Connecting people, sharing know-how, speeding up health research

Join the partnership

Innovative Medicines Initiative
Discover how patients, academic teams and small and large companies innovate through collaborative networks in IMI projects.

Stay informed of IMI Calls, activities and project achievements: subscribe to the IMI Newsletter on www.imi.europa.eu
Ongoing IMI projects are delivering impressive results, as demonstrated by the examples in this brochure, and new, large-scale projects are in the pipeline. By supporting the exchange of knowledge and expertise among companies and between public and private partners, IMI is leading to achievements that would previously not have been possible. The ultimate goal is to speed up the development of safer and more effective medicines for patients.

As IMI’s innovative and ambitious projects are proving successful, the initiative is increasingly attracting interest from researchers and organisations outside the EU as well.

“By fostering collaboration between large companies and public partners, IMI is driving the innovation which is urgently needed to deliver safer and better medicines for patients. The scientific achievements of ongoing IMI projects demonstrate that this new model for pharmaceutical R&D is the way forward.”

Michel Goldman
IMI Executive Director

For patients’ organisations and for researchers in universities and small and medium-sized enterprises (SMEs), IMI offers unique opportunities: participants in IMI projects gain access to knowledge and expertise from industry partners, and collaboration increases their international visibility. The involvement of regulatory agencies in IMI projects enhances translation of research results into better treatments for patients.

Delivering pharmaceutical research through public-private partnerships

Ongoing IMI projects are delivering impressive results, as demonstrated by the examples in this brochure, and new, large-scale projects are in the pipeline. By supporting the exchange of knowledge and expertise among companies and between public and private partners, IMI is leading to achievements that would previously not have been possible. The ultimate goal is to speed up the development of safer and more effective medicines for patients.

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With its €2 billion budget, the Innovative Medicines Initiative (IMI) is the world’s largest public-private partnership in health research and development (R&D). IMI is a joint undertaking between the European Union (EU) and the European Federation of Pharmaceutical Industries and Associations (EFPIA). The EU contributes €1 billion in cash through its Seventh Framework Programme (FP7/2007-2013). EFPIA companies contribute €1 billion in kind to the IMI projects.
The projects that have been launched by the Innovative Medicines Initiative (IMI) are generating significant results, in areas such as schizophrenia, asthma, cancer, diabetes, chronic pain, lung disease and drug safety. The achievements featured in this brochure confirm that IMI is on track to achieving its goals: creating new insights that help move drug development forward by pooling knowledge and expertise from public and private partners.

The IMI Education & Training projects have set up training courses and information platforms for students and scientists that wish to develop their career in the area of drug safety, pre-clinical testing or any other aspect of drug discovery and development. This allows industry and other research organisations to recruit better trained scientists (see page 13 of this brochure).

Small and medium-sized enterprises are well-represented and play an essential role in many IMI project consortia. Examples (page 11) show how the collaboration with industry helps them to translate their findings into useful applications. In addition, the visibility they gain in the project consortia could lead to other interesting partnerships.

Patients and patients’ organisations are also successfully involved in many IMI projects, as key partners for the development of more effective and safer drugs. Patients provide important information about their condition and its impact on their daily lives, and they can contribute to, for instance, the development of personalised medicine.

Over 200 publications in scientific journals have resulted from IMI projects and more are added every month. A detailed list is available at: www.imi.europa.eu/content/scientific-publications.

IMI projects are generating impressive results

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IMI is currently funding 37 projects, involving about 3500 participants, including:
- 346 R&D teams from EFPIA companies;
- 509 academic teams;
- 91 teams from small and medium-sized enterprises;
- 20 patients’ organisations;
- 8 regulatory agencies

For a detailed and updated overview of projects, see: www.imi.europa.eu/content/ongoing-projects

“IMI allows us to galvanise Europe’s large pharmaceutical companies around important health issues to an extent which is impossible to achieve with traditional EU research funding. It creates a real win-win situation for everybody, including also regulators, patients’ organisations, small and medium-sized enterprises, and academic researchers.”

