**Press Release:**

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**World’s prominent biosimilar development experts have returned to Budapest to the 2nd Annual Biosimilars Forum on 5 – 6 October, 2017.**

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

The professionally very fruitful 2nd Biosimilars Forum was hosted in Budapest, 5 – 6 October, 2017 by Accelsiors CRO with participation of internationally renowned experts of biosimilar drug development such as Prof. Dr. László Endrényi (Professor Emeritus of University of Toronto), Andrea Laslop (Head of Scientific Office, Austrian Medicines and Medical Devices Agency), Helmut Schütz (Owner at BEBAC – Consultancy Services), and clinical researchers, biostatisticians, regulatory professionals and sponsors from around the world.

This year’s two-day forum covered important issues and specific areas of debate facing clinical development teams specialized on biosimilars. The program of the event was very comprehensive and integrated multiple perspectives on current biosimilar research.

**Focused on statistical and regulatory perspectives of biosimilar development**

The 2nd Annual Biosimilars Forum welcomed László Endrényi Professor Emeritus from the University of Toronto who presented a lecture about Scientific factors in biosimilar product development. A very substantial course was delivered by Helmut Schütz, owner at BEBAC – Consultancy Services, who gave a detailed overview about open issues in the assessment of bioequivalence and biosimilarity.

The EMA regulatory expert Andrea Laslop showcased her keynote presentation about the 12 years of biosimilars in Europe and provided an essential understanding of the European regulatory framework. The regulatory part of the forum was further strengthened by Ina-Christine Rondak’s lecture (Seconded National Expert from Technische Universität München to EMA), she presented a useful overview of regulatory perspective on comparison of quality attributes in drug development.

As a very interesting novelty in this year’s program Prof. Janos Szebeni, Director of the Nanomedicine Research and Education Center delivered a keynote presentation about the immune side effects and unsolved issues in bio- and nanosimilar development.

The program of the event gave deep insight into the statistical perspective of biosimilar research. The prominent lecturers such as László Tóthfalusi (Associate Professor of Semmelweis Medical University), Bernd Jilma (Vice Chair, Department Clinical Pharmacology, Medical University of Vienna) and Johanna Mielke (Biostatistician at Novartis Pharma AG) provided an overview about scientific principles and methodologies used in the design and analysis of biosimilar studies as well as their recent industry experiences.

The members of the round table section from industry, regulatory and academic site had a really fruitful and constructive discussion both on actual challenges and open issues of biosimilar development. The participants of this open discussion such as Stephan Lehr (Biostatistician, Austrian Medicines and Medical Devices Agency and President of Viennese Section of IBS), Heike Wöhling (Head of Biostatistics, Sandoz Biopharmaceuticals), Ildikó ARADI (Head of Clinical Development of Biologics, Gedeon Richter Plc., Vice-Chair, European Generic medicines Association – European Biosimilars Group), Franz KÖNIG (Associate Professor at Medical Unversity of Vienna, Section for Medical Statistics), Vid STANULOVIC (Consultant, Clinical Development and Pharmacovigilance) had a highly constructive conversation about regulatory and industry perspectives of biosimilars, recent developments, as well as about essential statistical methods and high-level research.

The organizers are delighted that they could establish an opportunity with this event series for a constructive and open dialogue between medical statisticians, regulatory professionals, clinical researchers and sponsors with whom they collaborate and many interested people visited the event to learn and network. Visitors could take part in the experience with some of the world’s most prominent experts of this innovative field who gave a detailed overview in biosimilar product development and gave a guidance how to adjust clinical research practice to effective legislation or vice versa, raised ideas on how legislation could be developed further to meet the challenges this quickly developing field pose.

The organizers of the 2nd Annual Biosimilars Forum are proud that they once more had the chance to support biosimilar development professionals and they have assisted in sharing of recent scientific and practical knowledge aimed at increasing effectiveness of drug research.

**Contact:** event@accelsiors.com

**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.