



EUROPE'S PARTNERSHIP FOR HEALTH

Innovative Medicines Initiative
Highlights 2017

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FOREWORD

The Innovative Medicines Initiative (IMI) was founded on the principle of open innovation, which means creating a dynamic, networked, multi-stakeholder, collaborative innovation ecosystem. IMI puts open innovation into practice by building ambitious projects that bring together academics, large pharmaceutical companies, small and medium-sized enterprises (SMEs), patient groups, and medicines regulators to join forces and share resources, ideas and expertise to tackle some of the biggest challenges in medical research and drug development.

Our open innovation approach allows us to achieve results and make a difference faster and at an unprecedented scale. Most importantly, our projects are now delivering results that could not have been achieved without the public-private partnership model.

However, we are not resting on our laurels. The medical research and drug development landscape is constantly changing, and IMI must adapt accordingly. For example, digital technologies are playing an increasingly important role in research and healthcare. The research and development of innovative medicines also offers immense opportunities for Europe's vibrant community of small and medium-sized enterprises (SMEs). Patients quite rightly want and expect to be fully involved in research that ultimately affects them. The rise of innovative medicines also poses new challenges for regulators, health technology assessment bodies, and payers. At IMI, we are already responding to these trends, and we are taking steps to do even more.

Meanwhile, the IMI community continues to grow; we have now launched more than 85 projects bringing together over 11 500 scientists and experts from across Europe and beyond; together, they are working to tackle some of the biggest challenges facing society today. This brochure highlights some of the most significant results generated by our projects so far. However, the results presented here represent just a fraction of the results our projects are delivering, and I encourage you to visit our own and our projects' websites and find out more.



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Pierre Meulien

Executive Director

Brussels, Spring 2017

INTRODUCING IMI

The Innovative Medicines Initiative (IMI) was launched in 2008 with the goal of speeding up the development of safer and more effective medicines through a public-private partnership (PPP). Today, IMI has established itself as a model for open innovation, with experts from different sectors and countries working together and sharing expertise, ideas and resources. The benefits of this approach are evident from the many significant results generated by IMI's projects, which are delivering scientifically-excellent outputs that are helping to address some of the biggest health challenges facing our societies today, while also boosting the competitiveness of Europe's pharmaceutical sector.

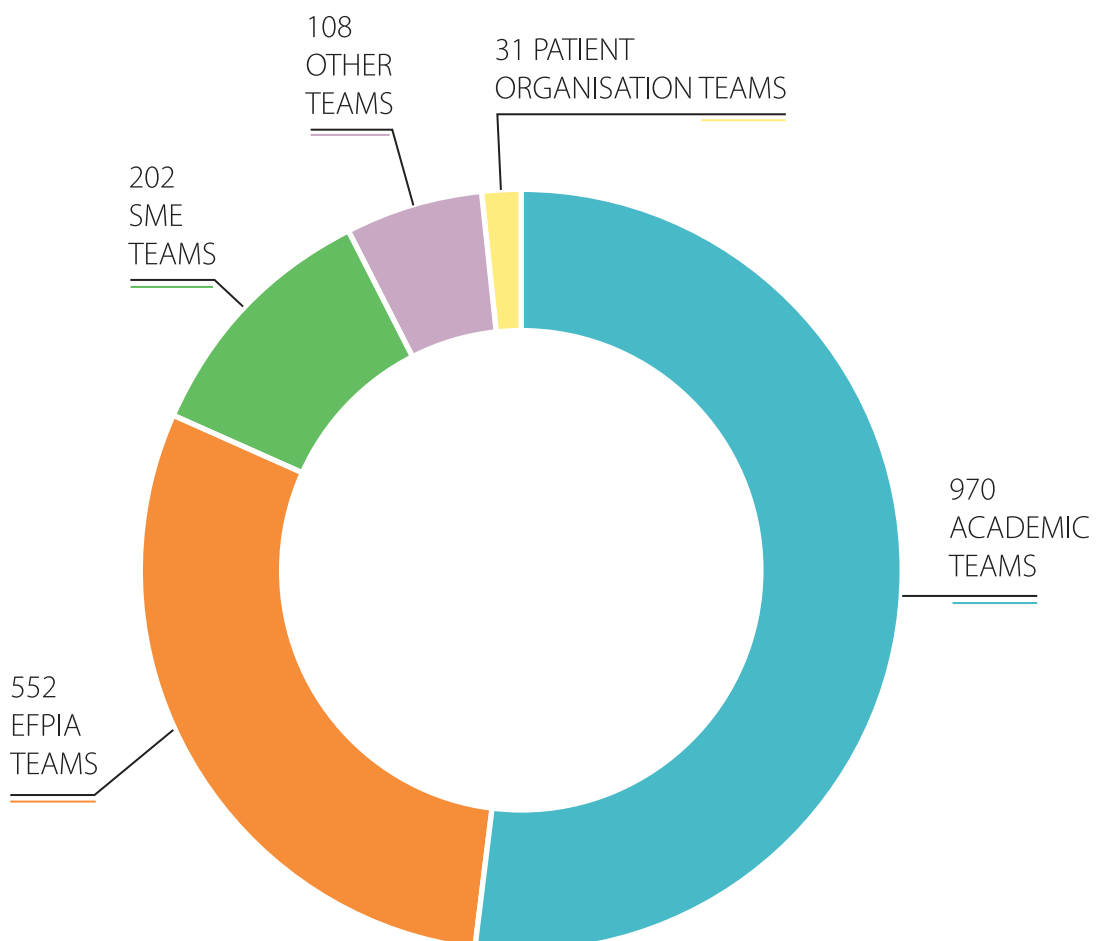
A new collaborative ecosystem

Collaboration is key to IMI's success. IMI's projects represent a community of over 9 000 researchers from academic teams, pharmaceutical companies, other large companies (e.g. in diagnostics, animal health, information technology, and imaging), SMEs, patient groups and regulators from across Europe and beyond. Through IMI, they are working together to tackle some of the biggest challenges in health

research – challenges that are simply too big for any single company, university or even country to take on alone. IMI facilitates these collaborations by acting as a neutral third party, providing impartial advice and support to all partners before, during and after the project.

Getting to grips with intellectual property

Intellectual property (IP) represents a challenging



Health priorities in the IMI Strategic Research Agenda 2014

- antimicrobial resistance
- neurodegenerative diseases
- ageing-associated diseases
- osteoarthritis
- psychiatric diseases
- cancer
- cardiovascular diseases
- respiratory diseases
- rare/orphan diseases
- diabetes
- immune-mediated diseases
- vaccines

area for collaborations involving so many diverse stakeholders. IMI's IP policy has proven effective at protecting project partners' interests while encouraging the sharing and exploitation of knowledge. The IP policy's strength lies in its flexibility; this allows it to be readily adapted to the needs of each project. Thanks to the IP policy, project partners are sharing compounds, data and knowledge with one another in an unprecedented way.