Ruxandra Draghia-Akli
Director, Directorate Health,
DG Research and Innovation,
European Commission
Roch Doliveux
Chair of the IMI Governing Board,
CEO of UCB

Schizophrenia drug trials require less time and more women
The length of clinical trials (usually six weeks) in which patients on active treatment are compared to patients taking a placebo (a mock treatment) could be shortened by one or two weeks, according to research from the IMI project NEWMEDS. In addition, more women should be included in trials, as women appear to respond less to placebos than men, yet less than a third of the participants in the trials studied were female. The new insights would not have been possible without the collaboration between the companies involved in the NEWMEDS project, who have pooled their data to create the largest known database of studies on schizophrenia, including information on over 23,000 patients from 67 studies in over 25 countries.

The database offers the industry and the academic community unique opportunities for the development of tools and models that will help find targeted treatments for schizophrenia. An analysis of this data also revealed that so-called negative schizophrenia symptoms could respond better in these studies than was previously thought. Schizophrenia patients are said to have negative symptoms when they lack behaviors that are found in healthy people. For example, people with schizophrenia may appear to lack emotion or the ability to feel pleasure or act spontaneously. The NEWMEDS consortium discovered that around half of all patients who complete six weeks of treatment with second generation antipsychotic drugs have no pronounced negative symptoms anymore - an effect that has been largely overlooked before.

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Linking knowledge in a (tran)smart way
Knowledge management is key to the success of many IMI projects, and the tranSMART system is lifting it to a higher level. TranSMART is a translational medicine platform based on open source software and data. It helps researchers to link together previously separate and incompatible data sets from clinical trials, preclinical tests and other sources. This integration enables much wider searches and analysis of medical data, leading to new insights in drug development. TranSMART was originally developed by Johnson & Johnson for its own projects. However, it quickly became clear that the system could be extremely useful for other groups. The first IMI project to use tranSMART was U-BIOPRED, which is using it to collate its own data on asthma with those on chronic obstructive pulmonary disease (COPD) from four different companies. The partners can access the data and use it to test new hypotheses. Other ongoing projects that are implementing tranSMART are OncoTrack, SAFE-T and BTCure, and other projects are also planning to use the system. The knowledge management project eTRIKS will support efforts to take tranSMART to the next level.

Reinvigorating Europe’s pharmaceutical industry

“Most experts agree that the complexity of the new science is so big, the amount of data that exists is so vast, the opportunities are so large, that no company or academic can harness the power of new technologies and information on their own. The time is now for academia and industry to join forces and unleash the creative potential in Europe, in order to harness new technology and discover new platforms that enable new medicines, to be invented for the benefit of the ageing European population.”

Watch the video of Roch Doliveux on IMI at: www.youtube.com/watch?v=O6hFPhuHuc

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Empowering patients to become partners in pharmaceutical R&D

In a number of IMI projects, patients are helping to move research forward by providing information and updates about their condition. In other projects, the presence of patients’ organisations in the project consortium ensures that patients’ voices are heard.

Patients’ perceptions of COPD

Patients are directly involved in the IMI project PROactive, which has made significant progress to better gauge the impacts of chronic obstructive pulmonary disease (COPD) on patients’ physical activity - the first step towards optimal management of the disease. The inability to be physically active is one of the main complaints of patients, but was so far difficult to capture. Interviews with patients revealed what they consider important to overall quality of life: the amount of physical activity (e.g. how far someone can walk), the symptoms triggered by the activity (e.g. shortness of breath) and the way the patient has to adapt his activities (e.g. stopping to rest). Tests in larger groups of patients revealed that two aspects suffice to capture physical activity: 1) the amount and 2) the difficulty. The PROactive team is now creating a tool that combines questions on these aspects with input from activity monitors (small external devices that are worn by the patient and that measure activity levels).

