PharmaTrain
MASTERING MEDICINES DEVELOPMENT

European Curricula for Global Expertise

European Post-graduate Training in Pharmaceutical Medicine and Drug Development

Joint Conference of European Human Pharmacological Societies

Ingrid Klingmann, AGAH

Current Situation

- Only 4 countries in Europe have established for physicians a “specialisation in pharmaceutical medicine”: UK, Ireland, Belgium and Switzerland. As it would require an established specialisation in half of the EU countries to make this specialisation mandatory in all EU countries, there is currently no chance to achieve this
- In all countries there is a “specialisation in clinical pharmacology” established
- There are a number of master programmes in special areas of medicines development like toxicology, translational medicine, clinical research, pharmacovigilance and pharmacoepidemiology, etc., available for physicians and non-physicians
- There are 14 Diploma- and Master Courses in pharmaceutical medicine established in Europe

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Are we prepared for the change?

"Change will not come if we wait for some other person or some other time. We are the ones we've been waiting for. We are the change that we seek"

Barack Obama, 2008

IMI: Joining Public and Private

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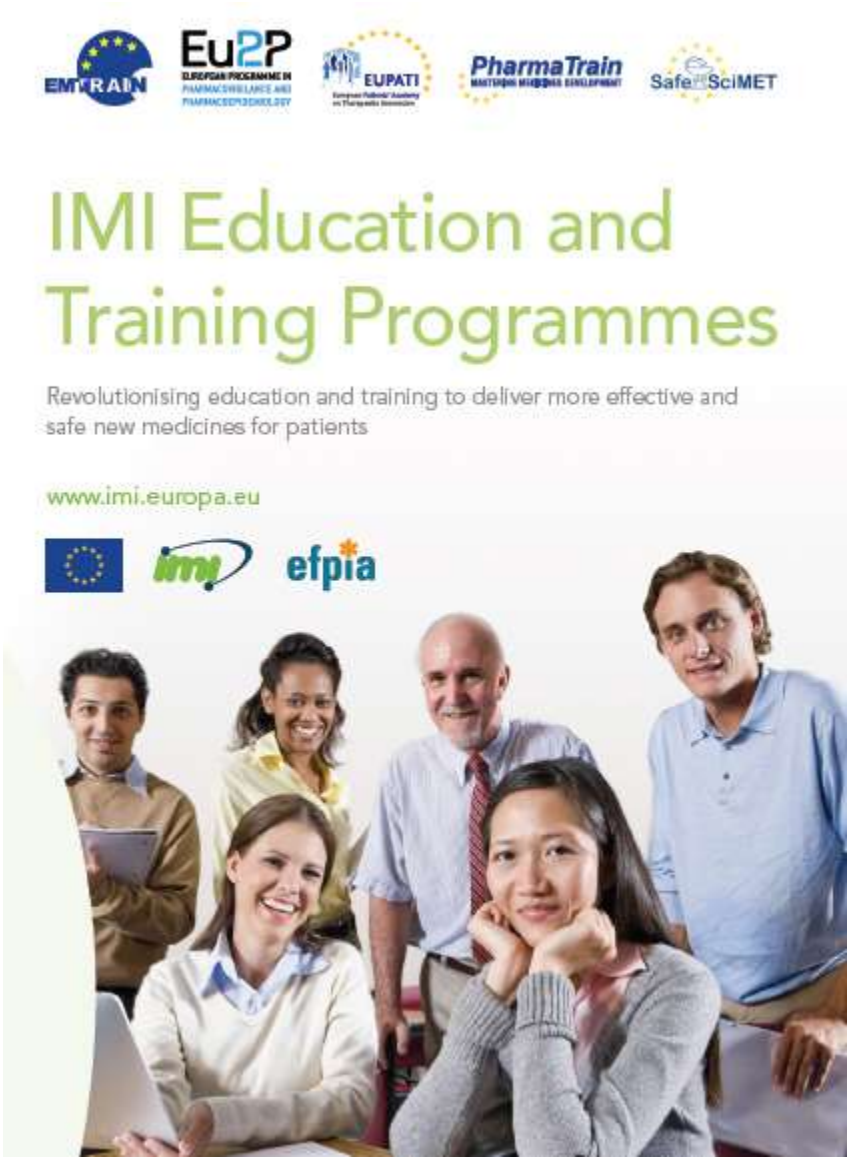
IMI Education and Training Programmes



