Training Programmes in Pharmaceutical Medicine and Drug Development Sciences

First Year Results
What patients need

What Europe needs

- Our patients need effective, safe and affordable medicines for treatment of disease (ca. 1200 unmet needs!)

- The development of a medicine – from molecule to practical use – follows a complex and competitive, long lasting (> 10y), risky (only one of 100 compounds get to market) and very expensive (ca. Euro 1 billion) path

- Europe needs to optimise this value path of quality research and development, regulation and market access for affordable medicines.

- This project is an intensified interaction of Universities, regulators and big and small pharmaceutical industry in our highly competitive world.

- The industry will need to adapt a new business model collaborating with regulators and buyers.

- **PharmaTrain aims to reduce this gap in knowledge, expertise and competence by addressing all categories of key players involved in this process by intense and comprehensive (postgraduate) training in the science of integrated development of medicines and in Pharmaceutical Medicine**
What we will do about it

• Since May 2009, in the ‘Prepare Phase’, the PharmaTrain team has critically assessed the training needs and crafted a new pan-European training programme to remove these bottlenecks in the current drug development process whilst striving for excellence in execution.

• The entire training clockwork for practically all key players concerned has been shaped into three core programmes:
  - Base Courses (6 modules, 900 training hours)
  - Master Programmes (6+6 Extension modules or 12 Integrated modules, both 1800 training hours both with a Master Thesis, both using Bologna-principles and both with University accreditation)
  - European Specialist in Pharmaceutical, integrated examination and accreditation by national medical/professional associations

• Shared standards have been created for these entire programmes

• The programmes are for all professionals engaged in drug development (PhDs and MDs)

➔ Programmes will be implemented in the ‘Learn Phase’ (M13-M36) – starting in autumn 2010 – and refined in a second training cycle in the ‘Confirm Phase’ (M37-M60)
What is Pharmaceutical Medicine?
What is Drug Development Sciences?

Pharmaceutical Medicine is the medical scientific discipline concerned with the discovery, development, evaluation, registration, monitoring and medical aspects of marketing of medicines for the benefit of patients and public health.

Drug Development Science is shaped by scientific advances, changing regulatory requirements and pharmaco-economic conditions. It is critical to the industry as an engagement tool that considers patient outcomes as the centre of everything it does.
Innovative approach

• Create Training Centres of Excellence which partner Universities can aspire to.

• Develop, share and implement an innovative Syllabus broken down in modules for:
  - Incl. Base Courses, Masters’ Programmes and advanced electives, Continuing Professional Development

• Use the same Syllabus and the same Introduction Module/Course for all training programmes, unité de doctrine!

• The programme is not just for physicians but all professionals engaged in drug development

• Offer different blends of face-to-face and e-learning teaching by jointly creating state of the art e-modules.

• Provide access for all interested parties in Europe by sponsorship (industry in-kind) and supporting student participation.

PharmaTrain’s concerted training is unique in the world; it will provide a new category of experts in integrated quality drug development and regulation.
Postgraduate Three Tier and Two Dimensional Modular Process: Master Dimension and Specialist Dimension

Concept
- Syllabus-based
- Learning outcomes
- Base Course / Master extension
- Modularity
- ECTS/modul (1+3+1)
- Mobility
- "Good Bologna Practice, GBP"

Learning Paths
- mono-centric, 20% e-blended
- multi-centric, 50% e-blended
- distant, 80% e-blended

Workload
- 60 ECTS à 30 hrs
  = 1800 hrs
  = 1 academic year

30 ECTS Knowledge
60 ECTS Expertise
90 ECTS Competence

30 ECTS

CPD
Lifelong learning

MDDS/MSc

Base-Courses
Extension Modules
Work-Project
- Thesis (10 ECTS)
- Electives
- (Research) Project
# IMI PharmaTrain Postgraduate Training Programmes in Drug Development Sciences/Pharmaceutical Medicine – New European Standards

