

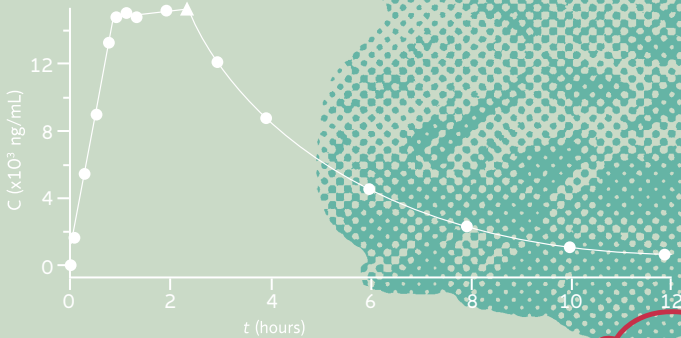


Conference
in Memory of
Professor
Laszlo Endreanyi

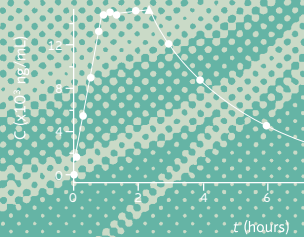
SCIENTIFIC PROGRAM

22-23
May
2023

Main
Building
University
of Athens
Greece



**Bioavailability-
Bioequivalence**
From Classification
to Virtualisation &
Anything in Between





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22-23
May 2023

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University of Athens
Athens, Greece



WELCOME MESSAGE

Dear colleagues,

We wish to welcome you all to Athens. This memorial meeting is dedicated to Laszlo Endrenyi who was chair of Pharmacology at the University of Toronto, Canada with an international leading role in Pharmacokinetics, Bioavailability and Bioequivalence.

The topics of the meeting cover all scientific and regulatory disciplines from drug discovery and formulation strategies up to pharmacokinetics-pharmacodynamics and the assessment of bioavailability and bioequivalence of formulations. Emphasis will be given to those studies based on virtualization or involving virtualization elements or platforms. These *in silico* methodologies are applied to the whole spectrum of drug research as well as to the development of generics. In this vein, physiologically based pharmacokinetic modeling and virtual bioequivalence studies are valuable tools today for the development of new drugs and generics. Eminent world-wide scientists from academia, regulatory Agencies and industry are listed among the confirmed speakers.

Co-chairs

Professor Panos Macheras

National & Kapodistrian University of Athens, Greece

Professor Imre Klebovich

Semmelweis University, Budapest, Hungary

Professor Amin Rostami

The University of Manchester & Certara, United Kingdom



Laszlo's exceptional contributions to the field of pharmacokinetics, bioavailability and bioequivalence are held in the highest regard. We who had the good fortune to know Laszlo for so many years, and those who ever met Laszlo, were so greatly benefited from his insight and scientific contributions. Above all, Laszlo was a true gentleman, always smiling and always graciously sharing his brilliance and friendship.



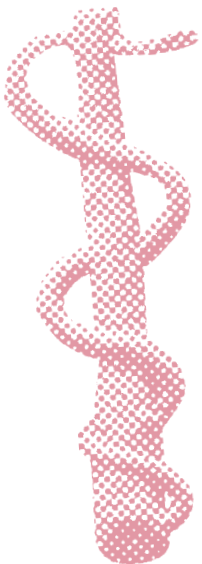
COMMITTEES

Co-chairs

- **Professor Panos Macheras**
National & Kapodistrian University of Athens,
ATHENA Research, Greece
- **Professor Imre Klebovich**
Semmelweis University, Budapest, Hungary
- **Professor Amin Rostami**
The University of Manchester & Certara, United Kingdom

Scientific Committee

- **Leslie Z. Benet** (USA)
- **Meir Bialer** (IL)
- **Robert Bies** (USA)
- **Erem Bilensoy** (Turkey)
- **Henning H. Blume** (DE)
- **George Digenis** (USA)
- **Aris Dokoumetzidis** (GR)
- **A. Atilla Hincal** (TR)
- **Milena Jadrijević-Mladar Takač** (HR)
- **José A. Guimarães Morais** (PT)
- **Stefan Mühlebach** (CH)
- **Urve Pääver** (EE)
- **Carl C. Peck** (USA)
- **Sandy Pang** (CA)
- **Olavi Pelkonen** (FI)
- **Christos Reppas** (GR)
- **Malcolm Rowland** (UK)
- **Geoffrey Tucker** (UK)
- **Vinod P. Shah** (USA)
- **Michael Weiss** (DE)
- **Clive G. Wilson** (UK)





