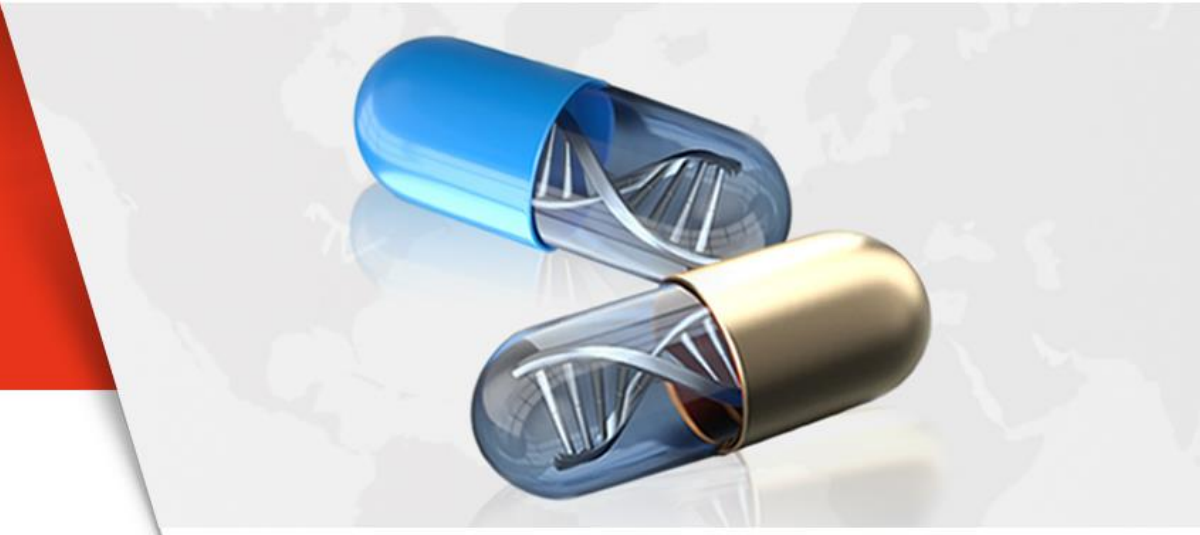
4th Annual Biosimilars Forum

Statistical and Regulatory Perspectives in Biosimilar Development

2019

17–18 OCTOBER | **Budapest,** Hungary



World's prominent drug development experts will return to Budapest to the 4th Annual Biosimilars Forum

- *Day 1:*

COURSE in advanced biostatistics

- *Day 2:*

Clinical studies and regulatory questions

Join us for discovery, networking and inspiration at our 4th professional event in a row, and focus on statistical and regulatory perspectives in biosimilar development with leading experts from the fields of regulatory, academic and clinical research.

www.biosimsforum.com

4th annual event with participation of subject matter experts and prominent professionals from the field of biosimilar development

This 2-day series of events consists of a professional short COURSE in advanced biostatistical methodologies (on October 17th) and a SYMPOSIUM DAY with invited presentations and round table session (scheduled for October 18th) comprising burning issues in biosimilar development with a dedicated focus on the statistical and regulatory aspects of follow-on biologics.

Scientific Programme Committee

Bernd JILMA
Vice Chair, Department Clinical Pharmacology, Medical University of Vienna

Franz KÖNIG
Associate Professor, Medical University of Vienna, Sectior for Medical Statistics

Ildikó ARADI
Former Vice-Chair, Medicines for Europe, Biosimilar Medicines Group

Stephan LEHR
Statistician, Austrian Medicines and Medical Devices Agency; Former President, Viennese Section of IBS

Julia SINGER
Chief Scientific Officer, Accelsiors; President, Hungarian Society for Clinical Biostatistics

Heike WÖHLING
Director Biostatistics for Biostatistics Biosimilars, Analytics group, Novartis

Regulatory Keynote Speaker

Andrea LASLOP
European Regulatory Expert, Head of Scientific Office, Austrian Medicines and Medical Devices Agency

The specialty of the event series is that it brings the regulators, industry leaders, clinical researchers as well as medical scientists together from around the world and provides an opportunity for a constructive dialogue between them about the burning issues, future challenges of biosimilars.

ORGANIZERS

Viennese Section of the International Biometric Society

Hungarian Society for Clinical Biostatistics

Accelsiors CRO Ltd.

