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**IMI Key Messages**

**2014**

* [Top level messages](#toplevel)
* [Messages for other industries](#otherindustries)
* [Messages for academic researchers](#academics)
* [Messages for SMEs](#SMEs) and mid-sized companies
* [Messages for patients and their families](#patients)
* [Messages for policy makers](#policymakers)
* [Messages for regulators](#regulators) and payers
* [Messages for the general public](#public)
* [Annex](#annex)

**Top level messages**

**In terms of both budget and scope, IMI is the world’s biggest public-private partnership in the life sciences**

* €3.276 billion budget for period 2014-2024
€2 billion budget for period 2008-2013.
* Making progress in tackling some of the biggest challenges in medical research and drug development, where no single organisation, company or country could do it alone.
* IMI is a partnership between the EU and the European Federation of Pharmaceutical Industries and Associations (EFPIA). Other industries are also welcome to join.
* The EU financial contribution comes from the research and innovation framework programme, Horizon 2020
* Big pharmaceutical companies do not receive funding, but contribute to projects with dedicated resources, such as their researchers’ time or access to equipment and materials.

**IMI accelerates the development of, and patient access to, new treatments, especially in areas where treatments are lacking / where the impact of a disease on society is particularly high**

* Strategic Research Agenda for IMI 2 aligned with 2013 update of World Health Organization report on Priority Medicines for Europe and the World
* Major investments under IMI 1 in infectious diseases, brain disorders, metabolic disease (e.g. diabetes), and immune diseases
* Strong focus on medicines safety (IMI 1 and 2)
* Focus on personalised medicine (increased under IMI 2)
* Projects cover the whole drug development process, from understanding the underlying causes of disease right through to assessing the benefits and risks of medicines and vaccines once they are on the market

**By acting as a neutral broker, IMI facilitates collaboration and enables joint investments to tackle challenges that are too big for any one company, organisation or country to tackle alone**

* Since 2009, 46 public-private consortia launched for a total budget of €1.6 billion
* Intellectual Property agreements facilitated by flexible policy
* Efficient, trusted neutral platform fostering collaboration between multiple stakeholders including universities, industry, SMEs, patient groups, and regulators and payers
* Defining common agenda / priorities
* Moving the boundaries of non-competitive work by offering a truly unique environment for dialogue on research and development

**IMI delivers breakthroughs that are having an impact on drug research and development and, ultimately, patients’ lives**

* IMI research is scientifically excellent – citation impact is twice world average and projects regularly post in leading journals (Nature, Science, etc.)
* Projects are delivering:
	+ a better understanding of the underlying causes of disease
	+ new potential targets for drugs
	+ new potential medicines
	+ new tools and methods to detect drug safety issues early in development
	+ new tools and methods to detect drug efficacy issues early in development
	+ new facilities to support drug development
	+ innovative clinical trial designs
	+ new pan-European clinical networks
	+ new methods to survey the benefits and risks of medicines and vaccines once they are on the market
	+ new education programmes to train the next generation of drug development specialists
	+ new business opportunities for SMEs
* Securing regulatory relevance of projects outputs via regulators’ involvement

**IMI is evolving, with a stronger focus on the needs of patients and society and with simpler, more attractive rules and procedures**

Evolution in scientific focus

* Stronger focus on needs of patients and society, including unmet needs
* Strategic Research Agenda aligned with 2013 update of World Health Organization report on Priority Medicines for Europe and the World
* Increased emphasis on improving patient access to innovative medicines (in addition to medicines development)
* Focus on personalised medicine (the right treatment for the right patient at the right time)

Simpler, more attractive rules and procedures

* Funding rates and reporting rules aligned with Horizon 2020
* 100% reimbursement of direct costs for research actions plus 25% flat rate for overhead/indirect cost
* Protection for beneficiaries under H2020 Guarantee Fund
* Funding for all non-profit organisations (not just research-based organisations)
* Funding for mid-sized companies (i.e. annual turnover of up to €500 million)
* Companies from other industries (e.g. biomedical imaging, medical information technology, diagnostics, animal health) can contribute in kind (so contributions matched by IMI funding)

[**Top**](#top)

