

IMI1 Final Project Report Public Summary

Project Acronym: PharmaTrain

Project Title: Pharmaceutical Medicines
Training

Grant Agreement: 115013

Project Duration: 01/05/2009 – 30/04/2014

1. Executive summary

The Final Report includes the 5th Annual Work Progress and Financial Report, summarising the project confirmation and sustain phase from May 1st, 2013, to April 30th, 2014, enabled by a systematic IMI PharmaTrain project countdown plan as well as the overall achievements of the 5-year project. PharmaTrain has achieved its sustainability by successful implementation of PharmaTrain Federation as the successor organisation including the required governance, organisation structure, work plan and financial basis to continue the implementation process of the PharmaTrain concepts and successful co-application for E&T ENSO (IMI-TRAIN).

(note: in PharmaTrain the terms “Medicines Development” and “Pharmaceutical Medicine” are used synonymously).

1.1 Project rationale and overall objectives of the project

- To provide a Europe-wide comprehensive solution to training needs of integrated medicines development (sciences) 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 and align quality improved modular programmes of advanced studies in medicines development – value chain from molecule to patient – leading to a postgraduate Master and Specialist qualification based on the Bologna credit and title system with 60+ ECTS credits. In addition, a portfolio of short courses and e-learning modules should improve flexible individual training opportunities.
- It is expected that systematic and standardised training of key-professionals involved in the development of medicines will improve overall competencies, which eventually will help to improve decision making, reduce mistakes and lead to safer medicines, more economically and faster for patients in need.
- Another objective is to sustain the project results beyond its termination by end of April 2014.

1.2 Overall deliverables of the project

- All objectives and deliverables of the project have been met. These will be summarised in section 2 below. Most relevant documents are available on the public PharmaTrain website. In summary, these are: PharmaTrain Syllabi and Curricula in Medicines Development; a Syllabus and Curriculum for a new Master of Regulatory Affairs; the Quality System, the concept for the new professional title “Specialist in Medicines Development” (SMD); the Clinical Investigator Training

Concept (CLIC), as well as access to 10 e-learning compact modules. In addition, the Quality System and a Short Course recognition process aligned with www.on-course.eu, is a major achievement. The PharmaTrain Manual document, the curricula of 26 Elective Modules and the Good Examination Practices guide will be available on the PharmaTrain Web platform to which members of PharmaTrain Federation, former partners in IMI PharmaTrain and IMI JU have access.

- PharmaTrain is now well known for high-quality training in medicines development and a steadily increasing network of stakeholders in this field of Education & Training (E&T).
- Quality assurance is based on the quality criteria developed jointly by the IMI JU Education & Training (E&T) projects (“9 Cross Project Quality Criteria”) and the SOP-based processes developed in PharmaTrain to recognise training centres and Short Courses, as the “Implementation Process of Shared Standards” and the “PharmaTrain CPD recognition and flagging request” process.
- The original network of more than 20 European Universities, which grew together within PharmaTrain, was enlarged by 10 Universities from Eastern Europe (CEMDC course) and with nine Universities from non-European countries which joined the network as “Affiliates”. These Universities are keen to adapt their training courses to the high PharmaTrain Quality Standards, to develop new courses and to participate in the network of course providers and other stakeholders.
- The PharmaTrain shared standards and the cross-project quality criteria have now been implemented by 13 Universities (11 are partners in PharmaTrain and two Universities joined the network as an Affiliate (University of Aveiro in Portugal, and Stellenbosch University, Cape Town, South Africa). These 13 Universities achieved the award of a Centre of Excellence and also started to mutually recognise ECTS and trainees.
- The number of PharmaTrain approved Short Courses increased to 150 courses by successful implementation of the recognition process aligned with www.on-course.eu and led by the PharmaTrain CPD Access Panel.
- PharmaTrain Federation with ca. 50 members will sustain the outputs of IMI PharmaTrain and participate in the IMI ENSO project “IMI-TRAIN”.

