PharmaTrain Global
Competence-based Global Training Excellence for Better Medicines

Business Plan
Draft Short Version 0.5
for PharmaTrain Federation
proposed by the IMI PharmaTrain Executive Board

April 5, 2013
www.pharmatrain.eu
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Executive Summary

★ PharmaTrain Global standardises and grows **job-defined and competence-based training products** in medicines development from a nucleus of 45 accredited University Centres of Excellence around the world in partnership with universities, pharmaceutical industry, regulatory agencies and standard setting societies.

★ **Novel personalised and full competence-based descriptions of different key players** in the medicines development* process are mapped against competences / learning outcomes which are derived from Syllabus topics covering the entire medicines development process from molecule to patient.

★ With the **PharmaTrain Competence Profiler** individual strengths and weaknesses can be quantified – at entry, executive and expert levels – and shortcomings can be addressed with appropriate competence-defined training modules from the PharmaTrain platform.

★ PharmaTrain Global provides **new PharmaTrain Certification** for Clinical Investigators and awards a new PharmaTrain Specialist in Medicines Development.

★ **New didactic methodology and technology as well as high-quality e-products** will be developed with a global scope to complement and, to some extent, replace over time the face-to-face training.

(* Medicines development is used synonymously with drug development)
Better trained postgraduate professionals working anywhere in this world in the field of medicines development and regulation transform their overall understanding and competence into the excellent and efficient execution of integrated medicines development and life-cycle management to develop better and safer medicines.
Mission Statement

PharmaTrain™ facilitates and validates high-quality educational programmes to produce well-trained medicines development professionals who improve the delivery of better medicines for enhanced patients’ health through:

- Developing **competence-based profiles of key jobs in medicines development** which will be linked to the (cognitive) competences/learning outcomes mapped to the Syllabus topics reflecting the entire medicines development process

- **Operation excellence** with quality standards including: syllabi, curricula, learning outcomes, examinations and competence profiles

- A comprehensive range of **medicines development training activities** including: Diploma Base courses, Masters programmes, Specialist programmes and single modules, also suitable for Continuous Professional Development (CPD)

- **PharmaTrain recognised centres** in Europe and expanding to recognised centres in Asia/Pacific, North and South America and Africa

- Developing and maintaining a **global public private partnership** which addresses the needs of the “students” facilitating flexible, high-quality courses and programmes which support career development and mobility
IMI PharmaTrain Project as a Base

The five-year IMI PharmaTrain project (May 2009-April 2014) – in parallel to EMTRAIN, SafeSciMET, EU2P and EUPATI – has developed a framework for pharmaceutical development that enables to create values for all stakeholders:

- Quality based **Diploma Courses, Master Programmes, Elective Modules, CPD Modules** and e-learning platform: e-library, e-directory, e-services
- **Syllabus** topics (180) covering the content from molecule to market
- **Learning Outcomes** (60) mapped to the Syllabus
- **Competences** (70) in seven domains derived from LOs fitting the industry’ workplace needs
- **Quality management system** with a stepwise process improvement cycle
- PharmaTrain **brand** representing global E&T quality in medicines development
- European and global **network** of stakeholders incl. some 30 universities
- Foundation of the successor **organisation** to prepare sustainability
PharmaTrain Opportunities

★ Medicines development is in a continuing change mode to improve safety, quality and economy of the medicines development process. With the IMI PharmaTrain Project industries focus in partnership with academia, regulatory authorities and learned societies – for the first time in history – on the training of the individual scientists’ competences involved in the process.

★ In the last five years, the IMI PharmaTrain project has delivered new shared training standards, new curricula as well as a collaborative network of 45 universities around the world in partnership with pharmaceutical companies, regulators and learned societies involving all key-players in the medicines development process.

★ A tight European Public Private Partnership and the beginning of a global network can now be systematically expanded into Training Standards in all other parts of the world.

★ Financial (travel) restrictions and potential absence from the job require more distant blended learning/training necessitating production of novel interactive e-learning products.
PharmaTrain – Ways to Grow

Globalise Network

Commercialise Portfolio

Expand Services and new Products
Global University Membership Network 2014

In bold: European University Core Partners (23) and CEMDC Universities (11), affiliated membership based on a Memorandum of Understanding (MoU; 7)
In italics: those (5) with documented interest in writing
A new concept: One course for 12 universities

- Czech Republic, Prague
- Estonia, Tartu
- Hungary, Budapest (lead)
- Lithuania, Kaunas
- Poland, Warsaw
- Portugal, Lisbon
- Romania, Targu Mures
- Serbia, Belgrade
- Serbia, Novi Sad
- Slovakia, Bratislava
- Slovenia, Ljubljana
- Turkey, Ankara

Cooperative European Drug Development Course
Novel personalised Competence-based Job Profile

This is related to a process-oriented competence description of Modules on the Training Platform:

**Job competence profile(s)**

- **top-down use**

60 on-the-job based competences
incl. knowledge, skills and attitudes in 7 domains

- **bottom-up construction**

60 learning outcomes / cognitive competences

180 syllabus topics / broken down in 6 base modules

Medicines Development Process: Molecule to Patient
The PharmaTrain Specialist in Medicines Development is defined by the following competence domains*:

I 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.

