

6th Munich Seminar on Veterinary Clinical Studies (Based on VICH GL9 (Good Clinical Practice))

Program: Version 20JAN09

29APR09	Items	Presented by
09:30	Come to together Coffee	All
09.45	1. Introduction and history	Klaus Hellmann / Malcolm Pott
10.15	2. Investigator, sponsor and monitor responsibilities	Klaus Hellmann
11.00	Coffee break	All
11.15	3. Designing the study: Protocol	Malcolm Pott
12.30	Lunch and Coffee	All
14.00	4. Monitoring of Clinical Studies (investigators, laboratories)	Isabel Radeloff
14:30	5. Reporting of the study: Final Study Report	Klaus Hellmann
15:00	Coffee break	All
15:15	6. Deficiency of clinical studies from a regulatory perspective	Gesine Hahn (tbc)
16.00	1. Workshop: Group work on Part 1: Investigator, Sponsor and Monitor Interactions Part 2: Case Studies	All
17.00	1. Workshop: Presentations, discussions	All
18:00	End of Day 1	
19.30	Dinner in Munich	Voluntary, invited
30APR09		
08.30	7. Obtaining regulatory approval for clinical studies in the EU	Klaus Hellmann
09.15	8. Clinical supplies requirements	Klaus Hellmann
09:45	Coffee Break	All
10.00	9. Data Capture and Data Management	Isabel Radeloff
11:00	Coffee Break	All
11:15	10. Statistical planning and conduct	Torsten Küneth
12.30	Lunch and Coffee	All
14:00	2. Workshop: Group work on Data Management and Statistics	All
14:45	2. Workshop: Presentations, discussions	All
16.00	Closing of Seminar	Klaus Hellmann
16:15	End of Seminar	

Dr. med. vet. Gesine Hahn, Member of EMEA Efficacy Working Party, BVL, Berlin, D
 Dr. med. vet. Isabel Radeloff (EOQ Auditorin), KLIFOVET, München, D
 Dr. Malcolm Pott, MRCVS, Cadport Consultancy, Maidenhead, UK
 Dr. Thorsten Küneth, Dipl. Math., München, D
 Dr. med. vet. Klaus Hellmann, Dipl. ECVPT, Auditor EOQ, KLIFOVET, München, D