Final report Pharmatrain – imi-train 3.11.

From: Heinrich Klech - Leader WP3 imitrain

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Start of the project: June 2014

End of project; July 2016

Background and Summary

The imi-train project-objective for Pharmatrain was the development of a global implementation plan and the implementation of a single European country (Italy) pilot of the **Specialist in Medicines Development (SMD) concept**. Pharmatrains work was put as one the main deliverables of imi-trains WP3 focusing on competence development. This work package was co-led by PharmaTrain and SafeSciMET to develop and implement competency development profiles, competence assessments and competency portfolios

„The Specialist in Medicines Development (SMD) is a competency-based, workplace-centred education and training certification programme in Medicines Development, comprising a knowledge base covering the PharmaTrain Syllabus for Medicines Development Science, delivered and assessed through modular curricula, and the acquisition and demonstration of competencies for medicines development across seven domains of the competency curriculum. Participants in this mentored, vocational programme acquire knowledge and competencies within a framework of assessment, appraisal and annual review of progress and achievement. On completion, participants receive the SMD Certificate from the PharmaTrain Certification Board (PCB)." See also

http://www.pharmatrain.eu/_downloads/SMD_Certification_Programme_V1.pdf

After constitution of the WP3 consortium the work was done by informal personal meetings, formal conferences and presentations as well as visits with national and international stakeholders.

Various national and international **stakeholders** were identified and had been subject of various formal and informal consultations. In order to successfully embrace the Italian stakeholders community an **Italian SMD implementation group** was developed and is still in place as part of the national **Italian SMD certification board.**

Three stakeholders conferences in Italy have taken place in 2015 and 2016.

A special task force developed the charter and the policies of the **global Pharmatrain SMD Certification board (gPCB)**. Since January 2015 the global board is working in 6 weeks intervals. The global board overlooks and governs the developments of the national board and the implementation of the SMD concept in Italy. Additionally the gPCB takes the lead for the development of the SMD concept in other countries and the planned international roll out. See also

http://www.pharmatrain.eu/_downloads/CHARTER_PharmaTrain_Certification_Board_V1_0_Dec_2014.pdf

The overall SMD concept and the Italian pilot was reported and published in various interdisciplinary conferences in Europe, in Japan and in Latin America . Lately at the EMBL conference,Heidelberg, in July 2016
http://www.emtrain.eu/files/lifetrain/ws2015/posters/PharmaTrain_SMD_Poster_Lifetrain.pdf

Paralell to the efforts in Italy there was a successful development of the **SMD concept in Japan**. There a local Japanese PCB was founded and the recruitment of candidates and of mentors has already started. http://japhmed.jp/smd/smd.html

As of the end of imi-train working period the Italian pilot is in the recruitment phase for candidates. It is driven for the future by SSFA, the Italian association of pharmaceutical physicians, by the Italian PCB, by the global PCB and by the two sponsoring institutions Pharmatrain and IFAPP. The two latter organisations are also the drivers for further geographic roll out.

The learnings from the pilot are the following:

1) Knowledge development as part of the SMD concept is commonly accepted in Italy and majorily supported. Various institutions in Italy provide excellent tuition on academic and non-academic level
2) Competence development by means of a work based and mentored vocational programe needs strong argumentation and "marketing" efforts among the employers in the environment of biotech, CROs and Pharma industry. Consistent and strong efforts are needed both on local industry as well on EFPIA level to highlight the value of such competence development programs. The continuation of the SMD pilot efforts will be crucial to signal the added value of such work based development programs for the candidates and for the various stakeholders. The very positive development in Japan and adherence to the concept is giving rise to the hope that Europe will follow in their footsteps.
3) SMD should be seen as an example which easily could be followed through competence programs for other specialties such as safety medicine, regulatory, Phamacovigilance etc. Some joined activities in this direction have already started within the framework of imi-train.

