

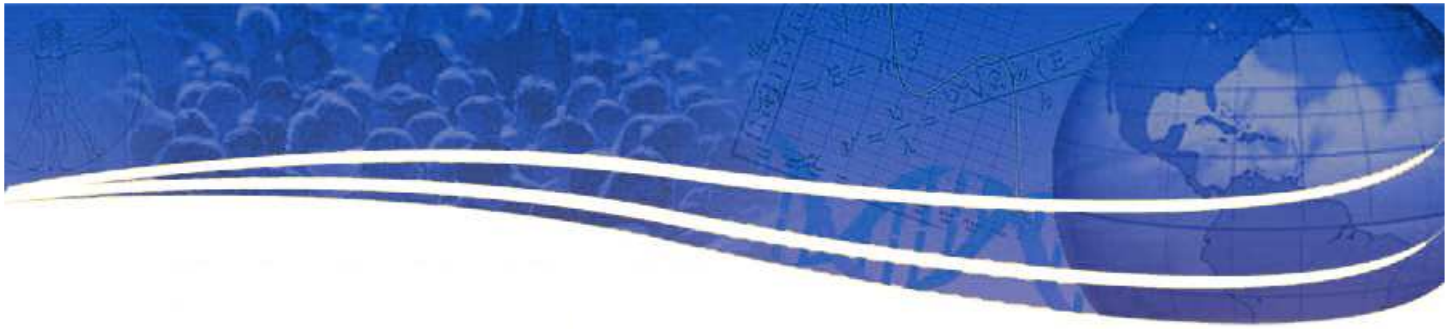


# Presentation of the 1<sup>st</sup> European **M**arket **A**ccess University Diploma

*A unique and innovative course*

The programme follows each step of the life cycle of a drug, integrating market access theory and practice for results that can be applied in the real world. Students will acquire the necessary skills to implement and develop a market access plan.

[www.EMAUD.org](http://www.EMAUD.org)



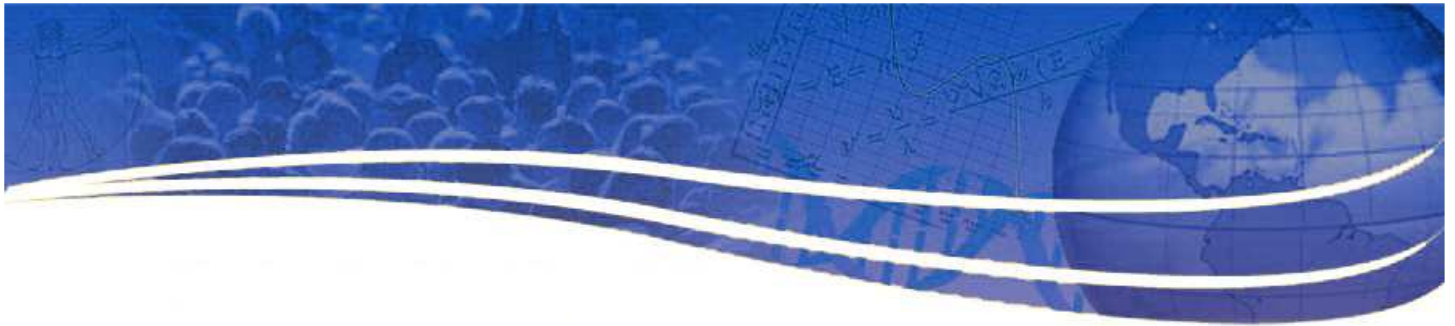
## Module 1: Market Access Environment – 24h

### Objective

Set the scene: health environment, health policies, market access regulations

### Activities

- Introduction to the concept of market access
- Why has market access emerged?
- Decision-making chain
  - National stakeholders
  - Regional stakeholders
  - Local stakeholders
- Market access strategies
  - Adapting the strategy for each market access stakeholder
- Market access policies in Europe
- Market access policies outside Europe (USA, Canada, Australia, Japan and New-Zealand)
- Market access perspectives and drug development
  - Key activities, outputs and benefits from Phase I to LCM: when to do what?