**Messages for other industries**

**IMI welcomes the participation of companies from a broad range of healthcare-related sectors**

* Key sectors for healthcare research include biomedical imaging, medical information technology, diagnostic industries, animal health industries
* Project participants gain access to expertise of leading academics, SMEs, and patient groups in their field
* Implementation of game-changing pre-competitive research programmes that could not be carried out by one company or organisation working alone – de-risking novel areas of R&D
* Ensuring translation of great science into medical practice
* Leverages public investment

**IMI is an attractive instrument to implement collaborative programmes involving industrial and non-industrial partners**

* €3.276 billion for 2014-2024 - the largest PPP in life sciences
* Industry drives the agenda
* Intellectual Property agreements facilitated by flexible policy
* Tailor made structure, light governance and cost effective management
* Efficient trusted neutral platform fostering collaboration between key stakeholders
* Development of R&D strategies inclusive of regulators and patients

[**Top**](#top)

**Messages for academic researchers**

**IMI now has more attractive funding and reporting rules**

* Funding rates and reporting rules aligned with Horizon 2020
* 100% reimbursement of direct costs for research actions plus 25% flat rate for overhead/indirect cost
* Protection for beneficiaries under H2020 Guarantee Fund
* Funding for all non-profit organisations
* All IMI funding goes to partners from academia, SMEs, patient groups, etc. Large pharmaceutical companies do not receive IMI funding but pay for their own involvement in the project.

**IMI offers unique opportunities to translate breakthrough discoveries into clinically useful tools and products through open innovation networks**

* Strong focus on benefits for patients / society and on unmet needs.
* Better understanding of disease mechanisms – move towards personalised medicine
* Developing novel innovative approaches
* Ensuring translation of great science into medical practice (renewed emphasis on patient access to new treatments)
* Research on a scale that no single company or institution can achieve alone
* Sharing data, resources and expertise
* Creation of unprecedented scientific networks
* Validation of results
* Transparent academic-industrial collaboration allowing mutual scientific exchange under well-defined consortium agreements (hence, avoiding the usual unexpected commercial interests intervening with scientific exchange).

**IMI projects are generating scientifically excellent results**

* Citation impact of papers above world and European averages (citation impact twice world average, and one quarter of papers ‘highly cited’, i.e. in top 10% for category of journal and year of publication), many papers in leading journals (e.g. Nature, Science, PNAS…)
* Collaborative papers (e.g. with authors from academia and industry, or authors from different countries) have a higher citation impact than non-collaborative papers (e.g. with authors from just academia or just industry).

**IMI is creating new training schemes designed to address specific unmet needs identified by affected individuals/carers**

**IMI has a flexible intellectual property (IP) policy that brings many benefits**

* Ensures all partners’ interests are respected
* Can be adapted to any project
* Offers incentives to participate and innovate
* Focus is on exploitation

[**Top**](#top)

**Messages for SMEs and mid-sized companies**

**IMI now has simpler funding and reporting rules**

* Funding rates and reporting rules aligned with Horizon 2020
* 100% reimbursement of direct costs for research actions plus 25% flat rate for overhead/indirect cost
* Protection for beneficiaries under H2020 Guarantee Fund
* Funding for all non-profit organisations

**IMI supports small and medium-sized enterprises and mid-sized companies engaged in drug development and innovation**

* Funding – direct financial support for innovative research and development
* Acceleration – specialist project partners to accelerate development of early stage pipelines, fast-tracking promising technologies for greater investor value
* Access – enhancing access to markets, access to large pharmaceutical companies (and their know-how and culture), new business opportunities
* Networking – inclusion in open innovation networks, opportunity to exploit new research areas, facilitation of technology transfer between different areas of research
* Advice – management of IPR, support regarding alternative sources of European funding
* Global profile – enhance your visibility and attractiveness through high-level project partnership, building an international reputation
* New in IMI 2 – companies that do not meet the EU definition of an SME and are not EFPIA members are eligible for IMI funding.

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[**Top**](#top)

**Messages for patients and their families**

**IMI projects are focused on patients’ interests**

* IMI 2 includes a renewed focus on delivering benefits for patients and society
* Direct patient involvement in IMI projects, from consultation to decision making
* Innovative reliable tools to provide personalised medicine by predicting likely benefits and potential risks, thereby helping patients to make informed decisions on their treatment
* Putting patients and caregivers at the centre of decisions on efficacy and risk
* Tailoring therapies to patients’ individual needs
* Speeding up patient access to innovative drugs
* Education programme dedicated to patients to help them engage more effectively in health research and innovation
* IMI projects are delivering new clinical trial designs that will result in a greater proportion of patients receiving a trial drug, and a smaller proportion receiving a placebo
* IMI projects are developing tools to help regulators like the European Medicines Agency and healthcare authorities to assess the benefits and risks of medicines and decide if medicines should be approved for use in patients, and to help patients decide if a treatment is right for them.

