

Lp.	Name of Session	Type of Session	Number of lectures' hours	Number of workshop hours	ECTS credits
1	Study Phases, Background of Clinical Trials.	Lecture/Workshop	8	2	2
2	Study Start-up Activities from site identification through Pre-initiation.	Lecture/Workshop	10	5	3
3	Maintenance Studies from Initiation through close out.	Lecture/Workshop	10	10	5
4	Types of Visits.	Lecture/Workshop	12	3	2
5	Relevant Study Systems (EDC, IRT, CTMS, e-LAB).	Lecture/Workshop	25	15	6
6	Evaluation of overall compliance and performance of safety (AE, ADR, SAE, SUSAR).	Lecture	10		2
7	Biostatistics, Internal and Final Analysis.	Lecture/Workshop	10	5	4
8	Audits & Regulatory Inspections.	Lecture	10		1
9	Project Goals – work with team members, strategy for efficient project planning, support and meet the study timelines.	Lecture/Workshop	15	5	3
10	Build relationship with Project Team and Study Team – Soft Skills.	Lecture	10		1
11	Interview and Curriculum Vitae, Explore work in a matrix environment. Final Exam.	Lecture/Workshop	5	10	3