



Jordan University of Science and Technology
Faculty of Pharmacy
Pharmacy Department

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| PHAR705 Design Of Clinical Studies - JNQF Level: 9 |
| First Semester 2024-2025 |

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| Course Catalog |
| 1 Credit Hours. The course deals with various designs of clinical research such as observational studies and clinical trials in the context of epidemiological concepts, and with considerations of medical, ethical and therapeutic requirements. |
| Teaching Method: On Campus |

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| Text Book | |
| Title | Fundamentals of Clinical Trials |
| Author(s) | Lawrence Friedman, Curt Furberg, David DeMets, Christopher B. Granger, et al. |
| Edition | 1st Edition |
| Short Name | Ref 1 |
| Other Information | Springer,2015 |

Course References

| Short name | Book name | Author(s) | Edition | Other Information |
|------------|------------------------------------|------------------------------|-------------|--|
| Ref 2 | Understanding Pharmacoepidemiology | Yi Yang and Donna West-Strum | 1st Edition | The McGraw-Hill Companies, Inc. 2011 |
| Ref 3 | Pharmacoepidemiology | Brian L. Strom | 6th Edition | Wiley & Sons, Incorporated, John. 2019 |

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| Instructor | |
| Name | Dr. SHOROQ ALTAWALBEH |
| Office Location | P2 L-0 |
| Office Hours | |
| Email | smallawalbeh@just.edu.jo |

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| Class Schedule & Room |
| Section 1: Lecture Time: Thu : 09:30 - 10:30 Room: M3305 |

| Tentative List of Topics Covered | | |
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| Weeks | Topic | References |
| Weeks 1, 2, 3, 4 | Introduction to Randomized Clinical Trials | From Ref 1 |
| Weeks 5, 6, 7 | Observational Study Designs in Clinical Research | From Ref 2 , From Ref 3 |
| Week 9 | Measures of Association | From Ref 2 , From Ref 3 |
| Weeks 10, 11 | Bias, Confounding Interaction in Clinical Studies | From Ref 2 , From Ref 3 |
| Week 11 | Causality Assessment | From Ref 1 , From Ref 2 |
| Week 11 | Evaluation of the Clinical Research Literature | From Ref 2 , From Ref 3 |
| Week 12 | Medication Utilization Patterns | From Ref 2 , From Ref 3 |
| Week 13 | Medication Safety and Pharmacovigilance | From Ref 2 , From Ref 3 |

| Mapping of Course Outcomes to Program Outcomes and NQF Outcomes | Course Outcome Weight (Out of 100%) | Assessment method |
|---|-------------------------------------|-------------------|
| Understand clinical trial designs and highlight the strengths and limitations of conducting clinical trials [1PLO-CP2.1][1L9K1] | 20% | Mid Exam |

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|---|-----|---|
| Understand observational study designs and highlight the strengths and limitations of each study design. [1PLO-CP2.1] [1L9K1] | 30% | Mid Exam |
| Discuss specific types of clinical research, identify threats to validity in clinical research, and explore strategies to prevent or manage these threats. [1PLO-CP2.1] [1L9K2] | 30% | Final exam |
| Criticize literature from reliable data sources [1PLO-CP3.1] [1L9K3] | 20% | Final term project; evaluating clinical studies |

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| PLO1.1 | PLO2.1 | PLO3.2 | PLO3.3 | PLO2.2 | PLO2.3 | PLO2.4 | PLO3.1 | PLO3.4 | PLO3.5 | PLO3.6 | PLO4.1 | PLO4.2 | PLO4.3 | PLO4.4 | PLO5.1 | PLO-PT1.1 | PLO-PT2.1 | PLO-PT2.2 | PLO-PT3.1 |
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| Relationship to NQF Outcomes (Out of 100%) | | |
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| L9K1 | L9K2 | L9K3 |
| 50 | 30 | 20 |

| Evaluation | |
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| Assessment Tool | Weight |
| Mid Exam | 50% |
| Final exam | 30% |
| Final term project; evaluating clinical studies | 20% |

| Policy | |
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| Exams | The format for the exams is generally multiple-choice questions (MCQS) and essay questions. Grades will not be given out via e-mail Makeup exam should not be given unless there is a valid excuse. Arrangements to take an exam at a time different than the one scheduled MUST be made prior to the scheduled exam time. |
| Cheating | Prohibited. The commitment of the acts of cheating and deceit such as copying during examinations, altering examinations for re-grade, plagiarism of homework assignments, and in any way representing the work of others as your own is dishonest and will not be tolerated. Standard JUST policy will be applied المادة 7: إذا ضبط الطالب أثناء الامتحان أو الاختبار متلبساً بالغيش فتوقع عليه العقوبات التالية مجتمعة اعتباره راسباً في ذلك الامتحان أو الاختبار الغاء تسجيله في بقية المساقات المسجل لها في ذلك الفصل فصله من الجامعة لمدة فصل دراسي واحد، و هو الفصل التالي للفصل الذي ضبط فيه |
| Attendance | Excellent attendance is expected. JUST policy requires the faculty member to assign ZERO grade (35) if a student missed 10% of the classes that are not excused. If you miss class, it is your responsibility to find out about any announcements or assignments you may have missed. |
| Participation | Highly encouraged to achieve class objectives |

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