European Medicines Research Training Network (EMTRAIN)

European Programme in Pharmacovigilance and Pharmacoepidemiology (Eu2P)

Pharmaceutical Medicines Training Programme (PharmaTrain)

European Modular Education and Training Programme in Safety Sciences for Medicines (SafeSciMET)

European Patients Academy on Therapeutic Innovation (EUPATI)

IMI EMTRAIN: Key Messages

PhD programme

We build a programme for public-private partnership PhD students who understand industry needs

EMTRAIN strengthens the pan-European community of scientists in medicines development

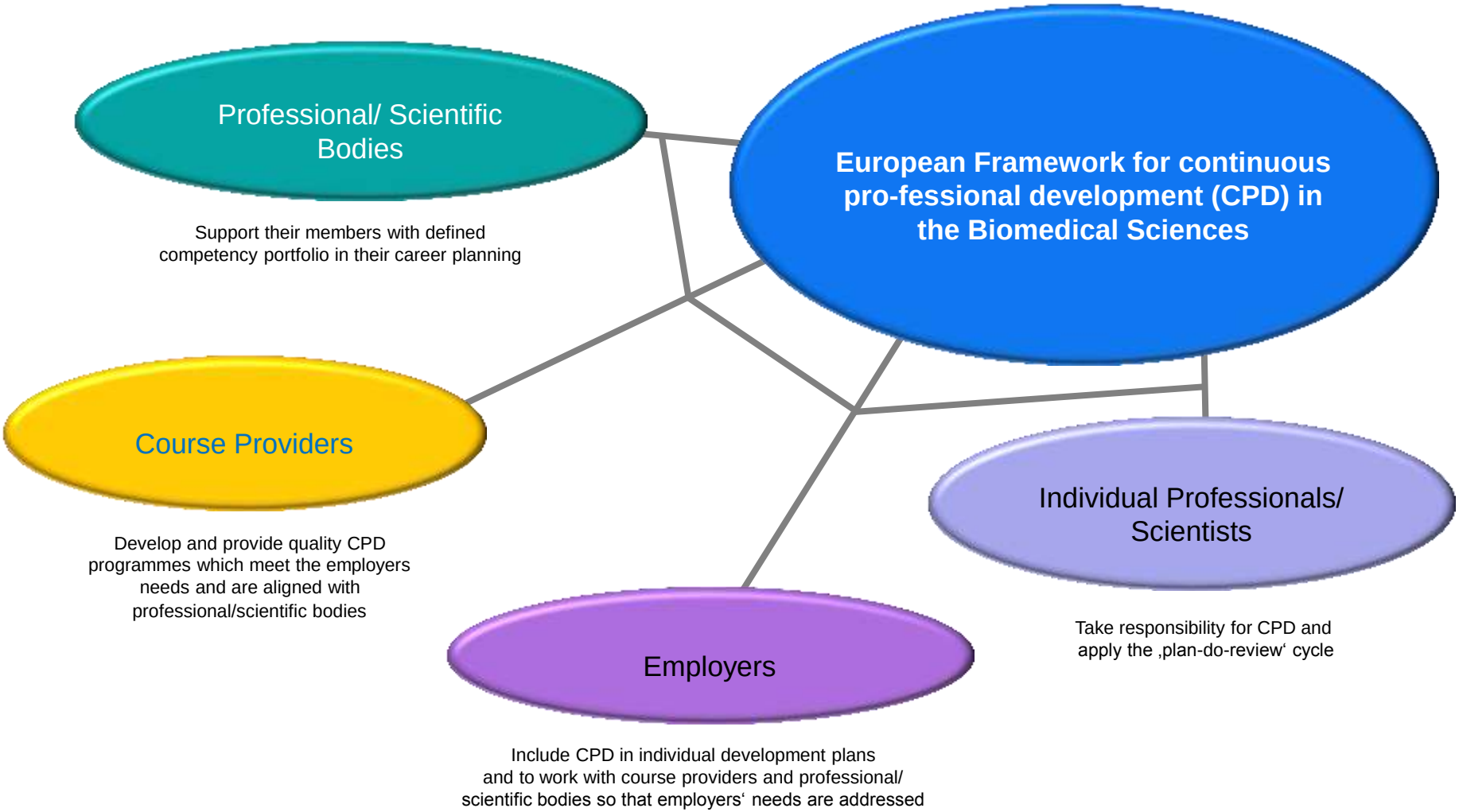
on-course®

We provide a comprehensive **on-course®** catalogue (www.on-course.eu) with quality indicators and tools/methodologies