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TOPICS

Dissolution

IVVC

Formulations
and Modified
Release
Formulations

BCS and
BDDCS

Biowaivers

Biosimilars

Pharmacodynamic
Endpoints for BE

Regulatory
Science

POPPK-PD and
Pharmacometrics
Applications to
Assess BE

Conduct of
PBPK and
Virtual BE

"Anything in between"

Factors: Genomic, pharmacogenomic, immunological, chemical, food

Delivery: From in vitro transfer embryos to intramuscular, pulmonary, intranasal, and brain drug delivery

Virtualization: Machine learning techniques, artificial intelligence, in silico studies

Pharmacodynamics: Beyond therapeutic equivalence



SCIENTIFIC PROGRAM

Monday, 22 May 2023

10:00

Welcome Message

Moderators: **C. Kittas**, Ex- Rector, National and Kapodistrian University of Athens

Y. Ioannidis, Department of Informatics, National and Kapodistrian University of Athens, ACM president

Invited Lectures

10:30–10:50 From mathematics to algorithms to helping society

I. Emiris, ATHENA Research Center, Department of Informatics, National and Kapodistrian University of Athens, Greece

10:50–11:10 3D Printing in pharmacy and pharmaceutical sciences

D. Douroumis, Centre for Innovation in Process Engineering and Research, University of Greenwich, London, UK

11:10–11:30 Multiscale analysis of the COVID-19 waves in Greece

D. Goussis, Khalifa University, Abu Dhabi, UAE

11:30–12:00

COFFEE BREAK

12:00–14:00

FIRST SESSION “Bioavailability-PBPK models”

Moderators: **J. Morais**, University of Lisbon, Lisbon, Portugal

A. Hincal, Hacettepe University, Ankara, Turkey

12:00–12:30 Is the gut out-evolved by progress in modern food technology?

C. G. Wilson, Strathclyde Institute of Pharmacy and Biomedical Science, Glasgow, Scotland, UK

12:30–13:00 Absorption PBPK models in regulatory applications: The EMA experience.

A. Dokoumetzidis, Faculty of Pharmacy, National and Kapodistrian University of Athens, Athens, Greece

13:00–13:30 The Explanation for Why Calculated Bioavailability May Be Greater Than 100%: Regulatory, Therapeutics and PBPK Implications

L. Benet, Department of Bioengineering and Therapeutic Sciences, School of Pharmacy and Medicine, University of California, San Francisco, CA, USA

13:30–14:00 Dependence of bioavailability on mean absorption time: What does it tell us?

M. Weiss, Department of Pharmacology, Martin Luther University Halle (Saale) Germany

14:00–14:45

BREAK

14:45–16:45

SECOND SESSION “Bioequivalence-Virtual Bioequivalence”

Moderators: **M. Rowland**, University of Manchester, Manchester, UK

V. Shah, Former Senior Scientist FDA, USA

14:45–15:15 Practical Strategies in Embracing Modelling in BA/BE: Revisiting the Debate on Modalities of M&S in Relation to Its Adoption

A. Rostami, University of Manchester, Manchester, UK

15:15–15:45 Is TOST toast - so, what is BEST?

C. C. Peck, NDA Partners LLC, Department of Bioengineering and Therapeutic Sciences, Schools of Pharmacy and Medicine, University of California, San Francisco, CA, USA

15:45–16:15 Bioequivalence: Exceptions to the rule

M. Guirguis, Applied Pharmaceutical Innovation, Edmonton AB, Canada

16:15–16:45 Micro-dosing. What have we learnt?

