

INNOVATIVE MEDICINES INITIATIVE



With its €2 billion budget, the Innovative Medicines Initiative (IMI) is the world's largest public-private partnership in health research and development.

By building collaborative networks of innovation, IMI aims to speed up the development of safer and more effective medicines for patients.

Ongoing IMI projects are already generating impressive achievements, resulting in over 200 publications in scientific journals. IMI currently supports 37 projects involving 3,500 people in around 1,000 research teams, and new large-scale projects are in the pipeline. By sharing knowledge and expertise, the partners in IMI consortia are delivering results that would not have been possible otherwise.

For patients' organisations and for researchers in universities and small and medium-

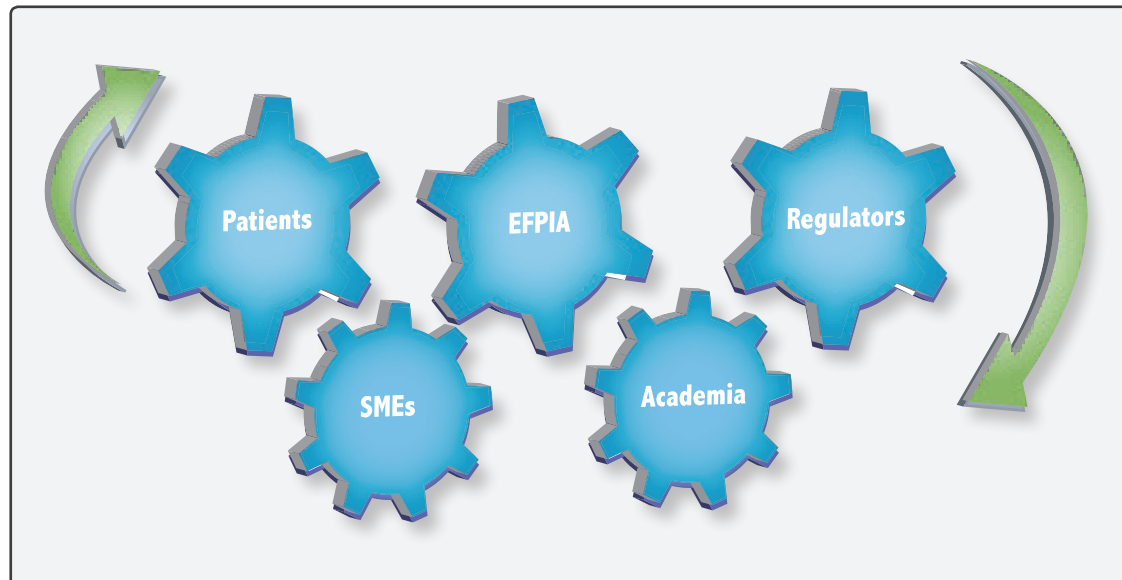
sized enterprises (SMEs), IMI offers unique opportunities. Participants in IMI projects gain access to knowledge and expertise from industry partners, and the collaboration increases their international visibility.

The involvement of regulatory agencies in IMI projects enhances the translation of research results into better treatments for patients.

IMI is a joint undertaking between the European Union 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). This is matched by in kind contributions worth €1 billion from EFPIA companies.