SOME SPEAKERS & SPECIAL GUESTS

Academic and clinical researchers, regulatory representatives and industry leaders will gather together from around the world to share with each other their perspectives on the most important issues of biosimilar research. The event will provide a detailed overview of current development challenges of follow-on biologics and guidance for their handling.

Speakers:

Robert SCHALL
Professor of University of the Free State, South Africa

Divan BURGER
Senior Lecturer, Department of Statistics, University of Pretoria, South Africa

Andrea LASLOP
Head of Scientific Office, Austrian Medicines and Medical Devices Agency (AGES)

László TÓTHFALUSI
Associate Professor, Faculty of Pharmacology, Semmelweis Medical University, Hungary

Júlia SINGER
CSO, Accelsiors CRO Ltd.; President, Hungarian Society for Clinical Biostatistics

Arne RING
Head of Biometrics and Statistical Programming, medac GmbH

Andreas BRANDT
Statistical assessor, Federal Institute for Drugs and Medical Devices (BfArM)

Ina-Christine RONDAK
Biostatistician (Seconded National Expert), European Medicines Agency

Stephan LEHR
Biostatistician, Austrian Medicines & Medical Devices Agency

PROGRAMME

COURSE DAY

17 OCT, 2019

Professional course in advanced biostatistics about *Robust methods for assessment of average and scaled average bioequivalence*, will be delivered by prominent biosimilar research expert scientists. Please, click here to reach the abstract of the course!

SYMPOSIUM DAY

18 OCT, 2019

Invited professional presentations and round table sessions with strong focus on *statistical and regulatory perspectives in biosimilar development*, presented by leading experts from the fields of regulatory, academic and clinical research.

During these two interactive days the forum ensures maximum knowledge transfer among professionals, regulators and leading subject matter experts in biosimilar development to exchange and elaborate on the best practices and to debate the evolving landscape, pitfalls and current prespectives of biosimilars.

17th OCT – Course Day Programme

Professional short course in advanced biostatistical methodologies:

Robust methods for assessment of average and scaled average bioequivalence

Robert SCHALL, Professor, Department of Mathematical Statistics and Actuarial Science, University of the Free State, South Africa

Divan BURGER, Senior Lecturer, Department of Statistics, University of Pretoria, South Africa

Summary: The short course presents robust methods for the assessment of both average and of scaled average bioequivalence, based on data from conventional cross-over studies and replicate design cross-over studies. Initially, in an empirical study of a large number of average bioequivalence studies, the results of the (i) classic, (ii) conventional nonparametric and (iii) Bayesian robust analyses are compared, and the need for robust analyses is discussed. Thereafter, the classic and Bayesian robust methods are applied to a group of replicate design bioequivalence studies, and diagnostic plots and outlier diagnostics for such studies are presented. Robust analysis of replicate design bioequivalence data affects not only the estimation of the location parameters of the test and reference formulations, but also the within-reference scaling factor; a proposal is made for the appropriate handling of this matter. The proposed Bayesian robust methodology is flexible with regard to study design (conventional cross-over, replicate design cross-over, parallel design) and with regard to the handling of outliers and skewness in the data.

AGENDA:

- 13:00 - 14:00 | Registration

14:00 - 15:00 | 1st PART

A. Objectives

B. Rationale

1. *Potential Need for Robust Methodology*
2. *Approach: Bayesian Framework / t-Distribution*

C. Average Bioequivalence

1. *Statistical Model*
2. *Types of Outlier*
3. *Robust Methodology*

15:00 - 15:20 | Coffee break

15:20 - 16:40 | 2nd PART

4. *Empirical Study*
   a. Data Pool
   b. Need for Robust Methodology
      i. Degrees of Freedom
      ii. Shift in Point and Interval Estimates
      iii. Relative Confidence Interval Widths
   c. Method Comparison: Agreement between Methods
5. *Simulation study: Confidence Interval Coverage / Power*

D. Scaled Average Bioequivalence

1. *Statistical Model*
2. *Types of Outlier*
3. *Outlier plots*
4. *Robust Methodology*

16:40 - 17:00 | Coffee break

17:00 - 18:00 | 3rd PART

5. *Empirical Study*
   a. Data Pool
   b. Need for Robust Methodology: Confidence Intervals and Degrees of Freedom
6. *Method Comparison: Agreement Between Methods*
7. *Simulation study: Confidence interval coverage / Power*

