Readiness Assessment Quiz - IRAT #1 (vaccines) - Team Primary Literature Presentation	1 hr		
4/23 0900-1000	3	Module: Anticoagulation in Cancer Patients		1,2,3,4	C. DeRemer
	3.1	WATCH: Anticoagulation in Cancer Patients	1 hr		C. DeRemer
	3.2	READ: Apixaban for the Treatment of VTE Associated with Cancer. N Eng J Med 2020;382:1599-1607	0.5 hr		
	3.3	PREPARE: Trial #3 Assessment	0.5 hr		
	3.4	Active Learning Session 3: - Readiness Assessment Quiz – IRAT #2 (anticoagulation) -Team Primary Literature Presentation	1 hr		
4/26 0900-1000	4	Module: Immunotherapy in NSCLC		1,2,3,4	DeRemer
	4.1	WATCH: Immunotherapy in NSCLC	1hr		DeRemer
	4.2	READ: Nivolumab plus ipilimumab in advanced non-	0.5 hr		

		small cell lung cancer. N Eng J Med 2019 Nov;381: 2020-2031			
	4.3	PREPARE: Trial #4 Assessment	0.5 hr		
	4.4	Active Learning Session 4: - Readiness Assessment Quiz – IRAT #3 (lung cancer) - Team Primary Literature Presentation	1 hr		
4/27 0900-1000	5	Module: Small Molecule Inhibitors to Treat Leukemias – CML		1,2,3,4	DeRemer
	5.1	WATCH: Inhibiting BCR-ABL	1 hr		DeRemer
	5.2	READ: Groups Bad Blood and Checkpoints – IRIS Study – Imatinib compared with interferon and low dose cytarabine for newly diagnosed chronic phase CML. N Eng J Med 2003; 348:994-1004; Groups Better than Warfarin and Seek and Destroy – DASISION Study – Dasatinib versus imatinib in newly diagnosed chronic phase CML. N Eng J Med 2010; 2260-2270.	0.5 hr		
	5.3	PREPARE: Trial # 5 Assessment	0.5 hr		
	5.4	Active Learning Session 5: - Team Debate: Which frontline BCR-ABL inhibitor is the best front line therapy? - Online Mock Final Exam	1 hr		
4/28 0900-1000	6	Module: Acute Myeloid Leukemia		1,2,3,4	DeRemer
	6.1	WATCH: AML – Integration of Novel Therapies into Clinical Practice	1 hr		Kowalski
	6.2	READ: CPX-351 (cytarabine and daunorubicin) Liposome for Injection Versus Conventional Cytarabine Plus Daunorubicin in Older Patients With Newly Diagnosed Secondary Acute Myeloid Leukemia. J Clin Oncol. 2018 Sept 10;36(26):2684-92	0.5 hr		

	6.3	PREPARE: Trial #6 Assessment	0.5 hr		
	6.4	Active Learning Session 6: - Team Primary Literature Presentation	1 hr		
4/29 0900-1000	7	Module: ALL		1,2,3,4	Adams
	7.1	WATCH: Acute lymphoblastic leukemia	1 hr		Adams
	7.2	READ: Group A: Inotuzumab ozogamicin versus standard therapy for ALL. N Eng J Med 2016;375(8):740-53 Group B: Blinatumomab versus chemotherapy for advanced ALL. N Eng J Med 2017;376:836-847	0.5 hr		
	7.3	PREPARE: Trial #7 Assessment	0.5 hr		
	7.4	Active Learning Session 7: - Readiness Assessment Quiz – IRAT #4 (ALL) TEAM DEBATE: Which agent is better in heavily pretreated ALL?	1 hr		
4/30 0900-1000	8	Module: MM		1,2,3,4	DeRemer
	8.1	WATCH: Multiple myeloma	1 hr		DeRemer
	8.2	READ: Daratumumab, lenalidomide, and dexamethasone for multiple myeloma. N Engl J Med 2016; 375(14):1319-1331	0.5 hr		
	8.3	PREPARE: Trial #8 Assessment	0.5 hr		
	8.4	Active Learning Session 8: - Team Primary Literature Presentation	1 hr		
5/3 0900-1000	9	Module: Lymphomas		1,2,3,4	Wheeler
	9.1	WATCH: Lymphomas	1 hr		Wheeler
	9.2	READ: Dose-Adjusted EPOCH-R therapy in primary mediastinal B-Cell Lymphoma. NEJM 2013; 368;15: 1408-1416	0.5 hr		
	9.3	PREPARE: Trial #9 Assessment	0.5 hr		
	9.4	Active Learning Session 9:	1 hr		

		- Team Primary Literature Presentation			
5/4 0900-1000	10	Module: CART		1,2,3,4	Wheeler
	10.1	WATCH: The Emergence of Chimeric Antigen Receptor T-Cell Therapy (CART) in the Treatment of Hematologic Malignancies	1 hr		Wheeler
	10.2	READ: Axicabtagene Ciloleucel CAR T-Cell Therapy in Refractory Large B-Cell Lymphoma. N Engl J Med 2017 Dec 28;377(26):2531-2544	0.5 hr		
	10.3	PREPARE: Trial #10 Assessment	0.5 hr		
	10.4	Active Learning Session 10: - Team Primary Literature Presentation	1 hr		
5/5		Reading Day			
5/6 1100-1300		Final Exam			

Required Textbooks/Readings

- There are no required textbooks for this course.
- Required readings will be posted on Canvas.

Other Required Learning Resources

None

Materials & Supplies Fees

None

Student Evaluation & Grading

Assessment Item	Grade Percentage
Online pre-ALS quizzes (5)	20%
Mock Online Final Exam	10%
Trial Assessments (10) (group submission) (Appendix B)	35%
Participation in active learning sessions (10) (See Appendix C)	10%

Assessment Item	Grade Percentage
Team debate (See Appendix D)	
Final Exam	25%
Total	100%

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/>

Percentage Range	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

Pharm.D. Course Policies

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

Appendix A. Course Directory

Teaching Partnership Leader/Course Director:

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

- Email: dderemer@ufl.edu
- Office: HPNP 3308/GNV
- 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

Academic Coordinator:

Misti Merrill

Email: mmerrill@cop.ufl.edu

Phone: 352-273-5617

Absence/Tardy Email: absent3PD@cop.ufl.edu

Educational Coordinators:

McKenzie Wallen

Email: mwallen@cop.ufl.edu

Office: Jacksonville Campus

Iverta Allen

Email: iallen1@cop.ufl.edu

Office: Orlando Campus

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.)

Other Teaching Partnership Faculty Members:

Course Faculty and Office Hours

Teaching Partnership Leader:

Brooke Adams, Pharm.D., BCOP

Clinical Specialist – Blood and Marrow Transplantation

Email: caada0002@shands.ufl.edu

Christina DeRemer, Pharm.D., BCACP, BCPS, FASHP

Clinical Associate Professor

cderemer@cop.ufl.edu

Sarah Wheeler, Pharm.D., BCOP

Clinical Specialist – Blood and Marrow Transplantation

Email: whees@shands.ufl.edu

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

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 D: 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:					

