POWER2DM

Predictive model-based decision support for diabetes patient empowerment

POWER2DM BACKGROUND

- **H2020 PHC-28-2015** (21 april 2015):
- Self management of health and disease and decision support systems based on predictive computer modelling used by the patient him or herself

- **Expected impact:**
- • Improving the participation of the patient in the care process.
- • Improving the management of a disease by reducing the number of severe episodes and complications.
- • Increasing the importance of the prevention sector in healthcare using predictive modelling.
- • Boosting the development of personal devices used for self-management of health.
- • Improving individual self-control of health and of disease prevention

POWER2DM OBJECTIVE

- The main objective of POWER2DM is to develop and validate a personalized self-management support system (SMSS) for Type-1 and Type-2 diabetes patients that combines and integrates: (i) a decision support system (DSS) based on interlinked predictive computer models; (ii) automated e-coaching and advice functionalities based on Behavioural Change Theories; and (iii) real-time personal data processing and interpretation.

POWER2DM was awarded the maximum score (5 points) on each of the criteria: Excellence, Impact and Implementation

POWER2DM's budget is 5MEuro and it will run 42 months starting Feb 1, 2016

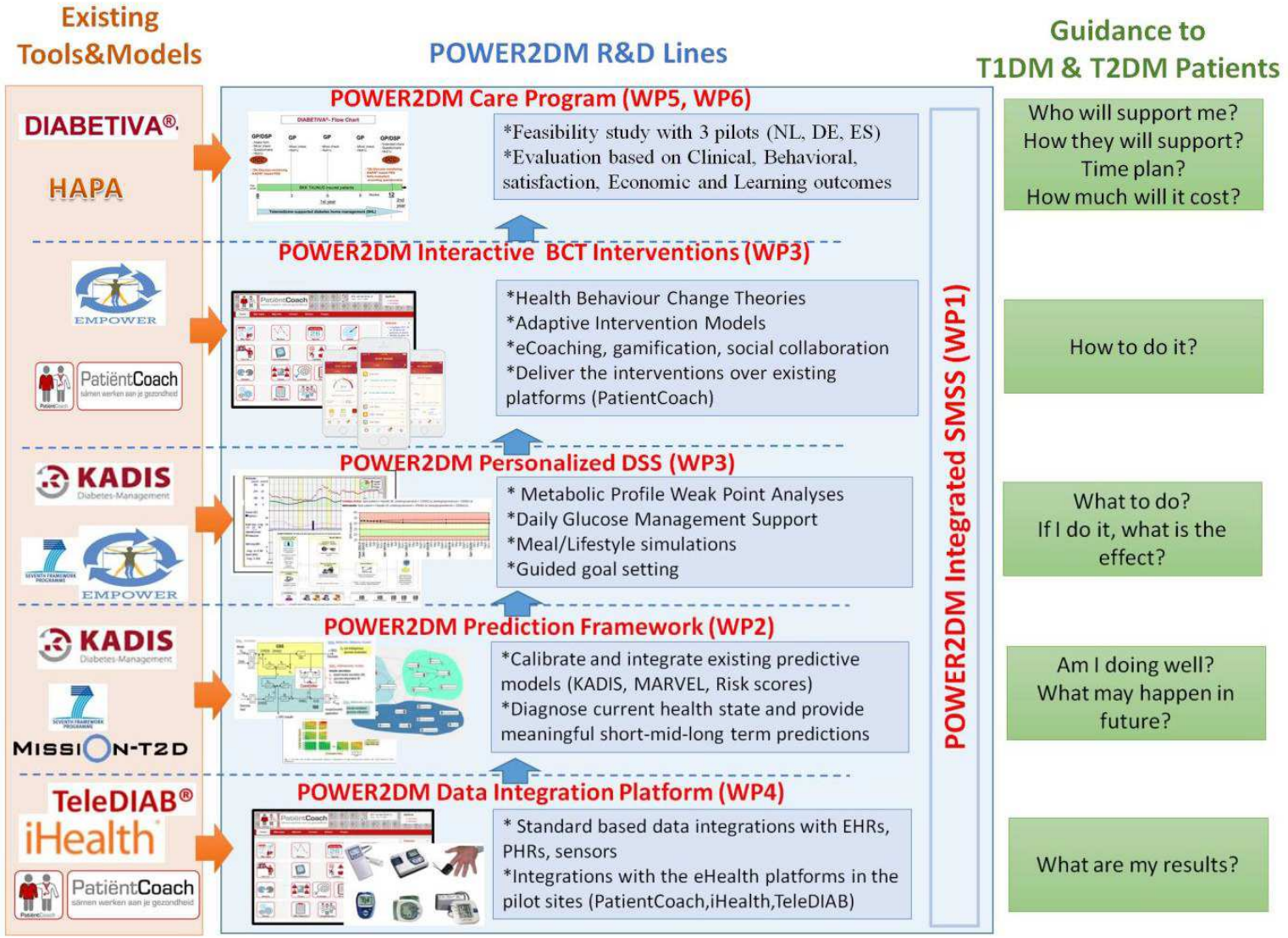
POWER2DM CONSORTIUM

Participant organization name	Part. short name	Country	Role in the Project
Nederlandse Organisatie voor Toegepast Natuurwetenschappelijk Onderzoek	TNO	NL	**Coordinator**, **Innovation & Dissemination Manager**, Predictive Models, Behaviour Change Interventions
Institute of Diabetes "Gerhardt Katsch" Karlsburg	IDK	DE	**Predictive Models**, Clinical Expertise, Pilot Site
SRDC Yazilim Arastirma ve Gelistirme ve Danismanlik Ticaret Limited Sirketi	SRDC	TR	**ICT development**; Decision Support, eHealth Infrastructure, web/mobile GUI
Leiden University Medical Center	LUMC	NL	Pilot Site, Clinical Expertise, **Evaluation, Ethical Manager**
SAS Servicio Andaluz de Salud	SAS	ES	**Pilot** Site, Clinical Expertise
Salzburg Research Forschungs Gesellschaft	SRFG	AT	**Decision Support**, Behaviour Change Interventions
PrimeData	PD	NL	**Data integrator**
iHealth EU	iHealth	FR	Exploitation manager, Sensor network, mHealth Provider

POWER2DM consortium partners and roles

POWER2DM CHARACTERISTICS

… From Existing Models & Tools and POWER2DM R&D Lines to Guidance Provided to Patients



POWER2DM TECHNICAL OBJECTIVES (1)