E. Discussion / Summary

18th OCT – Symposium Day Agenda

8:30 – 9:00 | 2nd day Registration

9:00 – 10:20 | **THEORETICAL CONSIDERATIONS** | *Session Chair:* ***Stephan LEHR***

9:00 – 9:05

- **Symposium opening**

Stephan LEHR, Biostatistician, Austrian Medicines and Medical Devices Agency; Former President of the Viennese Section of the International Biometric Society, Austria

9:05 – 9:30

- **Balaam's Design Revisited**

Júlia SINGER, Chief Scientific Officer, Accelsiors CRO Ltd.;
President of the Hungarian Society for Clinical Biostatistics, Hungary

Co-author: Joëlle MONNET GAUD, Director, Biostatistics, Fresenius-Kabi SwissBioSim GmbH, Switzerland

9:30 – 9:55

- **Measuring switchability using observational data**

László TÓTHFALUSI, Associate Professor, Faculty of Pharmacology, Semmelweis Medical University, Hungary

Co-author: László ENDRÉNYI, Professor Emeritus of Pharmacology and Biostatistics, University of Toronto; Canada

9:55 – 10:20

- **Applications of the expected power (statistical assurance) for bioequivalence trials**

Arne RING, Professor of Statistics, University of the Free State, South Africa;
Head of Biometrics and Statistical Programming, medac GmbH, Germany

10:20 – 10:45 | Coffee break and networking

10:45 – 12:30 | **REGULATORY QUESTIONS**

10:45 – 11:30

- *Regulatory Keynote:* **Current challenges in the development of biosimilars**

Andrea LASLOP, Head of Scientific Office, Austrian Medicines and Medical Devices Agency; Member of the Scientific Advice Working Party (SAWP) of the EMA, Austria

11:30 – 11:50

- **Regulatory reflections on biosimilar development and statistical methods used at quality level**

Ina-Christine RONDAK, Biostatistician, Seconded National Expert from Klinikum rechts der Isar of Technische Universität München to EMA, Germany

11:50 – 12:10

- **Quality and statistics: bringing two worlds together**

Andreas BRANDT, Statistical assessor, Federal Institute for Drugs and Medical Devices (BfArM), Germany

12:10 – 12:30

- **Is similarity different? – Recent developments from the regulatory perspective**

Stephan LEHR, Biostatistician, Austrian Medicines and Medical Devices Agency; Former President of the Viennese Section of the International Biometric Society, Austria

12:30 – 13:30 | Lunch break and networking

13:30 – 15:00 | **CHALLENGE THE REGULATOR - REGULATORY PANEL DISCUSSION**

This extended Regulatory Panel Discussion and Q&A type of interaction replies to critical questions from the audience with a focus on the current regulatory requirements, approval process and burning issues of debate facing clinical development teams specialized on biosimilars.

During this discussion we will look for answers also to that how to handle differences between regulatory guideline recommendations and clinical research practice and how to adjust clinical development practice to effective legislation, or vice versa.

- Moderator:

Stephan LEHR, Biostatistician, Austrian Medicines and Medical Devices Agency; Former President of the Viennese Section of the International Biometric Society, Austria

- Panel members:

Andrea LASLOP, Head of Scientific Office, Austrian Medicines and Medical Devices Agency; Member of the Scientific Advice Working Party (SAWP) of the EMA, Austria

Andreas BRANDT, Statistical assessor, Federal Institute for Drugs and Medical Devices (BfArM), Germany

Ina-Christine RONDAK, Biostatistician, Seconded National Expert from Klinikum rechts der Isar of Technische Universität München to EMA, Germany

Ágnes GYURASICS, Unit Head, National Institute of Pharmacy and Nutrition, Hungary Hungarian member of EMA Committee for Human Medicinal Products (CHMP), and EMA Paediatric Committee (PDCO)

15:00 – 15:30 | Coffee break and networking

15:30 – 16:30 | **ROUND TABLE DISCUSSIONS**

- Moderator:

Helmut SCHÜTZ, Owner at BEBAC – Consultancy Services for Bioequivalence and Bioavailability Studies, Austria

- Discussants:

Industry perspective: *Heike WÖHLING,* Director Biostatistics for Biostatistics Biosimilars, Analytics group, Novartis, Germany

