

## Course programme "Construction of trial protocols for controlled clinical trials", May 11-15 2020

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 15<sup>th</sup> of May) and the candidates will receive comments and suggestions for improvement.

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