

Press release

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Major new report reveals socio-economic impact of Innovative Medicines Initiative projects

Brussels, Belgium, 18 May 2016 –Innovative Medicines Initiative (IMI) projects are generating socioeconomic impacts on a number of fronts, reveals a major new analysis by independent experts. The report shows how the first projects launched by IMI are making concrete improvements to pharmaceutical research and development (R&D); leveraging funding; creating new knowledge and tools; and making Europe an attractive place to carry out research. Importantly the report notes that many of the projects' achievements would not have been possible without IMI.

The report was produced by a panel of independent, high-level experts from the fields of health economics and research and innovation policy. The group analysed in detail the outputs and impacts of the first nine IMI projects to finish. Between them, they have a total budget of €217.6 million, and cover areas such as diabetes, medicines safety, schizophrenia and depression, education and training, chronic pain, and severe asthma.

IMI projects are delivering on IMI's goal of helping to make concrete improvements to the medicines development process

Broadly, most of the impacts identified by the experts fall into the category of improvements to the medicines R&D processes. As such, the report demonstrates that IMI is delivering on its goal, set out in the legislation creating IMI, of 'significantly improving the efficiency and effectiveness of the drug development process'.

Here one very clear impact is the vast amounts of new knowledge generated by the projects, which between them have already published 546 scientific papers, with more in the pipeline. The projects have also developed and tested many new tools for studying diseases and developing new drugs. For example, in a world first, the IMIDIA project developed a functional line of human pancreatic beta cells (the cells which go wrong in diabetes). These make it easier for scientists to study diabetes in the lab. Furthermore, in some cases (including IMIDIA), new tools and resources developed by IMI projects have been commercialised, often by small and medium-sized enterprises (SMEs). In the long term, the knowledge and tools arising from these projects should help to speed up drug development, improve clinical trial design, cut costs, reduce the need for animal testing, and cut failure rates in drug development.

IMI projects are creating long-lasting collaborative networks

The report also highlights IMI's role in creating long-lasting, collaborative networks. For many of the projects studied, the groups involved had never worked together before embarking on the IMI project together. Collaborating allowed the partners to share ideas, knowledge and experiences as well as risks. The benefits of these collaborations are evidenced by the fact that in several cases, the partners are continuing to collaborate even though the IMI project is over.

IMI leverages additional funding for medicines research and development

Through IMI, the European Commission invested a total of \in 82.3 million in the 9 projects studied. On top of this, EFPIA companies committed \in 104.8 million to the projects and a further \in 30.5 million came from other sources. This means that every euro invested in IMI by European taxpayers leveraged an additional \in 1.64.





IMI is making Europe an attractive place to carry out pharmaceutical research

The report also notes that the projects have helped to raise the profile and reputation of Europe as a location for medical and pharmaceutical research.

Pierre Meulien, IMI Executive Director commented: 'This report is at the cutting edge of evaluation research, and represents an important element in IMI's efforts to demonstrate with hard facts and figures how it is delivering on its goals. The volume and scale of project outputs and impacts identified by the experts is particularly exciting when one considers that they come from just 9 of the 71 projects IMI has launched so far.'

Carlos Moedas, European Commissioner for Research, Science and Innovation, said: 'This independent report confirms that IMI is delivering on its objectives. Public-private partnerships such as IMI are making the lives of Europeans better, create jobs and boost our competitiveness. They deliver results that single companies or countries could not achieve alone.'

Marc de Garidel, Chairman & CEO of Ipsen Group and Deputy Chair of the IMI Governing Board said: 'This report demonstrates how IMI is helping industry to make big changes in the manner in which new medicines are developed, streamlining R&D processes, having a more collaborative approach, and thus ultimately bringing innovation more effectively to the patient.'

The report includes a number of recommendations on how IMI can maximise the socio-economic impacts of its projects. Over the coming months, IMI will analyse the recommendations and determine how best to implement them.