Understanding severe asthma

The U-BIOPRED consortium is recruiting up to 1,000 people in a major pan-European new study of severe asthma, a chronic and potentially life-threatening condition. U-BIOPRED researchers draw on data related to blood, airway tissue, lung function, CT-scans, the nose and exhaled air, plus reports of patients’ own experiences, to build up a detailed picture of each individual’s condition. By comparing data from hundreds of adults and children, the team is developing and validating methods to characterise different kinds of severe asthma, paving the way towards personalised treatments for patients - an undertaking that would be impossible for any research team on its own. The consortium has already produced an international consensus statement for the diagnosis and definition of severe asthma, which represents a key step towards the development of innovative patient-tailored therapies. Patients’ input has proven important, particularly in decisions on ethical matters in clinical trials.

Empowering patients

The patient-led initiative EUPATI is developing the first European Patients’ Academy on Therapeutic Innovation, which will empower patients and patients’ organisations to engage and to become true partners, effective advocates and advisors in medicines research. The Patients’ Academy will produce comprehensive, scientifically reliable and user-friendly educational material and an online public library for patients on medicines development. Well-informed patients are better placed to make decisions about their participation in R&D, and they can help to put patients’ needs at the heart of drug development, for example by joining scientific, ethical and regulatory committees or getting involved in clinical trial design. The consortium includes patients’ organisations, academic groups, non-governmental organisations (NGOs) and pharmaceutical companies. Through the project’s multilingual website www.patientsacademy.eu, interested parties can become members of the EUPATI Network. The project started in February 2012 and is reviewing pre-existing educational resources to better understand unmet needs and best practice. The Patients’ Academy’s first public workshop for patient organisations and other stakeholders, as well as a first focus group meeting to better understand the educational needs of patient advocates, was held in September 2012.

“IMI is giving patients a more active role in drug development, by involving them in projects that rely on patients reporting on their conditions, and through collaborations with patients’ organisations. IMI also offers training and information that empowers patients to engage more effectively in the development and approval of new treatments and to become true partners in pharmaceutical R&D.”
“The progress made by the IMIDIA consortium has been substantial. The consortium partners have used our beta-cell lines to better understand beta-cells, which represents breakthrough knowledge towards a cure for diabetes. Thanks to this collaboration, the robustness of our beta-cells has been validated by large pharma companies - a major advantage for a biotechnology company like Endocells. The collaboration has stimulated work for the combination of novel technologies and the development of new expertise, which is critical to move forward towards a cure for diabetes.”

Anne-Fabienne Weitsch
CEO of Endocells, participant in the IMIDIA project

Predicting side-effects of drugs early in development

The eTOX consortium is developing innovative computer models that predict if a candidate-drug would be likely to cause organ toxicities which might result in adverse events in patients. Amongst them, one such model aims at predicting cardiac toxicity. Currently, many promising drug candidates fail because they turn out to be toxic to the heart. The new eTOX system should help researchers identify drug safety problems earlier in the drug development process. The tool, called eTOXsys is expected to significantly improve the current state of the art for predicting drug toxicity. Users will simply need to enter a small amount of information, such as the structure of the compound, and the system will deliver information on the likelihood of toxicity of the compound. The system’s prediction is built on databases from public sources as well as legacy toxicity reports held by participating pharmaceutical companies, that were brought together for the first time in the frame of the project. The four SMEs in the eTOX consortium are contributing scientific excellence and state of the art technologies in biochemico-informatics which are key to the success of eTOX.

Better treatments for Alzheimer’s disease

Over seven million Europeans suffer from Alzheimer’s disease and there are few effective treatments available. The PharmaCog consortium is developing methods to enable identification of the most promising drugs earlier in the development process. PharmaCog researchers have demonstrated that sleep deprivation in human volunteers can induce cognitive impairment similar to that of patients with Alzheimer’s and could represent a model in which to test candidate drugs. Studies are being extended to include trans-cranial electrical stimulation as a second clinical model of cognitive impairment. In addition, the PharmaCog consortium has reported progress in developing non-invasive cost-effective and patient-friendly methods for measuring the progress of Alzheimer’s disease.