Scope, Objectives, deliverables and cross project interactions

A) Overall WP3 scope

Competence development: This work package is co-led by PharmaTrain and SafeSciMET to develop and implement competency development profiles, competence assessments and competency portfolios

B) PharmaTrain objectives

Develop a global implementation plan and implement a single European country (Italy) pilot of the Specialist in Medicines Development (SMD) concept

C) Cross projects interactions and collaborations

Pharmatrain as contributor to WP3 closely collaborated with other WPs of imi-train

- With WP1 for the overall communication strategy together with Eu2P and SafeSAciMET
- With WP2 in terms of identifying position and communication on the imitrain website in close collaboration with Eu2P www.imi-train.eu
- In WP3 with the partner SafeSciMET for cross project recognition of modules and of alignment with policies
- With WP4 for coordination of overall strategic guidance and future plans in close collaboration with EMTRAIN

D) Deliverables

Develop a global implementation plan and implement a single European country (Italy) pilot of the Specialist in Medicines Development (SMD) concept

a. Establish the certification board: definition of tasks, selection of members, set up and development of SOPs
b. Identify pharmaceutical companies, CROs, competent authorities and other suitable employers interested in joining the on the job training and mentoring programme
c. Establish the local and regional mentor faculty
d. Implement a training plan for mentors (training workshops, etc.)
e. Enable the SMD degree acceptance in the Italian professional environment
f. Implement the SMD as European register arriving at CPD accreditation body for European registration
g. Marketing support and exploration of implementing PharmaTrain Federation as a global accreditation body

- **The SMD Certification Board**
  - The PharmaTrain Certification Board Task Force (PCB TF) is in action since January 2015 has successfully met its target
    - Election of the four leading members
    - The remaining 6 members of PCB will be elected/selected until end January
    - Finalized and approved all the PCB ground rules/documents by the TF members
    - Guidelines for mentors and training workplaces developed and information campaign started
    - The PCB works closely with the imi-train-SMD Italy implementation group and will have joint TCs every 6 weeks in order to meet the milestones

      See also: http://www.pharmatrain.eu/_downloads/CHARTER_PharmaTrain_Certification_Board_V1_0_Dec_2014.pdf

- **12 months deliverables and Progress report untill end June 2015**

  The global Pharmatrain (SMD) coordination board (PCB) meets in 6 weeks intervals since Jan 2015. For time being the Italian branch (SMD Italy implementation group) is integrated in the PCB. The Italian branch of PCB was recently joined by influential leaders from the Italian science and regulatory environment

  a. PCB has set up rules and a governance structure. Part of it is project management for the future, quality assurance and q-management aspects.
  b. In June 10th-11th 2015 an Italian stakeholder conference was held in Rome in close cooperation with IFAPP (International federation of pharmaceutical physicians) and SSFA (the Italian association of applied pharmaceutical science). 75 delegates were present among them a Japanese delegation interested in transferring the programe to Asia. Important stakeholders such as the Italian Regulatory agency (AIFA), several universities and the Italian associations of CROs were present and held lectures. Unfortunately the Italian association of drug manufacturers (Farmindustria) was not present. Programe, Proceedings, abstracts and presentations are available on the website of Pharmatrain (http://www.pharmatrain.eu/_downloads/PTF_IFAPP_SSFA_Conference_Rome_program.pdf) as well as on the website of SSFA (http://www.ssfa.it/Page.asp?SitoID=1&PaginaID=1481)
  c. 12 month deliverable: Enrolement of candidates. The conference in Rome was the start up for the identification and search for candidates and mentors for the SMD programe. It turned out that the SMD programe seems to be more attractive for SMEs and for CROs rather than for big Pharma. The Italian implementation team works hard to make progress here and will provide further progress reports. It is expected that by 2016 we would have the first candidates to be included in the programe.
  d. In parallel the SMD concept was presented in 2 scientific international conferences (Lifetrain workshop in March 2015 in Brussels and the DIA Europe meeting in May 2015 in Paris). The presentation (H.Klech, P.Stonier**:** PharmaTrain Specialist in Medicines Certification Programme: SMD Curriculum Path & Certification Process) can be found in http://www.emtrain.eu/files/lifetrain/ws2015/posters/PharmaTrain_SMD_Poster_Lifetrain.pdf
  e. Successful Global steps in Japan. The Japanese Association of Pharmaceutical Medicine in close collaboration with PharmaTrain and imitrain is also about to implement a Japanese SMD programe. A Japanese board will be founded soon and will work with the global PCB.. Currently the group develops its guidelines and SOPs in close alignment with the global SMD rules and guidelines. The interest in japan is already rising. So far 7 candidiates are lined up for the start of the programme.

