



BioBridges 2025

September 25–26 ● Prague, Czech Republic



Scientific program

Thursday, September 25

9:00–10:30 Morning session 1

Biosimilars – update

René Anour (AGES)

45 min.

Generic oligonucleotides

Liselijn Wisman (Synthon)

45 min.

10:30–11:00

Coffee break

11:00–12:30 Morning session 2

Inflation of guidelines – EMA guideline (“old BE gdl”), ICH M13A and PSBGs

Kumar Ramu (QPS)

45 min.

Semaglutide with salcaprozate sodium (SNAC) – ICH M13A food effect

Nuno Silva (Universidade de Lisboa)

45 min.

12:30–13:45

Lunch

13:45–15:30 Afternoon session 1

Product specific guidance EMA vs FDA, need for an additional study with a proton pump inhibitor for generics

Carolien Versantvoort (MEB)

45 min.

pAUCs case study and more beyond...

Vit Perlik (BioBridges)

30 min.



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Bridging clinical practice and regulation: bioavailability of LAI and MR antipsychotics in light of EMA guidelines

Simona Savu (3S)

30 min.

15:30–16:00

Coffee break

16:00–17:30

Afternoon session 1

ICH M13B

Jiří Hofmann (Zentiva)

45 min.

Evaluation of Incurred Subject Period Re-analysis (ISPR) as a tool to distinguish fraudulent pharmacokinetic profile pairs from non-fraudulent pairs

Anders Fuglsang (Fuglsang Pharma)

45 min.

19:30–22:30

Networking dinner

Friday, September 26

9:00–10:30

Morning session 1

Therapeutic equivalence of nasal products – comparison of quality attributes

Peter Caspers (MEB)

45 min.

OIP development in practice: Overcoming barriers to bioequivalence

Zuzanna Miś, Przemysław Reszka (Polpharma)

45 min.

10:30–11:00

Coffee break

11:00–12:30

Morning session 2

ICH M15, and the implications for model based IVIVC (PBPK, popPK)

Paula Muñiz (CTI)

45 min.



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PBPK analysis for pediatric extrapolation

Anuradha Kulasekaran (Reckitt Health)

30 min.

From practice to evidence: Leveraging unique Czech RWD to support regulatory documentation

Patrik Cachnín (TME solutions)

30 min.

12:30–13:45

Lunch