



You are  
invited  
to



## 2<sup>nd</sup> 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 2<sup>nd</sup> 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 **day-long course** (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

#### ***+ One more planned presentation***

about **NANOSIMILAR** development  
presented by an invited special expert of  
this innovative field (Under preparation)

### ORGANIZERS



Viennese Section of  
the International  
Biometric Society



Hungarian Society for  
Clinical Biostatistics



Accelsiors CRO Ltd.

## PLANNED AGENDA

### 1st day: COURSES with special lecturers

 5<sup>th</sup> OCT, 2017

The program of the day will be lectured and supported by international experts. Main planned topics of the course day:



*Title of lecture:*

“Scientific factors in biosimilar product development” presented by

**Prof Dr. Laszlo ENDRENYI**

Professor Emeritus of Pharmacology and Statistics, **University of Toronto**,  
Former President of **Canadian Society for Pharmaceutical Scientists**



*Title of course:*

“Open issues in the assessment of bioequivalence and biosimilarity”  
lectured by

**Helmut SCHÜTZ**

Owner at BEBAC - **Consultancy Services for Bioequivalence and Bioavailability Studies**

### 2nd day: SYMPOSIUM and ROUND TABLE

 6<sup>th</sup> OCT, 2017


**FOCUS on Statistical and Regulatory Perspectives in Bio- and Nanosimilar Development**

Planned topics for presentations and discussions with participation of scientific experts and prominent professionals from the field of clinical research:

EMA "Statistics for quality comparison" reflection paper is out for public consultation (*problem statement, and feedback from industry received*)

- Recent developments in assessing biosimilarity
- Clinical study designs
- Update on the last year review of the development program of registered Biosimilars in the EU (based on the EPARs)

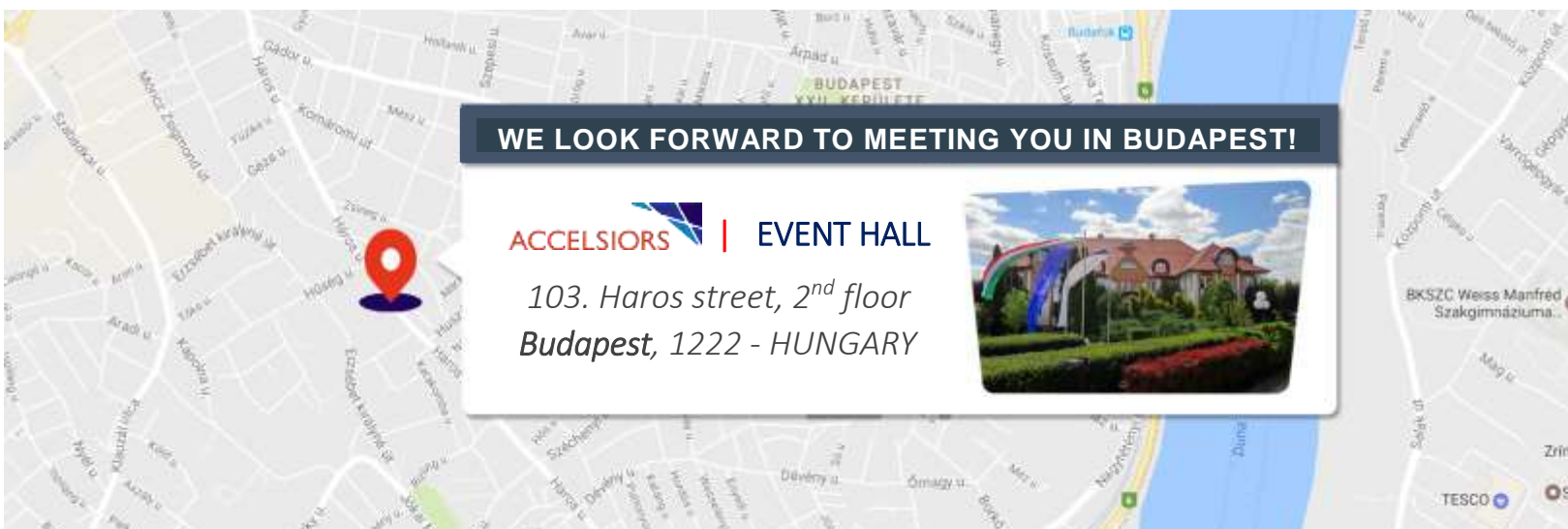
The final agenda and the list of lectures and speakers of the 2nd Biosimilars Forum is under preparation. The program of the event will be supported and complemented by international experts.

Please, visit the dedicated website of the event to learn more!



[www.biosimsforum.com](http://www.biosimsforum.com)

## LOCATION OF THE EVENT



## REGISTRATION FEES

- Two-day event: 300 Euros
- 1<sup>st</sup> day course only: 250 Euros
- 2<sup>nd</sup> day only: 100 Euros

WBS and ISCB members can attend the 2<sup>nd</sup> day symposium **for free**.

## REGISTRATION DEADLINE

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

**25<sup>th</sup> September 2017**

- Website: [www.biosimsforum.com](http://www.biosimsforum.com)
- Contact: [event@accelsiors.com](mailto:event@accelsiors.com)

## About the 1<sup>st</sup> Biosimilars Forum (2016)



The very successful 1<sup>st</sup> Annual Biosimilars Forum was hosted in Budapest in the October of the last year by Accelsiors 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!