BIRLA INSTITUTE OF TECHNOLOGY AND SCIENCE PILANI HYDERABAD CAMPUS

First Semester 2022-2023
Course Handout (Part II)

Date: 26/08/2022

In addition to Part-I (general handout for all courses appended to the time table) this portion gives further specific details regarding the course.

Course No. : PHA G543
Course Title : Clinical Research
Instructor-in-charge : Arti Dhar

Course Description : Fundamentals of clinical trials including design, conduct, analysis and interpretation, randomization and blinding methods, sample size determination, recruitment methods, choice of controls, ethical, regulatory and research clearance including GCP, trial requirements-multi-centric/collaborative and related operational issues, data collection, processing, protocol management and quality control issues, interim analysis and critical review of intervention and therapies, design and results, statistical techniques in analysis and interpretation of results, documentation and reporting, pharmacovigilance

1. Scope and Objective of the course:

There is a growing need for clinical researchers in the health industries (Pharmaceutical, biotechnology/medical device companies, research institutes, hospitals) involved in the development of new drugs and therapies. This course is aimed to students in conducting clinical trials on humans with new drugs/therapies before they are introduced to the market. Students completing the course work will gain specialized knowledge and skills required to design, monitor and manage clinical trials. Courses include the drug development process; regulations, guidelines and standards; research methodology and biostatistics; clinical trial organization, monitoring and documentation; and project management.

2. Learning Outcomes:

This course imparts knowledge of new drug research and development; bioethics and institutional review board; regulatory control of clinical trials for NDA and ANDA application; Good Clinical Practices (GCP); related ICH guidelines; applied clinical epidemiology and biostatistics; clinical trial study design; trial development (protocol, case report form and data management); clinical trial management-coordinating clinical trial at the site, documentation methodology, implementing monitoring plan and performing quality control; statistical analysis and data interpretation; monitoring obligations and methods; and medical writing and report preparation for various submissions.

3. Text Book (T)

T1: Lawrence Friedman, Curt Furberg and David DeMets, “Fundamentals of Clinical Trials,” Spring Verlag, New York, 3rd Edition, 1998.

T2: Shein-Chung Chow, Jen-Pei Liu, “Design and analysis of clinical trials,” Wiley-IEEE, 2003.

Reference Books ®:

R1: Steven Piantadosi, “Clinical trials – A methodologic perspective,” John Wiley & Sons, 2005.

R2: Richard Guarino, “New Drug Approval Process,” Marcel Dekker, New York, 2nd edition, Vol. 56, 1993.

R3: S. Bolton, “Pharmaceutical Statistics: Practical and clinical application,” 3rd edition, Marcel Dekker, New York, 1997.

4. Course Plan:

S. No.	Learning objectives	Topic to be covered	Reference
1, 2	Overview of clinical trials and research vis-à-vis need	Introduction to clinical research. Regulatory control of clinical trials for NDA and ANDA application	T1 Ch. 1 T2 Ch. 2 R2 Ch. 1-3, 5, 10, 11
3-6	Basic design considerations for clinical research	Decision on goals; primary questions to be answered; population and patient selection; decision on response variables	T1 Ch. 2 and 3 T2 Ch. 3
7-12	Understanding various designs and their requirements employed in clinical research	Designs for clinical trials including classification, blinding, randomization techniques, baseline assessment	T1 Ch. 4, 5, 6, and 8 T2 Ch. 3, 4 and 7 R3 Ch. 11
13-20	Biostatistical consideration for clinical trials	Application of statistical tools, decision on sample size	T1 Ch. 7
21-24	Ethical clearance for clinical research	Bioethics and institutional review board. Good clinical practice (GCP) and related ICH guidelines	Class notes
25-28	Clinical trial development (protocol, case report form and data management)	Development of trial development (Protocol, recruitment, case report form and data management)	T1 Ch. 9 T2 Ch. 14
29-32	Assessment of drug or device related side effects and short and long term safety issues	Adverse reaction monitoring and safety assessment	T1 Ch. 11 T2 Ch. 13
33-38	Applied clinical epidemiology and biostatistical consideration for clinical trials	Application of statistical tools, decision on statistical analysis and data interpretation; survival analysis	T1 14, 16 T2 Ch. 10, 11 R3 Ch. 4, 6

39	Assessment of effect of intervention on health related quality of life	Assessment of health related quality of life	T1 Ch. 12
40-42	All aspects of clinical research management	Clinical trial management – coordinating clinical trial at the site, documentation methodology, implementing monitoring plan, Report writing	T1 Ch. 10, 13, 15 and 17 T2 Ch. 8 and 12

5. Evaluation Scheme:

Component	Duration	Weightage (%)	Date and time	Remarks
Pre-midterm test	60 minutes	10%	To be announced in class	CB
Mid-term test	90 minutes	20%	03/11 1.30 - 3.00PM	CB
Assignments/ seminars		40%	To be announced in class	OB
Comprehensive exam	180 minutes	30%	26/12/2022 (AN)	CB (15%) + OB (15%)

6. Mid-semester evaluation: will be announced after 2nd test.
7. Attendance: regularity in attendance will be one of the criteria in deciding the borderline cases at the time of final grading
8. Grading Procedure:
    1. It is not necessary that all the five grades (i.e. A to E) would be awarded.
    2. In borderline cases subjective judgement will be exercised for pull-up's (max. 2%). Basic guiding factors will be regularity, consistency in performance (above average) or/and steady improvement throughout the semester.
9. Make-up exam: make-up will be given only for genuine reasons. It is expected that students shall avoid misuse of this feature.
10. Chamber consultation hours: to be announced in the class.
11. Notices: notices pertaining to this course will be displayed only on Pharmacy group notice board.

Academic Honesty and Integrity Policy: Academic honesty and integrity are to be maintained by all the students throughout the semester and no type of academic dishonesty is acceptable.

Instructor-in-charge

PHA G543