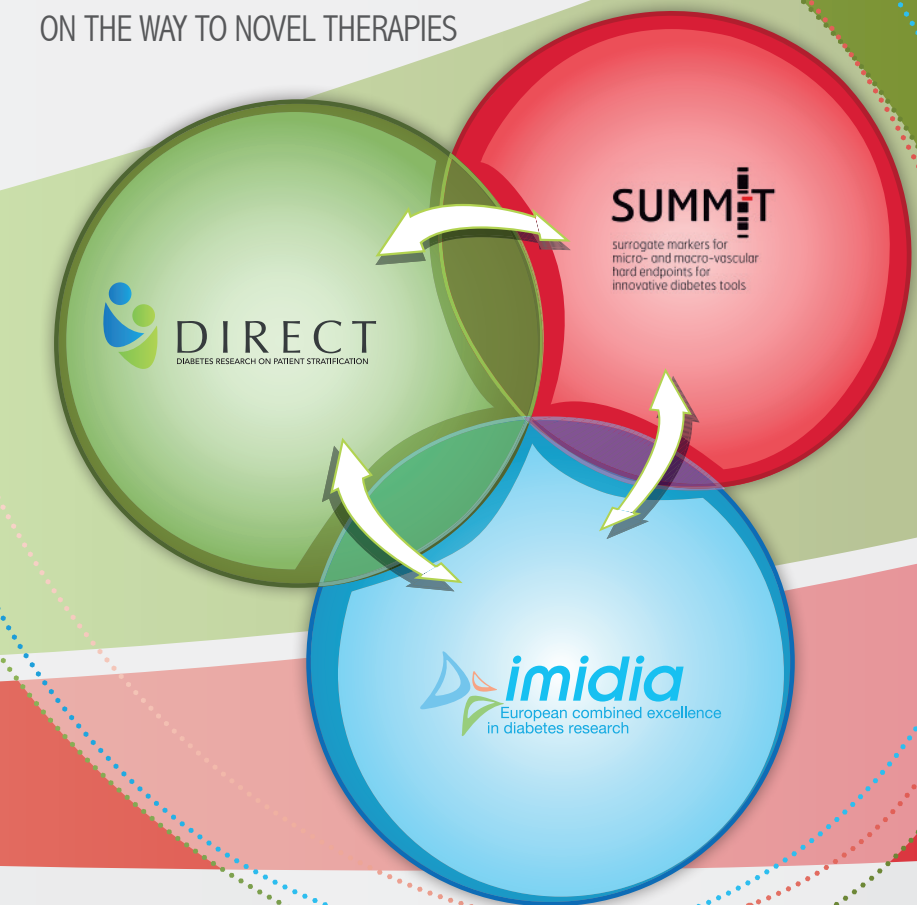
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INNOVATION THROUGH PUBLIC-PRIVATE PARTNERSHIPS



THE IMI DIABETES PLATFORM

COLLABORATIVE APPROACHES TO OVERCOME KEY BOTTLENECKS ON THE WAY TO NOVEL THERAPIES



ACKNOWLEDGEMENT

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Three scientific consortia delivering game changing solutions for this major health burden of the 21st century within a unique European public-private-partnership – the Innovative Medicines Initiative (IMI)*

* Innovative Medicines Initiative: a public-private partnership between the European Commission (EC) and the European Federation of Pharmaceutical Industries and Associations (EFPIA), consisting of 35 leading pharmaceutical companies.

THE IMI DIABETES PLATFORM

COLLABORATIVE APPROACHES TO OVERCOME KEY BOTTLENECKS ON THE WAY TO NOVEL THERAPIES

IMIDIA – DIRECT – SUMMIT: 3 European diabetes projects bringing together leading experts from academia, industry and biotech. Under the umbrella of the Innovative Medicines Initiative (IMI) they are working together on the joint development of novel solutions for improved disease management.

Worldwide it is estimated that there are already around 366 million diabetic patients. This number is expected to rise to 552 million by 2030, making diabetes an increasing burden both for society and health care systems and hence one of the biggest social economical challenges of our time.

Although current symptomatic treatment has improved substantially over recent decades, there still remains an urgent need for

- better treatment and prevention of severe diabetic complications
- better understanding and addressing of the heterogeneity of diabetes
- slowing down disease progression and ultimately finding a cure for diabetes.

The 3 projects, which focus their efforts on the key aspects:

- **therapies to slow down progression of diabetes with focus on pancreatic beta-cells (IMIDIA)**
- **patient stratification to determine best treatment options for each patient (DIRECT)**
- **therapy of late-stage micro- and macro-vascular complications (SUMMIT)**

together constitute one of the most holistic discovery approaches in diabetes research to date and pave the way for collaboration to exploit clinical trials and biomarker synergies.

This will accelerate access to novel therapies with improved efficacy and safety. Earlier prediction of disease progression and therapy response together with an improved benefit-risk assessment of drug treatment will enable the heterogeneous population of diabetes patients to receive individualized therapy and help to remove some of the major hurdles in today's drug development process.

