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A focus on patients

The Innovative Medicines Initiative in action

Research and Innovation

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The Innovative Medicines Initiative in action

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Foreword

The Innovative Medicines Initiative (IMI) is the world's largest public-private initiative in life sciences aiming to speed up the development of better and safer medicines. It brings together the latest research and cutting-edge technology to boost innovation and entrepreneurship in the pharmaceutical sector, to meet the challenges faced by patients and society as a whole. The Initiative is a genuine example of collaboration at its best between the key stakeholders involved in healthcare research, including universities, pharmaceutical and other industries, small and medium-sized enterprises (SMEs), patient organisations, and regulators. This partnership is leveraging R&D investment across Europe in this sector and helping to improve the regulatory environment.

In common with other R&D intensive sectors, the pharmaceutical sector needs help to break down the barriers that hinder innovation and drive up costs. So, in line with the Commission's priorities for growth and competitiveness, and the need to reduce the heavy bureaucratic burdens, especially for SMEs, IMI brings the public sector (European Commission) and the private sector (pharmaceutical industry) to the same table to innovate for the benefit of the patient – particularly in areas where there is an unmet medical or social need. This ambitious mode of collaboration in health research is providing inspiration across the globe and similar bodies are now being established in the USA and Japan.

The importance of R&D in this sector is underlined by the Council conclusions of 1 December 2014, which emphasised the need to facilitate the transfer of scientific advances into innovative medicinal products and to accelerate patient access to innovative affordable therapies with added value for patients. The stakes are high.

Carlos Moedas
European Commissioner
Research, Science and Innovation

The European pharmaceutical sector includes 40 global companies and about 2 000 small- and medium-sized biotechnology enterprises. In 2013 the sector came first in Europe in terms of R&D intensity having invested close to €30 000 million in R&D. It employed more than 690 000 people and generated three to four times more employment indirectly.

The Initiative was set-up to mobilise public-private investment by pooling resources to create a vibrant innovation ecosystem based on partnership. It demonstrates how the concept of Open Innovation can lead to tangible results. Demand for more accessible and affordable healthcare is increasing, which means that we must maximise investment in disease prevention, new medicines and treatments, health promotion and active participation. No single initiative, however, can realistically provide all the solutions, especially in the pharmaceutical sector where breakthroughs are often made only after years of painstaking research. Nevertheless, in addressing the current needs of patients through extensive research, IMI is making substantial progress as illustrated by the examples presented in this booklet.

This booklet presents a snapshot, not the complete picture. In fact no static publication can capture the real-time dynamism of IMI's ambitious programme of activities, but it does highlight the real value of public-private partnership in such an important sector to EU citizens.

At the heart of medical innovation

IMI supports patients through collaborative research projects and by building networks of industrial and academic experts – a means to boost drug innovation and disease prevention in Europe.

Europeans are living longer, healthier lives thanks to the contribution of phenomenal advances made by medical science to prevent, diagnose and treat diseases. However, treatments for many other types of diseases remain to be found.

These include Alzheimer's disease, which has become one of the most serious public health issues in Europe. In addition, some bacteria have evolved to the extent that they are resistant to current treatments, requiring adjustments to practices or new antibiotics.

Tackling these diseases, and many others, requires the coordinated efforts of specialists with a wide range of expertise.

The EU response

The Innovative Medicines Initiative (IMI) plays a leading role in the EU's efforts to remove barriers to the discovery of new treatments. IMI was created in 2008 to speed up the discovery and development of new and better medicines for patients.

Since then, IMI has invested and continues to invest in breakthrough medical research. The priority areas for funding include:

- Antimicrobial resistance – infectious agents are evolving to develop resistance to current antibiotics killing 25 000 people in the EU alone every year.
- Cardiovascular diseases – the top cause of deaths in the EU and globally. They include ischaemic heart disease and stroke and account for about two million deaths in the EU each year.
- Diabetes – affects one in twelve people and can damage the heart, blood vessels, eyes, kidneys and nerves and lead to premature death. Some 384 million people worldwide suffer from diabetes.
- Neuro-degenerative diseases – such as Alzheimer's, which represents the vast majority of dementia cases, with chronic or progressive effects on memory, thinking, behaviour and the ability to perform everyday activities. The number of people living with dementia worldwide is currently estimated at over 35 million.
- Psychiatric diseases – mental disorders such as schizophrenia, which affects more than 21 million people worldwide, and depression, affecting 350 million.
- Respiratory diseases – such as chronic obstructive pulmonary disease (COPD), a lung disease that is projected to be the fourth leading cause of death worldwide by 2030. About three million people worldwide died of COPD in 2012.