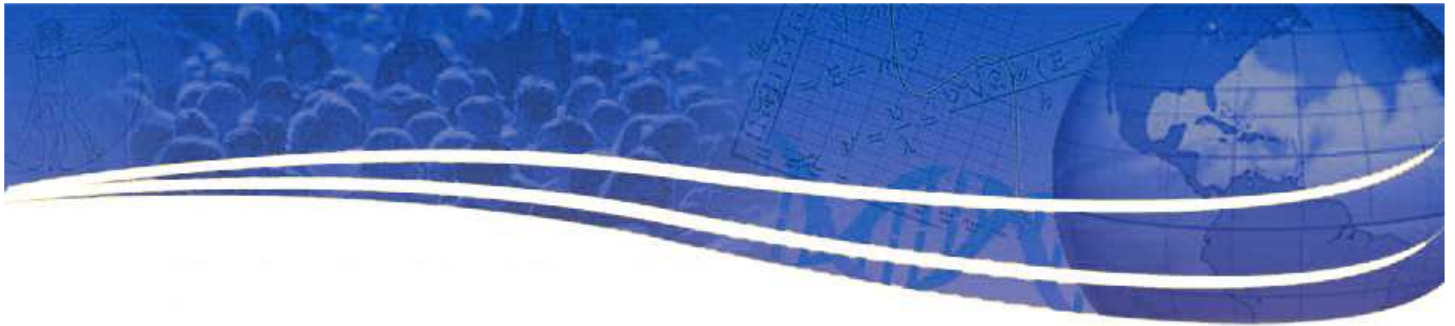
## Module 2: Market Access Activities in Early Preparation Phase I/II – 24h

### Objectives

- Market Access Gap Analysis
- Support to portfolio decision making
- Drivers and barriers
- Incorporate Market Access issues in clinical development (P&R, HTA and Market Access Plan)

### Activities

- Disease Environment/Management
  - Desk Research
    - Mapping
    - Literature Review (PRO, competitors, disease management, policy review, Guidelines, HTA assessment)
  - Observational studies (cohort, database)
- Pricing
  - Payer landscape research
  - Price anchoring studies
  - Reimbursability evaluation
- Health Economics Outcomes Research
  - Conceptual Model
  - PRO development
  - COI studies
  - Ballpark Modelling/Value Based Pricing
  - Early cost-effectiveness evaluation
  - Early HTA advice



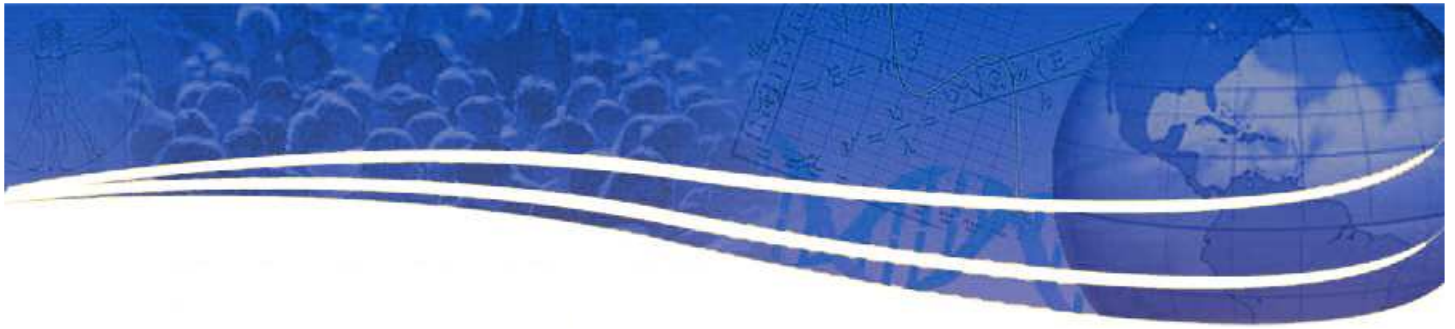
### Module 3: Market Access Activities in Phase III/Pre Launch - 24h

#### Objectives

- Monitor Changes
- Support to Portfolio decision making
- Incorporate Market Access Issues in Clinical Development
- Create Value Story

#### Activities

- Disease Environment/Management
  - Desk Research
    - Mapping
    - Literature Review (PRO, competitors, disease management, policy review, Guidelines, HTA assessment)
  - Observational Studies (cohort, database)
- Pricing
  - P&R environment
  - Price sensitivity
  - Payer research
  - Pricing sequence
  - Price strategy
  - P&R risk evaluation
- HEOR
  - Endpoint Model, FDA/EMA document (labeling claims)
  - PRO development
  - HEOR analyses of Clinical Studies
  - Clinical Relevance, indirect comparison
  - Preparation HTA sequence
- Affiliates Responsibilities
  - Alert local issues
  - Scientific stakeholder management
  - Local studies
  - Publication cost-effectiveness evaluation



