

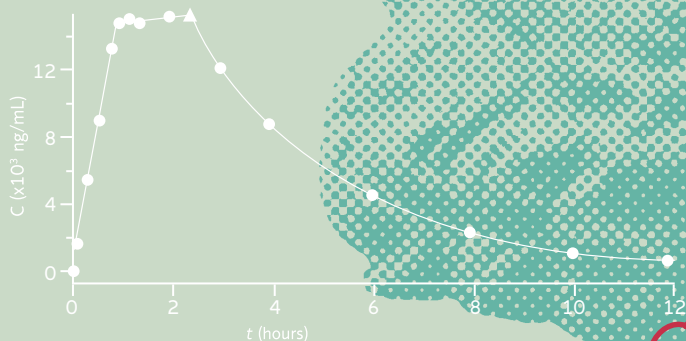


Conference  
in Memory of  
Professor  
Laszlo Endrényi

# FINAL PROGRAM

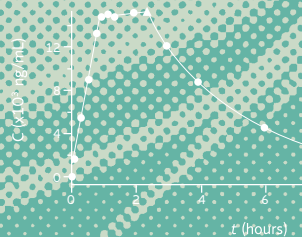
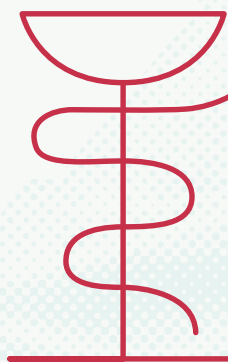
22-23  
May  
2023

Main  
Building  
University  
of Athens  
Greece



## Bioavailability- Bioequivalence

From Classification  
to Virtualisation &  
Anything in Between





22-23  
May 2023

Main Building  
University of Athens  
Athens, Greece



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## 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)



## 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

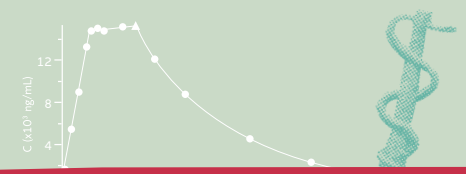
### "Anything in between"

**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

SCIENTIFIC PROGRAM

Monday, 22 May 2023

Monday, 22 May 2023

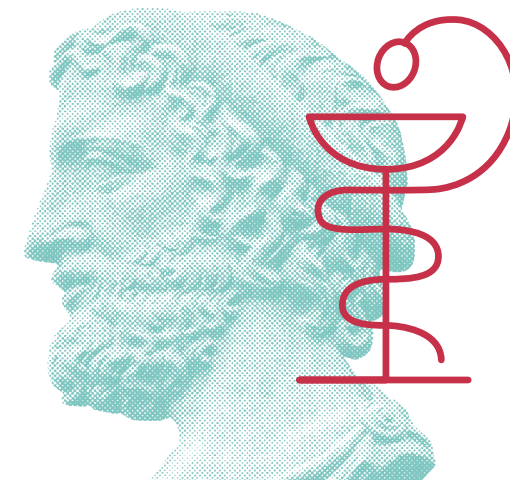
MAIN HALL

10:00	<p><b>Welcome Message</b> Moderators: <b>C. Kittas</b>, Ex- Rector, National and Kapodistrian University of Athens <b>Y. Ioannidis</b>, Department of Informatics, National and Kapodistrian University of Athens, ACM president</p> <p><b>Invited Lectures</b></p> <p><b>10:30–10:50</b> From mathematics to algorithms to helping society <b>I. Emiris</b>, ATHENA Research Center, Department of Informatics, National and Kapodistrian University of Athens, Greece</p> <p><b>10:50–11:10</b> 3D Printing in pharmacy and pharmaceutical sciences <b>D. Douroumis</b>, Centre for Innovation in Process Engineering and Research, University of Greenwich, London, UK</p> <p><b>11:10–11:30</b> Multiscale analysis of the COVID-19 waves in Greece <b>D. Goussis</b>, Khalifa University, Abu Dabi, UAE</p>
11:30–12:00	COFFEE BREAK