- **References and bibliography**

1) Links to all TCs and conference reports (imi-train-projectmanagement.emtrain.eu**)** http://imi-train-projectmanagement.emtrain.eu/index.php/repository/3-wp3-competence-development/4-wp3-competence-development
2) Published posters/abstracts/reports with links
http://www.emtrain.eu/files/lifetrain/ws2015/posters/PharmaTrain_SMD_Poster_Lifetrain.pdf
http://www.pharmatrain.eu/_downloads/PTF_IFAPP_SSFA_Conference_Rome_program.pdf
http://www.ssfa.it/Page.asp?SitoID=1&PaginaID=1481

- **Links to websites**

1. Pharmatrain Federation www.pharmatrain.eu
http://www.pharmatrain.eu/the_smd_programme/index.html
2. Imitrain www.imitrain.eu
3. IFAPP (International Federation of Associations of Pharmaceutical Physicians) www. http://ifapp.org/About-ifapp
4. SSFA(Italy) http://www.ssfa.it/it/smd
5. JAPhMed (Japan) http://japhmed.jp/smd/smd.html

Attachement A

Activities of the global PCB by Peter Stonier

SMD Curriculum Path & Certification Process

'The Specialist in Medicines Development (SMD) is a competency-based, workplace-centred education and training certification programme in Medicines Development, comprising a knowledge base covering the PharmaTrain Syllabus for Medicines Development Science, delivered and assessed through modular curricula, and the acquisition and demonstration of competencies for medicines development across seven domains of the competency curriculum. Participants in this mentored, vocational programme acquire knowledge and competencies within a framework of assessment, appraisal and annual review of progress and achievement. On completion, participants receive the SMD Certificate from the PharmaTrain Certification Board (PCB).'

Global PharmaTrain Certification Board (gPCB)

It was agreed in *imitrain* WorkPackage3 (WP3) that the process and route to develop and deliver the PharmaTrain E&T vocational certification programme, the Specialist in Medicines Development (SMD), was through the establishment and work of a global PharmaTrain Certification Board (gPCB).

Constitution and Membership of gPCB

The gPCB would be introduced under a Charter (PCB Charter Version V1.0, Dec'14) under the auspices of PharmaTrain Federation (PTF) and endorsed by *imitrain (Charter attached).*

The gPCB was established in March 2015 by appointment, through PTF, of an Executive Chair and Vice-Chair on a 4-year term, appointment as standing members of the incumbent Presidents of PTF and of IFAPP (International Federation of Associations of Pharmaceutical Physicians and Pharmaceutical Medicine), and election (through PTF and IFAPP) of six individual members of the gPCB for 4-year terms. Apart from PTF & IFAPP Presidents, all gPCB members were present as individuals, not representatives.

The membership of the gPCB is currently: Executive Chair: Prof Peter Stonier (UK); Vice-Chair: Dr Domenico Criscuolo (Italy); PTF President: Dr Ingrid Klingmann (Belgium); IFAPP President: Prof Honorio Silva (USA) (until Apr'16: Dr Gustavo Kesselring, Brazil); Members: Dr Kirsteen Donaldson (UK); Dr Luciano Fuccella (Italy); Dr Kyoko Imamura (Japan); Prof Heinrich Klech (Austria); Dr Joao Massud (Brazil); Prof Bernd Rosenkranz (S. Africa).

