



# The new strategic approach to better medicines in IMI2 – Example Diabetes Mellitus

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## *Improved strategic decision making for collaborative Public Private Partnership IMI2 within a disease area*

- \* Strategic approach for selected disease areas
- \* Harvest synergies across projects within the SGGs as well as other initiatives
- \* Understand and react to strategic gaps
- \* Drive extension of projects towards application

# Diabetes – the strategic landscape



Strategic Governing Group  
Diabetes / Metabolic Disorders

	Early Onset	Pre Diabetes	Overt Diabetes	Complications
Definition / Diagnosis	-	Not official	Yes	Yes
Symptomatic Treatment	Research	Partial (20% non responders)	Yes	Poor (Multi morbid)
Cure	Potential	Potential	No	No
Compensation	-	-	Yes	Yes
Regulatory Rules	Non existent	Non existent	Yes – Cardiovascular Risk	Yes

# Results of strategic mapping

Early Onset

↓ Pre-Diabetes

↓ Diabetes

↓ Complications

Genetic  
Disposition

Risk factors

β-Cell Dysfunction

IGT / IFG

Overt type 2 Diabetes

Complications

## CLUSTER 1: **Treatment Option Focus**

UNVEILING NOVEL DIAGNOSIS AND TREATMENT PARADIGMS FOR EARLY ONSET AND PROGRESSION TO DIABETES

- Metabolic control by the endocrine pancreas
- Pathways and non-glucose-dependent factors involved in insulin resistance and progression to type 2 diabetes, macrovascular complications and renal failure (Heterogeneity of T2D)

## CLUSTER 2: **Patient Focus**

EXPERIMENTAL MEDICINE APPROACHES TO EFFICACEOUS DIABETES TREATMENT

- Innovative clinical diabetes trial designs
- Improved outcome parameters for diabetes trials

## CLUSTER 3: **Society Focus**

HEALTH SYSTEMS SUSTAINABILITY OF TREATMENT INTERVENTIONS

- Overall cost evaluation of diabetes treatment
- Collection and modelling of "Big Data" from diabetic populations

