

## PROGRAMME

### October 19, 2022 - Day 1

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#### PRE-ICPM 2022 MEETING SESSIONS

##### 08:30-09:30 EU CTR Greece Workshop: “IMPLEMENTATION ACHIEVEMENTS & CHALLENGES”

Chairs:

**Eugenia Fouza**, PharmD, *ex Deputy Head of National Organization for Medicines Pharmaceutical Research & Studies Direction*

**Varvara Baroutsou**, MD, PhD, GFMD, EMAUD, *Consultant Internal Medicine, Pharmaceutical Medicine, ELEFI President, IFAPP President Elect*

*European Union Clinical Trials Regulation Workshop with Greek stakeholders:*

- EUCTR Country Requirements from Ministry of Health  
**Ioannis Kotsiopoulos**, *Secretary General for Health Services at Ministry of Health, Greece (\*)*
- EUCTR Regulatory considerations  
**Leonidas Klironomos**, PharmD, *Deputy Head of National Organization for Medicines Clinical Trials Department (\*)*
- EUCTR National Ethics Committee for Clinical Trials considerations  
**Theofilos Kolettis**, *Professor in Cardiology, University of Ioannina, Greece*
- EUCTR Hellenic Association of Clinical Research Organizations (HACRO) considerations  
**Evangelia Koraki**, *President HACRO (\*)*
- Pharma Industry Representatives considerations  
**SFEE, PIF, PEF, SAFEE**

##### 09:30-10:00 Discussion

##### 10:00-10:30 Break

##### 10:30-11:30 Round table: “TRANSLATIONAL RESEARCH AND PRECISION MEDICINE PROJECTS”

Chair:

**Vangelis Manolopoulos**, *Professor, Laboratory of Pharmacology, Medical School, Democritus University of Thrace, and Clinical Pharmacology and Precision Medicine Unit, Academic General Hospital of Evros, Alexandroupolis, Greece*

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(\*) *has been invited and pending reply*



# 20th International Conference on Pharmaceutical Medicine

Hybrid Meeting 19-21 October 2022 SNFCC, Athens – Greece

## What lies ahead in Pharmaceutical Medicine

[www.icpm2022.gr](http://www.icpm2022.gr)

### Speakers:

- Hellenic Sepsis Study Group Research

**Evangelos J. Giamarellos-Bourboulis**, MD, PhD, FISAC, Professor of Internal Medicine, Director: Master (MSc) Program of Infectious Diseases, 4th Department of Internal Medicine, ATTIKON University Hospital

- Biomedical Research Foundation of the Academy of Athens Research

**Constantin Tamvakopoulos**, PhD, Investigator - Professor Level, Clinical, Experimental Surgery & Translational Research Lab Head, Biomedical Research Foundation of the Academy of Athens (\*)

- Development of small molecule neurotrophin mimetics against neurodegenerative diseases

**Dr Theodora Calogeropoulou**, Research Director Institute of Chemical Biology (ICB.), National Hellenic Research Foundation

11:30-12:00 Discussion

12:00 End of Pre-ICPM 2022 Meeting Sessions

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## October 19, 2022 - Day 1

11:00 Registrations

12:00-13:00 Welcome lunch

### MAIN HALL - HYBRID

13:00 Official opening

Chairs:

*Varvara Baroutsou, MD, PhD, GFMD, EMAUD, Consultant Internal Medicine, Pharmaceutical Medicine, ELEFI President, IFAPP President Elect*

*Marco Romano, IFAPP President*

Officials addresses:

- *Mina Gaga, MD, PhD, Alternate Minister of Health, Ministry of Health, Greece (\*)*
- *Meletios Athanasios Dimopoulos, Dean of National and Kapodistrian University of Athens*
- *Nikos Dedes, President Greek Patients Society*

Greek Pharmaceutical Industry stakeholders addresses (*to be invited*):

- *SFEE, President Greece*
- *Panhellenic Pharmaceutical Association, President Greece*
- *Pharma Innovation Forum, President Greece*
- *SAFEE, President Greece*