The Charter and some key supporting documents were introduced in December 2014.

The modus operandi of gPCB was by monthly TeleConference (and ad hoc F2F meetings).

The fixed agenda of the gPCB TC meetings:

PCB MATTERS: Minutes, PCB Items; IIG (SEG*) Italy matters; PCB Links and liaisons; Standards and quality; Finance, business plan, administration. (*SEG=SMD Executive Group. The SEG will replace IIG once implementation phase is complete.)

WORK AGENDA: SMD Overview and documentation; Italy, Japan, Other - implementation steps & feedback; SMD Roles and Responsibilities; Trainee eligibility and enrolment; SMD Knowledge Base

(Syllabus) and Assessment; SMD Competencies Curriculum; SMD Programme and Assessment; SMD Work-Places; SMD in Practice; AOB & Next meeting.

Changes: During the period the Italian Implementation Group (IIG), responsible for the implementation of SMD in the pilot country, Italy, was included in the gPCB TCs (adding Dr Francesco De Tomasi and Dr Marco Romano to the TC group). On the change in presidency of IFAPP in April 2016, Prof Honorio Silva replaced Dr Gustavo Kesselring on the gPCB.

Results and Achievements: The gPCB TC met 16 times between March 2015 and July 2016. To address the agenda it was expected that SMD programme content (knowledge and competencies), minimum expectations for programme coverage, standards, processes and procedures, assessment and documentation would be developed and harmonised as far as possible for international use, and agreed alongside the simultaneous on-the-ground planning, prioritisation of activities and implementation of the SMD in the pilot country, Italy. This programme was accompanied for much of the period by a second pilot country, namely Japan.

The essential elements of progress along this route were a. the establishment of a National PCB (nPCB Italy), reporting to gPCB, and responsible locally to work with IIG to develop and implement SMD in Italy; b. gain the understanding, support and where possible endorsement from national stakeholder bodies in government, medicine, academia and pharmaceutical industry; c. to agree the common knowledge base as the PharmaTrain Syllabus for Pharmaceutical Medicine and Medicines Development Science, and the Competencies Curriculum (as developed by PharmaTrain with IFAPP and the Faculty of Pharmaceutical Medicine); d. to agree the practical and sequential steps to implementation, Eligibility & enrolment of trainees, eligibility, enrolment and training of Mentors, Agreed participation of workplaces, Records, Assessments, implementation of system for appraisal and annual evaluation; financial considerations, administration and communication (and several other keys components to the organisation and administration of SMD on the ground).

Much of this was achieved, and in parallel similar achievement and progress was made in Japan.

Two F2F meetings were held in Italy: a. 2-3 March 2016 Milan; Meeting between gPCB and IIG to update on progress in Italy and plan for next steps and approaches to stakeholders and launch of SMD. b. International Roundtable of stakeholders in SMD, meeting on 4 April in Rome, which was effectively seen as the launch of SMD in Italy (see separate report)..

At the same time as the Rome meeting, Japan announced its own launch of SMD.

Poster presentations of SMD were prepared and presented at Life-Train Workshops.

Conclusion: The gPCB was established by Charter in March 2015 to initially oversee the development and launch of SMD. The gPCB facilitated the development and delivery of SMD, with a launch in Italy and in Japan. The gPCB will continue its work as a global Certification Board going forwards and after the end of *imitrain,* to work with Italy, Japan, and other countries to follow with their SMD programmes.

The past 12 months were very important for the SMD project in Italy: several key achievements were reached, in order to plan for a successful launch of this initiative.

Starting from September 2015, a team composed of four member of SSFA (the Italian Association of Pharmaceutical Medicine) was established: the members are Domenico Criscuolo, Francesco De Tomasi, Luciano Fuccella and Marco Romano.

