



9th ESTP International Expert Workshop
"Assessment of the Biological/Toxicological Relevance of Clinical Pathology Changes"

TUESDAY 05th April 2022

13:00 - 13:25	Monika Keresztes (Boehringer Ingelheim, D)	5'	Welcome, organizational information, introduction
	Lindsay Tomlinson (Pfizer, USA)	10'	Background ESTP workshop information
	Monika Keresztes	10'	Survey
	Gabriele Pohlmeier-Esch (Boehringer Ingelheim, D) (chair)		1st session: Biological variation and comparators for clinical pathology analytes
13:25 - 13:55	Daniela Ennulat (GlaxoSmithKline, USA)	20'+10'	Biological variability in clinical pathology data interpretation
13:55 - 14:20	Volker Strauss (BASF, D)	15'+10'	(Pre-)study and historical controls as well as breeder reference ranges for evaluation of biological variation
14:20 - 14:50	Lila Ramaiah (Pfizer, USA)	20'+10'	Tools to assess variability - moving beyond statistical significance testing
14:50 - 15:20	moderated by session chair	30'	Expert discussion: How to convey importance of test item-related clinical pathology changes - individual experiences and differences from anatomic pathology
15:20 - 15:40			Coffee break
	Lindsay Tomlinson (chair)		2nd session: How to report and position test item-related clinical pathology changes?
15:40 - 16:00	Gabriele Pohlmeier-Esch	10'+10'	Format and style of clinical pathology contributions
16:00 - 16:15	Monika Keresztes	10'+5'	Considerations for assessment of indirect clinical pathology changes
16:15 - 16:30	Laura Boone (Labcorp, USA)	10'+5'	Considerations for Clinical Pathology Effects without Correlating Anatomic Pathology Findings
16:30 - 16:50	moderated by session chair	20'	Expert discussion: How to convey importance of test item-related clinical pathology changes? Concept of toxicological relevance
16:50 - 17:00	Gabriele Pohlmeier-Esch	10'	Wrap-up Day 1

WEDNESDAY 06th April 2022

13:00 - 13:20	Monika Keresztes	10'	Welcome, organizational information
	Gabriele Pohlmeier-Esch	10'	Wrap-up Day 1
	Monika Keresztes (chair)		3rd session: Considerations about the importance of effects on novel markers
13:20 - 13:50	Petra Vinken (Janssen, B)	20'+10'	Non conventional or exploratory safety biomarkers: value and limitations in nonclinical studies
13:50 - 14:20	Ellen Evans (retired from Pfizer, USA)	20'+10'	Relevance of changes in immunophenotyping
14:20 - 14:50	moderated by session chair	30'	Expert discussion: Toxicological relevance of novel markers
14:50 - 15:10			Coffee break
	Gabriele Pohlmeier-Esch (chair)		4th session: Wrap-up and take home messages
15:10 - 15:40	Monika Keresztes, Lindsay Tomlinson, Alexius Freyberger (Bayer, D)	20'+10'	Case examples
15:40 - 16:00	Gabriele Pohlmeier-Esch (moderator)	20'	Expert discussion: Algorithm: test item-related - toxicologically relevant - adverse
16:00 - 16:10		10'	Q&A
16:10 - 16:30	Lindsay Tomlinson (moderator)	20'	Expert discussion: Toxicological/biological relevance: definition refinement
16:30 - 16:40		10'	Q&A
16:40 - 16:50	Gabriele Pohlmeier-Esch	10'	Wrap-up Day 2 and take-home messages
16:50 - 17:00		10'	Closing remarks