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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

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

DECEMBER 10, 2012

**"Ion Minea" Auditorium / Clinic of Neurology
CLUJ-NAPOCA | ROMANIA**

Welcome Address

It is a pleasure to welcome you to the 5th edition Seminars of the Neurosciences Department, "Statistical Concepts in Clinical Studies", December 10th, 2012. The seminars are hosted by the Department of Neurosciences, Faculty of Medicine, University of Medicine and Pharmacy "Iuliu Hațieganu" Cluj-Napoca.

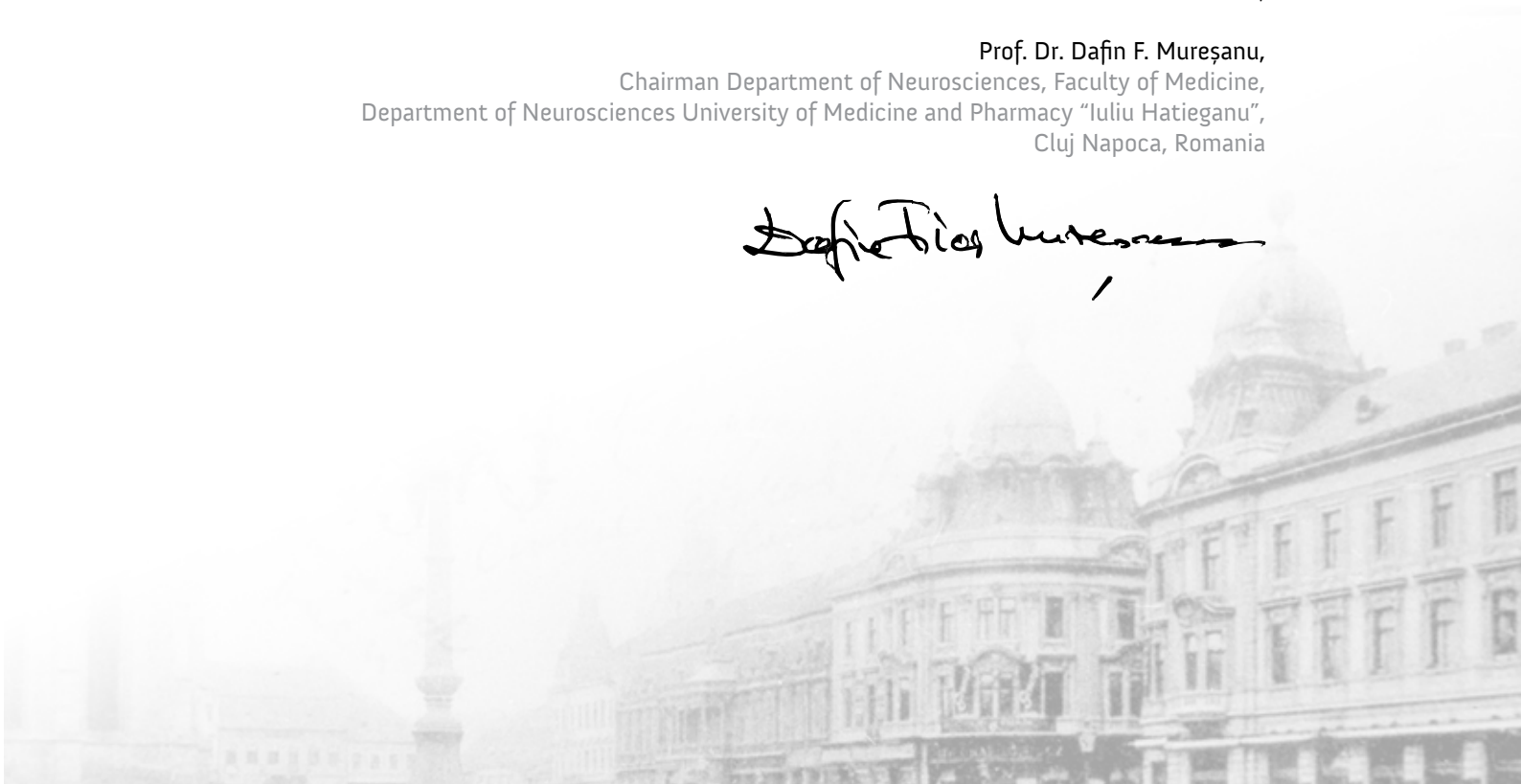

These seminars aim to establish a highly useful framework enabling local specialists to benefit from the expertise of our invited speakers who are part of associated international faculty of our Department of Neurosciences. Our goal is to flourish over years and set up an educational network tool meeting 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. DaŃin F. Mureșanu,
Chairman Department of Neurosciences, Faculty of Medicine,
Department of Neurosciences University of Medicine and Pharmacy "Iuliu Hațieganu",
Cluj Napoca, Romania



Organizers



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University of Medicine and Pharmacy
"Iuliu Hatieganu", Cluj Napoca, Romania
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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.
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Scientific Program

Monday, December 10th, 2012

“Ion Minea” Auditorium / Clinic of Neurology

15:00 - 16:00

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

16:00 - 16:10

Session Break

16:10 - 17:10

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

17:10 - 17:20

Session Break

17:20 - 18:20

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



Abstracts

The primary goal of the statistical lectures is to provide non-statisticians with an 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 adress the following issues:

1. Hypothesis testing and statistical significance: the basic concept of a statistical test. One-sided and two-sided tests. Definition and interpretation of P-values. Level of significance. Correct and false interpretation of significance through examples from the literature.
2. 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?
3. Proper interpretation of study results: examples from recent TBI trials. Pros and cons of dichotomization. Univariate vs. multidimensional approach. Current recommendations. What can we learn from „failed“ studies.



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