1.3 Summary of progress versus plan since last period

There were no negative deviations but rather over-performance and broadening of the project’s scope:

In line with the PharmaTrain countdown plan the following results and documents were finalised based on the work of previous years:

- The results of PharmaTrain dedicated to quality improvement and harmonisation of training in Medicines Development, Regulatory Affairs as well as training for clinical investigators and the concept for “Specialist in Medicines Development” was put together in the “PharmaTrain Manual Curriculum Standards and Best Practices”. The Manual was developed by almost all partners during the course of the project and is now in a final version V2.0 incl. all appendices shown below. Since most Appendices are deliverables in the different Work Packages and for achieving a better overview, the numeration of deliverables is included here as well:

A) Appendices: Complete Training Programme Contents

1. 12.1 PharmaTrain Syllabus 2010 V1.0, February 2010= Del 1,2,5-WP3
2. 12.2 Curriculum and Learning Outcomes Diploma (Base) Course V2.0, April 2012= Del 1,2,5-WP3
3. 12.3 Curriculum and Learning Outcomes Integration Master Modules, MMD, V1.0=Del 1,2,5-WP3
4. 12.4 Elective Modules with Learning Outcomes (12.4.1-12.4.26)=Del 10-WP3/WP6
5. 12.5 MRA (Master of Regulatory Affairs) Syllabus, Curriculum and Learning Outcomes, V1.1, June 2013=Del 1-WP2b
6. 12.6 A European approach to Clinical Investigator Training and Certification, CLIC, V1.0=Del 11-WP2a
7. 12.7 Diploma (Course) for Clinical Trial Professionals, DCTP Approach, V1.0=Del 12-WP2a
8. 12.8. Specialist in Medicines Development (SMD), Procedural Document V1.0=Del19-WP3

B) Appendices: Guidelines and Documents

9. 13.1 Learning Outcomes and Bloom's Taxonomy, V1.0
10. 13.2 PharmaTrain e-Learning Product Development Guide, V1.0=Del 4-WP4
11. 13.3 PharmaTrain Examination Guide, V2.0, Del 1-WP7a
12. 13.4 Specialist in Medicines Development (SMD) Competency Curriculum, V1.0=Del 19a-WP3
13. 13.5 CPD Recognition Process, V1.0=Del 10a-WP2a
14. 13.6 PharmaTrain Flagging Request Form=Del 10b-WP2a
15. 13.7 Memorandum of Understanding for Affiliates, V1.1=Del 9-WP2a
16. 13.8 PharmaTrain Quality System V1.0=Del 7-WP8 incl. enclosures
 17. 13.8.1 Quality Assurance Guide: SOP, V1.1=Del 3,4,5-WP8
 18. 13.8.2 Applicant's Checklist, V1.0=Del 3,4,5-WP8
 19. 13.8.3 Reporting Template and eQMS, V1.1=Del 3,4,5-WP8
 20. 13.8.4 Guideline e Quality Standards, V1.1=Del 6-WP8
21. 13.9 PharmaTrain Branding Guidelines, V1.0=Del 12-WP2a/WP1
22. 13.10 PharmaTrain Ethics Guide V1.0=Del 2-WP7b

Details and documentation is available in Tab 2.1 below (Manual=Del 6-WP2a/WP3 and Appendices)

- The 12th and 13th University achieved the award of a Centre of Excellence based on the earlier established SOP-based Procedure (Implementation Process of Shared Standards). These are the University of Aveiro in Portugal and Stellenbosch University Cape Town, South Africa which joined PharmaTrain as "Affiliates". Stellenbosch is the first University outside Europe to become a PharmaTrain Centre of Excellence. The network and course portfolio of PharmaTrain Centres of Excellence is available on www.pharmatrain.eu. The Mutual Inter-University Modular Acceptance paper (Del 15-WP2a) signature process is currently ongoing but so far it has already been signed by six universities (Centres of Excellence) and mutual acceptance of ECTS and students mobility between Centres of Excellence and Short Courses providers made progress, see Update 58.
- In addition to the Centres of Excellence, nine course providers requested a PharmaTrain flag for more than 100 courses (flagging request aligned with www.on-course.eu). The CPD Access Panel accepted courses from seven of the nine course providers. All Short Courses are available on www.pharmatrain.eu, Del 10a,b-WP2a).