International stakeholders addresses:

- *WHO Regional Office Executive (\*)*
- *Lembit Rägo, Dr, MD, PhD, Secretary-General, Council for International Organizations of Medical Sciences (CIOMS), Geneva, Switzerland*
- *WMA Executive (\*)*

14:00-14:30 Break

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**14:30-15:00 Keynote speech: “DEVELOPMENT OF NOVEL GENETIC TOOLS IN BIOMEDICAL RESEARCH”**

Chair:

**Varvara Baroutsou, MD, PhD, GFMD, EMAUD, Consultant Internal Medicine, Pharmaceutical Medicine, President ELEFI, IFAPP President Elect**

Speaker:

**Prof. N. Tavernarakis, European Research Council Vice President, Chairman of the Board of Directors at the Foundation for Research and Technology-Hellas (FORTH), Research Director at the Institute of Molecular Biology and Biotechnology (IMBB), and Professor of Molecular Systems Biology at the Medical School of the University of Crete, Heraklion, Greece**

**15:00-16:30 Round table: “THE IMPACT OF THE EUROPEAN CLINICAL TRIALS REGULATION ON GLOBAL CLINICAL DEVELOPMENT”**

Chair:

**Ingrid Klingmann, MD, PhD, Chairman at EFGCP, President at PharmaTrain Federation, Managing Director at Pharmaplex**

Speakers:

**‘Will the EU Clinical Trial Regulation make Europe a more attractive region for global sponsors of clinical trials?’  
Magda Chlebus, Executive Director Science Policy and Regulatory Affairs, EFPIA**

**‘Will the new EU regulatory framework for trials in different vulnerable populations set the standard for more diversity?’**

**Kaisa Immonen, Director of Policy, EPF (\*)**

**‘Will the EU become the driver for transparency of clinical trial results?’**

**Fergus Sweeney, Head of Division, Clinical Studies and Manufacturing Taskforce, EMA (\*)**

**16:30-17:00 Break**

**17:00-18:00 Round table: “PATIENT AND PUBLIC INVOLVEMENT (PPI) IN MEDICINES R&D: LET’S WALK THE TALK”**

Chair:

**Cordula Landgraf, Director Communication and Stakeholder Engagement, SCTO, Switzerland; Member of IFAPP Board of Officers**

**‘PROMs as foundation of patient-centric clinical research’**

Speakers:

**‘Empowering patients: patient involvement in the whole life cycle of a medicinal product - overview & case study’**

**Christoph Meier, MD, Head, Department of Internal Medicine, University Hospital Zurich, Switzerland**

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‘Empowering patients: patient involvement in the whole life cycle of a medicinal product - overview & case study’

Jan Geissler, *Advocates, Germany* (\*)

**18:00-18:30** Dialogue: “BIOMEDICAL RESEARCH FOR GLOBAL PUBLIC INTEREST”

Chair:

Marco Romano, *IFAPP President*

Discussants:

Andreas Papapetropoulos, *BPharm, PhD, FAHA, FBPhS, Professor & Director Laboratory of Pharmacology, Faculty of Pharmacy, National and Kapodistrian University of Athens, EPHAR Secretary General*

Varvara Baroutsou, *MD, PhD, GFMD, EMAUD, Consultant Internal Medicine, Pharmaceutical Medicine, ELEFI President, IFAPP President Elect*

**18:30 -19:00** Open Call Speakers Session

**19:00** Adjourn of Day 1

**20:00** Conference Reception

**October 19, 2022 - Day 1**

**PARALLEL HALL - ONLY VIRTUAL**

**11:00-12:00 Session: “UKRAINIAN WAR CRISIS IMPACT ON CLINICAL TRIALS: ETHICAL ASPECTS AND PATIENT RIGHTS”**

Chair:

**Sandor Kerpel Fronius (\*)**

Speakers:

**Francis P. Crawley, BPhil., Executive Director, Good Clinical Practice Alliance (GCPA) & SIDCER (\*)**

**Chieko Kurihara, BSocSc, specially appointed Professor, Kanagawa Dental University, and Member of the IFAPP Ethics Working Group (\*)**

