

IMI's added value

Project outputs linked to early socio-economic impacts

The Innovative Medicines Initiative (IMI) is a **public-private partnership** between the European Union (represented by the European Commission) and the European pharmaceutical industry (represented by EFPIA, the European Federation of Pharmaceutical Industries and Associations).

'Pre-competitive research is capability driven and not product driven. Pre- or non-competitive activities are, from an industrial perspective, activities that do not lead directly to the approval of a medicine or a vaccine.'

Expert panel – Socio-economic Impact assessment (2007)

IMI is working to improve health by speeding up the development of, and patient access to, innovative medicines, particularly in areas where there is an unmet medical or social need.

It does this by **facilitating collaboration** between the key players involved in healthcare research, including universities, the pharmaceutical and other industries, small and medium-sized enterprises (SMEs), patient organisations, and medicines regulators.

The concepts of **pre-competitive research** and **collaborative innovation** are key elements of the IMI framework. An analysis of the results delivered so far reveal that IMI is more than delivering on its ambitious objectives, with results benefitting industry (big and small) and patients alike in areas where collaboration is key to success. As such **it represents excellent value for money for the EU**.

The first 10 IMI projects will reach the end of their IMI funding cycle by the end of 2015. As part of the evaluation of the final project outputs, IMI has commissioned an external evaluation of the actual and potential socio-economic benefits which will provide a framework for identifying how project outputs become impacts.

Some significant scientific impacts

IMI activities focus on **translating research** 'from bench to bedside', describing how basic scientific knowledge is converted into potential clinical products. While the **average time** for research evidence to reach clinical practice is **17 years**¹, IMI-funded research has already **improved the quality of science** through the development and validation of new technologies.

Today, IMI has established itself as a pioneer of open collaboration, a novel way of working that is radically changing the shape of the pharmaceutical research and development (R&D) landscape.

The benefits of this approach are evident from the many scientifically-excellent results generated by IMI's projects, which are helping to address some of the biggest challenges in

IMI is improving the drug development process

460+ new biomarker candidates identified or under validation, promising better diagnosis & treatment design for patients

50+ new animal models developed or standardised, helping to save time & money in the search for new drugs

100+ new *in vitro* models & 100+ new *in silico* (computer-based) models, providing increased safety for patients

20+ new drug targets identified, or currently considered, or under validation speeding up the discovery of new medicines

25+ new tools to facilitate drug development diagnostics, like imaging, making drug discovery more targeted

65+ clinical trials completed or ongoing in bringing novel treatments directly to patients, with 18 000+ patients

¹ Morris, Wooding & Grant (2011) JR Soc Med, Vol 104:510-520

health research and boost the competitiveness of Europe's pharmaceutical sector.

European-wide synergies come with new approaches that offer time and cost savings through effective partnerships collaboration on an unprecedented scale. Fewer uncertainties mean lower discovery costs which are shared across both industry and academic and other project partners.

IMI projects currently involve:

- **845** academic teams
- **480** EFPIA teams
- **169** SMEs
- **26** patient organisations
- **17** regulators
- **over 7 000** researchers.

IMI builds evidence for policies

Moves towards a **personalised approach to medicines** mean targeting smaller groups of patients to provide more effective, safer treatments. IMI has a pivotal role in creating a more productive European R&D environment by generating the evidence needed for new drug development pathways and for integration into decision-making processes to ensure patient access to innovative medicines.

Over 50% of IMI projects have regulators represented either as partners or advisors. **Better cooperation with regulatory authorities means faster progress** in developing effective new treatments for patients. IMI's projects have developed close and productive relationships with the European Medicines Agency (EMA) and other regulators are in close consultation with IMI's projects. A number of projects have already received EMA qualification advice of novel methodologies for medicine development to maximise potential impacts of project results on regulatory practices.

IMI project **GetReal** is developing new ways of incorporating real-life clinical data into drug development, helping pharmaceutical companies take better decisions during drug development and supporting healthcare decision makers in granting patients access to a new treatment. **EU-AIMS** has been instrumental in the EMA concept paper on the development of medicinal products for the treatment of Autism Spectrum Disorder. **WEB-RADR** has launched a smartphone app that will make it easier for patients, carers and healthcare professionals to report side effects of medicines to regulatory authorities.