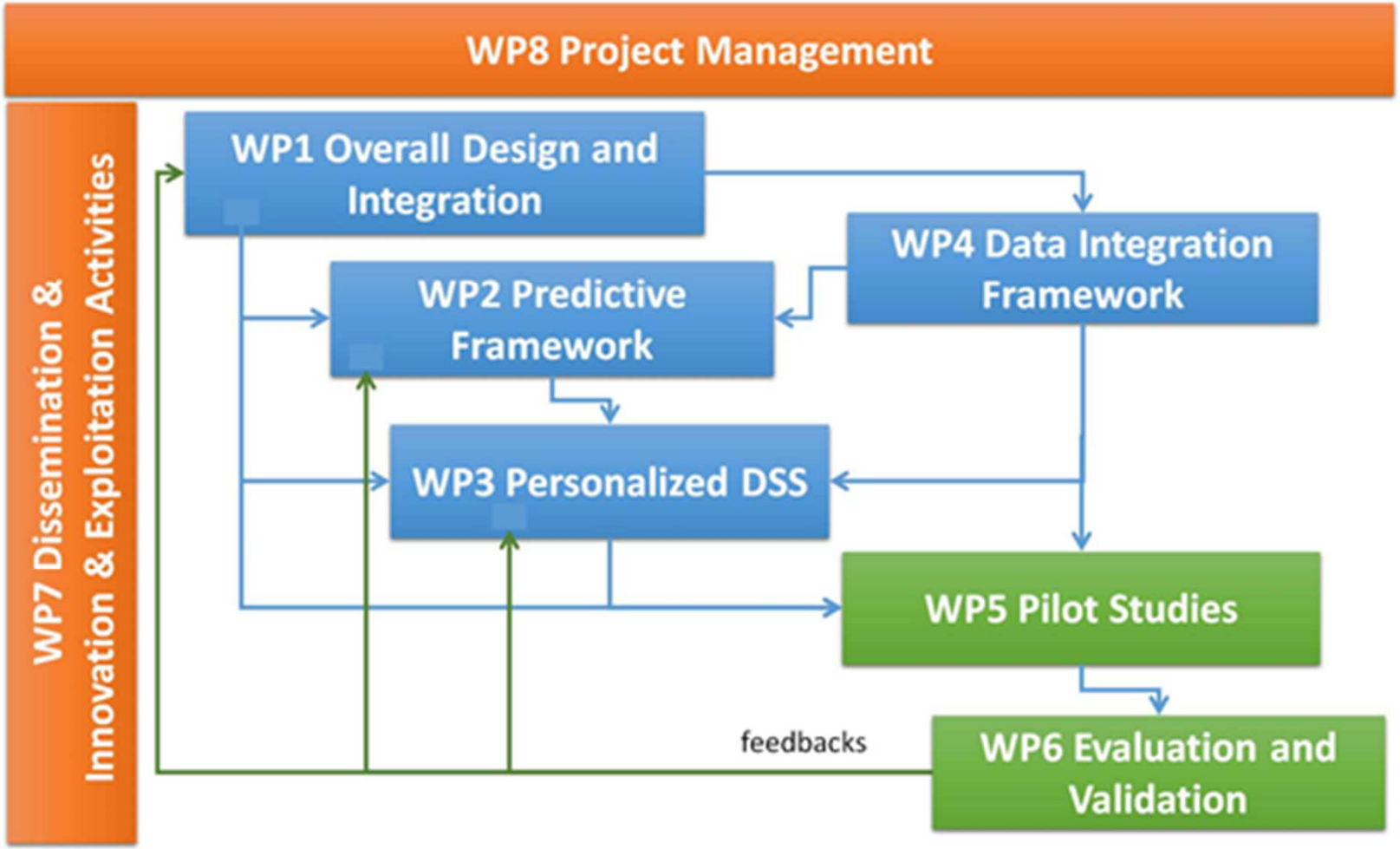
- TO1 - Deliver a personalized, integrated SMSS that offers action (care) plans in terms of changes in lifestyle, nutrition, physical activity and therapy adjustment for short term optimal metabolic control, medium term prevention of deterioration and long term avoidance of diabetes complications.
- TO2 - Deliver a patient-targeted decision support system (DSS) by utilizing and interlinking predictive models for the short- (KADIS), medium- (MT2D-Marvel), and long-term (risk score models).
- TO3 - Deliver an innovative Action Plan Engine building on EMPOWER, for personalized adaptive computer-aided health behaviour change interventions to support the patient to obtain and maintain healthy behaviour change.

POWER2DM TECHNICAL OBJECTIVES (2)

- TO4 - Deliver a cloud-based Data Integration Platform to collect and process the patient data in real time, establishing the patient profile. The bottom layer of this platform will be built up from integrated existing personal health systems, wearable sensors and mobile self-monitoring device data sources, for real-time collection of clinical, patient, therapeutic, behavioural, lifestyle, physical activity and dietary data. The upper layer, running on the cloud, will consist of a well-defined data model and API to process the data, enrich the data semantically, perform data quality assessment and store the result as time series data for the use by the predictive decision support and computer-aided health behaviour change intervention systems.
- TO5 - Deliver validation proof of the integrated SMSS system in terms of health outcomes, adherence to care programmes, acceptance of the new organizational process including the ICT components by care providers. Validation will take place in three existing regional settings in The Netherlands, Spain and Germany, using POWER2DM functionalities connected with different regional self-management support systems and following the regional guidelines for diabetes care.
- TO6 - Deliver a mobile interface to the POWER2DM SMSS for use on smart phones and tablets, thus stimulating EU industry in the area of personal devices, eHealth and self-management support tools.