- The e-learning products on “Basis of formulating dose-response”, “Ethical issues in clinical research”, “Registration of a medicinal product”, “Medicines Safety” and “Health Economics” were completed and put on the public website www.pharmatrain.eu. In total 10 e-products are available incl. e-CLIC.
- A second round of integrated examinations between FPM, UK, University of Basel (ECPM) and university of Brussels (Pharmed) was carried out and evaluated (Del 2b, 3b, 4b-WP7a). The pool of MCQ questions was enlarged.
- The Ethics Guide was created (Del 2-WP7b), delivered July 2014
- The University of Copenhagen, University of Basel (ECPM), King’s College London and Hertfordshire signed a MoU (Del 2-WP2b) for joint execution of the Master of Regulatory Affairs (Del 1-WP2b). These Universities will deliver this new programme together with Medicademy, TOPRA and DIA-Europe.
- The first CLIC courses were given based on the CLIC concept paper (University of Aveiro), and implementation of the CLIC training concept is under development in Hungary and France.
- The concept of the Diploma Course for Clinical Trial Professionals (Del 12-WP2a) with 30 ECTS was completed, however, still requires a Europe-wide consensus process with interested universities. The Clinical Trial Unit at University Hospital in Basel in collaboration with ECPM (University of Basel) have successfully organised the course over two cycles and are currently running the course a third time.
- The concept for the Specialist in Medicines Development was finalised (see SMD Procedural Document and Competence Curriculum, Del 19-WP3). The SMD concept will be implemented in IMI-TRAIN, an approved ENSO project of the E&T projects EMTRAIN, SafeSciMET, EU2P and PharmaTrain.
- In terms of globalisation the network was increased to nine Universities which have signed the MoU; two signed in the (fifth) year (final year). After the end of IMI PharmaTrain, a membership application for PharmaTrain Federation will be the official document for joining. Fudan University, Shanghai became a member recently and Tokyo University is at the stage of becoming a member in PharmaTrain Federation soon. Two of these Affiliates (University of Aveiro, Portugal and Stellenbosch University, Cape Town, South Africa) have been assessed and awarded Centre of Excellence.
- In terms of communication, monthly internal Updates were published (no 49 – 60, Del 5-WP2a) as well as 4 Career Drivers (Del 4-WP2a) between May 2013 and April 2014 dedicated to the public. Career Drivers have been distributed by partners in PharmaTrain to their networks.
- Trademark (TM), registration of “PharmaTrain” was continued and a successful registration was achieved for Switzerland, EU, Australia, Israel, Singapore, Turkey and USA. The registration process is still ongoing in China, Japan and Russia. This will be followed up by PharmaTrain Federation.
- PharmaTrain Federation is in the position to take over the outputs of IMI PharmaTrain in terms of sustainability and most public partners became a member of PharmaTrain Federation. The business concept from 2013, mentioned in the 4th report, was restructured. PharmaTrain Federation joined the EMTRAIN consortium in order to participate in IMI-TRAIN.

1.4 Significant achievements since last report

In section 1.3 the results in the last, fifth, year were summarised. In addition we want to highlight the following:

All relevant documents were finalised, in particular the PharmaTrain “Manual - Curriculum Standards and Best Practices”. This document and its appendices summarise the PharmaTrain shared standards and training concepts (Medicines Development, Regulatory Affairs, Clinical Investigators, Specialist in Medicines Development, e-library).

The first trainees started their studies to achieve a Diploma and Master degree by booking courses at several PharmaTrain Centres of Excellence (Update 59) and Universities started to accept ECTS from other Centres of Excellence partner universities.

Successful increase of the number of network partners (Affiliates, members in PharmaTrain Federation) which is a major prerequisite to achieve sustainability.

Increased awareness of Medicines Development training in Europe and abroad – PharmaTrain developed into being recognised for high quality training standards and as certification body in this area.

The CLIC concept created a high level of interest in several countries. Universities in Portugal, Hungary, France and Tokyo University in Japan are currently working on implementing the concept in their countries. Other IMI projects, e.g. Combacte 6A, consider organising their training of clinical investigators within PharmaTrain Federation’s CLIC infrastructure. Discussions are also ongoing with TransCelerate.

Most public partners in IMI PharmaTrain became members in PharmaTrain Federation incl. all Centre of Excellence – Universities. PharmaTrain Federation successfully became the successor organisation.

1.5 Scientific and technical results/foregrounds of the project

The website www.pharmatrain.eu.