ENDS

Notes to Editors

- The full report will be available for download from the IMI website <u>www.imi.europa.eu</u> on 18 May 2016.
- Information on the experts and a summary of the projects analysed can be found below.

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The authors: bios and quotes

Charles Edquist, Professor of Innovation at the Centre for Innovation Research and Competence in the Learning Economy (CIRCLE)

About Professor Edquist: Professor Edquist was involved with the IMI1 Impact Assessment in 2007. His expertise is in systems of innovation and innovation policy: technologies, institutions and organisations and he contributed to the development of the systems of innovation (SI) approach.



Bengt Jönsson, Professor Emeritus in the Department of Economics at Stockholm School of Economics

About Professor Jönsson: Professor Jönsson's expertise covers a broad range of health economics issues including financing and organisation of health services, the economics of innovation in health, and economic evaluation of public health and medical care.

Katherine Payne, Professor of Health Economics at the Manchester Centre for Health Economics, University of Manchester

About Professor Payne: Professor Payne's expertise is as an academic health economist working with different clinical research groups (pharmacy, psychiatry, and genetics) with a particular interest in stratified medicine and the impact of new genomic technologies.

Quote: 'Innovation in medicines is an important goal for society if it achieves improved health and well-being at an affordable cost. Funding from IMI has the potential to enable the timely and effective development of better and safer medicines for patients. It is, however, vital that such IMI funding is directed towards the projects with the best potential for success. By conducting this review process IMI has recognised this need to appraise whether existing projects have met expectations and realised socio-economic benefits to societies. In some instances it was clear that socio-economic benefits had been achieved but IMI must continue to use robust processes to ensure the effective use of scarce funding budgets to allow its programme of work to maximise the benefits to society from innovative medicines in Europe.'

Robert Tijssen, Professor of Science and Innovation Studies at Leiden University

About Professor Tijssen: Professor Tijssen was also was involved with the IMI1 Impact Assessment in 2007. His expertise is in quantitative studies of research cooperation, performance indicators for university rankings, university research and industrial R&D, socio-economic impacts of science.

Quote: 'Having done this first assessment, of just 9 projects, I do believe that IMI's added value for medicines development has become more clearer and tangible. And what it has also taught me is that successful IMI projects are not only about producing the agreed "deliverables", but even more so about building mutual understanding, trust and appreciation between public science and industry R&D.'

Rapporteur: Graeme Blackett, Director, BiGGAR Economics

About Mr Blackett: Graeme Blackett is an applied economist with 25 years of experience in economic consultancy including economic appraisal, evaluation and economic impact experience of universities and of the life sciences sector.

Quote: 'The socio-economic assessment of IMI was unlike typical evaluations of innovation programmes, because rather than supporting the development of new or improved products and processes directly, the IMI projects have tackled issues with the innovation system itself, and so the socio-economic benefits will occur as a result of a more fit for purpose innovation system for medicines in Europe.'



About the projects featured in the report

The projects featured were all launched under IMI's 1st Call for proposals. As such they started in 2009-2010 and have now finished. The tables below summarising the projects' position in the innovation ecosystem, outcomes, and impacts, are drawn from the report.

IMIDIA (diabetes)	Improving beta-cell function and identification of diagnostic biomarkers for treatment monitoring in diabetes		
Position in innova ecosystem	tion	Mediators and intermediate outcomes	Socio-economic impacts
Pre-clinical research development of tool	n – s & biomarkers	60 scientific publications (citation rate 1.47 & 18.9% highly cited) New human cell line Biobank of human beta cells Database New animal models New biomarkers Novel imaging techniques New collaborations	Platform for development of new drugs – new tools & techniques which will allow novel treatments to develop
Budget	IMI funding: EFPIA funding: Other funding: Total:	 €8 060 760 €16 940 659 €2 445 590 €27 447 009 	
Find out more	Report: page 26 Website: <u>www.in</u> Project factshee	<u>midia.org</u> t: <u>www.imi.europa.eu/content/imidia</u>	<u>a</u>

