1. Introduction

Many factors contribute to successful research, and well-trained professionals, who are committed to staying at the leading edge of developments in their field, are the underlying foundation. Europe is taking leadership to retain global competitiveness in medicines research and development by building the right environment for innovative education and training. This environment needs to address several challenges. Firstly, the lack of mobility across national borders is a major hurdle to Europe’s competitiveness: highly qualified professionals may have to undergo retraining to enable them to advance their careers outside of the country or sector in which they received their initial training. Secondly, there is a perceived gap between the competencies that graduates come out of university with and the competencies that employers look for\textsuperscript{[1,2]}. Thirdly, established mechanisms for maintaining professional competency are being challenged by rapid changes in science and technology — especially the increasingly rapid de-
velopment of disruptive technologies (new technologies that unexpectedly displace established ones; next-generation sequencing is a good example)\[3\], the cross-disciplinary, team-working nature of modern science and the need for greater communication and collaboration across and beyond traditional boundaries. In medicines research, development, processing, delivery and usage there is a huge variation in the types of scientists required, yet traditional scientific training tends neither to recognise, nor to cater for, these differences.

The Innovative Medicines Initiative (IMI)\[4\] and Europe’s emerging biological and medical research infrastructures\[5\] were established to help Europe strengthen its position in research and development (R&D). IMI is Europe’s largest public–private partnership; it is a joint undertaking between the European Commission and the European Federation of Pharmaceutical Industries and Associations (EFPIA)\[6\]. Through a series of innovative education and training programmes\[7\], IMI aims to address the current lack of holistic, integrative and translational approaches in education and training, and is therefore a unique part of a broader effort to strengthen Europe’s competitiveness in medicines R&D in the face of increased global competition.

The Biological and Medical Sciences Research Infrastructures (BMS RIs)\[8\] on the ESFRI Roadmap are pan-European facilities, resources and related services used by the scientific community, which provide an interdisciplinary, innovative environment where world-leading scientists conduct world class research and employ cutting-edge technologies based on open access across all BMS RIs. Implementation of the BMS RIs acts as a driving force across more than one thousand European research institutions and two million researchers\[8\]. Research Infrastructures have been recognized as key foundations for building a truly effective European Research Area\[9\] and their implementation is one of the priorities of the Innovation Union\[10\]. As well as providing pan-European open access to cutting-edge technology platforms for academia and industry, and promoting interdisciplinary research in biological and medical sciences across Europe, they have an explicit mission to provide training and education to future professionals in the life sciences.

Over the past five years, the IMI Education and Training projects, coordinated by the EMTRAIN project, have consulted broadly to develop LifeTrain — the European Common Framework for Continuing Professional Development\[11\]. An important goal of LifeTrain is to address the issues summarised above by supporting medical, biomedical and pharmaceutical professionals to work collaboratively across disciplines and national boundaries more readily. Our discussions have involved representatives from European professional/scientific bodies; the ESFRI BMS RIs; the European Association for Bio-Industries (Europa-Bio); major employers in pharmaceutical R&D (the EFPIA companies), national regulatory agencies, the European Medicines Agency (EMA), small and medium-sized enterprises (SMEs) and major contract research organisations (CROs); the European University Association (EUA); the European Science Foundation (ESF); the Organisation for PhD Education in Biomedicine and Health Sciences in the European System (Orpheus) and many private course providers.

2. LifeTrain Framework

The LifeTrain framework consists of a series of key messages (Box 1) and four sets of agreed principles (Box 2), one each for professional/scientific bodies, course providers, employers, and individual professionals. Here, we present the current version of the framework and provide some background to explain why it has gained broad support. On the website\[12\], we list the organisations and individuals that have worked with us to shape the framework, flagging those institutions that have formally signed up to the agreed principles of the framework and are committed to working towards the implementation of LifeTrain. The framework continues to evolve as we engage with a broader community, and we warmly invite those who have not yet participated in this initiative to do so.

