

Landmark Clinical Trials

PHRD 5072

CRN# 64278

Updated: 2021-01-04

I. Contact Information

Course Coordinator

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Office hours: MW 0800 – 1030; TR 1300-1530

II. Course Prerequisites/Co-requisites

Pre-requisites - PHRD 4052: Research Methods & Literature Evaluation

- PHRD 4064: Cardiovascular Module [Therapeutics I]

- PHRD 4072: Endocrine Module [Therapeutics II]

Co-requisites - PHRD 4085: Infectious Diseases Module [4085 Therapeutics III]

III. Course Description

(3 SCH) Advanced medical literature evaluation with focus on “landmark” trials, those which have a substantive influence on evidence-based medicine and clinical practice.

IV. Curricular Objectives & Outcomes

Domain 1 – Foundational Knowledge

1.1 Learner (Learner) – Develop, integrate, and apply knowledge from the foundational sciences (i.e., *pharmaceutical, social/behavioral/administrative, and clinical sciences*) to evaluate the scientific literature, explain drug action, solve therapeutic problems, and advance population health and *patient-centered care*.

Domain 3 – Approach to Practice and Care

3.1 Problem Solving (Problem Solver) – Identify problems; explore and prioritize potential strategies; and design, implement, and evaluate a viable solution.

3.2 Educator (Educator) – Educate all audiences by determining the most effective and enduring ways to impart information and assess understanding.

3.6 Communication (Communicator) – Effectively communicate verbally and nonverbally when interacting with an individual, group, or organization.

Domain 4 – Personal and Professional Development

4.1 Self-awareness (Self-aware) – Examine and reflect on personal knowledge, skills, abilities, beliefs, biases, motivation, and emotions that could enhance or limit personal or professional growth.

4.2 Leadership (Leader) – Demonstrate responsibility for creating and achieving shared goals, regardless of position.

4.3 Professionalism (Professional) – Exhibit behaviors and values that are consistent with the trust given to the profession by patients, other healthcare providers, and society.

V. Course-Specific Objectives & Outcomes

- A. Develop a system for reading and evaluating primary medical literature (Learner, Self-aware).
- B. Break down medical literature into standard sections and communicate key points to healthcare professionals (Communicator, Educator).
- C. When reading primary medical literature, discern the answers to three critical questions (Problem-Solver)
 - 1. Is this a true finding?
 - 2. Can I apply this finding to my patients?
 - 3. Will this finding change my practice?
- D. Identify standard study designs (Learner), and defend or criticize the ethics of deviations from standard study designs (Professional).
- E. Determine patient-, population-, and institution-specific factors influencing the application of findings from primary medical literature (Professional).
- F. Work in a team to apply findings from primary medical literature to patients or populations (Leader).
- G. Present current standards of care in therapeutics from a perspective of landmark clinical trials (Learner, Educator).

VI. Course Topics

Topics will include research methods, evaluation of medical literature, biostatistics, and pharmacotherapy with an emphasis on cardiology, diabetes, and infectious disease.

VII. Instructional Methods & Activities

Students will participate in class mainly through active group discussion, problem-based learning, team-based learning, and both individual and group presentations. Slideshows and lectures will be used only minimally. Group activities will be student-led with faculty assistance when needed.

Students are expected to come to class prepared to actively participate in the day's activities. Most presentations will require a submitted assignment before class. Communication, leadership, professionalism, and the degree of participation will be assessed by faculty and by peers. Students should expect to present multiple times during the semester. Some quizzes and both exams will have a brief oral component; some quizzes may be online.

Technology to be used: Moodle™, drug information resources.

VIII. Evaluation & Grade Assignment

Peer Evaluation of Participation and Professionalism	10
Faculty Evaluation of Participation and Professionalism	10
Midterm Exam	10
Final Exam	15
Quizzes (5)	15
Individual/Small Group Journal Mini-Presentation	10
Group Journal Mini-Presentations (3)	15
Group Journal Presentation	10
In-Class Games & Activities	5
Total	100

Letter grades are determined as follows:

90+ = A

80-89 = B

70-79 = C

60-69 = D

59- = F

Grades will be rounded to the nearest whole number.

Late submission of any assignment will result in a penalty, as specified in the activity description. Late submission of any online quiz will result in zero (0) points for the online portion of that quiz.

Undergraduate midterm grades will be posted online for students to view via Banner. Midterm grades indicate a student's status at mid-semester only and do not indicate the final performance outcome of a student.

Written exam questions may be multiple-choice, fill-in-the-blank, short-answer, case- or scenario-based discussion, essay, or any other format deemed appropriate by the Course Coordinator. Oral exam questions will be assessed in the course meeting room or the faculty instructor's office. Oral responses will be recorded.

Written exams and quizzes will be individual work only. Oral quizzes will be team-based, and last approximately 15 minutes. The oral component of the final exam will be individual and last 5-10 minutes.