The “PharmaTrain Manual - Curriculum Standards and Best Practices” and appendices summarise the achieved shared standards and results of IMI PharmaTrain incl. Syllabus and Curricula for training in Medicines Development and Regulatory Affairs.

10 e-learning products (1 ECTS each) on www.pharmatrain.eu.

IMI JU E&T quality criteria (list of nine cross project quality criteria).

PharmaTrain Quality System incl.:

- Defined SOP based “Implementation Process of Shared Standards” to recognise training centres (QA process).
- A defined quality assurance process for Short Courses (CPD recognition process and flagging process aligned with www.on-course.eu and led by the CPD Access Panel).

The guideline “Good Examination Practices”.

The PharmaTrain Ethics Guide.

The concept for the “Specialist in Medicines Development” and the Competence Curriculum.

The concept of the “European Approach to Clinical Investigator Training”, the CLIC initiative.

Sustained network of more than 50 stakeholders in Medicines Development and successful operational start of PharmaTrain Federation.

A network of 10 Universities in Central – Eastern Europe (CEMDC course).

Globalisation of the network (7 members in PharmaTrain Federation are from US, Asia or Africa).

TM Registration of PharmaTrain in most relevant countries.

PharmaTrain Branding Guidelines and logos.

Publications: Updates 1-60 and Career Drivers 1 – 18.

Publications as listed in section 4.7.

Memoranda of Understandings and agreement documents:

- Affiliates to join IMI PharmaTrain
- Agreement between CEMDC Universities (Semmelweis University)
- Agreement between four universities to jointly implement the Master of Regulatory Affairs
- Multiple Inter-University Module acceptance

1.6 Potential impact and main dissemination activities and exploitation of results

The PharmaTrain project has contributed to the socio-economic benefits of the European citizens by providing high quality education and training for a broad range of professionals in medicines development. This has enhanced the knowledge economy and by supporting the medicines development academia and industry have contributed, albeit to a small degree, to the overall economy.

IMI projects were specifically developed to address bottlenecks in the medicines development process and to speed up the delivery of new, safer medicines to patients. PharmaTrain has successfully removed some of those bottlenecks. Although it is too early to demonstrate a direct

impact on the health of European citizens, the provision of high quality courses can be thought of as a surrogate endpoint. We are confident that in future this growing cohort of better trained medicines development professionals will enable better, safer medicines to be developed.

PharmaTrain has developed a network of European course providers and experienced industry representatives who all share common standards, who jointly improved the course content to make it as industry-relevant as possible and who have jointly developed an assessment procedure for course providers to ensure that course providers recognised as Centres of Excellence are reliable institutions for optimal education of industry researchers. The original network was expanded to include universities in Central Eastern Europe (CEMDC course) and the provision of a 80% distance learning course by Hibernia College effectively removed the European geographical barriers to accessing the courses. This has undoubtedly increased Europe's competitiveness as professionals at all levels have benefited from these courses and will in turn contribute to the innovations essential for a thriving research environment. PharmaTrain has established Europe's leading position as demonstrated by non-European affiliates joining PharmaTrain so they too can access these state-of-the-art programmes.

Not only has PharmaTrain successfully delivered all the "stretched project goals" – exceeding expectations, it has also secured sustainability by transitioning to the PharmaTrain Federation – a not-for-profit organisation. This will ensure that the return on investment is maximised by delivering continuity and further growth; future support and membership of Pharma companies in the PharmaTrain Federation is still a goal to achieve. The impact of the PharmaTrain project alone was limited due to the 5-year project life. However, the PharmaTrain Federation is now able to build on the achievements and spread these without further time restraints, to a much broader community of healthcare professionals and medicines development professionals. The global expansion, which has already started, will further increase the impact on the scientific community.

1.7 Lessons learned and further opportunities for research.

1.7.1 Please indicate how the collaboration in a public private partnership (PPP) has been an added value to achieve the objectives of the project

The industry stakeholders had clearly identified the need for a higher level (Master level) of training which addressed the needs for targeted, continuing professional development. This was different from the more academic approach which had previously been available. The combination of the practice-orientated industry partners and the academics' expertise in developing state-of-the-art courses resulted in a new level of education and training which could not have been attained by either group alone. The partners also worked closely together to deliver the courses, allowing "real world case studies" to be integrated into a high quality pedagogic environment (this observation covers all WPs). The opportunity to combine the content knowledge of the private partners with the public partners' expertise in educational methodology enhances the quality and relevance of examination questions (WP7a). Company representatives are invited as faculty members and examiners in the PharmaTrain courses. The result is a suite of courses which are the envy of the rest of the world.

