



17th Munich Workshop on VICH Good Clinical Practice and efficacy studies in animals

May 7th & 8th 2020

Webinar via Zoom

Day 1		
Time	Topic	Presenters
12:30	<u>Welcome and introduction to veterinary GCP</u> <ul style="list-style-type: none"> ▪ Introduction of participants ▪ The legal framework <ul style="list-style-type: none"> ○ VMPs: Dir. 2001/82 ff and Reg 2019/4 and 6 ○ Feed Additives: 1831/2003 and new transparency requirements 	Klaus Hellmann Klifovet AG, Germany
13:30	<u>The regulatory view in the assessment of clinical efficacy of VMPs</u> <ul style="list-style-type: none"> ▪ What needs to be covered? ▪ What are the potential pitfalls? ▪ What are the main challenges for assessors and how to address those? 	Paul McNeill Health Products Regulatory Authority, Ireland
14:15	Coffee Break Use your barista qualities for a good coffee at home	
14:45	<u>Dose finding and confirmation – Defining suitable efficacy parameter</u> <ul style="list-style-type: none"> ▪ How to define suitable efficacy parameters ▪ Statistical significance versus clinical relevance ▪ Interpretation of results ▪ Consequences for SPC 	Klaus Hellmann Klifovet AG, Germany
15:15	<u>Considerations for studies under field conditions</u> <ul style="list-style-type: none"> ▪ General requirements ▪ Study design ▪ Formal requirements to the study protocol and the final study report 	Claudia Schneider Klifovet AG, Germany
16:00 - 17:30	<u>Workshop: Design of clinical studies – Preparing a study outline</u>	Claudia Schneider & Lena Naderer Klifovet AG, Germany
End of Day 1		



Day 2		
Time	Topic	Presenters
08:30	<u>Responsibilities in clinical studies and how to assure them</u> <ul style="list-style-type: none"> ▪ Sponsor ▪ Monitor ▪ Investigator 	Gabi Braun Klifovet AG, Germany
09:15	<u>Setting up clinical studies in the field</u> <ul style="list-style-type: none"> ▪ Investigator selection ▪ Patient recruitment and follow-up 	Miriam Rutz Klifovet AG, Germany
09:45	<u>Workshop: Monitoring of clinical studies – A case study</u>	Claudia Schneider & Kerstin Adler Klifovet AG, Germany
10:45	<p style="text-align: center;">Coffee break Use your barista qualities for a good coffee at home</p>	
11:15	<u>Clinical supplies requirements and obtaining regulatory approval</u>	Klaus Hellmann Klifovet AG, Germany
11:45	<u>Measures to assure quality in studies</u> <ul style="list-style-type: none"> ▪ Background – Quality management of clinical studies ▪ Elements for Quality ▪ QA vs. QC ▪ Quality assurance and auditing ▪ How to prepare a study site for an inspection 	Claudia Laskowski Klifovet AG, Germany
12:15	<p style="text-align: center;">Lunch break</p>	
13:00	<u>Data Management</u> <ul style="list-style-type: none"> ▪ GCP requirements ▪ Experiences with EDC compared to paper based DC ▪ Data analysis and reporting 	Dejan Cvejic Klifovet AG, Germany
13:30	<p style="text-align: center;">Coffee break Use your barista qualities for a good coffee at home</p>	
14:00	<u>Practical statistics planning and assessment</u> <ul style="list-style-type: none"> ▪ Population and sample ▪ Distribution and probability ▪ Types of data and their evaluation ▪ Hypotheses and errors ▪ Confidence intervals and sample sizes 	Kerstin Adler Klifovet AG, Germany
14:30	<u>Benefit- risk balance: the assessment of authorities</u>	Paul McNeill Health Products Regulatory Authority, Ireland
15:00	Closing remarks	Klaus Hellmann
15:15	End of Webinar	