

# EMAUD

European Market Access University Diploma

**2020-2021**

*An innovative & engaging course*

**EMAUD is run Market Access Society (MAS)**

EMAUD's program integrates market access theory and practice throughout each step of a drug's life cycle and allows for real-world application. Students acquire the necessary skills to develop and implement strategic market access plans.

**At each Module special attention will be given to the impact of COVID-19 that is disrupting pharma-industry business model**

**<https://www.emaud.eu/>**

**[www.marketaccesssociety.org](http://www.marketaccesssociety.org)**



**Market Access Society**

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## 5 modules, combining theory and practice:

- Module 1: Market Access Policy and Environment
- Module 2: Market Access Activities in Early Preparation Phase I/II
- Module 3: Market Access Activities in Phase III/Pre Launch
- Module 4: Market Access Activities in Launch/Post Launch/LCM
- [Module 4bis: Health Economics and Outcome Research \(optional\)](#)
- Module 5: Market Access for Vaccines, Medical Devices and Diagnostics

## Interactive Modules consist of:

- Pre-reading and preparation materials
- Group workshops
- Case studies

## First rate contributors and lecturers:

- Leading contributors join us from the academic world, pricing and HTA agencies, and industry organizations

## Access to Annual Market Access Day:

- Students are able to access and experience an international conference centered around the latest national regulations and future challenges with respect to economic constraints and/or payers requirements.
- A debate that cannot be missed!

## What does it take to achieve the EMAUD diploma?

- One of the following publications;
  - A Literature review, or review of a decision, or a landscape analysis, or case studies, or health economics projects, or pharmaco-epidemiology projects, or pricing study;

**AND**

- A publication submitted to a PubMed indexed scientific journal.

Support is provided to students who have little experience in writing a publication, if needed.

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## Module 1 – 28h

### Market Access Environment

#### Objective

- Set the scene: health environment, health policies, market access regulations across a broad range of countries. Country-specific policies are presented by Public Agency Representatives and country experts.
- Impact of COVID-19 pandemic on pharmaceutical industry business model and focus on market access **(NEW)**

#### Activities

- Introduction to market access definition, concept, and principles
  - National stakeholders
  - Regional stakeholders
  - Local stakeholders
  - Why has market access emerged? Decision-making chain
  - Market access strategies
    - Adapting the strategy for each market access stakeholder
- Impact of COVID-19 pandemic on pharmaceutical industry business model and focus on market access **(NEW)**

#### Market access policies in Europe

- Market access policies outside Europe (USA, Canada, Australia, Japan, and China)
- Market access perspectives and drug development
- Key activities, outputs and benefits from Phase I to LCM: what should you do and when should you do it?

#### Workshop & Case study

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## Module 2 – 28h

### Market Access Activities in Early Preparation Phase I/II

#### Objectives

- Market Access landscape and strategy
- Gap Analysis and activity prioritization
- Market access planning, budgeting, and execution
- Support to development decision making
- Drivers and barriers of market access
- Incorporate market access issues in clinical development (P&R, HTA, and Market Access Plan)

#### Activities

- Landscape analysis
  - Desk Research
    - Disease understanding
    - Mapping
    - Literature Review (PRO, competitors, disease management, policy review, Guidelines, HTA assessment)
- Pricing
  - Payer research
  - Price anchoring studies
  - Reimbursement evaluation
- Market Access Agreements
- Early HTA advice
- Value story development and Gap Analysis

#### Workshop & Case study

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## Module 3 – 28h

### Market Access Activities in Phase III/Pre-Launch

#### Objectives

- Monitor Environmental Changes
- Advocacy
- Managing uncertainty
- Pricing studies
- Market access focus on specific products

#### Activities

- Pricing
  - P&R environment
  - Price sensitivity
  - Payer research
  - External reference pricing
  - Pricing sequence
  - Price strategy
  - P&R risk evaluation
- Building an effective advocacy strategy to support market access
- Market access specificities in emerging countries
- Market access of specific products
  - Orphan drugs
  - Oncology products
  - **Regenerative medicine (one full day) New**
  - Mature products
  - Value added medicine
  - Combined products (fix combination and device drugs combination)
  - Biosimilars