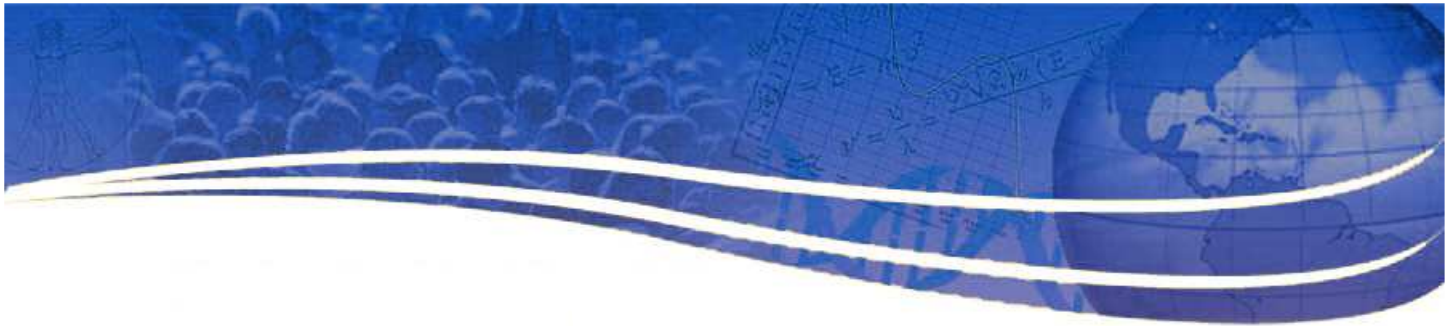
## Module 4: Market Access Activities in Launch/Post Launch/LCM – 24h

### Objective

Achieve P&R, HTA recommendation and Formulary inclusion at optimal prices/restrictions

### Activities

- Pricing
  - Launch
    - Negotiation guide
    - Core Value Dossier
    - Adaptation Core Value Dossier to Local Needs
    - Strategic advice
  - Life Cycle
    - Price database
    - Coordination sequence
    - Price Erosion
- HEOR/Epidemiology
  - Launch
    - FDA/EMA PRO submission dossier
    - Publication HEOR evidence (Cost-effectiveness, comparative effectiveness, clinical relevance, Phase III HEOR results)
    - Standard HTA dossier
    - Local Adaptation (Cost-effectiveness and Local HTA dossier)
    - HE studies
    - Post-hoc analyses
    - Publications
  - Life Cycle
    - IITs
    - Observational studies to demonstrate real life effectiveness (cohort, databases)
    - Scientific Lobbying
    - Anticipate re-evaluation and update HTA dossier
    - Monitor New entrants/Environment
- Affiliates Responsibilities
  - Alert local issues/Policy management
  - Scientific stakeholder management & Patient advocacy
  - Local studies
  - Adaptation, Submission and Negotiations
  - Communication/ Management of HTA decisions



## Module 5: Risk Management and Decision Sciences – 24h

### Objectives

- Enhance managerial understanding of decision making processes
- Address the many complex phenomena of the decision making process

### Activities

- Decision science theory
- Risk management concepts and applications
- Insurance theory and risk management applied to market access
- Portfolio management : integration of market access constraints
- Decision sciences and risk management as tool for tomorrow market access
- Risk sharing applied to market access

## Workshop: Strategic Planning - *time to be confirmed*

### Objective

Application for strategic planning

### Activities

- Establish Core Team who develop
  - Global Master Plan
  - Core Value / HTA dossier
- Insert real example presented by external speakers



### ★ **A 5-module-course to be taken in 1 to 3 years**

The course is composed of 5 modules of 4 consecutive days scheduled during the year. Each module counts for 24 hours, which represents a total of 120 hours for the complete course.

The 5 modules can be done separately not necessarily in only one year and not in any specific order (for example module 1 & 3 the first year, module 2 the second year, and module 4 & 5 the third year).

The course is validated after the submission of a professional thesis. The thesis could be either a company case study for professional candidates on a study break, or a literature review for student candidates completing their Masters or equivalent.

### ★ **A course exclusively given in English**

Speakers and contributors come from institutional organizations, the academic world and the healthcare industry of Europe and outside Europe.

### ★ **To apply**

- Fill in a candidacy form (for the whole diploma or by module)
- Submit a CV and a cover letter
- Send your application to [application@emaud.org](mailto:application@emaud.org)

### ★ **Contact**

- EMAUD Chairmen
  - Pr. Mondher Toumi, [mondher.toumi@univ-lyon1.fr](mailto:mondher.toumi@univ-lyon1.fr)
  - Pr. Michel Lamure, [lamure@univ-lyon1.fr](mailto:lamure@univ-lyon1.fr)
  - Pr. Marc Bui, [marc.bui@ephe.sorbonne.fr](mailto:marc.bui@ephe.sorbonne.fr)
- EMAUD Coordinator
  - Mrs. Gaëlle Chatelier, [gaelle.chatelier@emaud.org](mailto:gaelle.chatelier@emaud.org)
- EMAUD Communication
  - Mrs. Odile Barthez, [odile.barthez@emaud.org](mailto:odile.barthez@emaud.org)