3rd Annual Biosimilars Forum

Statistical and Regulatory Perspectives in Bio- and Nanosimilar Development

2018

25–27 OCTOBER | **Budapest,** Hungary

World's prominent drug development experts will return to Budapest to the 3rd Annual Biosimilars Forum

• *Day 1:*	• *Day 2:*	• *Day 3:*
PK short courses	**Clinical studies and regulatory questions**	**Nanosimilars**

Join us for discovery, networking and inspiration at our 3rd professional event in a row, and focus on statistical and regulatory perspectives in bio- and nanosimilar development with leading experts from the fields of regulatory, academic and clinical research.

www.biosimsforum.com

3rd annual event with participation of subject matter experts and prominent professionals from the field of clinical research

This three-day series of events consists of a COURSE day with two professional masterclass sessions, a SYMPOSIUM day (invited presentations and round table discussion), and a SEMINAR DAY (lectured by special experts from the field of nanotechnology-formulated drug development), comprising issues in Bio- and Nanosimilar development.

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

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

KEYNOTE PRESENTATIONS

Regulatory Keynote Presentation:

The biosimilar concept revisited – is there a need for change?

Andrea LASLOP
Unit Head, Austrian Medicines and Medical Devices Agency

Scientific Keynote Presentation:

Bioequivalence of highly variable drug products – an update

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

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

Andrea LASLOP
Unit head, Austrian Medicines and Medical Devices Agency

Raj BAWA
President of Bawa Biotech LLC; Founding Director of American Society for

Emmanuelle VINCENT
Head of Biostatistics and Data Management, Fresenius-Kabi

Ludwig A. HOTHORN
Professor of Biostatistics at Leibniz Universität Hannover, Faculty of Natural Sciences,

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

Gert STORM
Professor of Targeted Nanomedicine at the University of Utrecht;

Thomas JAKI
Professor of Statistics, Medical and Pharmaceutical Statistics, Lancaster University

Phillip PALLMANN
Deputy Director Research Design and Conduct Service, Cardiff University

Johanna MIELKE
Early Stage Research Fellow, IDEAS Innovative Training Network

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

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

Marina A. DOBROVOLSKAIA
Senior Principal Scientist and Head of the Immunology Section at the Nanotechnology Characterization Laboratory

AGENDA

PK COURSE DAY

25 OCT, 2018

with 2 professional course sessions on *statistical and pharmacokinetical aspects of biosimilarity assessment*, will be delivered by prominent biosimilar research expert scientists. Please, click here to reach the abstracts of the courses!

SYMPOSIUM DAY

26 OCT, 2018

with invited professional presentations, posters and round table session, will be focusing on *statistical and regulatory perspectives in bio- and nanosimilar development*, presented by leading experts from the fields of regulatory, academic and clinical research.

SEMINAR DAY

in Nanomedicines

27 OCT, 2018

NEW IN 2018: the 3rd-day consists of professional Seminar sessions regarding *current perspectives of bio- and nanosimilar drug development*, will be lectured by special international experts from the field of nanotechnology-formulated research.

1st DAY AGENDA

PK SHORT COURSES with special lecturers

25th OCT, 2018

8:30 - 9:00	**1st day Registration**
9:00 - 12:30	**MORNING COURSE SESSION** **Uni- and multivariate Bioequivalence of PK parameters** *Lecturers of the Course Session: Thomas JAKI and Phillip PALLMANN* *Schedule of the course:* 9:00 – 10:00 | 1st part of COURSE 10:00 – 10:20 | Coffee break: refreshments & networking 10:20 – 11:20 | 2nd part of COURSE 11:20 – 11:40 | Coffee break: refreshments & networking 11:40 – 12:30 | 3rd part of COURSE
12:30 - 14:00	**Lunch break**
14:00 - 17:30	**AFTERNOON COURSE SESSION** **Statistical aspects of equivalence testing for biosimilar studies: multiple, differently-scaled endpoints** *Lecture of the Course Session: Ludwig A. HOTHORN* *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 - 17:30 | 3rd part of COURSE
17:30 - 18:00	**Discussion**

ABSTRACTS are available at www.biosimsforum.com

2nd DAY AGENDA

SYMPOSIUM DAY: Clinical studies and regulatory

26th OCT, 2018

9:00 - 9:30	**Registration** (for those attending only day 2)
9:30 - 9:50	*Johanna MIELKE:* **An update on development strategies of recently approved biosimilars in Europe**
9:50 - 10:30	*Scientific Keynote Presentation* | *László ENDRÉNYI (Co-author: László TÓTHFALUSI):* **Bioequivalence of highly variable drug products – an update**
10:30 - 10:50	*Ágnes GYURASICS:* **Challenging issues in extrapolation of totality of evidence to pediatric indications in case of biosimilars**
10:50 - 11:10	**Coffee break: refreshments & networking**
11:10 - 11:50	*Regulatory Keynote Presentation* | *Andrea LASLOP:* **The biosimilar concept revisited – is there a need for change?**
11:50 - 12:10	*Emmanuelle VINCENT:* **Opportunities and limitations of a blinded sample size reassessment in biosimilars development**
12:10 - 12:40	*Johanna MIELKE:* **Incorporating historical information in biosimilar trials: Challenges and a hybrid Bayesian-frequentist approach**
12:40 - 14:00	Lunch break
14:00 - 14:40	*János SZEBENI:* **Animal models of immunogenicity and immune toxico-equivalence testing of nano-biopharmaceuticals** | *Presented by:*
14:40 - 15:10	*Heike WOEHLING:* **How the increase of assay sensitivity influences the immunogenicity**
15:10 - 15:30	Coffee break: refreshments & networking
15:30 - 17:30	**Round table discussion** Moderator: *Helmut SCHÜTZ* Discussants: ▪ Regulatory perspective: *Andrea LASLOP* ▪ Industry perspective: *Heike WOEHLING* Panel members: ▪ *Ildikó ARADI* ▪ *Ágnes GYURASICS* ▪ *Júlia SINGER* ▪ *Emmanuelle VINCENT* ▪ *Johanna MIELKE*