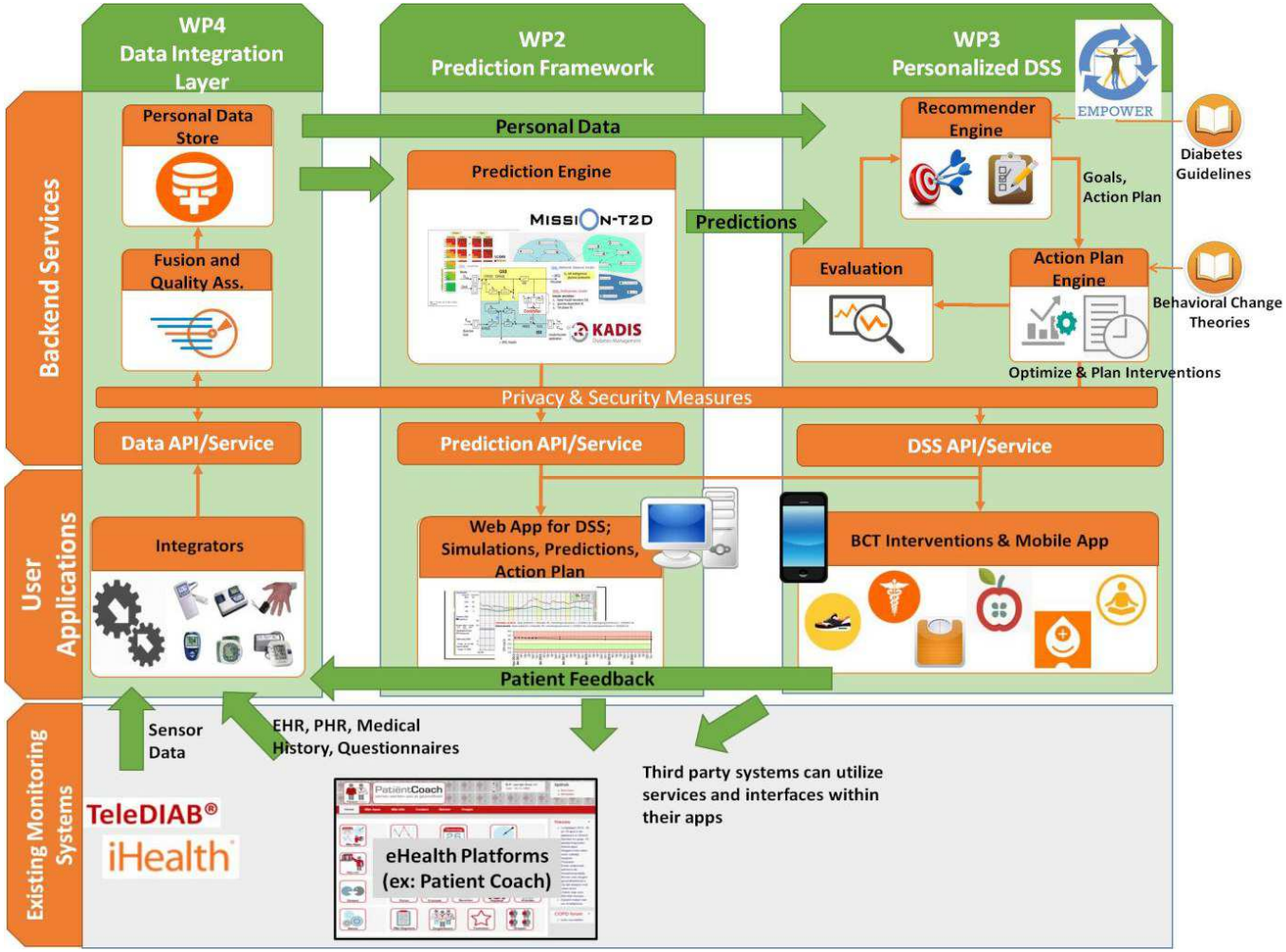
POWER2DM WP STRUCTURE

- The project consists of 8 Workpackages



WP1-OVERALL DESIGN AND INTEGRATION

- WP leader: SRDC Software Research and Development Company



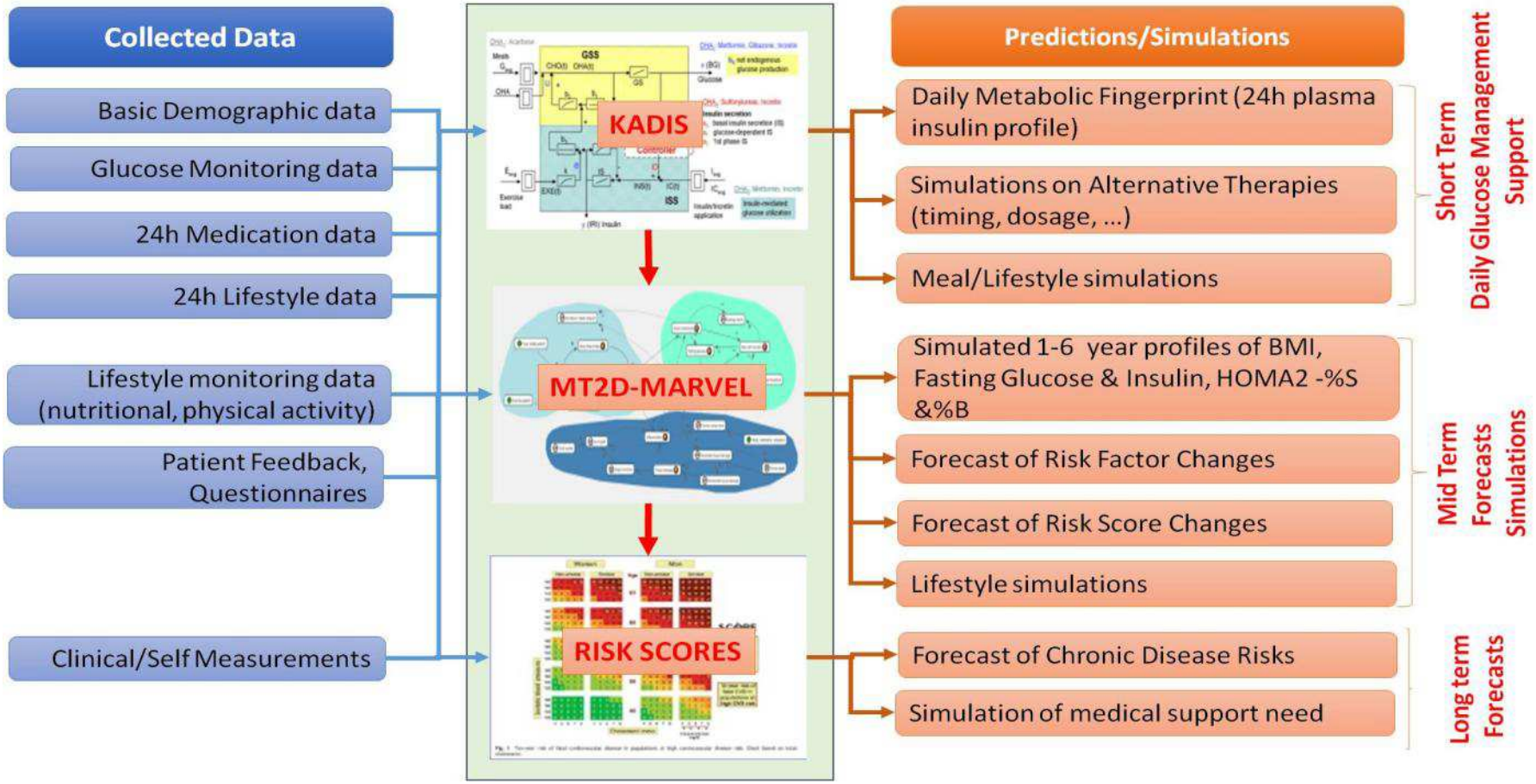
POWER2DM SMSS Architecture

WP1 - OBJECTIVES

- Definition of scenarios and storyboard to illustrate and facilitate discussion about the POWER2DM SMSS framework for the architecture and the design of the care process for care provider and especially the support of the self-care process and the glucose management of the patient.
- Definition of the scientific problem, analysing the scientific and technical requirements of POWER2DM architecture and its components.
- Designing POWER2DM architecture and its components by ensuring co-design and co-production between end users, the technical team and the external stakeholders via communication and liaison activities.
- Realizing the POWER2DM system by integrating all of the components according to the design before the experimentation and piloting phase
- Assuring the quality and correctness of the software by continuous testing activities
- Providing and managing software releases and prototypes

WP2 – PREDICTIVE FRAMEWORK

WP leader: IDK Institut für Diabetes Karlsburg



POWER2DM collected data, predictive models, prediction and simulation capabilities

PREDICTIVE MODELS IN WP2

...Interlinked models at 3 different timescales

- KADIS (KArlsburg Diabetes Information System): short-term prediction model, based on 24-72h glucose profiles, that generates a personal metabolic fingerprint and allows to simulate different intervention strategies. Developed and validated by partner IDK Karlsburg, in operational use for the TeleDIAB® program (http://www.diabetes-service-center.de/).
- MT2D-Marvel: 1-6 year forecasting model for the simulation of the effect of Type-2 diabetes lifestyle interventions. Developed by partner TNO in EU-FP7 project MISSION-T2D (http://www.mission-t2d.eu/).
- Risk Score Models: a collection of long-term prediction models for various diabetes complications. These models use sets of risk factors based on analysis of cohort studies.