**17:15-18:00 Session: “FACULTY PHARMACEUTICAL MEDICINE, UK”**

Chair:

**Brigitte Franke-Bray, (MD PhD) FFPM GFMD, Specialist in Pharmaceutical Medicine FMH, Treasurer IFAPP**

Speaker:

‘Education & training at the Faculty of Pharmaceutical Medicine’,

**Peter Stonier, Director of Education & Training at the Faculty of Pharmaceutical Medicine, UK (\*)**

**18:00-19:00 Oral Presentations & e-posters session (North & South America, West Africa & Western Europe)**

Chairs:

**Maria Polydorou, PharmD, MSc Clinical Pharmacy, Director of Pfizer's Pharmacovigilance Departments for Southeastern Europe (Cluster Safety Lead for SEEU)**

**Eleonora Sarikou, BSc Biology, MBA, Pharmacovigilance & Regulatory Manager, Medical Department GlaxoSmithKline Greece**

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## October 20, 2022 - Day 2

### MAIN HALL - HYBRID

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**08:00-09:00** Oral presentations & e-posters session (Eastern Europe, East Africa, Middle East, Asia, Australia & New Zealand)

Chairs:

**Grigorios Agkyralidis**, PharmD, Regulatory Affairs Head, Boehringer Ingelheim, Greece

**Dimitra Tsapoga**, Biotechnology MSc, Medical & Clinical Head Creative, Greece, ELEFI Board Member (\*)

**09:00-10:30** Round table: “CLINICAL DATA FOR SAFETY AND PERFORMANCE OF MEDICAL DEVICES (MD) TO OBTAIN MARKET AUTHORIZATION APPROVAL”

Chair:

**Ghazaleh Gouya**, Priv. Doz Dr. med Cardiologist, Founder of Gouya insights, GPMed Board Member & IFAPP Board Member

Speakers:

‘Design of clinical MD investigations and approvable endpoints’

**Dr. Andreas Beust**, Chief Scientific Officer, GCP-Service International Ltd. & Co. KG

‘How much clinical data from Medical Device studies is enough for CE mark?’

**Shayesteh Fürst-Ladani**, MBA, MSc, GFMD, Senior Vice President SFL, Head of SFL Group

‘Guidance documents’

**Tom Melvin**, Clinical Manager, Medical Devices and Senior Medical Officer at Health Products Regulatory Authority (HPRA)

**10:30-11:00** Break

**11:00-12:30** Round table: “INSTITUTIONAL RESEARCH GOVERNANCE”

Chairs:

**Chieko Kurihara**, BSocSc, specially appointed Professor, Kanagawa Dental University, and Member of the IFAPP Ethics Working Group

**Takis Vidalis**, Lawyer, PhD in Law, Senior Advisor National Bioethics Committee of Greece, BioMedLex Coordinator

Speakers:

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‘Association for the Accreditation of Human Research Protection Programs (AAHRPP), IRB Governance, Institutional Governance for the Patient Protection Program’

**Elyse I. Summers, JD, President and CEO AAHRPP**

‘CIOMS Principles of Good Governance for Research Institutions (PGGRI)’

**Dr. Dominique Sprumont, Prof. University Neuchatel, Chairman Research Ethics Committee of the Canton of Vaud, Switzerland**

‘Bio-Bank and Database challenges’

*Speaker tba*

**12:30-13:30 Session: “RWD TRENDS IN PHARMACOEPIDEMOLOGY AND OPPORTUNITIES FOR RWE”**

Chairs:

**Brigitte Franke-Bray, (MD PhD) FFPM GFMD, Specialist in Pharmaceutical Medicine FMH, Treasurer IFAPP**

**Elena Panitti, MD, Global Head RWE Excellence Novartis, Basel, Switzerland**

Speakers:

‘Quality in RWD Initiative in Austria’

**Priv. Doz. Dr. Johannes Pleiner-Duxneuner, President GPMed (\*)**

‘MHRA guidance on the use of real-world data in clinical studies to support regulatory decisions’