- Immune-mediated diseases – such as rheumatoid arthritis, multiple sclerosis, juvenile diabetes. Up to 2.5 million people are estimated to have multiple sclerosis, 500 000 of them in the EU.

- Ageing-associated diseases – such as lower back pain, hearing loss and osteoarthritis, a deterioration of cartilage in joints, leading to stiffness, pain and impaired movement. Osteoarthritis is the single most common cause of disability in older adults.

- Cancer – a leading cause of death worldwide, accounting for 8.2 million deaths in 2012.

- Rare diseases – represent more than 7 000 diseases with no available treatment that affect 30 million Europeans.

- Vaccine development – the aim is to speed up the development of new, effective vaccines or improve existing ones for a range of diseases, including influenza, Ebola or whooping cough.

Meeting unmet needs

With IMI, the EU is responding to gaps in treating current public health issues identified by the World Health Organization[1] (WHO). This response serves to drive much-needed attention to diseases that must still be addressed by the medical industry.

IMI's vision is to deliver 'the right prevention and treatment for the right patient at the right time'. This vision maintains a strong focus on the development of new medicines, and the tools and methods to speed up patient access to new treatments.

The organisation is structured to meet these patient needs. It is set up as a public-private partnership between the European Union represented by the European Commission and the European pharmaceutical industry represented by the European Federation of Pharmaceutical Industries and Associations (EFPIA).

This structure enables IMI to bring together a broad range of partners from industry, academia, patient organisations and regulators to work together on solving medical challenges that no single entity or even sector could solve alone.

It also allows IMI to respond to immediate global health threats and diseases for which public and private funders do not invest enough in developing prevention and treatments.

For example, outbreaks of Ebola still continue to affect parts of Africa, mainly because there is no efficacious vaccine or treatment for the disease. During the outbreak that began in western Africa in 2014, IMI was able to rapidly launch a number of projects investigating promising vaccines and tools for rapid diagnosis. IMI also has a project dedicated to ensuring the acceptance and uptake of new vaccines.

[1] Priority Medicines for Europe and the World 2013 & Update, WHO. http://goo.gl/SUk1UX

Thematic approach

IMI delivers via thematic funding calls for research proposals. Funding for 2008-2024 adds up to over €5 billion, making it the world's largest public-private partnership in health research.

Half of IMI's funding comes from the EU's research and innovation programmes. The other half comes from large companies and organisations, mostly EFPIA members. These companies do not receive any EU funding, but contribute to the projects 'in kind', for example by investing their researchers' time in projects, providing access to research facilities and providing resources.

Altogether, IMI-funded projects so far involve a community of over 7 000 researchers from academic teams, pharmaceutical companies, SMEs, patient groups and regulators from across Europe and beyond. They are involved throughout the research and innovation process, ultimately bringing products to patients, to all of us.

This collaborative effort focuses on personalised medicine – ensuring that research targets the health care needs of diverse populations and individuals by delivering targeted measures to prevent and treat diseases.

In addition to disease-oriented projects, other projects focus on broader challenges. These include a better understanding of the underlying causes of disease, the sustainability of drug production, and the use of big data for biomedical research and innovation. IMI also supports education and training projects for researchers as well as patients.

Long-term challenge

Delivering new medicines is a long-term challenge given the time it takes to develop them. However, through its projects, IMI has already started to deliver public health benefits.

Some IMI-funded projects have overcome challenges to drug development by improving processes and by delivering new and innovative diagnostic and therapeutic tools to patients.

For example, U-BIOPRED[2] created awareness in the medical profession of the different types of asthma, which can be identified through tests. This achievement will allow doctors to identify each person's unique type of asthma and to treat the disease using approaches best suited to that particular patient. By shifting thinking of asthma as a single disease with a single treatment, the project helps to make personalised medicine a reality.

Another project, SUMMIT[3], identified six proteins whose presence in combination with other indicators has improved the prediction of cardiovascular disease (CVD) in people with type 2 diabetes. The discovery will allow doctors to make an early diagnosis to help keep the disease under control at an early stage.