KADIS® DIABETES MANAGEMENT (WP2)

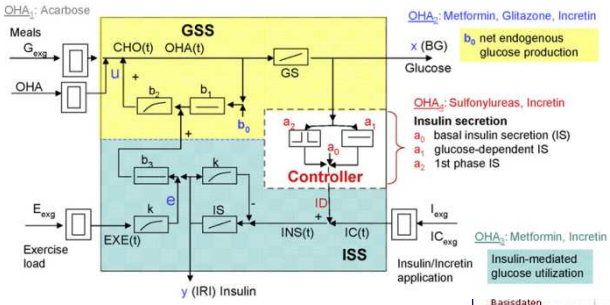
Data

(Semi) Continuous Glucose Monitoring data

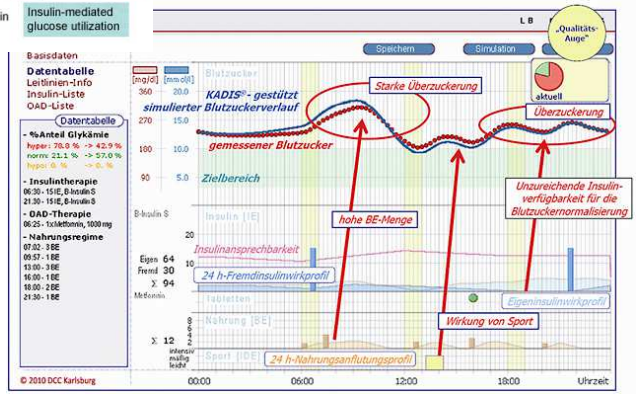
24h Medication/lifestyle data: carbohydrate intake, exercise, insulin administration, glucose-lowering medicine use

Basic data: Age, gender, BMI, onset & type of diabetes

Control system model



Personal parameter determination based on all data. Graphical display for the user



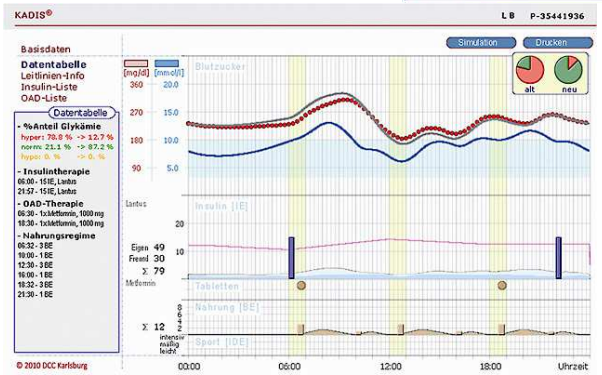
Result

Simulated 24h plasma insulin profile

Fasting plasma glucose and insulin for HOMA-2

Decision Support (DSS) functionality

Interactive simulations to decide on improved lifestyle/ medicine scenario overcoming weak points



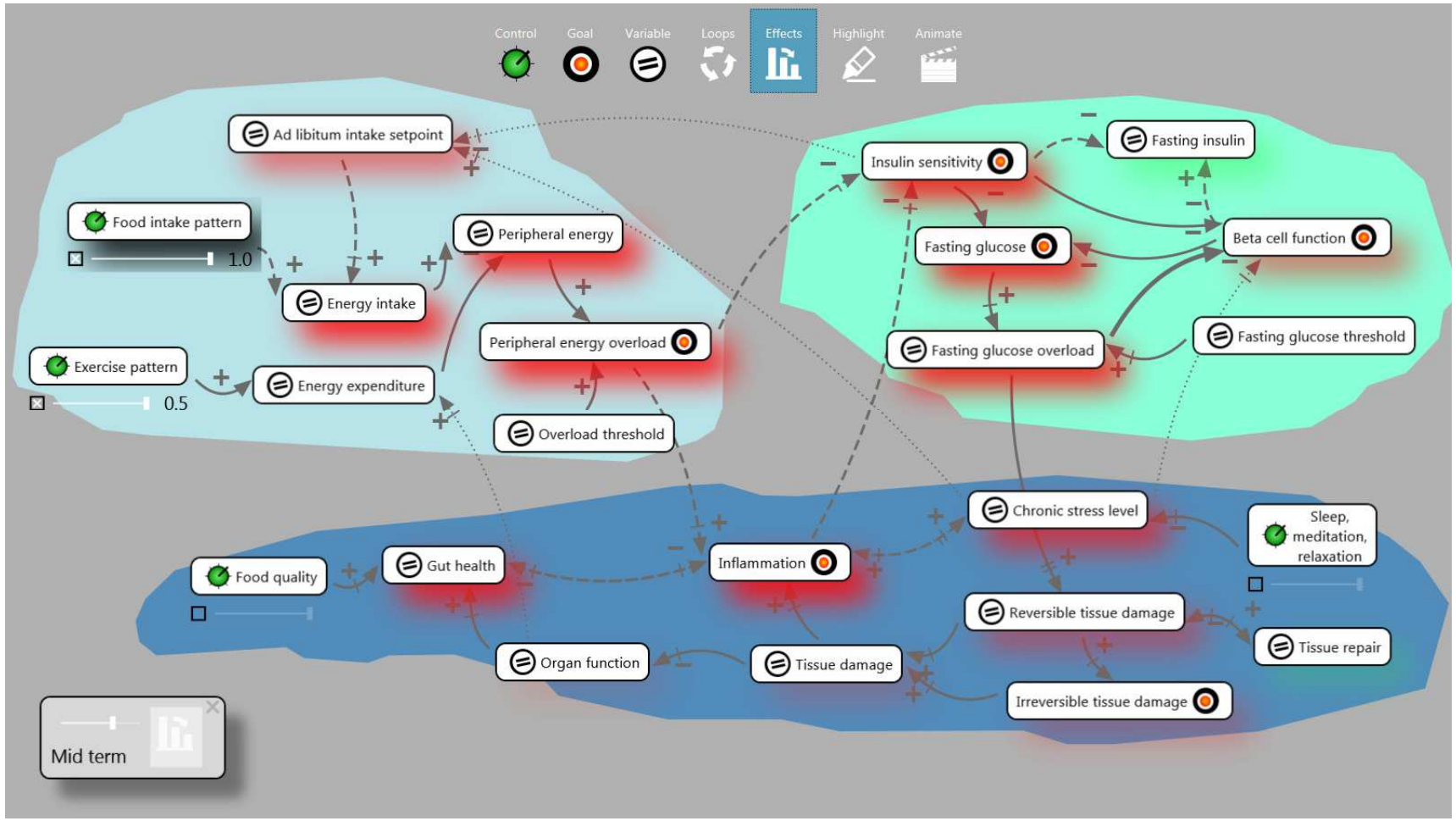
KADIS

Salz sieder et al.(2011) Model-based Decision support in Diabetes Care. Computer Methods and Programs in Biomedicine 102: 206–218

Salzsieder and Augstein (2011) The Karlsburg Diabetes Management System: Translation from Research to eHealth Application. J Diab Sci Technol 5: 13-22

