

You are
invited
to



1st ANNUAL BIOSIMILARS FORUM ACCELSORS

6 – 7 OCTOBER 2016

This two-day event is targeted at clinical research professionals working in the area of biosimilars.

Accelsiors
Háros Street 103, Budapest 1222 Hungary

Topics will include current issues and challenges confronting researchers in this important field. The objective is to provide participants with an environment to engage in open and constructive dialogue with like colleagues to facilitate collaboration.

Organizers:

Accelsiors Ltd

Wiener Biometrische Sektion

Hungarian Society for
Clinical Biostatistics

Design and Analysis of Biosimilars



Instructor:

Shein-Chung Chow,
PhD

Professor

Special lecturer

Department of Biostatistics and Bioinformatics
Duke University School of Medicine

COURSE AGENDA

6 October 2016 afternoon

Lecture 1:

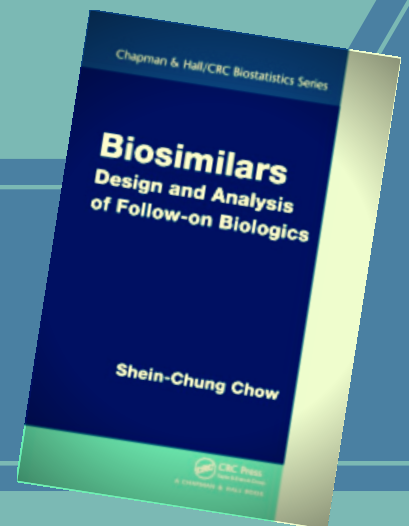
Assessing Biosimilarity: Issues and Recent Developments

Lecture 2:

Assessing Interchangeability: Issues, Designs, and Statistical methods

Lecture 3:

Analytical Similarity Assessment in Biosimilar Studies



The presentation materials will be developed based on the 3rd edition of the book entitled

“Design and Analysis of Bioavailability and Bioequivalence Studies” by Chow SC and Liu JP published in 2008 which was by Chapman and Hall/CRC Press, Taylor & Francis, New York and the book entitled **“Biosimilars: Design and Analysis of Follow-on Biologics”** by Chow SC published in 2013, which was also published by Chapman and Hall/CRC Press, Taylor & Francis, New York.

SYMPOSIUM AGENDA

7 October 2016

Morning session

Selected presentations

- **Interchangeability of biological drug products**

László Endrényi (Professor Emeritus of pharmacology and statistics, University of Toronto)

László Tóthfalusi

(Associate Professor, Faculty of Pharmacology, University of Budapest)

- **Clinical trials for authorized biosimilars in the European Union: A systematic review**

Johanna Mielke (Novartis)

Bernd Gilma (Vice Chair, Department of Clinical Pharmacology, Medical University Vienna)

Franz Koenig (Associate Professor, Medical University Vienna)

Byron Jones (Novartis)

Afternoon session

Round table with invited clinical experts

REGISTRATION DEADLINE

25 Sept 2016

REGISTRATION FEES:

Two-day event:	300 Euros
Short course only (first day):	250 Euros
Second day only:	100 Euros



For Free

**WBS and ISCB members can attend the symposium
(second day)**

This event is adjacent to another important international meeting in Budapest: Challenges in the Assessment of Similarity or Equivalence of Biologicals and Complex Drugs, October 10-11 (SRACD 2016)

http://sracd.hu/wp-content/uploads/2014/08/SRACD2016_FirstCircular_online.pdf

CONTACT:
il.kovacs@accelsiors.com



Háros street 103, 1222 Budapest



We look forward
to meeting you
in Budapest!

Accelsiors team