IMI's goals

IMI's goals in its second phase (IMI2: 2014-2024) are set out in the EU legislation creating the programme and are:

- improve the current drug development process by providing support for the development of tools, standards and approaches to assess efficacy, safety and quality of regulated health products;
- develop diagnostic and treatment biomarkers for diseases clearly linked to clinical relevance and approved by regulators;
- where possible, reduce the time to reach clinical proof of concept in medicine development, such as for cancer, immunological, respiratory, neurological and neurodegenerative diseases;
- increase the success rate in clinical trials of priority medicines identified by the World Health Organisation;
- develop new therapies for diseases for which there is a high unmet need, such as Alzheimer's disease and limited market incentives, such as antimicrobial resistance;
- reduce the failure rate of vaccine candidates in phase III clinical trials through new biomarkers for initial efficacy and safety checks.

2 300
jobs



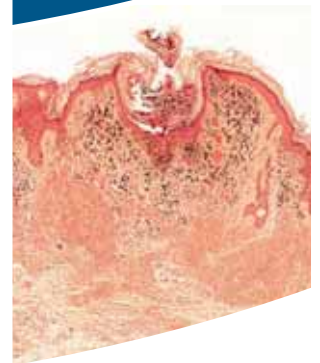
1 749
publications



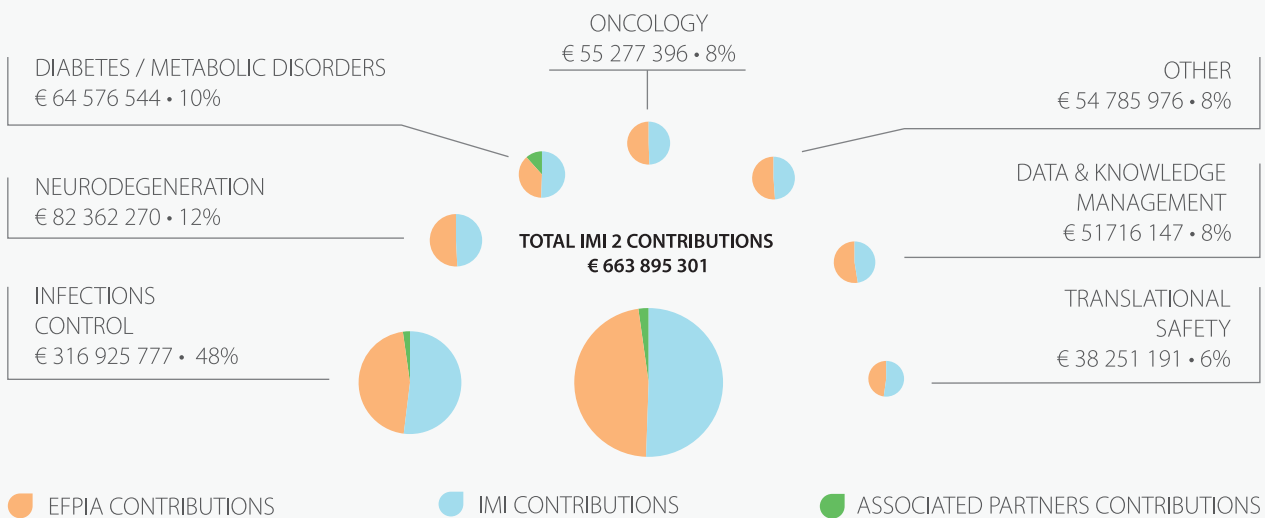
20
patent
applications



13
spin-offs



IMI 2 funding distribution per research area



Follow the money

With a total budget of over €5 billion, IMI is the world's biggest public-private partnership in health research. IMI is funded jointly by the European Union (represented by the European Commission) and the European pharmaceutical industry (represented by EFPIA, the European Federation of Pharmaceutical Industries and Associations).

For the IMI 2 programme (2014-2024), the total budget is €3.276 billion, of which:

- €1.638 billion (half the budget) comes from the Horizon 2020, the EU's framework programme for research and innovation;
- €1.425 billion is committed to the programme by EFPIA companies;
- up to €213 million can be committed by other life science industries or organisations that decide to contribute to IMI 2 as members or Associated Partners in individual projects.

For the IMI 1 programme (2008-2013), the total budget is €2 billion, of which:

- €1 billion comes from the EU's Seventh Framework Programme for Research (FP7);
- €1 billion comes from in-kind contributions by EFPIA companies.

In IMI projects, the EU funding supports the participation in its projects of organisations like universities, research organisations, patient organisations, small and medium-sized enterprises, and (under IMI 2) mid-sized companies. EFPIA companies and Associated Partners do not receive any funding through IMI, but contribute to the projects 'in kind', for example with their researchers' time, or by providing access to research facilities or resources.

IMI supports projects covering different disease areas and drug development challenges

An analysis of the IMI project portfolio reveals that over a third of the IMI budget goes to research into infectious diseases. Projects here are tackling issues such as antimicrobial resistance, Ebola, tuberculosis, and vaccine safety and efficacy. Other priorities include drug discovery (which covers projects on drug development and drug efficacy), brain disorders (including Alzheimer's disease, autism, schizophrenia, depression, and chronic pain), metabolic disorders (such as diabetes) and cancer.

The projects cover the full spectrum of drug discovery and development, from understanding the underlying causes of disease and identifying potential drugs and drug targets, through testing potential drugs for safety and efficacy, to clinical trial design, and monitoring the benefits and risks of medicines and vaccines once they are in use.

TURNING EU LEGISLATION INTO RESEARCH AND INNOVATION PROJECTS



EU legislation

Creates IMI and sets IMI objectives



IMI Strategic Research Agenda

Aligned with World Health Organization priorities



Annual research priorities

- ✓ Developed by EFPIA and other stakeholders, including European Commission
- ✓ Agreed by the IMI Governing Board
- ✓ Outlined in the IMI Annual Work Plan



Draft Call topics

- ✓ Drafted by EFPIA companies & Associated Partners
- ✓ Ideas can be suggested from external stakeholders
- ✓ Further developed through consultations with European Commission, IMI States Representatives Group, IMI Scientific Committee
- ✓ Finally approved by the IMI Governing Board



Launch of an IMI Call for proposals

- ✓ Usually includes 4 to 8 topics
- ✓ Launched on IMI website and European Commission participant portal



Submission of short proposals (stage 1)

- ✓ Applicant consortia submit short proposals
- ✓ They are made of academic organisations, SMEs, mid-sized companies, patient groups, regulators, and others
- ✓ Short proposals are evaluated by independent experts



Submission of full proposals (stage 2)

- ✓ The consortium that submitted the top-ranked short proposal is invited to join the EFPIA companies (and Associated Partners) that first drafted the topic, to develop a full proposal
- ✓ This full proposal also undergoes evaluation by independent experts



Project launch

If the full proposal receives a positive review, and the Governing Board gives its green light, the project can start

Note: Although most IMI Calls for proposals follow the two-stage approach described here, IMI also launches other types Calls for proposals (for example through a single stage procedure). The details of the process for each Call are always described in the Call documents, and potential applicants are advised to read these carefully.

COLLABORATING FOR CURES – IMI TACKLES UNMET NEEDS IN MEDICINE

Although medical research has saved countless lives over the years, there are still many diseases for which there is no cure, or where treatments are only effective in some patients. Very often, these diseases are so complex, that only a collaborative effort uniting all stakeholders involved in health research can hope to make progress, and that's where IMI comes in.

The EPAD project – pioneering a new approach to Alzheimer's clinical trials.