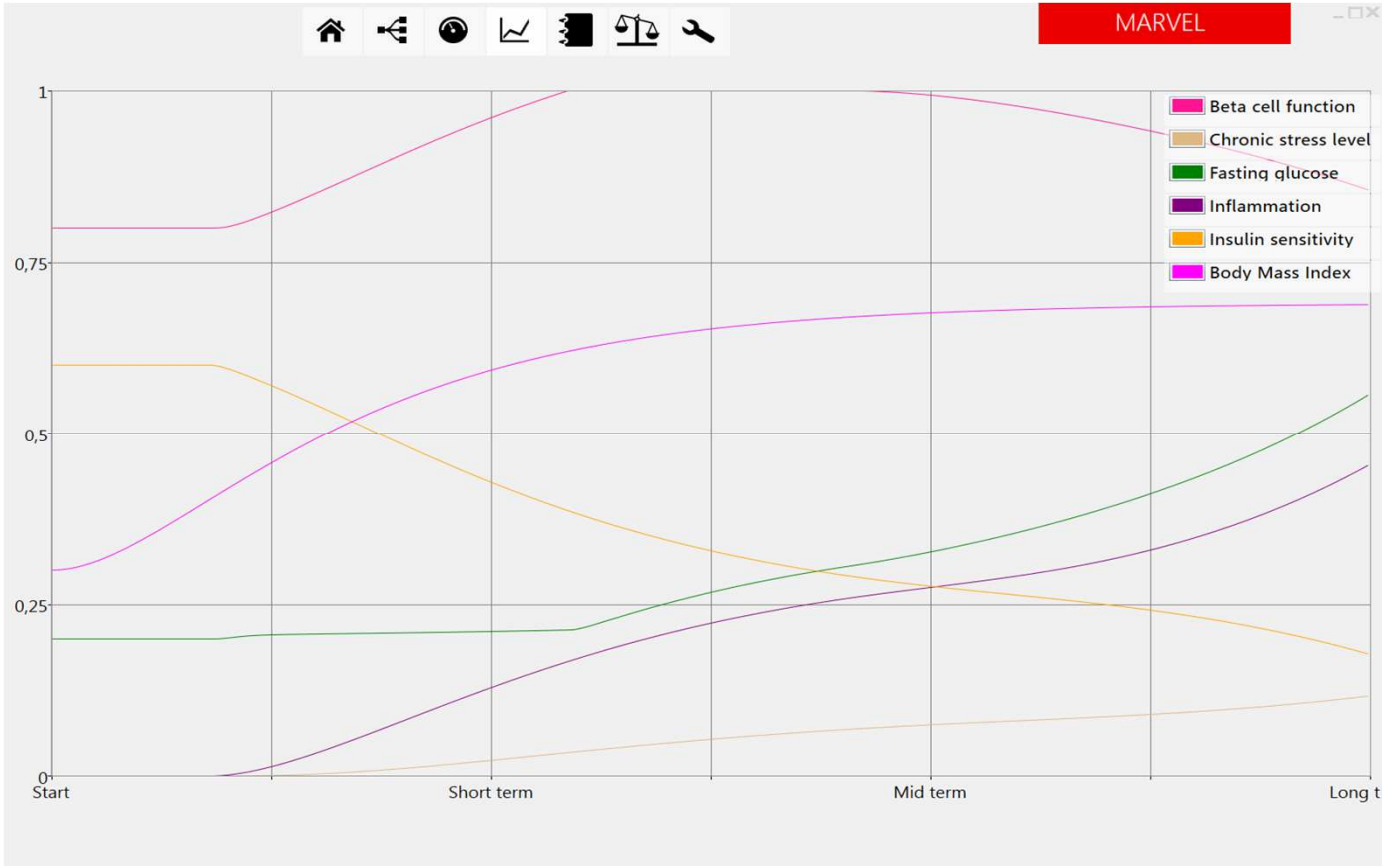
MT2D-MARVEL MODEL (WP2)

- Causal effect model
- High aggregation level, 1-6 years timescale



MT2D-MARVEL MODEL (2)

- Model use: scenario simulations



Validation: very similar patterns reported for Whitehall II cohort

Example: chronic large excess food intake results in an increasing Body Mass Index over the simulated period of 6 years, accompanied by an almost complete deterioration of insulin sensitivity and an increase of inflammation. Beta cell function compensates in the first ~3 years but declines afterwards, whereafter glucose levels start to rise strongly .

RISK SCORE MODELS (WP2)

- Model use: estimation % risk for getting diabetes complications

e.g. Prediction of kidney-related outcomes in patients with type-2 diabetes.
M.J. Jardine et al., Am J Kidney Dis. 60(5):770, 2012

Table 3. Multivariable HRs for Study Outcomes in the Final Risk Prediction Models

	Major Kidney-Related Events (n = 10,506)		New-Onset Albuminuria (n = 7,286)	
Variables	HR (95% CI)	*P*	HR (95% CI)	*P*
Sex (men vs women)	2.45 (1.68-3.55)	<0.001		
Ethnicity (Asian vs non-Asian)			1.67 (1.52-1.83)	<0.001
eGFR (per 10-mL/min/1.73 m^2 increase)	0.61 (0.56-0.68)	<0.001	0.94 (0.92-0.96)	<0.001
Urinary ACR (per log μg/mg increase)	1.57 (1.40-1.75)	<0.001	1.57 (1.48-1.66)	<0.001
Systolic blood pressure (per 10-mm Hg increase)	1.12 (1.05-1.21)	0.001	1.04 (1.02-1.06)	<0.001
Blood pressure–lowering treatment at baseline (yes vs no)			1.20 (1.11-1.31)	<0.001
Hemoglobin A_{1c} (per 1% increase)	1.12 (1.03-1.23)	0.01	1.04 (1.02-1.07)	0.002
Diabetic retinopathy (yes vs no)	1.52 (1.09-2.14)	0.02	1.28 (1.18-1.40)	<0.001
Waist circumference (per 10-cm increase)	—	—	1.05 (1.01-1.08)	0.01
Age at completion of formal education (≤15 vs ≥16 y)	1.51 (1.08-2.11)	0.02	—	—

Note: Each model adjusted for randomly assigned treatments.
Abbreviations: ACR, albumin-creatinine ratio; CI, confidence interval; eGFR, estimated glomerular filtration rate; HR, hazard ratio.

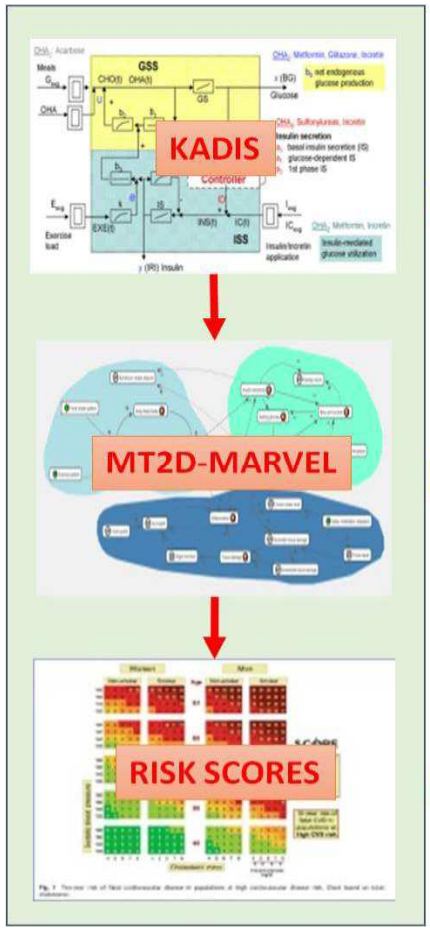
Am J Kidney Dis. 2012;60(5):770-778 773

Other diabetes complications: cardiac failure, foot ulcers, microvascular complications, retinopathy

WP2 - OBJECTIVES

- The primary goal of WP2 is to develop innovative programs, modules, and tools for short-term (Task 2.1) and long-term (Task 2.2) risk detection and risk prevention (Task 2.3) in personalized diabetes care and management by supporting patients efficiently in diabetes home monitoring and diabetes home care with patient-centered, real time decision support systems (DSS) which can finally be implemented into mobile-phone-based self-management equipments (Task 2.4).

WP leader: Salzburg Research Forschungs Gesellschaft



DSS Functionalities	Examples
Personal Weak Point support for Daily Metabolic Profile Daily Glucose Management Support Meal/Lifestyle Simulations	* Which meals to take? * Yes/no/how much physical exercise? * Yes/no medicine compliance? * Is my therapy optimal, Do I need to see a doctor?
Mid Term Lifestyle simulations Guided Goal Setting Planning further examinations and tests	* Which and how much lifestyle change is required and optimal for me for a certain objective? * Yes/no to discuss this with doctor? * Which goals to set for a healthier lifestyle plan?
Long term forecasts and simulations	Yes/no extra effort to reach the goal? Are my efforts worthwhile? When to make a next appointment?

