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UNIVERSITY OF
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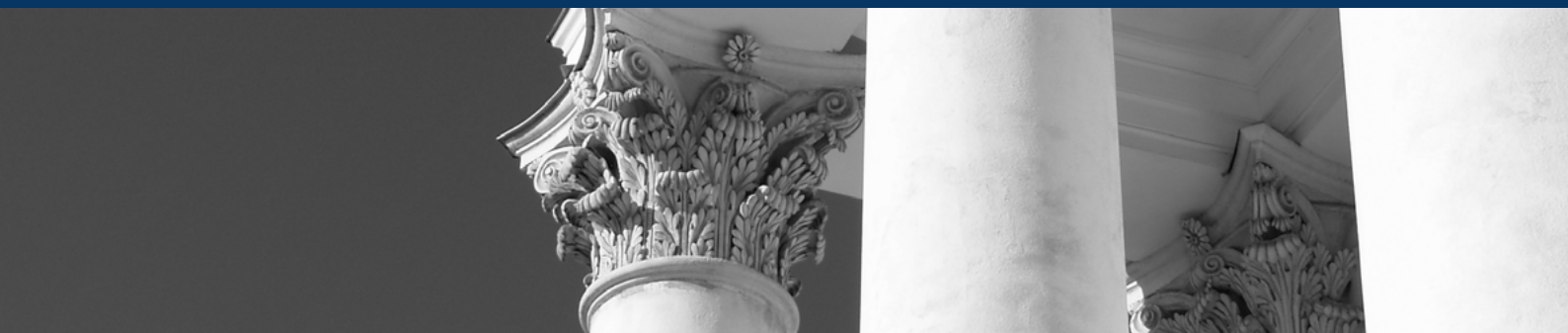


"IULIU HAȚIEGANU" UNIVERSITY
OF MEDICINE AND PHARMACY

DOCTORAL SCHOOL NEUROSCIENCE PROGRAM

2022-2023 | M 2.3.3

4 APRIL, 2023
VIRTUAL MEETING



PhD NEUROSCIENCE PROGRAM COORDINATOR



Dafin F. Mureșanu

President of the European Federation of
NeuroRehabilitation Societies (EFNR)

Secretary General AMN
(Academy for Multidisciplinary Neurotraumatology)

Past President of the Romanian Society of Neurology

Professor of Neurology, Chairman Department of
Neurosciences "Iuliu Hatieganu" University of Medicine
and Pharmacy, Cluj-Napoca, Romania

INTERNATIONAL GUEST LECTURER



Johannes Vester

Invited Associate Professor, Department of
Neurosciences, "Iuliu Hatieganu" University of
Medicine and Pharmacy, Cluj-Napoca, Romania

Senior Consultant Biometry and Clinical Research

idv - Data Analysis and Study Planning, Germany

PhD NEUROSCIENCE PROGRAM FACULTY 2022-2023

Claudio Bassetti / Switzerland

Ettore Beghi / Italy

Natan Bornstein / Israel

Michael Brainin / Austria

Anca Dana Buzoianu / Romania

Michael Chopp / USA

László Csiba / Hungary

Marc Fisher / USA

Urs Fischer / Switzerland

Ioan Ștefan Florian / Romania

Antonio Federico / Italy

Francesca Federico / Italy

Max Hiltz / Germany

Wolf Dieter Heiss / Germany

Tudor Jovin / USA

Maurizio Leone / Italy

Dafin F. Mureșanu / Romania

Milija Mijajlovic / Serbia

Lăcrămioara Perju-Dumbravă / Romania

Maura Pugliatti / Italy

Johannes Vester / Germany

ORGANIZER



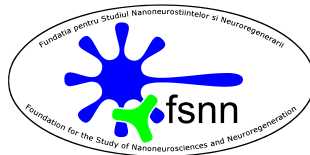
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COURSE PROGRAM

COURSE PROGRAM

4 APRIL, 2023

VIRTUAL MEETING

12:00 – 12:30

Johannes Vester / Germany
Basic understanding of a statistical test

12:30 - 13:00

Johannes Vester / Germany
Effect sizes and confidence intervals – basic understanding of
principle biometric features in clinical research

13:00 – 13:30

Johannes Vester / Germany
Interpreting meta-analyses within the framework of
evidence-based medicine

13:30 – 14:00

Johannes Vester / Germany
The importance of quality assurance



**INTERNATIONAL GUEST
LECTURER**



JOHANNES VESTER

GERMANY

Born in 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. From 1976 to 1979, he additionally completed the curriculum on biostatistics 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.