DIABETES MELLITUS is a chronic, incapacitating disease associated with **severe chronic complications** such as heart disease and stroke, and damage to the blood vessels, kidneys and eyes. Both the disease and its complications impose an immense burden on patients' quality of life and can be correlated with an increased mortality. **Currently there is no cure for diabetes** and treatment options are limited. **Insulin** is the hormone that is released after food consumption from **pancreatic beta-cells** into the blood and lowers blood glucose levels by facilitating glucose uptake into insulin target cells.

BLOOD GLUCOSE LEVELS are elevated because the pancreatic beta-cells can not or do not produce sufficient insulin in type 1 and type 2 diabetes patients respectively.

TYPE 1 DIABETES is the insulin-dependent, immune-mediated or juvenile-onset form of diabetes. It is caused by an auto-immune reaction, where the body's defence system attacks the insulin-producing beta-cells leading to their rapid demise.

TYPE 2 DIABETES results from a progressive demise of pancreatic beta-cells caused by the insulin resistance of insulin target cells. As a result of increasing insulin resistance and reduced insulin secretion over time because of diminished beta-cell mass, the average blood glucose level rises unrelentingly and supplemental insulin injections may be needed as the disease progresses. Although a **number of risk factors are known, it is not yet clear why the course of type 2 diabetes and response to therapy varies between patients** leading to the need for **patient stratification and personalized medicines therapy**. Worldwide, 90-95 % of people with diabetes have type 2 diabetes.

THERAPEUTIC COSTS for the treatment of diabetes are estimated to account for between 5 and 10 % of total healthcare spending in the world, which represents a huge burden on welfare systems – both in Europe and the U.S. as well as in other developed and developing countries.



- Sanofi*
- **Université de Lausanne***
- Servier*
- AstraZeneca
- Boehringer Ingelheim
- Centre National de la Recherche Scientifique (CNRS, Paris)
- Commissariat à l'Energie Atomique
- Endocells Sàrl
- Imperial College London
- Institut Suisse de Bioinformatique
- Institut National de la Santé et de la Recherche Médicale (INSERM)
- Eli Lilly
- Medizinische Hochschule Hannover
- Novartis
- Novo Nordisk
- F. Hoffmann-La Roche
- Technische Universität Dresden
- Università di Pisa
- Université Paris Diderot-Paris 7
- Université de Genève
- Vrije Universiteit Brussel

* **Coordinating and managing participants**



- Sanofi*
- **University of Dundee***
- University of Bath
- Consiglio Nazionale delle Ricerche (ISIB, Padova)
- Technical University of Denmark
- Eberhard Karls Universität Tübingen
- Helmholtz Zentrum München
- Institut d'Investigacions Biomediques August Pi i Sunyer
- Imperial College London
- Kungliga Tekniska Högskolan
- Centre National de la Recherche Scientifique (CNRS, Lille)
- Leiden University Medical Center
- University of Copenhagen
- University of Eastern Finland
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- Universitaet Ulm
- VU University Medical Center
- Novo Nordisk
- **Eli Lilly***
- Servier
- Centre Hospitalier Régional Universitaire de Lille

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IMIDIA

IMPROVING BETA-CELL FUNCTION AND IDENTIFICATION OF DIAGNOSTIC BIOMARKERS FOR TREATMENT MONITORING IN DIABETES

IMIDIA addresses the key bottlenecks in the development of beta-cell focused therapies delivering:

- Novel tools for the study of:
 - Human beta-cell development, function and survival
 - Human beta-cell functional modulation by potential therapeutic compounds
 - In-vivo beta-cell imaging
- Biomarkers:
 - For the diagnosis and prognosis of beta-cell failure
 - For monitoring diabetes progression and treatment
- Knowledge:
 - Of novel pathways and sites that control beta-cell proliferation, differentiation and apoptosis,
 - Of the role of nutrient-regulated pathways in controlling beta-cell mass and function.