**David Brown, Statistician, Medicines and Healthcare products Regulatory Agency (MHRA), MHRA-Licensing (\*)**

‘A vision for use of real-world evidence in EU medicines regulation EMA Initiative on RWE’

**Xavier Kurz, Head of Surveillance & Epidemiology Service Inspections, Human Medicines Pharmacovigilance & Committees Division, EMA (\*)**

**13:30-14:30 Lunch break**

**14:30-16:00 Round table: “NEWLY EMERGING ETHICAL ISSUES WITH DATA DRIVEN RESEARCH AND DATA SHARING”**

Chairs:

**Kotone Matsuyama, Professor, Department of Health Policy and Management, and Vice President of Center for Strategic Research Initiative, Nippon Medical School & IFAPP Ethics Group Chair**

**Varvara Baroutsou, MD, PhD, GFMD, EMAUD, Consultant Internal Medicine, Pharmaceutical Medicine, ELEFI President, IFAPP President Elect**

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Speakers:

‘The WMA’s Declaration of Taipei, the EU’s GDPR, and the EMA’s Policy 0070: The Impact of Ethics, Law, and Policy on Data Sharing Practices in Europe’

**Francis P. Crawley**, *BPhil., Executive Director, Good Clinical Practice Alliance (GCPA) & SIDCER*

‘Current situation and issues with the Data driven Research in Japan’

**Chieko Kurihara**, *BSocSc, specially appointed Professor, Kanagawa Dental University, and Member of the IFAPP Ethics Working Group*

‘Current situation and issues with the Data driven Research in US’

**Laura Biven**, *PhD, Branch Chief for Integrated Infrastructure and Emerging Technologies Office of Data Science Strategy Division of Program Coordination, Planning and Strategic Initiatives Office of the Director National Institutes of Health*

**16:00-16:30 Break**

**16:30-18:00 Round table: “PAEDIATRIC MEDICINAL PRODUCTS - STILL A MATTER OF DISCUSSION”**

Chair:

**Birka Lehmann**, *Senior Expert for Drug Regulatory Affairs and Lecturer at the University of Bonn, Germany*

Speakers:

‘Clinical trials with minors - report from the c4c project’

**Heidrun Hildebrand**, *Bayer AG, Pediatric Development Alliance Manager*

‘Patients/Parents involvement in development of medicinal products’

**Dimitrios Athanasiou**, *Patient representative at the PDCO*

‘Extrapolation - a concept to avoid unnecessary clinical trials in minors’

**Silke Gastine**, *Pharmacometrics Expert at Sanofi, Germany (\*)*

**18:00-19:00 Round table: “PROFESSIONAL DEVELOPMENT IN PHARMACEUTICAL MEDICINE - SHAPING YOUR CAREER IN PHARMACEUTICAL MEDICINE”**

Chairs:

**Annette Mollet**, *PhD, dipl. Pharm. Med. SwAPP, MBA, Head of Education & Training of the European Center of Pharmaceutical Medicine at the University of Basel, Switzerland*

**Marco Romano**, *IFAPP President*

Speaker:

**Nikolaos Tsokanas**, *BSc (Hons), MSc, MBA, Medical Operations & Quality Systems Cluster Head Bayer (GR, CY, BG, MD, RO, Ukraine)*

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**19:00** Adjourn of Day 2

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**October 20, 2022 - Day 2**

PARALLEL HALL - ONLY VIRTUAL

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**11:00-12:30 Round table: “CONTINUING EDUCATION IN PHARMACEUTICAL MEDICINE”**

*Asian expectation to new education and training for all in Pharmaceutical Medicine*

Chairs:

**Ajay Tiku**, MBChB, MMed (Int Med), Region Medical Head APMA Region (Asia Pacific, Middle East and Africa), Novartis Pharma

**Kyoko Imamura**, MD, PhD, Dr MedSci, GFMD, IFAPP Past President, Visiting Professor Tokyo University

Speakers:

