



“Alexandru Ioan Cuza” University of Iasi
Faculty of Computer Science

“Lucian Blaga” University
Faculty of Medicine

Statistical Perspective in Medicine and Pharma Industry

6th – 8th November 2014

Faculty of Medicine, “Lucian Blaga” University of Sibiu

Invited speakers:

David W Warne - “Bayesian Methods for Binomial Data” and “Biostatistics Quality Matters”

Anca Vitcu - “An Introduction to Statistical Analysis of Network Data in Medical and Pharmacological Systems Research”

Organizing Committee:

Liana Bera (Faculty of Medicine, “Lucian Blaga” University, Sibiu)

Gabriela Cioca (Faculty of Medicine, “Lucian Blaga” University, Sibiu)

Felicia Gligor (Faculty of Medicine, “Lucian Blaga” University, Sibiu)

Loredana Vonica Gligor (Faculty of Medicine, “Lucian Blaga” University, Sibiu)

Anca Ignat (Faculty of Computer Science, “Alexandru Ioan Cuza” University of Iasi)

Silviu Morar (Faculty of Medicine, “Lucian Blaga” University, Sibiu)

Manuela Pumnea (Faculty of Medicine, “Lucian Blaga” University, Sibiu)

Corina Vernic (“Victor Babes” University of Medicine and Pharmacy, Timisoara)

Anca Vitcu (Faculty of Computer Science, “Alexandru Ioan Cuza” University of Iasi)

Event developed under the aegis of the International Society for Clinical Biostatistics (ISCB).

Description

The three short courses set up on a laboratory learning environment will include case studies and practical sessions on network analysis and biostatistics in medicine and the pharma industry – the current and future challenges.

Biographic Details

David W Warne, BSc, MSc, PhD, CStat

Consultant biostatistician, with more than 20 successful years experience in clinical development, directing the statistical aspects of phase 1-4 clinical trials, expert in process and quality management, with a long lasting collaboration in leading positions with Pharma companies as Serono (1995-2006, Geneva) and Merck Serono (2007-2013, Geneva).

Dr. David W Warne helped create successful submission packages for health authorities in US, EU and Japan, designed and ran studies with innovative statistical methodology, provided the statistical perspective in cross-functional teams working on process improvement. He had an important role in the industry review of health authority statistical and clinical guidance documents, e.g. (Draft Guidance for Industry Guidance on Adaptive Design Clinical Trials for Drugs and Biologics [FDA, 2010]; Draft Guidance for Industry on Non-Inferiority Clinical Trials [FDA, 2010]; Guideline on non-clinical and clinical development of similar biological medicinal products containing recombinant human follicle stimulating hormone (r-hFSH) [EMA, 2010]). During his career, Dr. Warne was involved in outsourcing work to Japan, Africa, India and Europe, and participated in a number of audits in Australia and Europe.

After over 20 years of dedicated work in ISCB, since 1992 as Executive Committee Member, Newsletter Editor, Webmaster, Secretary, Vice-President, Dr. David W Warne will soon become ISCB President for 2015-16.

Anca Vitcu, PhD

Associate Professor, collaborate with the Faculty of Computer Science, “Alexandru Ioan Cuza” University of Iasi since 2002 on training and research programmes approaching topics like stochastic processes, complex adaptive systems modeling, social network analysis. Dr. Vitcu had a lengthy and fruitful cooperation as sampling and data analysis adviser with UN Agencies (WHO (Geneva), UNICEF (Bucharest), UNECE (Geneva), UNDP (Bucharest)), national and international non-governmental organizations (Romanian National Institute of Statistics (Bucharest), National Institute of Public Health (Bucharest), International Center for Migration, Health and Development (Geneva)), Governmental Institutions (Romanian Parliament (Commission for European Integration), Institute for Research and Crime Prevention (Ministry of Interior)) being involved in key projects focused on social and epidemiological related issues. Since 2010 she is coordinating the Romanian National Group of the International Society for Clinical Biostatistics, and since 2011 is acting as Secretary of the ISCB National Groups Subcommittee.

Representative of the Organizing Committee

Liana Bera, PhD

Associate Professor at the Faculty of Medicine („Lucian Blaga” University, Sibiu), Head of the Medical Informatics and Biostatistics Department, member of the European Federation of Medical Informatics and network coordinators of the Romanian National Group of the International Society for Clinical Biostatistics, dr. Bera published 110 scientific articles in the fields of medical informatics and biostatistics, and was involved as task force member in a number of national and international projects.

Outline and Schedule

Thursday, 6 November

Session I

9:00-9:30 Introduction

Session II

9:30-10:30 Bayesian Methods for Binary Data (Part I) – David W Warne

10:30-11:00 Q & A

11:00-11:30 *Coffee Break*

Session III

11:30-13:00 Bayesian Methods for Binary Data (Part II) – David W Warne

13:00-13:30 Q & A

13:30-15:00 Lunch

Session IV

15:00-16:30 Overview on Network Analysis – Anca Vitcu

16:30-17:00 Q & A

17:00 + team building, visits, dinner

Friday, 7 November

Session V

9:00-10:30 Biostatistics Quality Matters (Part I) – David W Warne

10:30-11:00 Q & A

11:00-11:30 *Coffee Break*

Session VI

11:30-13:00 Biostatistics Quality Matters (Part II) – David W Warne

13:00-13:30 Q & A

13:30-15:00 Lunch

Session VII

15:00-16:30 Analysis of Complex Networks in Medical and Pharmacological Systems Research –
Anca Vitcu

16:30-17:00 Q & A

17:00 + team building, visits, dinner

Saturday, 8 November

Session VIII

Workshop "Biostatistics and Pharma – Moving East?"

9:00- 9:30 "Success stories" – David W Warne

9:30-11:00 Academic community and Pharma companies presentations – coord. Liana Bera

11:00-11:30 "ISCB, past, present and future" – David W Warne

11:30-12:00 "ISCB-RNG challenges" – Anca Vitcu

12:00 + – Social events

Participation fee: 50 RON

The fee payment is allowed until 3rd November 2014, in the following account:

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Details to be mentioned: ISCB course, 6-8 November 2014, Sibiu, participant name

Contact persons:

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Sponsors: ISCB, ISCB-Romanian National Group