MARCAR Biomarkers and molecular tumor classification for non-genotoxic carcinogenesis (medicines safety)

Position in innovation ecosystem	Mediators and intermediate outcomes	Socio-economic impacts
Research on drug safety, to develop new models & tools for use in supporting pre-clinical and	35 scientific publications (average citation 2.07-2.70 & 28.9% highly cited)	Potential for cost savings, reduced animal testing & time savings in drug development.
clinical medicines development (animal testing stage)	Tool for measuring new biomarkers Systems to speed up search for &	<i>If</i> regulators change carcinogenicity study requirements.
	validation of biomarkers Tool for scanning candidate drugs	Potential for reduced drug-induced side effects & associated healthcare costs.



Budget	IMI funding:	€6 049 578
	EFPIA funding:	€5 155 604
	Other funding:	€1 905 508
	Total:	€13 110 690
Find out more	Report: page 31	
	Website: www.im	i-marcar.eu
	Project factsheet:	www.imi.europa.eu/content/marcar

NEWMEDS Novel methods leading to new medications in depression and schizophrenia (schizophrenia & depression)

Position in innovation ecosystem		Mediators and intermediate outcomes	Socio-economic impacts
Pre-clinical testing, human studies, clini pre-clinical and clini for drug discovery	experimental ical trials; new cal methods	95 scientific publications (average citation 2.83 & 28.9% highly cited) New animal models Potential biomarkers Tools to test biomarkers Imaging tools	New methods & tools for developing new medicines but no new medicines yet.
Budget	IMI funding: EFPIA funding: Other funding: Total:	€8 986 216 €13 789 412 €2 074 047 €24 849 675	
Find out more	Report: page 35 Website: <u>www.r</u> Project factshee	newmeds-europe.com t: www.imi.europa.eu/content/newm	neds_

PharmaTrain Pharmaceutical Medicine Training Programme (education & training)

Position in innovation ecosystem	Mediators and intermediate outcomes	Socio-economic impacts
Training (covering all aspects of drug development pathway)	9 Masters programmes156 single module courses497 students graduating715 continuing professional development (CPD) trainees	Productivity of medicines development process. Depends on implementation of competencies-based approach to employment and progression.



Total:	€7 631 528
Other funding:	€632 047
EFPIA funding:	€3 489 181

Find out more Report: 39 Website: <u>www.pharmatrain.eu</u> Project factsheet: <u>www.imi.europa.eu/content/pharmatrain</u> Twitter: @pharmatraineu

PROTECT	Pharmacoepidemiolocal research on outcomes of therapeutics by a European consortium
(medicines safety)	

Position in innovation ecosystem		Mediators and intermediate outcomes	Socio-economic impacts
Post-marketing surv	eillance	61 scientific publications (average citation 1.36 & 16.4% highly cited). Series of guidance and recommendations. Increased collaboration	Potential impacts if recommendations implemented and if regulators speed up approval decision making – so new drugs to market sooner (& so available to patients sooner).
Budget	IMI funding: EFPIA funding: Other funding: Total:	€11 009 715 €10 864 491 €6 743 176 €28 617 382	
Find out more	Report: page 44 Website: <u>www.in</u> Project factshee	<u>mi-protect.eu</u> <u>protectbenefitrisk.e</u> :: <u>www.imi.europa.eu/content/prote</u>	eu ct

Twitter: @PROTECT_BR

SAFE-T Safer and faster evidence-based translation (medicines safety)

Position in innovation ecosystem	Mediators and intermediate outcomes	Socio-economic impacts
All stages of drug development from preclinical to clinical development, registration, and post marketing	22 scientific publications (average citation 2.12 & 28.57% highly cited) 20 promising biomarker candidates Biobank Database	Spin-off company to be set up in 2016 Future impacts depend on validation and use of biomarkers. If this happens, would impact on drug development process safety, time & cost.