II To design, execute & evaluate exploratory & confirmatory clinical trials and prepare manuscripts or reports for publication & regulatory submissions.

III 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.

IV 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.

V To combine the principles of clinical research & business ethics for the conduct of clinical trials & commercial operations within the organisation.

VI 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.

VII To interpret the principles & practices of people management & leadership, using effective communication techniques & interpersonal skills to influence key stakeholders & achieve the scientific & business objectives.

* Each domain contains ca. 10 competences
From Syllabus to LOs / Cognitive Competences

Each of the 6 Modules contains 10 Learning Outcomes (LOs)

Example: 3 Syllabus topics map 1 Learning Outcome

Cognitive competences (= Learning Outcomes) are combined with mentorised on-the-job-training for quantifiable full competence (performance)

One Syllabus topic may be represented in several Modules

180 Syllabus topics
Matching process: Training needs and offers

**Training needs** (red)
- assessed by PharmaTrain Competence Profiler

**Training offers** (yellow)
- PharmaTrain assessed modular training platform

A: Expert level
B: Executive level
C: Entry level

* Of PharmaTrain assessed Training providers
PharmaTrain Products and Services

### Products

<table>
<thead>
<tr>
<th>Products</th>
<th>Code</th>
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</thead>
<tbody>
<tr>
<td>Clinical Investigator Certification Courses</td>
<td>CLIC</td>
</tr>
<tr>
<td>Diploma Course for Trial Professionals</td>
<td>DCTP</td>
</tr>
<tr>
<td>Diploma in Medicines Development</td>
<td>DIMD</td>
</tr>
<tr>
<td>Master of Medicines Development</td>
<td>MMD</td>
</tr>
<tr>
<td>Specialist in Medicines Development</td>
<td>SMD</td>
</tr>
<tr>
<td>Master of Regulatory Affairs</td>
<td>MRA</td>
</tr>
<tr>
<td>Elective Modules (Forum)</td>
<td>ELM</td>
</tr>
<tr>
<td>CPD Modules</td>
<td>CPD</td>
</tr>
</tbody>
</table>

### Individual Services

- Course Recognition Process
- Centre Recognition
- Examinations
- Certifications/Re-certifications
- e-Platform
- Competence Profiler

### General Services

- E&T System Development and Maintenance
- Standards and Quality Management Process
- Global Network
- Marketing and Communication
- PharmaTrain Brand
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
Molecule to Marketplace
teaching the complete PharmaTrain Syllabus

- DBM 1 Introductory Module One
- DBM 2 Non-clinical Testing to Proof of Concept in Humans
- DBM 3 Exploratory and confirmatory Clinical Development
- DBM 4 Clinical Trials: Methodology and Biostatistics
- DBM 5 Regulatory Affairs, Safety and Pharmacovigilance
- DBM 6 Healthcare Marketplace and Economics of Healthcare

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
Extension Master of Medicines Development

'Extension Master' of Medicines Development

- University of Basel
- Semmelweis University
- University Claude Bernard Lyon
- Catholic University of Rome
- University of Osaka
- University of Tel Aviv

Training Centres providing an Extension MMD
PharmaTrain Centres of Excellence
Awards in bold

- Diploma Course
  - ELM: All six Electives can be selected from the Electives Modules’ Forum (see chart below) or any other recognised modules (hatched ellipse)

- Extension Master
  - 60(-90) ECTS incl. Thesis

- ELM: All six Electives can be selected from the Electives Modules’ Forum (see chart below) or any other recognised modules (hatched ellipse)
‘Integrated Master’ of Medicines Development

Training Centres providing an Integrated MMD PharmaTrain Centres of Excellence Awards in bold

- University of Cardiff
- University of Duisburg-Essen
- King’s College London
- University of Milano-Bicocca
- Trinity College Dublin
- Hibernia College Dublin

- University of Aveira, Portugal
- University of Stellenbosch
- Yonsei University Seoul
- University of São Paulo
- University of Buenos Aires
- University of Mexico

Masters 60-90 ECTS incl. Thesis

Diploma 30 ECTS

IMM, Integration Master Modules
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 ellipse)
**European* Elective Modules’ Forum**

