



# POWER2DM

“Predictive model-based decision support for diabetes patient empowerment”

**Research and Innovation Project**

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

## POWER2DM D1.2

### Requirements Specification of the POWER2DM Architecture

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PD	PrimeData	Netherlands
iHealth	iHealth EU	France

## TABLE OF CONTENTS

Table of contents.....	4
1 Introduction.....	5
1.1 Purpose and Scope.....	5
1.2 References.....	5
1.3 Definitions and Acronyms.....	5
1.4 Methodology.....	5
2 Overall System Description.....	5
2.1 POWER2DM SMSS System Perspective.....	5
2.2 Actors in Use Cases.....	7
2.3 POWER2DM SMSS Use Cases.....	8
2.3.1 UC1 – Registration of Anamnesis into POWER2DM.....	12
2.3.2 UC2 – Register Barriers into POWER2DM.....	14
2.3.3 UC3 - KADIS based Q-Score Analysis and Metabolic Fingerprint Analysis.....	14
2.3.4 UC4 – Evaluation of Risks and Outcome Expectancies (by using MT2D-MARVEL and risk score models).....	18
2.3.5 UC5 – Finalizing and Registration of Treatment Plan and Goals into POWER2DM ..	24
2.3.6 UC6- Review/Adjustments of Self-Management Goals.....	30
2.3.7 UC7- View, Specification and Adjustments of Action Plan.....	33
2.3.8 UC8- Collecting daily observations from patient.....	37
2.3.9 UC9- Delivering JITAI interventions at runtime during daily life.....	40
2.3.10 UC10- Self-evaluation with provided feedbacks.....	42
2.3.11 UC11 – Introducing the POWER2DM system to patient.....	44
2.3.12 UC12 – Configure SMSS.....	44
2.3.13 UC13 – User and Security Management for POWER2DM.....	45
3 POWER2DM SMSS Specific Requirements.....	49
3.1 POWER2DM Shared Decision Making Application Requirements.....	49
3.2 POWER2DM Action Plan Engine Requirements.....	51
3.3 POWER2DM Mobile Application Requirements.....	52
3.4 POWER2DM Communication Engine Requirements.....	53
3.5 POWER2DM Prediction Service Requirements.....	55
3.6 POWER2DM Personal Data Store Requirements.....	57
3.7 POWER2DM User Management, Authentication and Authorization Framework Requirements.....	58
4 POWER2DM SMSS Patient Recommendations.....	60
4.1 Introduction.....	60
4.2 Results.....	60

# 1 INTRODUCTION

## 1.1 Purpose and Scope

The purpose of deliverable D1.2 is to describe the functional and technical requirements of POWER2DM SMSS architecture. Its first objective is to identify the high-level components of POWER2DM platform, and how these components should work together to realize the pilot application scenarios, in order to serve as a basis for the conceptual design phase (Task 1.3). Then, a set of high level use cases and flow of them in different phases; shared decision making phase, self-management phase are given. The use cases provide the main idea behind the described functionality/scenario and do not provide the specific details which will be studied in WP2 and WP3 and given by decision trees, algorithms, etc. Thereafter, basic technical requirements for each main component are given in this direction. Finally, a set of recommendations from diabetes patients are included.

## 1.2 References

- POWER2DM Description of Work (Proposal)
- D1.1 User Requirements and Use Case Scenarios
- D4.1 Personal Data Model and Service API

## 1.3 Definitions and Acronyms

**Table 1 List of Abbreviations and Acronyms**

Abbreviation/ Acronym	DEFINITION
CGM	Continuous Glucose Monitoring
DM-QOL	Diabetes Management Quality of Life
FHIR	Fast Healthcare Interoperability Resources
HL7	Health Level 7
IEEE	Institute of Electrical and Electronics Engineers
SMSS	Self-Management Support System
JITAI	Just-in-time adaptive intervention
ODL	Observation of daily life
T1DM	Type 1 diabetes
T2DM	Type 2 diabetes

## 1.4 Methodology

The conception of this Requirements Specification Document follows the recommendations of the well-established standards IEEE Std. 830-1998 and IEEE Std. 1233-1998 (Guides for software/system requirements specifications).

# 2 OVERALL SYSTEM DESCRIPTION

## 2.1 POWER2DM SMSS System Perspective

**POWER2DM Shared Decision Making Application:** This should be an application (with user interfaces) that will support the healthcare professional in shared decision making phase to enter data to POWER2DM as well as visualize and evaluate patient's data collected during self-management phase;

- registration of anamnesis and problems

- enter treatment goals and committed actions by using POWER2DM prediction capabilities (POWER2DM Prediction Services), so that the consequences of various actions can be compared to support shared decision making.
- analysis of problems and barriers identified in self-management and update treatment goals and action plans accordingly

The final version of the treatment goals and committed actions will be the input for the Action Plan Engine.

**POWER2DM Action Plan Engine:** The starting point for the Action Plan Engine are the treatment goals and the treatment plan provided by the Shared Decision Making Application. The Action Plan Engine is a complete web application (with user interfaces) that supports patient’s self-management for:

- Specification of values and if applicable of barriers
- Specification and update of self-management goals (e.g. in case of a new/updated treatment plan or when self-management goals are not realistic)
- Planning of activities periodically (basically weekly)
- Collecting ODL (Observations of Daily Life) data – in POWER2DM patient data basically will be collected through medical devices, mobile app and over user interfaces of Action Plan Engine
- Evaluation of performance by providing feedback periodically (basically weekly)
- Algorithms to identify barriers for self-management and offer a set of interventions based on the identified barrier
- Update of activities and/or self-management goals if feedback low performance.

The Action Plan Engine provides interventions based on the collected ODLs (e.g. feedback on planned activities, motivational messages and tips for fostering or improving self-management activities). Interventions are provided periodically, typically in weekly cycles.

