

AAVPT Sponsored Workshop on:
Issues and Alternatives for Safety Assessment of
Macrocytic Lactones in P-glycoprotein Deficient Dogs

Oct 23-24, 2018 at the Rockville, MD Hilton

Day 1 - October 23, 2018

Section	Session Title	Focus	Speaker	Timing
1	Canine MDR Background	General overview	Katrina Mealey	20 mins
2	Understanding the Current Collie Model	What do we do now to assess safety in macrocytic lactones?		
	Cheri-Hill Model overview	Overview of existing model, pros/cons	Michael Ulrich, Cheri-Hill	20-30 mins
	AH Pharma experience with the Collie model	Challenges with model, pros/cons	3-5 Industry Speakers TBD	10 mins per speaker
	FDA experience with the Collie Model	How does FDA evaluate use data from this model?	FDA/CVM Reviewer, Lea Cranford	20 mins
	Roundtable question and answer			30 mins
3	Rodent model alternatives to screen in drug development	Are there viable rodent alternatives?		
	CVM mouse knock in model	Pros/cons of these and other models	Mike Myers	15 min
	Taconic Knock out model		C. Scott Knauer	15 min
	Roundtable question and answer			20 mins
4	<i>In silico/vitro</i> models to assess PgP	Are there viable <i>in silico/vitro</i> alternatives?		
	Ussing chambers pros/cons	What are the criteria for understanding the data?	David Braden	15 min
	CACO ₂ /MDCK models		David Braden	15 min
	WSU <i>in vitro</i> model		Katrina Mealey	15 min
	<i>In silico</i> models	Are there any predictive models?	Marilyn Martinez	15 min
	Roundtable question and answer			30 min
End of Day 1: Capture and prioritize ideas for Day 2 brainstorming				
Day 2- October 24, 2018				
Section				
5	Facilitated Brainstorming Session: Are there viable alternatives to Collie studies or ways to improve Collie studies?			~120 mins
	Table team exercise	<i>Teams to focus on evaluating, prioritizing ideas from Day 1 and will present back to the full audience</i>		
6	Facilitated Brainstorming Session - What is needed to validate a replacement model?			~120 mins
	Table team exercise	<i>Team discussion followed by presentation of ideas to full audience</i>		
7	Wrap up	Summarize next steps		30 mins