

European initiatives for better training in medicines development

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Abstract: In the last decade, the environment for medicines development has undergone unprecedented change, including: a shift from predominantly big Pharma to one of extensive industry–academia and SME partnerships and collaborations, greater emphasis on understanding the molecular basis of disease for stratified and personalised medicine, and a focus on societal/patients’ needs and priorities.

A variety of European initiatives have been established to support the training of scientists/professionals involved in medicines development in order to respond to this constantly changing, demanding, and chaotic landscape. Some of these initiatives are directed specifically at medicines development, some address scientific research including training relevant to medicines development, and some support general training needs which can include medicines development.

There are a number of European initiatives supporting better training in medicines development. They differ in their approach, ranging from IMI (specific to medicines development) to Erasmus+ (boosting skills and employability in all areas). The scope, budgets, and requirements differ considerably and they each have to be reviewed in detail to decide which might be the most appropriate for a particular target group. The common theme is to support the aims of the European Research Area (ERA), i.e., a significant improvement in Europe’s research performance to promote growth and job creation.

Keywords: IMI, ESFRI BMS Research Infrastructures, Erasmus+, Marie Skłodowska–Curie actions, Horizon 2020, ERA, EIT KIC

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1. Introduction

In the last decade, the environment for medicines development has undergone unprecedented change including:

- a shift from predominantly big Pharma to one of extensive industry–academia and SME partnerships and collaborations;
- greater emphasis on understanding the molecular basis of disease for stratified and personalised medicine;
- and a focus on societal/patients’ needs and priorities.

A variety of European initiatives have been established to support the training of scientists and professionals involved in medicines development in order to respond to this constantly changing, demanding and chaotic landscape. Some of these initiatives are directed specifically at medicines development, some address scientific research including training relevant to medicines development, and some support general training needs which can include medicines development. The major initiatives are described below.

2. Innovative Medicines Initiative (IMI) Projects

The biggest driver of training in medicines develop-

ment is the Innovative Medicines Initiative (IMI)^[1], “Europe’s largest public–private initiative aiming to speed up the development of better and safer medicines for patients. IMI supports collaborative research projects and builds networks of industrial and academic experts in order to boost pharmaceutical innovation in Europe. It is a joint undertaking between the European Union and the European Federation of Pharmaceutical Industries and Associations (EFPIA).” IMI1 covered the project applications from 2009–2014 and was part of EU Framework Project 7 (FP7); IMI2 covers the period from 2014–2020 and is part of Horizon 2020.

In IMI1, education and training needs were defined in the Research Agenda^[2] as the “fourth pillar” required to remove bottlenecks in the medicines development process. Five projects were set up to address these gaps:

- the European Medicines Research Training Network^[3],
- the European Programme in Pharmacovigilance and Pharmacoepidemiology^[4],
- the Pharmaceutical Medicine Training Programme^[5],
- the European Modular Education and Training Programme in Safety Sciences for Medicines^[6],
- and the European Patient Academy for Therapeutic Innovation (EUPATI)^[7].

All are public–private partnerships (PPPs) designed to provide better training in aspects of medicines development. EUPATI provides education for patients whilst the other projects address the needs of the scientific community.

Three of the projects (Eu2P, PharmaTrain and SafeSciMET) have developed flexible, Master’s-level modular programmes. The modules can be taken as short courses for continuing professional development (CPD) or combined to provide certificates, diplomas or, in combination with a dissertation, a Master’s degree. These projects have addressed the challenges of collaboration between universities, and between universities and industry. Different models have evolved, including several universities each delivering the same curriculum to the same standards (e.g. PharmaTrain), several universities jointly delivering a single programme and providing joint certificates or a joint Master’s degree (e.g. Eu2P), and several universities jointly delivering a single programme where one university awards a Master’s degree (SafeSciMET). Both

the content and the teaching methodologies (distance-learning, e-learning, e-lite, blended learning and face-to-face) have been developed to address the changing and diverse needs of their respective audiences. The consortia combine academic pedagogic expertise with practical industry experience—bridging education and professional training. PharmaTrain has also developed a library^[8] of free e-learning programmes as an introduction to many of the course modules.

EMTRAIN has developed tools, processes, and networks to support education and training. The course catalogue on-course^{®[9,10]} contains around 7000 post-graduate courses in biomedical sciences (Master’s, short courses and PhD programmes), incorporating quality standards^[11] developed by the IMI Education and Training projects, a teaching methodologies toolkit, and flags from professional/scientific bodies indicating which courses meet their requirements (Figure 1). This is also used for research into European courses and for gap analysis. The LifeTrain^[12] framework for CPD in biomedical sciences focuses on competency profiles, competence assessments and competency portfolios, i.e., training beyond knowledge acquisition^[13]. The third “product” is a cohort of industry-aware, early-stage researchers supported with a framework document, annual workshops and a LinkedIn network.