Since 1982 he holds > 100 advanced training courses on biometry for professionals in clinical research as well as teaching courses for university institutions and international societies.

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

Since 1995 he is Senior Consultant for Biometry & Clinical Research at the Institute for Data Analysis and Study Planning (IDV). He planned and evaluated about 150 randomized clinical studies worldwide and is member of various international Advisory Boards and Steering Committees including participation as biometric expert in regulatory authority panels, in FDA, EMA, and BfArM hearings, and in workshops of the International Biometric Society (IBS).

Statistical peer reviewer for leading medical journals such as Stroke (American Heart Association).

Since 2013 - Statistical Expert and Elected Member of the International Scientific Committee of the Society for the Study of Neuroprotection and Neuroplasticity (SSNN).

Since 2013 - Statistical Expert and Elected Member of the World Academy for Multidisciplinary Neurotraumatology (AMN).

Since 2015 - Member of the PhD Neuroscience International Faculty, "Iuliu Hatieganu" University of Medicine and Pharmacy, Cluj-Napoca, Romania.

Since 2017 - Invited Associate Professor, Department of Neuroscience, "Iuliu Hatieganu" University of Medicine and Pharmacy, Cluj-Napoca, Romania.

Since 2018 - Co-Chair EAN Guideline Task Force Neurorehabilitation.

Since 2018 - Head Biometry & Clinical Research at the Institute for Data Analysis and Study Planning (IDV).

Since 2018 - President of the Academy for Multidisciplinary Neurotraumatology (AMN).



DAFIN F. MUREȘANU

ROMANIA

Professor of Neurology, Senior Neurologist, Chairman of the Neurosciences Department, Faculty of Medicine, "Iuliu Hatieganu" University of Medicine and Pharmacy Cluj-Napoca, President of the European Federation of Neurorehabilitation Societies (EFNR), Chairman Communication Committee of the European Academy of Neurology (EAN), Past President of the Romanian Society of Neurology, President of the Society for the Study of Neuroprotection and Neuroplasticity (SSNN), Chairman "RoNeuro" Institute for Neurological Research and Diagnostic, Corresponding Member of the Romanian Academy, Member of the Academy of Medical Sciences, Romania and secretary of its Cluj Branch. He is member of 17 scientific international societies (being Member of the American Neurological Association (ANA) - Fellow of ANA (FANA) since 2012) and 10 national ones, being part of the executive board of most of these societies. Professor Dafin F. Muresanu is also a specialist in Leadership and Management of Research and Health Care Systems (specialization in "Management and Leadership, Arthur Anderson Institute, Illinois, USA, 1998"; "MBA – Master of Business Administration - Health Care Systems Management, The Danube University - Krems, Austria, 2003"). He has performed valuable scientific research in high interest fields such as: neurobiology of central nervous system (CNS) lesion mechanisms; neurobiology of neuroprotection and neuroregeneration of CNS; the role of the Blood-brain barrier (BBB) in CNS diseases; developing comorbidities in animal models to be used in testing therapeutic paradigms; nanoparticles neurotoxicity upon CNS; the role of nanoparticles in enhancing the transportation of pharmacological therapeutic agents through the BBB; cerebral vascular diseases; neurodegenerative pathology; traumatic brain injury; neurorehabilitation of the central and peripheral nervous system; clarifying and thoroughgoing study on the classic concepts of Neurotrophicity, Neuroprotection, Neuroplasticity and Neurogenesis by bringing up the Endogenous Defense Activity (EDA) concept, as a continuous nonlinear process, that integrates the four aforementioned concepts, in a biological inseparable manner.

