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 IMI projects, enhances the translation of 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), and EFPIA companies in kind contributions worth €1 billion from EFPIA companies.

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THE IMI DIABETES PLATFORM

Collaborative Approaches to Overcome Key Barriers on the Way to Novel Therapies

IMI – DIRECT – SUMMIT

3 European diabetes projects bringing together leading experts from academia, industry and biotech. The funding of the Innovative Medicines Initiative (IMI) is working together on the joint development of novel solutions for improved diabetes management.

Worldwide it is estimated that there are already around 366 million diabetic patients. This number is expected to rise to 522 million by 2030, making diabetes an increasing burden both for society and healthcare systems and hence one of the biggest social economical challenges of our time.

Although current symptomatic treatment has improved substantially over the 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 (IMIDA)
- 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.

Direct addresses the personalized medicine 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 and thereby improve 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.

IMIDA

**Improving Beta-cell Function and Identification of Diagnostic Biomarkers for Treatment Monitoring in Diabetes**

IMIDA addresses the key bottleneck 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 response

- 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

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

www.imida.org

**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 a heavy burden on the healthcare system and quality of life can be restored with an accelerated innovation. 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 bloodstream, lowers blood glucose levels by facilitating glucose uptake into insulin target cells.**

**Blood Glucose Levels** are elevated because the pancreatic beta-cells fail to produce enough insulin or the body’s response to insulin is insufficient. This is known as type 1 diabetes in children and type 2 diabetes in adults.

**TYPE 1 DIABETES** is an insulin-dependent, immune-mediated or juvenile-onset form of diabetes. The immune system overreacts to 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, the number of remaining beta-cells is reduced, the average blood glucose level rises unregulatively and supplemental insulin injections may be required 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 medicine. Therefore, 50-90 % 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 US as well as in other developed and developing countries.

**SUMMIT**

**Diabetes Research on Patient Stratification**

SUMMIT addresses the urgent therapeutic need for novel treatments of diabetic complications beyond glucose-lowering therapies. The consensus is to spend up-to-date clinical trials in order to bring novel medications to the patients early.

- Identifying susceptibility markers that can be used to:
  - Identify patients at high risk of complications
  - Monitor progression, reduction or prevention of diabetic complications and response to therapy

- Serve as useful surrogate endpoints in clinical trials

- Developing novel imaging techniques to monitor atherosclerosis and associated 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 vivo disease modeling tools to replicate diabetic complications.

**www.imi-summit.eu**