Dementia already affects over 47 million people globally, and as populations age, this figure is set to rise to over 131 million by 2050. The disease places a huge and growing burden on health and social care systems and on the families and carers of those affected. Yet despite decades of research, there is still neither treatment nor cure for the disease.

One important way of tackling dementia could lie in treating people while they are in the very earliest stages of the disease, when they may have little or nothing in the way of symptoms, and this is where IMI's EPAD project comes in. EPAD is pioneering a novel, more flexible approach to clinical trials of drugs designed to prevent Alzheimer's dementia.

The project achieved its first milestone in summer 2016 when it recruited the first volunteers into a major study that will add to our understanding of the earliest stages of dementia, before symptoms appear. The project is now working to recruit a total of 6 000 people from across Europe to take part in the study. Participants will have regular health checks including blood tests and brain scans. Researchers will also track their thinking skills over time using tests of mental agility. The team hopes to develop tests to identify early signs of Alzheimer's disease that may indicate when a person is at risk of dementia before symptoms appear. They will then invite these people to take part in clinical trials aimed at testing interventions that could delay, or even prevent, the onset of dementia.

By using a pioneering 'adaptive' clinical trial model,

the project will be able to test multiple treatments at the same time, and analyse the results continuously. The adaptive trial model also allows a more rapid assessment of treatments and the identification of groups of patients that respond best to them.

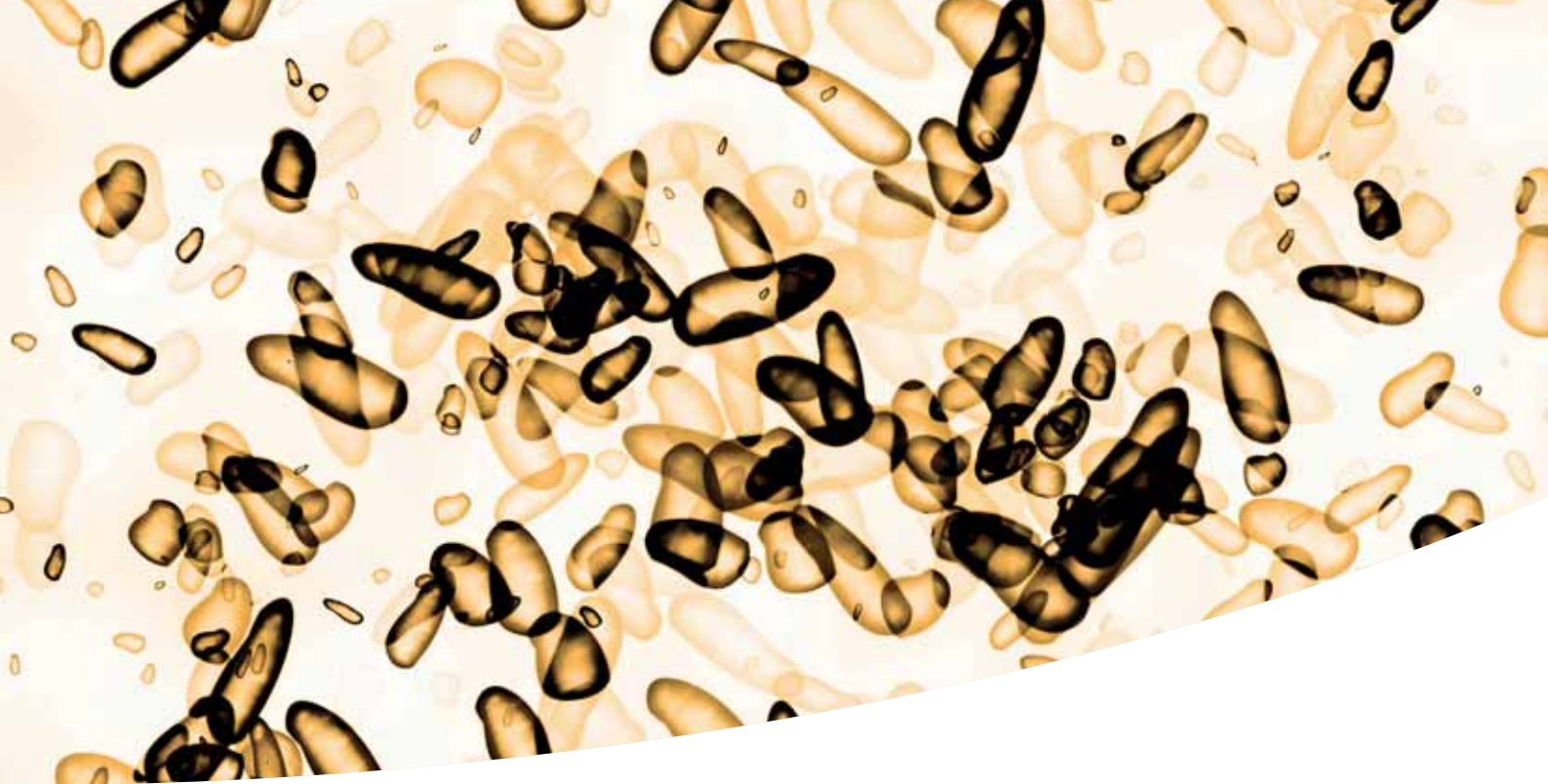
Ultimately, the hope is that EPAD, along with IMI's other dementia projects, will reinvigorate the development of treatments for one of the most challenging diseases facing our ageing societies.

New Drugs for Bad Bugs – IMI tackles the scourge of antimicrobial resistance

Antibiotic-resistant bacteria kill 25 000 people in the EU every year, and cost the economy €1.5 billion. The IMI programme New Drugs for Bad Bugs (ND4BB) 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. The programme currently comprises seven projects that are now starting to deliver on their promise of re-invigorating antibiotic research and development.

For example, the TRANSLOCATION project was set up to work out how to get antibiotics into bacteria and stop the bacteria from destroying or expelling the drugs before they can take effect. The team has developed new techniques to analyse the uptake of antibiotics by bacteria, and worked out the structure of a number of the proteins found in the membranes of bacteria that cause many infections. These proteins play a vital role transporting substances (including, potentially, antibiotics) into and out of bacterial cells.

The COMBACTE project is establishing a pan-Euro-



pean network of clinical trial sites that are ready to carry out high-quality clinical studies of new antibiotics for multi-drug resistant bacteria. By summer 2016, the project's networks counted over 750 hospitals and over 500 laboratories right across Europe. A number of clinical studies using the network are now underway. For example, the SAATELLITE study is investigating a drug called MEDI4893 that targets a toxin produced by *Staphylococcus aureus*, a bacteria often associated with hospital-associated infections and linked to resistance issues.

Another important ND4BB project is DRIVE-AB, which is tackling a contradiction at the heart of antibiotic development: on the one hand, pharmaceutical companies make money by selling large volumes of the drugs they develop. On the other hand, the use of new antibiotics should be restricted, so as to minimise the risk of bacteria developing resistance to them. As a result of this situation, sales are low and the costs of development often exceed the potential return on investment. This project is developing recommendations for new commercial models that provide industry with an incentive to invest in this area while ensuring that new antibiotics are used wisely.