POWER2DM predictive models, DSS Functionalities, and their way of guidance for individuals

WP3 - OBJECTIVES

- The overall goal of WP3 is the design and development of a personalised decision support system, in particular:
- - To select the required self-management DSS functionalities
- - To develop dynamic behaviour change intervention models for a personalised decision support system based on behaviour change theory (BCT)
- - To improve the EMPOWER Recommender Engine for automated adaption of goals and action plan based on predictions (WP2)
- - To improve the EMPOWER Action Plan Engine and develop a guidance-based goal specification process including a feedback mechanism based on the available patient profile and WP2's Predictive Framework
- - To develop the Web and Mobile-phone GUI components to deliver the DSS functionality and behavioural change interventions
- - To integrate the models, services and the GUI components into Personalized Self-Management DSS System for guided goal setting, activity planning needed to foster behavioural changes, delivering adaptive BCT interventions.

WP leader: PrimeData

Data	Action to Collect	Related System	Frequency of Collection	Burden on Patient
Baseline Data required for predictive models - will be collected in longer periods				
Basic Health Data	Data Integration	EHR	Once	None
Health Questionnaires	Filling out the Questionnaires	EHR	Initially and before every co-decision making/evaluation visit (2-4 per year)	Minimal
24h Glucose Monitoring Data	Device Integration	GM/CGM Device	Initially and for every therapy change (2 per year)	High
24h Intensive Lifestyle and Medication Monitoring (2 days long)	Input on meals and medicine taken	Web/mHealth Application	Initially and before every co-decision making/evaluation visit (2-4 per year)	Medium
Daily data by telemonitoring				
Physical Activity Tracking	Device Integration	Activity Tracking Device	Continuous	Minimal
Nutritional and Calorie Intake	Guided Patient Input	Web/mHealth Application	Daily initially, optional later	Medium
Daily Glucose Measurements	Device Integration	GM Device	Optional	Medium
Medication Intake	Device Integration, Input from patient	Device or Web/mHealth Application	Optional	Medium
Other patient feedbacks (symptoms, events, emotions)	Guided Patient Input	Web/mHealth Application	Guided	Minimal
Short-term periodic measurements				
Vital Signs (Blood Pressure , Weight, etc)	Device Integration	Medical Device	When needed (2-4 per week)	Minimal
Other clinical/self measurements (Fingerprick cholesterol, 24h urine for kidney risk factors)	Data Integration	EHR, Cloud Services	2-4 per year	Medium

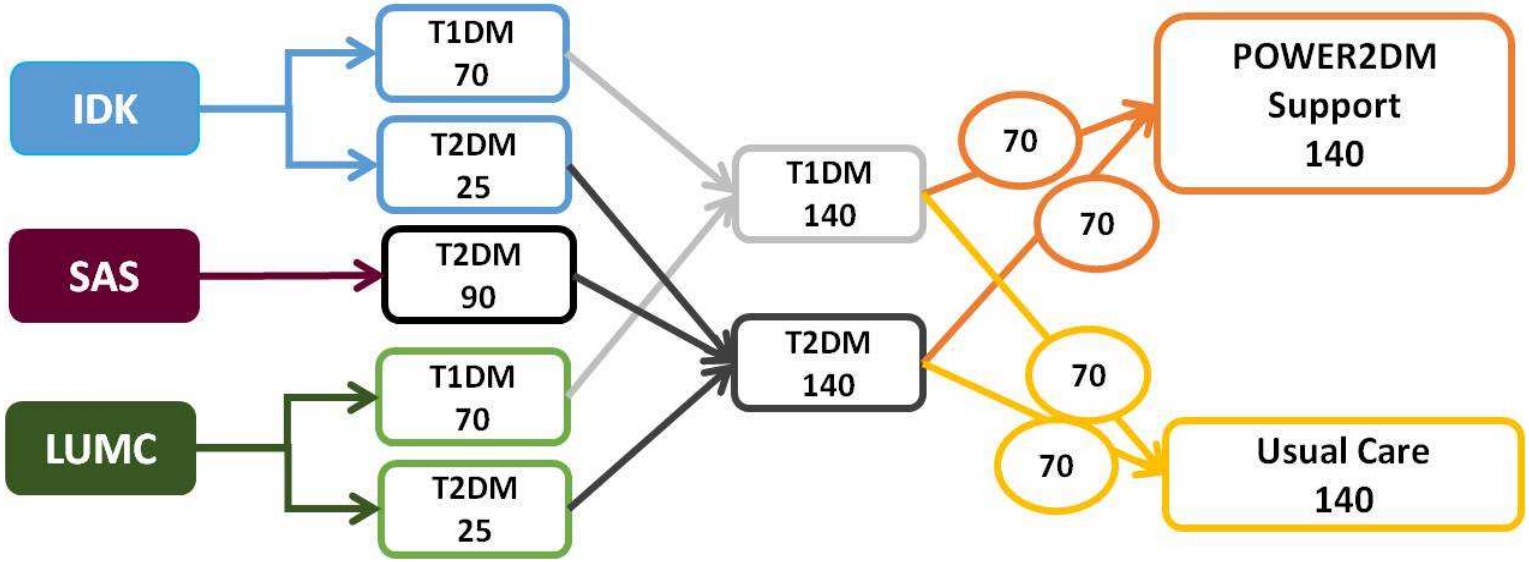
WP4 - OBJECTIVES

- Set specifications of all the data needed for the overall system according to data model defined in design phase
- Develop and deploy the data integration platform based on the requirements of pilot sites for both Quantification and Evaluation campaigns
- Choice of On-body, Home and On-phone Sensors, Wearable devices
- Define and develop API for data extraction into E-Health platform
- Provide devices and support for pilot studies
- Implement data extraction from official health records (EHR)
- Implement data extraction from personal devices (Clouds, PHR)
- Implement functionalities in the different languages of the pilot studies
- Integrate POWER2DM Services and GUI components to eHealth systems (e.g. PatientCoach) in Pilot Sites

WP5 – PILOT STUDIES

- WP leader: SAS (Servicio Andaluz de Salud)

1) Quantification campaign (4 months; small scale to validate data requirements)
2) Evaluation campaign: RCT (18 months; 280 diabetes patients)



Evaluation Campaign: distribution of patients over pilot sites, disease groups and intervention groups

WP5 - OBJECTIVES

- The aim of POWER2DM test campaigns will be twofold. In the first half of the project they will be performed so as to ground the model with experimental data and quantify and fine-tune the developed WP2 computational models. In the second half of the project, evaluation campaigns will involve execution in the three challenging pilot sites and will serve both model optimization and validation purposes (WP6)

WP6 – EVALUATION AND VALIDATION

- WP Leader: LUMC

OUTCOMES	Knowledge Awareness	Behaviour Changes	Self Efficacy	Health Status Outcomes	Clinical Outcomes	Cost Effectiveness
IMP.	IMPROVED SELF-MANAGEMENT OF DIABETES				IMPROVED PHYSICAL HEALTH	COSTS
IMPACT INDICATORS	Diabetes knowledge Diabetes related skills Application of knowledge	Physical activity Healthful eating Medication adherence Problem solving & Skills (glucose msrm., insulin injection, etc) Sick day management Appropriate attendance for medical care	Empowerment Coping skills Confidence with self-management Participation in goal setting and decision making	Well-being Quality of life Satisfaction	*Physical* Weight, BMI, Blood Pressure *Biochemical* HBA1c *Complications Presence,* Frequency, severity and duration *Therapy* mproved therapeutic regime accuracy	*Individual and the family:* - Out of pocket expenses - Loss of income *Societal:* - Cost of products - Financial burden of complications - Loss of productivity
METRICS /METHODS	Summary of Diabetes Self-Care Activities Diabetes Knowledge Test	Pedometer, Carb intake per day Pill count, Medication records Adjusted food, medication, activity Blood glucose testing Contacts with healthcare provider	Treatment Self-Regulation Questionnaire Diabetes Empowerment Scale Self-Efficacy of patients with Type 2 diabetes scale	Well Being Questionnaire Disease Specific Quality of Life Questionnaire Appraisal of Diabetes Scale	Sensors to measure vital signs Care records Number of trial and error therapeutic regimes	Avg direct costs for patients Avg indirect costs for patients Number of days away from work Quality-adjusted life year