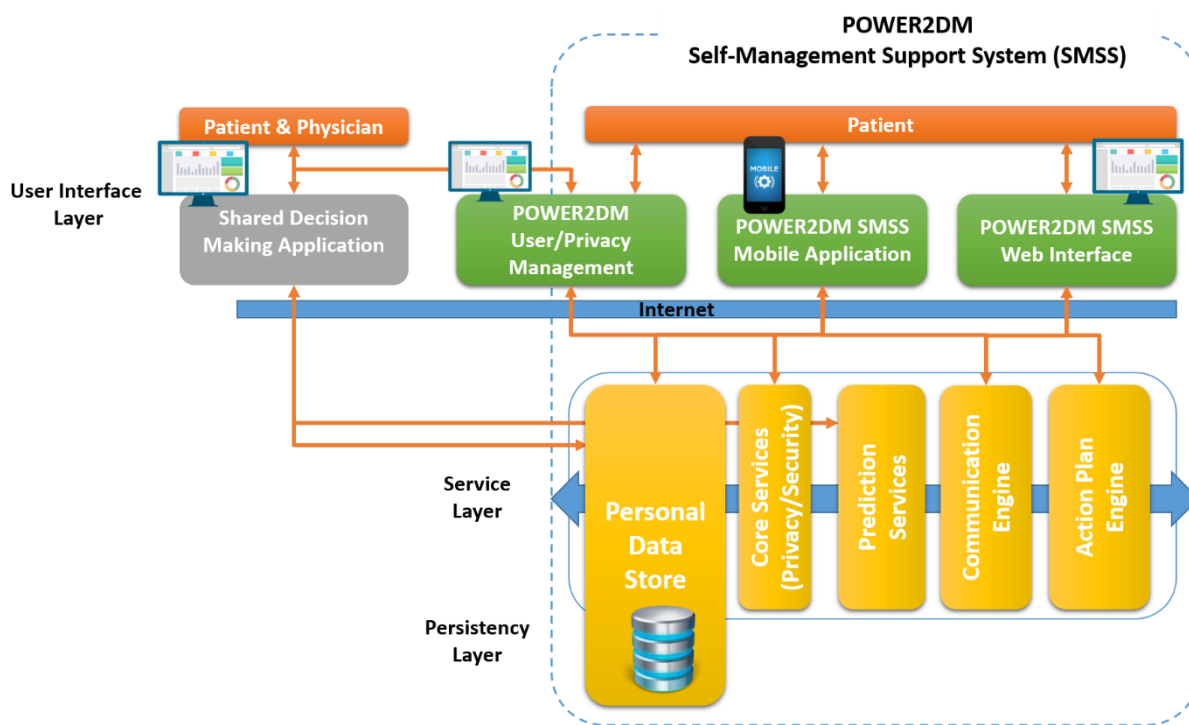


Figure 1 POWER2DM Major Components

**POWER2DM Communication Engine:** It is a backend intelligence service aiming to recognize patient's preferences and life-style patterns from collected data. Based on these recognized patterns and preferences it plans Just-In-Time Adaptive Interventions (JITAI; Nahum-Shani et al., 2014). JITAI are self-management interventions that are initiated by the POWER2DM SMSS system (specifically Communication Engine) automatically during daily life of the patient according to the changing context of the patient. The idea is to adapt the frequency, content and type of interventions accordingly. Examples of JITAI are: (a) warning that after a loaded breakfast the patient should have a light lunch in order to manage his blood glucose, or (b) patient only does half his planned exercise and receives a motivating message to finish the complete exercise.

Planned JITAI will be delivered to patients through;

- the dashboard that will be developed in Action Plan Engine
- the push notifications for POWER2DM Mobile Application

**POWER2DM Mobile Application:** This is the mobile application to interact with the patient during self-management for

- delivering JITAI interventions
- collection of ODL data; manual guided data entry by patient and/or connecting and retrieving measurements from medical devices and transfer them to Personal Data Store
- customization of user profile and settings

**POWER2DM Prediction Services:** All short, mid and long-term predictive models are exposed as web services in a way that are consumable by other relevant components through the internet (KADIS, MT2D-MARVEL and Risk Score models as prediction service). The prediction services will interact with the following POWER2DM components. The Shared Decision Making Application will interact to get KADIS predictions, MT2D-Marvel Predictions and Risk Score calculations during shared decision making phase. The Communication Engine will interact with prediction services for JITAI interventions.

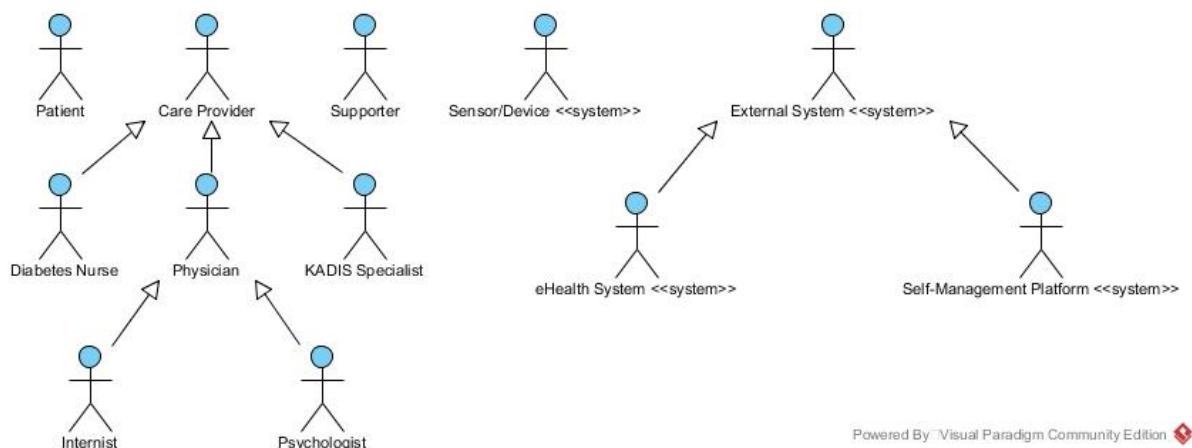
**POWER2DM Personal Data Store:** This is the secure component that will store any patient data that needs to be recorded in the system and provide a secure RESTful service for other POWER2DM components to access and update recorded data.

**POWER2DM Sensor Processing Module:** (Task 4.4) This component will be defined in the design phase; functionalities are not concrete at this point.

**POWER2DM User Management, Authentication and Authorization Framework:** This is the component that will handle user management, authentication and authorization processes as a central trusted service for POWER2DM. It will provide a web based user interface for sign-in, account registration, and access control management.