Some early economic impacts

IMI's public-private model makes **more efficient use of EU funds**. For every €1 of public money at least €2 is spent on research & development within IMI's projects.

The pharmaceutical industry has a **higher R&D intensity of 14.4%**² than any other industrial sector. It is a major source of comparative advantage and growth, and outstrips other innovation-based industries. The **research-based pharmaceutical industry** is a major high-technology employer³ in Europe and the economic value per employee is greater than for comparable industries⁴.

The actions of developing, engaging, and employing skilled people constitute a kind of commercialisation of research knowledge. IMI activities have created significant opportunities for recruitment and employment in life sciences and related R&D and there are now **2 272 full-time jobs employing and developing highly-skilled personnel directly associated** with IMI projects.⁵ Every job directly associated with life science R&D

² The 2014 EU industrial R&D investment scoreboard, European Commission, JRC, DG RTD

³ Source: EFPIA: Pharmaceutical industry in figures (2015, 2013)

⁴ Source: Eurostat database on employment accessed in March 2015

⁵ Official figures based on project description of work in person/months

produces a **leveraged effect** of creating **further jobs indirectly elsewhere in the economy**. This means that IMI projects have potentially created around **13 000 jobs** within the European economic area, as studies recently completed for the UK indicate that 1 R&D job is associated with between 3 and 5.7 jobs in the economy as a whole.⁶

Small and medium-sized enterprises (SMEs) are **key players** in the healthcare innovation sector. The majority specialise in **biotech** and **IT / data management** & have been able to benefit beyond their expected contribution to projects. There are currently **169 SMEs** involved in IMI projects, and **15.8%** of IMI funding goes to SMEs with **16%** of IMI beneficiaries are SMEs.

Endocells, a **French-based SME** in the IMI **diabetes** project **IMIDIA**, developed the first ever human beta cell lines to be cultured in the lab that behave naturally. Their innovative technology has been fast-tracked because of collaboration with pharma partners. They now have a commercial product, a market for their cell line and their customer base is increased.

Chemotargets, based in **Spain** in the **eTOX** project on **medicines safety**, has a project-independent licencing agreement for use of their modelling approaches with one of the large pharma companies as a result of participating in the IMI project.

ICDD, another **French SME**, is working on protein profiling of **Alzheimer's disease** patients. Thanks to its participation in an IMI project, it has been able to access animal models, blood samples from patients across Europe and clinical data from multi-site European studies, tools that are normally beyond the reach of small companies.

Taros Chemicals, based in **Germany**, is a key player in IMI's **European Lead Factory** project. The project is developing a **major new pan-European platform** for drug discovery which comprises a large compound collection and associated screening centre.

Commercialisations of project outputs include:

- **13 new spin-off** creations
- **6 trademarks**
- **3 licensing** deals
- **33 results implementation** by industry
- **17 sustainability plans**
- **7 commercialisations**
- **20 patent applications**
- **3.2 patents per €10 million** of costs accepted by IMI.

Firalis, from **France**, participates in the IMI project **SAFE-T**, and credits its participation in an IMI project for being able to **increase from 6 to 50 employees**.

EBISC participant, **Roslin Cells Ltd**, has initiated a new spin out in **UK** named Roslin Cell Sciences Ltd.

Open PHACTS has created a sustainable pay-to-use platform that links up diverse drug discovery databases, through the spin-off **Open PHACTS Foundation**.

Cellular Phenomics & Oncology from **Berlin**, is a spin-off from **cancer project ONCOTRACK** to conduct the biological and pharmacological testing of new cancer therapeutics and diagnostics in preclinical models.

Education and training project **Pharmatrain** has created the **PharmaTrain Federation** to manage and continue developing project 'assets' created during the IMI-funding phase.