**Course Providers to choose from:**

<table>
<thead>
<tr>
<th>Provider</th>
<th>Website</th>
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<tbody>
<tr>
<td>Brussels, Pharmed</td>
<td><a href="http://www.ulb.ac.be/medecine/pharmed">www.ulb.ac.be/medecine/pharmed</a></td>
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<tr>
<td>Karolinska</td>
<td><a href="http://www.karolinska.se">www.karolinska.se</a></td>
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<tr>
<td>Basel, ECPM</td>
<td><a href="http://www.ecpm.ch">www.ecpm.ch</a></td>
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<td>Budapest</td>
<td><a href="http://gyogyszerfejlesztes.hu">http://gyogyszerfejlesztes.hu</a></td>
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<tr>
<td>University of Barcelona</td>
<td><a href="http://www.uab.es">www.uab.es</a></td>
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<tr>
<td>Lyon, Eudipharm</td>
<td><a href="http://www.eudipharm.net">www.eudipharm.net</a></td>
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<tr>
<td>Belgrade</td>
<td>www.</td>
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<tr>
<td>Cardiff</td>
<td><a href="http://www.cardiff.ac.uk">www.cardiff.ac.uk</a></td>
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<tr>
<td>Duisburg-Essen</td>
<td><a href="http://www.uni-due.de">www.uni-due.de</a></td>
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<tr>
<td>Hibernia College</td>
<td><a href="http://www.hiberniacollege.net">www.hiberniacollege.net</a></td>
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<tr>
<td>Milano</td>
<td><a href="http://www.masterfarmaco.medicina.unimib.it">www.masterfarmaco.medicina.unimib.it</a></td>
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<tr>
<td>Rome</td>
<td><a href="http://www.rm.unicatt.it/master">www.rm.unicatt.it/master</a></td>
</tr>
<tr>
<td>Surrey</td>
<td>www2.surrey.ac.uk</td>
</tr>
<tr>
<td>Dublin, Trinity</td>
<td><a href="http://www.pac.ie/tcd">www.pac.ie/tcd</a></td>
</tr>
<tr>
<td>King’s College London</td>
<td><a href="http://www.kcl.ac.uk">www.kcl.ac.uk</a></td>
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**Programme Details:**

- **Base Courses 30 ECTS**  
  - 6 Base-Modules  
- **MDDS 60+ ECTS**  
  - 13 Modules  
  - 12 Integrated Master Programme  
  - Training programme of the University of Gothenburg is being revisited at present.

In addition to the above 17 Universities, the PharmaTrain PPP includes another 6 Universities in collaboration with competent authorities, EFPIA partner companies and other learned societies.

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*(1) 6 Base-Modules  
(2) 12 Extension Master Programme (12 total)  
(3) 12 Integrated Master Programme  
Version 3.15.2010*
CEDDC Participating Universities

- Bulgaria
- Croatia
- Czech Republic
- Estonia
- Greece
- Ireland (Hibernia College)
- Hungary
- Israel
- Lithuania
- Poland
- Romania
- Slovakia
- VSCR
Expected outcomes 1/2

• We will set new high-quality standards for job-based training integrated into a European (Bologna-compliant) University network, linked to competent (regulatory) authorities in a structured partnership with big and small pharmaceutical industry

• We will foster a new quality of understanding of the complex drug development process and teach the timely and economical execution of the process: less errors, less time, less costs as well as increased safety and more user-friendliness

• Accessible for all key players in all of Europe incl. new Member States and affiliated countries.
Expected outcomes 2/2

• We will graduate over 300 trainees from the 6 Base Courses and Diploma Programmes who may apply for a Specialists Title in Pharmaceutical Medicine / Drug Development Sciences

• We will develop up to 300 trainees as Master in Drug Development Sciences

• We will thereby enhance the quality, efficacy, safety and affordability of medicines that meet patient’s needs
Expected benefit to patients

- Innovative compounds will be better targeted to the cause and the course of the disease – more effective and safer
- A new process of understanding the integrated development of medicines will lead to:
  - better overall comprehension of the process and less errors (or failures)
  - more effective and safer medicines that match the patient’s needs better
  - reduction of overall cost of the process and, eventually, lower the prize of a medicine used in day-to-day practice

**Better trained physicians and better medicines keep better treated patients happier!**
Added value of the consortium

- PharmaTrain is a partnership of key institutions involved in face-to-face, interactive and blended e-learning education and training.

- PharmaTrain partners apply jointly developed standards and support material for faculty.