LifeTrain

We ensure broad stakeholder support for 21st century skills, CPD and competency portfolios

The IMI LifeTrain Framework



SafeSciMET

Pan-European Education and Training programme, addressing gaps in current drug safety education and training in Europe

Providing 20 new Courses along the whole translational trajectory of drug safety sciences

Providing pharmaceutical industry and regulators with properly trained staff to address the complex issues in drug development and safety

SafeSciMET
Course Domains

5 Domains:

1. Drug Discovery and Development
2. Pharmaceutical Aspects of Drug Safety
3. Adverse Drug Reactions / Predictive Toxicology / 3R's
4. Non-Clinical Safety
5. Clinical Safety

1-6 courses/ Domain

complying with pre-defined quality criteria

What is Eu2P?

- A public private **collaborative** educational project that develop a **full on-line training programme** in **Pharmacovigilance** and **Pharmacoepidemiology**

  (Funded by IMI-JU in September 2009)

- **The principal goals of this training being to improve**
  - the understanding of medicines-related outcomes (utilization, benefit and risk)
  - the quality of the studies conducted for these outcomes
  - and to provide tools and methods for decision-making and communication related to medicines benefit and risk.

Eu2P academic curriculum and training adapts to the current ways of working of private companies

Eu2P catalogue

7 Specialisation fields

- **Basics** in pharmacovigilance & pharmacoepidemiology
- **Benefit assessment**
- **Risk identification and quantification**
- **Benefit-risk assessment**
- **Public health**
- **Risk communication**

Courses at introductory, intermediate & advanced levels

Build a flexible curriculum

Modular training workload

Choose **part-time or full-time**
Perform research project at work

On-line based training

Make the most of **time-availability**
Easily interact with trainers **network**

On-the-job training

Course from **anyplace, anytime**
Learn and **stay at job**

PharmaTrain Objectives

- **To provide a Europe-wide comprehensive solution to training needs of integrated drug development for all professionals involved**, incl. physicians, pharmacists, pharmaceutical scientists, biologists, biometricians, health economists, safety & regulatory scientists **from universities, regulatory agencies, all industry as well as research ethics committees & investigators**
- **To create (new) multi-modular programmes of advanced studies in pharmaceutical medicine / medicines development sciences leading to a postgraduate Master Sc / Specialist qualification and accreditation, and based on the Bologna credit and title system with 60+ ECTS credits**

PharmaTrain – in a Nutshell

- ★ Standardised and accredited syllabus
- ★ modular CPD platform à la carte
- ★ focusing on key players in medicines development and regulation as well as clinical research/investigators
- ★ enhancing university-industry training collaboration
- ★ learning outcomes and competencies oriented
- ★ quality assessed, incl. accreditation and certification
- ★ pan-European, a 24 universities network
- ★ going global, with 16 universities affiliates

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From Syllabus Topics to Modular Content
Learning Outcomes and Competencies

covering the entire medicines development process

↓

180 topics

↓

14 Syllabus Sections

↓

6-12 module programmes (taught at master level)

↓

6-10 Learning outcomes per module towards Diploma/Master degree (academic)

towards a set of cognitive competencies required for Specialist titles (vocational)

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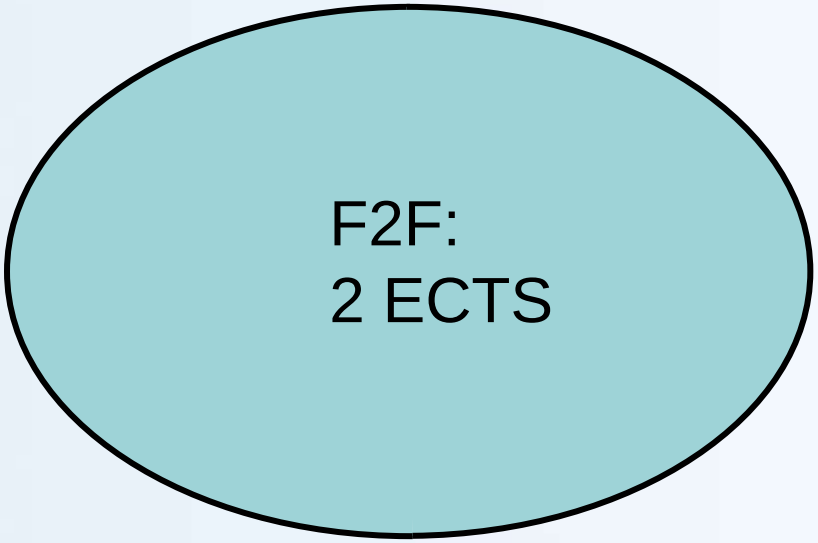
The PharmaTrain Module