Meanwhile, the unprecedented levels of data sharing between the 12 public and 18 private partners in the eTOX[4] project resulted in the launch of a rich database and a new approach to predicting a drug's toxicity. This advance promises to significantly help improve the safety of new medicines.

[2] U-BIOPRED website: http://goo.gl/QF2zJY
[3] SUMMIT website: http://www.imi-summit.eu/
[4] eTox website: http://www.e-tox.net/

A commitment to patients

These early successes are due in part to IMI's commitment to ensure funded projects put patients at the centre of their research and innovation activities. This approach has led to worldwide recognition of IMI as a model public-private partnership, an example of how medical research and innovation could be aligned more with patient needs.

The following pages present four other projects developing breakthrough advances that highlight IMI's contribution to medical research – and to patients' health.

They are:

- **EU-AIMS** – providing ground-breaking research on the genetic factors behind autism;
- **ND4BB** – addressing antimicrobial resistance to current drugs;
- **NEWMEDS** – developed the largest set of clinical trial data on mental disorders to boost the discovery of new treatments;
- **PROactive** – created a platform to help patients with chronic obstructive pulmonary disease improve their ability to participate in physical activity.

IMI-funded projects at a glance

IMI-funded projects are leading to breakthrough discoveries that are having an impact on drug research and development and, ultimately, patients' lives. Current projects are focused on major health issues such as neurological conditions, diabetes, respiratory diseases, cancer, inflammation and infection, obesity, antimicrobial resistance, Alzheimer's disease and cancer. IMI funding aims to deliver:

- better understanding of the underlying causes of disease and drug behaviour in the body;
- better use of big data for biomedical research and innovation;
- environmentally-sustainable drug production;
- new potential targets for drugs;
- new potential medicines;
- new tools and methods to detect drug safety issues and efficacy early in development;
- new facilities to support drug development;
- innovative clinical trial designs;
- new pan-European clinical networks;
- new methods to survey the benefits and risks of medicines and vaccines once they are on the market;
- new education programmes to train patients and other stakeholders;
- new business opportunities for SMEs.

A closer look at the many faces of autism

The EU-AIMS project is identifying the biological causes of autism and has developed innovative approaches to speed up development of new, more effective treatments for the mental disorder.

Today, there is no drug designed specifically to treat autism. Yet, about 1 person in 100 lives with some form of autism. Patients – including children and adolescents – have difficulties relating to and communicating with others, among other impairments. Their symptoms can range from a mild to severe disability, requiring constant care.

Many aspects of this complex mental disorder are poorly known, in part due to a lack of understanding of autism's biological causes. Through EU-AIMS, Europe is taking the lead in coordinating a global effort to identify these biological triggers.

This effort paves the way for the development of new, safe and effective treatments, says project academic coordinator Declan Murphy of King's College London.

"Let's put it this way," he says. "Suppose you have 100 people with autism and among them there are 10 causes of the condition. Today we would test one type of treatment on all of them. If the treatment works on one type of condition then the result would be a 1 in 10 hit rate. The trial would not be deemed to be a success."

Once the various biological causes of autism are identified, he says, doctors would be able to adjust treatments to an individual's specific condition. Patients would also not be needlessly exposed to medicines that don't work for them. Researchers would be able to test and discover new treatments more efficiently.

Murphy continues: "If the same trial was run according to type of autism, we would quickly see that the treatment worked on 10 out of 10 patients of a specific sub-type. The treatment would not be ruled out. A new treatment would have been discovered for that particular type of autism."

EU-AIMS, which ends in March 2017, has already made a number of important discoveries. Its approaches are now about to be brought into clinics.

Among these discoveries: it has found that some of the brain changes associated with autism could be reversible, and revealed that autism affects men's and women's brains differently. Its researchers have also discovered that a father's age plays a role in the genetic risk of having autism. The older a father is at a child's birth, the greater the risk.

New ways are being developed to detect autism early in life, so that children and youngsters can receive treatment as quickly as possible when symptoms first appear. This would make a true difference.

The project is also contributing to new treatment guidelines being put together by the European Medicines Agency, and it is setting up two of the largest ever clinical trials for autism. The first looks at the risk of autism in a younger brother or sister of a child with autism, while the second is following how symptoms can change with age.

EU-AIMS is also developing promising genetic and cellular-based methods to accelerate the development of new medicines as well as biomarkers for selecting and stratifying patients in clinical trials.