ARGYRIADES HALL

12:00–14:00	<p><b>FIRST SESSION “Bioavailability-PBPK models”</b> Moderators: <b>J. Morais</b>, University of Lisbon, Lisbon, Portugal <b>A. Hincal</b>, Hacettepe University, Ankara, Turkey</p> <p><b>12:00–12:30</b> Is the gut out-evolved by progress in modern food technology? <b>C. G. Wilson</b>, Strathclyde Institute of Pharmacy and Biomedical Science, Glasgow, Scotland, UK</p> <p><b>12:30–13:00</b> Absorption PBPK models in regulatory applications: The EMA experience. <b>A. Dokoumetzidis</b>, Faculty of Pharmacy, National and Kapodistrian University of Athens, Athens, Greece</p> <p><b>13:00–13:30</b> The Explanation for Why Calculated Bioavailability May Be Greater Than 100%: Regulatory, Therapeutics and PBPK Implications <b>L. Benet</b>, Department of Bioengineering and Therapeutic Sciences, School of Pharmacy and Medicine, University of California, San Francisco, CA, USA</p> <p><b>13:30–14:00</b> Dependence of bioavailability on mean absorption time: What does it tell us? <b>M. Weiss</b>, Department of Pharmacology, Martin Luther University Halle (Saale) Germany</p>
14:00–14:45	BREAK
14:45–16:45	<p><b>SECOND SESSION “Bioequivalence-Virtual Bioequivalence”</b> Moderators: <b>M. Rowland</b>, University of Manchester, Manchester, UK <b>V. Shah</b>, Former Senior Scientist FDA, USA</p> <p><b>14:45–15:15</b> Practical Strategies in Embracing Modelling in BA/BE: Revisiting the Debate on Modalities of M&amp;S in Relation to Its Adoption <b>A. Rostami</b>, University of Manchester, Manchester, UK</p> <p><b>15:15–15:45</b> Is TOST toast - so, what is BEST? <b>C. C. Peck</b>, NDA Partners LLC, Department of Bioengineering and Therapeutic Sciences, Schools of Pharmacy and Medicine, University of California, San Francisco, CA, USA</p> <p><b>15:45–16:15</b> Bioequivalence: Exceptions to the rule <b>M. Guirguis</b>, Applied Pharmaceutical Innovation, Edmonton AB, Canada</p>

16:15–16:45	<p>Micro-dosing. What have we learnt? <b>M. Rowland</b>, University of Manchester, Manchester, UK</p>
16:45–17:15	COFFEE BREAK
17:15–17:30	<p>PBPK based Virtual Drugs Equivalence Assessment - from bioequivalence via therapeutic equivalence to pharmacotherapeutic interchange and beyond <b>Sebastian Polak</b>, Certara UK, Jagiellonian University Medical College</p>
17:30–18:00	<p>Model-Based Bioequivalence Approaches for complex generic products <b>M. P. Ducharme</b>, Learn and Confirm Inc, Faculté de Pharmacie, University of Montreal, Montreal, Canada</p>
18:00–18:30	<p><b>SESSION DEDICATED to Laszlo Endrenyi</b> Moderators: <b>C. Peck</b>, NDA Partners LLC, Department of Bioengineering and Therapeutic Sciences, Schools of Pharmacy and Medicine, University of California, San Francisco, CA, USA <b>I. Klebovich</b>, Semmelweis University, Budapest, Hungary</p>
18:30–19:45	<p><b>THIRD SESSION “Virtualization”</b> Moderators: <b>L. Benet</b>, University of California, San Francisco, CA, USA <b>M. Bialer</b>, School of Pharmacy, Faculty of Medicine, Hebrew University of Jerusalem, Israel</p> <p><b>18:30–19:00</b> Decoding the chemistry with manifold embedding and predicting drug developability with deep learning. <b>L. Tonglei</b>, University of Purdue, West Lafayette, IN, USA</p> <p><b>19:00–19:30</b> Physiologically Based Biopharmaceutics Modeling to inform Formulation Selection and to define the Bioequivalence Safe Space (Zoom) <b>T. Heimbach</b>, PhD MRL, Sterile &amp; Specialty Products Group Biopharmaceutics Merck &amp; Co. Inc.</p> <p><b>19:30–19:45</b> A physiologically - based pharmacokinetic modeling for clinical drug dosing in pediatrics Carbamazepine – Simcyp simulations (Zoom) <b>Enkelejda Goci</b><sup>1,2</sup>, <b>Joyce van der Heijden</b><sup>3</sup>, <b>Saskia de Wildt</b><sup>3,4</sup> <sup>1</sup>Pharmaceutical Research Center, Faculty of Medical Sciences, Aldent University, <sup>2</sup>Department of Pharmacy, Faculty of Medicine, University of Medicine, Tirana, <sup>3</sup>Department of Pharmacology and Toxicology, Radboud University Medical Center, <sup>4</sup>Erasmus MC Sophia Children’s Hospital</p>
20:30	<p><b>Congress Dinner*</b> Kostis Palamas Building, 48 Akadimias Street &amp; Sina Street (extra cost applicable)</p>