Recently EMTRAIN, Eu2P, PharmaTrain and SafeSciMET successfully obtained additional IMI funding and work collaboratively as IMI-TRAIN. This allows the strengths of the different projects to be combined. For example, Eu2P which has a distance learning programme has worked with colleagues from SafeSciMET to convert some of their face-to-face programmes into blended learning programmes. Another example would be the PharmaTrain/IFAPP competency profile for specialists in medicines development^[14] moving into an implementation phase with a pilot study being undertaken in Italy. EMTRAIN/PharmaTrain expertise in competency development is also being used by SafeSciMET to develop a new competency profile for drug safety scientists.

EUPATI has developed a regional network to support the programme, an advanced training course in medicines development with a face-to-face course for 100 patient advocates, and an extensive, multi-language toolbox of training resources which is being rolled out to over 100,000 patients across Europe. In the context of EUPATI, a patient advocate is a repre-

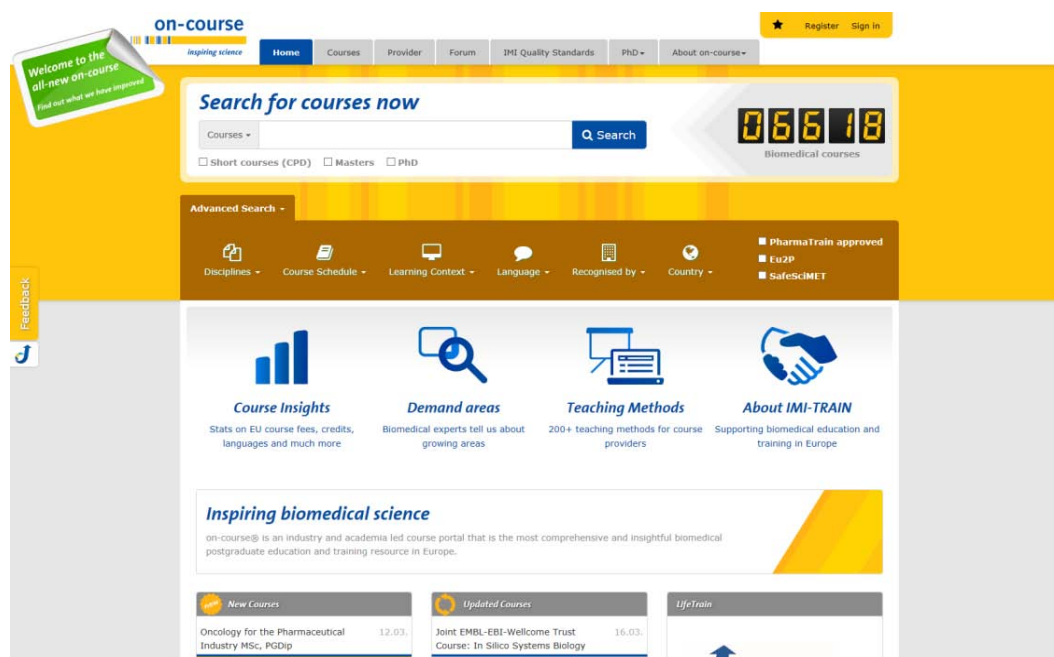


Figure 1. Homepage of the on-course® website.

representative of a patient organisation who influences the health policy environment to ensure it reflects the views of the organisation and a genuine patient's perspective.

In addition, many of the IMI science projects have developed training materials based on their discoveries, either alone or in conjunction with one of the education and training projects. For example, the results about safety biomarker research from the project SAFE-T^[15] are being integrated into the SafeSciMET courses. IMI2 has a Strategic Research Agenda which includes training as part of the Implementation Strategy section. However, there have not yet been any training project proposals announced for IMI2.

3. European Strategy Forum for Research Infrastructures (ESFRI) in Biological and Medical Sciences (BMS) and Research Infrastructures (RIs)

The ESFRI BMS Research Infrastructures^[16] were set up to contribute to the implementation of the Europe 2020 strategy and its Innovation Union Flagship Initiative, and enable the building up of the European Research Area (ERA)^[17]. They are at various stages in their development. Six such infrastructures are now established as legal entities and provide training both internally and externally:

- The European Clinical Research Infrastructure Network (ECRIN-ERIC)^[18],
- Bio-banking and Bio-molecular Resources Infrastructure (BBMRI-ERIC)^[19],
- European Infrastructure for Translational Medicine (EATRIS-ERIC)^[20],
- European Life-sciences Infrastructure for Biological Information (ELIXIR/EMBL)^[21],
- European Research Infrastructure for phenotyping and archiving of model mammalian genomes (INFRAFRONTIER GmbH)^[22],
- Structural Biology Research Infrastructure (INSTRUCT)^[23].

They are also partners in EMTRAIN. The other seven BMS RIs are in the preparatory phase, during which training is internal only.

All of these RIs provide training in their respective area of expertise. These are all highly relevant to medicines development. In most cases, the training is very practical, e.g. advanced RNA-Seq and CHIP-Seq analysis, hands-on experience of high throughput protein (HTP) expression screening with an emphasis on methods to study “difficult” targets, and mouse clinic state-of-the-art phenotyping technologies. In some cases, the courses are developed in conjunction with an industry advisory committee (e.g. ELIXIR).