## 2.2 Actors in Use Cases

Figure 2 illustrates the actors involved in the use cases. Only actors that are external to POWER2DM system are listed here and POWER2DM system actors are not described here.



**Figure 2 Actors Involved in POWER2DM Use Cases**

**Patient** is T1DM or T2DM patient that is registered to POWER2DM Care Program and will use POWER2DM SMSS to manage his/her diabetes.

**Care Provider** is a healthcare professional that takes role in the care process of patient.

- **Diabetes Nurse** is the special diabetes nurse that take role in POWER2DM Care Program and support Physicians in especially administrative operations in POWER2DM process
- **Physician** is any type of physician that take role in POWER2DM Care Program to manage the care plan of patient
  - **Internist** is the diabetes specialist who is leading the POWER2DM Care Program for patient
- **Supporter** is any person close to patient (from family, friend, etc.) that supports patient in his/her POWER2DM Care Program by taking small roles in the process
- **Sensor/Device** (system actor) is any medical device or sensor to be used by patient to collect daily data
- **External System** (system actor) is any healthcare related system external to POWER2DM that provides data for POWER2DM
  - **External eHealth System** (system actor) is existing eHealth systems of the care facilities and care providers that are managing the POWER2DM Care Program for their patients.
  - **External Self-Management Platform** (system actor) is a mobile application, cloud service for a medical device set, etc. that collects data from patient and provides a service for other systems to access these data if patient allows it. POWER2DM will be integrated with the selected ones to retrieve data to its platform.

### 2.3 POWER2DM SMSS Use Cases

POWER2DM care program will consist of the following phases;

- **Shared Decision Making Phase:** This phase covers the consultation where patient and physician together analyses the health status of the patient and determine the treatment goals and plans for the next self-management phase. Figure 3 illustrates the flow of use cases for this phase describing how POWER2DM system will help these users to perform these tasks.



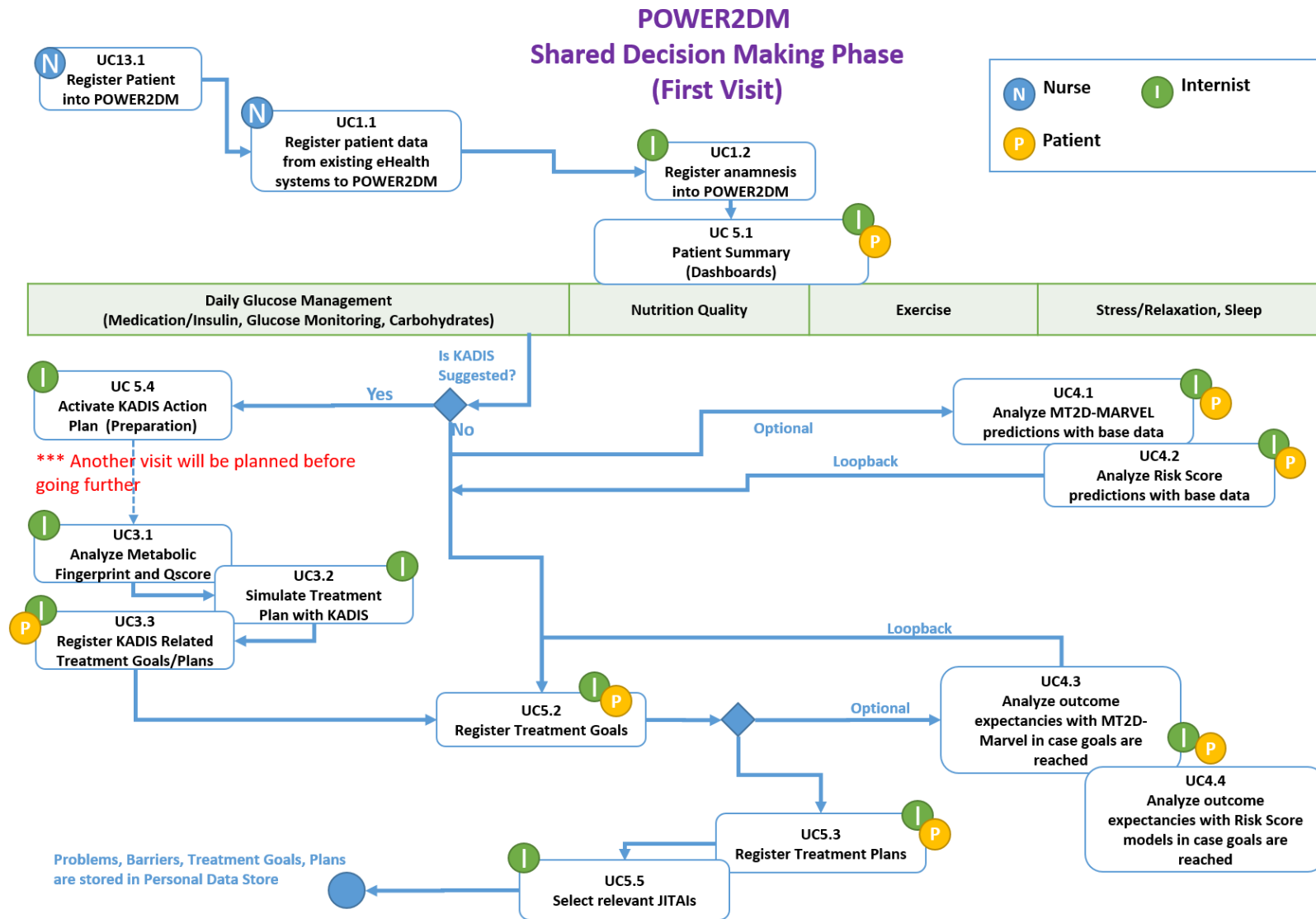
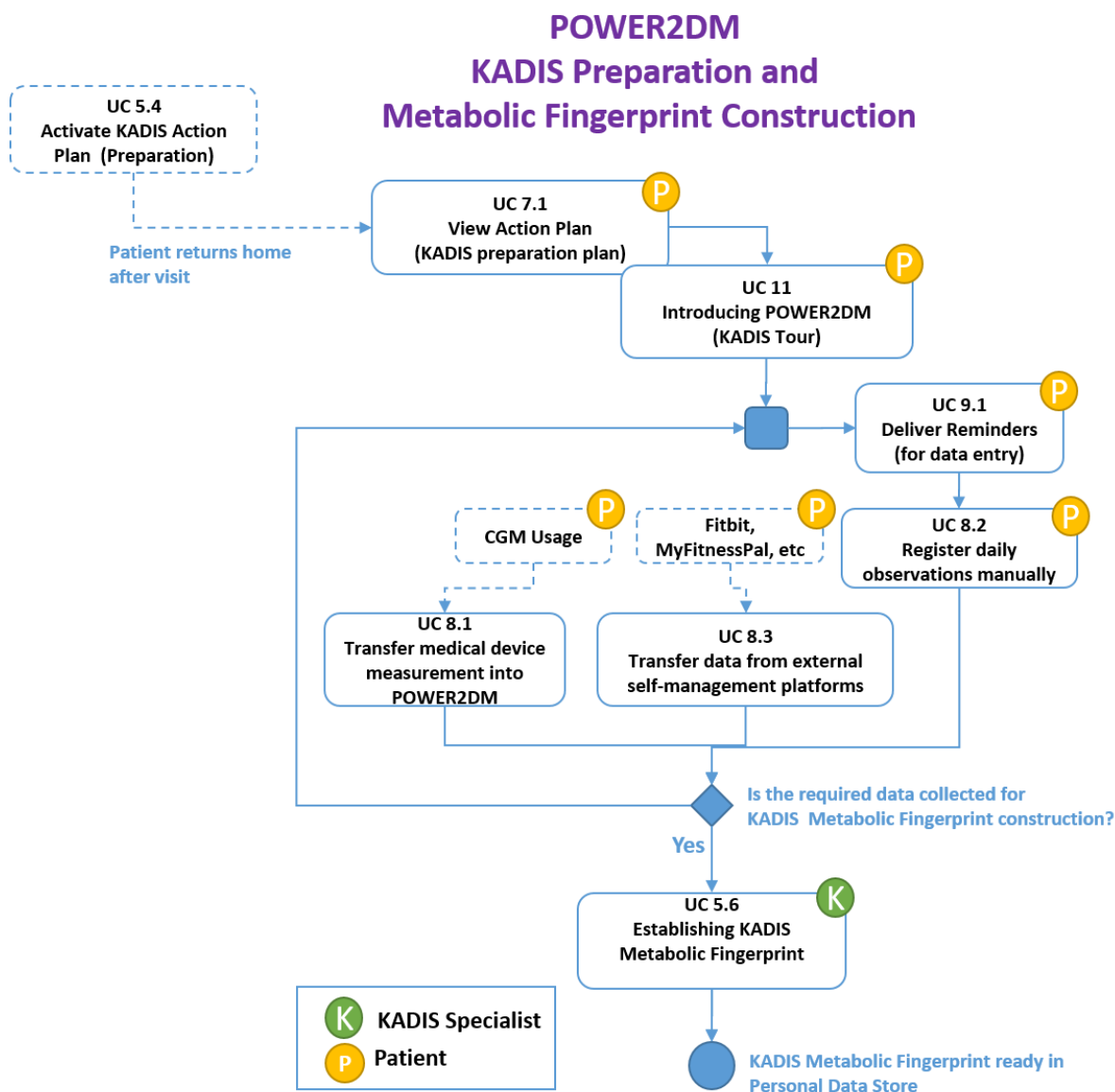


