

## 5 Education and Training

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### 5.1 Summary

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Based on consultation with stakeholders, the E&T workstream has identified a number of gaps within education & training in support of the medicines development process. A SWOT analysis was made, resulting in a number of recommendations.

The scope of the activities within E&T is to establish the European Medicines Research Academy (EMRA). EMRA is a pan-European platform for education and training, covering the whole lifecycle of a medicine. EMRA supports the education and training of current and future professionals involved in biomedical R&D, including regulatory officers. Further, the platform should provide the basis for information on the medicines development process, including the rules governing the process, to stakeholders who are not directly involved in the process, such as members of research ethics committees, journalists, venture capitalists and patients. To complete the loop, patients should be involved as they can make a contribution to the determination of what and how the professionals acquire skills and knowledge.

The EMRA should be based on existing centres of excellence within the relevant disciplines. It is not intended to build a system for E&T parallel to existing universities and higher education institutions. The activities in the E&T work stream have close links to the activities in the Bologna Process to establish the European Higher Education Area by 2010.

The activities suggested have been prioritised. The top priorities are to:

- Establish the EMRA, including a central co-ordinating unit and an advisory E&T council;
- Establish programmes for integrated medicines development and for ethics committees and patient organisations;
- Establish programmes for safety sciences, scientists within pharmaceutical R&D and Pharmaceutical Medicine professionals;
- Establish regulatory affairs-based programmes;
- Establish programmes for bio-statisticians, bioinformaticians and biomedical informaticians.

It is proposed to establish the programmes at centres of excellence across Europe. The courses are to be held twice a year. Other activities will be needed in parallel. These include:

- Establishing criteria for centres of excellence and the identification of these;
- Options for closer collaboration between academia and industry in terms of E&T, including an incentive system to facilitate mobility;
- Re-evaluate the evaluation process for academics;
- Open dialogue with EU member states on curricula, including establishing European criteria for curricula;
- The development of an accreditation system for E&T;
- Mapping existing Public–Private partnerships in E&T;
- Identifying existing relevant European curricula.

It is important to realise that medicines R&D requires a trans-disciplinary approach, involving many of the traditional scientific areas within life sciences and, in addition, technological areas such as biotechnology, nanotechnology, medical technology and IT.

### 5.2 Introduction

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The objective of this chapter is to describe the gaps that have been identified relating to education and training in the medicines development process. It will also discuss how to bridge these gaps to align with the new tools and requirements of the process to provide new medicines for the benefit of patients, science and society.

Europe has great potential for innovation because of its excellent science, education and training base. However, it is lagging behind because of a lack of adequate funding, insufficient co-ordination of efforts and resources and weak strategic intent, as well as an inability to react with sufficient speed and force to new challenges and opportunities.

The Strategic Research Agenda will propose changes to the way contemporary medicines R&D is performed. The identified gaps and bottlenecks will be addressed by new technologies and new paradigms for the assessment of safety and efficacy as well as for medical practice. The gaps and bottlenecks that exist in the Education and Training (E&T) of scientists within life sciences who will be, or are, involved in the medicines development process will also need to be addressed. Furthermore, the consultation with stakeholders during the creation of this SRA revealed a need for people indirectly involved in the medicines R&D process, including patient organisations and the public, to gain an insight into how it operates.

#### **Definition of Education and Training:**

In the context of the Innovative Medicines Initiative, Education & Training is defined in the following way:<sup>47</sup>

- Education encompasses teaching and learning specific skills, and also something less tangible but more profound: the imparting of knowledge, good judgement and wisdom;
- Training is the teaching of vocational or practical proficiency, and relates to specific useful skills.

## **5.3 Gap analysis**

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### **5.3.1 General Gaps**

Following consultation with stakeholders in workshops in February, April and May 2005,<sup>48</sup> an analysis of the gaps within education & training in support of the medicines development process was carried out. The gaps cover three groups of knowledge; overview, specialist and bridging and a number of specific gaps.