Therefore paving the way for a paradigm shift in diabetes therapy – from symptomatic treatment to cure.

www.imidia.org

DIRECT

DIABETES RESEARCH ON PATIENT STRATIFICATION

DIRECT addresses the personalized medicines approach in type 2 diabetes patients. The focus of the consortium is the identification of novel surrogate markers that can be used for patient stratification according to glycaemic deterioration and treatment response by:

- Completing phenotyping of already well-characterized subjects from large cohorts in Europe
- Establishing a high quality European databank with phenotypical datasets
- Developing a systems biology platform by integrating clinical and biological data, transcriptional and functional genomics, proteomics, metabolomics and other relevant data
- Developing novel data mining tools and algorithms to generate stratification biomarker candidates
- Identifying novel biomarkers for type 2 diabetes subtypes with
 - rapid development and progression of diabetes
 - altered response to diabetes treatment
- Validating the novel biomarker candidates in a large intervention trial to delay diabetes or pre-diabetes or in smaller trials of treatment response

www.direct-diabetes.org

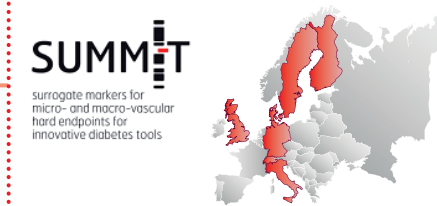
SUMMIT

SURROGATE MARKERS FOR MICRO- AND MACROVASCULAR HARD ENDPOINTS FOR INNOVATIVE DIABETES TOOLS

SUMMIT addresses the urgent therapeutic need for novel treatments of diabetic complications beyond glucose-lowering therapies. The consortium's key objective is to speed up long-lasting clinical trials in order to bring novel medications to the patients earlier by:

- Identifying susceptibility markers that can be used to
 - identify patients at high risk of complications
 - monitor progression, reduction or prevention of diabetic complications and/or response to therapy
 - serve as useful surrogate endpoints in clinical trials
- Developing novel imaging techniques to monitor atherosclerosis and retinopathy progression with high sensitivity and diagnostic accuracy that are useful as non-invasive markers
- Developing animal models adequately reproducing diabetic complications in men to better investigate key pathogenic mechanisms and predict outcomes of therapeutic interventions in the clinical setting
- Developing *in silico* disease modeling tools to replicate diabetic complications




www.imi-summit.eu



- **Boehringer Ingelheim***
- **Lunds Universitet***
- Biocomputing Platforms OY
- Karolinska Institutet
- Helmholtz Zentrum München
- Istituto di Ricerche Farmacologiche „Mario Negri“
- University of Cambridge
- **University of Dundee***
- University of Exeter
- Goeteborgs Universitet
- Samfundet Folkhälsan i svenska Finland rf
- Terveystieteiden tutkimuskeskus
- University of Oxford
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- Università degli Studi di Pavia
- Università di Pisa
- Università Cattolica del Sacro Cuore
- Turun Yliopisto
- University of Edinburgh
- **Eli Lilly***
- AstraZeneca
- F. Hoffmann-La Roche
- Università di Firenze
- Sanofi
- Pfizer

* **Coordinating and managing participants**

THE IMI DIABETES PLATFORM – FACTS & FIGURES

	 www.imidia.org	 www.direct-diabetes.org	 www.imi-summit.eu
START DATE:	01/02/2010	01/02/2012	01/09/2009
DURATION:	60 months	84 months	60 months
NO. OF PARTICIPANTS	21 (12/8/1) ¹	25 (21/4/0) ¹	26 (19/6/1) ¹
DEDICATED RESOURCES FROM EFPIA PHARMA PARTNERS	16.7 Mio. €	16.5 Mio. €	14.1 Mio. €
DEDICATED RESOURCES FROM PUBLIC AND SME ² PARTNERS	9.2 Mio. €	26.6 Mio. €	18.5 Mio. €
TOTAL PROJECT BUDGET	25.9 Mio. €	43.1 Mio. €	32.6 Mio. €
IMI FUNDING TO PUBLIC AND SME PARTNERS	7.1 Mio. €	21.4 Mio. €	14.0 Mio. €
¹ PARTNER DISTRIBUTION ACADEMIA/PHARMA/SME			
² SMALL AND MEDIUM SIZED ENTERPRISES			

There are 4 to 8 companies participating in each consortia. Each of these companies provides dedicated resources for example in the form of scientists, equipment and/or consumables without receiving IMI funding.