Figure 3 Flow of Use Cases in Shared Decision Making Phase



**Figure 4 Flow of use cases for KADIS Preparation and Metabolic Fingerprint Construction**

- KADIS Preparation and Metabolic Fingerprint Construction Phase:** In this phase, baseline health data (blood glucose measurements, dietary intakes, exercises, etc. for 3-day period) is collected to understand the patient's health status and to set a base for prediction models (KADIS and MARVEL). Therefore, after the first consultation, introduction of POWER2DM patient goes home and use the system for data collection in this period. Figure 4 illustrates the flow of use cases for this phase.
- Self-Management Phase:** This is the whole self-management phase (e.g. 3 months) between the consultations (shared-decision making phases). Figure 5 illustrates the flow of use cases. There is a periodic cycle (e.g. 2 weeks) in which patient evaluates and updates his goals and action plans, then daily self-management and at the end of cycle a self-evaluation with the aid of POWER2DM SMSS. The daily cycle illustrates how POWER2DM SMSS helps patient in his/her daily self-management.

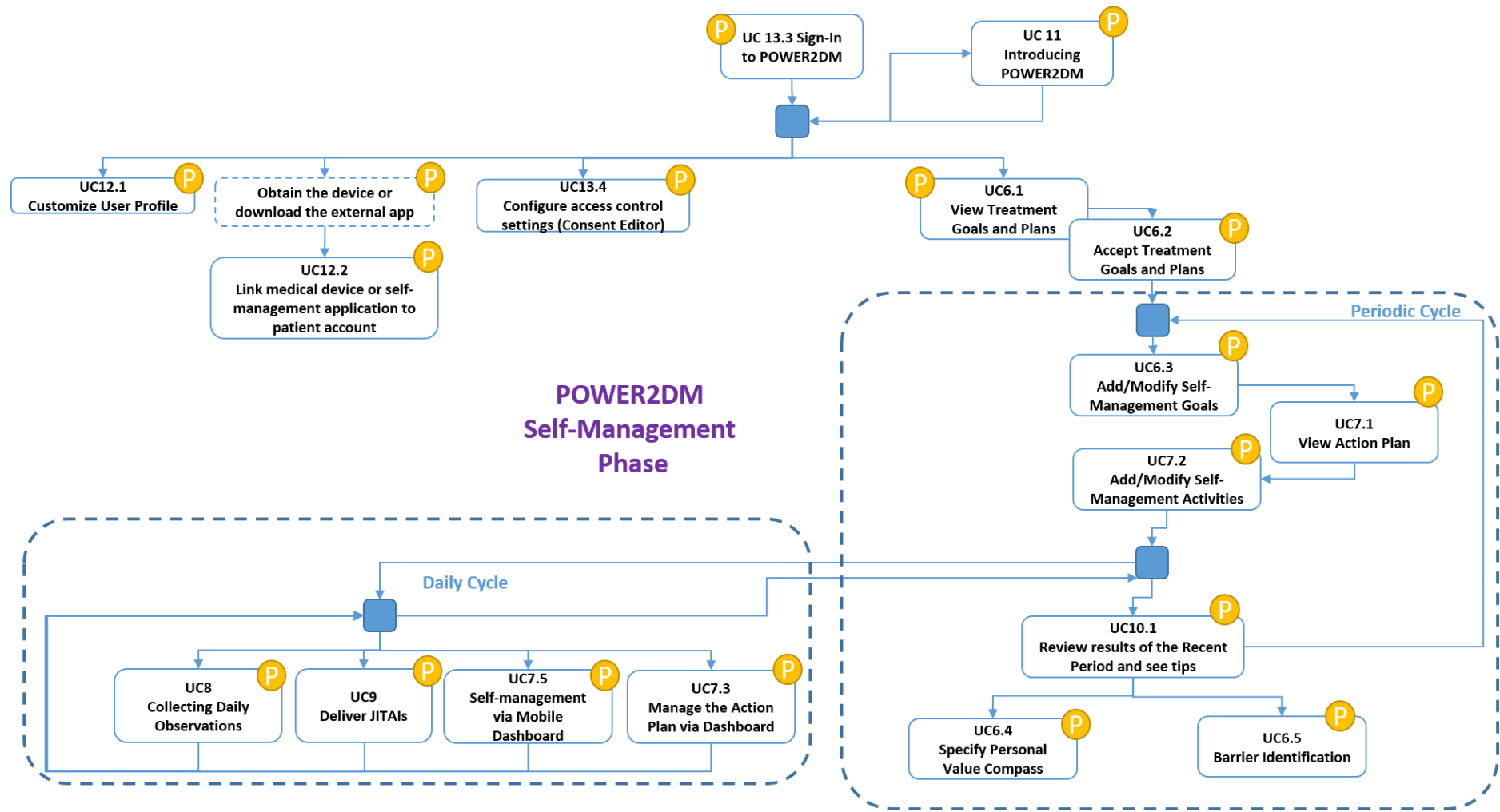


Figure 5 Use case flows for Self-Management phase

## 2.3.1 UC1 – Registration of Anamnesis into POWER2DM

### 2.3.1.1 UC1.1 - Register patient data from existing eHealth systems to POWER2DM

<b>Description</b>	<i>Patient's clinical information, diagnoses, lab and questionnaire results which are collected by the external eHealth system is registered to POWER2DM either by automated data integration or manual data entry.</i>
<b>Parent</b>	<i>UC1</i>
<b>Included sub-use cases</b>	-
<b>Extended sub-use cases</b>	-
<b>Scope</b>	<i>POWER2DM Shared Decision Making Application (user interface for manual entry) POWER2DM Personal Data Store (data storage backend)</i>
<b>Actor(s)</b>	<i>Diabetes Nurse eHealth System &lt;&lt;system&gt;&gt; (external system like PatientCoach or TeleDIAB)</i>
<b>Goal</b>	<i>Registering the data collected by external eHealth system to POWER2DM.</i>
<b>Trigger</b>	<i>Manually through POWER2DM Shared Decision Making Application</i>
<b>Frequency</b>	<i>Possibly for each Shared Decision making encounter when new data (lab result, questionnaire, etc) is available within eHealth system of the healthcare facility to register to POWER2DM.</i>

#### Preconditions

1. *Diabetes Nurse is logged on the POWER2DM*
2. *Diabetes Nurse is authorized to access the patient data in external eHealth system*
3. *Diabetes Nurse is authorized to register patient data to POWER2DM*

#### Success Postconditions

1. *Related patient data available in eHealth system is transferred to POWER2DM Personal Data Store*

#### Main Flow

The following steps will illustrate the manual entry (where system integration is not possible);

1. *Diabetes Nurse selects the patient from the list of patients registered in POWER2DM Care Program*
2. *Diabetes Nurse navigates to the Data Registration tab of POWER2DM Shared Decision Making Web Application*
3. *Diabetes Nurse enters the following information into the forms;*
  - i. *Diagnoses related with diabetes*
  - ii. *Latest lab results available in the eHealth system*
  - iii. *Latest questionnaire results applied to patient via eHealth system*
4. *Diabetes Nurse clicks to save button and system stores the information to the POWER2DM Personal Data Store*

#### Alternative Flows

The following steps will illustrate the automatic integration;

1. *Diabetes Nurse selects the patient from the list of patients registered in POWER2DM Care Program*
2. *Diabetes Nurse navigates to the Data Registration page of POWER2DM Shared Decision Making Web Application*

3. *Diabetes Nurse links the patient account in eHealth system with the patient’s POWER2DM account*
4. *Latest data records available in the eHealth System is transferred to Personal Data Store automatically*

**Open Issues**

1. The type of records that may be transferred to POWER2DM from external systems need to be clarified.

**2.3.1.2 UC1.2 Register Anamnesis into POWER2DM**

<b>Description</b>	<i>Internist registers anamnesis for patient into POWER2DM</i>
<b>Parent</b>	<i>UC1</i>
<b>Included sub-use cases</b>	-
<b>Extended sub-use cases</b>	-
<b>Scope</b>	<i>POWER2DM Shared Decision Making Application (user interface for manual entry) POWER2DM Personal Data Store (data storage backend)</i>
<b>Actor(s)</b>	<i>Internist</i>
<b>Goal</b>	<i>Registering anamnesis for patient into POWER2DM</i>
<b>Trigger</b>	<i>Manually through POWER2DM Shared Decision Making Application</i>
<b>Frequency</b>	<i>For each shared decision making encounter</i>

**Preconditions**

1. *Internist is logged on the POWER2DM*
2. *Internist is authorized to access/update the patient data in POWER2DM*

**Success Postconditions**

1. *Patient records related with Anamnesis are stored into POWER2DM Personal Data Store*

**Main Flow**

1. *Internist selects the patient from the list of patients registered in POWER2DM Care Program*
2. *Internist navigates to the Anamnesis tab of POWER2DM Shared Decision Making Web Application*
3. *The application shows a list of possible problems (e.g. dose too low) for each category (e.g. insulin/medication, carbohydrates, glucose monitoring)*
4. *Internist selects the problems that patient has from this list and write some notes for each of them if it is necessary*
5. *Internist click the save button and all information is stored into POWER2DM Personal Data Store*

