

Drug Benefit–Risk Assessment

Instructor's information:

Course Coordinator name:	Dr. Yasser Albogami
E-amil:	Yalbogami@ksu.edu.sa
Instructor name:	Dr. Hanan M Alyousef
E-amil:	Halyousef@ksu.edu.sa
Guest Speaker name:	Dr. Ahmed Alkhalidi
E-amil:	afkhalidi@sfda.gov.sa
Guest Speaker name:	Dr. Nasser Alqahtani
E-amil:	NMQAHTANI@hotmail.com
Course Materials:	https://lms.ksu.edu.sa/

Course information:

Course Title:	Drug Benefit-Risk Assessment
Course Code:	EDRA-543
Credit Hours:	2 (2+0)
Course description:	This course focuses on drug benefit-risk assessment, which is a key element in approving drugs for therapeutic uses. Benefit-risk assessment is used during drug development, preclinical and clinical research, regulatory review and post-market safety monitoring, and students will learn various perspectives on how to identify, assess, and incorporate it into the drug decision-making process. By the end of the course, students will be able to understand and use various methodologies pertaining to different benefit-risk processes applied by various stakeholders.
Course Objectives; (i.e., Learning Outcomes)	<ol style="list-style-type: none"> 1. Explain advanced knowledge of drug benefit-risk assessment 2. Identify the appropriate tools for benefit-risk assessment throughout the drug lifecycle 3. Evaluate various drug benefit-risk assessment methodologies applied by the stakeholders 4. Understand the current regulations of the Saudi FDA and WHO guidelines concerning benefit-risk assessment of medicinal products 5. Acquire the professional skill to describe and discuss the usefulness of benefit risk assessment to healthcare practice

References; (Textbooks, Articles, etc...)	<ol style="list-style-type: none">1. The International Conference on Harmonization (ICH) guideline2. Benefit-Risk Assessment for New Drug and Biological Products Guidance for Industry (USFDA)3. SFDA clinical considerations for efficacy and safety assessment4. https://sfda.gov.sa/sites/default/files/2023-07/Clinical_Considerations_forEfficacy_andSafety_final.pdf5. General Considerations for Preclinical Studies Submissions https://www.sfda.gov.sa/sites/default/files/2024-03/General-ConsiderationsPreclinicalStudiesSubmissions.pdf6. Benefit-Risk Assessment of Medicines The Development and Application of a Universal Framework for Decision-Making and Effective Communication by James Leong , Sam Salek , Stuart Walker, ISBN: 978-3-319-15805-17. Materials provided on the LMS
--	--

Course Syllabus: First Semester (Autumn (2024)

Class Time (TUESDAY 06:30 P.M.- 08:20 P.M.)

W	Date	Topics	Instructor's name
1	20/08/2024	Introduction to Drug BRA	Dr. Albogami
2	27/08/2024	Pre-Approval Drug BRA 1: Clinical Trials and Drug Efficacy	Dr. Alkhalidi
3	03/09/2024	Pre-Approval Drug BRA 2: Safety and Risk Assessment	Dr. Alkhalidi
4	10/09/2024	Pre-Approval Drug BRA 3: BR of Cell and Gene Therapies	Dr. Alkhalidi
5	17/09/2024	Advanced Therapeutics Benefit Risk Assessment	Dr. Alkhalidi
6	24/09/2024	Pharmacovigilance and Signal Detection	Dr. Alqahtani
7	01/10/2024	Postmarketing Safety Studies	Dr. Alqahtani
8	08/10/2024	Mid-term Exam	
9	15/10/2024	Risk Management and Mitigation Strategies	Dr. Alqahtani
10	22/10/2024	Benefit-Risk Communication	Dr. Alqahtani
11	29/10/2024	Drug BRA in Hospital & Community Pharmacy	Dr. Alyousef
12	05/11/2024	Risk Evaluations in Hospital & Community Pharmacy	Dr. Alyousef
07/11-16/11/2024		AUTUMN BREAK	
13	19/11/2024	Herbal Benefit-Risk Assessment	Dr. Alyousef
14	26/12/2024	Emerging Trends and Future Directions	Dr. Albogami
15	03/12/2024	Students' Project Presentations	Dr. Albogami
16	08/12/2024 Final Exam Week		
17	15/12/2024 Final Exam Week		
18	22/12/2024 Final Exam Week	Final Exam (EDRA-543) on TUESDAY (24/12/2024) 5-30 P.M.-7:30 P.M.	