The first task was to prepare SOPs for the Italian program: we could use some drafts already available, but the team had to work for about 4 months (from September to December 2015) to adjust the available drafts to the Italian environment. In addition, some informative material was prepared , to be used in forthcoming meetings with key players in the Italian scenario of Pharmaceutical Medicine.

Once completed this first task, the Italian team started to approach key members of Italian Institutions, in order to establish the National Pharmatrain Certification Board (nPCB). After some meetings and phone contacts, we were able to confirm the following members who accepted to join the nPCB:

- Dr Domenico Criscuolo, Dr Francesco De Tomasi, Dr Luciano Fuccella and Dr Marco Romano representing SSFA, and also ensuring a strong link with the Global PCB;
- Dr Sandra Petraglia representing AIFA;
- Prof Sergio Bonini representing EMA;
- Dr Ranieri Guerra representing the Ministry of Health;
- Prof Giorgio Cantelli Forti representing SIF (Italian Society of Pharmacology);
- Prof Vittorio Locatelli representing the master of the Bicocca University in Milano (PT centre of excellence);
- Prof Pierluigi Navarra representing the master of the Catholic University in Rome (PT centre of excellence);

Once formed, the nPCB had the first meeting in Rome at AIFA facilities on February 15, 2016: this meeting was very useful to share goals and responsibilities in the SMD implementation in Italy. It was also agreed on the opportunity to have a formal event, to underline the launch of the SMD project in Italy and to stress the link with the gPCB. This event took place in Rome on May 31, 2016: it was a round table for invitation only, and its success can be appreciated in the enclosed report. (see separate report from the round table, attached)

To complete the efforts in place before the summer break, it is important to underline that we have posted an SMD page in the SSFA website (www.ssfa.it): the SSFA website has more than 2000 visits per month, and is the key vehicle of information to professionals in Pharmaceutical Medicine.

Next steps for the coming months are to send a message to all students who completed in past years the various masters in Pharmaceutical Medicine in Italy (an audience of about 1000 professionals), to underline the importance to join the SMD program at conferences, round tables and other scientific events, and to publish regularly news on the SMD program in the SSFA bimonthly newsletter.

We expect to recruit the first mentors and applicants in the last quarter of 2016.

Attachement B

International Round Table on Pharmatrain Specialist in Medicines Development in Italy – Roma, 31 May 2016

From: Doemenico Criscuolo

The PharmaTrain Federation (PTF), in collaboration with IFAPP and SSFA, organized this round table, whose participation was limited to key stakeholders and the directors of master courses in Pharmaceutical Medicine active in Italy. The aim of the meeting was two-fold: to stimulate the participation of more Italian master courses in the PTF, for a more harmonized educational offer to Italian students, and to launch the Specialist in Medicines Development (SMD) programme.

The meeting was opened by Dr Marco Romano, President of SSFA, who welcomed all participants, with a special thanks to the four international guests, and underlined the significant support offered by SSFA in the educational activities in Italy.