Pre:
incl. e-Learning
1 ECTS



Post:
Assignments
Assessments
2 ECTS

1 credit point (accd. European Credit Transfer System (ECTS)) = min 25 hrs

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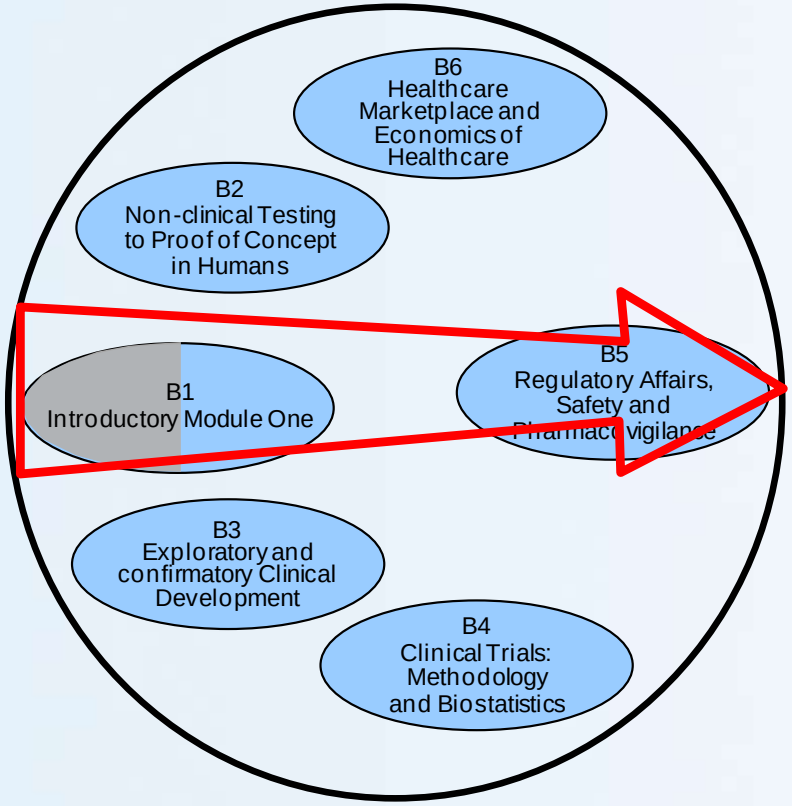
Diploma Base Course

Molecule to Marketplace

teaching the complete PharmaTrain Syllabus



DMD
DIPLOMA IN MEDICINES DEVELOPMENT

Training Centres providing DMD
PharmaTrain Centres of Excellence Awards
in bold

- **University of Basel**
- **University of Brussels**
- **Semmelweis University**
- **University Claude Bernard Lyon**
- **Catholic University of Rome**
- Three Universities in Barcelona
- University of Belgrade
- UCSF in SF and in DC
- Peking University
- University of Osaka
- University of Tel Aviv
- Moscow University