Many of the players involved in the medicines R&D process need an integrated overview of the entire process, at a variety of levels. For specialised professionals, such as managers, project managers and project team members, it is important that they have an understanding of the interdisciplinary aspects of pharmaceutical R&D, and the requirements of the downstream process towards the availability of the medicine to patients within all three main topics of the regulatory dossier: non-clinical, clinical and quality (CMC<sup>49</sup>). A high level, 'helicopter' view is essential for many stakeholders in the process, for example regulatory authority personnel, clinical investigators, university teachers, ethics committee members and journalists.

For specialists, there is a profound need for qualified personnel within the natural, technical, pharmaceutical and medical sciences. Furthermore, there is a need for ongoing training to keep them updated with scientific and technology developments.

With respect to bridging, there is a need for the training of specialists who require knowledge from another scientific area than the one they studied.

### **5.3.2 Specific Gaps**

The specific gaps that have been identified include:

- The current organisation of universities facilitates the building of silos, where each scientific area lives its own life without much interaction with other areas. This is contributing to the fragmentation of European research;<sup>50,51</sup>
- In most European countries, the scientific interaction between scientists in academia, industry and regulatory authorities are minimal, and often the movement of intellect is uni-directional towards industry. A situation where there is a flow of expertise between the three parties will facilitate share and exchange of knowledge;
- Translational science from basic and non-clinical research to the clinical sciences. There is often little or no interaction between clinical scientists and, say, human biologists, even though they may work on the same scientific topics. This gap is critical, and has yet to be bridged. Transla-

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<sup>47</sup> Source Wikipedia, The Free Encyclopedia, <http://www.wikipedia.org>

<sup>48</sup> Reports from workshops, E&T1, E&T2, E&T3 are available on the Innovative Medicines website: [http://europa.eu.int/comm/research/fp6/index\\_en.cfm?p=1\\_innomed](http://europa.eu.int/comm/research/fp6/index_en.cfm?p=1_innomed)

<sup>49</sup> CMC: Chemistry, Manufacturing and Control

<sup>50</sup> Wilson EO, *Consilience: The Unity of Knowledge*. ISBN: 0679450777

<sup>51</sup> Busquin P, At the 'Communicating European Research' conference on 11 May 2004

[http://ica.cordis.lu/search/index.cfm?fuseaction=news.simpledocument&N\\_RCN=22027&CFID=994044&CFTOKEN=61399528](http://ica.cordis.lu/search/index.cfm?fuseaction=news.simpledocument&N_RCN=22027&CFID=994044&CFTOKEN=61399528)

tional medicine is emerging as an attempt to bridge this gap from bench to bedside and back again by combining a thorough understanding of the biology of a disease with the clinical picture<sup>52</sup>.

- Scientists are urgently needed within these specific areas:
  - Safety scientists with a much broader spectrum of knowledge than the traditional toxicologist. The future safety scientist will have to integrate knowledge accumulated from many safety-relevant disciplines (for example primary and secondary pharmacology, functional genomics, safety pharmacology, physiology, pathophysiology, physical chemistry, animal and clinical toxicology, cellular biology, biochemistry and animal physiology, with all their specialist branches) if they are to excel in modern risk assessment and risk management;<sup>53</sup>
  - Pharmacology, non-clinical and clinical;
  - Postgraduate physicians specialised in pharmaceutical medicine;
  - Scientists skilled in bioinformatics, biosimulation, knowledge management, systems biology, systems toxicology, systems pharmacology and physiology (*in vivo* whole organism), pharmaceutical biotechnology, and *in silico* modelling;
  - Medical statisticians and biostatisticians;
  - Medical imaging is increasingly being used in both basic and clinical research. A need has been identified both in terms of trained scientists and technicians and in access to the technology, which is expensive to establish. This issue was dealt with in the efficacy part of this document;
- Establishing a curriculum for medicines development for professionals needing profound insight in the process;
- Continuous professional development, including an update on new scientific developments and technologies for scientists, physicians, patients and carers;
- Faculties and undergraduate students are not realising the career opportunities within biomedical R&D, especially within fields such as veterinary medicine, pharmacy, biology, and medicine, where the focus is on the traditional career paths;<sup>54</sup>
- The implementation of the Clinical Trial (GCP) directive<sup>55</sup> means there is a need for the training of regulatory personnel for GCP inspections, clinical investigators, monitors, clinical research associates, patients and people working for patient organisations and ethics committee members. A thorough understanding of the rules governing clinical research is a prerequisite for Europe to keep, and possibly strengthen, its position within clinical research;
- People working in SMEs, especially in the early phases of medicines R&D, need an integrated overview of the medicines development process, including regulatory requirements, business skills and understanding of the business environment;
- Journalists, venture capitalists and the public lack an understanding of the conditions for and the process of medicines development, including the risk–benefit evaluation involved;
- Patient organisations have substantial knowledge of specific diseases and patient needs. This knowledge should be utilised in the medicines R&D process;
- European education needs to strive for excellence, and competitive systems have to be put in place for a continuous improvement of the scientific level in Europe.