The first session, chaired by the undersigned, had the objective to introduce the background: the first speaker, Dr Mike Hardman for the IMI-train initiative, summarized in 20 minutes the European activities of several years, informing the audience that the IMI partnership for health, which initially was planned to last from 2009 to 2014 with 2 billion euro funds, is now extended until 2024, and has more than 5 billion euro of available funds. Several educational projects have been supported, on the basis of the idea that there is " no research without trained and competent researchers". He reminded the audience of several achievements, like the development of on-course (a web platform for all post-graduate courses in Europe), SafeSciMET (specially designed courses for Safety Sciences), Eu2P (courses in Pharmacovigilance and Pharmacoepidemiology) and PharmaTrain (modular courses on Pharmaceutical Medicine). The next steps are represented by the development of programmes of continuing education, because " every professional in the biomedical sciences needs to develop and maintain an optimal level of professional competence". The second speaker, Dr Ingrid Klingmann, President of PTF, summarized the significant achievements of the initial steps, which lasted from 2009 to 2014, and reached the target to produce the PT syllabus, the concept of a modular programme, and the recognition, all over Europe, of 12 "Centres of Excellence" which met the rigorous quality criteria of PTF. The next objectives of the PTF are the enlargement of the number of recognized centres, in order to get a more harmonized educational offer to European students. The last speaker of this session was Prof Peter Stonier, chair of the global PTF certification board, who stressed the importance of a programme of continuing education. The SMD programme was designed for this purpose, and will be implemented initially in Italy and in Japan, to be then disseminated on a world-wide basis. Candidates for the SMD are students who, whilst working in a recognised centre for medicines development, gain knowledge, practical skills and managerial competencies of the SMD curriculum. The programme is facilitated by a tutor who will help to ensure the trainee fulfils the requirements of the curriculum over a period of 2-4 years; the programme length depending on the amount of prior knowledge the trainee has acquired through diploma or master courses covering the content of the PharmaTrain Syllabus for medicines development.

In the second session, the chairperson Dr Luciano M Fuccella opened the activities by reading a kind message sent by Prof Sergio Bonini (EMA) who, unable to attend in person, wanted to stress the importance of training in Pharmaceutical Medicine and expressed his appreciation for the efforts taking place in Italy on this issue. Dr Sandra Petraglia (AIFA) also underlined the high level of interest, always expressed by the Italian drug agency, for the educational activities established in Italy, which represent a success story for our Country. Entering the Italian scenario in more details, the following two presentations were delivered by Prof Antonio Torsello (University Milano Bicocca) and by Dr Francesco De Tomasi (Catholic University of Rome), who illustrated the key features of the two master courses which got the PT recognition of "centre of excellence". One of the most important results for the students of these two masters is the value of their title: in fact, almost all students have a job after a few months from the end of their courses. Then Prof Fabrizio De Ponti (SIF) had the opportunity to inform that also the Italian Society of Pharmacology has started a similar programme of continuos education, in order to assign the title of "certified pharmacologist". All these presentations raised interest, and there was an hour time of open discussion, allowing representative of other master courses to get useful clarifications from the speakers.

In the afternoon session, chaired by Dr Francesco De Tomasi, the first speaker brought a real life experience of a programme of continuing education he followed in the UK. Dr Edward Nagy, now a medical director in pharmacovigilance in GSK, started on a voluntary basis his SMD programme when he was working at ICON: he informed us that during the tutorship period he had four different tutors, who helped and advised him to reach the planned targets. He commented that this programme " needs committment and dedication", and underlined that "the trainee drives the interactions and the training. Tutor enthusiasm is sometimes variable (due to workload, number of mentors available, personal factors); it is not always possible to have the mentor co-located with the trainee or the mentor being the direct line manager". In conclusion, he listed the key personal achievements obtained by attending this programme and stated that "Yes, it was worth the time and commitment". The last part of the meeting was devoted to a general discussion, with opinions expressed by three Italian medical directors (Drs Marie Georges Besse, Patrizia Nardini, Gianni De Crescenzo), by the CROs (Dr Marco Romano) and by one general manager of a biotech company (Dr Lucio Rovati).

In conclusion, it was a very informative round table, which was very useful to disseminate the key principles of harmonization of master courses, and the need of a continuing education. As a first result, it is interesting to underline that 3 directors of master courses (State University of Milano, University of Catania and University of Camerino) expressed their wish to follow the PTF syllabus, as a first step to gain the PTF recognition. The SMD programme is now officially open to students, and I am pleased to inform you that we have already received some requests for enrolment. All relevant information will soon be available on the SSFA website (www.ssfa.it) , where a section will be devoted to SMD. All information will be in English, as we have already one international application pending.