M. Rowland, University of Manchester, Manchester, UK



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Monday, 22 May 2023

16:45–17:15

COFFEE BREAK

17:15–17:30 PBPK based Virtual Drugs Equivalence Assessment - from bioequivalence via therapeutic equivalence to pharmacotherapeutic interchange and beyond
Sebastian Polak, Certara UK, Jagiellonian University Medical College

17:30–18:00 Model-Based Bioequivalence Approaches for complex generic products
M. P. Ducharme, Learn and Confirm Inc, Faculté de Pharmacie, University of Montreal, Montreal, Canada

18:00–18:30

SESSION DEDICATED to Laszlo Endrenyi

Moderators: **C. Peck**, NDA Partners LLC, Department of Bioengineering and Therapeutic Sciences, Schools of Pharmacy and Medicine, University of California, San Francisco, CA, USA
I. Klebovich, Semmelweis University, Budapest, Hungary

18:30–19:45

THIRD SESSION “Virtualization”

Moderators: **L. Benet**, University of California, San Francisco, CA, USA
M. Bialer, School of Pharmacy, Faculty of Medicine, Hebrew University of Jerusalem, Israel

18:30–19:00 Decoding the chemistry with manifold embedding and predicting drug developability with deep learning.
L. Tonglei, University of Purdue, West Lafayette, IN, USA

19:00–19:30 Physiologically Based Biopharmaceutics Modeling to inform Formulation Selection and to define the Bioequivalence Safe Space (Zoom)
T. Heimbach, PhD MRL, Sterile & Specialty Products Group Biopharmaceutics Merck & Co. Inc.

19:30–19:45 A physiologically - based pharmacokinetic modeling for clinical drug dosing in pediatrics Carbamazepine – Simcyp simulations (Zoom)
Enkelejda Goci^{1,2}, **Joyce van der Heijden**³, **Saskia de Wildt**^{3,4}
¹Pharmacotherapeutic Research Center, Faculty of Medical Sciences, Aldent University, ²Department of Pharmacy, Faculty of Medicine, University of Medicine, Tirana, ³Department of Pharmacology and Toxicology, Radboud University Medical Center, ⁴Erasmus MC Sophia Children’s Hospital

20:30

Congress Dinner*

Kostis Palamas Building, 48 Akadimias Street & Sina Street (*extra cost applicable*)





SCIENTIFIC PROGRAM

Tuesday, 23 May 2023

09:00–11:45

FOURTH SESSION “Advances in Pharmaceutical Sciences”

Moderators: **P. Macheras**, Faculty of Pharmacy, National and Kapodistrian University of Athens, ATHENA Research Center, Athens, Greece
M. Jadrijevic-Mladar Takac, Faculty of Pharmacy and Biochemistry, University of Zagreb, Zagreb, Croatia

09:00–09:30 The peaks and troughs of alkyl-carbamates in epilepsy therapy: what have we learnt in the period between valproate (1993) and cenobamate (2019)?

M. Bialer, School of Pharmacy, Faculty of Medicine, The Hebrew University of Jerusalem, Jerusalem, Israel

09:30–10:00 Prediction of BCS and ECCS of macrolides in new drug discovery - focus on substituted azithromycin derivatives and their conjugates

M. Jadrijevic-Mladar Takac¹, T. Takac², T. Jednačak²

¹Faculty of Pharmacy and Biochemistry, University of Zagreb, Zagreb, Croatia; ²Faculty of science, University of Zagreb, Zagreb, Croatia

10:00–10:30 Dual ligand targeted Doxorubicin stealth liposomes as therapeutic against triple negative breast cancer

F. Gkartzou, E. Natsaridis, S. Mourtas, S. G. Antimisiaris

Lab Pharm Technology, University of Patras, Rio-Patras, Greece & FORTH/ICE-HT, Platani-Patras, Greece

10:30–11:00 In vitro evaluation of differences in early exposure.

M. Vertzoni, Department of Pharmacy, National and Kapodistrian University of Athens, Athens, Greece

11:00–11:15 Targeted delivery of imiquimod to mesenteric and retroperitoneal lymph nodes following oral administration

Haojie Chen¹, Liuhan Ji¹, Abigail Wong¹, Yenju Chu¹, Wanshan Feng¹, Dong-hyun Kim¹, Michael J. Stocks¹, Pavel Gershkovich¹

¹University of Nottingham

11:15–11:45 New strategies for buccal drug delivery using emerging technologies.