Within Horizon 2020 there is also funding for

“strengthening the human capital of research infrastructures” e.g. INFRASUPP-3^[24]. These are specific to the RIs but address the training needs of researchers working in these areas which have broader relevance.

There have been opportunities for an RI to collaborate directly with an IMI education and training project. For example, ECRIN and PharmaTrain have jointly developed a European approach to clinical investigator training^[25] which includes an e-learning programme, e-CLIC.

4. Marie Skłodowska–Curie Actions

“The Marie Skłodowska–Curie Actions (MSCA)^[26] provide grants for all stages of researchers’ careers—be they doctoral candidates or highly experienced researchers—and encourage transnational, intersectoral and interdisciplinary mobility. The MSCA enable research-focused organisations (universities, research centres, and companies) to host talented foreign researchers and to create strategic partnerships with leading institutions worldwide. The MSCA aim to equip researchers with the necessary skills and international experience for a successful career, either in the public or the private sector. The programme responds to the challenges sometimes faced by researchers, offering them attractive working conditions and the opportunity to move between academic and other settings.”

These programmes now include:

- Research networks (ITN): support for Innovative Training Networks that organise research training programmes providing experience outside academia, hence developing innovation and employability skills. ITNs include industrial doctorates, in which non-academic organisations have an equal role to universities with respect to the researcher’s time and supervision, and joint doctoral degrees delivered by several universities. Furthermore, non-European organisations can participate as additional partners in ITNs, enabling doctoral-level candidates to gain experience outside Europe during their training.
- Individual fellowships (IF) to support experienced researchers undertaking mobility between countries, optionally to the non-academic sector.
- Research and Innovation Staff Exchanges (RISE), to provide international and inter-sectoral cooperation. RISE supports short-term

mobility of research and innovation staff at all career levels, from the most junior (post-graduate) to the most senior (management).

- Co-funding of regional, national and international programmes (COFUND) that finance fellowships involving mobility to or from another country.

5. The European & Developing Countries Clinical Trials Partnership (EDCTP)

EDCTP^[27] is funded by Horizon 2020^[28]. “EDCTP aims to accelerate the development of new or improved drugs, vaccines, microbicides and diagnostics against HIV/AIDS, tuberculosis and malaria as well as other poverty-related and neglected infectious diseases in Sub-Saharan Africa, with a focus on phase II and III clinical trials.”

One of their activities is capacity building with training to support the clinical trials, e.g. a fellowship programme. The fellowship scheme targets junior- to mid-career researchers or clinical staff who are employed by an institution in a low- to middle-income country (LMIC) where they are working on activities within the scope of EDCTP. Fellows are expected to improve their professional skills significantly through the fellowships, and upon their return they will also contribute to enhanced capacity of research institutions in LMICs, including training of peers. Furthermore, the scheme will strengthen collaboration between research institutions, researchers and clinical staff in LMICs, and pharmaceutical companies.

6. European Institute of Innovation and Technology (EIT) and Knowledge Innovation Communities (KICs)

“The EIT is an independent EU body set up in 2008 to spur innovation and entrepreneurship across Europe to overcome some of its greatest challenges. It brings together leading universities, research labs and companies to form dynamic cross-border partnerships—Knowledge and Innovation Communities, KICs—that develop innovative products and services, start new companies, and train a new generation of entrepreneurs.^[29]”

In 2015, a new KIC in Healthy Living and Active Ageing^[30] was approved. The partnership will promote entrepreneurship and develop innovations for healthy living and active ageing, providing Europe with new opportunities and resources. This will be

achieved through delivering products, concepts and services, including educational programmes that will nurture talents and train the workforce of tomorrow. Their stated aim is: “by 2018, to create, among others, 70 start-ups per year and have 1,000,000 students participating in our educational online programmes per year.” This new generation of entrepreneurs are likely to work in the area of medicines development as well as many others.

7. Erasmus+

Erasmus+^[31] is the new EU programme for Education, Training, Youth and Sport for 2014–2020. The Erasmus+ programme aims to boost skills and employability, as well as modernise Education, Training, and Youth work. The opportunities for education and training include: Strategic Partnerships in the field of education and training, Knowledge Alliances, and Sector Skills Alliances. These programmes support all fields of education and training.

8. Conclusions

There are a number of European initiatives supporting better training in medicines development. They differ in their approach, ranging from IMI (specific to medicines development) to Erasmus+ (boosting skills and employability in all areas). The scopes, budgets, and requirements differ considerably and they each have to be reviewed in detail to decide which might be the most appropriate for a particular target group. The common theme is to support the aims of the ERA^[17], i.e., a significant improvement in Europe’s research performance, to promote growth and job creation.

Conflict of Interest and Funding

The author is a Coordinator of the IMI EMTRAIN project but there is no conflict of interest.

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