**Alternative Flows**

*4.1 If Physician feels that the listed problems do not correspond to identified problem, he/she registers the problem by entering a textual description.*

**Open Issues**

None

### 2.3.2 UC2 – Register Barriers into POWER2DM

<b>Description</b>	<i>Physician registers identified barriers for patient into POWER2DM by relating them with registered problems (UC2).</i>
<b>Parent</b>	-
<b>Included sub-use cases</b>	-
<b>Extended sub-use cases</b>	-
<b>Scope</b>	<i>POWER2DM Shared Decision Making Application (user interface for manual entry) POWER2DM Personal Data Store (data storage backend)</i>
<b>Actor(s)</b>	<i>Internist (+Psychologist) Patient</i>
<b>Goal</b>	<i>Registering identified barriers for patient into POWER2DM</i>
<b>Trigger</b>	<i>Manually through POWER2DM Shared Decision Making Application</i>
<b>Frequency</b>	<i>For each shared decision making encounter</i>

#### Preconditions

1. *Physician is logged on the POWER2DM*
2. *Physician is authorized to access/update the patient data in POWER2DM*

#### Success Postconditions

1. *Patient's records related with Barrier Identification are stored into POWER2DM Personal Data Store*

#### Main Flow

1. *Physician navigates to the Barrier Identification tab of POWER2DM Shared Decision Making Web Application*
2. *The application lists the registered problems in anamnesis step*
3. *Physician selects a problem and the application lists possible barriers for the selected problem*
4. *Physician selects the ones that correspond to identified barriers for that problem*
5. *[Loop to step 3] for barrier registration of other problems*
6. *Physician clicks the save button and all information is stored into POWER2DM Personal Data Store*

#### Alternative Flows

4.1 *If Physician feels that the listed barriers do not correspond to identified barrier, he/she registers the barrier by entering a textual description.*

#### Open Issues

None

### 2.3.3 UC3 - KADIS based Q-Score Analysis and Metabolic Fingerprint Analysis

#### 2.3.3.1 UC3.1 – Analyze Metabolic Fingerprint and Q-Score

<b>Description</b>	<i>Internist and patient analyze the metabolic fingerprint and Q-Score analysis created by KADIS model.</i>
<b>Parent</b>	<i>UC3</i>

<b>Included sub-use cases</b>	-
<b>Extended sub-use cases</b>	-
<b>Scope</b>	<i>POWER2DM Shared Decision Making Application (user interface for visualization) POWER2DM Personal Data Store (data storage backend)</i>
<b>Actor(s)</b>	<i>Internist Patient</i>
<b>Goal</b>	<i>Analyzing and understanding the Daily Glucose Profile of the patient and scores and risks showing how well blood glucose management is achieved</i>
<b>Trigger</b>	<i>Manually through POWER2DM Shared Decision Making Application</i>
<b>Frequency</b>	<i>For each shared decision making encounter if it is decided to use KADIS for the patient</i>

### Preconditions

1. *Internist is logged on the POWER2DM*
2. *Internist is authorized to access/update the patient data in POWER2DM*
3. *Metabolic Fingerprint and Q-Score analysis have already been done and results are stored in POWER2DM Personal Data Store (UC5.6)*

### Success Postconditions

1. *Internist and patient views the Metabolic fingerprint and Q-Score analysis results*

### Main Flow

1. *Internist navigates to the Metabolic Fingerprint tab of POWER2DM Shared Decision Making Web Application*
2. *The application retrieves the Metabolic Fingerprint and Q-Score results from POWER2DM Personal Data Store and visualize them*
3. *Internist discusses with patient to validate that 5 components of the Q-score match problems as identified in anamnesis (UC1.2)*
4. *Internist discusses with patient to validate that main potentials of improvement as indicated by the Q-score match problems and treatment plan as identified in anamnesis (UC1.2 and KADIS simulation (UC3.2))*

### Alternative Flows

*None*

### Open Issues

1. It should be specified when the Metabolic Fingerprint analysis will be done within the process
2. The utilization of KADIS model depends on the validation to be done in Quantification Campaign (WP5). The requirements will be updated based on the decision taken after the Quantification campaign.

#### 2.3.3.2 UC3.2 - Simulate a Treatment plan with KADIS model

<b>Description</b>	<i>Internist simulates a treatment plan; insulin/medication plan, dietary intake and exercise plan on KADIS model and Metabolic Fingerprint of patient.</i>
<b>Parent</b>	<i>UC3</i>
<b>Included sub-</b>	-

<b>use cases</b>	
<b>Extended sub-use cases</b>	-
<b>Scope</b>	<i>POWER2DM Shared Decision Making Application (user interface for visualization) POWER2DM Prediction Service (backend service to run KADIS model for simulation) POWER2DM Personal Data Store (data storage backend)</i>
<b>Actor(s)</b>	<i>Internist Patient</i>
<b>Goal</b>	<i>Analyzing the possible results of alternative medication/insulin and dietary intake plans on patient's daily blood glucose levels to select the optimum treatment plan</i>
<b>Trigger</b>	<i>Manually through POWER2DM Shared Decision Making Application</i>
<b>Frequency</b>	<i>During shared decision making encounters when patient does not reach optimum glucose management and it is decided to use KADIS for patient</i>

### Preconditions

1. *Internist is logged on the POWER2DM*
2. *Internist is authorized to access/update the patient data in POWER2DM*
3. *Metabolic Fingerprint and Q-Score analysis have already been done and results are stored in POWER2DM Personal Data Store*

### Success Postconditions

1. *Internist and patient perform simulations with alternative medication plans (e.g. timing, dosage, type of medication), dietary intake plans (e.g. time and calorie restriction per meal) and exercise plans and see the predicted blood glucose levels (during the whole day) when current parameters are applied*
2. *The predictions corresponding to approved treatment plan is stored in POWER2DM Personal Data Store*