Evaluations and scores will be given to students within 1 week of the assessment or assignment due date. Exams will not be returned to the student; the Course Coordinator is available to review exams with students by appointment. Students who wish to challenge questions must do so within 1 week of scores being returned and should do so in writing. The result of challenges and the method for adjusting scores will be decided at sole discretion of the Course Coordinator.

Student Success Policy: <http://www.ulm.edu/pharmacy/documents/ospa/earlyintervention.pdf>

Remediation Policy: <http://www.ulm.edu/pharmacy/documents/ospa/remediationpolicy.pdf>

IX. Class Policies & Procedures

At a minimum, all policies stated in the current ULM Student Policy Manual & Organizational Handbook should be followed (see <http://www.ulm.edu/studentpolicy/>). Additional class policies include:

A. Textbooks & Materials

No single text is required. Students must use a variety of literature sources, including but not limited to: primary literature found through ULM School of Pharmacy Library Resources and Clinical Guidelines found from the originating organizations. Required texts not available to the student will be provided via Moodle.

B. Attendance Policy

This course relies heavily upon active participation in class, for which prompt and consistent attendance is imperative. Students should be in class on time and prepared. If for whatever reason, a student anticipates missing or being late to class, that student should inform the course coordinator as soon as possible *before* being absent from or late to class.

The ULM School of Pharmacy follows the University Attendance Policy (see http://catalog.ulm.edu/content.php?catoid=23&navoid=2875&hl=attendance&returnto=search#Class_Attendance_Regulations_Excused_Absences). Students should pay attention to the requirement to attend 75% of scheduled class meetings.

This course follows the ULM School of Pharmacy Excused Absence Policy (see <http://www.ulm.edu/pharmacy/documents/ospa/excusedabsence.pdf>). Note that the course coordinator is the only person who can grant an excused absence.

C. Make-Up Policy

Any student missing a graded exercise (exam, quiz, in-class activity, presentation, etc.) *must* contact the course coordinator prior to the graded exercise. If a student cannot contact the Course Coordinator prior to the graded exercise, the student must contact the coordinator within 24 hours of the graded exercise. Provided that this policy is followed *and* an excused absence is granted, the graded exercise may be made up.

Make-up graded exercises may be at the same level or higher than the original assignment. Failure to attend a scheduled make-up will result in a zero (0) point grade for the exercise.

D. Academic Integrity

Faculty and students must observe ULM published policies on Academic Dishonesty (see page 4 in the *ULM Student Policy Manual* – <http://www.ulm.edu/studentpolicy>) and the School of Pharmacy published policy on *Professional and Ethical Conduct* (see <http://www.ulm.edu/pharmacy/documents/ospa/codeofconduct040617.pdf>).

E. Course Evaluation Policy

At a minimum, students are expected to complete an online course evaluation as well as any evaluation administered in class by the School of Pharmacy.

Changes to this class rely on student feedback. Therefore, individual feedback is encouraged throughout the course.

F. Student Services

Information concerning student services in the School of Pharmacy can be found in the School of Pharmacy *Student Handbook*. In particular, students should pay attention to the School's technical standards and policies concerning students with special needs. ULM student services, such as the Student Success Center (see <http://ulm.edu/cass/>), Counseling Center (<http://ulm.edu/counselingcenter>), and Student Health Services (<http://ulm.edu/healthclinic/>), is available at the Student Services website (<http://ulm.edu/studentaffairs>).

If you are having problems with emotional, social, or behavioral issues, please call any of the mental health clinics on the ULM campus to make an appointment. All services are free to ULM students, staff, and faculty, and are strictly confidential.

- School of Pharmacy Office of Student and Professional Affairs 342-3800
- ULM Counseling Center: 342-5220
- Marriage and Family Therapy Clinic: 342-5678
- Community Counseling Center: 342-1263
- ULM HELPS (Helping Educators and Learners Prevent Suicide) Project Office: 342-1335

The University of Louisiana Monroe strives to serve students with special needs through compliance with Sections 504 of the Rehabilitation Act of 1973 and the Americans with Disabilities Act. These laws mandate that postsecondary institutions provide equal access to programs and services for students with disabilities without creating changes to the essential elements of the curriculum. While students with special needs are expected to meet our institution's academic standards, they are given the opportunity to fulfill learner outcomes in alternative ways. Examples of accommodations may include, but are not limited to, testing accommodations (oral testing, extended time for exams), interpreters, relocation of inaccessible classrooms, permission to audiotape lectures, note-taking assistance, and course substitutions.

Title IX of the Education Amendments of 1972 prohibits sex discrimination against any participant in an educational program or activity that receives federal funds, including federal loans and grants. Furthermore, Title IX prohibits sex discrimination to include sexual misconduct, sexual violence, sexual harassment, and retaliation. If you encounter unlawful sexual harassment or gender-based discrimination, please contact Student Services at 342-5230 or to file a complaint, visit www.ulm.edu/titleix.

G. Emergency Procedures

Please review the emergency escape plan in the classrooms and hallways of the Bienville Building. Move quickly and orderly to the appropriate stairwell and exit the building. The meeting place for this class will be at the ULM College of Pharmacy sign on the lawn in the front of the Bienville building. Under no circumstances is the elevator to be used for emergency evacuation. Any student needing assistance should notify the professor immediately.