#### Workshop & Case study

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## Module 4 – 28h

### Market Access Activities in Launch/Post-Launch/LCM

#### Objectives

- Achieve P&R, HTA recommendations, and formulary inclusion at optimal prices/restrictions

#### Activities

- Final Pricing Strategy
- Launch
  - Negotiation guide
  - Core Value Dossier
  - Adaptation Core Value Dossier to Local Needs
  - Strategic advice
- Negotiation Skills and Strategy
- Life Cycle
  - Price database; Coordination sequence; Price Erosion
  - HEOR/Epidemiology
    - Launch
      - FDA/EMEA 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; real life effectiveness
      - Scientific Lobbying
      - Anticipate re-evaluation and update HTA dossier
      - Monitor New entrants/Environment
- Interaction Affiliates Region and corporate functions for successful market access

#### Workshop & Case study

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## Module 4bis – 18h (optional)

### Health economics and outcome research

#### Objectives

- Understand the concepts of HEOR and execute basic exercises including:
  - Develop specification of a model
  - Develop a model
  - Develop a utility instrument
  - Develop a protocol for micro-costing
  - Critical review of a model
- Morning lectures are centered around theory, while the afternoon session is dedicated to practical exercises

#### Activities

- Health Economics and Outcome Research
  - Conceptual Model
  - PRO Development
  - COI Studies
  - Ballpark Modelling/Value-Based Pricing
  - Early cost-effectiveness evaluation
  - Different types of models

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## Module 5 – 28h

### Market Access for Vaccines, Medical Devices, and Diagnostics

#### Objectives

- Understand the specificities of Market Access for Vaccines, Medical Devices, and Diagnostics.

#### Activities

- Overview of the market and strategy
- Mapping of the access process in Europe and outside Europe
- Definition, regulation, classification, certification
- HTA and NITAG
- Vaccines in emerging countries: a worldwide paradigm
- Specificities for health economics assessment and value demonstration
- Innovation and future challenges
- Value-based pricing for diagnostics and devices

#### Workshop & Case study



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### Why a diploma in Market Access?

Market Access is a complex process. Today, it is the fourth hurdle in drug development and an inescapable reality. It has become the driver of the global income of a new product/drug. No company providing drugs or devices can expect to succeed without designing a pricing and reimbursement strategy early in the development process. The concept of Market Access requires as much knowledge as professional capabilities. It is situated at a crossroads of multiple disciplines that all form an integral part of a valid, comprehensive course. The EMAUD course, exclusively taught in English, is a pioneer degree in the field of Market Access. Speakers and contributors come from institutional organizations, the academic world, and the healthcare industry. Their presentations will cover Market Access Policies, Pricing in Europe and outside Europe, Health Economics, Health Technology Assessment, Risk Management, and Decision Sciences.

### What is the objective of the EMAUD diploma?

- Gain an advanced understanding of the market access environment and principles
- Focus on the latest regulations and guidelines in Europe and outside Europe
- Draw a map of new actors: how they are becoming inescapable decision makers
- Obtain techniques and tools to implement in students' real-world business
- Develop knowledge in decision sciences
- Facilitate collaboration and contacts with experts from different organizations, public or private, who are main actors in the health industry and who confront these issues everyday
- Deliver the best practices of leading companies

### Key Learnings:

- Set up a successful pricing and market strategy
- Develop, validate, and execute a market access plan
- Build a value story which optimizes market access
- Understand the strengths and pitfalls of available evidence
- Design pricing research
- Define a pricing strategy
- Anticipate the future paradigm shifts in market access

### Who should attend EMAUD?

EMAUD is intended for students and professionals in the fields of life sciences and healthcare industries, including policy decision makers.

### Contributors

European HTA and pricing agencies, non-governmental agencies, industry representatives, and academics.

