

Course programme "Construction of trial protocols for controlled clinical trials", October 11-15 2021

The course consists of theoretical lectures combined with practical exercises related to own research. During the practical exercises, the candidates develop their own trial protocol. The protocol is delivered as exam (Friday 15th of October) and the candidates will receive comments and suggestions for improvement.

		Lecture
Monday	09.00	History of – and processes in control clinical research
	10.00	Aim and hypotheses
	11.00	Population, selection and sampling
	12.00	Lunch
	13.00	Work session with own trial protocol
	15.00	Randomisation and stratification
	16.00	Discontinuation from the trial
	17.00	End of day
Tuesday	09.00	Study design overview
	10.00	Parallel and stratified design
	11.00	Factorial design
	12.00	Lunch
	13.00	Work session with own trial protocol
	15.00	Latin square – multi-cross-over design
	16.00	Semi-cross over design
	17.00	End of day
Wednesday	09.00	Adaptive and sequential design
	12.00	Lunch
	13.00	Response surface pathway design
	15.00	Work session with own trial protocol
	17.00	End of day
Thursday	09.00	Registration and observations
	11.00	Study procedure, monitoring and GCP
	12.00	Lunch
	13.00	Work session with own trial protocol
	17.00	End of day
Friday	09.00	Data management and description
	10.00	Statistical model and sample size calculation
	13.00	Lunch
	14.00	Work session with own trial protocol
	17.00	Summary