POWER2DM impact indicators and associated metrics and methods

WP6 - OBJECTIVES

- The aim of WP6 is two-fold. First, it is aimed at evaluating the performance of the existing KADIS and MT2D-MARVEL prediction models and to assess to what extent POWER2DM applications can provide (additional) model inputs that are non-invasive, easy attainable and convenient for all patients. This work will be done in close cooperation with the Patient Organizations to be involved in the project under guidance of the IDF. Second, this work package is focused on the evaluation and validation, including the clinical and socio-economic and organizational impact of the final POWER2DM mHealth & prediction based personalised health system.

WP7 – DISSEMINATION, EXPLOITATION, INNOVATION

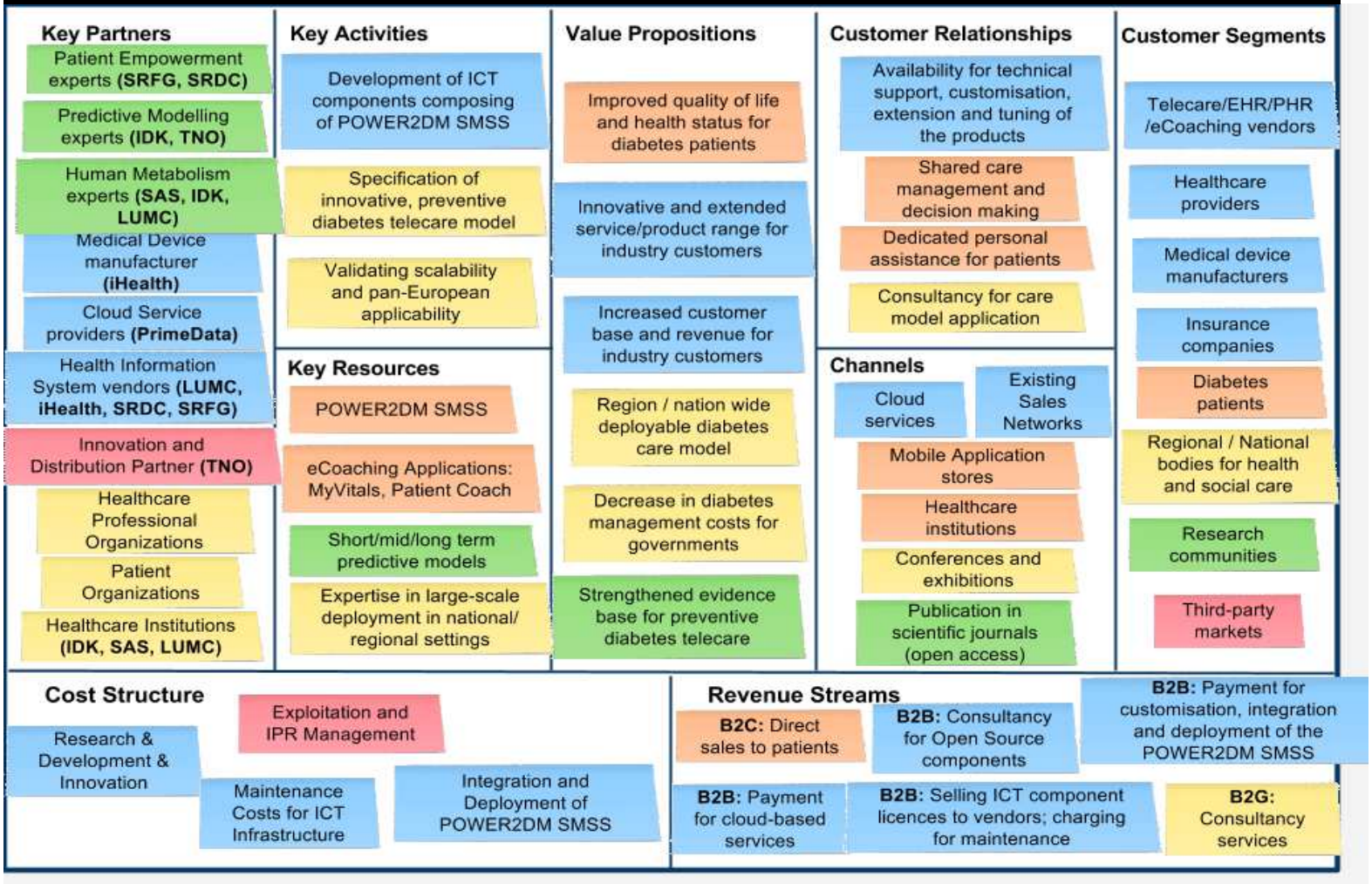
- WP leader: TNO

Results to Disseminate	To Whom	Why?	How?	When?
Project Idea and Approach	Press, General Public, Scientific Communities, Regulatory Bodies	Awareness, Attention	Project Website, Opening Event, Leaflet & Brochures, Press releases, Social media	Phase I M1-M3
Requirements and Initial Designs	Patients, Researchers ,Care Providers Expert networks, Regulatory Bodies, Health Insurers, mHealth SMEs	Get early feedback	Patient group workshops,Conferences, Open Review Questionnaires, Professional web forums	Phase I M1-M8
Intermediate prototypes (Prediction, DSS)	Scientific Community, Patients, Care Providers, Expert Networks, mHealth SMEs, Standardization bodies	Attracting, Open Innovation	Prototype demonstrations, Dem. videos, Publications, Fairs, hackhathons, Patient group workshops	Phase II M9-M20
Evaluation results after Quantification Campaign	Scientific Community, Patients, Care Providers, Insurers, Expert Networks	Proving capabilities	Publications, Conferences	Phase II M15-M20
Care protocol, intermediate pilot results and integrated system demonstrators	Insurance companies, Regulatory bodies, Expert Networks, Investors, Patients	Attracting Customers, Build Relationships	Fairs, Exhibitions, Demonstrations, Publications, Patient group workshops, Conferences, Workshops, Videos from pilot sites	Phase III M21-M42
Evaluation results, Social, Economic and Clinical Outcomes	Scientific Community, Insurers, Regulatory bodies, Patients, Care Providers, Expert Networks, Investors	Prove the benefit, Attract the Customers	Publications, Press releases, Patient group workshops, Leaflet & Brochures, Social media, Closing Event,	Phase III M36-M42

Summary of Dissemination Plan

WP7 – BUSINESS MODEL

- Blue: Industry enterprise-related elements (incl. insurance companies and healthcare providers)
1. Green: Research/scientific community-related elements
- Yellow: Government/public organization-related elements
- Orange: Patient-related elements
- Red: Dissemination & exploitation-related elements