‘Expectations in Medical Affairs’

**Matt Britland**, MD, Medical Director/Amgen, President/APPA (\*)

‘PCPM course as our future educational platform to learn pharmaceutical medicine’

**Dr Maria Caridad P. Purugganan**, Medical Director, Biofemme, the Women’s Health Division of UNILAB, Inc., Member Board of Directors, Philippine College of Pharmaceutical Medicine

‘PharmaTrain course (CoE course recognized by PharmaTrain)’

**Kotone Matsuyama**, (JAPhMed) Professor, Department of Health Policy and Management, and Vice President of Center for Strategic Research Initiative, Nippon Medical School & IFAPP Ethics Group Chair

‘MAPS interests and potential collaboration in education & certification’

**Victoria Elegant**, Adjunct Prof. MBBS, DRCOG, FPM, FFPM, Vice President, Medical Affairs, Amgen Asia Pacific, Global Lead, Access to Medicines, Amgen, President Asia Pacific, Medical Affairs Professional Society, Advisor, FPM Global

**13:30-14:30 Lunch Break**

**14:30-16:00 Round table: “CURRENT CHALLENGES & TRENDS IN HEALTH TECHNOLOGY ASSESSMENT FOR PATIENT ACCESS”**

*Supporting Future EU HTA system under the new HTA Regulation*

Chairs:

**Kostas Athanasakis**, Associate Professor, Health Economics

**Flora Bakopoulou**, Professor, Greece HTA Committee President

(\*) has been invited and pending reply



*Topics/Speakers tba  
Spain representative invited  
Portugal representative invited  
Italian representative invited*

**16:30-17:00** Session: “THE SELECTION OF KEY PERFORMANCE INDICATORS FOR AN ECONOMIC EVALUATION OF AI TECHNOLOGIES: THE CASE OF HOSMARTAI”

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Chair:

**Markos Ollandezos**, *Scientific Director, Panhellenic Pharmaceutical Association (\*)*

Speaker:

“Smart Hospital” with Artificial Intelligence Technologies (HosmartAI)’

**Magda Chatzikou**, *PhD, Partner PharmEcons Easy Access, SEP Hellenic Open University Health Care Management Partners at HORIZON 2020 in Healthcare Programme*

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**October 21, 2022 - Day 3**

**MAIN HALL - HYBRID**

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**09:00-09:30** Hellenic Biocluster: “GREEK START UP INNOVATION IN HEALTH AS A LEVER FOR R&D GROWTH”

Chair:

**Grigorios Rombopoulos, MD, Specialist in Endocrinology, CSO Novartis Greece**

Speaker:

**Ioanna Koukli, PhD, President HBio**

**09:30-11:00** Dialogue: “MEDICAL AFFAIRS ON EVOLVING MEDICAL LEADERSHIP, STRATEGIES AND UPSKILLING IN THE DIGITAL ERA”

Chairs:

**Athanasios Chaniotis, BSc in Chemistry, Strategic Alliances Manager, J&J Greece**

**Nikos Tsokanas, BSc (Hons), MSc, MBA, Medical Operations & Quality Systems Cluster Head, Bayer (GR, CY, BG, MD, RO, Ukraine)**

Discussants:

**Alex Moulis, PhD, Medical Director, Sandoz**

**Grigorios Rombopoulos, MD, Specialist in Endocrinology, CSO Novartis Greece**

**Thanassis Kotsanis, Cardiologist, Medical Director GR & CY/Cluster, Medical Director Southern Mediterranean & Black Sea, Bayer AG**

**11:00-11:30** Break

**11:30-13:00** Round table: “Artificial Intelligence and Modern Trends in Pharmacovigilance and Active Safety Surveillance”

Chairs:

**Sofia Drouska, PharmD, Deputy Director of Pharmacovigilance Department of National Organization for Medicines (\*)**

**Christina Tsougkou, PharmD, Safety Value Partner, Roche Hellas**

Speakers:

‘Active Safety Surveillance’