Several SMEs participating in the consortium, as well as clinicians and pharmaceutical companies, are developing innovative blood biomarkers for Alzheimer’s disease. Building essential collaborative links with academia and large companies, SMEs benefit from in kind resources from industry partners for both preclinical and clinical studies. They also have access to information on behavioral, anatomical and physiological characterization of the disease.

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- 91 SME teams are involved
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New tools for diabetes research and treatment

The IMIDIA consortium has achieved a major breakthrough in diabetes research. Researchers from academic institutions (INSERM, CNRS) together with the biotech company Endocells have generated the first human pancreatic beta-cell line. The cells behave functionally in much the same way as beta-cells in the human body, secreting insulin in response to high glucose levels. These important findings have been verified in a close collaboration between academic partners, Endocells and pharma partners within IMIDIA. As beta-cells in the pancreas play a key role in diabetes, these validated human beta-cell lines represent an invaluable new tool that was so far missing in diabetes research. The cell lines can now be used to develop new therapeutic approaches and will help to further improve disease management in diabetes. Within IMIDIA, diabetes researchers from academia and industry together with scientists from Imperial College London have identified a gene that disrupts insulin secretion in individuals with a rare form of type 2 diabetes called maturity onset diabetes of the young (MODY). The gene produces a protein called PASK (PAS kinase), which IMIDIA scientists have shown plays a key role in insulin secretion in humans. The discovery may have implications for diabetes treatment.

SMEs make their mark in IMI projects

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“The four SafeSciMet courses that I attended broadened my perspective from political science to life science and gave me a comprehensive overview of a drug's life cycle. I enjoyed the hands-on approach and the various stakeholders’ perspectives covered. With two other alumni, I published a commentary on our course assignment in the European Journal of Pharmaceutical Sciences. The courses and the people I met increased my insight of the pharmaceutical industry, which helped me to move from the Romanian Academic Society think tank to Pfizer’s Regional Public Policy Team in Brussels.”

IMI projects have developed and launched new training programmes, information platforms and quality standards in the area of pharmaceutical education and training.

The project SafeSciMET has launched a pan-European education and training programme on medicines safety. SafeSciMET’s 20 newly designed courses focus on holistic, integrative, and translational aspects of pre-clinical to clinical drug development, which are largely lacking in today’s educational programmes. Courses feature lectures by experts from both academia and industry, including case studies from industry. SafeSciMET’s modular structure allows scientists to select courses for their continued professional development. Completing the full programme leads to an Advanced Master’s degree in Safety Sciences. Feedback from the first course cycle in 2011 and 2012 has been very positive. Participants commented: ‘The course has exceeded my expectations’, and ‘I was very pleased with the structure, the content, and the quality of the presentations and the preparedness of the presenters’.

In the area of Medicines Development, the project PharmaTrain is bringing newly-created as well as existing Diploma (Base) Courses, Master Programmes and Continuous Professional Development courses to a European quality level. Such high-level training, based on the PharmaTrain Shared Standards in Medicines Development in Europe, will make the drug development process faster, more economical, more tailored to patients’ needs, and will give Europe a global advantage in developing new innovative medicines. The programme builds on the new and internationally recognised PharmaTrain Syllabus 2010 of the PharmaTrain Federation and will create a pan-European, collaborative network for comprehensive postgraduate training.

The Eu2P project has launched its online interactive PhD programme as well as Certificate and Master’s courses in pharmacovigilance and pharmacoepidemiology. The courses are delivered online and qualifications are awarded jointly by the academic partners in the project. The Eu2P courses address training needs, for both life science specialists and non-specialists. They are developed by a unique faculty of highly qualified professionals in these disciplines, who have combined experience from academia, industry and regulatory agencies.