Action on autism spectrum disorders

People with autism spectrum disorders (ASD) 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 autism, 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. It has also revealed that autism affects men's and women's brains differently, suggesting that researchers should not assume that findings in men with autism also apply to women. The project has also done a lot of research with babies – this is important because the earlier autism is diagnosed, the sooner treatment can start. For example, the project found that babies who move their eyes more often when looking at a picture are more likely to go on to develop ASD as children. In addition, children at risk of ASD respond differently to social cues (like 'peek-a-boo') to other babies.

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.

IMI IS MAKING THE DRUG DEVELOPMENT PROCESS MORE EFFICIENT

Currently, it takes over 10 years and costs over €1 billion to develop a new medicine, and many medicines development processes are extremely inefficient. IMI projects are helping to address these inefficiencies by delivering knowledge, tools and resources for the research community.

Capturing cancer's complexity – PREDECT models show the way

During the earlier stages of cancer drug development, researchers study cancer cells in the laboratory, for example in petri dishes. These simple, two-dimensional models of cancer are relatively cheap and easy to use, so they are still widely used in research, yet they do not accurately replicate real tumours in the body. This hinders the ability of researchers to study cancer in detail and develop new treatments. IMI's PREDECT project has developed a number of more complex, often three-dimensional models of prostate, breast and lung cancer that may more accurately mimic the behaviour of tumours in the body.

For example, the project has designed complex three-dimensional models that also include cells from the body's connective tissues which interact with the tumour. Analyses of the models reveal that these models' behaviour is much closer to that of cancer in the body. Scientists in the project are now using these models in their research.

Another group of researchers in the project is looking at improving ways of studying slices of tumours in the laboratory. Tumour slices provide a lot of information on the architecture and make-up of complex tumours. However, the act of creating a slice and keeping it alive can affect the cells' behaviour. Scientists from PREDECT have found ways to get around some of these issues to create samples that give more reliable results.

The new models, which are the result of collaboration

between scientists from small companies, universities, and large pharmaceutical companies, offer a number of advantages. Most notably, their complexity means scientists will be able to study tumours in the lab in unprecedented detail, and this will reduce their reliance on animal tests. The project has also published guidance to help researchers pick the right model for the right situation, as well as detailed guidance on how to use the models.

The European Lead Factory – reinvigorating drug discovery across Europe

A key tool in the earlier stages of drug development is a technique called High Throughput Screening (HTS), in which researchers screen large collections of chemical compounds in the hunt for molecules that could be used in their drug development programmes. Traditionally, access to pharmaceutical companies' large compound libraries was tightly restricted.

However, under the European Lead Factory, 7 companies have contributed over 300 000 of their own compounds to create a Joint European Compound Library (JECL). What's more, other organisations (primarily universities and SMEs) have created an additional 120 000 compounds for the library, meaning the project is well on track to achieving its goal of having half a million compounds in the JECL. Meanwhile analyses of the compounds already in the library show that they are very diverse and of a high quality, and the project has won an award for the system it uses to deal with intellectual property (IP) issues.



Researchers in universities and SMEs from across Europe can apply to carry out screening programmes on the JECL, using the project's state-of-the-art high throughput screening centre. By summer 2016, the project had completed over 50 screens and generated more than 3 000 hits. Feedback from users is overwhelmingly positive.

- The Netherlands Cancer Institute said that access to the European Lead Factory had fast-forwarded its oncology drug discovery work 'by several years'.
- Pharmaceutical company UCB said that access to the JECL had provided it with a list of 'highly interesting' compounds that would allow it to take a fresh look at a particularly challenging drug target.
- Scientists from the University of Oxford have filed a patent to protect compounds identified with the help of the project. The patent addresses multidrug resistance in bacterial infections.
- One university has founded a spin-out company based on the results of a screening programme.

EBiSC launches European stem cell bank – a unique resource for the research community

Most adult cells can only divide to produce other cells of the same type – for example, skin cells can only make other skin cells, and blood cells can only

make other blood cells. However, researchers are now able to reprogramme ordinary adult cells to create so-called induced pluripotent stem (iPS) cells. These cells are able to generate any kind of cell; as such, they offer researchers a good supply of different kinds of human cells that can be used in research and drug development. For example, iPS cells can be used to study disease biology, identify potential drug targets, and test drug safety and efficacy. In addition, iPS cells help to reduce the use of animals in research. For a long time, collections of iPS cells were scattered around the world, and their quality could not be guaranteed.

Now IMI's EBiSC project has created a European bank and accompanying catalogue of iPS cells that are available to academic and commercial scientists alike for use in research. The cell lines in the EBiSC catalogue were made and deposited by both EBiSC project partners and external organisations. The first batches included cells taken from people with neurodegenerative, heart, and eye diseases as well as from healthy donors. The project has already shipped lines to some users and initial feedback is positive.

According to the project partners, EBiSC is unique in establishing for the EU research community a platform for the provision at scale of standardised, high quality, research grade cell lines for disease modelling and scientific discovery purposes. Ultimately, they hope that the EBiSC iPS cell bank will become the 'go-to' resource for the characterisation, storage and distribution of high quality iPS cells.

IMI WORKS TO IMPROVE THE SAFETY OF NEW AND EXISTING TREATMENTS

Ensuring the safety of new and existing medicines and vaccines is a major issue for the healthcare sector. IMI projects are developing tests to improve the detection of toxicity issues both during drug development, and once medicines are on the market.

eTOX develops tools to detect safety issues early in drug development

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.

IMI's eTOX project is developing a suite of computer-based tools to predict toxicity that draw on existing data held in diverse databases. While some data used by eTOX is publicly available, some comes from legacy toxicity reports held by the participating pharmaceutical companies. For example, one tool

allows users 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. It also contributes to efforts to reduce animal testing.

WEB-RADR launches mobile apps for medicines safety monitoring

Even when a medicine is approved for release to the market, medicines regulators and pharmaceutical companies continue to monitor its safety. A major element of this work is the gathering of reports of 'adverse drug reactions' (ADRs), i.e. side effects that can be experienced during treatment. Today, patients experiencing ADRs report these side effects to their physician. However, paper-based report forms are not always available and are often perceived as inconvenient and complex. This reporting process is slow and inefficient, and side-effects are not detected until a sufficient volume of reports has been received.

Now IMI project WEB-RADR has launched a smartphone app that will make it easier for patients, carers and healthcare professionals to report side effects of medicines. The app, which is currently available for Croatia, the Netherlands, and the UK, allows people to quickly and simply report side effects directly to the national regulator (Croatia's Agency for Medicinal Products and Medical Devices,



HALMED; the Netherlands Pharmacovigilance Centre Lareb; and the UK Medicines and Healthcare products Regulatory Agency). The regulators can then use the information to decide if the guidelines on the use of the medicine in question need to be adapted in any way.

In addition, the app allows users to set up alerts to receive the latest information on specific medicines. All versions of the app are available in both the Apple App Store and Google Play.

By the end to the project, the WEB-RADR team plans to have a generic version of the app which will be available for adoption by Member States who wish to use the technology to supplement existing reporting mechanisms.

PROTECT helps to balance benefits and risks

All medicines come with both benefits and risks, and evaluating the balance between these is essential when making treatment decisions. However, decision-making with regards to benefit-risk assessment is often complex.