- PharmaTrain partners share best practices, concepts, contents and training (e)materials.

- Assessment and accreditation will be harmonised facilitating Bologna compliant universities and the international recognition of national professional associations medical specialist awards.

- PharmaTrain is committed to synergistic Cross-Project Collaboration with other IMI projects: particularly with EMTrain, SafeSciMET, EU2P and future E&T programmes.

→ *Training and Knowledge Sharing will give Europe a new competitive advantage.*
Achievement highlights - first year (1)

In the last year we delivered all objectives set in the Project Proposal.

- Syllabus reviewed by Futures Team and approved.
- Programme Learning Outcomes agreed.
- Programme modularised into 6 ‘Base’ and 6 Extension Master Modules
- 10 innovative e-learning modules conceptualised
- e-Library training repository created
- Online teaching “toolkit” and support system in ‘beta’ phase.
- Examinations unified
- Accreditation pathways defined
Achievement highlights - first year (2)

- Continuing Professional Development Platform structured
- Pan-European Cooperative Training Concept
- Facilitation Student access and (financial) support facilitated
- User-friendly quality management concept in place
- At least 5 new programmes using new syllabus will run in autumn 2010
  - ECPM, University of Basel
  - Hibernia College Ireland
  - King’s College London
  - Semmelweis University Budapest
  - University of Barcelona (together with Universities Autonomica and Pompeu Fabra)
- Existing programmes will adapt to new quality standards
Time and money

Financing:
• IMI funding: Euro 3.5 mio
• EFPIA contribution, mainly in kind: all in all Euro 3.1 mio
• Time of Public Partners is little compensated
• Total project cost: Euro 6.6 mio

Timing:
• Starting date: 1.5.2009
• Duration: 5 years
• Prepare Phase (M1-12), Learn Phase (M13-24), Confirm Phase (M25-48)

Project will be continued by the European Federation of Course Providers in Pharmaceutical Medicine, EFCPM
Project Partners

Public Partners:

European Federation of Courses in Pharmaceutical Medicine
University of Basel, European Centre of Pharmaceutical Medicine (ECPM)
International Federation of Associations of Pharmaceutical Physicians / Council for Education in Pharmaceutical Medicine
European Federation of Courses in Pharmaceutical Medicine
University of Basel, ECPM
International Federation of Associations of Pharmaceutical Physicians / Council for Education in Pharmaceutical Medicine
Faculty of Pharmaceutical Medicine
Pharmed, Université Libre de Bruxelles
Semmelweis University, Budapest
University Claude Bernard Lyon
Cardiff University
University of Surrey
Newcastle University
Hibernia College
University of Dublin, Trinity College
Vienna School of Clinical Research
University of Vienna
University of Belgrade

University of Duisburg-Essen
University Hospital of Freiburg i.Br.
Fondation Health Sciences e-Training (HSet), University of Lausanne
Bicocca University of Milano
Karolinska Institute
Göteborg University
Copenhagen University
Université de Strasbourg (former Université Louis Pasteur, Strasbourg)
Catholic University of Rome
University of Barcelona
Autonomous University of Barcelona
Universitat Pompeu Fabra, Barcelona
Drug Information Association Europe, DIA
European Federation of Pharmaceutical Sciences, EUFEPS
Medicines and Healthcare products Regulatory Agency, MHRA
Swissmedic
European Organisation for Research and Treatment of Cancer, EORTC
Dutch Top Institute Pharma
European Forum for Good Clinical Practice, EFGCP
King’s College London
Project Partners

**EFPIA Partners:**

- Pfizer Ltd.
- Bayer Schering Pharma AG
- AstraZeneca AB
- GlaxoSmithKline Research and Development Ltd.
- Merck KGaA / Merck Serono
- Novartis Pharma AG
- Amgen
- UCB Pharma SA
- F. Hoffmann-La Roche AG
- Novo Nordisk A/S
- Sanofi-Aventis R&D
- Janssen Pharmaceutica NV (Johnson & Johnson)
- Almirall S.A.
- Laboratories del Dr.Esteve, S.A.
- Orion Corporation, Orion Pharma

**Advisors:**

- European Medicines Agency, EMEA
- Europa Bio
- PriceWaterHouseCoopers
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