IMI results brought to market more rapidly

SUMMIT, an IMI **diabetes** project, has developed a breakthrough technique for a non-invasive ultrasound-based method which has wider applications for other types of patients. There are on-going negotiations to commercialise this technology.

⁶ Source: Chambers *et al* (2015) An assessment of the impact of the bioeconomy on the United Kingdom economy

CHEM21 is working to reduce the **environmental impact** of drug development and manufacture. Sanofi is now exploring how to industrialise CHEM21's process for producing an anti-fungal treatment. CHEM21 researchers are now patenting a chemical process developed by the project.

SafeSciMET has now commercialised 20 **drug safety sciences courses** as well as an accredited advanced MSc degree in Drug Safety Sciences.

U-BIOPRED has commercialised a provocative chemical agent developed by the project to be used as a tool for studying **severe asthma**.

EUROPAIN consortium **SME, Neuroscience Technologies**, based in **Spain**, has opened an affiliate in **UK** and have commercialised biomarkers discovered during the project. These biomarkers are already in use by researchers within and external to the project.

BioVacSafe SME Immunoarray has commercialised an ichip® antibody technology providing molecular diagnostics for measuring specific antibodies. The test has been launched in a commercial setting in the US.

EU-AIMS SME partner **Noldus Information Technology** in close collaboration with neuroscientists at the Brain Center Rudolf Magnus in the **Netherlands** has commercialised new tools to test behaviours in mouse models for autism. This saves money by allowing researchers to study how different drugs affect the behaviour and communication between different mouse lines.

Some early societal impacts

IMI **education and training** projects are working to increase European knowledge capital for the whole life-cycle of medicines research, from basic science through clinical development to pharmacovigilance.

Some **685 trainees** have followed PharmaTrain courses, with **over 28%** from pharmaceutical companies. **58 students** are following **EU2P's** flexible and fully e-learning programme, with access to **160 different topics**. The number of trainees enrolled in their Master degree has doubled in two years. More than **320+** students have participated in **20 new SafeSciMET** courses in drug safety sciences courses. **Information on 6 000+ courses** is available through **EMTRAIN's** 'On-course' online course portal.

IMI's education and training projects launched their **new pan-European LifeTrain framework** for continuing professional development in the biomedical sciences. **The framework** will enable biomedical professionals to work collaboratively across disciplines and national boundaries.

EUPATI is a **patient-led initiative** that aims to develop the first European Patients' Academy on Therapeutic Innovation, providing training courses, educational material and an online public library to empower patients to engage effectively in becoming true partners in pharmaceutical R&D. **The project** has developed a network of **1 000+ members** from **53 countries** with a wide mix of healthcare professionals, patients, caregivers, PR/communications specialists, industry and academic representatives.

Patients play an active role in IMI and its projects.

IMI has an active engagement strategy to **promote patient involvement** in its projects and activities. Patients are represented in IMI's Scientific Committee and as speakers and panellists in IMI events and agenda-setting. IMI projects also frequently focus on **patients' needs for personalised treatments**.

U-BIOPRED is working on treatments for severe asthma through a dedicated patient input platform where patients provide advice on ethical, scientific, and communication issues. **PROactive** is developing methods to incorporate the impact of chronic obstructive pulmonary disease (COPD) on patients' daily lives into drug development.

Patient organisation Alzheimer Europe is an active partner in the IMI projects **Pharma-Cog**, **AETIONOMY**, **EMIF** and **EPAD**. **EU-AIMS** is paving the way for new treatments for autism spectrum disorder.

US-based **patient advocacy group Autism Speaks** is a partner in the project and is contributing USD 1 million to its work.

Diabetes patient organisation JDRF has contributed to IMI's **IMIDIA** and **SUMMIT** projects and is now an **Associated Partner in IMI 2** as it will contribute resources and expertise to an IMI 2 project on diabetes.

People make the difference

In IMI projects, people make the difference. **The best scientists are engaged from academia, industry and SMEs**, they are the 'human capital', those skilled people who are the innovators who carry, circulate and apply knowledge, and who use the knowledge infrastructure, both for creating and absorbing innovations.