The project's breakthroughs are based on involving patient organisations in Europe and the USA as partners in EU-AIMS. For the first time in the world they have come together with researchers and industry to develop the infrastructure to discover new treatments for autism, says Murphy.

"It is crucial to involve people with the condition and to work closely with patients and their families."

He adds: "This involvement allows us to work closely with the autistic community and get input into the key research questions in autism. There is no 'us' and 'them'. It is crucial to involve people with the condition and to work closely with patients and their families."

This collaboration has led to an unique European Autism biobank and the means to openly share scientific data worldwide, opening these to a wider community of researchers worldwide. EU-AIMS has also established a clinical network, with about 92 sites in 37 European countries.

This platform has the potential of being used to test novel treatments using the biomarkers developed by EU-AIMS. This improvement will make possible the delivery of a much needed personalised medicine approach to autism.

More information on EU-AIMS: www.eu-aims.eu

The hunt for new weapons against killer bacteria

A major EU effort is underway through the ND4BB programme to stimulate the discovery of new antibiotics and save lives. The programme has already identified some promising drugs to counter the growing threat of antibiotic resistance in some very dangerous bacteria.

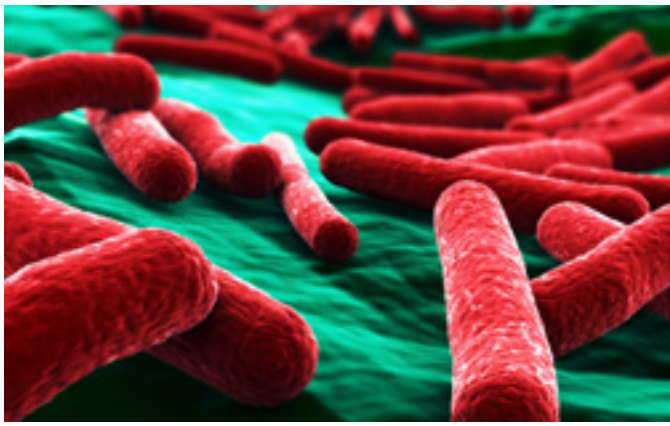
Antibiotics kill bacteria or stop them from growing – a powerful weapon against many infections. But through the overuse and misuse of antibiotics, bacteria are evolving to become resistant to them.

The World Health Organization[5] has said, "without coordinated action, the world is headed for a post-antibiotic era, in which common infections and minor injuries which have been treatable for decades can once again kill."

In the EU alone, 25 000 people die each year from infections caused by antibiotic-resistant bacteria. Two-thirds of these are due to a class known as gram-negative bacteria. They include those that cause pneumonia, bloodstream infections, meningitis and wound or surgical site infections in hospitals.

Furthermore, antimicrobials are vital for reducing the risk of complications in relation to common medical interventions, such as hip replacements, organ transplants, and cancer chemotherapy. Increasing antibiotic resistance potentially threatens the safety and efficacy of these medical interventions.

The ND4BB umbrella programme – New Drugs for Bad Bugs – is the EU's major contribution to the global effort to speed up the discovery of new antibiotics and counter the growing threat.



ENABLE[6] is one of seven related projects in the programme. ENABLE has created a platform for developing promising drug candidates that could be effective against gram-negative bacteria. The aim is to develop at least one for early stage clinical testing in humans by 2019, says Claire Skentelbery of the European Biotechnology Network in Belgium and the project's communication and open call manager.

Together with the other projects in ND4BB, ENABLE contributes to a better understanding of how antibiotics work against gram-negative bacteria.

[5] http://www.who.int/mediacentre/news/releases/2014/amr-report/en/

[6] www.nd4bb-enable.eu

"It's high-risk research that could yield big results – access to novel antibiotics, and a reduction in deaths from antibiotic resistance," she says. "The project is drawing attention from across the world and is working alongside other agencies to help support programmes that deliver antibiotics to patients."

ND4BB is helping to tackle the scientific, regulatory, and business bottlenecks that hamper the development of new antibiotics. The other six projects in the programme are:

- TRANSLOCATION[7] – identifying new ways of getting antibiotics into bacteria and keeping them there so they can take effect. The project will work primarily on gram-negative pathogens such as *Escherichia coli* and *Klebsiella pneumoniae*.

- COMBACTE[8] – boosting antibiotic development by pioneering new ways of designing and running efficient clinical trials for novel antibiotics. To do so, the project has created a network of around 300 clinical sites in 34 countries. In 2014, it started conducting clinical trials of innovative agents against gram-positive bacteria.