IMI Education & Training project EMTRAIN has launched on-course® – Europe’s most comprehensive biomedical and medicines research and development postgraduate course portal. The portal is free and easy to use and offers information on over 4,000 courses taught in 20 languages in 39 countries and covering over 60 scientific and therapeutic areas. There is also an on-course® app, which can be downloaded to smartphones for free from Google Play (for Android phones) or the AppStore (for Apple products).

In addition, EMTRAIN, on behalf of all of IMI’s Education & Training (E&T) projects, has become an affiliate of the European Association for Quality Assurance in Higher Education (ENQA), a pan-European body that aims to contribute to the maintenance and enhancement of the quality of European higher education.
IMI projects offer a unique opportunity to researchers in universities and other non-profit research organisations to join forces with leading teams in the private sector. The success of this collaborative model is demonstrated by the achievements of all IMI projects, including the ones below.

Better understanding chronic pain
Chronic pain affects one in five European citizens and adequate treatments are often lacking. The EUROPAIN consortium has revealed important findings that contribute to a better understanding of the mechanisms of chronic pain. For instance, the scientists discovered similarity between pain caused by chemotherapy and the cold-induced pain caused by concentrated menthol. They have also identified a molecule that causes the pain of sunburn, raising hopes for the development of a molecule that causes the pain of sunburn, raising hopes for the development of drugs. MARCAR's development of early-stage and non-invasive tumor imaging data to identify non-invasive imaging markers of complications in blood vessels of cancer (non-genotoxic carcinogenesis). The detection of these so-called epigenetic changes can be used as early biological indicators (biomarkers) to predict if drugs in development are likely to cause unwanted effects (cancer) in patients. The findings will therefore contribute to a better assessment of the safety of candidate drugs.

Unique opportunities for academic teams

**Making research data more accessible**

The Open PHACTS consortium has developed an open and freely accessible web platform, an "Open Pharmacologcal Space", which will allow scientists to analyze diverse databases from both public and private sources in their hunt for new drugs and drug targets. A test version of this novel data mining tool is ready and has proven its worth, identifying relevant information (for instance, finding compounds that block a given drug target) in just seconds, while a traditional human search took days. The work has resulted in over 20 scientific publications providing solutions to major challenges in interconnecting and analyzing pharmacology data. The tool builds on the new concept of nanopublication, which is defined by Open PHACTS as the smallest unit of publishable information. With its nanopublication guidelines, Open PHACTS is promoting and adding to existing open standards, and demonstrates their use in a large scale, real world application. The platform has been presented at scientific conferences and will be open and publicly released in autumn 2012.

**Predicting complications of diabetes**

The SUMMIT consortium is developing methods to identify risk factors for chronic complications in diabetes patients. Diabetic complications, leading to stroke or problems with the heart, kidneys and eyes, impose an immense burden on the quality of life of the patients and account for more than 10% of health care costs in Europe. Together with other initiatives, SUMMIT has generated the largest data collection of genomic studies (Genome Wide Association Studies) up to date, including over 26 000 individuals with or without vascular or kidney complications of type 1 and type 2 diabetes. It will help the scientists to identify genetic factors that increase the risk of diabetic complications. A series of studies examining potential metabolic markers or indicators of vascular complications of diabetes is near completion. SUMMIT combines genomics, biomarkers and imaging data to identify non-invasive imaging markers of complications in blood vessels of carotid (large artery in neck and chest) examinations. For visualizing the high-risk atherosclerotic plaques (rich in fat deposits and inflammation) the consortium has developed a non-invasive ultrasound based technology, SUMMIT has construct-ed computer models that will help to predict complications and responses to treatment, on the basis of changes in the body.

**A new way of tracking tumor development**

The MARCAR consortium has developed and proved the effectiveness of methods that help identify chemical changes in the genetic material (chromosomes) that are related to cancer (non-genotoxic carcinogenesis). The detection of these so-called epigenetic changes can be used as early biological indicators (biomarkers) to predict if drugs in development are likely to cause unwanted effects (cancer) in patients. The findings will therefore contribute to a better assessment of the safety of candidate drugs.