D. G. Fatouros, Laboratory of Pharmaceutical Technology, Department of Pharmacy, Aristotle University of Thessaloniki, Thessaloniki, Greece

11:45–12:00

COFFEE BREAK

12:00–14:15

FOURTH SESSION CONTINUES “Advances in Pharmaceutical Sciences”

Moderators: **D. Rekkas**, Faculty of Pharmacy, National and Kapodistrian University of Athens, Greece,
P. Macheras, National and Kapodistrian University of Athens, ATHENA Research Center

12:00–12:30 Complex nanosystems and health sciences

C. Demetzos, Department of Pharmacy, National and Kapodistrian University of Athens, Greece

12:30–13:00 Biosimilars in clinical practice: Opportunities and Challenges

C. Fokoloros, Amgen, Athens, Greece

13:00–13:30 Cannabinoids: From chemical structure to pharmacology and regulatory aspects of their use

E. Skaltsa, Faculty of Pharmacy, National and Kapodistrian University of Athens, Athens, Greece

13:30–14:00 Towards an in silico integrated approach for testing and assessment of nanomaterials: from predicted indoor air concentrations to lung dose and biodistribution

A. Afantitis, Novamechanics, Piraeus, Greece



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14:00–14:15 RARE-ID: Preliminary results of targeted metabolomics study in pediatric patients with autism and rare neurological diseases
Yannis Dotsikas¹, Yannis Loukas¹, Maria Spanou², Georgia Thodi³, Eirini Mathaiou¹, Stafania Antonopoulou³, Maria Chatzidaki¹, Christos Skaloubakas⁴, Leonidas Bourikas⁴, Argirios Dinopoulos⁵

¹Department of Pharmacy, National and Kapodistrian University of Athens, Greece, Laboratory of Pharm. Analysis, Athens, Greece, ²3rd Department of Pediatrics, "Attikon" Hospital, National and Kapodistrian University of Athens, Greece, ³Molecular Diagnostics Department, Neogenetics Ltd, Athens, Greece, ⁴Habilis, Athens, Greece, ⁵1st Department of Pediatrics, St. Sophia's Children's Hospital, National and Kapodistrian University of Athens, Athens, Greece

14:15–15:15

BREAK

15:15–16:30

FOURTH SESSION CONTINUES

Moderators: **P. Dallas – P. Macheras**, Faculty of Pharmacy, National and Kapodistrian University of Athens, Greece

15:15–15:45 A robust model predictive control framework for the regulation of anesthesia process with Propofol
C. Sarimveis, National Technical University of Athens, Greece

15:45–16:15 The role of Artificial Intelligence in the in vitro Fertilization Clinical Embryology Laboratory: an automatic procedure or an additional evaluation of the embryos?
T. Triantafyllou, Iaso Maternity & Gynaecology Clinic, Athens, Greece

16:15–16:30 Design and development of low and medium-viscosity alginate beads loaded with Pluronic 188 nano-micelles

Chrystalla Protopapa¹, Flora Kalogeropoulou^{1,2}, Dimitra Papailiou^{1,2}, **Angeliki Siamidi¹**, Natassa Pippa¹, Marilena Vlachou¹

¹Section of Pharmaceutical Technology, Department of Pharmacy, School of Health Sciences, National and Kapodistrian University of Athens, Panepistimioupolis Zografou, 15771 Athens, Greece, ²Third Department of Medicine, Athens School of Medicine, National and Kapodistrian National and Kapodistrian University of Athens, "Sotiria" Hospital for Diseases of the Chest, Athens, Greece

16:30–16:45

COFFEE BREAK

16:45–18:45

FIFTH SESSION "From the Inception of the Finite Absorption Time Concept to a Novel Strategy for the Development of Generics"

Moderators: **C. G. Wilson**, Strathclyde Institute of Pharmacy and Biomedical Science, Glasgow, Scotland, UK
G. Digenis, USWORLDMEDS, Louisville, USA

16:45–17:15 The Finite Absorption Time concept in Oral drug absorption
P. Macheras, Faculty of Pharmacy, National and Kapodistrian University of Athens, ATHENA Research Center, Athens, Greece

17:15–17:45 The rise of Physiologically based finite time pharmacokinetic (PBFTP) models
A. Tsekouras, Department of Chemistry, National and Kapodistrian University of Athens, Athens, Greece

17:45–18:15 On the complementarity of PBPK and PBFTP models (Zoom)
Wu Di, Pharmaceutical Sciences and Clinical Supply, Merck & Co. Inc., Rahway, NJ, USA

18:15–18:45 Revamping Biopharmaceutics-Pharmacokinetics with scientific and regulatory implications for oral drug absorption