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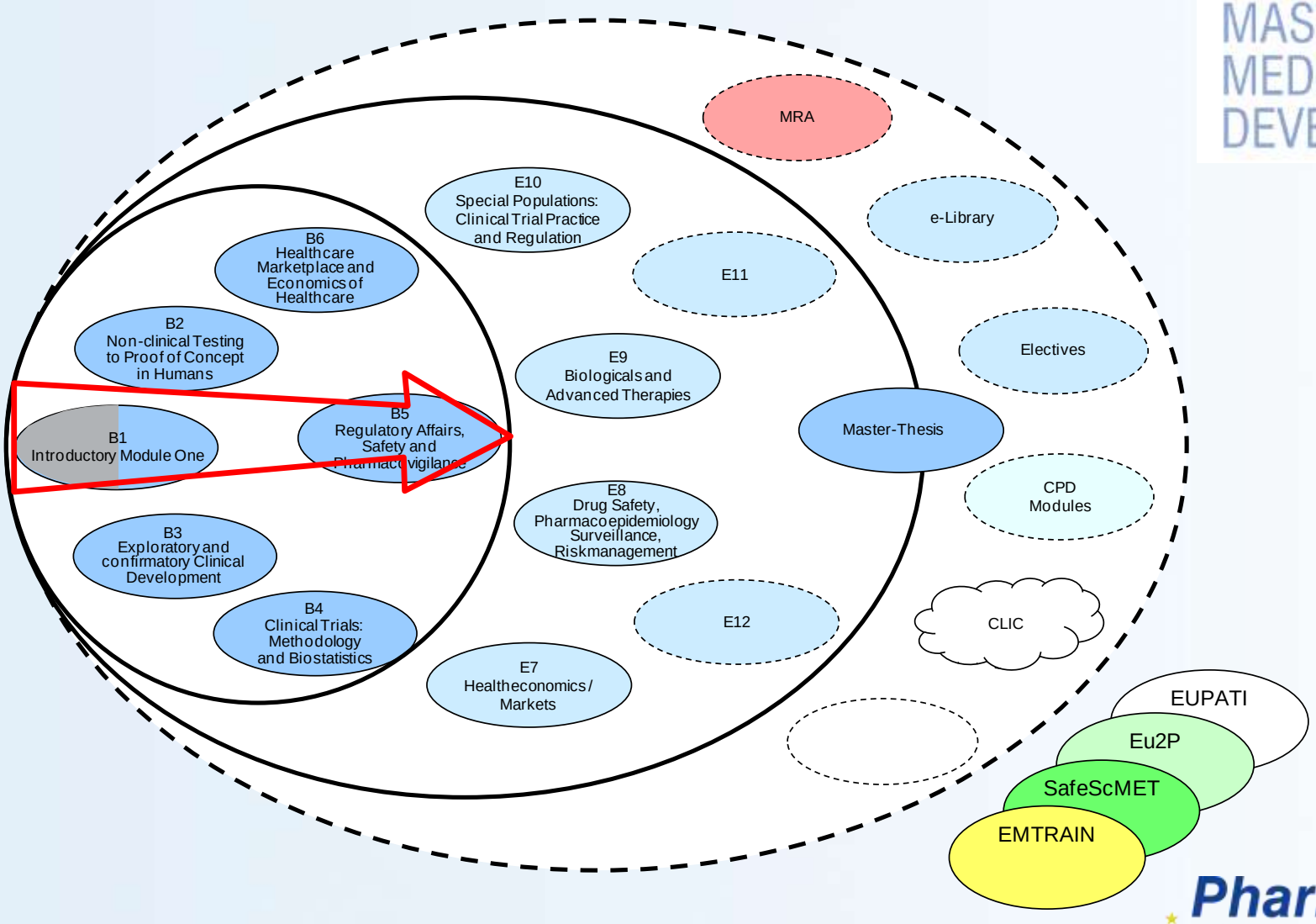
MMD
MASTER OF MEDICINES DEVELOPMENT



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European* Elective Modules' Forum

ELM 1	Medicines Regulation
ELM 2	Generic & Biosimilar Medicinal Products
ELM 3	Project Management in Medicines Development
ELM 4	Biomarkers and Surrogate Endpoints
ELM 5	Medicines Development for Rare Diseases
ELM 6	Medicines Development in Children
ELM 7	Medicines Development in a Geriatric Population
ELM 8	Practical Approach to Ethical & Legal Aspects of CTs
ELM 9	Systematic Review and Meta-Analysis
ELM 10	Pregnancy and Medications
ELM 11	Principles & Practices of Medical Devices Development
ELM 12	Disease-Biology Based Pharmacology
ELM 13	Model-based Medicines Development
ELM 14	Special Populations and Trial Practices (also EXM 8)
ELM 15	Pharmacoeconomics and Market (also EXM 1a)
ELM 16	Basics of Health Economics
ELM 17	Drug Safety & Pharmacovigilance
ELM 18	Pharmacoepidemiology
ELM 19	Life Sciences Executives
ELM 20	Biobusiness Development

e.g. **ELM 9** promoted on our e-Platform

* other parts of the world require different solutions incl. blended and e-learning