2.1 Key Messages

Through a series of workshops (2011, 2012, 2013 and 2015) and extensive consultation between workshops, LifeTrain’s stakeholders have agreed a set of key messages (Box 1) that summarise LifeTrain’s goals. To set these messages in context, we need to define some terms that have become part of our vocabulary during the process of developing LifeTrain, but may be unfamiliar or unclear to others.

Individual professionals have a responsibility to manage their own continuing professional development (CPD). This is true both for those in regulated professions, such as medicine or pharmacy, and those
working in unregulated professions, such as scientists in academic research or discovery biology. We define CPD in accordance with the definition used by the Professional Associations Research Network [13] as ‘the means by which professionals and scientists in their communities maintain, improve and broaden their knowledge and skills and develop the personal qualities required in their professional lives’.

Many regulated professions have their own processes for ensuring that their members maintain and develop their professional status. These processes frequently involve the maintenance of a portfolio of CPD that is audited by the relevant professional body. This body may award credits for participation in various activities, which may include taking formal training courses, attending conferences, educating or training others, and writing and refereeing papers. Traditionally, time spent on each activity has been a commonly used currency for awarding credits. This approach has been called into question [14] because it does not provide any evidence that learning has taken place or that it has been ‘transformative’, that is, embedded into working practice. Evidence is accumulating that competency-based approaches to planning and recording professional development are more effective [15]. Competency is ‘an observable ability of any professional, integrating multiple components such as knowledge, skills, values and attitudes’. Competencies are observable, so their acquisition can be validated objectively. Evidence to support competency can be collected in a ‘competency portfolio’.

At the beginning of a professional’s career, new competencies are frequently gained through formal learning, leading to recognised qualifications. This may be supplemented by non-formal learning [16], which takes place alongside the mainstream systems of education and training and does not typically lead to formalised certificates. As an individual progresses through his or her career, reliance on formal course-based learning decreases, and informal learning [16] comes to the forefront. Informal learning is a natural accompaniment to everyday life — ‘learning by experience’. Unlike formal learning, informal learning is not necessarily intentional, and so may not be recognised even by individuals themselves as contributing to their knowledge and skills. The competency-centric approach is attractive to LifeTrain’s stakeholders because it can be applied to informal and non-formal learning, in addition to formal learning.

Another model, which is helpful for individuals using a competency-based approach, is the ‘plan, do, review’ cycle (Figure 1). For this, an individual takes stock of the competencies that s/he already has, considers which ones s/he needs to develop, plans how to develop them, implements the plan, then records what s/he has learnt and reflects on how his or her competencies have developed before reiterating the cycle.

Training has to keep pace with emerging technologies for sciences to exploit them fully. For example, the widespread adoption of next-generation sequencing opens up new possibilities in target discovery and validation, in the development of personalised medicines, in re-purposing medicines, and in regulatory affairs. Biomedical pharmaceutical professionals working across the entire value chain recognise that they need to learn how to take advantage of these opportunities, but finding appropriate training is notoriously difficult. EMTRAIN is addressing this issue by providing and continuously developing on-course® [17] — the resource centre for LifeTrain’s stakeholders. At its simplest, on-course® could be described as a pan-European catalogue of courses for postgraduates and beyond in the biomedical sciences, which simplifies the task of identifying training that already exists. One thing that makes on-course® unique is that it incorporates a set of nine quality standards [18], developed jointly by the IMI Education and Training projects and supported by LifeTrain’s signatories. Course providers who enter their courses in on-course® are encouraged

Figure 1. The ‘plan, do, review’ cycle.
to provide information on which of the quality standards apply to their courses. This is entirely voluntary, but provides added information to course seekers that may help them to decide whether or not a particular course is appropriate for them.

In the future, we envisage on-course providing resources that will bring employers and professional bodies together to define competency profiles, define gaps and work with course providers to fill these. Individuals will be supported to plan their career development, maintain a competency portfolio and find training to fill skills gaps. Finally, course developers and providers will also be supported through guidance on learning methods that are especially appropriate for adult learners and that support their trainees to transform their learning into their daily working lives. Support for this approach has recently been strengthened by articles addressing the educational and training requirements to build 21st-century scientists[19].