Evaluation System for the course:

Schedule of Assessment Tasks for Students During the Semester		
Assessment task (e.g. essay, test, group project, examination, Presentation, assignments, and Midterms and final Exam)	Submission Date/ Time	Proportion of Final Assessment
Mid term	8 th week (08/10/2024)/Class Time	30 %
Class discussion and participation	Throughout the semester	15 %
Assignments (Check LMS)	Each student/group will be given a specific date as per the schedule set in the first class	15 %
Final Exam	18 th week (24/12/2024)	40 %

*Student Presentation Schedule: (If it is part of the assessment)

	Student Names	Topics	Date
1.	XXXX		
2.	XXXX		
3.	XXXX		
4.	XXXX		

* Instructions: **Please specify the rubric system as possible for the students**

***(Sample): is given below**

1. Presentation should not exceed XX min. including Q&A.
2. Presentation will focus on selected original published article (Review paper is not accepted)
3. Presentation format must follow:
 - a. Authors background
 - b. Theory(s) behind the technique
 - c. The purpose of the selected paper
 - d. Materials and methods used and any possible alternative suggestion (highly valuable)
 - e. Results and discussion (very important)
 - f. Conclusion
4. Presentation should be uploaded to the LMS at least 24hr in advance.

COURSE POLICIES:

A. ACADEMIC DISHONESTY/PLAGIARISM

Students are expected to attend all classes.

Students are expected to demonstrate professionalism and honesty during this course.

Academic dishonesty includes, but is not limited to, cheating, plagiarizing, fabricating of information or citations, facilitating acts of academic dishonesty by others, having unauthorized possession of examinations, submitting work of another person or work previously used without informing the instructor, or tampering with the academic work of other students. Students found in violation of such policy are subjected to disciplinary actions as per University Policy.

Please read the manual of study and tests for university students and operational rule (لائحة الدراسة والاختبارات للمرحلة الجامعية والقواعد التنفيذية المعتمدة) <http://dar.ksu.edu.sa/Regulations>

Also, check the graduate studies rules and regulations

<https://graduatestudies.ksu.edu.sa/ar/node/586>

B. CLASS PARTICIPATION AND PROFESSIONALISM

It is expected that all students come to class prepared by completing where applicable all assigned readings, online homework, and other assignments before class and ready to actively participate in classroom activities. Faculty will clarify and expand on the reading material.

Use of phones is prohibited during class. If you have emergency or need to make urgent phone call, ask for permission and when granted, you can leave the class and get back again.

C. GUIDELINES FOR E-MAIL COMMUNICATION

In general, basic rules of style or etiquette are expected when using E-mail to communicate with teaching staff. Also;

1. All emails should be sent from your KSU account ONLY
2. Mail should have a subject heading which reflects the content of the message.
3. Your message should begin with an appropriate salutation, including the name of the person being addressed, and end with the full name of sender.
4. Use mixed case and proper punctuation.
5. Current e-mail addresses for all students must be maintained in the Blackboard system. Each student must edit this in the "Personal Information" section of "Tools". Faculty will not be able to contact you if your email address is not updated and you could miss important

information about courses.

6. Check your e-mail daily. Most information and communication from instructors will come via e-mail or will be posted on Blackboard under announcements.
7. Direct your request to the appropriate person, as indicated below. Please note that discussion board posts are preferred whenever your questions do not involve personal matters to reduce the number of individual emails.
8. If you have a general course question or if you are unsure of where to direct questions, please, contact the Course Director. DO NOT send message to "All Instructors". At once.

D. ATTENDANCE AND EXCUSED ABSENCE

In the case of illness or prolonged absence, it is the student's responsibility to notify the Course Director within 5 days from the first date of absence. Exceptions to the five-day notification period are rare and can only be approved by the Vice Dean of postgraduate education. Upon acceptable documentation from a student, an official memorandum will be issued notifying faculty of an excused absence. In the case of a legitimate excused absence, course instructors will make all reasonable attempts to assist the student to satisfy requirements of the course.

Students missing 25% or more on attendance are forbidden from setting in the final exam per University Policy.

If a student missed a midterm exam for an ELIGIBLE reason, Student must submit proper documentation within 2 weeks of scheduled exam time to the faculty member and the course coordinator.

For any missed exams, student should fill a make-up exam form to obtain the necessary signatures and approvals from faculty member, the course director and head of the program.

The faculty member has the right to determine the method for make-up exam, which can be any of the following:

- i) Increasing the percentage of the remaining exams to cover the missed exam
- ii) Assigning the final exam, a higher percentage to cover the missed exam for that student
- iii) A make-up exam

E. CONFLICT RESOLUTION:

Any issues related to this course teaching and grading should be resolved with the course instructor promptly to ensure healthy learning atmosphere. Unresolved matter should be directed to the course coordinator. If matter is not yet resolved, please direct your complaint to the program head.