Professor Dafin F. Muresanu is coordinator in international educational programs of European Master (i.e. European Master in Stroke Medicine, University of Krems), organizer and co-organizer of many educational projects: European and international schools and courses (International School of Neurology, European Stroke Organisation Summer School, Danubian Neurological Society Teaching Courses, Seminars - Department of Neurosciences, European Teaching Courses on Neurorehabilitation) and scientific events: congresses, conferences, symposia (International Congresses of the Society for the Study of Neuroprotection and Neuroplasticity (SSNN), International Association of Neurorestoratology (IANR) & Global College for Neuroprotection and Neuroregeneration (GCNN) Conferences, Vascular Dementia Congresses (VaD), World Congresses on Controversies in Neurology (CONy), Danube Society Neurology Congresses, World Academy for Multidisciplinary Neurotraumatology (AMN) Congresses, Congresses of European Society for Clinical Neuropharmacology, European Congresses of Neurorehabilitation). His activity includes involvement in many national and international clinical studies and research projects, over 500 scientific participations as "invited speaker" in national and international scientific events, a significant portfolio of scientific articles (260 papers indexed on Web of Science-ISI, H-index: 25) as well as contributions in monographs and books published by prestigious international publishing houses. Prof. Dr. Dafin F. Muresanu has been honoured with: „Dimitrie Cantemir” Medal of the Academy of The Republic of Moldova in 2018, Ana Aslan Award 2018 - "Performance in the study of active aging and neuroscience", for the contribution to the development of Romanian medicine, National Order "Faithful Service" awarded by the President of Romania in 2017; "Iuliu Hatieganu" University of Medicine and Pharmacy Cluj-Napoca, Faculty of Medicine, the "Iuliu Hatieganu Great Award 2016" for the best educational project in the last five years; the Academy of Romanian Scientists, "Carol Davila Award for Medical Sciences / 2011", for the contribution to the Neurosurgery book "Tratat de Neurochirurgie" (vol.2), Editura Medicala, Bucuresti, 2011; the Faculty of Medicine, "Iuliu Hatieganu" University of Medicine and Pharmacy Cluj-Napoca "Octavian Fodor Award" for the best scientific activity of the year 2010 and the 2009 Romanian Academy "Gheorghe Marinescu Award" for advanced contributions in Neuroprotection and Neuroplasticity.



ABSTRACTS

BASIC UNDERSTANDING OF A STATISTICAL TEST

JOHANNES VESTER

idv - Data Analysis and Study Planning, Germany

The coin flipping example. Null hypothesis. Basic characteristics of the P-value. The concept of hypothesis testing and statistical significance. Common traps. Typical statistical tests.

EFFECT SIZES AND CONFIDENCE INTERVALS – BASIC UNDERSTANDING OF PRINCIPLE BIOMETRIC FEATURES IN CLINICAL RESEARCH

JOHANNES VESTER

idv - Data Analysis and Study Planning, Germany

Effect Sizes and Confidence Intervals. Why confidence intervals rather than P-values? Definition and handling in superiority and non-inferiority trials. Interpretation of the most common result situations. Examples from the literature. CONSORT requirements. ICH and FDA approach.

INTERPRETING META-ANALYSES WITHIN THE FRAMEWORK OF EVIDENCE-BASED MEDICINE

JOHANNES VESTER

idv - Data Analysis and Study Planning, Germany

The role of meta-analyses within the framework of evidence-based medicine as keystones in the development of guidelines and therapy recommendations. Basic concept. How to read a forest-plot. Fixed and random effects. Measures of heterogeneity. The Grading of Recommendations Assessment, Development and Evaluation. Key points of the GRADE system: imprecision, inconsistency, publication bias. Interpreting strength of recommendations. Examples from the literature.

THE IMPORTANCE OF QUALITY ASSURANCE

JOHANNES VESTER

idv - Data Analysis and Study Planning, Germany

Modern risk-based approaches and centralized statistical monitoring as basis for high precision RCTs. Why clinical trials fail. Practical examples from interactive study conduct control revealing common traps and problems in the conduct of clinical studies. New FDA and EMA approaches to ensure successful trials.



