KLIFOVET AG
ADDED VALUE TO ANIMAL HEALTH

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	**Welcome and introduction to veterinary GCP** ▪ Introduction of participants ▪ The legal framework ○ 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	**The regulatory view in the assessment of clinical efficacy of VMPs** ▪ 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	**Dose finding and confirmation – Defining suitable efficacy parameter** ▪ How to define suitable efficacy parameters ▪ Statistical significance versus clinical relevance ▪ Interpretation of results ▪ Consequences for SPC	**Klaus Hellmann** Klifovet AG, Germany
15:15	**Considerations for studies under field conditions** ▪ General requirements ▪ Study design ▪ Formal requirements to the study protocol and the final study report	**Claudia Schneider** Klifovet AG, Germany
16:00 - 17:30	**Workshop: Design of clinical studies – Preparing a study outline**	**Claudia Schneider & Lena Naderer** Klifovet AG, Germany
	End of Day 1	

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Day 2		
Time	**Topic**	**Presenters**
08:30	**Responsibilities in clinical studies and how to assure them** ▪ Sponsor ▪ Monitor ▪ Investigator	**Gabi Braun** Klifovet AG, Germany
09:15	**Setting up clinical studies in the field** ▪ Investigator selection ▪ Patient recruitment and follow-up	**Kerstin Adler** Klifovet AG, Germany
09:45	**Workshop: Monitoring of clinical studies – A case study**	**Claudia Schneider & Kerstin Adler** Klifovet AG, Germany
10:45	**Coffee break** Use your barista qualities for a good coffee at home	
11:15	**Clinical supplies requirements and obtaining regulatory approval**	**Klaus Hellmann** Klifovet AG, Germany
11:45	**Measures to assure quality in studies** ▪ 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	**Lunch break**	
13:00	**Data Management** ▪ GCP requirements ▪ Experiences with EDC compared to paper based DC ▪ Data analysis and reporting	**Dejan Cvejic** Klifovet AG, Germany
13:30	**Coffee break** Use your barista qualities for a good coffee at home	
14:00	**Practical statistics planning and assessment** ▪ Population and sample ▪ Distribution and probability ▪ Types of data and their evaluation ▪ Hypotheses and errors ▪ Confidence intervals and sample sizes	**To be confirmed** Klifovet AG, Germany
14:30	**Benefit- risk balance: the assessment of authorities**	**Paul McNeill** Health Products Regulatory Authority, Ireland
15:00	**Closing remarks**	**Klaus Hellmann**
15:15	End of Webinar	