You are invited to

2nd Annual Biosimilars Forum

Statistical and Regulatory Perspectives in Bio- and Nanosimilar Development

Focus on the most actual challenges of biosimilar development

This unique forum will cover important issues and specific areas of debate facing clinical development teams biosimilars with a strong scientific focus on statistical and regulatory perspectives. It is particularly useful for those who are interested in constructive and open dialogue between medical statisticians, regulatory professionals, clinical researchers and sponsors with whom they collaborate.

5 – 6 OCTOBER, 2017 | Budapest

The 2nd annual event with participation of scientific experts and prominent professionals from the field of clinical research

This two-day series of events – a continuation of the very successful 1st Annual Biosimilar Forum from last year – consists of a **course day** (scheduled for October 5th) and a **professional symposium** (invited presentations and round table session, scheduled for October 6th) regarding hot topics related to the development of biosimilars.

SCIENTIFIC PROGRAMME COMMITTEE

Ildikó ARADI
Head of Clinical Development of Biologics, Gedeon Richter Plc; Vice-Chair, Medicines for Europe, Biosimilar Medicines Group

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

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

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

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

Vid STANULOVIC
Consultant, Clinical Development and Pharmacovigilance

KEYNOTE PRESENTATIONS

12 years of biosimilars in Europe: *What is the exposure and response in our learning curve?*

Andrea LASLOP
Unit Head, Austrian Medicines and Medical Devices Agency

Immune side effects of biologicals and nanomedicines: *unsolved issues in bio- and nanosimilar development*

János SZEBENI
Director of the Nanomedicine Research and Education Center, Semmelweis Medical University, Budapest

ORGANIZERS

Viennese Section of the International Biometric Society

Hungarian Society for Clinical Biostatistics

ACCELSIORS CRO Ltd.

SPEAKERS:

László ENDRÉNYI
Professor Emeritus of Pharmacology and Biostatistics, University of Toronto;

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

Andrea LASLOP
Unit head, Austrian Medicines and Medical Devices Agency

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

Stephan LEHR
Biostatistician, Austrian Medicines and Medical Devices Agency, President, Viennese Section of IBS

Johanna MIELKE
Biostatistician, Novartis Pharma AG

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

János SZEBENI
Director of the Nanomedicine Research and Education Center, Semmelweis Medical University, Budapest,

László TÓTFALUSI
Associate Professor, Faculty of Pharmacology, Semmelweis Medical University, Budapest

LEARN MORE at the website of the event!

www.biosimsforum.com

AGENDA:

1st day: COURSES with special lecturers

5th OCT, 2017

11:00 - 12:00	**Registration**
12:00 - 13:00	**Scientific factors in biosimilar product development** | *Presented by:* ***László Endrényi***
13:00 - 14:00	**Lunch break**
14:00 - 17:40	**Open issues in the assessment of bioequivalence and biosimilarity** *The course is lectured by:* ***Helmut Schütz***

Main topics of the Course:

- Unequal carry-over – "solved" in BE but still an Issue in Assessing Biosimilarity?
- Multi-Group and Multi-Site Studies. To pool or not to pool?
- Group-Sequential and Two-Stage Designs.
- Reference-scaling and Control of the Type I Error.

Schedule of the course:

14:00 - 15:00	1st part of COURSE
15:00 - 15:20	Coffee break: refreshments & networking
15:20 - 16:20	2nd part of COURSE
16:20 - 16:40	Coffee break
16:40 - 17:40	3rd part of COURSE

