Course Outline and Policies

For Health Services Academy Islamabad

Course title:	**Clinical trials**
Instructors:	Dr. Abdur Rashid
Instructor CV/Profile	Dr. Abdur Rashid (Ph.D. Pharmaceutical Sciences), China Pharmaceutical University, Nanjing, China. He is an Ex. Director of the division of pharmacy services, DRAP. He has a total of 37 years of professional experience in the Public and Private sectors of Pakistan and at international levels such as Consultant with WHO, president of the Pharmacy Council of Pakistan, Chief of drug control and traditional medicine, and Chairman of the quality control board, etc. During the COVID pandemic, he played a substantial role as a chairman, of the clinical study committee(CSC) for a clinical trial, and vaccines approval on an expedited basis by ensuring patient safety.
Course Fee	Pakistani Candidates: PKR 60,000/- Overseas Candidates: USD /-

Class details	
Class Timing and Room	Online
Session Day(s)	Weekdays

Course Description
A clinical trial is a systematic investigation of human subjects for evaluating the safety & efficacy of any new drug. Clinical trials are a set of tests in medical research and drug development that generate safety and efficacy data for health interventions in human beings. Clinical Trial is the mainstay for bringing out New Drugs to the Market.

Course Objective

This course concludes with guidance on how to work with healthcare professionals, researchers, and clients. A clinical trial is designed to serve healthcare professionals to expand their understanding and practice regarding research. It attracts great interest to pharmacists, researchers, pharmacologists as well as other health professionals including Doctors, Nurses, Aide, Nutritionists, and complementary therapists.

Course Learning Outcomes

Knowledge Outcomes

- Principles of clinical trials
- Role of clinical trials and their importance?
- Different types of trials.
- Working with healthcare workers and clients
- Design clinical trials

Abilities Outcomes

- Systematic investigation of human subjects for evaluating the safety & efficacy of any new drug
- Phases of clinical trial
- drug development
- Drug Review Steps
- New Drug Application

Skills Outcomes

- strong organizational skills
- Observation
- Data analysis.
- ability to build effective relationships with trial center staff and colleagues
- excellent communication skills (both written and oral)

Teaching and Learning Methodology
This course will build on presentations, videos, readings, case studies and assignments. This course rests on several components – self-study, case discussions, interaction, as well as implementing Strategies to practice and application in the subject area: • Self-Study: • Student-Instructor Interaction online. • Discussion of selected questions, finding of examples, answering of questions etc. • Group Discussions. • Group project to practice and for application of concepts. • Preparation of short assignments. • Final report/project and discussion on a selected topic.

Course Plan				
Session	Chapters	Session Topic	Assessments	%
1	**Introduction, Motivation, and Ethics of Clinical Trials**	a. Historical examples b. Introduction to study designs and clinical trials c. Ethics and Historically derived principles i. Nuremberg Code ii. Declaration of Helsinki iii. Belmont Report d. Equipoise e. Informed consent		
2	**Phases, Contexts, Examples**	a. Description of trial phases (Phase 0, Phase I, II, III, and IV) b. Trial contexts (types of trials: pharma, devices, etc.) c. Trial examples		
3	**Study Protocol**	a. Introduction, background, Objectives b. Eligibility, Design, Randomization c. Intervention details, assessments and data collection, case report forms d. Violations e. Amendments		
4	**The Study Population and Cohort**	a. Study population b. Study cohort c. Recruitment (planning, strategies, and sources) d. Accrual (problems and solutions) e. Inclusiveness and Representation		

5	**Study/Trial Design**	a. Phase I designs i. Dose-finding designs b. Phase II designs i. Pilot studies ii. Single-arm iii. Historical control designs c. Phase III designs i. Factorial designs ii. Crossover designs iii. Multicenter studies d. Pilot studies e. Phase IV designs		
6	**Treatment Allocation**	a. . Randomization i. Simple ii. Blocked iii. Stratified b. Adaptive allocation c. Masking		
7	**Research Question, Outcomes, Measurement, and Data Capture**	a. Research Question b. Surrogate Outcomes c. Measures and endpoints d. Required observations e. Types of measures f. baseline measurements g. Case report forms h. Data collection i. Paper or electronic ii. Parsimony i. Database and software j. Staffing and resources		
8	**Data Monitoring, Trial Conduct**	a. Data quality assurance b. Data delinquency c. Data Monitoring d. Trial Conduct e. Occurrence and control of variation and bias		
9	**Introduction to Power and Sample Size**	a. Hypothesis testing b. P-values, confidence intervals **c.** General power/sample size, estimated effect size **d.** Matching sample size calculations to endpoints		

Prerequisite Skills and Knowledge to take this Course

Academic Conduct

At HSA academic honesty is mandatory. Absolutely no plagiarism/ cheating in any examination, quiz, assignment, report, and/or presentation by any student is tolerated.

Attendance Policy

- Students are required to regularly attend all lectures, computer laboratory sessions, seminars and fieldwork as may be specified. In case, a student accumulates more than the allowed number of absences, he will not be eligible for the Diploma for Professional Development.
- The provision of absences is only for emergencies.
- If absent on the final examination the certificate will not be issued.
- Students who are unable to appear for the final exam are required to submit a written application stating the reason for not appearing for the exam. HSA reserves the right to approve or deny such applications. If approved, the student will be allowed to sit for the exam within one month. Failure to do so, the student will only be given a Certificate of Attendance.
- The attendance on the first day of the Diploma is a must.
- A student must attend 80% of the classes to be eligible for the certificate.
- Students are required to be in time for their sessions. After 10 minutes of the start of class, the entrant will be marked late.
- Maximum of 4 late attendances will be allowed. Decision will be made by the faculty.
- It is expected that the students will always maintain proper dress code.

CONDUCT AND DISCIPLINE

A disciplinary action, leading to rustication, will be taken against students whose conduct is found objectionable at any time during study. The faculty and Vice Chancellor HSA will be the decision maker.

EVALUATION AND GRADING

The performance of participants is evaluated through continuous observation of the student's performance in the Diploma – the extent to which he/she participates in discussions and the case studies and exercises.

There will be quizzes, monthly hourly exams, and final exams at the end of the program. The total marks for passing the Diploma will be 60 out of a total of 100 marks.

Participants, who do not meet attendance or any other eligibility criteria, will not be allowed to appear in the final examination.

In the rating of participants, the following grading plan is used:

A+	95 - 100
An	87 - 94
B+	81 -86
B	72 - 80
C+	66 - 71
C	60 - 65
F	below 60 (Fail)