## CLUSTER 4: **Type 1 Diabetes Focus**

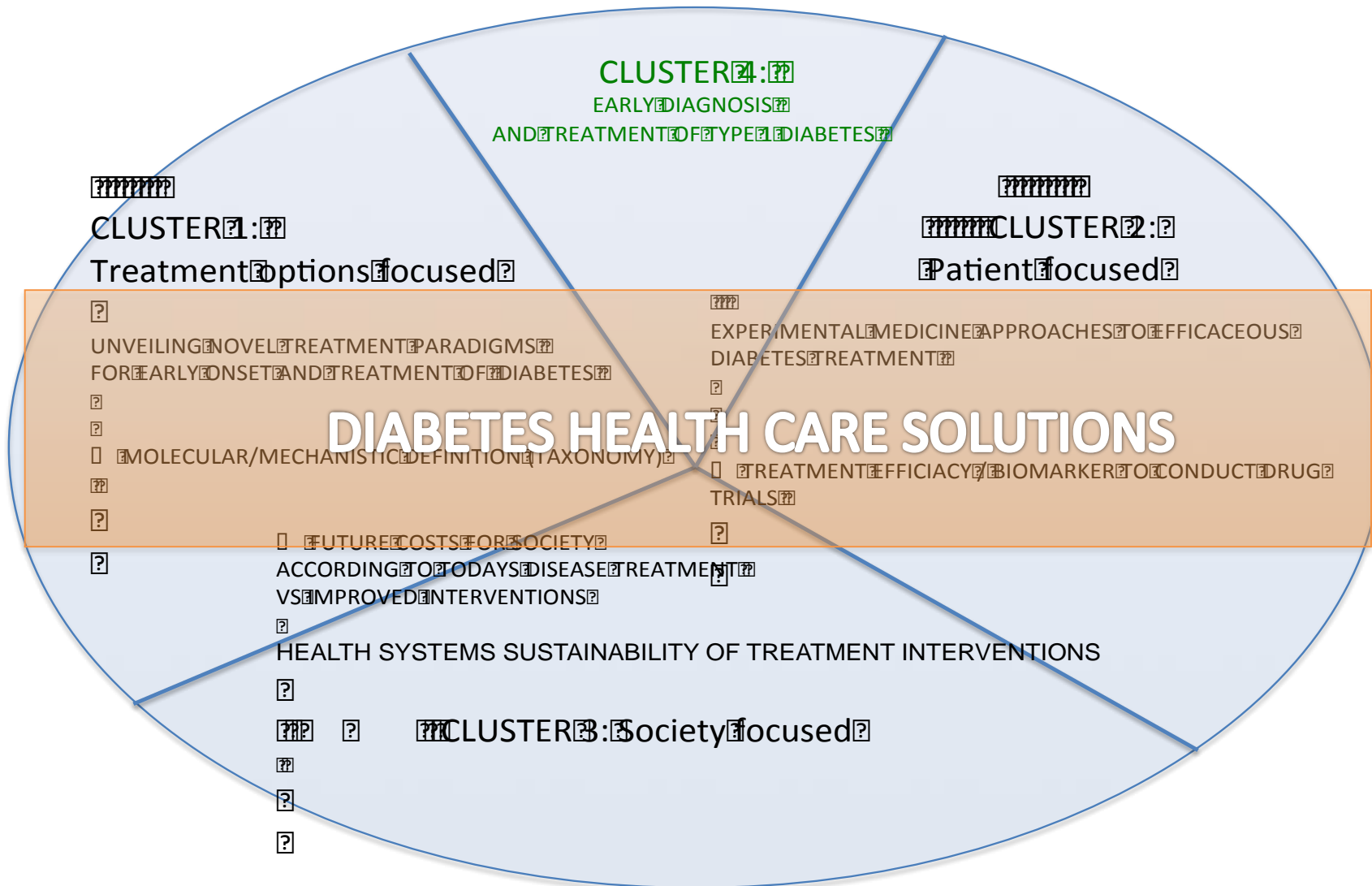
EARLY DIAGNOSIS AND TREATMENT OF TYPE 1 DIABETES

- Immunomodulation in type 1 diabetes (heterogeneity of T1D)
- Regenerative medicine
- Enabling technologies
- Clinical trials in children

# Strategic approach and complementarities



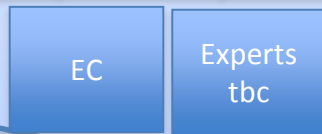
Strategic Governing Group  
Diabetes / Metabolic Disorders



# Setup and pipeline of projects



Strategic Governing Group



**Strategic aspects**

**CLUSTER 1:**  
UNVEILING NOVEL DIAGNOSIS AND TREATMENT PARADIGMS FOR EARLY ONSET AND PROGRESSION OF DIABETES

**CLUSTER 2:**  
EXPERIMENTAL MEDICINE APPROACHES TO EFFICACEOUS DIABETES TREATMENT

**CLUSTER 3:**  
HEALTH SYSTEMS SUSTAINABILITY OF TREATMENT INTERVENTIONS

**CLUSTER 4:**  
EARLY DIAGNOSIS AND TREATMENT OF TYPE 1 DIABETES

Assessing Risk and Progression of Prediabetes and T2DM to Enable Disease Modification

Addressing the Gaps in Efficient Diabetic Nephropathy (DN) Drug Development - tbc

Use of Electronic Health Record /Compliance parameters - tbc

Translational approaches to disease modifying therapy of Type 1 Diabetes Mellitus (T1DM)  
Budget: 35 Mio €

tbd:

Heterogeneity of T2DM/ Database of clinical trials for Type 2 Diabetes - tbc

.... tbd

.... tbd

**Implementation**





## Translational approaches to disease modifying therapy of Type 1 Diabetes Mellitus (T1DM)

<b>EFPIA Participants</b>	Sanofi, GSK, Novo, Lilly
<b>Associated partners to IMI</b>	JDRF, Helmsley Charitable Trust
<b>Project Budget</b>	35,26 Mio€  (in-Kind contribution: 17,63 Mio; IMI Funding: 17,63 Mio)
<b>Project Duration</b>	7 years
<b>Current status:</b>	Call topic published  Application deadline for applicant consortium: 12 Nov 2014



## Disease Biology and Translational Medicine (Target & Biomarker Identification)

- Establish pan-European clinical trial and translational research network
- Expand existing T1DM patient registries and prospective cohorts
- „Omics“ characterization of human samples from newborns, infants, children , adolescents and adults at risk of developing T1DM as well as from newly diagnosed T1DM patients
- Deep phenotypic characterization
- Establish systematic large-data and bio-bank repositories
- Explore imaging technologies for the use of patient identification and stratification
- Develop and characterize most translatable preclinical T1DM models for discovery

