



Innovative Medicines Initiative

Training Programmes in Pharmaceutical Medicine and Drug Development Sciences

First Year Results



efpia

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)***

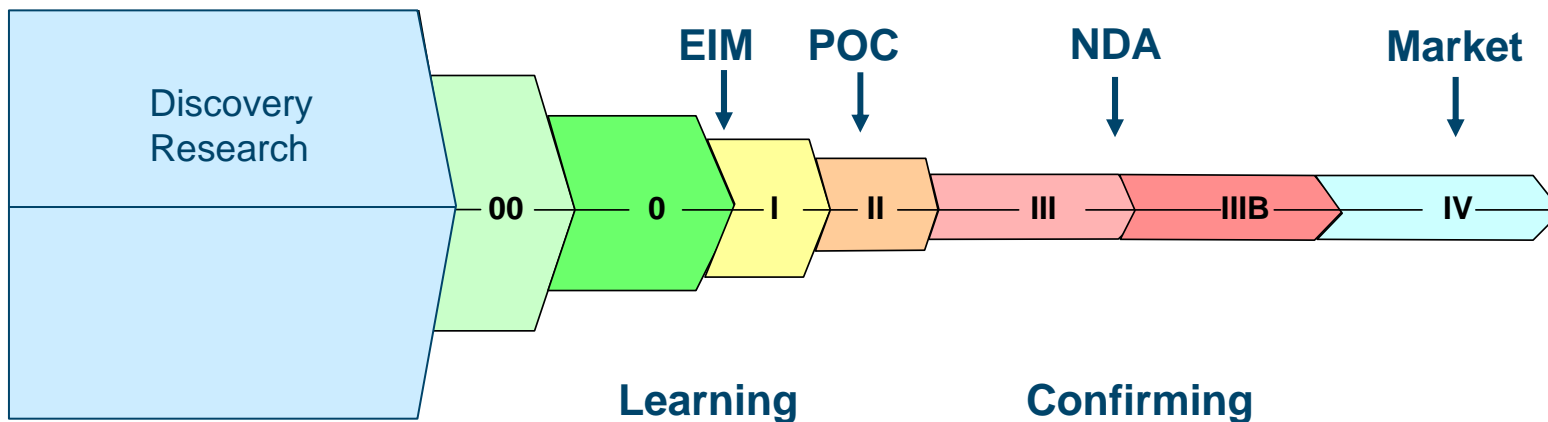


What is Pharmaceutical Medicine? What is Drug Development Sciences?



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
Process



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.



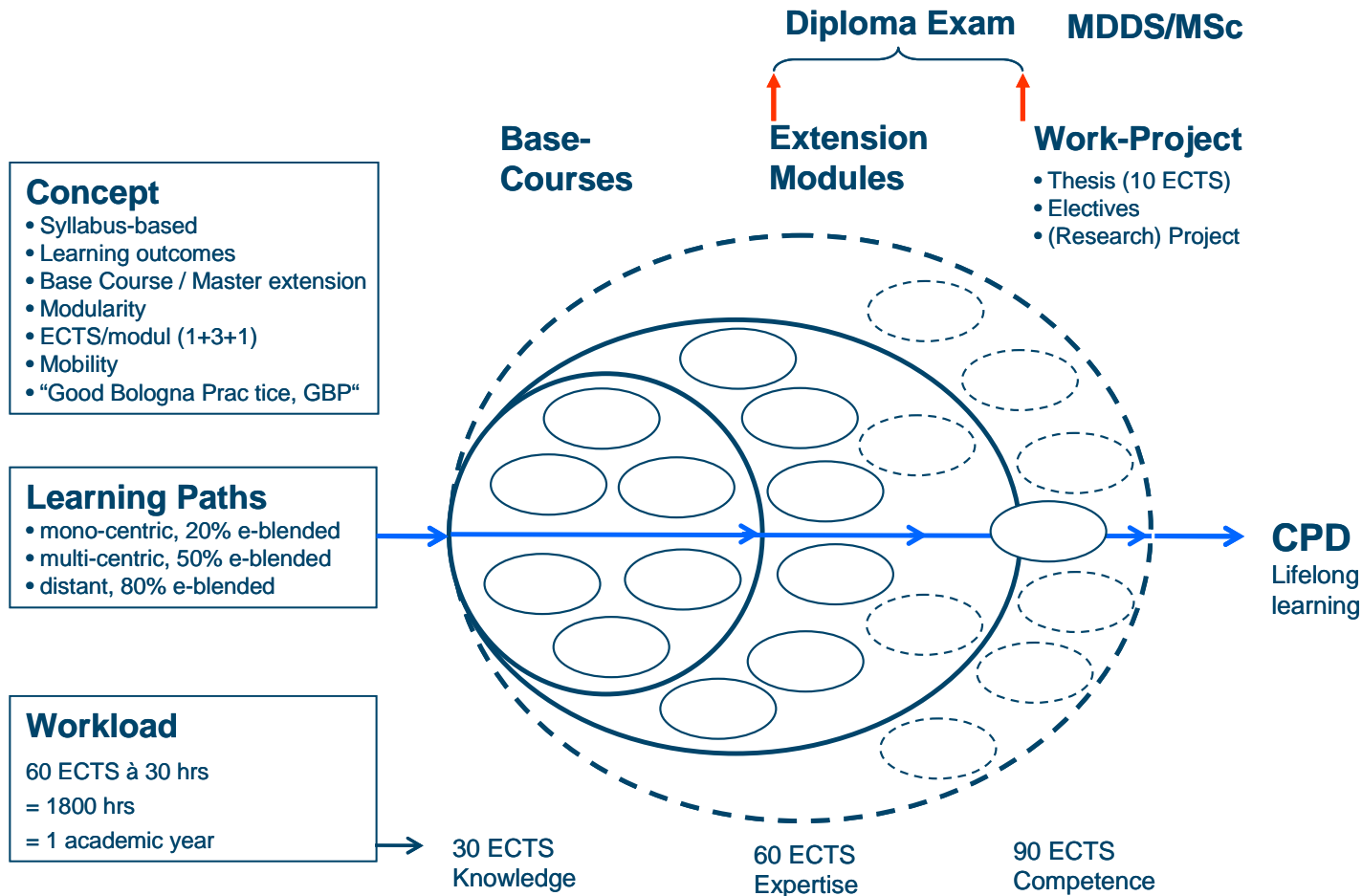
Innovative approach



- 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



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 price 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.

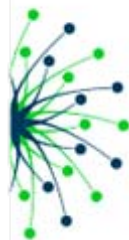
- Syllabus reviewed by Futures Team and approved.
- Programme Learning Outcomes agreed.
- Programme modularised into 6 'Base' and 6 Extension Master Modules
- 10 innovative e-learning modules conceptualised
- e-Library training repository created
- Online teaching “toolkit” and support system in ‘beta’ 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 Autonómica 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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