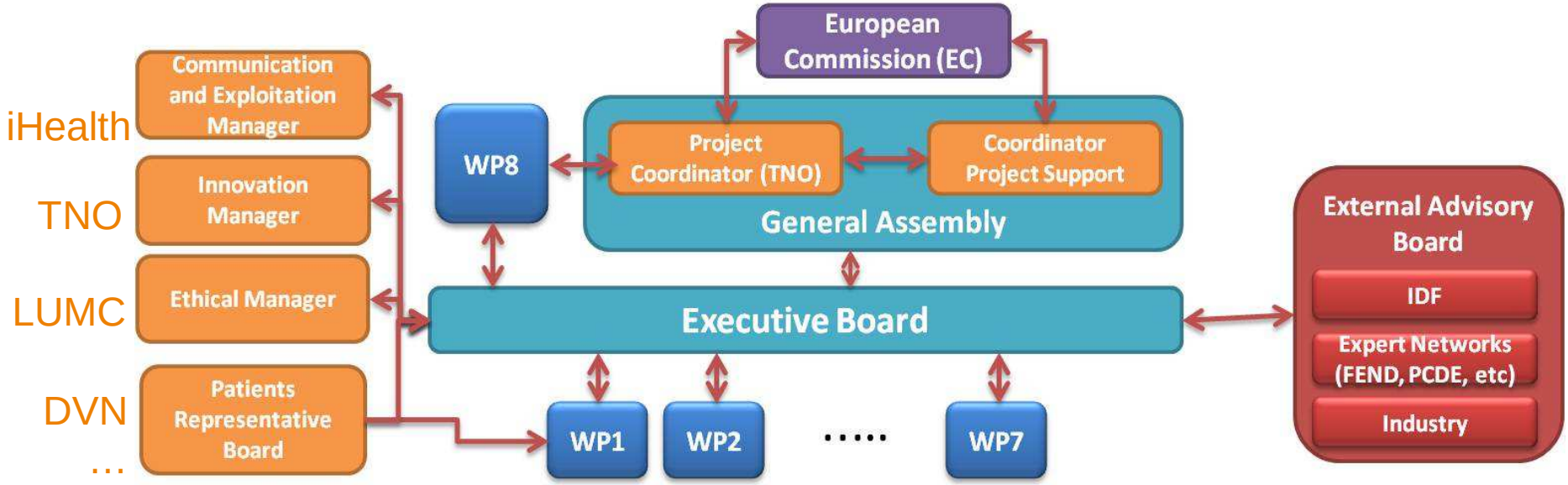


WP7 - OBJECTIVES

- WP7 will disseminate key information on the project, associated activities and outcomes to an international audience. Specific objectives are as follows:
- - Coordination of project dissemination and communication activities
- - Identification of business and market opportunities, and providing exploitation plans
- - Management of innovation and intellectual property rights
- - Liaison activities with the eHealth industry actors

WP8 – PROJECT MANAGEMENT

- WP leader: TNO



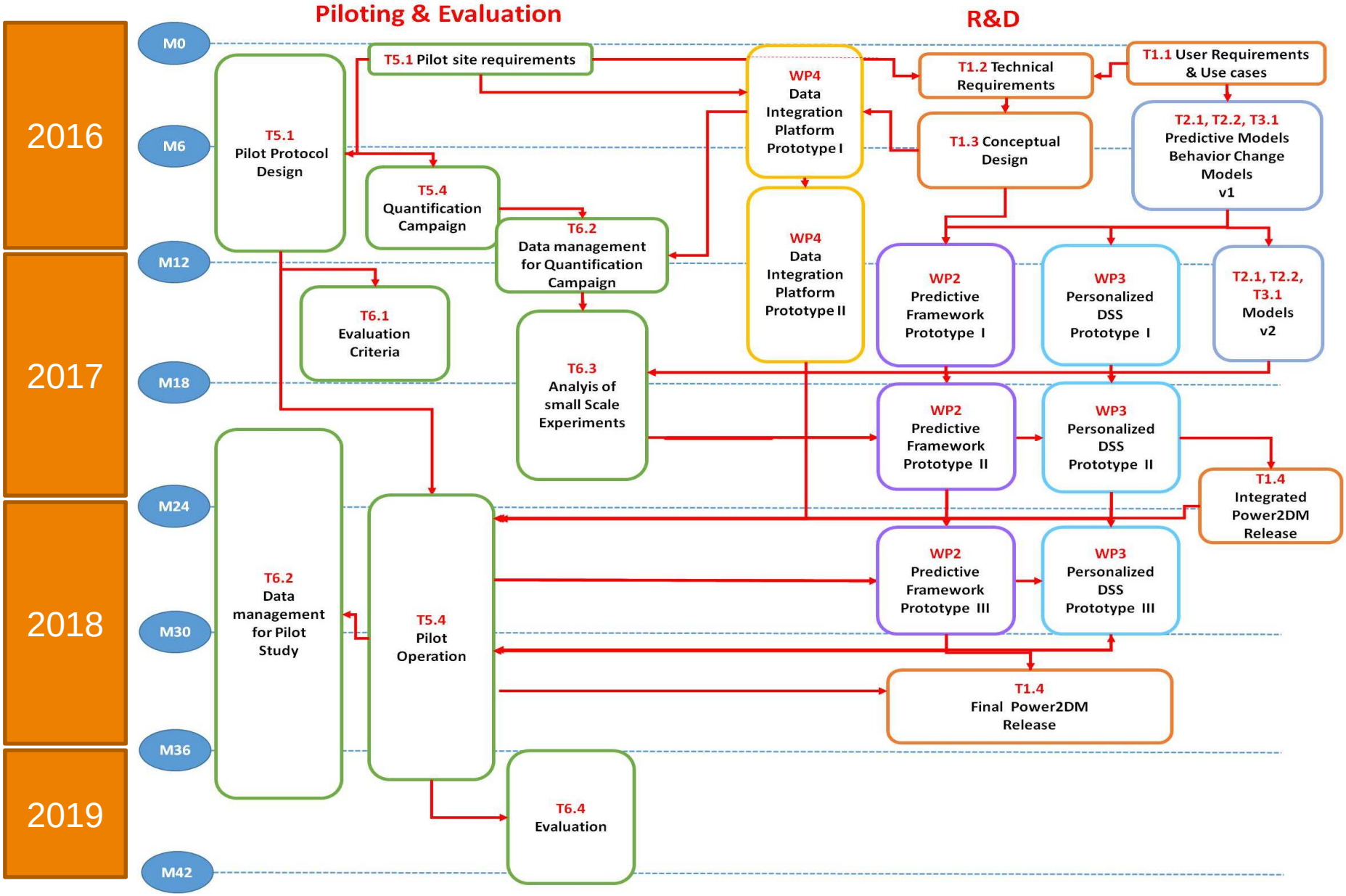
Management structure of POWER2DM

Patient Representatives Board (PR): The set-up of a Patient representatives (PR) board, co-chaired by LUMC and SAS will be achieved. The PR board will consist of 6 patients with diabetes and/or their families and carers, they will be recruited via local patient organisations/ patient bodies. They will engage with the Executive board, meeting annually, and inform decision making. Patients will be trained and appraised regularly of the project progress, outside of any formal meetings, they will provide advice on patient experience and ethical issues that may arise.

WP8 - OBJECTIVES

- To ensure achievement of the objectives of the project through effective and efficient management, financial control and administrative work of the project. Any discrepancies will be swiftly reported to the Commission.
- To coordinate a well-functioning and effective research consortium that consists of scientists from different disciplines as well as business partners and patients/clients representatives.
- To ensure scientific excellence, innovation and efficient implementation as well as valorisation (business modelling).
- To network and collaborate with other related consortia, projects and networks in Europe.
- To provide evaluation reports to the Commission as required.

PROJECT PHASING



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