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<sup>52</sup> Mankoff SP & al, Lost in Translation: Obstacles to Translational Medicine, Journal of Translational Medicine 2004, 2:14

<sup>53</sup> EUFEPS 2004, Report from EUFEPS Brainstorm Workshop on Safety Sciences, Brussels, April 2-3 • 2004

<sup>54</sup> However, some universities have included pharmaceutical medicine in the standard medical curriculum, e.g. University of Basel.

<sup>55</sup> Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, [http://europa.eu.int/smartapi/cgi/sga\\_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=32001L0020&model=guichett](http://europa.eu.int/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=EN&numdoc=32001L0020&model=guichett)

## 5.4 Recommendations

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In the process of stakeholder consultation in the development of this SRA, it became clear that the diversity, cultural and language differences within Europe represent both a strength and a weakness. The strength is the opportunity to view a challenge from a multitude of angles. The weakness is caused by the same diverse scientific, cultural and linguistic backgrounds resulting in conflicts based on misinterpretation and misunderstandings.

### European Strengths

- Strong biomedical-relevant research, which is the basis for education and training;
- A strong academic research presence in the field of pharmaceutical sciences;
- European research groups develop new concepts and can successfully compete with leading groups in the USA/Canada and Japan/Korea/Taiwan;
- Existing high-quality postgraduate courses in pharmaceutical medicine in the UK, Spain, Belgium, Sweden, Germany, France and Switzerland that are sought by professionals from outside Europe;<sup>56</sup>
- Pharmaceutical and clinical sciences have a number of scientists who are highly visible on the international stage, and who act globally as leaders in the field;
- Europe has a good infrastructure to facilitate research, for example clinical trials;
- Cultural diversity provides an opportunity for viewing a challenge from a multitude of angles;
- Europe still has a strong biomedical industry presence.

### European Weaknesses

- Shortage of funding for research;
- Insufficient co-ordination of funding programmes for life science research;
- Europe is separated by multiple languages, and the cultural diversity mentioned above. Few European scientists for whom English is not their native tongue master English to the same level as their mother tongue;
- Mobility: despite mobility programs offered by the EC, exchange of students and researchers within Europe is bureaucratic and not optimal;
- Mobility: attracting gifted young scientists from countries outside the EU is even more difficult;
- The public perception of the players, industry, regulators and scientists has deteriorated over the years, resulting in increasingly strict regulations and resistance in the public towards the introduction of new molecular biological findings because of a fear of the unknown;
- Critical mass: Europe has many high-quality universities and higher education institutions, but individually they are too small and in many cases locally, not European, focused. Only few examples of trans-national collaboration within E&T exist;<sup>57</sup>
- Introduction of new technologies is slow;
- Recognition of the importance of trans-disciplinary research is limited;
- Intellectual property: it is much more difficult to obtain a European patent than a US patent, especially for SMEs.

### Opportunities

- Many European organisations, including the European Commission, national states, industry organisations, patient organisations and learned societies have realised the weaknesses, as illustrated by this SRA;
- Political focus: with political will and adequate financing, Public–Private partnerships could overcome some of the weaknesses;
- Europe has the expertise to re-engineer the medicines R&D process for the benefit of science, patients and society.

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<sup>56</sup> These courses are covered by a common syllabus co-ordinated by the International Federation of Associations of Pharmaceutical Physicians (IFAPP)

<sup>57</sup> ULLA: European University Consortium for Pharmaceutical Research, <http://www.u-l-a.org>

## Threats

- The emerging economies in China and India could move high-level research and, thereby, education and training to their areas;
- Losing even more biomedical industry in Europe;
- Silo thinking within all groups of stakeholders;
- Lack of political will to do what needs to be done.