2.2 Agreed Principles

LifeTrain’s signatories have developed and agreed to four sets of principles, one for each stakeholder group. These principles are defined in Box 2. LifeTrain’s signatories also agree to the LifeTrain key messages and to engage in LifeTrain’s implementation process.

3. Impact on CPD Programmes in the Biomedical Sciences

LifeTrain has contributed to several international efforts to develop better, more responsive training for biomedical professionals and, whilst the core of our activities remains funded by the Innovative Medicines Initiative and has a European focus, our efforts are having an impact beyond Europe.

For example, LifeTrain's focus on defining competency requirements for different roles has had a major impact on education and training initiatives in computational biology. As a result, the International Society of Computational Biology (ISCB) published competency requirements for bioinformatics professionals in 2014[20] and is now consulting broadly, through a series of interactive workshops, to obtain further input to these requirements. The competency requirements defined by the ISCB have helped to shape several education and training initiatives. In the USA, several undergraduate and post-graduate courses are being reworked in light of the ISCB competency profiles; in Africa the H3BioNet consortium has developed a pan-African master's course in bioinformatics based on the ISCB competencies, and in Australia a bioinformatics engineering course has its learning objectives mapped to the ISCB competencies. This work has also influenced new CPD programmes for clinical bioinformatics in the UK: a newly developed competency profile, capturing the clinical bioinformatics competency requirements across a wide range of different roles in the UK’s National Health Service, is based on the ISCB profile[21].

LifeTrain has also influenced the coordination of CPD for European pharmacologists, as shown by the development and implementation of a new European Certified Pharmacologist scheme by EPHAR, the European Federation of Pharmacological Societies[22].

In clinical development, LifeTrain's approach has been shaped by the development of competency requirements for the specialist in medicines development, a new profession embraced by the International Federation of Associations of Pharmaceutical Physicians (IFAPP)[1]. A very similar approach is now being followed, supported by the imi-train project[23], to develop competency requirements for safety scientists working throughout the pharmaceutical value chain — from early-stage drug discovery through to post-launch pharmacovigilance. Newly funded EU projects (RI-train, CORBEL and ELIXIR-Excelerate) will develop competency profiles for managers and technical specialists of research infrastructures.

Implementing these proposed LifeTrain principles is still a challenge. The fragmentation of Europe, the traditional educational approaches, the lack of competency profiles in many areas, the lack of experience in assessing competency and the existing barriers to multidisciplinary training all have to be addressed. The above examples clearly demonstrate that such changes are possible, however much more still needs to be done. A cultural change is required in order to implement the education and training changes needed to achieve the demands of the European Research Area. Another important stepping stone, to help achieve this goal, will be the EMBL first open conference on lifelong learning in the biomedical sciences in July 2016[24]. Inspired by a series of LifeTrain Workshops, this is a new international forum to bring together the key influencers, policymakers, and stakeholders from academia and industry who will shape and implement how career-long continuing professional development is managed in the future.
4. An Open Community with a Unifying Goal

LifeTrain brings together many excellent, but disparate, activities into a process towards establishing a focused and coherent framework for continuing professional development in the biomedical sciences. This unique, pan-European collaborative approach provides the critical mass to achieve a pivotal cultural change in Europe’s biomedical, postgraduate researchers’ education and training, and is already influencing approaches to education and training far beyond Europe. It will make a major contribution to strengthen the skills and competencies of key professionals in a rapidly changing environment. In addition, it is a clear statement of Europe’s intent to strengthen its position in biomedical R&D.

LifeTrain’s signatories, which include multinational pharmaceutical companies, the biotechnological sector, European research infrastructures, professional and scientific bodies, higher education institutes and research institutes, have agreed to the principles of the framework (described in the next two sub-sections and reproduced with permission [12]) and to continue to collaborate to implement LifeTrain. We warmly invite others to participate. If you are interested in engaging with LifeTrain, Please contact us at www.lifetrain.eu/join-us/contact-us/.

4.1 Key Messages (Box 1)

Every professional in the biomedical sciences needs to develop and maintain an optimal level of professional competence in order to contribute to speeding up the development of better medicines for patients.