- COMBACTE-CARE[9] – combining two current antibiotics that together promise to combat bacterial infections known as 'carbapenem-resistant Enterobacteriaceae'. These are considered as among the most dangerous drug-resistant bacteria in the world. The Biomedical Advanced Research and Development Authority (BARDA), part of the US Department of Health and Human Services, joined the clinical study in September 2015.

- COMBACTE-MAGNET[10] – evaluating new approaches to preventing and treating life-threatening infections caused by gram-negative bacteria. It is also setting up a pan-European network to survey antibiotic resistance and healthcare associated infections.

- iABC[11] – developing two new inhaled antibiotics for patients with cystic fibrosis and bronchiectasis, a medical condition that injures the airway walls or prevents the airways from clearing mucus. It is also identifying ways to improve clinical trials of potential new treatments for these diseases.

- DRIVE-AB[12] – studying alternative business models to stimulate investments in antibiotic development. It is also looking into ways to encourage the responsible use of antibiotics.

ND4BB projects are critical for discovering new antibiotics and progressing them through the development pipeline to provide effective treatments for patients.

Despite the recognised need for new antimicrobials for clinical use, the reality is that only two new classes of antibiotics have been brought to market in the last 30 years and many drug developers have left the field.

ND4BB works to overcome these barriers to saving people's lives.

More information on ND4BB:
www.imi.europa.eu/content/nd4bb

"It's high-risk research that could yield big results – access to novel antibiotics eventually, and a reduction in deaths from antibiotic resistance."

7 www.translocation.eu
8 www.combacte.com
9 www.combacte.com/About-us/COMBACTE-CARE
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12 www.drive-ab.eu

Pioneering treatments for mental disorders

The NEWMEDS project shed new light on the underlying causes of schizophrenia and depression, developed new tools to aid in the development of new drugs to treat these conditions, and proposed new, more efficient ways of carrying out clinical trials for new treatments.

In Europe, 1 person in 10 will face a mental disorder at some time in their lives – with depression and schizophrenia among the leading causes of these illnesses. Depression is the most prevalent health problem in many EU countries.[13]

But even with rapid advances in research, very few new medicines have been developed for patients. To help overcome the bottlenecks, the NEWMEDS[14] project developed new approaches and techniques to help speed up access to new medicines that work and are safe for patients.

"NEWMEDS added to our understanding of depression and schizophrenia and should make it easier to study mental disorders – and find novel treatments," says project coordinator Tine Bryan Stensbøl from Lundbeck in Denmark.

The objective of NEWMEDS was to find ways to make clinical trials of potential treatments faster and more efficient, while maintaining high-levels of patient safety.

The project participants responded by pooling industry data – never shared before – into the largest dataset of clinical trials ever established in psychiatric research. The data was collected and shared from 99 clinical trials in schizophrenia and depression run by several pharmaceutical companies in over 25 countries – for a total of more than 37 000 patients.

The collection and detailed analyses carried out by NEWMEDS proved to be very valuable, says Stensbøl.

NEWMEDS demonstrated that early clinical trials of potential medicines for schizophrenia could be made shorter and more efficient by including more women, more people with certain types of symptoms, and younger patients.

In addition, research tools and the tests developed by the project will also enable scientists to better monitor the effects of candidate medicines at early stage trials, and to identify more precisely parts of the brain to target for treatment.

[13] http://ec.europa.eu/health/mental_health/docs/mhpact_en.pdf; http://www.mentalhealthandwellbeing.eu/

[14] www.newmeds-europe.com

The project pioneered an online tool to help prevent test subjects from enrolling simultaneously in several clinical trials. Multiple enrolments reduce the usefulness of trial results and can be dangerous to the health of the participants if interactions between experimental drugs occur.

New insights

The NEWMEDS researchers also carried out a large, systematic, study of healthy volunteers who carry changes in the number of copies of specific genes associated with schizophrenia. The research adds to scientific understanding of the risk factors of schizophrenia and should make it easier to study mental disorders, she says.

NEWMEDS has also improved the translation of research from the lab to the patient's bedside by developing animal models that more accurately mimic the biological defects underlying a disorder. The models are valuable when testing potential drugs for mental disorders.

"Ultimately novel drugs could be developed by industry – but it is important to understand that this will not be achieved without major investment in future research," Stensbøl concludes. "This project had its most promising achievements in its early discovery phases – thus it will take more time, energy and investment to harvest the full potential of these results."