### Main Flow

1. *Internist navigates to the Daily Metabolic Management tab of POWER2DM Shared Decision Making Web Application*
2. *Internist specifies the time, dosage and type of medication for insulin/medication intake and click on simulate button to start the simulation*
3. *The application sends the simulation parameters to POWER2DM Prediction Service and runs the simulation based on latest "Metabolic Fingerprint" of the patient*
4. *The application retrieves the results and visualize them*
5. *[Loop to step 2] for alternative medication plans*
6. *When Internist satisfies with the last medication plan, he/she passes to the next step,*
7. *Internist specifies the time and calorie values for each meal and click on simulate button to start the simulation*
8. *The application sends the simulation parameters (including the approved medication plan) to POWER2DM Prediction Service and runs the simulation based on latest "Metabolic Fingerprint" of the patient*
9. *The application retrieves the results and visualize them*
10. *[Loop to step 7] for alternative dietary plans*
11. *When Internist satisfies with the last dietary plan, he/she passes to the next step,*
12. *When Internist and Patient agrees on the medication and dietary intake instructions, Internist clicks on the "Next" button to pass the next phase (UC3.3) to register them as POWER2DM Treatment Goals and Action Plan.*
13. *In the meantime, the latest predicted Blood Glucose Profile and the inputs used for this prediction process are stored into POWER2DM Personal Data Store*



**Alternative Flows**

None

**Open Issues**

1. *KADIS analysis may require to update the anamnesis (UC1.2), how is this handled?*
2. The utilization of KADIS model depends on the validation to be done in Quantification Campaign (WP5). The requirements will be updated based on the decision taken after the Quantification campaign.

**2.3.3.3 UC3.3 – Register KADIS related partial treatment goals and plan to POWER2DM**

<b>Description</b>	<i>Internist registers the KADIS related partial treatment goals and plans which he/she identifies as a result of KADIS simulations (UC3.2)</i>
<b>Parent</b>	<i>UC3</i>
<b>Included sub-use cases</b>	-
<b>Extended sub-use cases</b>	-
<b>Scope</b>	<i>POWER2DM Shared Decision Making Application (user interface for data entry) POWER2DM Personal Data Store (data storage backend)</i>
<b>Actor(s)</b>	<i>Internist Patient</i>
<b>Goal</b>	<i>Store the KADIS related partial treatment goals and plan to POWER2DM</i>
<b>Trigger</b>	<i>Manually through POWER2DM Shared Decision Making Application by passing the next phase in UC3.2</i>
<b>Frequency</b>	<i>During shared decision making encounters when patient does not reach optimum glucose management and it is decided to use KADIS for patient</i>

**Preconditions**

1. *Internist is logged on the POWER2DM*
2. *Internist is authorized to access/update the patient data in POWER2DM*
3. *Approved simulation parameters for treatment plan alternatives from UC3.2 temporarily stored by POWER2DM Shared Decision Making Application*

**Success Postconditions**

1. *The decided KADIS related partial treatment goals and plans are stored in POWER2DM Personal Data Store*

**Main Flow**

1. *POWER2DM Shared Decision Making Web Application converts the approved simulation parameters in UC3.2 to POWER2DM Treatment Goals and Treatment Plan items (e.g. Treatment Plan: Eat your breakfast at 8:00 around 400 cal, Treatment Plan: Inject 10unit of insulin after breakfast, Goal: Decrease your QScore to ... in next 3 month)*
2. *Internist reviews them and makes changes if necessary*
3. *Internist clicks “register” button and all information is stored into POWER2DM Personal Data Store*

**Alternative Flows**

None

**Open Issues**

None

**2.3.4 UC4 – Evaluation of Risks and Outcome Expectancies (by using MT2D-MARVEL and risk score models)****2.3.4.1 UC4.1 Analyze MT2D-MARVEL predictions with the existing patient context**

<b>Description</b>	<i>By using the MT2D-MARVEL predictions, Internist shows patient the predicted change in some of his/her crucial parameters (e.g. BMI, Fasting Insulin, etc) in the upcoming years if he/she keeps his current lifestyle and health status</i>
<b>Parent</b>	<i>UC4</i>
<b>Included sub-use cases</b>	-
<b>Extended sub-use cases</b>	-
<b>Scope</b>	<i>POWER2DM Shared Decision Making Application (user interface for visualization) POWER2DM Prediction Service (to run MT2D-MARVEL model with the supplied data) POWER2DM Personal Data Store (data storage backend)</i>
<b>Actor(s)</b>	<i>Internist Patient</i>
<b>Goal</b>	<i>Analyzing the results of mid-term (1-6 years) MT2D-MARVEL predictions in case patient keeps his/her current lifestyle and behaviors</i>
<b>Trigger</b>	<i>Manually through POWER2DM Shared Decision Making Application</i>
<b>Frequency</b>	<i>For each shared decision making encounters if Internist decides it to be useful</i>

**Preconditions**

- 1. Internist is logged on the POWER2DM*
- 2. Internist is authorized to access/update the patient data in POWER2DM*
- 3. The required data for MT2D-MARVEL model execution is ready in POWER2DM Personal Data Store*
- 4. A selection has been made which model variables are goal variables (i.e. the ones considered relevant for showing the patient)*

**Success Postconditions**

- 1. Patient and Internist sees and analyze the MT2D-MARVEL's predicted goal parameters (e.g. BMI, Fasting Insulin) and how they change for the upcoming years if patient keeps his/her current lifestyle and behaviors*
- 2. The prediction results are stored in POWER2DM Personal Data Store*

**Main Flow**

- 1. Internist navigates to the Risk/Outcome Evaluation tab of POWER2DM Shared Decision Making Web Application*
- 2. Internist clicks "Show Mid-term Outcome Predictions" button*
- 3. The application retrieves the stored Reference Prediction curve and visualizes the goal variables as background curve*
- 4. The application retrieves the latest values for all input, neutral and goal variables for MT2D-MT2D-MARVEL from POWER2DM Personal Data Store and visualize the input parameters plus the goal variables*
  - i. Average physical activity (kcal/day) per day (average over at least last week, if available last month)*
  - ii. Average daily food intake (kcal/day) per day (average over at least last week, if available last month)*

- iii. *Food quality averages*
- iv. *Sleep relaxation pattern averages*
- v. *Goal variables*
- 5. *In the meantime, application sends the prediction query to POWER2DM Prediction Service with this latest data.*
- 6. *POWER2DM Prediction Service runs the MT2D-MARVEL model with the supplied data and returns the results*
- 7. *Prediction results of goal variables are visualized graphically on top of the background reference curve and Patient and Internist analyze the results*
- 8. *Predictions are stored in POWER2DM Personal Data Store as Current Prediction*