May also be direct clinical applications.

Budget	IMI funding:	€13 901 971
	EFPIA funding:	€13 575 483
	Other funding:	€4 198 802
	Total:	€31 676 256

 Find out more
 Report: page 48

 Website:
 www.imi-safe-t.eu

 Project factsheet:
 www.imi.europa.eu/content/safe-t

EUROPAIN Understanding chronic pain and improving its treatment (chronic pain)

Position in innovaties ecosystem	tion	Mediators and intermediate outcomes	Socio-economic impacts
Target identification, preclinical translational medicine, clinical (early & late), patient indication definitions & stratification.		160 scientific publications (average citation 1.98 & 23.08% highly cited) New animal model Cohort database and biobank New collaborations Targets for drug development	New assay products One spin-out Significantly future drug development and socio-economic benefits possible from better treatment of chronic pain. However, depends on further investment by pharma.
Budget	IMI funding: EFPIA funding: Other funding: Total:	€6 229 343 €11 165 740 €5 155 000 €22 550 083	
Find out more	Report: page 52 Website: <u>www.in</u>	nieuropain.org	

Project factsheet: www.imi.europa.eu/content/europain

U-BIOPRED Unbiased biomarkers for the prediction of respiratory disease outcomes (severe asthma)

Position in innovation ecosystem	Mediators and intermediate outcomes	Socio-economic impacts
Early stage biomarker	15 scientific publications (average	Future impacts from development
identification (stage 1 and stage	citation 2.27 & 37.93% highly	of medicines for severe asthma
2), including lead discovery.	cited)	depend on further work building on
Pre-clinical studies (laboratory &	Understanding asthma is	U-BIOPRED findings.



animal models).		heterogeneous Molecular 'handprints' Validated pre-clinical & clinical models Samples from unbiased patient cohorts	
Budget	IMI funding: EFPIA funding: Other funding: Total:	€9 935 501 €14 574 652 €2 415 549 €26 925 702	
Find out more	Report: page 56 Website: <u>www.ubiopred.eu</u> Project factsheet: <u>www.imi.europa.eu/content/u-biopred</u> Twitter: @UBIOPRED		

SUMMIT Surrogate markers for vascular micro- and macrovascular hard endpoints for innovative diabetes tools (diabetes)

Position in innovation ecosystem		Mediators and intermediate outcomes	Socio-economic impacts
Preclinical research Clinical research	I	98 scientific publications (average citation 1.78 & 18.75% highly cited) Novel imaging techniques Development of animal models Better biomarkers Continuing collaborations	Reduction of costs and time in the drug development process, but only if new tools adopted and biomarkers validated.
Budget	IMI funding: EFPIA funding: Other funding: Total:	€14 654 559 €15 222 050 €4 905 472 €34 782 081	
Find out more	Report: page 60 Website: <u>www.imi-summit.eu</u> Project factsheet: <u>www.imi.europa.eu/content/summit</u>		



About the Innovative Medicines Initiative

The Innovative Medicines Initiative (IMI) is working to improve health by speeding up the development of, and patient access to, the next generation of 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, pharmaceutical companies, other companies active in healthcare research, small and medium-sized enterprises (SMEs), patient organisations, and medicines regulators. This approach has proven highly successful, and IMI projects are delivering exciting results that are helping to advance the development of urgently-needed new treatments in diverse areas.

IMI is a partnership between the European Union and the European pharmaceutical industry, represented by the European Federation of Pharmaceutical Industries and Associations (EFPIA). Through the IMI 2 programme, IMI has a budget of €3.3 billion for the period 2014-2024. Half of this comes from the EU's research and innovation programme, Horizon 2020. The other half comes from large companies, mostly from the pharmaceutical sector; these do not receive any EU funding, but contribute to the projects 'in kind', for example by donating their researchers' time or providing access to research facilities or resources.

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