To ensure a common understanding of the scope of the E&T activities, the vision and mission for the endeavour that follow have been worked out.

## Vision

This vision provides a view of the European future for Education and Training related to the medicines R&D process.

By 2013, the European Technology Platform for Innovative Medicines will have established the European Medicines Research Academy (EMRA), a pan-European platform for education and training for professionals involved in biomedical R&D, including regulatory officers over the whole life-cycle of a medicine. The PhD programme supporting IMI activities has been completed.

The platform will include programmes for E&T covering the horizontal layer of integrated thinking over the entire medicines R&D process, as represented by the red oval in Figure 30 below, combined with specialised courses linked to the format for a registration dossier: non-clinical, quality and clinical, in the blue and yellow ovals in Figure 30. Furthermore, the platform will provide the basis for information on the medicines development process, including the rules governing the process, to stakeholders who are not directly involved in the process, such as journalists, venture capitalists and patients. By 2013, the suggested activities will have been implemented, and the results of this will be emerging. The ovals will be populated with existing and new courses, where some may be used both at a general level and at a specialised level.

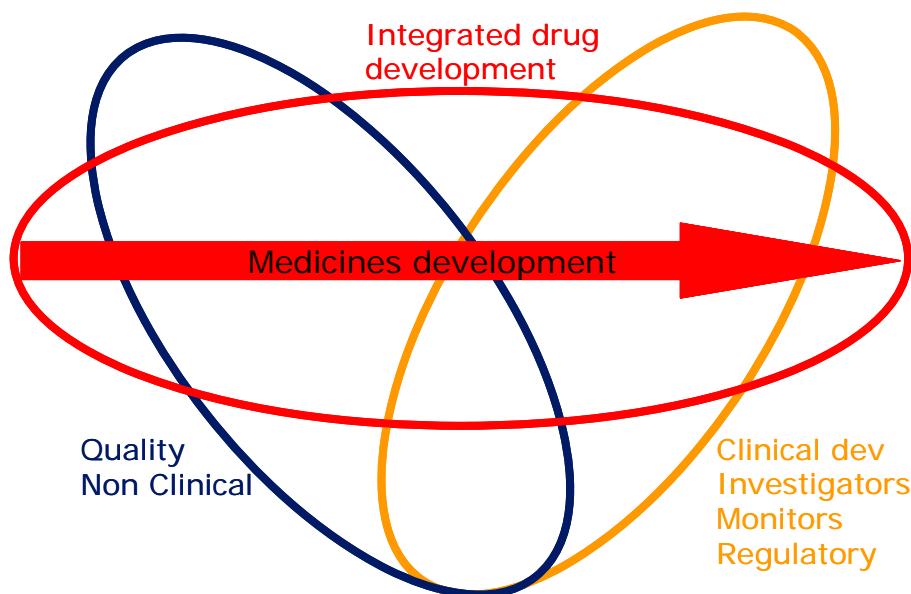


Figure 30 : Organisation of the E&T Platform.

The development of the E&T platform is in parallel with and supported by the Bologna Process, by which the European Higher Education Area<sup>58</sup> will be established in 2010 as a result of the 10 action lines from the Bologna process:<sup>59</sup>

- Pan-European comparable degrees, based on a two-cycle system;
- An established ECTS<sup>60</sup> system of credits;
- Increased mobility of students and university staff;
- Established quality assurance standards for education;
- Implemented lifelong learning strategies;
- Active involvement of stakeholders in higher education;
- Attractiveness of European higher education to students from Europe and other parts of the world;
- A clear link between the European Higher Education Area and the European Research Area linking undergraduate, graduate, doctoral and postdoctoral<sup>61</sup> education and training.

## Mission

The mission defines what the E&T platform will be doing in the future described in the vision. The E&T platform will:

- Build upon existing universities and higher education institutions in Europe by identifying centres of excellence within the various disciplines of medicines R&D, and stimulate collaboration between these centres;
- Provide E&T support to remove bottlenecks in the medicines R&D process;
- Establish multiple public–private partnerships within E&T for graduate, doctoral and postdoctoral education and training;
- Facilitate mobility between academia, industry and regulators;
- Help to create biomedical R&D leadership for Europe to benefit patients and society.