Firstly, there are many different ways of communicating benefits and risks, including via written texts and with different kinds of graphics.

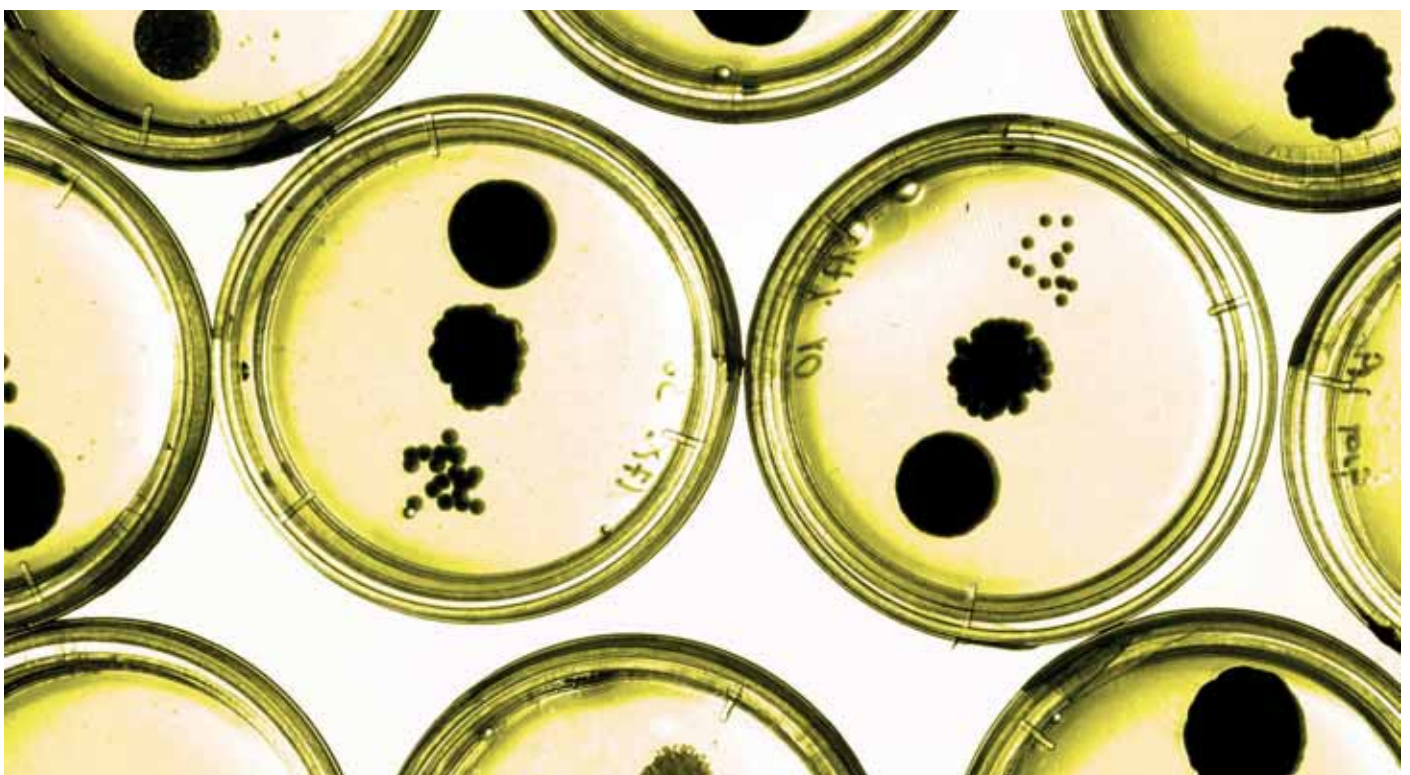
Secondly, diverse stakeholders need to be involved in

the process, including patients, healthcare providers, health technology assessors, regulators and pharmaceutical companies. It is therefore important to ensure transparent, robust and comprehensive methodologies are used, and also that patient and public preferences on benefits and risks feed into the decision-making process.

Using real life case studies, IMI's PROTECT project has studied in detail a range of different methods for assessing and visualising the benefits and risks of medicines. They have then drawn up a clear set of practical recommendations for benefit-risk decision processes and supporting tools, which the project hopes will serve as a valuable guide for people who are new to the world of benefit-risk assessment. These recommendations highlight key issues and considerations that are common to many approaches and benefit-risk decision problems.

The project has published its findings and recommendations online at protectbenefitrisk.eu and in a special issue of the scientific journal *Pharmacoepidemiology and Drug Safety*.

Although the PROTECT project has finished, its findings are being carried forward in other research projects and the recommended methods are being tested for their applicability in regulatory practice.



IMI SUPPORTS SMEs

Small and medium-sized enterprises (SMEs) are key players in the pharmaceutical research sector, and this is reflected in the large numbers of SMEs involved in IMI's projects. Taking part in an IMI project brings many benefits for SMEs, including enhanced visibility, knowledge, skills and networks.

There are around 200 SMEs in IMI's projects. The majority of these SMEs are biotech companies; of the rest, most are IT / data management companies, and a few work in project management. They account for around 15% of IMI funding beneficiaries and receive a similar percentage of IMI's budget.

Participating in IMI projects delivers a number of benefits to SMEs:

- Funding – direct financial support for innovative research and development
- Visibility – greater visibility across Europe in the academic world and pharmaceutical industry
- Knowledge – greater understanding of the drug development process in both academia and industry
- Access – enhanced access to new markets, business opportunities and funding sources
- Networking – inclusion in open innovation networks, with direct contact to leading researchers in universities and the industry
- Reputation – SMEs involved in IMI projects are known for the excellence of their research, their open innovation attitude, and their strong networks

ENABLE guides SMEs through antibiotic development

Antimicrobial resistance represents a major threat to public health, yet developing new antibiotics is extremely challenging. IMI's ENABLE project has set up 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

infections. Teams from SMEs and universities with potential antibiotics can apply to access the platform through the project's regular Calls for proposals.

Organisations that are accepted into the project benefit from the opportunity to collaborate with a diverse range of experts in microbiology, pharmacology and chemistry to help advance their molecule through the drug development process until it is an attractive candidate for clinical testing.

ENABLE also puts into practice some principles of collaboration and open innovation through an unprecedented intellectual property (IP) agreement. A key aspect of the agreement is that it allows improvements made to a molecule within the project to be assigned to the original molecule owner. At the same time, the project has mechanisms to compensate other partners that contributed to the improvements. The project therefore represents a clear opportunity to enhance in an open and transparent way the collaborative impact of pharmaceutical research, and the IP policy could prove inspirational for R&D collaborations in other disease areas.

One SME that has joined ENABLE is France-based Nosopharm. Thanks to this move, Nosopharm is advancing the development of a novel antibiotic it has created called NOSO-95179, which is designed to treat multidrug-resistant hospital-acquired infections.

IMIDIA cell line gives diabetes research a boost

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 over 400 million people worldwide, and that figure is likely to rise more than 600 million by 2040. 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.

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. In a world first, researchers from IMI's IMIDIA project 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, as it will make it easier for scientists to study beta cell function and development and develop new treatments.