[**Top**](#top)

**Messages for policymakers**

**IMI implements EU policies**

* Europe 2020
* Horizon 2020
* Active and healthy ageing
* Antimicrobial resistance
* Personalised medicine
* Pharmacovigilance
* Communication on the European Research Area (ERA)

**IMI contributes to improving European citizens’ quality of life**

* Speeding up the development of and patient access to new treatments in challenging disease areas, as identified by the World Health Organization (WHO)
* Improving drug efficacy and safety
* Addressing disease areas of high societal need

**IMI creates/maintains jobs and contributes to the competitiveness of the pharmaceutical sector in Europe**

* Leverages private sector investment in research (including in areas that may otherwise not be considered a funding priority)
* Creation of a workforce that is able to work cross-sector

**IMI has a flexible intellectual property (IP) policy that brings many benefits**

* Ensures all partners’ interests are respected
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**IMI projects are generating scientifically excellent results**

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[**Top**](#top)

**Messages for regulators and payers**

**IMI is developing tools to facilitate (innovative) drug approval by regulatory authorities and payers**

* Novel biomarkers
* New classification of diseases
* Novel methods for benefit/risk assessment and communication
* Novel tools for post-marketing surveillance
* New methods for integration of ‘real life’ date in drug development

**Through IMI, regulators and payers can have direct contact with collaborative consortia as opposed to individual research groups or institutes**

[**Top**](#top)

**Messages for general public**

**IMI is developing new treatments for diseases where there is a high, unmet societal need**

* Antimicrobial resistance
* Diseases associated with ageing
* Brain disorders / mental health

**IMI is contributing to improved medicine and vaccine safety**

**IMI creates/maintains jobs and contributes to the competitiveness of the pharmaceutical sector in Europe**

* Leverages private sector investment in research (including in areas that may otherwise not be considered a funding priority)
* Creation of a workforce that is able to work cross-sector

[**Top**](#top)

**Annex – examples from IMI projects to illustrate key messages**

*For more information on these success stories, visit the project factsheets at* [*http://www.imi.europa.eu/content/ongoing-projects*](http://www.imi.europa.eu/content/ongoing-projects) *(factsheets also include links to project websites), or contact the IMI Programme Office. The programme can also provide additional success stories if required.*

**Antimicrobial resistance**

* Illustrates IMI progress on major societal challenge affecting many Europeans
* Area where IMI provides incentive to invest in risky area
* Demonstrates how IMI is move the boundaries of pre-competitive (or non-competitive) research.

Antibiotic-resistant bacteria kill 25 000 people in the EU every year, and cost the economy €1.5 billion. IMI’s New Drugs 4 Bad Bugs (ND4BB) programme represents an unprecedented partnership between industry, academia and biotech organisations to combat antibiotic resistance in Europe by tackling the scientific, regulatory, and business challenges that are hampering the development of new antibiotics. In total, €750 million (over one third) of IMI’s total budget goes to projects tackling infectious diseases (this includes vaccine projects).

* The **COMBACTE** project focuses on addressing the barriers to clinical development. A key outcome of the project will be a high quality, pan-European clinical trial network. Dubbed COMBACTE CLIN-Net, it will be capable of recruiting sufficient patients into multinational trials at all stages of development. Alongside this, the project will also establish a pan-European laboratory network (COMBACTE LAB-Net), which will deliver epidemiological information and data from microbial surveillance work to guide the selection of clinical trial sites. Crucially, the COMBACTE team aims to generate innovative trial designs to facilitate the registration of novel antibacterial agents. It will also design and validate tests to support the diagnosis of patients, identify the most appropriate treatments, and monitor the patient’s response.
* **TRANSLOCATION** aims to enhance our understanding of how to get antibiotics into multi-resistant Gram-negative bacteria such as Escherichia coli and how to stop the bacteria from ejecting the drug. In sharing the knowledge and data discovered, TRANSLOCATION will develop guidelines for designing and developing new drugs to tackle antibiotic resistance and create an information centre for pre-existing and on-going antibacterial research data which will be used to establish best practices for future antibacterial drug discovery efforts.
* The **ENABLE** project is establishing a drug discovery platform for testing and optimising molecules that are still in the earlier stages of drug discovery but have the potential to become future drug candidates capable of treating resistant Gram-negative infections. Once up and running, the platform will be able to run several drug discovery programmes in parallel.
* Further projects are in the pipeline, including one which will develop concrete recommendations for new commercial models that provide industry with an incentive to invest in this area while ensuring that new antibiotics are used wisely.