<table>
<thead>
<tr>
<th>ELM 1</th>
<th>Medicines Regulation</th>
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<tbody>
<tr>
<td>ELM 2</td>
<td>Generic &amp; Biosimilar Medicinal Products</td>
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<tr>
<td>ELM 3</td>
<td>Project Management in Medicines Development</td>
</tr>
<tr>
<td>ELM 4</td>
<td>Biomarkers and Surrogate Endpoints</td>
</tr>
<tr>
<td>ELM 5</td>
<td>Medicines Development for Rare Diseases</td>
</tr>
<tr>
<td>ELM 6</td>
<td>Medicines Development in Children</td>
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<tr>
<td>ELM 7</td>
<td>Medicines Development in a Geriatric Population</td>
</tr>
<tr>
<td>ELM 8</td>
<td>Practical Approach to Ethical &amp; Legal Aspects of CTs</td>
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<tr>
<td>ELM 9</td>
<td>Systematic Review and Meta-Analysis</td>
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<tr>
<td>ELM 10</td>
<td>Pregnancy and Medications</td>
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<tr>
<td>ELM 11</td>
<td>Principles &amp; Practices of Medical Devices Development</td>
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<tr>
<td>ELM 12</td>
<td>Disease-Biology Based Pharmacology</td>
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<tr>
<td>ELM 13</td>
<td>Model-based Medicines Development</td>
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<tr>
<td>ELM 14</td>
<td>Special Populations and Trial Practices (also EXM 8)</td>
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<td>ELM 15</td>
<td>Pharmacoeconomics and Markets (also EXM 1a)</td>
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<td>ELM 18</td>
<td>Basics of Health Economics</td>
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<tr>
<td>ELM 19</td>
<td>Drug Safety &amp; Pharmacovigilance</td>
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<td>ELM 20</td>
<td>Pharmacoepidemiology</td>
</tr>
<tr>
<td>ELM 21</td>
<td>Life Sciences Executives</td>
</tr>
<tr>
<td>ELM 22</td>
<td>Biobusiness Development</td>
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*e.g. ELM 9 promoted on our e-Platform*

* other parts of the world require different solutions incl. blended and e-learning
**e-Platform: Service for e-Learning**

**e-Library** (self-produced, 20 e-products)

The PharmaTrain e-library integrates state-of-the-art newly developed blended learning modules with those collected from continuing survey to create a directory of online courses. The library is open to all partners, allowing them to blend the content into their modular courses in the way best suited to their institution. The repository will allow institutions to continue to develop more specialised extension modules, enhancing the learning experience by creating a holistic environment of teaching methodologies supporting the programme. In addition, this repository will evolve into a pan-European online e-campus, supporting faculty and students. Supporting material (e.g. book chapters, publications etc.) will be added and become part of the online repository.

The following e-modules are ready for you to use:
As long as the PharmaTrain project is running (until April 2014) the access to the e-learning modules is free of charge.

- [Introductory Module](#) (created by Hibernia, with the support of AZ, Pfizer and PHARMD)
- [A Therapeutic Module on Parkinson's Disease](#) (created by Hibernia, Pharmed and UCB)

**e-Directory** (screened from others, ca. 200 e-products)

**e-Learning** (production within PharmaTrain curriculum standards and Best Practices using preferred production sites and dedicated sponsors)
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
PharmaTrain Certification Process

★ **SMD**: PharmaTrain Specialist in Medicines Development

★ **SPM**: PharmaTrain Specialist in Pharmaceutical Medicine (so far in CH, UK, IRE, B)

★ **CLIC**: PharmaTrain Clinical Investigator Certificate

★ **DCTP**: PharmaTrain Diploma for Clinical Trial Professionals

★ **CPD**: **PharmaTrain** Certification of CPD modules (min. 1 ECTS!)

→ Above titles are awarded by the PharmaTrain Certification Board

→ Diploma Courses and Master programmes are certified by the individual partner university
European PharmaTrain Modular Product Portfolio

A total of > 200 Modules in Europe plus Global Partners build the integrated programmes and can be used à la carte:
Benefits for Employers

★ **Promote/motivate talented employees** by sending them to training
  • addressing the *practical training needs* of professionals
  • developed with *input from the industry, regulators and academia*
  • *delivered* by the industry, regulators and academia

★ **Creating a pool of optimally trained staff** for
  • *recruitment and career development*
  • *deployment, mobility and retention*
  • *enhancement of employees’ and teams’ outcome*

★ **Guaranteed high-quality** training by
  • applying *PharmaTrain Shared Standards*