**Pantelis Natsiavas, Researcher, Head of eHealth Lab Institute of Applied Biosciences, Centre of Research and Technology Hellas (INAB CERTH)**

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‘Artificial Intelligence applications in Pharmacovigilance’

**Karthick Sukumaran**, *Technology Enablement Director Intelligent Safety Automation, Roche & Sriram Venkateswaran*, *Data Scientist in Data Acquisition, Roche*

**13:00-14:00** Lunch break

**14:00-15:00** IFAPP HoD & General Assembly

**15:00-15:30** Nomination of President Elect 2022 and ICPM 2024

**15:30-16:00** Break

**16:00-17:30** Round table: “POST AUTHORIZATION COVID-19 VACCINES SAFETY AND PHARMACOEPIDEMOLOGY STUDIES”

Chair:

**Christos Kontogiorgis**, *Associate Professor Health and Environmental Protection, Medical School of Alexandroupolis, Democritus University, ENCePP expert (\*)*

Speakers:

‘The European perspective - ENCePP/Vac4eu Safety Monitoring Activities’

*Speaker tba*

‘The Canadian COVID-19 vaccine safety surveillance outcomes’

**Antonios Douros**, *Assistant Professor McGill University, Canada*

‘The background rates of adverse events of special interest for COVID-19 vaccine safety monitoring’

**Ioannis Petrakis**, *PhD, Senior Director, Global Medical Affairs, Gastroenterology Pipeline, Takeda US (\*)*

**17:30-18:30** Dialogue: “DIGITAL HEALTH, EMR & CLINICAL RESEARCH: WHERE WE ARE AND WHERE WE WILL GO”

Chairs:

**Konstantina Papageorgiou**, *PhD, Molecular Biologist, Associate Director Global Clinical Project Delivery*

**Varvara Baroutsou**, *MD, PhD, GFMD, EMAUD, Consultant Internal Medicine, Pharmaceutical Medicine, ELEFI President, IFAPP President Elect*

Discussants:

**Haralambos Karanikas**, *Assistant Professor, Department of Computer Science and Biomedical Informatics, University of Thessaly (\*)*

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*Vera Vazaiou, Senior Manager/Central Monitor Oversight Lead, Amgen*

*Aggelina Mavraki, Clinical Studies Unit Head, Sanofi Greece*

*Anna Aletra, Senior Trial Manager, Clinical Development Center Poland, Novo Nordisk*

**18:30** End of ICPM 2022

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**October 21, 2022 - Day 3**

PARALLEL HALL - ONLY VIRTUAL

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**11:30-13:00** Round table: “MODERN CLINICAL TRIALS & FUTURE RESEARCH TRENDS”

Chairs:

**Stefanos Tarazis, MD, PhD, Deputy Head of National Organization for Medicines, Pharmaceutical Research & Studies (\*)**

**Nikos Dedes, President Greek Patients' Association**

Speakers:

‘Latest artificial intelligence trends in clinical research’

**Dimitris Agrafiotis, PhD, Vice President Digital Worldwide Research Development and Medical Affairs, Pfizer**

‘Decentralized Clinical Trials’

**Robin Marcus, RN, BSN, Executive Director, Connected Health Strategy, Labcorp & Claire Campbel, Senior Digital Strategy and Solutions, Labcorp**

‘Patient recruitment & engagement in clinical trials’

**Melisa Harris, Associate Director Patient Relations, Recruitment, Engagement Labcorp (\*)**

**14:00-15:30** Dialogue: “PATIENT ENGAGEMENT PROGRAMMES”

Chair:

**Effie Simou, Assistant Professor Communication and Mass Media in Public Health, Health Policies, West Attika University**

**Yiannis Petrovas, BSc Chemistry, ELEFI Secretary General, Medical Operations Specialist, Medical Department, AbbVie, Greece**

Discussants:

**Zoe Grammatoglou, President KEFI Patient Association (\*)**

**Persefoni Augoustidou Savvopoulou, President KRIKOS ZOIS Patient Association**

**Dimitris Kontopidis, Vice President Greek Patient Association, General Director Humane Social Enterprise**

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