**Brain disorders**

* Illustrates IMI progress on major societal challenge affecting many Europeans
* Area where IMI provides incentive to invest in risky area

Brain disorders affect 1 in 3 Europeans and cost the economy almost €800 billion annually. There are very few effective treatments for brain disorders, and because the brain is such a complex organ, developing new drugs for brain disorders costs more and takes longer than for other disease areas. IMI has a number of projects in this area, and between them they are demonstrating that by collaborating, progress in this challenging area is possible. IMI is investing around €186 million in brain disorders research (around 10% of the total budget).

* People with **autism** experience difficulties in social interaction and communication, and often have unusual repetitive behaviours. Although autism affects 1 child in 110 and is a lifelong condition, there are no drugs designed specifically to treat the main symptoms. IMI’s EU-AIMS project is generating tools that will enhance our understanding of ASD, and ultimately pave the way for the development of new, safe and effective treatments for use in both children and adults.

**EU-AIMS** has already made a number of important discoveries. Among other things, it has found that some of the brain changes associated with autism could be reversible, and revealed that autism affects men’s and women’s brains differently. Elsewhere, the project is contributing to new treatment guidelines being compiled by the European Medicines Agency, and setting up two of the largest ever clinical studies of autism. The first study looks at the risk of autism in a younger brother or sister of a child with autism, while the second is tracking how symptoms change with age.

* There is an urgent need for new treatments for **Alzheimer’s disease**. The number of people affected worldwide is expected to reach 100 million by 2050, yet there is still no cure for Alzheimer’s and little in the way of treatments. IMI’s **Pharma-Cog** project is testing a matrix of biological markers to determine whether they can be used in tests to determine the efficacy of new Alzheimer’s treatments.

Elsewhere, the **EMIF-AD** project is linking up data from a variety of sources such as patient health records, research cohorts, biobanks, registries, epidemiology studies and biomarker research, including drug and disease history, test results, and gene sequencing. It will then analyse this data with the goal of pinpointing biological markers that could help researchers and doctors identify people at risk of developing Alzheimer’s before any symptoms emerge. Another project, **AETIONOMY**, is paving the way towards a new approach to the classification of neurodegenerative diseases, particularly Alzheimer’s and Parkinson’s diseases, thereby improving drug development and increasing patients’ chances of receiving a treatment that works for them.

**Diabetes**

* Illustrates IMI progress on major societal challenge affecting many Europeans
* IMIDIA beta cell line breakthrough included SME as a key player

Diabetes is a chronic disease in which patients’ blood sugar levels are elevated because the beta cells in the pancreas fail to produce enough insulin. It is estimated that diabetes affects around 366 million people worldwide, and that figure is likely to rise to 552 million by 2030. Patients are at risk of serious complications, including heart disease and stroke, and damage to the blood vessels, kidneys, and eyes. Diabetes therefore has a major impact on sufferers’ quality of life. Currently there is no cure for diabetes, and treatment options are limited. IMI is investing around €118 million in metabolic disease research (mostly diabetes).

* For many years, a major challenge for diabetes researchers was the lack of a human pancreatic beta cell line that survived (and so could be studied) in the lab; instead, scientists had to use rodent beta cell lines. Now, researchers from IMI’s **IMIDIA project** have developed a human pancreatic beta cell line that not only survives in the lab, but also behaves in much the same way as beta cells in the body. The result has been hailed as a breakthrough for diabetes research. Furthermore, the cell line was developed largely by an **SME**.
* The **SUMMIT project** is addressing the urgent need for new treatments to tackle the complications associated with diabetes, such as eye, kidney, and blood vessel problems. It has developed a revolutionary ultrasound device that identifies diabetic and other patients at imminent risk of a heart attack or stroke. The device is the subject of a patent application.
* The **DIRECT project** takes a personalised medicine approach to diabetes, as it is working to identify different varieties of diabetes and effective treatments to tackle them.

