CLINICAL TRIALS

1	Course Title:	CLINICAL TRIALS
2	Course Code:	TBY 6008
3	Type of Course:	Compulsory
4	Level of Course:	Third Cycle
5	Year of Study:	1
6	Semester:	1
7	ECTS Credits Allocated:	3.00
8	Theoretical (hour/week):	2.00
9	Practice (hour/week):	0.00
10	Laboratory (hour/week):	0
11	Prerequisites:	None
12	Language:	Turkish
13	Mode of Delivery:	Face to face
14	Course Coordinator:	Prof. Dr. İLKER ERCAN
15	Course Lecturers:	Prof. Dr. İ. ERCAN
16	Contact information of the Course Coordinator:	Prof. Dr. İ. ERCAN ercan@uludag.edu.tr 2953888 Uludağ Üniversity, Faculty of Medicine, Department of Biostatistics, 16059, Nilüfer, BURSA
17	Website:	http://saglikbilimleri.uludag.edu.tr/anabilimdallari.php
18	Objective of the Course:	To provide the learning of basic concepts of the clinical trials.
19	Contribution of the Course to Professional Development:	
20	Learning Outcomes:	
	1	To conduct a clinical trial.
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21	Course Content:	
	Course Content:	
Week	Theoretical	Practice
1	Basic Statistical Concepts	
2	Basic Design Considerations	
3	Randomization and Blinding	
4	Designs for Clinical Trials	
5	Designs for Clinical Trials in Oncology	

6	Classification of Clinical Trials	
7	Analysis of Continuous Data	
8	Analysis of Categorical Data	
9	Censored Data and Interim Analysis	
10	Sample Size Determination	
11	Issues in Efficacy Evaluation	
12	Safety Assessment	
13	Preparation and Implementation of a Clinical Protocol	
14	Clinical Data Management	

22	Textbooks, References and/or Other Materials:	1-Ozkaya G, Ediz B, Ercan I. Two-Stage Phase II Trials and Sample Size For Different Designs. Turkiye Klinikleri Journal of Biostatistics, 2012;4(2):70-80.(in Turkish). 2-Shein-Chung C, Jen-Pei L, Design and Analysis of Clinical Trials Concepts and Methodologies , John Wiley&Sons Inc, 2004. 3-Piantadosi S, Clinical Trials A Methodologic Perspective, John Wiley&Sons Inc, 1997.
23	Assesment	

TERM LEARNING ACTIVITIES	**NUMBER**	**WEIGHT**
Midterm Exam	0	0.00
Theoretical	1	100.00
Total		100.00
Success Grade		
Total		100.00
Course		

Activites	Number	Duration (hour)	Total Work Load (hour)
Theoretical	14	2.00	28.00
Practicals/Labs	0	0.00	0.00
Self study and preperation	0	0.00	0.00
Homeworks	0	0.00	0.00
Projects	0	0.00	0.00
Field Studies	0	0.00	0.00
Midterm exams	0	0.00	0.00
Others	14	4.00	56.00
Final Exams	1	5.00	5.00
Total Work Load			89.00
Total work load/ 30 hr			2.97
ECTS Credit of the Course			3.00

25	**CONTRIBUTION OF LEARNING OUTCOMES TO PROGRAMME QUALIFICATIONS**															
	PQ1	**PQ2**	**PQ3**	**PQ4**	**PQ5**	**PQ6**	**PQ7**	**PQ8**	**PQ9**	**PQ10**	**PQ11**	**PQ12**	**PQ13**	**PQ14**	**PQ15**	**PQ16**
ÖK1	4	4	4	5	3	0	0	0	0	0	0	0	0	0	0	0

LO: Learning Objectives PQ: Program Qualifications

Contribution Level:	**1 very low**	**2 low**	**3 Medium**	**4 High**	**5 Very High**