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MODULE 4

Place: Semmelweis University, Department of Pharmacology and Pharmacotherapy
Floor 4, Issekutz Room ,
1089 Budapest, Nagyárad tér 4.

Date: May 24-27, 2018

MODULE 4: CLINICAL TRIALS

Module Leaders: Anthony Fox and Kata Mazalin

PHARMATRAIN BASE COURSE **MODULE 4: CLINICAL TRIALS**
LEARNING OUTCOMES
At the end of this Module the student should be able to demonstrate an understanding of:
1. Various types of clinical studies and the methods used to choose the appropriate design .(Partly presented in previous module)
2. Main statistical methods used in clinical research. Handling of various types of data.(Partly presented in previous module)
3. Key issues involved in the conduct of a clinical study including investigator and site recruitment, investigative site management and conflict resolution.
4. Collection, evaluation and reporting of adverse event data in clinical trials.
5. Various quality management issues in clinical trials.
6. Impact of emerging results on the drug development plan.
7. Key operational and strategic issues in the clinical development plan.
8. Evaluation of the outcome of drug development: final therapeutic profile / usage of a medicine. Evidence Based Medicine
9. Role of the Target Product Profile (TPP) and Target Product Claims (TPC).
10. Role of the Drug Safety Monitoring Board (DSMB) and other relevant study committees.
11. Statistical issues in statistical report writing.
12. Evaluation and interpretation of clinical trial results.
13. Principles and practical application of critical appraisal.

Day 1 - May 24, 2018 – Thursday

Time	Name of Lecturers Titles and topics of the lectures and cases	Syllabus reference numbers	Learning outcomes
9:00-9:30	Kerpel-Fronius, S. and Fox, A. Introduction to Basic Module 4		
	Workshop: From non-clinical data to clinical development plan **Coordinator: Fox, A.**	9.21, 9.22 7.19, 9.23 11.2; 11.4; 11.5	6,7,8,9
9:30-10:00	Introduction and agreeing learning outcomes		
10:00-11:30	Set up syndicates and work on the pre-course material		
13:00-14:30	**Lunch**		
14:30-15:00	Syndicates discuss and request for further information if needed		
15:00: 16:00	Syndicates agree which product to develop		
16:00-16:50	Fox, A. Using Excel to plot data and calculate the basic PK parameters	9.6	2, 11
17:00 18:30	Syndicates develop their own protocol and hand in their protocol plan		

Day 2 - May 25, 2018 – Friday

Time	Name of Lecturers Titles and topics of the lectures and cases	Syllabus reference numbers	Learning outcomes
9:00-10:00	Receive data back and analyze		
10:00-12:00	Prepare a 10 slide presentation on the study		
12:00 13:00	Fox, A. Writing the statistical report	9.8, 9.19, 9.23	2, 11
13:00-14:30	**Lunch**		
14:30-16:00	Presentations, comments. Wrap up and close the workshop		
16:00-16:50	Tarnai, J. Quality Assurance in clinical trials	7.17; 8.16	5
17:00-17:50	Kerpel-Fronius, S. Writing the medical report	2.3, 7.16, 7.18, 7.19, 9.24	6, 8, 9, 12, 13

Day 3 - May 26, 2018 – Saturday

Time	Name of Lecturers Titles and topics of the lectures and cases	Syllabus reference numbers	Learning outcomes
9:00- 9:50	Mazalin, K. Types of data and standardization of measurement, laboratory values, (local and central laboratory) rating scales, VAS. Patient-reported outcomes (diaries, QoL measurements. Collection of adverse events within a trial. End-points of efficacy and of safety	7.6, 7.14, 9.12, 9.13, 9.14, 9.17	4, 7, 10
10:00- 10:50	Renczes, G. Clinical drug development in children	8.8, 8.13	1; 3; 7; 8, 12
11:00- 11:50	Mazalin, K. Feasibility testing and investigator recruitment; Qualification visits and investigator meetings. Project management of multicentric trials, EUDRACT, Clinial Trial Application (CTA), ethics opinion, resources and budget, timelines, conflict resolution (e.g. investigator discontinuation).	7.4, 7.7, 7.8, 7.9, 7.10, 7.11	3,10
12:00- 13:30	**Lunch**		
13:30- 14:20	Mazalin, K. CT conduct/site management: trial master file (TMF), monitoring and source data verification (SDV), handling of investigational product (IP) and drug accountability. Within-trial decisions (e.g. code-breaking, early term); emergency coverage	7.4, 7.12, 7.13, 7.14, 7.15, 7.16, 7.17	4, 7, 10
14:30- 15:20	Kerpel-Fronius, S. The types and the clinical significance of confirmatory and post marketing authorization CTs (Phase III and IV). Non-interventional and observational studies, Postmarketing Surveillance Studies (PMS), Studies related to risk management: Postauthorization safety study (PASS) and Postauthorization efficacy study (PAES) Evidence Based Medicine	6.1, 6.5, 6.7, 7.1, 7.2, 7.3, 7.6	1, 6, 12
15:30 16:20	Kerpel-Fronius, S. Clinical drug development in elderly patients	8.13	1; 3; 7; 8, 12, 13

Day 4 - May 27, 2018 – Sunday

Time	Name of Lecturers Titles and topics of the lectures and cases
9:00- 10:50	Writing of MCQ test
11:00- 12:00	Barótfi, Sz. Real Word Experience (RWE)
12:00	End of Module