17:40 - 18:00	**Discussion**

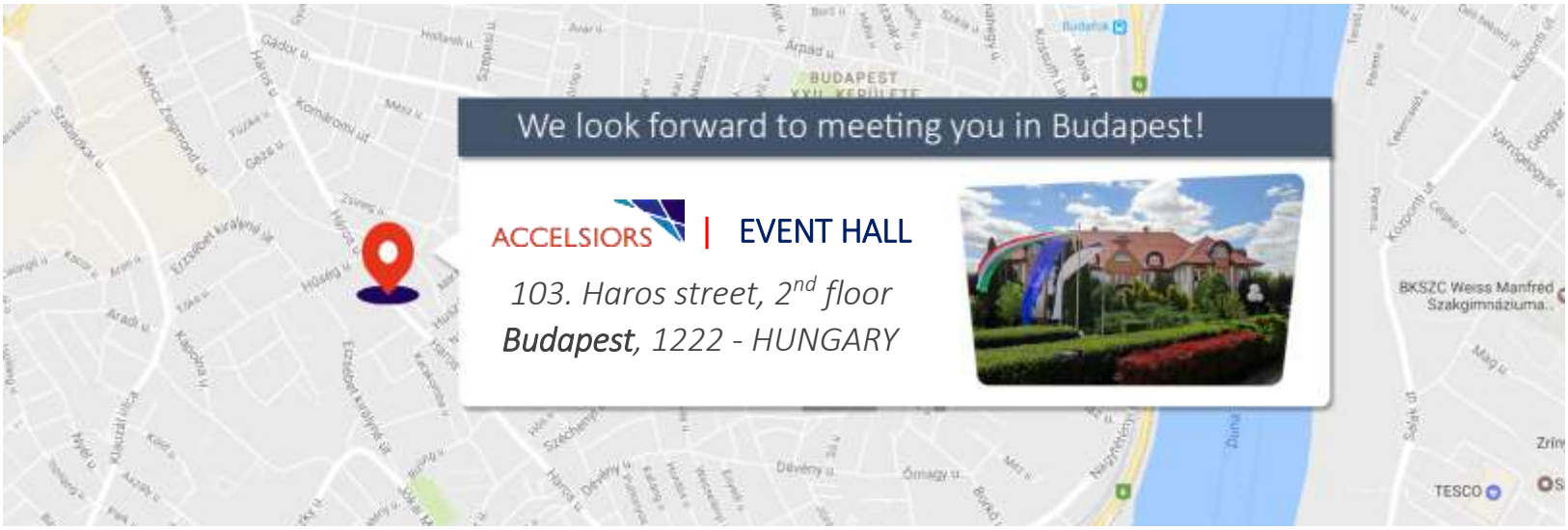
AGENDA

2nd day: SYMPOSIUM and ROUND TABLE

6th OCT, 2017

9:00 - 9:30	**Registration** (for those attending only day 2)
9:30 - 10:00	**Clinical trials for biosimilars in Europe: an updated systematic comparison of the clinical development programs** | *Presented by:* ***Johanna Mielke***
10:00 - 10:30	**Algorithms for evaluating reference scaled average bioequivalence: power, bias and consumer risk** | *Presented by:* ***László Tóthfalusi, László Endrényi***
10:30 - 11:00	**Investigating PK/PD in the steep ascending part of the dose response curve** | *Presented by:* ***Bernd Jilma***
11:00 - 11:30	**Coffee Break**
11:30 - 12:20	**1st Keynote lecture: 12 years of biosimilars in Europe: what's the exposure and response in our learning curve?** | *Presented by:* ***Andrea Laslop***
12:20 - 12:50	**Regulatory perspective on comparison of quality attributes in drug development** | *Presented by:* ***Ina-Christine Rondak, Stephan Lehr***
12:50 - 13:45	**Lunch Break**
13:45 - 14:25	**2nd Keynote lecture: Immune side effects of biologicals and nanomedicines: unsolved issues in bio- and nanosimilar development** | *Presented by:* ***János Szebeni***
14:25 - 14:45	**Coffee Break**
14:45 - 16:45	**Round table discussion** *Moderator:* ***Júlia Singer*** *(Chief Scientific Officer, Accelsiors Ltd.)* *Discussants:* ▪ Regulatory perspective: ***Stephan Lehr*** *(Biostatistician, Austrian Medicines and Medical Devices Agency)* ▪ Industry perspective: ***Heike Wöhling*** *(Head of Biostatistics, Sandoz Biopharmaceuticals)* *Panel members:* ▪ ***Ildikó Aradi*** *(Head of Clinical Development of Biologics, Gedeon Richter Plc., Vice-Chair, European Generic medicines Association - European Biosimilars Group)* ▪ ***Bernd Jilma*** *(Vice Chair, Department Clinical Pharmacology, Medical University of Vienna)* ▪ ***Franz König*** *(Associate Professor, Medical Unversity of Vienna, Section for Medical Statistics)* ▪ ***Andrea Laslop*** *(Unit Head, Austrian Medicines and Medical Devices Agency)* ▪ ***Johanna Mielke*** *(Biostatistician, Novartis Pharma AG)* ▪ ***Vid Stanulovic*** *(Consultant, Clinical Development and Pharmacovigilance)*

LOCATION OF THE EVENT



REGISTRATION FEES

- Two-day event: *300 Euros*
- 1st day course only: *250 Euros*
- 2nd day only: *100 Euros*

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

REGISTRATION DEADLINE

Please fill in the **Registration Form** on the webpage of the event and send us before

25th September 2017

- Website: www.biosimsforum.com
- Contact: event@accelsiors.com

About the 1st Biosimilars Forum (2016)

The very successful 1st Annual Biosimilars Forum was hosted in Budapest in the October of the last year by Acclesiors CRO with participation of international scientific experts such as *Shein-Chung Chow* (Professor of Duke University School of Medicine), *Prof Dr. László Endrényi* (Professor Emeritus of University of Toronto), and clinicians, statisticians and regulatory representatives gathered together from around the world to share with each other their perspectives on this hot topic of research in lectures and informal discussions. We had a successful and professionally fruitful event together, at its end the organizers expressed their intention to continue the series. Join us at Budapest in 5-6 of October, 2017 to continue this tradition!