**Medicines safety**

* Illustrates IMI progress in an area that is particularly important for patients, the general public, etc.

A major challenge in drug development is identifying potential drugs that may have unintended, harmful side effects by damaging vital organs such as the heart, liver, or kidneys. All too often, toxicity issues are picked up very late in development, when vast amounts of time and money have been spent on a potential drug. With this in mind, many IMI projects are developing tools and methodologies to detect drug safety issues much earlier in drug development.

* Scientists in the **eTOX project** have developed a computer model to test whether potential medicines could damage the heart. Users simply have to enter the molecular formula of the compound into the tool, and the system generates a simulated ECG (electrocardiograph). Clinicians routinely use ECGs to diagnose heart problems in their patients; in the same way, users can study the simulated ECG generated by the eTOX system to determine whether or not a compound is toxic to the heart. According to the project team, it provides better results than the currently-used computational systems.
* The **SAFE-T project** has evaluated 153 potential biological markers for drug-induced injury of the kidney, liver, and vascular system. Of these, 79 have been selected for further studies and the project is now working with the European Medicines Agency and the US Food and Drug Administration to obtain regulatory acceptance of these biological markers as reliable tools for use in drug development.
* Vaccines are a highly-effective public health measure, saving some two to three million lives worldwide every year. However, in Europe, public distrust in immunisation programs is limiting high vaccine uptake, resulting in outbreaks of vaccine-preventable infectious diseases. Bringing together the European Centre for Disease Prevention and Control and the European Medicines Agency, as well as national public health and regulatory bodies, vaccine manufacturers and academic experts, the **ADVANCE project** is developing and testing methods and guidelines to pave the way for a framework capable of rapidly delivering reliable data on the benefits and risks of vaccines that are on the market. This framework should both help regulators and public health authorities make decisions on vaccination strategies.

**SMEs**

* Illustrates successes of SMEs in IMI
* Highlights impact of IMI on competitiveness of pharmaceutical sector as a whole

**135 SMEs** are involved in IMI’s 46 ongoing projects from the first 8 Calls for proposals. The majority of these SMEs are **biotech companies**; of the rest, most are IT / data management companies, and a few work in project management. SMEs account for **15% of IMI funding beneficiaries** and **receive 18.4% of IMI’s budget** under the first 8 Calls.

* German SME **Taros Chemicals** boasts expertise in synthetic and medicinal chemistry and hit-to-lead development. The company is a key player in IMI’s **European Lead Factory** project, which is developing a major new pan-European platform for drug discovery comprising a large compound collection and associated screening centre. For Taros, participating in an IMI project has delivered many benefits, ranging from an expansion of the company’s labs, to the acquisition of new skills and a deeper understanding of the pharmaceutical business.
* French SME **Endocells** is a key player in the diabetes project **IMIDIA**, where it drove the development of the world’s first human beta cell line.

**Intellectual property**

All IMI projects include intellectual property in their Project Agreements, so any example could be used here. However, the following projects are particularly illustrative of what can be done thanks to the IMI IP policy.

* **European Lead Factory**

The European Lead Factory is a pan-European platform for drug discovery that is set to give a major boost to drug discovery in Europe. Comprising a collection of half a million compounds and a screening centre, the European Lead Factory will offer researchers in academia, small and medium-sized enterprises (SMEs) and patient organisations an unprecedented opportunity to advance medical research and develop new medicines.

The pharmaceutical companies in the consortium will contribute a total of over 300 000 compounds to the project to create a joint compound collection. To this will be added an estimated additional 200 000 novel compounds generated by public partner contributions during the project, resulting in a unique Joint European Compound Collection with some 500 000 compounds. The European Lead Factory combines the power of the pharmaceutical industry’s previously inaccessible compound libraries with the innovation of the academic communities in designing novel compounds and the expertise of many SMEs in HTS and library generation.

* **ENABLE**

While there is a strong need for new medicines to treat resistant Gram-negative infections, the industrial pipeline of new drugs remains quite limited. The ENABLE project is creating and managing a drug discovery platform for testing and optimising molecules that are still in the earlier stages of drug discovery but have the potential to become future drug candidates capable of treating resistant Gram-negative infections. Once up and running, the platform will be able to run several drug discovery programmes in parallel.

