



## Pharmaceutical Medicine

### Current Trends in Health Technology Assessment: From a life-cycle perspective to RWE and patient-centred HTA

*Deree Faculty Lounge*

#### SCHEDULE

**Day 1 | Friday, April 5, 2024 | 10:00-16:00**

**Moderator Varvara Baroutsou**

10:00-10:10 Moderator welcome and introduction  
**Dr. Varvara Baroutsou**, MD, GFMD, EMAUD, IFAPP President

**10:10-13:00 Health Technology Assessment (HTA) and its importance in Health Care systems**  
**Eugena Stamuli**, Pharmacist, Health Economist MSc, Director HES Choices

10:10-11:15 What is HTA and what are the Processes of HTA: assessment, evidence interpretation & appraisal, decision-making space

11:15-11:30 Break

11:30-12:45 Impact on & involvement in HTA of various stakeholders: health policy makers, public/tax-payers/societal viewpoint, patients

12:45-13:00 Break

**13:00-16:00 Epidemiology, Pharmacoepidemiology & Health Technology Assessment**  
**Dr. Varvara Baroutsou**, MD, GFMD, EMAUD, IFAPP President

13:00-14:15 Role of epidemiological research in HTA / Pharmacoepidemiology Study designs, ethical and quality standards based on EnCePP guidelines

14:15-14:45 Break

14:45-15:45 Pharmacoepidemiology surveillance of medicines by European Medicines Agency and EnCePP

15:45-16:00 Highlights & Discussion



**Day 2 | Saturday, April 6, 2024 | 10:00-16:00**

**Moderator Varvara Baroutsou**

10:00-10:10 Introduction & key learnings of Day 1 for Day 2  
**Dr. Varvara Baroutsou**, MD, GFMD, EMAUD, IFAPP President

**10:10-13:00 Various HTA Paradigms across Countries (e.g., QALY based, MCDA, Efficiency-Frontier) and Associated Structures**

**Eugena Stamuli**, Pharmacist, Health Economist MSc, Director HES Choices

10:10-11:15 How HTA organisations are structured / Key aspects of HTA: Clinical evidence, economic evaluation, budget impact and uncertainty

11:15-11:30 Break

11:30-12:45 Types of HTAs and various thresholds (e.g., rare diseases, ATMPs) / Possible ways of interacting with HTA (patients, public and other stakeholders) / Transparency of process, confidentiality, and conflict of interest

12:45-13:00 Break

**13:00-16:00 HTA vs Regulatory (European Medicines Agency)**

**Dr. Varvara Baroutsou**, MD, GFMD, EMAUD, IFAPP President

13:00-14:15 Regulators Perspective, HTA Bodies Perspective and the European Regulation on HTA

14:15-14:45 Break

14:45-15:45 EUnetHTA core model, Joint Scientific Consultation & Joint Scientific Assessment, Joint Regulatory and HTA processes, HTA aspects in Early Product Development (e.g., clinical trial designs) EU HTA Regulation -Member States Coordination on HTA

15:45-16:00 Highlights & Discussion

**Day 3 | Friday, April 12, 2024 | 10:00-16:00**

**Moderator Varvara Baroutsou**

10:00-10:10 Introduction & key learnings of Day 2 for Day 3  
**Dr. Varvara Baroutsou**, MD, GFMD, EMAUD, IFAPP President

**10:10-13:00 Developing HTA submission for new products- Clinical Evidence**

**Dr. Varvara Baroutsou**, MD, GFMD, EMAUD, IFAPP President



10:10-11:15 Primary Evidence collection – type of Data that are required, stage at which data are collected and type of Study Designs (e.g., RCT, observational) - Strengths and Limitations

11:15-11:30 Break

11:30-12:45 Patient-Reported Outcomes vs. Clinical outcomes: role of each in HTA. Secondary Evidence collection: systematic reviews, meta-analyses (direct, indirect meta-analysis). Analysis alongside clinical trials vs. modelling studies

12:45-13:00 Break

**13:00-16:00 Resource use and Costing data/evidence: sources and how to collect them. Types of Economic Analysis**

**Eugena Stamuli**, Pharmacist, Health Economist MSc, Director HES Choices

13:00-14:15 Full Economic Evaluation (cost-effectiveness, cost-utility data) and Cost-consequences Analyses

14:15-14:45 Break

14:45-15:45 Budget Impact (and why it is needed alongside cost-effectiveness/utility analyses)

15:45-16:00 Highlights & Discussion

**Day 4 | Saturday, April 13, 2024 | 10:00-16:00**

**Moderator Varvara Baroutsou**

10:00-10:10 Introduction & key learnings of Day 3 for Day 4  
**Dr. Varvara Baroutsou**, MD, GFMD, EMAUD, IFAPP President

**10:10-13:00 HTA in practice: Payment models and Value-based pricing**

**Eugena Stamuli**, Pharmacist, Health Economist MSc, Director HES Choices

10:10-11:15 Managed Entry Agreements, Risk-sharing/performance-based, Coverage with Evidence Development, Innovative Payment models

11:15-11:30 Break

11:30-12:45 Value-based Pricing. Disinvestment decisions/ Opportunity cost

12:45-13:00 Break



**13:00-16:00 HTA Regulation Implementation**

**Dr. Varvara Baroutsou**, MD, GFMD, EMAUD, IFAPP President

13:00-14:15 Building a new EU level Environment: European Collaboration between Regulators and Health Technology Assessment Bodies. Collaboration under the New HTA Regulation and Contributing to faster Patient Access

14:15-14:45 Break

14:45-15:45 European Methodology -what is required to achieve the outcomes? How to prepare for the New HTA Regulation implementation / Patients and Citizens involvement: Now and in the Future. Sharing and Collaboration between HTA Bodies and Stakeholders

15:45-16:00 Highlights & Discussion