3rd DAY AGENDA

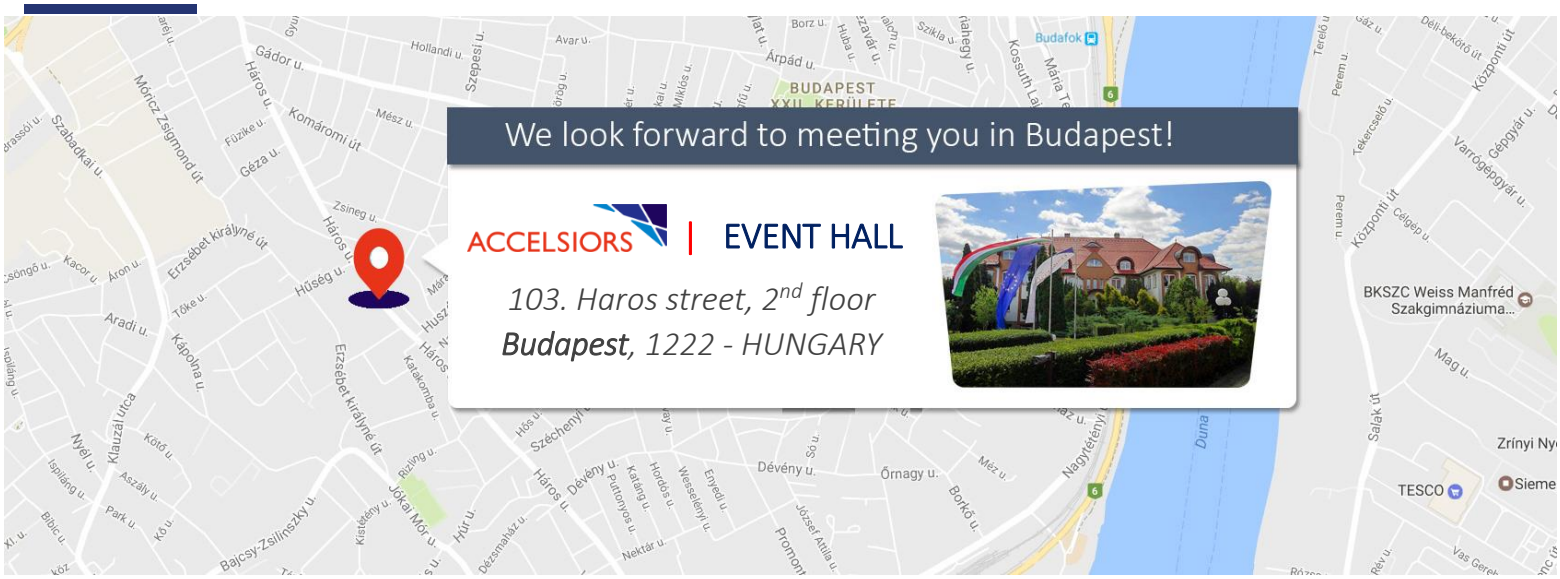
SEMINARS in Nanomeicines

27th OCT, 2018

9:00 - 9:30	**3rd day Registration**
9:30 - 12:30	**MORNING SEMINAR SESSION** **The Era of Biosimilars and Nanosimilars: Current Perspectives** *Lecture of the Seminar: Raj BAWA* *Schedule of the course:* 9:30 – 10:30 | 1st part of Seminar 10:30 – 11:00 | Coffee break: refreshments & networking 11:00 – 12:30 | 2nd part of Seminar
12:30 - 13:30	**Lunch break**
13:30 - 14:15	*Marina A. DOBROVOLSKAIA:* **The immunological characterization of nanotechnology-formulated drugs**
14:15 - 14:30	**Coffee break: refreshments & networking**
14:30 - 15:15	*Gert STORM:* **Targeted Nanomedicine: State of Art and Future Developments**
15:15 - 15:30	**Coffee break: refreshments & networking**
15:30 - 16:30	**Panel discussion** Moderator: *János SZEBENI* Panel members: ▪ *Raj BAWA* ▪ *Gert STORM*

LEARN MORE at the website of the event! www.biosimsforum.com

LOCATION OF THE EVENT



The forum is built on a modular basis, each module can be attended independently from the others. Book your place as soon as possible because places are limited in number!

REGISTRATION FEES

- 3-day event pass: *€ 400*
- Two-day event: *€ 300*
- 1st day courses only: *€ 250*
- 2nd day only: *€ 100*
- 3rd day only: *€ 150*

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

19th of October, 2018

CONTACT

- Contact: event@accelsiors.com

LEARN MORE ABOUT OUR PREVIOUS EVENTS

At the Annual Biosimilars Forum event series, clinicians, statisticians and regulatory representatives gathered together from around the world to share with each other their perspectives on this key topic of research.

Click on the button below and take a look at the professional lectures of our events, short video interviews with the key speakers, photo galleries and more.

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