## Key Objectives

The key objectives define what is to be achieved going forward:

- Establish a co-ordinating council, with the relevant stakeholders being represented,<sup>62</sup> and with expert sub-groups to assess the availability and quality of training in non-clinical, clinical, quality (CMC) and integrated drug development. This activity includes mapping of availability and the content of existing courses;
- Establish criteria for centres of excellence and, based on these, assessment of institutions already involved in E&T, and audit of E&T activities within disciplines;
- Identify centres and institutions with appropriate expertise to deliver courses and training;
- Overcome silo thinking. Pharmaceutical research is best done via a trans-disciplinary approach, but many researchers still think in disciplines in order to ‘protect’ their fields. This can be combated via:
  - Activities to make researchers realise that a combination of expertise improves research and innovation;
  - Stimulation of trans-disciplinary E&T, for example a combination of pharmacist/chemical engineer, medicine and technology.
- Overcome the language barrier. English is used for textbooks and courses in all participating universities and higher education institutions;<sup>63</sup>

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<sup>58</sup> [http://www.eua.be/eua/en/Research\\_linking.jsp](http://www.eua.be/eua/en/Research_linking.jsp)

<sup>59</sup> <http://www.bologna-bergen2005.no/EN/BASIC/Pros-descr.HTM> and [http://www.bologna-bergen2005.no/Docs/Norway/041014Fact\\_Sheet\\_Bologna-Process.pdf](http://www.bologna-bergen2005.no/Docs/Norway/041014Fact_Sheet_Bologna-Process.pdf)

<sup>60</sup> ECTS: European Credit Transfer System. [http://europa.eu.int/comm/education/programmes/socrates/ects\\_en.html](http://europa.eu.int/comm/education/programmes/socrates/ects_en.html)

<sup>61</sup> Postdoctoral in this context means after obtaining a PhD or doctorate

<sup>62</sup> Suggested stakeholders are: Industry and SMEs, Relevant/involved learned societies, Patients and/or consumers, Academia, through well-defined Europe-wide accepted bodies (e.g. Faculties organisations etc), Relevant Professional Organisations

<sup>63</sup> EU support could stimulate this process e.g. by support to highly qualified scientists to write textbooks in English to facilitate distribution of knowledge within Europe

- Harmonisation of E&T on a European level to create a European Community of Pharmaceutical and Medicines Researchers. This requires pan-European grades to be established on the basis of the Bologna architecture, using the ECTS system;
- Develop regional Centres of Reference serving as clusters, and co-ordination of activities within a European sub-region;
- Ensure the qualification of enthusiastic and skilled scientists by encouraging the professional development of motivated individuals by embarking on MD and/or PhD programmes;
- Developing pharmaceutical medicine as a specific postgraduate discipline of medicine;
- Identify available finances to set up new courses and training facilities;
- Establish courses so stakeholders can easily obtain a basic knowledge of the whole R&D process, including an understanding of relevant regulatory guidelines;
- Provide training for people working in a scientific field who were not originally trained in that field. This covers both people changing their profile within a company (manager/project leader) or scientists who need knowledge within a new area of expertise. In addition, provide training to external stakeholders entering the field such as journalists;
- Constantly identify and update new scientific and technology developments and rapid implementation of corresponding training courses. Assess the current availability of expertise in new and emerging fields of technology across Europe, for example toxicogenomics and other omics, combinatorial chemistry, systems biology and nanobiotechnology;
- Increase mobility between academia, industry and regulatory bodies, in a triangular way;
- Establish rapidly accessible mobility awards to allow pan-European access to courses and training facilities, including interaction with the Marie Curie units at the European Commission;
- Provide systematic postdoctoral E&T, and the necessary finance to support it. Generate a pan-European life-long learning initiative related to medicines research, including a credits system for professionals in the context of continued professional development (CPD), and update of original degree. This should be co-ordinated with other CPD programmes;
- Create standardised quality measures to be used for accreditation and evaluation of courses and guarantee sustainability. Expand the model across the different levels of education.

