

## 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He had an important role in the industry review of health authority statistical and clinical guidance documents, e.g. (Draft Guidance for Industry Guidance on Adaptive Design Clinical Trials for Drugs and Biologics [FDA, 2010]; Draft Guidance for Industry on Non-Inferiority Clinical Trials [FDA, 2010]; Guideline on non-clinical and clinical development of similar biological medicinal products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 3<sup>rd</sup> November 2014, in the following account:

**Name: Fundația „Alumni – Universitatea Alexandru Ioan Cuza din Iași”**

**Cont RON:**

IBAN: RO90BRDE240SV76562202400

BRD Suc. Iași

Str. Anastasie Panu 1B – 2A

SWIFT BRDEROBU

BIC BRDE

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

**Only for the Romanian pharmacists** (optional) - please see the attachment

**“Colegiul Farmaciștilor din România” offers 18 hours of lifelong pharmaceutical learning.**

**Fee for credits: 15 RON<sup>\*)</sup>**

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

**Cont RON:**

IBAN: RO45BACX0000000036832250

Unicredit Tiriac Bank, sucursala Unirea

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

**<sup>\*)</sup> the fee for lifelong pharmaceutical learning credits is additional to the participation fee**

#### **Contact persons:**

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**Sponsors:** ISCB, ISCB-Romanian National Group



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**COMISIA PROFESIONAL – ȘTIINȚIFICĂ**

Către,

**ISCB ROMANIAN NATIONAL GROUP**

**Nr.450/16.10.2014**

Ca urmare a solicitării dvs., Comisia Profesional - Științifică a Colegiului Farmaciștilor din România a acordat **18 ore de Educație Farmaceutică Continuă** farmaciștilor participanți la Cursul cu titlul „Statistical Perspective in Medicine and Pharma Industry”; manifestarea se va desfășura în perioada 6-8 noiembrie 2014 la Universitatea „Lucian Blaga” din Sibiu, Facultatea de Medicină.

De asemenea, vă comunicăm că, în conformitate cu prevederile Deciziei Nr. 4/2008 a Consiliului Național al Colegiului Farmaciștilor din România, se percepe taxa de creditare în valoare de 15 lei/ participant, plătită în contul Colegiului Farmaciștilor din România, Cod IBAN: RO45 BACX 0000 0000 3683 2250, deschis la Unicredit Ţiriac Bank, sucursala Unirea.

**Cu stimă,**

**PREȘEDINTELE  
COLEGIULUI FARMACIȘTILOR DIN ROMÂNIA  
Prof. Univ. Dr. Farm. LUPULIASA DUMITRU**