French SME Endocells was at the heart of the discovery, and is now licensing it. For Endocells, participation in IMIDIA brought a number of benefits. For example, the pharmaceutical companies in the project were able to validate the applicability of the human beta cell lines.

More broadly, the Endocells team gained access to some of Europe's leading diabetes experts, and with it access to the latest scientific knowledge for the

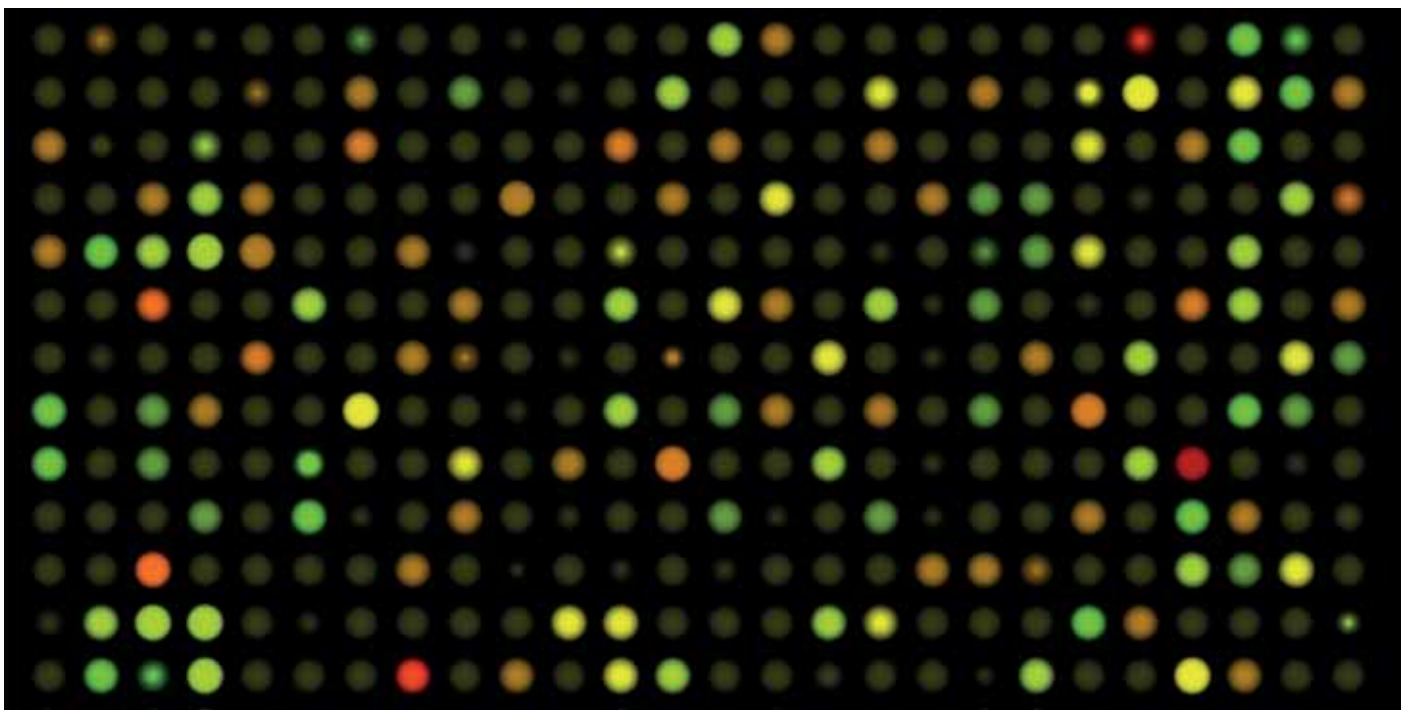
future development of new treatments for diabetes.

eTRIKS inspires a spin-off for scientific data analysis

IMI projects don't just support existing small companies – sometimes they help to create new ones! One company with roots in an IMI project is ITTM (Information Technology for Translational Medicine, S.A.), a Luxembourg-based company which was built on the knowledge and expertise gained during the eTRIKS project.

While working on eTRIKS, researchers from the University of Luxembourg realised that there is a high demand for cleaning, filtering, hosting and standardising data in the pharmaceutical sector. Those services were outside of the scope of the eTRIKS project, which mainly focuses on providing an open source platform for knowledge management.

So, the Luxembourg partners involved in the project started a new company, ITTM. The expertise gained during eTRIKS regarding curation and standardisation of data is the building block of ITTM's service offers. Furthermore, the fledgling company succeeded in getting the POST group of Luxembourg as a strategic investor. They own big, very secure data centres, which gives ITTM a very professional hosting infrastructure.



IMI INVOLVES PATIENTS IN ITS ACTIVITIES

Patients (and their families and carers) can make a vital contribution to medical research, making it more effective and more oriented to patient needs. IMI therefore champions a patient-centric approach, encouraging all the projects it supports to work in partnership with patients wherever possible.

Patients can contribute to research in diverse ways – in addition to advising projects on patients' priorities, patients can provide valuable insights and expertise on issues like study design, ethics, communications, governance, and more. IMI and its projects have developed extensive materials to help both patients and others ensure that patients are fully integrated into research.



EUPATI – educating patients in medicines research and development

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.

The project's educational toolbox on medicines R&D is online at www.eupati.eu. Designed for patients, patient groups, and anyone interested in learning more about medicines R&D, the freely-accessible toolbox includes materials covering drug discovery, clinical development, regulatory affairs, medicines safety, pharmacovigilance, and health technology assessment. The toolbox is available in seven languages: English, French, German, Spanish, Italian, Polish and Russian. It was designed by patients in collaboration with experts from other stakeholder groups such as academia and industry.

Elsewhere, the project has provided over 100 patients and patient advocates with intensive training (through online and face-to-face modules) in medicines R&D. The course graduates are now putting their new-found knowledge and skills to good use across Europe and beyond.

U-BIOPRED – putting patients at the heart of severe asthma research

Severe asthma is notoriously difficult to treat; many patients struggle to control their symptoms and

the disease seriously impacts their daily lives. The IMI project U-BIOPRED succeeded in identifying a number of subtypes of severe asthma, and this knowledge is already helping researchers from universities, pharmaceutical companies and patient groups in their search for new, more effective treatments.

Patients were involved in U-BIOPRED from the beginning, most notably via a specially-created Patient Input Platform, and their input was a key factor in the project's success. The project partners drew on their experience to compile a short, practical guide on patient engagement for people planning on applying for, or developing EU healthcare research projects. The project's advice can be summarised as follows:

- Before the project starts, get patients involved as soon as possible, budget for their involvement, and set up a patient input platform.
- During the project, provide coordination and support for patients and communicate with them regularly and clearly. Patients can provide input on all aspects of projects, especially issues

such as patient recruitment in clinical studies, and communication with wider (non-scientific) audiences.

- As projects draw to a close, patients can play a key role in gaining visibility for projects in public, patient and policy settings, and encouraging other patients to get involved in research.

Giving Alzheimer's disease patients a voice in IMI projects

Patient organisation Alzheimer Europe is an active partner in many IMI dementia projects, including PharmaCog, AETIONOMY and EPAD. In addition to providing the patient perspective on the projects' activities, Alzheimer Europe plays a key role in communicating about the projects and their successes to a wider audience, including people with dementia and their carers as well as politicians. Furthermore, Alzheimer Europe ensures that people with dementia are given advisory roles in projects – this is important because people with dementia are increasingly keen to get involved in research that could eventually impact their care.