* **NEWMEDS**

Schizophrenia affects around 24 million people globally, yet few truly game-changing medications have reached the market in the last few years. Enter the NEWMEDS project, where the companies involved in the project have pooled their data to create the largest-known database of studies on schizophrenia, including information on over 23 000 patients from 67 studies in over 25 countries.

Clinical trials in which patients on active treatment are compared to patients taking a placebo normally take six weeks. However, by analysing their immense database, NEWMEDS researchers have found that these trials could be shortened by a week or two. NEWMEDS research also suggests that more women should be included in trials; currently they account for under a third of trial participants yet they respond less to placebos than men. The project has also found that so-called negative schizophrenia symptoms (e.g. an inability to feel pleasure or act spontaneously) could respond better in these studies than was previously thought, something that has been largely overlooked before.

**Patient involvement in research**

* IMI’s flagship project for patients is **EUPATI**, which is establishing a European Patients’ Academy on Therapeutic Innovation, with training courses, educational material and an online public library that will empower patients to engage more effectively in the development and approval of new treatments and become true partners in pharmaceutical R&D.
* Another project with strong patient involvement is **U-BIOPRED**, which is paving the way for personalised medicine to treat **severe asthma**. Patients are heavily involved in the project; as well as taking part in the clinical study, they have provided advice on ethical, scientific, and communication issues, giving the patient's perspective throughout.

**New tools for drug discovery**

*For more information on any of these, contact the IMI Programme Office*

* SUMMIT – developed novel ultrasound tool to detect atherosclerosis plaques at risk of rupture (patent pending)
* EU-AIMS – discovered some brain changes associated with autism are reversible
* Europain – discovered molecule that causes the pain of sunburn
* SAFE-T – validating biomarkers for drug-induced injury of liver, kidney and vascular system
* EMIF – using big data to study Alzheimer’s and diabetes
* PROactive – developing patient-reported outcome tools for chronic obstructive pulmonary disease (COPD)
* NEWMEDS – optimising clinical trial design for schizophrenia drugs
* COMBACTE and NEWMEDS – creating new clinical networks
* EHR4CR – exploring re-use of health records for clinical research
* AETIONOMY and PRECISESADS – new classifications of dementia and lupus / rheumatoid arthritis respectively
* U-BIOPRED – creating a systems biology approach to severe asthma and paving the way for personalised treatments

**Education and training**

* IMI’s **EMTRAIN project** has developed on-course®, Europe’s most comprehensive biomedical and medicines research and development postgraduate course portal. The portal gathers together information on over 5 000 courses taught in 20 languages in 39 countries and covering over 60 scientific and therapeutic areas. Free and easy to use, on-course allows users to search for courses by type (Masters, PhD, short course), schedule (full or part time, modular), learning type (distance, face-to-face, mixed), language, location, and scientific / therapeutic area. Users can also search for courses delivered by IMI’s Education & Training projects. For each course on the site, on-course® provides a course description, list of modules (if relevant), details of fees, contact information, and links to the course website. Finally, for people looking for courses while on the move, there is the on-course® app, which can be downloaded to smartphones for free.
* The **Eu2P project** offers courses in pharmacovigilance and pharmacoepidemiology with specialties in benefit assessment, regulatory aspects, risk quantification, public health and risk communication. Eu2P was awarded an education technology prize in the higher education category at the 2012 Salon Educatec-Educatice in Paris, France.
* The **SafeSciMET project** provides courses on safety sciences. Students can take individual short courses or follow a full programme to receive a Master of Advanced Safety Sciences of Medicines.
* Among other things, the **PharmaTrain project** has created the Cooperative European Medicines Development Course (CEMDC), a postgraduate qualification in medicines development run by a network of 10 universities. The universities involved in the CEMDC are located in Estonia, Hungary, Lithuania, Poland, Portugal, Romania, Serbia, Slovakia, Slovenia, and Turkey. The initiative therefore gives students from the central and Eastern European and Mediterranean regions the opportunity to benefit from the very best teaching offered jointly by all participating universities. The university network concept was developed because in small countries and countries with small pharmaceutical industries, only a network concept can guarantee long-lasting sustainability of the programme.