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IULIU HATIEGANU
CLUJ-NAPOCA



FACULTY of MEDICINE
DEPARTMENT of
NEUROSCIENCES



THE SOCIETY FOR THE STUDY OF
NEUROPROTECTION AND
NEUROPLASTICITY



**International
School of Neurology**

Seminars

Statistical Concepts in Clinical Studies II

**Department of Neurosciences
University of Medicine and
Pharmacy "Iuliu Hatieganu"
Cluj-Napoca | Romania**

**DECEMBER 9 -10, 2013
"Ion Minea" Auditorium / Clinic of Neurology
CLUJ-NAPOCA | ROMANIA**

Welcome Address

It is a pleasure to welcome you to the 8th edition Seminars of the Neurosciences Department, "Statistical Concepts in Clinical Studies II", December 9-10, 2013. The seminars are hosted by the Department of Neurosciences, Faculty of Medicine, University of Medicine and Pharmacy "Iuliu Hațieganu" Cluj-Napoca.

These seminars aim to establish a highly useful framework enabling local specialists to benefit from the expertise of our invited speakers who are part of associated international faculty of our Department of Neurosciences. Our goal is to flourish over years and set up an educational network tool meeting our junior and senior specialists' needs.

In contrast to large international conferences, the intention behind these seminars is to create an informal and intimate setting, which hopefully will stimulate open discussions. As organizers, we would therefore be deeply grateful if you participate and share your time with us.

We are looking forward to your active participation in this educational event!

With consideration,

Prof. Dr. Dafin F. Mureșanu,
Chairman Department of Neurosciences, Faculty of Medicine,
University of Medicine and Pharmacy "Iuliu Hațieganu",
Cluj Napoca, Romania



Dafin F. Mureșanu



Organizers



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THE SOCIETY FOR THE STUDY OF
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The Society for the Study of
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**International
School of Neurology**

International School of Neurology



Speaker

Born, 1952, he specialized in Veterinary Medicine between 1971 and 1974 at the University in Munich, then changed to the University in Cologne in 1974 and specialized in Human Medicine from 1974 to 1980. In 1976 to 1979, he additionally studied biometric methods for pharmacology and clinical research at the Institute for Data Analysis and Study Planning in Munich.

While studying human medicine, he completed research work on pattern recognition in the visual brain and developed a pharmacodynamic Neuron Simulation Model at the Institute for Medical Documentation and Statistics of the University at Cologne.

From 1985 to 1995, he was member of the Ultrahigh Dexamethasone Head Injury Study Group and leading biometrician of the German GUDHIS Study.

Since 1982 he holds advanced training courses on biometry for professionals in clinical research and university establishments. His work also involves human engineering of biometric software and GCP-compliant tutorials for biometric appraisal of clinical studies.

Since 1995 he cooperates closely with the Institute for Data Analysis and Study Planning as Senior Consultant for Biometry & Clinical Research. He planned and evaluated about 150 randomized clinical studies worldwide and is member of various international advisory boards including participation as biometric expert in regulatory authority panels and in FDA, EMEA, and BfArM hearings.



**JOHANNES C.
VESTER**
/GERMANY



Scientific Program



Scientific Program

December 9th, 2013

“Ion Minea” Auditorium / Clinic of Neurology

09:00 - 10:00

Hypothesis Testing and Statistical Significance:
The Basic Concept of a Statistical Test (Part I)
/ Johannes C. Vester (Germany)

10:00 - 11:00

Hypothesis Testing and Statistical Significance:
The Basic Concept of a Statistical Test (Part II)
/ Johannes C. Vester (Germany)

11:00 - 11:30

Coffee Break

11:30 - 12:30

P-Values, Effect Sizes and Confidence Intervals: Definition and
Handling in Superiority and Non-Inferiority Trials (Part I)
/ Johannes C. Vester (Germany)

12:30 - 13:30

P-Values, Effect Sizes and Confidence Intervals: Definition and
Handling in Superiority and Non-Inferiority Trials (Part II)
/ Johannes C. Vester (Germany)

13:30 - 14:30

Lunch

14:30 - 15:30

Definition and interpretation of common effect sizes for binary,
ordinal and continuous data:
rate difference, odds ratio, mean, median, Mann-Whitney (Part I)
/ Johannes C. Vester (Germany)

15:30 - 16:30

Definition and interpretation of common effect sizes for binary,
ordinal and continuous data:
rate difference, odds ratio, mean, median, Mann-Whitney (Part II)
/ Johannes C. Vester (Germany)

20:00

Welcome reception

December 10th, 2013

“Ion Minea” Auditorium / Clinic of Neurology

09:00 - 10:00

Meta-Analyses:
Basic concept, how to read forest-plots, common traps. (Part I)
/ Johannes C. Vester (Germany)

10:00 - 11:00

Meta-Analyses:
Basic concept, how to read forest-plots, common traps. (Part II)
/ Johannes C. Vester (Germany)

11:00 - 11:30

Coffee Break

11:30 - 12:30

Proper Interpretation of Study Results:
Examples from Recent TBI Trials (Part I)
/ Johannes C. Vester (Germany)

12:30 - 13:30

Proper Interpretation of Study Results:
Examples from Recent TBI Trials (Part II)
/ Johannes C. Vester (Germany)

13:30 - 14:30

Lunch

14:30 - 15:30

Quality assurance in clinical studies: modern risk-based approaches.
Practical examples from interactive study conduct control (ISCCS®)
revealing common traps and problems. (Part I)
/ Johannes C. Vester (Germany)

15:30 - 16:30

Quality assurance in clinical studies: modern risk-based approaches.
Practical examples from interactive study conduct control (ISCCS®)
revealing common traps and problems. (Part II)
/ Johannes C. Vester (Germany)

20.30

Dinner



Abstracts



Abstracts

The primary goal of the statistical lectures is to provide non-statisticians with a basic understanding of the interconnections and relationships which are important in practice and the ability to implement and apply this basic knowledge in the proper interpretation of study results.

The lectures will address the following issues:

1. Effect sizes and confidence intervals: Basic principles and interpretation. Relationship with significance tests. Definition and handling in superiority and non-inferiority trials. Why confidence intervals rather than P-values?
2. Meta-Analyses: Basic concept. How to read a forest-plot. Correct and false interpretation of meta-analyses through examples from the literature. Common traps.
3. Evidence-based medicine: Basic concept. From effect sizes to quality of evidence. Key points of the GRADE system. Interpreting strength of recommendations.
4. Quality assurance in clinical studies: modern risk-based approaches and central statistical monitoring. Practical examples from interactive study conduct control (ISCCS®) revealing common traps and problems in the conduct of clinical studies.
5. Definition and interpretation of common effect sizes for binary, ordinal and continuous data: rate difference, odds ratio, mean, median, Mann-Whitney



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