IMI IS TRAINING THE NEXT GENERATION OF EXPERTS IN MEDICINES DEVELOPMENT

Education and training projects are developing courses and information materials to help both new and existing professionals stay abreast of the latest developments in medical and pharmaceutical research and so advance in their careers.

Advance your career with Eu2P

IMI's Eu2P project runs numerous courses covering various aspects of medicines research and development. The courses range from short, 'bite-sized' online courses to full Master's programmes and even a PhD programme. Courses are delivered primarily online, although some include face-to-face training as well. Subjects covered include pharmacovigilance, medicines benefit-risk assessments, medicines regulation, public health, and medicines risk communication. The courses were designed and are reviewed jointly by the universities, regulatory agencies, and pharmaceutical companies in the project, meaning that the content is grounded in the real world. Most importantly, the flexible nature of the courses makes them ideal for existing professionals who want to develop their skills and learn about the latest developments in pharmacovigilance while working full time.

On-course helps students find the right course

IMI's EMTRAIN project has developed on-course® (www.on-course.eu), Europe's most comprehensive biomedical and medicines research and development postgraduate course portal. The portal gathers together information on over 7 500 courses taught in more than 25 languages in 35+ countries and covering over a wide range of 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.



QUALITY COLLABORATIONS – IMI PROMOTES EXCELLENCE IN SCIENCE

An analysis of the scientific papers coming out of IMI projects reveals that IMI is delivering research of a high quality, with many projects publishing in top journals. The study, carried out for IMI by Thomson Reuters also reveals the power of collaboration, both between countries and between sectors.

- By the end of 2015, IMI projects had produced 1678 scientific papers – a 48% increase compared to the total number of papers published by the end of 2014.
- IMI research is published in some of the most prestigious journals in the world, including the New England Journal of Medicine, Nature, and the Lancet.
- IMI research has a citation impact of 1.93 - almost twice the world average (baseline of 1.0) and nearly twice the EU average (1.10).
- Around a quarter (23.5%) of IMI papers are 'highly cited', meaning they are in the top 10% of papers for that journal category and year, when ranked by number of citations received.
- On both measures, IMI research compares favourably to research funded by other well-established, high-profile medical research funding organisations.

The power of collaboration

IMI research is collaborative. More than half (58.5%) of all papers feature authors from different sectors (e.g. universities, pharmaceutical companies, small companies, patient organisations). More than half (53.3%) include authors from more than one country.

Papers with authors from multiple sectors or international co-authors have a higher citation impact than papers with authors from just one sector or one country respectively.



GET INVOLVED

IMI owes its success to the involvement in its activities of people from a wide range of sectors and countries. This page gives an overview of the different ways you can get involved in IMI. For more information on any of these options, visit the IMI website or contact the IMI Programme Office.

Become a partner in an IMI project

Any organisation carrying out work relevant to IMI's objectives can participate in an IMI project. To join a new project, you will need to form or join a consortium and apply for support in response to an open Call for proposals. Details of the Call topics, who is eligible to receive funding, and information on how to apply are published with each Call for proposals.

Join a project advisory board

Most IMI projects have a number of committees that provide advice and guidance on issues such as ethics and patient involvement. Committee members who are not also full project partners do not receive funding directly from IMI, although the project may be able to reimburse some expenses. For details of opportunities in this area, contact the projects directly.

Propose an idea for a project

Organisations can suggest ideas for IMI projects by filling in a simple form on the IMI website. Organisations that choose this option should be aware that if their idea is used in an IMI Call for proposals, they will still have to apply for funding like any other organisation.

Join IMI as an Associated Partner

Under IMI2, any legal entity (except for EFPIA companies) can become an IMI Associated Partner. Like EFPIA partners, Associated Partners do not receive funding from IMI, but contribute to the projects, mainly through in-kind contributions. Any resources they put into a project are matched by IMI, making this a good way of leveraging precious resources. As contributors to the project, Associated Partners are involved in the definition of the project.

Join EFPIA

EFPIA members (including corporate members, members of national EFPIA associations, and EFPIA 'Partners in Research') are entitled to contribute to IMI projects and see that contribution matched by EU funding. As EFPIA members, they are also fully represented on the IMI Governing Board, and can contribute to EFPIA's broader research policies.

Become an IMI member

Currently, IMI has two full members: the European Union and EFPIA. According to the legislation creating IMI2, other organisations may also apply to become full members of IMI2 (with all the rights and responsibilities that membership entails).

MEET IMI'S PROJECTS

INFECTIOUS DISEASES

New Drugs for Bad Bugs programme (antimicrobial resistance)

COMBACTE	Combatting bacterial resistance in Europe	www.combacte.com
COMBACTE-CARE	Combatting bacterial resistance in Europe - carbapenem resistance	www.combacte.com/combacte-care
COMBACTE-MAGNET	Combatting bacterial resistance in Europe - molecules against gram negative infections	www.combacte.com/combacte-magnet
DRIVE-AB	Driving re-investment in R&D and responsible antibiotic use	www.drive-ab.eu
ENABLE	European Gram negative antibacterial engine	www.nd4bb-enable.eu
iABC Programme	IABC programme	www.qub.ac.uk/sites/iABC
Translocation	Molecular basis of the outer membrane permeability	www.nd4bb.eu

Ebola+ programme (Ebola and related diseases)

EBODAC	Communication strategy and tools for optimizing the impact of Ebola vaccination deployment.	www.ebovac.org/ebodac
EbolaMoDRAD	Ebola virus: modern approaches for developing bedside rapid diagnostics	www.ebolamodrad.eu
EBOMAN	Manufacturing and development for rapid access Ebola vaccine	www.ebovac.org/eboman
EBOVAC1	Development of a prophylactic Ebola vaccine using an heterologous prime-boost regimen	www.ebovac.org
EBOVAC2	Development of a prophylactic Ebola vaccine using an heterologous prime-boost regimen: phase II	www.ebovac2.com
FILODIAG	Ultra-fast molecular filovirus diagnostics	www.filodiag.eu
Mofna	Mobile filovirus nucleic acid test	www.imi.europa.eu/content/mofna
VSV-EBOVAC	Vaccine safety and immunogenicity signatures of human responses to VSV-ZEBOV	www.vsv-ebovac.eu

Vaccines

ADVANCE	Accelerated development of vaccine benefit-risk collaboration in Europe	www.advance-vaccines.eu
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BioVacSafe	Biomarkers for enhanced vaccine safety	www.biovacsafe.eu
FLUCOP	Standardization and development of assays for assessment of influenza vaccines correlates of protection	www.flucop.eu
PERISCOPE	Pertussis correlates of protection Europe	www.periscope-project.eu
VAC2VAC	Vaccine lot to vaccine lot comparison by consistency testing	www.vac2vac.eu
ZAPI	Zoonotic anticipation and preparedness initiative	www.zapi-imi.eu

Other infectious disease projects

PreDiCT-TB	Model-based preclinical development of anti-tuberculosis drug combinations	www.predict-tb.eu
RAPP-ID	Development of rapid point-of-care test platforms for infectious diseases	www.rapp-id.eu
RESCEU	Respiratory syncytial virus consortium in Europe	resc-eu.org