★ **Flexibility** to choose
  • *à la carte* from a wide range of *CPD “short” courses*
  • *Diploma Courses or Master Programmes*
  • reflecting *global drug development models*

(Benefits for Trainees and Learned Societies see Business Plan Full Version)
Benefits for Training Centres

★ Being a **proactive member** of the organisation
  - driving *E&T in Medicines Development*
  - sharing *educational experience* – content, analysis and methodology
  - enhancing regular adjustments to *medicines development needs*

★ The **PharmaTrain brand** supports
  - *awareness* and *acceptance* of courses and course providers
  - *Europe-wide* and *global*
  - by *trainees*, the *industry* and *regulatory authorities*

★ PharmaTrain **website**
  - *advertising* the values of PharmaTrain recognised E&T
  - with *services* for the course provider (e.g. flagging request)

★ **Access to**
  - central *examination* and
  - *certification* pathways for different professionals

(Benefits for Trainees and Learned Societies see Business Plan Full Version)
Standards and Iterative Quality Management Process

PharmaTrain Manual
Curriculum Standards and Best Practices

- Syllabus / Content
- Learning Outcomes (Competencies)
- e-Learning / active preparation and assignments
- Modules / Curricula
- Specialist-track integrated examination
- Modular assessments

CPD Platform

Performance Improvement: Feedback

Quality Assurance of Shared Standards

Accreditation of Centres Certification of Trainees

Self-assessment

Report

Assessors

Control-assessment

QA WP8

Training Centre
Legal Situation

PharmaTrain Federation is the owner of

- **www.pharmatrain.eu**

- **PharmaTrain™** trademark in the countries who have signed the 5th Madrid Agreement Concerning the International Registration of Marks

- IMI PharmaTrain has **contracts** with
  - 23 Universities in Europe (11 CEMDC) and
  - 7 signed **Memoranda of Understanding** with Affiliates in Portugal and outside Europe (another 5 pending signature).

- **Challenges** to be addressed:
  - Transfer of intellectual property rights to the new organisation (e.g. of e-Learning products)
PharmaTrain Federation: Membership

The position of the members concerning their activity for the Federation is reflected in the membership structure:

**Active Members**
- Public Organisations (Course Providers, Universities, Institutions, NGOs)
- Private Organisations (Course Providers)
- Private Corporations (Industry, Foundations etc.)
  - Sponsor Member Silver
  - Sponsor Member Gold
- Individual Members (professionals, trainees, alumni)

**Associate Members**
- Public Organisations (Institutions, NGOs)
- Private Organisations (Industry, Foundations etc.)
PharmaTrain Federation: Organisation

PharmaTrain Federation is organised as a

★ Swiss federation
★ founded in 2009
★ with 19 institutional and 7 individual members (as of March 2013)
★ members are representatives of all stakeholders
  • Industry
  • Universities
  • Public and Private Course Providers
  • Learned Societies and Scientific Bodies
  • Employees/trainees (Alumni)
  • Other Individuals

...potential future collaboration with existing 80 public and private partners in the IMI PharmaTrain project as well as newly attracted membership in the PharmaTrain Federation
PharmaTrain Federation: Structure

★ PharmaTrain Federation organs
  • General Assembly
  • Executive Board (Chair, Co-Chairs, CFO, Executive Members)
  • Executive Office (Secretary General, Assistant(s))

★ Working Groups / Networks (NET)
  • Strategy Development NET
  • Regional Hub Development NET
  • Curricula Examination NET
  • Blended and e-learning NET
  • Master-level universities training Net (incl. MRA)
  • CLIC Course Provider NET
  • Quality Management, NET and Certification Board
## Business Plan Implementation Strategy

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<tr>
<th>2014 (5-12)</th>
<th><strong>Launch</strong></th>
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<tbody>
<tr>
<td></td>
<td>Consolidate and commercialise products and services</td>
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<tr>
<td></td>
<td>Extend collaborative network and clarify structure (hubs?)</td>
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<tr>
<td></td>
<td>Boost PharmaTrain awareness (brand)</td>
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<tr>
<th>2015-2016</th>
<th><strong>Drive</strong></th>
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<tr>
<td></td>
<td>Globalise network possibly with a main focus on Asia</td>
</tr>
<tr>
<td></td>
<td>Fully implement products in the globalised network</td>
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<td></td>
<td>Expand products and services portfolio</td>
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<thead>
<tr>
<th>2017-2018</th>
<th><strong>Expand</strong></th>
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<tbody>
<tr>
<td></td>
<td>Create new products and services</td>
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<tr>
<td></td>
<td>Increase network possibly with a main focus on Africa and collaboration with foundations</td>
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</tbody>
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A more detailed business development plan will be established in early 2014.