These scientists publish in some of the top peer-reviewed journals world-wide. IMI project researchers are winning recognition across Europe and world-wide. Recent awards include:

- European College of Neuro-psychopharmacology Award (2015)
- Martín Villar Research Award
- Lewis Sheiner Award
- Best Practice Award from BIO-IT World (Research and drug discovery category)
- European Respiratory Society Chronic obstructive pulmonary disease research Award (2014)
- L'Oréal-UNESCO UK & Ireland for Women in Science Fellowship
- Best Practice Award from BIO-IT World (Honest Data Broker Award)

IMI project publications have been published in more than **473 journals**, and **74% of papers** were published in **top quartile journals**, including the *Journal of the American Medical Association*, *Science* and *Nature Publishing Group* titles.

World-class science and increased levels of R&D excellence

- **1 134+ publications**
- **9 359 citations**
- **2.19 IMI citation impact** against 1.10 as the EU average citation impact
- **470+ publications** for 2014

Source: Thomson Reuters analysis 2015

Around **24% of papers** from IMI projects were in the world's **top 10% of papers** for that journal category/year of publication, ranked by number of citations received.

IMI projects are creating specialised research networks and facilities

IMI's **New Drugs 4 Bad Bugs** 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.

IMI's **Ebola+ platform** is contributing to efforts to tackle a wide range of challenges in Ebola research, including vaccines development, clinical trials, storage and transport, as well as diagnostics. A clinical trial of an investigational Ebola vaccine regimen is now underway in Kambia, Sierra Leone thanks to the IMI projects EBOVAC1, EBODAC and EBOMAN.

Even in the short term, the benefits to the local community of the 'EBOVAC-Salone' trial are immense. **New facilities** had to be built to run the study, including the **first emergency room** at the local district hospital, and a **vaccine storage facility**. In addition, the project provides both **jobs and training** for local healthcare workers, who will also gain valuable experience by working on the trial. In the longer term, the community may also benefit if the vaccine regimen is approved.

EU-AIMS set up a clinical research network in **autism** which currently consists of **75 sites** spread across **37 European countries** and covering nearly **15 000 patient visits** per year

COMBACTE set up CLIN-Net, a pan-European clinical trial hospital network of **+300 clinical sites** in **37 countries** to conduct high-quality clinical studies, to find new **antimicrobials against resistant bacterial pathogens**

PROTECT established the open access European drug consumption database of **45 298 adverse drug reactions** for **654 medicines** using data for **17 European countries**

In summary

IMI's projects launched under the IMI programme are delivering results that **confirm the importance of the public-private partnership model** in the wider research landscape. At the same time, IMI is committed to **addressing the new, ambitious goals of the IMI 2 programme** and ensuring that it will deliver results that will make a real difference to the lives of patients in Europe and beyond.

IMI has proven particularly successful at attracting **small and medium-sized enterprises (SMEs)**, which receive 18% of the funding from the first 9 Calls for proposals. Under the programme, IMI has created a **thriving community of over 7 000 scientists** working in different disciplines across Europe and beyond. It has established a reputation for **scientific excellence** and is recognised as a **global leader in open innovation** in health research and medicines development.

IMI projects are **delivering breakthroughs** that are helping to overcome some of the biggest challenges in medicines development. IMI projects are also helping to improve procedures for monitoring the benefits and risks of medicines once they are on the market.

IMI projects are **establishing resources and facilities to boost drug discovery in Europe**. IMI is developing **new tools for research**. As well as advancing research in important areas like **dementia, diabetes, and medicines safety**, these tools will help to **reduce the use of animals in research** – all in the spirit of an **unprecedented degree of collaboration** amongst private companies, sharing data and building efficiencies to bring innovation to patients.

Through the IMI programme, the pharmaceutical industry committed €1 billion to collaborative research centred on Europe. Moreover, the success of IMI 1 convinced the industry to pledge a further €1.4 billion through the IMI 2 programme, which is now underway. Interestingly, anecdotal evidence suggests that some companies are choosing to carry out certain research and development activities in Europe because of IMI.

More information on IMI

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