"NEWMEDS added to our understanding of depression and schizophrenia and should make it easier to study mental disorders – and find novel treatments."

A patient-centred approach to treating respiratory disease

The PROactive project has developed new patient-centred tools to help patients with severe chronic obstructive respiratory disease (COPD) get more personalised treatments and lead more active and productive lives.

COPD is a treatable and preventable disease of the lungs affecting approximately 5 to 10% of the population over 50 years of age. Many patients with COPD will end up dying prematurely. In Europe alone, some 300 000 Europeans die each year[15] from COPD.

A long-term condition, COPD affects the lungs and impairs the capacity to breathe. This is first noticed during exercise and indeed during any physical activity. Patients usually experience a progressive decline of their health, and often have to reduce physical activity and modify their normal way of life.

Treatment exists to help alleviate these symptoms but no tools existed to capture simultaneously whether patients are becoming more active with these treatments, or whether physical activity becomes easier, ultimately improving the lives of these patients.

In response, PROactive has developed new tools to assess physical activity – from a patient's perspective. PROactive designed, with direct patient input, a conceptual framework on physical activity based on their experience with physical activity and what it means to them.

"The new tools will give doctors, nurses and other healthcare providers and researchers unique information on the effect of treatment on their patients," says Thierry Troosters of the University of Leuven, the project's scientific coordinator. "They will also make a real difference to the way new medicines and other interventions are developed by making sure that outcomes that matter most to patients are considered."

Patient perspectives matter

Improving treatments for diseases in areas that are relevant to patients is of utmost importance. Information obtained directly from patients, and confirmed in large studies, identified that the amount of physical activity and the difficulty experienced in doing daily activities are the two most important aspects of assessing physical activity. The PROactive tools are geared to capture these dimensions. This makes the tools more comprehensive than just assessing physical activity by using, for example, a step counter or a questionnaire.

[15] European Lung Foundation: http://www.europeanlung.org/assets/files/en/infographics/copd.pdf
European Respiratory Society: http://www.erswhitebook.org/chapters/chronic-obstructive-pulmonary-disease/

“Our programme may also have contributed to the insight that new drugs could be offered with a more effective package of care, which also involves exercise, physical activity and behavioural change.”

The PROactive consortium developed two tools: one for use on a daily basis and one for use during clinical visits. The choice of the appropriate tool depends on the type of research question to be answered.

The tools will allow patients to report the amount of activity they were doing as well as the difficulties they had in doing those activities. PROactive tested them on more than 600 patients with COPD.

Pharmaceutical companies are already using the new tools to test the effect of their drugs on physical activity, says Troosters.

“Our programme may also have contributed to the insight that new drugs could be offered with a more effective package of care, which also involves exercise, physical activity and behavioural change” he says. “This is a more holistic approach to benefit patients.”

The future of respiratory medicine?

“PROactive has raised awareness of the importance of improving physical activity in treating COPD,” says Troosters. “It will help develop new, more effective drugs for treating the disease for the benefit of patients. I also believe that our patient-centred approach can be adapted to help patients with other types of diseases. From the project it became clear that different interventions – including the use of drugs, but also encouraging patients to live more active and healthy lives – may have complementary effects on health. Clinical trials which adopt several of these strategies may prove to be more effective in helping patients increase their physical activity and improve their health.”

More information on PROactive:
www.proactivecopd.com

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Patients are at the heart of the EU's Innovative Medicines Initiative (IMI) that seeks to speed up the development of more effective and safer medicines. Created in 2008 as a public-private partnership, IMI plays a leading role in the EU's efforts to remove barriers to the discovery of new treatments. It does this through collaborative research projects and by building networks of industrial, academic experts, researchers, regulators, clinicians and patients.

IMI is part of the EU's response to treatment gaps identified by the World Health Organization (WHO). The initiative drives much-needed attention to diseases that continue to blight lives here in Europe, and worldwide. Want to know more? This booklet introduces the IMI's work as well as the exciting results generated by four projects on priority diseases.

"*It's high-risk research that could yield big results – access to novel antibiotics eventually, and a reduction in deaths from antibiotic resistance.*"

Claire Skentelbery, communication and open call manager for the ENABLE project.

"*It is crucial to involve people with the condition and to work closely with patients and their families.*"

Declan Murphy, academic coordinator for the EU-AIMS project.

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