

March 4th	Title	Duration	Form	Speaker	Content
08:15 – 08:45	<i>Ontvangst met koffie en thee</i>				
08:45 – 09:00	Opening en introductions	0u15	Plenary presentation	Dr. Piet van der Wal, Medical Director NovoNordisk	<ul style="list-style-type: none"> • Welcome • Introductions • Confidentiality • Introduction in relevance of topic for medical advisor
09:00 - 10:45	Datamanagement	1u45	Plenary presentation & Discussion	Peter Stokman, Senior Director Clinical Datamanagement MSD (Organon)	<ul style="list-style-type: none"> • Clinical Development • ICH: the 'How' of Development • GCP & GCP in Clinical Data Management • Audits & Inspections, findings • Minimum Requirements • History of datamanagement • State-of-the art datamanagement; EDC and EPRO and consequences in practice • Transparency and Pharmaceutical Clinical Research (Ethics & Image)
10:45 – 11:00	Introduction Philippe Lehert	0u15		Prof. dr. Philippe Lehert, Prof. Statistics Univerities of Louvain (Belgium) and Melbourne (Australia), consulting statistician for the United Nations and WHO and statistic advisor to EMEA	<ul style="list-style-type: none"> • Mini-exam in statistics
10:45 – 11:00	<i>Koffie</i>				
11:00 – 12:00	Describing statistics	1u30	Plenaire presentatie	Philippe Lehert	<ul style="list-style-type: none"> • Data-types • Handling of bias, confounders and missing data • P-values and confidence

					intervals <ul style="list-style-type: none"> • Definition of population: ITT, LOCF • Discuss exam
12:00 - 13:00	Lunch				
13:00 – 14:45	Power calculation in clinical trials	0u45	Plenary presentation & Discussion	Philippe Lehert	Parameters required to perform powercalculation, Techniques of PC.
14:45 – 14:30	Basic principles of AN(C)OVA	0u45	Plenary presentation & Discussion	Philippe Lehert	Basic theory and rationale for choosing ANCOVA
14:30 – 15:15	Non-inferiority designs	0u45	Plenary presentation & Discussion	Philippe Lehert	What it is and how it can be implemented
15:15 - 15:30	Thee				
15:15 – 16:15	Evidence based medicine: the art of meta-analysis	0u45	Plenary presentation & Discussion	Philippe Lehert	Modern techniques and requirements
16:15 – 17:15	Cases from Real Life Practice		Plenary Discussion of Cases	Philippe Lehert	Time for your questions and discussion of the learnings of the day
17:15 – 17:45	Samenvatting, evaluatie en afsluiting			Piet van der Wal	<ul style="list-style-type: none"> • Evaluation • Summary • Take home messages