### **Management of European Medicines Research Academy (EMRA)**

EMRA is a network of universities and higher education institutions. Further, EMRA is the co-ordinating body for activities related to Education and Training in the Innovative Medicines Initiative.

EMRA will be hosted by one of the participating universities as a central co-ordinating unit (the hub) at a location characterised by high-quality industry contacts and recognised science. The host university should have proven capabilities for international networking on E&T. The governance of EMRA will be handled by the EMRA Council, with representatives from:

- Participating universities and higher education institutions;
- Relevant learned societies;
- Industry;
- A few representatives from ministries responsible for higher education;
- Representative from the Bologna Process;
- Representatives from the IMI Safety, Efficacy and KM work streams.

The role of the EMRA Council is to follow the development of EMRA according to the plans that have been laid out, co-ordinate E&T activities in the IMI cornerstones of Safety, Efficacy, Knowledge Management and Education & Training, advice on E&T issues, and to provide recommendations to the IMI Scientific Committee on E&T.

## **5.5 Implementation Plan and Resources**

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The pan-European platform for education and training cannot be established overnight. Careful mapping of existing activities within E&T is needed, including the identification of European centres of excellence that can act as drivers and role models for other institutions and regions in Europe. Many proposals have been suggested during the consultation process with stakeholders. Based on the mapping, these proposals should be fleshed out with detailed implementation plans, including the evaluation of potential specific PhD grants. An E&T programme will be established to focus on scientific bottlenecks in the medicines R&D and management process, covering the following eight areas:

1. Integrated medicines development;
2. Ethics committee and patient organisation programmes;

3. Safety science programmes;
4. Other scientists within pharmaceutical R&D;
5. Pharmaceutical medicine professionals;
6. Regulatory affairs-based programmes;
7. Biostatisticians programme;
8. Bioinformaticians and biomedical informaticians programme.

The activities will be carried out with active participation of the relevant stakeholders, as shown below:

- The first priority is to establish a central co-ordinating unit;
- The second priority is to establish an advisory E&T council;
- Priority number three is to establish a programme for integrated medicines development and for ethics committees and patient organisations;
- The fourth priority is to establish programmes for safety sciences, and scientists within pharmaceutical R&D;
- Priority five is to establish programmes for pharmaceutical medicine professionals, regulatory affairs, biostatisticians, bioinformaticians and biomedical informaticians.

It is proposed that the third and fourth priority programmes are to be established at centres of excellence to be identified across Europe. Courses are to be held twice a year at four centres for each topic.

Within the first year, mapping to identify existing courses that will populate Figure 30 is a primary activity, as is planning the specific programmes set out below, together with a number of parallel activities. Eight major critical areas have been identified where there is a specific need for courses to support both current need and foreseen changes to the medicines R&D process.

## PhD Programme

To facilitate interaction between academia and industry and to ensure that researchers gain an insight into the business-related aspects of R&D, it is recommended that 60 PhD grants should be established for each of the eight areas listed in the table below, i.e. 480 PhD grants. This programme should involve the co-operation of a university, a PhD fellow and an enterprise in a defined R&D project, linked to IMI activities, including PhDs covering the medicines development process. Two supervisors will guide the industrial PhD fellow, one from the university and one from the enterprise. The industrial PhD fellow is employed by the company on a full-time basis, and paid for the entire period. The salary for the PhD student could be split as a public-private partnership, where 50% is paid by the EC/Marie Curie Action programme, and 50% by the enterprise in question. To facilitate participation from SMEs, a proportion of these PhDs should be fully financed by the EC.

The plan is to roll out the PhD programme in three sequences. The first call will be in the second half of 2007, covering one-third of the programme, for commencement in 2008. The second and third calls will be in the second halves of 2008 and 2009, for commencement in 2009 and 2010. The PhD students will thus have completed their studies by 2013.

The remaining priorities appear in the table below. Details on the activities and the budget are described in the report from the workshop of 20 May 2005. Where the cost is indicated as zero, this is included in the running cost of the co-ordinating unit. The costs of the recommendations are estimates, and will be subject to further analysis as appropriate.