Students are encouraged to sign up for ULM automatic emergency alerts (see <http://ulm.edu/ens/>).

H. Discipline/Course-Specific Policies

Students are responsible for all information on Moodle and instructor websites. Students are expected to check these sources regularly to access class materials, required readings, assignments, and other information necessary for this course. Course announcements may be made in class or by email; students are responsible for course announcements made by either of these methods.

I. Physical Location/Address

Federal Regulations require determination and verification of every student's physical location while enrolled in classes (where they are physically located while taking classes), regardless of delivery method (on-campus, online). At the beginning of every semester and whenever physical location changes, students must update or verify their current location through banner (https://ssb-prod.ec.ulm.edu/PROD/bwggkogad.P_SelectAtypUpdate). Students should do this by the end of the first week of classes.

J. Requirements for Registered Pharmacist (R.Ph.) License

This course may be a requirement for the Doctor of Pharmacy degree in Pharmacy. Completion of degree requirements leads to eligibility for professional licensure and/or certification in Louisiana upon graduation. Federal Regulations require universities to provide information to students about the alignment between Louisiana's requirements and those of other states. ULM has created a web page with discipline-specific information containing hyperlinks to Licensure Boards in the United States (<https://www.ulm.edu/professional-licensure-disclosures/index.html>). Program Directors and/or faculty will discuss this information with you during advising or other program meetings but is also available to answer questions and address any concerns you might have. It is also important to note that licensure or certification requirements are subject to change. Although ULM Program Directors annually review and update licensure information for every state, the faculty recommends that before enrolling in a program and throughout enrollment, students communicate with the applicable state board to confirm understanding and whether upon completion of ULM's program, they will meet requirements.

X. Tentative Course Schedule

Class Meetings: TR 15:00 – 16:15 in B110

Week	Day	Topic/Activity
(1)	1/12	Course Overview Group Formation/Assignments Introduction to Literature Evaluation
	1/14	Literature Evaluation – Background, Study Design & Patients
(2)	1/19	Literature Evaluation – Outcomes and Outcome Measures Quiz #1 (Online) – Due Friday 17:00
	1/21	Literature Evaluation – Results & Biostatistics
(3)	1/26	Literature Evaluation – Results & Biostatistics
	1/28	Literature Evaluation – Clinical Significance
(4)	2/2	Literature Evaluation – Overview Quiz #2 (Online) – Due Friday 17:00
	2/4	Journal Club Presentation Example (Guest Faculty) Group Orientation Overview of Landmark Clinical Trials
(5)	2/9	<u>Diabetes treatment and complications:</u> UKPDS, DCCT
	2/11	<u>Diabetes control:</u> ADVANCE, NICE-SUGAR
(6)	2/16*	<i>Mardi Gras Holiday</i>
	2/18	Midterm Exam (Materials through 2/9) (Written only)
(7)	2/23	<u>CV outcomes in diabetes:</u> ACCORD, RECORD
	2/25	<u>CV outcomes in diabetes:</u> EMPA-REG OUTCOME, DPP
(8)	3/2	<u>Statins in cardiovascular disease:</u> 4S, CARDS
	3/4	<u>CV risks with antihypertensives:</u> HOPE, ALLHAT
(9)	3/09	Quiz #3 Oral scheduled during class time & office hours Online due Friday 17:00 (Midterm grade cutoff – grades due 3 / 15) Midterm Peer Evaluations due Friday 17:00 <u>Anti-platelets:</u> CAPRIE, CURE
	3/11	<u>Anti-platelets:</u> PLATO, PEGASUS-TIMI 54
(10)	3/16	<u>β-blockers in heart failure:</u> MERIT-HF, COPERNICUS
	3/18	<u>ACE-inhibitors in heart failure:</u> CONSENSUS, SOLVD

(11)	3/23	<u>Aldosterone antagonists in heart failure:</u> RALES, EPHESUS
	3/25	<u>Nepriylsin inhibition in heart failure:</u> PARADIGM-HF <u>PCSK9 inhibitors in cardiovascular disease:</u> FOURIER
(12)	3/30	Quiz #4 Oral scheduled during class time & office hours Online due Friday 17:00 <u>Oncology:*</u> HERA E2100
	4/1	<u>10 x '20 (CABP):</u> FOCUS, SOLITAIRE-ORAL
(13)	4/6*	<i>Spring Break</i>
	4/8*	
(14)	4/13	Quiz #5 Oral scheduled during class time & office hours Online due Friday 17:00 <u>10 x '20 (HAP):</u> ATTAIN <u>10 x '20 (UTI):</u> ASPECT-cUTI
	4/15	<u>10 X '20 (ABSSI):</u> CANVAS, SOLO
(15)	4/20	Group Final Journal Club Presentations
	4/22	
(16)	4/27	Make-up presentations (as needed)
	4/29	Written Final Exam
(B)	5/4	Makeup (as needed)
	5/6	Evaluations
Final Grades due 5/17		