2nd Annual Biosimilars Forum

Statistical and Regulatory Perspectives in Bio- and Nanosimilar Development

5-6 October, 2017, Budapest, Hungary

Focus on the most actual challenges of Bio- and Nanosimilar development

Accelsiors CRO Ltd. has partnered with the Viennese Section of the International Biometric Society and the Hungarian Society for Clinical Biostatistics once again to deliver this scientific forum for research management, leadership and support teams working in and for biosimilar drug development.

This unique forum will cover important issues and specific areas of debate facing clinical development teams specialized on 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.

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 Biosimilars Forum in Budapest from last year – consists of a day-long course (on October 5th) and a professional symposium (invited presentations and round table session, scheduled for October 6th) regarding hot topics related to the drug development of biosimilars. The program of the event will be supported and complemented by international subject experts.

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, Vienna Biometric Section of IBS)
- Julia SINGER (Chief Scientific Officer, Acclesiors; President, Hungarian Society for Clinical Biostatistics)
- Vid STANULOVIC (Consultant, Clinical Development and Pharmacovigilance)

Keynote presentations:

1. "**12 years of biosimilars in Europe**: what is the exposure and response in our learning curve?" - presented by Andrea LASLOP (Unit Head, Austrian Medicines and Medical Devices Agency);
2. "**Immune side effects of biologicals and nanomedicines**: unsolved issues in bio- and nanosimilar development" – presented by Prof. Janos Szebeni (Director of the Nanomedicine Research and Education Center at Semmelweis Medical University, Budapest)

AGENDA:

- **5th October, 2017 - Professional Course with special lecturer:**

- "Scientific factors in biosimilar product development" – The lecture is presented by: Laszlo ENDRENYI (Professor Emeritus of Pharmacology and Statistics, University of Toronto, Former President of Canadian Society for Pharmaceutical Scientists)
- "Open issues in the assessment of bioequivalence and biosimilarity" – The course is lectured by: Helmut SCHÜTZ (Owner at BEBAC – Consultancy Services for Bioequivalence and Bioavailability Studies)

- **6th October, 2017 - Symposium and Round Table**
  Planned topics for presentations and discussions with a strong professional focus on Statistical and Regulatory Perspectives in Biosimilar Development:
  - EMA "Statistics for quality comparison" reflection paper is out for public consultation
  - Recent developments in assessing biosimilarity
  - Update on the last year review of the development program of registered Biosims in the EU (based on the EPARs)

  Some professional lectures from the programme of the day:

  - "Investigating PK/PD in the steep ascending part of the dose response curve" - presented by Bernd JILMA (Vice Chair, Department Clinical Pharmacology, Medical University of Vienna)
  - "Statistical considerations in the biosimilarity assessment of quality attributes" - presented by Stephan LEHR (Biostatistician, Austrian Medicines and Medical Devices Agency, President, Viennese Section of IBS)
  - „Regulatory perspective on comparison of quality attributes in drug development" - presented by Ina-Christine RONDAK (Biostatistician, Seconded National Expert from Klinikum rechts der Isar of Technische Universität München to EMA)
  - "Algorithms for evaluating reference scaled average bioequivalence: Power, bias and consumer risk" László Tóthfalusi (Associate Professor, Faculty of Pharmacology, Semmelweis Medical University of Budapest) (co-author: Laszlo Endrenyi)
  - "Clinical trials for biosimilars in Europe: an updated systematic comparison of the clinical development programs" - presented by Johanna MIELKE (Biostatistician, Novartis Pharma AG)

  WBS and ISCB members can attend the second day symposium for free.

Registration deadline: 25th September, 2017

LOCATION: Accelsiors CRO Services Ltd., 103. Háros Street, 1222 Budapest, Hungary

For more information, please visit http://www.biosimsforum.com/. We look forward to meeting you in Budapest!

Contact: event@accelsiors.com

- **Press pack:**biosimsforum.com/press-kit
- 1st Biosimilars Forum Aftermovie

About the Organizers:

The Annual Biosimilars Forum event series was founded in 2016 by two prestigious Central European scientific societies, the Viennese Section of the IBS and the Hungarian Society for Clinical Biostatistics

in cooperation with the Accelsiors CRO Ltd., aimed at increasing effectiveness of clinical research and in order to provide even more effective support in sharing of recent scientific and practical knowledge for biosimilar drug development professionals.

- The Viennese Section of the International Biometric Society is part of the ROeS, the Austrian Swiss Region of the International Biometric Society. WBS is a non-profit organization which provides a professional forum for discussions of how to apply statistical methods in biological and medical science.
- The Hungarian Society for Clinical Biostatistics is a national group of ISCB, and it was founded to stimulate research into the principles and methodology used in the design and analysis of clinical research and to increase the relevance of statistical theory to the real world of clinical medicine.
- Accelsiors – as a scientific driven CRO – has been a committed supporter of biosimilar drug development. Many of their professionals were involved into biosimilar drug development from the early beginnings, guided and managed the first biosimilar development projects and professionally supporting clinical trials as well as registration in this innovative field and being active in the clinical research arena in the past two decades.