In particular, in the process of building up the e-library, the collaboration between EFPIA and academia has been exemplary. Indeed, several e learning modules or the material used to create

them, have been offered as in-kind contribution by EFPIA companies who are private partners of PharmaTrain (WP4).

The PPP was very useful in providing a special grant for hiring a managerial help for the CEMDC (Roche for WP5). For the CEMDC course an additional educational value came from the teachers working in the various pharmaceutical companies and regulatory agencies. They provided the practical background based on experience working for the pharmaceutical industry or regulatory agency.

1.7.2 From your experience, please propose any recommendations/ solutions which could be useful for a PPP

One of the most important attributes of a successful partnership is clarity of expectations. PharmaTrain was the first call project to start and as such had to develop the rules during the project. The lack of clarity about the exact nature of the in-kind contribution from the private partners hampered the project management. In addition, while some companies fulfilled or over-fulfilled their commitments, other companies did not get involved in the project as originally committed. The comprehensive project management process (resources, budgets and timelines) was different from the usual academic environment and the requirements only became clear during the process e.g. with audits. Also the private partners had first to find out how to handle IMI commitments administratively. Until the end of the PharmaTrain project, however, transparency for the project manager on resource allocation to claimed budgets on the private partner side was not achieved. Finally, the ambiguity around the private partner commitment to the entire IMI programme, versus individual projects led to misunderstandings and frustration. Therefore, future projects should have a comprehensive understanding of the resources, timelines and budgets per project for all partners from the start and provide a mechanism for transparency of resources and budgets of all partners and will then be better equipped to manage expectations of all partners and stakeholders.

The landscape for education and training in the major pharmaceutical companies changed considerably. This was driven by the financial crisis and restructuring of the companies. In EFPIA companies, staff changed quite often and a large amount of work was taken over by public partners. The lack of clarity about the in-kind resources, EFPIA contribution at an IMI programme level versus single project level led to the need for an additional “tender list” which was partially successful.

The PPP partnership failed in bridging the industrial need for highly trained personnel and the support necessary for educating the young generation. Course providers and in particular the Centres of Excellence, awaited an increase of trainees coming from EFPIA companies. This increase did not happen. The universities and the industry would gain from a better cooperation in education and training for professionals working in R&D in industry. The pharmaceutical industry should look at education and training as a mean to ensure quality and sustainability in all functions, e.g. by supporting their present or prospective employees in terms of providing free time for education and support to tuition fees. Additionally, new approaches might be necessary for improving practical teaching. For example the industry could provide interesting practical problems to be solved by the students during their education. This might develop the entrepreneurial interest of the students and might in some cases provide useful solutions to the industry, see PharmaTrain SMD (Specialist in Medicines Development) concept.

1.7.3 In view of your project achievements, please provide your views on potential new research to further advance the field

Potential new research in this area of education and training includes rapid identification of emerging needs (to prevent future bottlenecks) and generating a comprehensive set of highly flexible solutions for all learning styles to meet these needs.

As a project in Education & Training, the following observations were made. The landscape changed during the project due mainly to the financial crisis and the restructuring of many EFPIA companies. This resulted in changes to the course requirements (e. g. greater emphasis on e-/distance- learning and thus less time out of the office for the participants). There were fewer course participants than had previously been expected. In addition, some companies tend to invest more in in-house learning. However, there is no independent, objective mechanism in place to validate the content and quality of these in-house training courses.

High quality standards are extremely important and allow participants to choose the best courses to meet their training needs.

From a private company perspective there was a need for a greater degree of collaboration between the IMI Education & Training projects as the different projects gave rise to confusion.

There is an increasing need to address competence development, beyond knowledge acquisition, and this is the focus of the PharmaTrain Specialist in Medicines Development which will be implemented as part of the collaborative IMI-TRAIN project.