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# PSI Scientific Committee Webinar: Statistical Challenges in Analytical Comparability and Biosimilarity Assessment

**Dates:** 15 – 15 Oct, 2019

2:00pm to 3:30pm

**Speakers:**

- Thomas Lang (EMA BSWP / AGES)
- Johanna Mielke (Bayer)
- Bruno Boulanger (Pharmalex)

This webinar will discuss statistical requirements for the assessment of analytical comparability and similarity assessments, for example between biosimilars and reference products or before and after manufacturing changes. This topic has been the subject of a recent EMA reflection paper and an EFSPi working group. New strategies are proposed as an alternative to mean comparisons and include the assessment of ranges, inferential approaches or the use of Bayesian methods.



Thomas  
Lang (EMA  
BSWP /  
AGES)

Thomas Lang is biostatistician by training. He spent eight years in academic research, followed by three years in clinical research in the pharmaceutical industry. He currently works as senior statistical assessor for the Austrian Agency for Health and Food Safety. For more than nine years he was a member of the Scientific Advice Working Party at EMA. In his current role of a member of the Biostatistics Working Party Thomas acted as rapporteur for the EMA Reflection paper on statistical methodology for the comparative assessment of quality attributes in drug development.



Johanna  
Mielke  
(Bayer)

Johanna studied Statistics at TU Dortmund University (Germany). Afterwards, she joined the Statistical Methodology Group at Novartis in Basel (Switzerland) as a Doctoral Candidate. Her research was focussed on the development of statistical methodologies for clinical biosimilar development. After completing her Ph.D. in 2018, Johanna started to work as a Data Scientist at Bayer in Wuppertal (Germany).



Bruno  
Boulanger  
(Pharmalex)

Bruno has 25 years of experience in several areas of pharmaceutical research and industry including discovery, toxicology, CMC and early clinical phases. He holds various positions in Europe and in USA. Bruno joined UCB Pharma in 2007 as Director of Exploratory Statistics. Bruno is also since 2000 Lecturer at the Université of Liège, in the School of Pharmacy, teaching Design of Experiments and Statistics. He is also a USP Expert, member of the Committee of Experts in Statistics since 2010. Bruno has authored or co-authored more than 100 publications in applied statistics.