An individual competency portfolio should capture all relevant information in a transparent, easy-to-understand way in order to facilitate mobility between: scientific disciplines; academia, health authorities and industry; jobs and countries; and to support career development.

Continuing professional development (CPD) is essential and should be driven by each individual in agreement with their employer and in compliance with the requirements of the respective professional/scientific bodies.

CPD should be part of a “plan, do, review” cycle and can include formal, non-formal and informal learning. Each individual should reflect on the learning and its application in practice.

Objective assessments of competence should be made by the individual and by others, on a regular basis throughout the individual’s professional working life.

Needs should be identified and professional training courses developed and delivered in collaboration between industry, technical experts, and course providers (including universities). They should meet the needs of adult-learners and should be available on on-course®.

The ‘plan, do, review’ cycle is shown in Figure 1.

4.2 Agreed Principles (Box 2)

Professional/scientific bodies will:

1. Encourage members to establish and develop professional competencies by the provision of a framework for lifelong learning and professional recognition
2. Support their membership in the development and maintenance of a competency portfolio
3. Recognise the importance of relevant trans-disciplinary and generic competencies
4. Recognise core competencies from other IMI LifeTrain partner professional/scientific bodies
5. Work towards the implementation of the IMI Education and Training Quality Standard
6. Recognise continuing education courses that fulfil the appropriate IMI Education and Training Quality Standard as part of an individual’s CPD
7. Recognise the added value of periodic auditing of CPD records

Employers will:

1. Provide input to the development of CPD competency and learning requirements, to ensure employer needs are addressed
2. Recognise the roles and requirements of professional/scientific bodies
3. Recognise the value of competency portfolios in career development
4. Include CPD in individual recruitment and development plans
5. Recognise the value of CPD courses which meet the IMI Education and Training Quality Standard and recommend them for training
6. Advise future employees about the importance of maintaining professional competence and include CPD requirements in job adverts
7. Recognise the importance of temporary work placements for enhancing learning, networking and mobility
Course providers will:
1. Develop and deliver professional training courses in collaboration with industry and other employers
2. Recognise the IMI Education Training Quality Standard and, when applicable, meet these standards
3. Address and meet the needs of adult learners. Provide flexible, modular/short courses with provision of varied learning methodologies
4. Work with LifeTrain to raise awareness of on-course® and, where feasible, enter and update data

Individual professionals will:
1. Develop and maintain an optimal level of professional competence in their respective and related function(s) in order to contribute to speeding up the development of better medicines for patients
2. Take responsibility for their continuing professional development
3. Work closely with employers and professional/scientific bodies to maintain professional competence
4. Take advantage of the “Plan-Do-Review Cycle” new competencies
5. Develop and maintain a competency portfolio and share relevant information with professional/scientific bodies and employers

Conflict of Interest and Funding
No conflict of interest has been reported by the authors. EMTRAIN has received support from the Innovative Medicines Initiative Joint Undertaking[25] under grant agreement no. 115015, resources of which are composed of financial contribution from the European Union’s Seventh Framework Programme (FP7/2007-2013) and EFPIA companies in kind contribution. We gratefully acknowledge this financial support.

Acknowledgements
We would also like to thank the many individuals, too numerous to mention individually, who have provided input to LifeTrain to date.