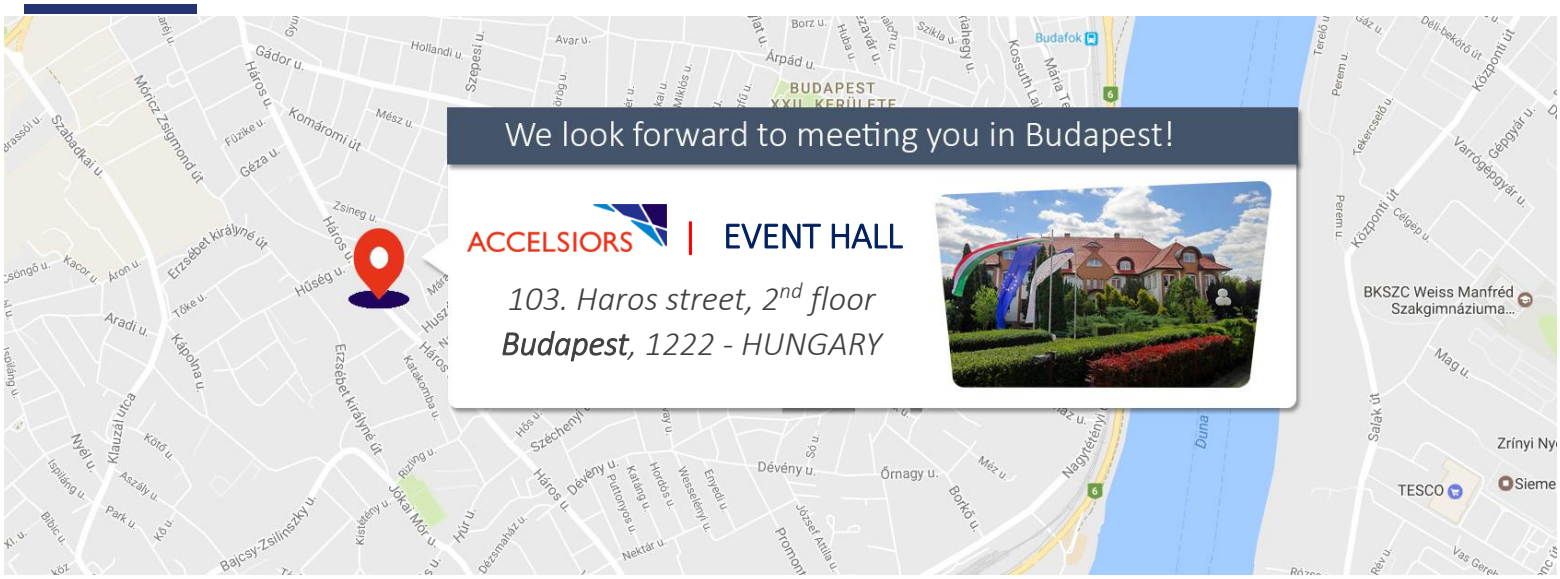
Regulatory perspective: *Andrea LASLOP,* Head of Scientific Office, Austrian Medicines and Medical Devices Agency (AGES); Member of the Scientific Advice Working Party (SAWP) of the EMA; Austria

- Panel members:

Julia SINGER, Chief Scientific Officer, Accelsiors CRO Ltd.; President of the Hungarian Society for Clinical Biostatistics, Hungary

Stephan LEHR, Biostatistician, Austrian Medicines and Medical Devices Agency; Former President of the Viennese Section of the International Biometric Society, Austria

VENUE



Join us for inspiration, discovery and meet leading biosimilar development experts at our professional forum! Participation is useful for research management, leadership and support teams working in and for biosimilars.

REGISTRATION FEES

- Two-day event: *€ 350 + VAT*
- 1st day courses only: *€ 275 + VAT*
- 2nd day only: *€ 125 + VAT*

WBS and *ISCB* members can attend the 2nd day symposium for free.

› **Tickets** are available at biosimsforum.com

DISCOUNTS

- **30% Early Bird** discount by 25th MAY,
- **15% Advance Round** discount by 01th SEP,

Book your seat as soon as possible because places are limited in number.

CONTACT

› event@accelsiors.com

LEARN MORE ABOUT OUR PREVIOUS EVENTS

The specialty of the event series is that it brings the regulators, industry leaders, clinical researchers as well as medical scientists together from around the world and provides an opportunity for a dialogue between them about their perspectives, the burning issues and challenges of biosimilars. Please, take a look at the lectures of our previous events, video interviews with the key speakers or photo galleries.

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