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## ACADEMIC INSTITUTIONS

### University of Aix-Marseille, France

Prof. Mondher TOUMI

Prof. Pascal AUQUIER

### University of Lyon 1, France

Prof. Michel LAMURE

### Tufts Center for the Study of Drug Development, USA

Prof. Joshua COHEN

### Health Economics Institute, Sweden

Prof. Ulf PERSSON

### University of Bocconi, Italy

Prof. Claudio JOMMI

Dr. Monica Hildegard OTTO

### University of Aberdeen, Scotland

Prof. Mandy RYAN

### Corvinus University of Budapest, Hungary

Prof. David DANKO

### Catholic University of Sacred Heart Rome

Prof. Walter RICCIARDI

### University of Tokyo, Japan

Dr. Ataru IGARASHI

## CONSULTANCY

### CPS Research, UK

Prof. Alan WADE

### Creativ-Ceutical, France

Dr. Samuel ABALLEA

Dr. Aurélie MILLIER

### Commutateur Online

Nick HICKS

### Analysis Group, Inc.

Christian FROIS

### Tech2Market, France

Mr. Mathieu CYNOBER

### European MS Platform, Belgium

Mr. Christoph THALHEIM

### Medicines Development and Training service, France

## GOVERNMENTAL INSTITUTIONS

### HAS, France

Dr. Anne D'ANDON

Mrs. Corinne COLLIGNON

Mrs. Nadia NAOUR

### NICE, UK

Mr. Mark CAMPBELL

Dr. Salyy DOSS

### Ministry of Health, Poland

Mr. Jakub ADAMSKI

### IQWiG, Germany

Dr. Markos DINTSIOS

Prof. Andreas GERBER

Dr. Stefan SAUERLAND

Dr. Stefan LACHIMI

### G-BA, Germany

Dr. Thomas MÜLLER

Mrs. Petra NIES

Dr. Meriem BOUSLOUK

### CATSALUT, Spain

Mrs. Cristina ESPINOSA Catalan Health and Social Care Consortium, Spain

Prof. Antoni GILABERT

Regular lecturers

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## PHARMACEUTICAL INDUSTRY

### **Lundbeck**

Dr. Susana MURTEIRA (Japan)  
Mr. Clément FRANCOIS (USA)  
Dr. Patrice VERPILLAT (France)  
Mrs. Dominique MILEA (Singapore)

### **Amgen, France**

Dr. Chantal GUILHAUME

### **MSD, France**

Mrs. Sibiliala QUILICI

### **Sanofi Pasteur, France**

Mrs. Anne TASSET-TISSEAU  
Mrs. Christelle SAINT-SARDOS

### **GSK Biologicals**

Dr. Baudouin STANDAERT

### **Novo Nordisk, Denmark**

Mr. Michiel HEMELS  
Mr. Rasmus JENSEN

### **Genomic Health, Switzerland**

Mrs. Juliette PLUN-FAVREAU

### **Novartis, Switzerland**

Mr. Patrick MOLLON

### **Astellas Pharma, UK**

Dr. Isaac ODEYEMI

### **Synovate, UK**

Mr. Chris KING

### **Ipsen, France**

Mrs. Gabrielle NAYROLES  
Dr. Simon SHOHET

### **Eucomed, Belgium**

Mr. Merlin RIETSCHER

### **Abbott, Switzerland**

Mrs. Kelly WONG

### **TEVA, The Netherlands**

Mr. Adam PLICH

### **Air Liquide, France**

Mrs. Patricia ALEGRE

Regular lecturers

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**A 5 module course completed in 1-3 years, online** The course is composed of 5 modules, each module runs for 5 consecutive days, with 1 HEOR optional module. Each module accounts for 28 hours, representing a total of 140 hours for the completion of the course. The 5 modules can be done separately and not necessarily in one year nor in any specific order (for example students may attend module 1 & 3 the first year, module 2 the second year, and module 4 & 5 during the third year). The course is validated after the submission of 2 professional theses:

- A Literature review, or review of a decision, or a landscape analysis, or case studies, or health economics projects, or pharmaco-epidemiology projects, or pricing study;

AND

- A draft publication that should be submitted\* to a scientific journal. If needed, support will be provided to students who have little experience in writing a publication.

*\*The submission will be sufficient to qualify for the diploma.*

## 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

Please send CV and a cover letter to: [application@emaud.eu](mailto:application@emaud.eu)

Your application will be reviewed by a selection committee, and within one week you will receive a decision reached by the committee. If accepted, you will then receive your registration file.

## Contact

- **Chairman**  
Prof. Mondher Toumi, [mondher.toumi@emaud.eu](mailto:mondher.toumi@emaud.eu)
- **Administrative Support**  
[administration@emaud.eu](mailto:administration@emaud.eu)