P. Macheras, Faculty of Pharmacy, National and Kapodistrian University of Athens, ATHENA Research Center, Athens, Greece

18:45–19:00

Wrapping up

L. Benet, I. Klebovich, P. Macheras, C. Peck



GENERAL INFORMATION



Congress Dates
22-23 May 2023

Venue
Argyriades amphitheater at the Main Building of the University of Athens
Panepistimiou Ave, 30, 106 79, Athens, Greece
Metro station Panepistimio (red line)

Secretariat Operating Hours

Monday, 22 May 2023	09:00–20:00
Tuesday, 23 May 2023	08:30–19:00

Language

The official language of the Congress will be English.
No translation will be provided for participants.

Congress Dinner

The congress dinner will take place on 22 May 2023 at “Kostis Palamas” building. The cost is 40€ per person.

Certificates

Certificates of attendance will be electronically sent to all participants, following the completion of the evaluation form.

CONGRESS SECRETARIAT

PROFESSIONAL CONGRESS ORGANIZER (PCO)
AFEA S.A. Travel & Congress Services



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Tel: +30 2103668895, **Fax:** +30 210363511
e-mail: congress@afea.gr

ABOUT ATHENS

The City

A unique combination of the old and the new, set up against a spectacular Mediterranean landscape, Athens inspires its visitors, leaving its mark in their hearts and minds. Surrounded by a lining of stunning seas and mountains, this city is filled with gems just waiting to be discovered. Each year, more and more travelers are choosing Athens for their leisure and business travel all year round. There are several reasons; Athens offers a variety of things to see and do, and most of the times, under favorable weather conditions. Athens is an ideal congress destination, combining state-of-the-art infrastructure, excellent conference facilities and easy access from all over the world with world-class cultural attractions, diverse entertainment and natural beauty.

Weather

Athens is an ideal year-round destination with comfortable and favorable climate conditions for travel and sightseeing. Rainfall is minimal and the summers (May through August) are dry and hot with temperatures ranging, on average, from 78° to 94°F or 20° to 34°C.





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Shopping Hours

Major outlets Monday-Friday. 9:00-21:00; small shops Monday, Wednesday 9:00 to 15:30; Friday, 9:00 to 20:30; Saturday 9:00 to 15:30.

The airport

The award-winning Athens International Airport, Eleftherios Venizelos, serves 83 international destinations. Its close proximity to the city center -just 27 km from the hotel-, 30 minutes by car and 40 minutes by metro -through line 3, makes Athens easily accessible.

Transportation

Network includes new buses, pollution-free trolleys, tram and a revamped electric railway system that connects to the metro lines. Taxis can be used, which are also inexpensive considering the European standards. At Athens Airport you can find a wide variety of options regarding ground transportation:

Bus: There are 4 bus lines which connect the airport to the city centre. One single ticket costs 9€. For more information about the bus lines and routes, you may visit oasa.gr.

Taxi: Taxis can be used, which are also inexpensive by European standards (40€ from Athens to the airport). As Uber function is not available in Greece, you may use the Taxi Beat instead. For more information, you may visit thebeat.co/gr-en/.

Train: Athens Airport is connected via suburban rail to Athens Central Railway Station (Larissis Station), Port of Pireaus and Kiato.

Metro: To access by metro, take Athens Metro Line 3 at the Airport's Railway Station. For more information, you may visit the official site of the www.aia.gr

Currency

Greece uses Euro (€).

Time

Greece is GMT+2.

ATMs

They are widely available in Greece for Master or Visa cardholders.

Banks

Banks are open from Monday to Thursday, 8:00-14:30 hours and on Friday, 8:00-14:00 hours; on Saturdays and Sundays they are closed. Central branches of some banks may be found open until 20.00 daily and from 10.00 to 16.30 on Saturdays. For further details while in Athens please consult your hotel concierge.

Credit cards

All major credit cards are accepted in almost all hotels, shops, and restaurants. Stickers in the front windows will advise you as to which cards are accepted.

Electricity

Electricity is 220 V/50 Hz. Plugs are the standard continental (DIN) type with two round pins.

Emergency Numbers

Emergency	112
Ambulance	166
Fire Department	199
Police	100
Coast Guard	108
Tourist Police	171

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