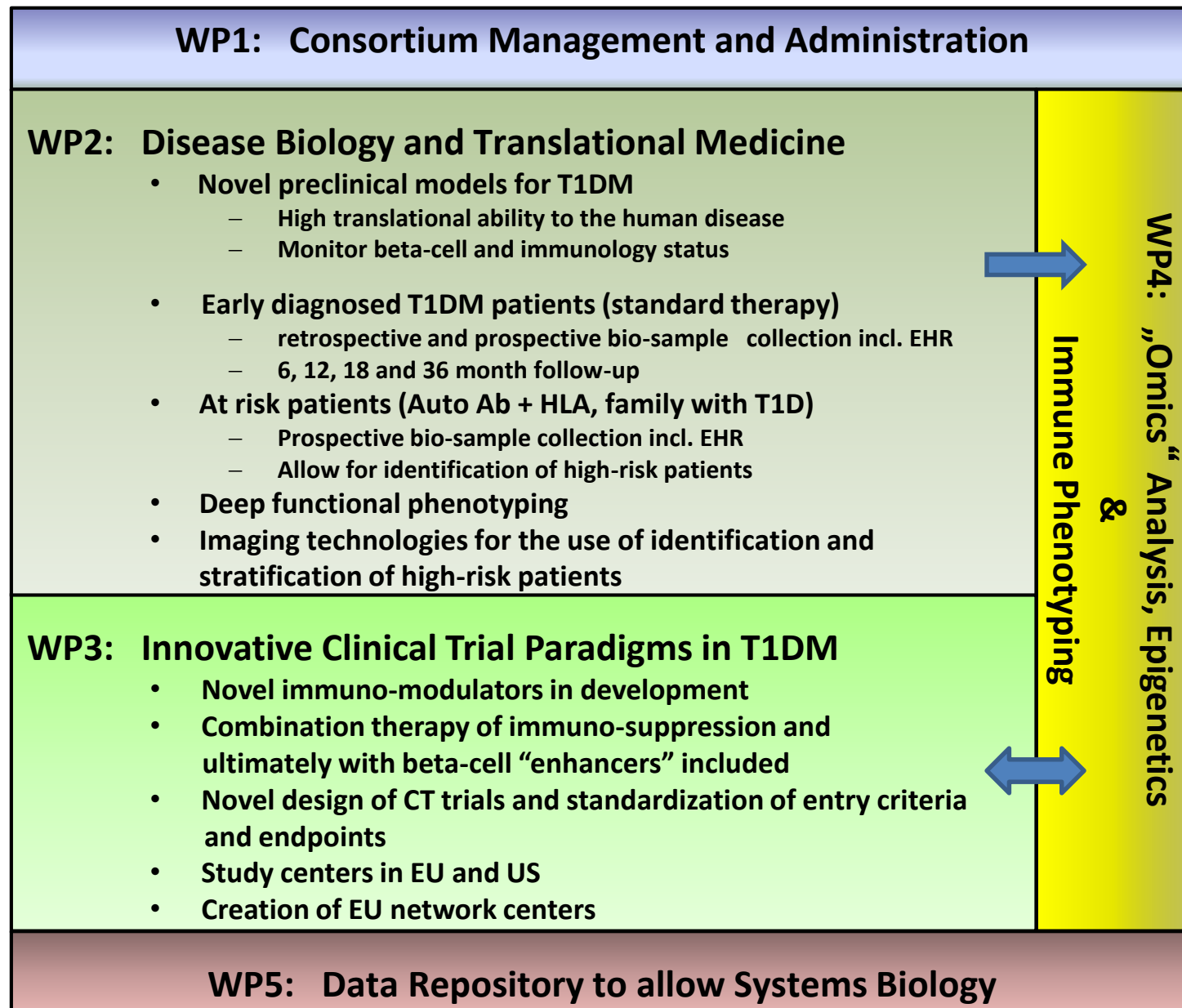
## Innovative Clinical Trial Paradigms

- Develop standardized entry criteria and endpoints for T1DM trials
- Test and develop novel bio-statistical methodologies applicable to new compositions of relevant endpoints
- Evaluate novel mono- and combination therapy approach

## Patient Participation

- Set up T1DM Patient Advisory Board Committee with T1DM patients, individuals at risk of developing T1DM and family members of children and adults with T1DM
- Seek for input from patients and family members into T1DM research







**A pan-European clinical trial and translational research network** including a clinical registry of eligible people with T1DM

- Academic endocrine clinics and associated supporting departments
- Basic, translational, and clinical researchers from the fields of T1DM autoimmunity and  $\beta$ -cell biology,
- Drug discovery and medical staff in Pharmaceutical Industry and Small and Medium size Enterprises.
- Hands-on data base specialists and big data managers
- Patient organizations/representatives
- Experts in regulatory science and health technology assessment preferably representing European health authorities

# Summary:

- IMI2 - Strategic Governance Groups (SGGs) established
- SGG Diabetes / Metabolic Disorders - developed strategic landscape addressing key patient needs
- Framework to create ideas / launch call topic texts (projects)
- 1<sup>st</sup> Diabetes project in IMI2:  
**Translational approaches to disease modifying therapy of Type 1 Diabetes Mellitus (T1DM)**
  - **Project budget 35,26 Mio € = Biggest T1DM project in Europe**
  - Call topic launched 9<sup>th</sup> July 2014
  - Deadline for applicant consortium **12<sup>th</sup> Nov. 2014**