References
1. Silva H, Stonier P, Buhler F R, et al. 2013, Core competencies for pharmaceutical physicians and drug development scientists. Frontiers in Pharmacology, vol.4: 105. http://dx.doi.org/10.3389/fphar.2013.00105
2. Muindi F and Keller JB, 2015, Emerging network of resources for exploring paths beyond academia. Nature Biotechnology, vol.33: 775–778. http://dx.doi.org/10.1038/nbt.3282
3. Christensen C M, 1997, The innovator’s dilemma: When new technologies cause great firms to fail. Boston, Massachusetts, USA: Harvard Business School Press.
4. The Innovative Medicines Initiative (IMI) Scientific Research Agenda: Revision 2011, n.d., viewed September 25, 2015, <http://www.imi.europa.eu/content/research-agenda>
5. What are RIs? European Commission Research and Innovation, n.d., viewed September 18, 2015, <http://ec.europa.eu/research/infrastructures/index_en.cfm?pg=what>
6. European Federation of Pharmaceutical Industries and Associations (EFPIA) home page, n.d., viewed September 20, 2015, <http://www.efpia.eu/>
7. Projects: Ongoing projects, Innovative Medicines Initiative (IMI), n.d., viewed September 25, 2015, <http://www.imi.europa.eu/content/ongoing-projects>
8. Position paper on Horizon 2020: ESFRI Biological and Medical Research Infrastructures, 2013, viewed September 25, 2015, <www.infrafrontier.eu/sites/infrafrontier.eu/files/upload/public/pdf/BMS_RI_PositionHorizon2012.pdf>
9. Green paper on The European Research Area (ERA): New perspectives [COM(2007) 161], viewed September 17, 2015, <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52007DC0161>
10. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions [COM(2010) 346], viewed September 25, 2015, <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM:2010:0546:FIN>
11. Hardman M, Brooksbank C, Johnson C, et al. 2013, LifeTrain: Towards a European framework for continuing professional development in biomedical sciences. Nature Reviews Drug Discovery, vol.12: 407–408. http://dx.doi.org/10.1038/nrd4026
12. LifeTrain, n.d., viewed November 11, 2015, <www.lifetrain.eu>
13. How important is CPD? Professional Associations Research Network, n.d., viewed September 20, 2015, <http://www.parnglobal.com/about-our-research/continuing-professional-development>
14. Davis NL and Willis CE, 2004, A new metric for continuing medical education credit. *Journal of Continuing Education in the Health Professions*, vol.24(3): 139–144. http://dx.doi.org/10.1002/chp.1340240304

15. Campbell C, Silver I, Sherbino I, et al. 2010, Competency-based continuing professional development. *Medical Teacher*, vol.32(8): 657–662. http://dx.doi.org/10.3109/0142159X.2010.500708

16. Cedefop, 2009, European guidelines for validating non-formal and informal learning. Luxembourg: Office for Official Publications of the European Communities.

17. Payton A, Janko C, Renn O, et al. 2013, On-course® portal: A tool for in-service training and career development for biomedical scientists. *Drug Discovery Today*, vol.18(17–18): 803–806. http://dx.doi.org/10.1016/j.drudis.2013.04.004

18. Klech H, Brooksbank C, Price S, et al. 2012, European initiative towards quality standards in education and training for discovery, development and use of medicines. *European Journal of Pharmaceutical Sciences*, vol.45(5): 515–520. http://dx.doi.org/10.1016/j.ejps.2011.12.005

19. Nurse P, Sunami A, Polka J, et al. 2015, STEM education: To build a scientist. *Nature*, vol.523: 371–373. http://dx.doi.org/10.1038/nj7560-371a

20. Welch L, Lewitter F, Schwartz R, et al. 2014, Bioinformatics curriculum guidelines: Toward a definition of core competencies. *PLoS Computational Biology*, vol.10: e1003496. http://dx.doi.org/10.1371/journal.pcbi.1003496

21. Ellard S, Thornton J, Atman T, Boustred C, Brooksbank C, et al. 2015, *Developing Clinical Bioinformatics Training in the NHS — a Timeline for Action*. UK: Health Education England.

22. Griesbacher T and Drago F, 2014, European Certified Pharmacologists (EuCP): Standards for postgraduate professional training in pharmacology established by EPHAR, the Federation of European Pharmacological Societies. *Intrinsic Activity*, vol.2(Suppl. 1): A3.1.

23. Imi-train: Education and training in the medical, biomedical and pharmaceutical sciences, n.d., viewed September 25, 2015, <http://www.imi-train.eu>

24. EMBL Conference series, n.d., viewed September 25, 2015, <http://www.embl.de/training/events/2016/LLL16-01/index.html>

25. The Innovative Medicines Initiative (IMI), n.d., viewed September 25, 2015, <http://www.imi.europa.eu>