Tuesday, 23 May 2023

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 falbamate (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 Takac**<sup>1</sup>, T. Takac<sup>2</sup>, T. Jednačak<sup>2</sup>  
<sup>1</sup>Faculty of Pharmacy and Biochemistry, University of Zagreb, Zagreb, Croatia; <sup>2</sup>Faculty 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 Chen**<sup>1</sup>, Liuhan Ji<sup>1</sup>, Abigail Wong<sup>1</sup>, Yenju Chu<sup>1</sup>, Wanshan Feng<sup>1</sup>, Dong-hyun Kim<sup>1</sup>, Michael J. Stocks<sup>1</sup>, Pavel Gershkovich<sup>1</sup>  
<sup>1</sup>University 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  
**P. Magiatis**, 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  
**N. Cheimarios**<sup>a</sup>, P. Tsiros<sup>b</sup>, A. Tsoumanis<sup>a</sup>, A. C. Ø. Jensen<sup>c</sup>, G. Melagraki<sup>d</sup>, I. Lynch<sup>e</sup>, H. Sarimveis<sup>b</sup> and A. Afantitis<sup>a</sup>  
<sup>a</sup>NovaMechanics Ltd, Nicosia, Cyprus.  
<sup>b</sup>School of Chemical Engineering, National Technical University of Athens, Athens, Greece.  
<sup>c</sup>The National Research Centre for the Working Environment, Denmark  
<sup>d</sup>Hellenic Army Academy, Athens, Greece  
<sup>e</sup>School of Geography, Earth and Environmental Sciences, University of Birmingham, Birmingham, UK

14:00–14:15 RARE-ID: Preliminary results of targeted metabolomics study in pediatric patients with autism and rare neurological diseases  
**Yannis Dotsikas**<sup>1</sup>, Yannis Loukas<sup>1</sup>, Maria Spanou<sup>2</sup>, Georgia Thodi<sup>3</sup>, Eirini Mathaiou<sup>1</sup>, Stafania Antonopoulou<sup>3</sup>, Maria Chatzidaki<sup>1</sup>, Christos Skaloubakas<sup>4</sup>, Leonidas Bourikas<sup>4</sup>, Argirios Dinopoulos<sup>5</sup>

<sup>1</sup>Department of Pharmacy, National and Kapodistrian University of Athens, Greece, Laboratory of Pharm. Analysis, Athens, Greece, <sup>2</sup>3rd Department of Pediatrics, “Attikon” Hospital, National and Kapodistrian University of Athens, Greece, <sup>3</sup>Molecular Diagnostics Department, Neogenetics Ltd, Athens, Greece, <sup>4</sup>Habilis, Athens, Greece, <sup>5</sup>1st 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 Protopapa<sup>1</sup>, Flora Kalogeropoulou<sup>1,2</sup>, Dimitra Papailiou<sup>1,2</sup>, **Angeliki Siamidi**<sup>1</sup>, Natassa Pippa<sup>1</sup>, Marilena Vlachou<sup>1</sup>  
<sup>1</sup>Section of Pharmaceutical Technology, Department of Pharmacy, School of Health Sciences, National and Kapodistrian University of Athens, Panepistimioupolis Zografou, 15771 Athens, Greece, <sup>2</sup>Third 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**





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