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PharmaTrain e-Library

- The PharmaTrain **e-Master in Medicines Development**
- The PharmaTrain **e-Master in Regulatory Affairs**
- **e-Compacts** (1 ECTS)
  - eC1 An introductory module
  - eC2 Translational medicine
  - eC3 Biological/monoclonal antibody full development
  - eC4 Safety module
  - eC5 Medicines regulation
  - eC6 Health economics and market
  - eC7 Module on therapeutic area 1, Parkinson's disease
  - eC8 Module on therapeutic area 2, Asthma
  - eC9 eCLIC, an online Clinical Investigators Course
  - eC10 A "train the trainers" initiative
- **e-Electives** (5 ECTS):
  - eE1 Write and Review a CTD
  - eE2 Generics and Biosimilars
  - eE3 Medical Devices
- **Video** lectures

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Unified Multiple Choice Question (MCQ) Examination Process

- Standardised MCQ Examination,120 questions
- Managed question pool
  - Faculty of Pharmaceutical Medicine, Royal Colleges of Physicians, UK
- At each collaborating centre
- Centralised analysis of MCQ answers with inter-centre and inter-examination comparisons, University of Berne (?)

IMI E&T Cross Project Quality Criteria

A formalised and transparent QA/QC policy

1 University accreditation OR a suitable system for approving, monitoring and reviewing the training offered

2 A system for ensuring quality of teaching staff

3 Regular review of the QA/QC processes

A set of documented criteria for individual modules, courses or course programmes

4 Defined and transparent admission criteria

5 A predefined set of teaching objectives, leading to defined learning outcomes

6 Adequate facilities, infrastructure, leadership and competences

7 Assessment of the trainees' achievement according to the learning outcomes

8 A system for collecting, assessing and addressing feedback

9 Adequate reference materials

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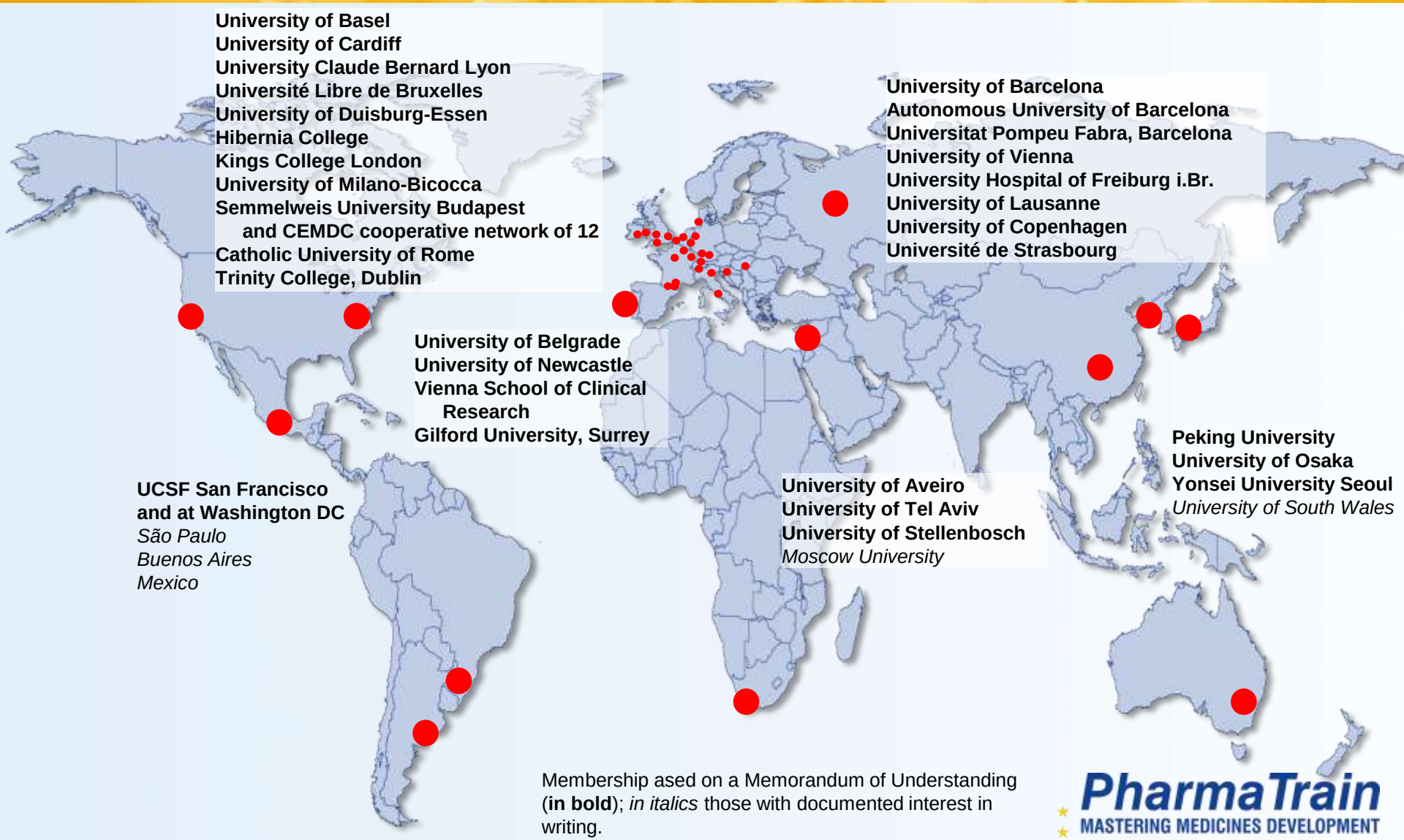
Global University Membership Network 2014