DISEASES OF THE BRAIN AND CENTRAL NERVOUS SYSTEM

Dementia

ADAPTED	Alzheimer's disease apolipoprotein pathology for treatment elucidation and development	www.imi-adapted.eu
AETIONOMY	Organising mechanistic knowledge about neurodegenerative diseases for the improvement of drug development and therapy	www.aetionomy.eu
AMYPAD	Amyloid imaging to prevent Alzheimer's disease	www.amypad.eu
EMIF	European medical information framework	www.emif.eu
EPAD	European prevention of Alzheimer's dementia consortium	www.ep-ad.org
MOPEAD	Models of patient engagement for Alzheimer's disease	www.mopead.eu

PHAGO	Inflammation and AD: modulating microglia function - focussing on TREM2 and CD33	www.phago.eu
PHARMA-COG	Prediction of cognitive properties of new drug candidates for neurodegenerative diseases in the early clinical development	www.pharmacog.eu
PRISM	Psychiatric ratings using intermediate stratified markers: providing quantitative biological measures to facilitate the discovery and development of new treatments for social and cognitive deficits in AD, SZ, and MD	www.prism-project.eu

Other brain / central nervous system disorders

EU-AIMS	European autism interventions - a multicentre study for developing new medications	www.eu-aims.eu
EUROPAIN	Understanding chronic pain and improving its treatment	www.imieuropain.org
NEWMEDS	Novel methods leading to new medications in depression and schizophrenia	www.newmeds-europe.com
RADAR-CNS	Remote assessment of disease and relapse in central nervous system disorders	www.radar-cns.org

DIABETES

BEAt-DKD	Biomarker enterprise to attack DKD	
DIRECT	Diabetes research on patient stratification	www.direct-diabetes.org
EMIF	European medical information framework	www.emif.eu
IMIDIA	Improving beta-cell function and identification of diagnostic biomarkers for treatment monitoring in diabetes	www.imidia.org
INNODIA	Translational approaches to disease modifying therapy of type 1 diabetes: an innovative approach towards understanding and arresting type 1 diabetes.	www.nnodia.eu

RHAPSODY	Assessing risk and progression of pre-diabetes and type 2 diabetes to enable disease modification	www.imi-rhapsody.eu
SUMMIT	Surrogate markers for vascular micro- and macrovascular hard endpoints for innovative diabetes tools	www.imi-summit.eu

CANCER

CANCER-ID	Cancer treatment and monitoring through identification of circulating tumour cells and tumour related nucleic acids in blood	www.cancer-id.eu
OncoTrack	Methods for systematic next generation oncology biomarker development	www.oncotrack.eu
PREDECT	New models for preclinical evaluation of drug efficacy in common solid tumours	www.preduct.eu
QUIC-CONCEPT	Quantitative imaging in cancer: connecting cellular processes with therapy	www.quic-concept.eu

RESPIRATORY DISEASE

PRO- Active	Physical activity as a crucial patient reported outcome in COPD	www.imi.europa.eu/content/pro-active
U-BIOPRED	Unbiased biomarkers for the prediction of respiratory disease outcomes	www.ubiopred.eu

INFLAMMATORY AUTOIMMUNE DISEASE

BTCURE	Be the cure	www.btcure.eu
PRECISESADS	Molecular reclassification to find clinically useful biomarkers for systemic autoimmune diseases	www.precisesads.eu

FRAILITY

SPRINTT	Sarcopenia and physical frailty in older people: multi-component treatment strategies	www.mysprintt.eu
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OSTEOARTHRITIS

APPROACH	Applied public-private research enabling osteoarthritis clinical headway	www.approachproject.eu
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TOOLS, RESOURCES AND KNOWLEDGE FOR DRUG DISCOVERY AND DEVELOPMENT

Compact	Collaboration on the optimisation of macromolecular pharmaceutical access to cellular targets	www.compact-research.org
K4DD	Kinetics for drug discovery	www.k4dd.eu
OrBiTo	Oral biopharmaceutics tools	www.orbitoproject.eu
ELF	European lead factory	www.europeanleadfactory.eu
ULTRA-DD	Unrestricted leveraging of targets for research advancement and drug discovery	www.ultra-dd.org
StemBANCC	Stem cells for biological assays of novel drugs and predictive toxicology	www.stembancc.org
EBISC	European bank for induced pluripotent stem cells	www.ebisc.org

MEDICINES SAFETY

eTOX	Integrating bioinformatics and cheminformatics approaches for the development of expert systems allowing the in silico prediction of toxicities	www.etoxproject.eu
MARCAR	Biomarkers and molecular tumor classification for non-genotoxic carcinogenesis	www.imi-marcar.eu

SAFE-T	Safer and faster evidence-based translation	www.imi-safe-t.eu
ABIRISK	Anti-biopharmaceutical immunization: prediction and analysis of clinical relevance to minimize the risk	www.abirisk.eu
MIP-DILI	Mechanism-based integrated systems for the prediction of drug-induced liver injury	www.mip-dili.eu
TransQST	Translational quantitative systems toxicology to improve the understanding of the safety of medicines	transqst.org

REGULATORY ISSUES AND HEALTH TECHNOLOGY ASSESSMENT

PROTECT	Pharmacoepidemiological research on outcomes of therapeutics by a European consortium	www.imi-protect.eu
ADAPT-SMART	Accelerated development of appropriate patient therapies: a sustainable, multi-stakeholder approach from research to treatment-outcomes	www.adaptsmart.eu
PREFER	Patient preferences in benefit-risk assessments during the drug life cycle	www.imi-prefer.eu
WEB-RADR	Recognising adverse drug reactions	www.web-radr.eu
GetReal	Incorporating real-life clinical data into drug development	www.imi-getreal.eu

KNOWLEDGE MANAGEMENT

DDMoRe	Drug disease model resources	www.ddmore.eu
EHR4CR	Electronic health record systems for clinical research	www.ehr4cr.eu
Open PHACTS	The open pharmacological concepts triple store	www.openphacts.org
eTRIKS	Delivering European translational information & knowledge management services	www.etricks.org
EMIF	European medical information framework	www.emif.eu

Big Data for Better Outcomes programme

ROADMAP	Real world outcomes across the AD spectrum for better care: multi-modal data access platform	www.roadmap-alzheimer.org
HARMONY	Healthcare alliance for resourceful medicines offensive against neoplasms in hematology	
DO->IT	Big data for better outcomes, policy innovation and healthcare system transformation	

ENVIRONMENTAL IMPACTS

CHEM21	Chemical manufacturing methods for the 21st century pharmaceutical industries	www.chem21.eu
iPiE	Intelligent assessment of pharmaceutical in the environment	www.i-pie.org

EDUCATION AND TRAINING

EMTRAIN	European medicines research training network	www.emtrain.eu
EU2P	European programme in pharmacovigilance and pharmacoepidemiology	www.eu2p.org
PharmaTrain	Pharmaceutical medicine training programme	www.pharmatrain.eu
SafeSciMET	European modular education and training programme in safety sciences for medicines	www.safescimet.eu
EUPATI	European patients' academy on therapeutic innovation	www.patientsacademy.eu

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