Activity	Duration (months)	Costs (€)
<b>Short term budget</b>		
Establish central co-ordinating unit, hiring personnel	3	20,000
Running central co-ordinating unit in the first year, including the following specific activities	12	355,000
Establish a council with representation of stakeholders	2	0

Activity	Duration (months)	Costs (€)
Meetings with the council, one every three months, 20 participants	12	90,800
1. Integrated medicines development, mapping and implementation plan (Priority score 10/10) Two meetings with relevant stakeholders (10 participants)	6	22,700
2. Ethics committee and patient organisation programmes, mapping and implementation plan (Priority score 10/10) Two meetings with relevant stakeholders (10 participants)	6	22,700
3. Safety science programmes, mapping and implementation plan (Priority score 9/10) Two meetings with relevant stakeholders (10 participants)	12	22,700
4. Scientists within pharmaceutical R&D, mapping and implementation plan (Priority score 9/10) Two meetings with relevant stakeholders (10 participants)	12	22,700
5. Pharmaceutical medicine, mapping and implementation plan (Priority score 9/10) Two meetings with relevant stakeholders (10 participants)	12	22,700
6. Regulatory affairs based programmes, mapping and implementation plan (Priority score 8/10) Two meetings with relevant stakeholders (10 participants)	12	22,700
7. Biostatisticians, mapping and implementation plan (Priority score 7/10) Two meetings with relevant stakeholders (10 participants)	12	22,700
8. Bioinformaticians and biomedical informaticians, mapping and implementation plan (Priority score 7/10) Two meetings with relevant stakeholders (10 participants)	12	22,700
<b>Parallel activities</b>		
Establish criteria for what a centre of excellence in education is, to qualify the centre as a partner in a pan-European platform for education and training, identification of these centres Three meetings with relevant stakeholders (10 participants)	6	34,050
Explore the option for universities and higher education institutions to open their courses to participants from industry and to utilise industry competence in the faculty	6	0
Revisit the evaluation process of academics, also considering industrial experience. Currently, often only the number of publications in high-quality journals is taken into account for applicants to academic positions Two meetings with relevant stakeholders (10 participants)	12	22,700
Open dialogue with EU member states on curricula	12	0

Activity	Duration (months)	Costs (€)
Establish European criteria for curricula. Although the ECTS system and the Bologna Process will result in broader comparability of degrees, for PhD courses in particular there is no pan-European quality system. Some universities already ask for a given number of publications and/or patents. This should be standardised throughout Europe <sup>64</sup> Two meetings with relevant stakeholders (10 participants)	12	22,700
Explore an incentive system with EU-wide recognition and support to facilitate mobility of people to and from academia and industry Two meetings with relevant stakeholders (10 participants)	12	22,700
Establish an accreditation council for the European Medicines Research Academy Three meetings with relevant stakeholders (10 participants)	12	34,050
Map existing PPP in PhD training, e.g. graduate schools of research	12	0
<b>Total short-term budget</b>		<b>783,650</b>

The long-term budget to establish the E&T platform is pending mapping activities, as mentioned above, and detailed implementation plans. The following is, therefore, a rough estimate for a six-year period.

Activity	Costs (€ mn)
Running central co-ordinating unit for six years	2.1
For each of the following programmes, the estimate is based on two courses per annum of one month duration for 26 participants in four centres of excellence across Europe	
1. Integrated Medicines Development	3.2
2. Ethics committee and patient organisation programmes	3.2
3. Safety science programmes	
3.1 Development of a new curriculum	0.5
3.2 Courses	3.2
4. Scientists within pharmaceutical R&D	3.2
5. Pharmaceutical medicine	3.2
6. Regulatory affairs based programmes	3.2
7. Bio-statisticians	3.2
8. Bioinformaticians and biomedical informaticians	3.2
480 PhD grants, 60 PhDs for each of the eight areas (€150,000 each)	72.0
<b>Total long-term budget</b>	<b>100.2</b>

Note: The long-term budget includes the total cost for training programmes, not taking into account that course fees may be paid by (some of) the participants. This would be feasible for some of the courses, but not for those such as ethics committee members and representatives from patient organisations. Furthermore, the extent of co-financing via public-private partnership is not accounted for.