Membership ased on a Memorandum of Understanding (**in bold**); *in italics* those with documented interest in writing.

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A PharmaTrain Specialist in Medicines Development needs to be able:

- To identify unmet therapeutic needs, evaluate the evidence for a new candidate for clinical development and design a Clinical Development Plan for a Target Product Profile. (Domain I)
- To design, execute & evaluate exploratory & confirmatory clinical trials and prepare manuscripts or reports for publication & regulatory submissions. (Domain II)
- To interpret effectively the regulatory requirements for the clinical development of a new drug through the product life-cycle to ensure its appropriate therapeutic use & proper risk management. (Domain III)
- To evaluate the choice, application & analysis of post-authorisation surveillance methods to meet the requirements of national/international agencies for proper information & risk minimisation to patients & clinical trial subjects. (Domain IV)
- To combine the principles of clinical research & business ethics for the conduct of clinical trials & commercial operations within the organisation. (Domain V)
- To appraise the pharmaceutical business activities in the healthcare environment to ensure that they remain appropriate, ethical & legal to keep the welfare of patients & subjects at the forefront of decision-making in the promotion of medicines & design of clinical trials. (Domain VI)
- To interpret the principles & practices of people management & leadership, using effective communication techniques & interpersonal skills to influence key stakeholders & achieve the scientific & business objectives. (Domain VII)