In addition, MARCAR has demonstrated that magnetic resonance imaging (MRI) can be used to reliably detect liver tumors in mice when they are just 1 mm across - previously more invasive techniques were required to pick up tumors of this size. As MRIs are non-invasive, they can be repeated at different stages of the study, meaning that fewer animals are needed to obtain reliable results. The fact that MRIs can be used to detect tumors at an early stage and to monitor their reversibility makes them an invaluable tool in assessing the cancer risk of potential drugs. MARCAR's development of early biomarkers and non-invasive tumor imaging methods should ultimately help reduce the need for long-term experiments in animals.
The mission of the European Medicines Agency (EMA) is to promote public health by protecting patients against ineffective or unsafe drugs, and by supporting the research community in bringing better and safer drugs to patients. EMA is an active partner in the IMI projects where our missions align, giving due consideration to an appropriate relationship between regulator and regulated industry. Our experience confirms that the PPP model effectively supports the development, licensing and monitoring of tomorrow’s drugs, in the best interest of patients.

Regulatory authorities involved in IMI projects receive advanced information on tools and methodologies under development. This enables them to provide feedback and recommendations in real time and to anticipate and optimise the approval process.

Through their participation in IMI consortia, they gain insight into the operational strategies and corporate cultures of both industrial and academic project partners.

Strengthening the monitoring of the safety of medicines

An excellent example is the PROTECT project, which is coordinated by the European Medicines Agency. The goal of PROTECT is to strengthen the monitoring of the benefit-risk of medicines in Europe. This will be achieved by developing a set of innovative tools and methods that enhance the early detection and assessment of adverse drug reactions from different data sources, and enable the integration and presentation of data on benefits and risks. These methods are tested in real-life situations in order to provide patients, prescribers, public health authorities, regulators and pharmaceutical companies with accurate and useful information supporting risk management. The participation of several regulatory agencies in PROTECT facilitates the implementation of the new methodology in the standard procedure for risk-benefit analysis by the regulatory agencies and the communication of the results to the public.

The following are two examples of publicly available outcomes. An inventory on databases of drug utilisation in Europe has been compiled from 11 countries. This inventory is useful for researchers and is now used within PROTECT to study the population exposed to selected drugs of interest. A database of all adverse drug reactions listed in the product information of medicines authorised at the European level has been created. It facilitates the detection of possible drug safety issues in spontaneous reports of adverse drug reactions received from patients and health care professionals.

Detecting drug side effects at an earlier stage

The SAFE-T consortium has enrolled patients in major studies that aim to boost scientists’ ability to determine whether or not a potential drug will be toxic to the kidney, liver or vascular system. Drug-induced toxicity is a serious problem in drug development and for treatment of patients. The SAFE-T scientists are testing the potential of biological markers (biomarkers) to detect damage to the organs while it is still in the early stages and progression to serious injury may still be prevented. Studies of this scale would not have been possible without intense interdisciplinary and cross-institutional collaboration. The scientific strategy adopted by the SAFE-T consortium for the testing of biomarkers on patients’ blood and other samples has been agreed with the European Medicines Agency (EMA) and the U.S. Food and Drug Administration (FDA). This scientific advice from regulatory authorities is a key step in the qualification of novel biomarkers. The SAFE-T consortium is also collaborating with the Predictive Safety Testing Consortium, which is led by the US-based Critical Path Institute.
IMI launches new projects several times a year, through Calls for proposals. Research consortia wishing to participate should submit an Expression of Interest in response to the Call, following the rules outlined on the IMI website.

The evaluation and selection of the winning proposals is based on independent peer review, and concluded by a Grant Agreement and a Project Agreement.

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## Ongoing IMI Projects

### Projects launched in 2009 and 2010

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<td>Quantitative imaging in cancer connecting cellular processes with therapy</td>
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Projects launched in 2012

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More details, including lists of participants and links to project websites: www.imi.europa.eu

*The institution responsible for the coordination of partners receiving public funds originating from the European Commission.
Joining forces for better medicines

www.imi.europa.eu