First Semester 2016-17
Course Handout (Part II)

01/08/2016

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 **: HEMANT R. JADHAV**

1. **Course Description:**

Overview of new drug research and development; Bioethics and institutional review board; regulatory control of clinical trials for NDA & ANDA application; Good Clinical Practice (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 & report preparation for various submissions.

2. 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.

3. Text Book (T):

T1: Lawrence M Friedman, Curt D Furberg and David L DeMets, "Fundamentals of Clinical Trials", Spring Verlag, New York, 3rd Edn., 1998.

T2: Shein-Chung Chow, Jen-Pei Liu, "Design and Analysis of Clinical Trials", Wiley-IEEE, 2003.

Reference Books (R):

R1: Steven Piantadosi, "Clinical Trials-A Methodologic Perspective", John Wiley & Sons, 2005.

R2: R A Guarino, "New Drug Approval Process" Marcel Dekker, New York, 2nd Edn., Vol. 56, 1993.

4. Course Plan:

Sr.	Learning Objectives	Topic to be covered	Reference
1.	Overview of clinical trials	Introduction to clinical research	T1 Ch. 1
2.	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 & 3 T2 Ch. 3

3.	Understanding US-FDA requirements for clinical trials	Regulatory control of clinical trials for NDA & ANDA application	R2 Ch. 1-3, 5, 10, 11
4.	GCP and ICH guidelines pertinent to clinical research	Good Clinical Practice (GCP) and related ICH guidelines	Class notes
5.	Understanding various designs and their requirements employed in clinical research	Designs for clinical trials, classification of clinical trials, blinding, randomization techniques, baseline assessment	T1 Ch. 4, 5, 6 & 8 T2 Ch. 3, 4,7
6.	Applied clinical epidemiology and biostatistical consideration for clinical trials	Application of statistical tools, decision on sample size and power; Statistical analysis and data interpretation; survival analysis	T1 Ch. 7, 14, 16 R3 Ch. 4, 6
7.	Clinical trial protocol related documentation	Clinical trial protocol, recruitment, case report form and data management	T1 Ch. 9 T2 Ch. 14
8.	Clinical research data management	Data quality and its control, problems in data collection and methods to minimize poor data, participant compliance, monitoring response variables, study termination methods	T1 Ch. 10, 13, 15, 17 T2 Ch. 8, 12
9.	Documentation and report writing	Medical writing & report preparation for various submissions.	T2 Ch. 15

5. Evaluation Scheme:

Component	Duration	Weightage (%)	Date & Time	Remarks
Mid-sem Test	90 min	30	5/10 4:00 - 5:30 PM	CB
Continuous assessment		40	Continuous	
Comprehensive Exam	120 min	30	7/12 AN	CB and OB

*Continuous assessment will be based on theory covered in the class. Topics and number will be announced in class. It will be in terms of home assignments, tutorials, projects, laboratory, viva-voce, class participation

Reading Assignments: Students are advised to read, collect additional information on the above mentioned topics from journals and other online sources.
Attendance: Although attendance is not compulsory, regularity in theory and practical classes will be decisive factor during grading, especially in borderline cases.
Chamber Consultation Hour: To be announced in the class.
Make-up policy: Generally make-up will be considered for regular students only.
Notices: Concerning this course will be displayed on Pharmacy N. B.

Instructor-in-Charge
PHA G543