



BioBridges 2023



September 21–22, Prague, Czech Republic

Scientific program

Thursday, September 21

8:30–9:00 Registration

9:00–9:10 Opening remarks

9:10-10:20 Morning session 1

M13 guideline series: status update

Susana Almeida (Medicines for Europe)

20 min

M13 and QnDAs DPls

Volodymyr Stus (Polpharma)

20 min

Discussion

30 min

10:20-10:40 Coffee break

10:40-12:10 Morning session 2

Tmax/pAUCs

Jiří Hofmann (Zentiva)

20 min

Tadalafil Tmax – case study

Paolo Biffignandi (VI.REL Pharma)

20 min

pAUCs and clinical relevance for LALA

Vit Perlik (Faculty of Medicine, Charles University, Consultant)

20 min

Discussion

30 min

12:10-13:40 Lunch

13:40-15:10 Afternoon session 1

NTIs

Paulo Paixão (Universidade de Lisboa) 20 min

Current thinking of a tailored clinical approach in biosimilars

René Anour (AGES) 20 min

Equivalence for lozenges: in vitro in vivo and link between both

Jean-Michel Cardot (Consultant) 20 min

Discussion

30 min

15:10-15:30 Coffee break

15:30-17:00 Afternoon session 2

Detection of data manipulation in bioequivalence trials

Anders Fuglsang (Fuglsang Pharma) 20 min

Sex- and group-related problems in BE - a delusion

Helmut Schütz (BEBAC) 20 min

Comparison and interpretation of dissolution time profiles of oral tablets using
a first-principles-based disintegration-dissolution model: a contribution to model-
informed drug development

Stefan Horkovics-Kovats (Consultant) 20 min

Discussion

30 min

19:00-23:00 Dinner at Villa Gröbovka

Friday, September 22**9:00-10:10 Morning session 1**

RWE - real world evidence/RWD real world data

Steffen Thirstrup (CMO EMA) 20 min

RWE - real world evidence/RWD real world data - case study	
Mariusz Mogielnicki (Polfarma)	20 min
Discussion	30 min
10:10-10:30	Coffee break
11:00-12:30	Morning session 2
BCS-based biowaivers and waivers for additional strength, M 13 comments	
Mary Malamatari (MHRA)	20 min
Well-established use - case studies	
Jana Klimasová (SUKL)	20 min
Hybrid as registration route for alternative formulations and posologies to increase patient comfort/adherence	
Paula Muñiz (CTI)	20 min
Discussion	30 min
End of meeting	
12:30-13:30	Lunch