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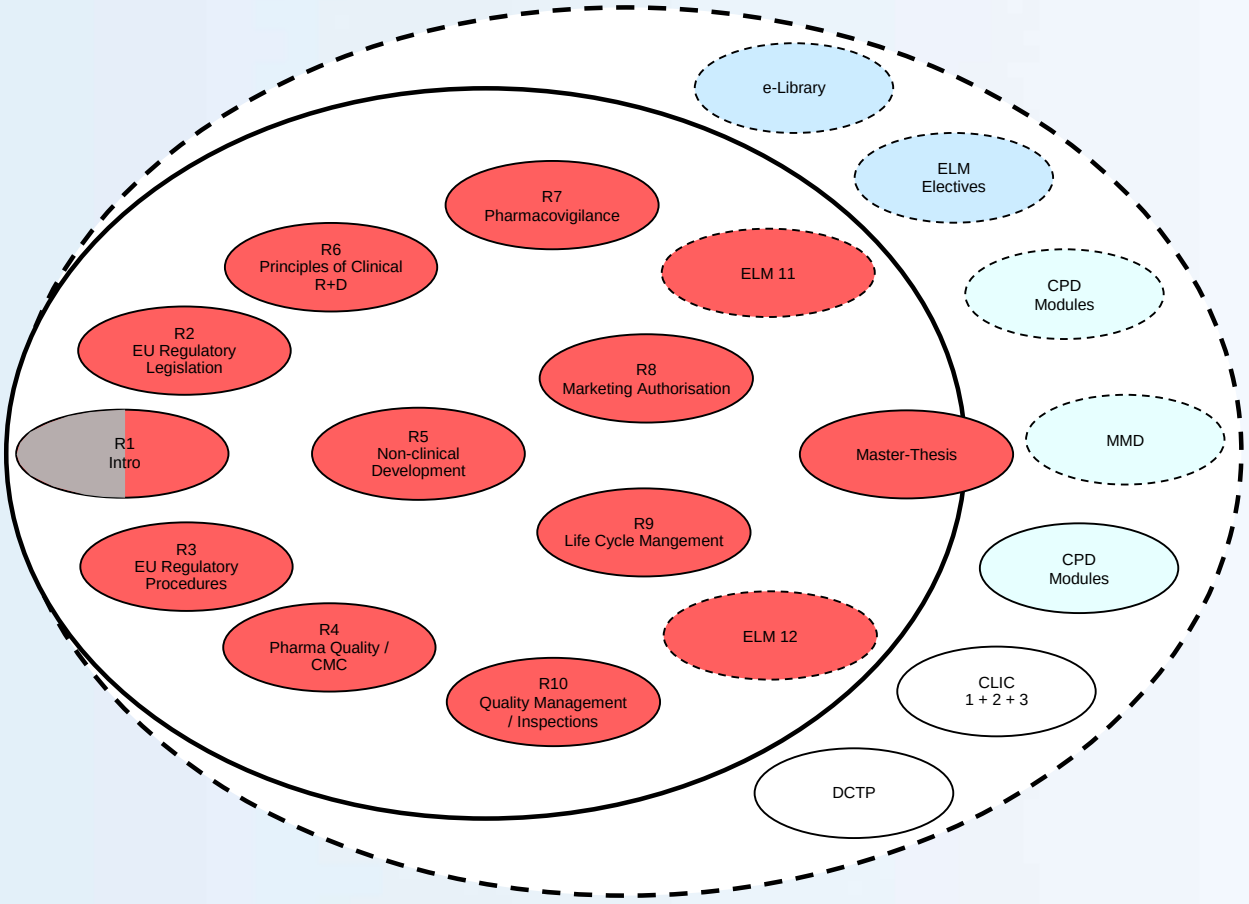
Master of Regulatory Affairs



MRA
MASTER OF REGULATORY AFFAIRS

Joint venture

- **University of Copenhagen – Medicademy**
- **University of Basel – ECPM**
- **King's College London**
- **University of Hertfordshire – TOPRA**

Two ELMs can be chosen from the Electives Modules' Forum or any other recognised modules (hatched elipse)

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Clinical Investigator Certification

- Definition of 3 (or 4) training levels:
  - Study Managers/Site staff
  - Principal Investigators
  - Sponsor-Investigators (in collaboration with ECRIN)
  - Phase 1 investigators?
- Development of different “PharmaTrain syllabus” adapted to the training needs of these investigator responsibility levels
- Development of Curriculum Options (number of hours, f2f, eLearning, blended) with learning outcomes
- Definition of quality standards for the courses with PharmaTrain course recognition
- Certification (with PharmaTrain stamp) nationally by PharmaTrain–associated Universities

CLIC
CLINICAL INVESTIGATOR CERTIFICATION

PharmaTrain
MASTERING MEDICINES DEVELOPMENT

Clinical Investigator Certification

- Establish "**PharmaTrain Course Recognition**" awards for public and private courses applying the PharmaTrain standard
- Define **examination** process and establish examination options in physical proximity to investigators
- Develop PharmaTrain University **CLIC network** (n = 23 + 11+ 6(-12)) in collaboration with ECRIN and subsequently any other non-university based CLIC-providers
- **Certification** (with PharmaTrain stamp) nationally or regionally by PharmaTrain-associated Universities
- PharmaTrain has already developed "**eCLIC**" (eC9) as a suitable tool to prepare for each Investigator-level examination

CLIC
CLINICAL INVESTIGATOR CERTIFICATION

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PharmaTrain Products and Services

Das Chart ist gut!!!

Products	
Clinical Investigator Certification Courses	CLIC
Diploma Course for Trial Professionals	DCTP
Diploma in Medicines Development	DIMD
Master of Medicines Development	MMD
Specialist in Medicines Development	SMD
Master of Regulatory Affairs	MRA
Elective Modules (Forum)	ELM
CPD Modules	CPD

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Where Would Training in Human Pharmacology Fit?

- Diploma Course for Trial Professionals
- Master in Medicines Development
- CLIC
- CPD Modules

- Diploma in Human Pharmacology
- Master in Human Pharmacology
- CLIC for Phase I investigators
- CPD Modules

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