<sup>64</sup> The Zagreb Declaration 2004 on harmonisation of PhD programmes in Medicine and Health Sciences, [http://bio.mef.hr/conference/docs/Zagreb\\_Declaration\\_UK.htm](http://bio.mef.hr/conference/docs/Zagreb_Declaration_UK.htm)

## Key Success Factors

- Support from all relevant stakeholders, especially the European biomedical industry, academia, learned societies, patient groups, regulatory bodies and the European Commission;
- Minimum bureaucracy to allow maximum flexibility and rapid action;
- As some of the activities are building on the progress of the Bologna Process, the progress of this will be closely followed via the conferences in 2005, 2007 and 2009 and the result by 2010.

## Performance Measures

For a permanent control of the progress and performance, the following measures and criteria might be applied:

- Number of attendees at courses, and qualifications achieved;
- Number of trainees employed in the biomedical industry and related fields;
- Number of students coming to Europe from abroad, especially from the USA;
- Development of curricula accepted by the scientific community;
- Acceptance and familiarisation of qualifications by universities, the scientific community, employers and regulatory bodies;
- Increased understanding of the needs and problems the biomedical industry has in regulatory, governmental and public bodies;
- Better informed public and patient groups;
- Increased investment in EU biomedical (this is a long term success measure);
- Raised level of innovation.

## 5.6 List of Contributors

<b>Education &amp; Training</b>			
<b>Stakeholders Group</b>	<b>Last Name</b>	<b>First Name</b>	<b>Institution</b>
<b>European Commission</b>	Donnelly	Fergal	DG Research
	Hogan	Stephane	DG Research
	Norstedt	Irene	DG Research
	Schmitz	Bruno	DG Research
<b>Academia</b>	Algorta	Jaime	Foundation Leia
	Bjerrum	Ole J.	Danish University of Pharmaceutical Sciences
	Bryce	Charles	Napier University
	Bühler	Fritz	European Center of Pharmaceutical Medicine
	Catapano	Alberico L.	University of Milano
	Demotes-Mainard	Jacques	INSERM
	Duchêne	Dominique	Faculté de Pharmacie de Paris
	Ecker	Gerhard	University of Vienna
	Esquerra	Guifré	Generalitat de Catalunya
	Foth	Heidi	University of Halle
	Frokjaer	Sven	Danish University of Pharmaceutical Sciences
	Gennery	Brian	University of Surrey
	Godfraind	Théophile	Université Catholique de Louvain
	Holthoefer	Harry	Technomedicum, Finland
	Ja Crommelin	Daan	University of Utrecht
	Janko	Christa	Vienna School of Clinical Research
	Kaufmann	Jean-Michel	Université Libre de Bruxelles
	Martinez Arca	Sonia	Barcelona Scientific Park
	Meijer	Dirk K. F.	Groningen University
	Mosekilde	Erik	Danish Technical University
	Mulder	Gerard	Leiden University
	Noe	Chrisitan R.	University of Vienna
	Odysseos	Andreani D.	University of Cyprus
	Pellicciari	Roberto	University of Perugia
	Ronsisvalle	Giuseppe	University of Catania
	Rowland	Malcolm	University of Manchester
	Sanz	Ferran	Universitat Pompeu Fabra
	<b>Regulatory Authorities</b>	Aronsson	Bo
Purves		John	EMA
<b>Companies, Pharma &amp; SME</b>	Benel	Laurent M.	Cephalon
	Boubekeur	Karima	Roche
	Collis	Michael G.	Pfizer
	Dirach (Chair)	Jorgen	NovoNordisk
	Farr	Ibrahim	Pivotal
	Fernandez-Cano	Paloma	MSD
	Fröstl	Wolfgang	Novartis
	Hughes-Wilson	Wills	EBE
	Lahuerta	Juan	GSK
	Lesur	Brigitte	Cephalon
	Lihanova	Zuzana	Biotika a.s.
	Michaelis	Uwe	MediGene AG
	Skingle	Malcolm	GSK
	Sterz	Helmut	Pfizer
	Strandgaard	Karen	EFPIA
	Van der Waart	Menno	Organon
	Wärngard	Lars	Vinnova
	<b>Patient Organisations</b>	Poortman	Ysbrand
<b>Others</b>	Crawley	Francis P.	Good Clinical Practice Alliance