**Alternative Flows**

*None*

**Open Issues**

- 1. *Choice of goal variables?*
- 2. *In addition to expected trajectories of model variables, it is desired to also show the associated impacts on the patient daily life. What to visualize and how, still needs to be decided*

**2.3.4.2 UC4.2 Analyze Risk Score predictions with the existing patient context**

<b>Description</b>	<i>Internist shows patient the risk score evaluations for patient for diabetic complications (CVD, kidney diseases, etc.) with his/her current lifestyle and health status</i>
<b>Parent</b>	<i>UC4</i>
<b>Included sub-use cases</b>	-
<b>Extended sub-use cases</b>	-
<b>Scope</b>	<i>POWER2DM Shared Decision Making Application (user interface for visualization) POWER2DM Prediction Service (to run Risk Score models with the supplied data) POWER2DM Personal Data Store (data storage backend)</i>
<b>Actor(s)</b>	<i>Internist Patient</i>
<b>Goal</b>	<i>Analyzing the risk of developing diabetic complications for the next ... years for the patient with his/her current lifestyle and diabetes management performance</i>
<b>Trigger</b>	<i>Manually through POWER2DM Shared Decision Making Application</i>
<b>Frequency</b>	<i>For each shared decision making encounter if Internist decides it to be useful</i>

**Preconditions**

- 1. *Internist is logged on the POWER2DM*
- 2. *Internist is authorized to access/update the patient data in POWER2DM*
- 3. *The required data for Risk Score models execution is ready in POWER2DM Personal Data Store*

**Success Postconditions**

- 1. *Patient and Internist analyze the risk assessment results*
- 2. *Risk assessment results are stored in POWER2DM Personal Data Store*

**Main Flow**

1. Internist navigates to the Risk/Outcome Evaluation tab of POWER2DM Shared Decision Making Web Application
2. Internist clicks “Show Long Term Risk Evaluations for Cardiovascular Diseases” button
3. The application retrieves the latest values for all required input variables for UKPDS (or ADVANCE) Cardiovascular Risk Engine from POWER2DM Personal Data Store and visualize them e.g. (Age, HbA1c, Systolic BP, duration of diabetes, etc)
4. In the meantime, application sends a risk assessment query POWER2DM Prediction Service with this latest data
5. POWER2DM Prediction Service runs the UKPDS Cardiovascular (or ADVANCE Cardiovascular) risk engine with the supplied data and return the results
6. Prediction results (e.g. Ten-year CHD risk, fatal CHD risk, stroke risk, fatal stroke risk) are visualized and Patient and Internist analyze the results
7. Predictions are stored in POWER2DM Personal Data Store
8. Then, Internist clicks “Show Long Term Risk Evaluations for Kidney Diseases” button
9. The application retrieves the latest values for all required input variables for ADVANCE Kidney Risk Engine from POWER2DM Personal Data Store and visualize them (e.g. waist circumference, Systolic-Diastolic Blood Pressure, HbA1c, age, ethnicity, etc)
10. In the meantime, application sends a risk assessment query POWER2DM Prediction Service with this latest data
11. POWER2DM Prediction Service runs the ADVANCE Kidney risk engine with the supplied data and return the results
12. Prediction results (e.g. New onset albuminuria risk, major kidney related risk) are visualized and Patient and Internist analyze the results
13. Then, if patient is T1D, Internist clicks “Show Long Term Risk Evaluations for Major Outcomes in T1D” button
14. The application retrieves the latest values for all required input variables for Major Outcomes in T1D Risk Engine from POWER2DM Personal Data Store and visualize them (i.e. waist-hip ratio, albumin/creatinine ratio, HDL-C, HbA1c, age)
15. In the meantime, application sends a risk assessment query POWER2DM Prediction Service with this latest data
16. POWER2DM Prediction Service runs the Major Outcomes in T1D risk engine with the supplied data and return the results
17. Prediction results (major CHD, stroke, end-stage renal failure, amputations, blindness and all-cause death) are visualized and Patient and Internist analyze the results
18. Predictions are stored in POWER2DM Personal Data Store

### Alternative Flows

None

### Open Issues

None

#### 2.3.4.3 UC4.3 Analyze outcome expectancies with MT2D-Marvel in case goals are reached

<b>Description</b>	<i>Internist show patient the outcome expectancies (e.g. BMI, fasting glucose, etc) in the upcoming years if Patient can reach a specific goal (e.g. decrease average daily food intake to ...) by using MT2D-MARVEL predictions. The comparison of these (improvement if patient reaches the goals) with the expectations assuming that patient keeps his current lifestyle and status are also shown to the patient.</i>
<b>Parent</b>	UC4
<b>Included sub-use cases</b>	-
<b>Extended sub-use cases</b>	-

<b>Scope</b>	<i>POWER2DM Shared Decision Making Application (user interface for visualization) POWER2DM Prediction Service (to run MT2D-MARVEL model with the supplied data) POWER2DM Personal Data Store (data storage backend)</i>
<b>Actor(s)</b>	<i>Internist Patient</i>
<b>Goal</b>	<i>Show patient how his/her specific goal variables and impact on daily life may change if he can achieve to reach the related goals</i>
<b>Trigger</b>	<i>Manually through POWER2DM Shared Decision Making Application</i>
<b>Frequency</b>	<i>For each shared decision making encounter if Internist decides this is necessary</i>

### Preconditions

- 1. Internist is logged on the POWER2DM*
- 2. Internist is authorized to access/update the patient data in POWER2DM*
- 3. The required data for MT2D-MARVEL model execution is ready in POWER2DM Personal Data Store*

### Success Postconditions

- 1. Internist and Patient sees how the goal variables and impacts on daily life will change with the given simulation parameters*
- 2. The Reference Prediction is updated*

### Main Flow

- 1. Internist navigates to the Risk/Outcome Evaluation tab of POWER2DM Shared Decision Making Web Application*
- 2. Internist clicks “Simulate Mid-Term Outcomes” button*
- 3. Application shows stored Current Prediction on top of the Reference Prediction*
- 4. Application shows sliders for MT2D-MARVEL control variables and retrieves and visualize latest values for MT2D-MARVEL neutral variables*
- 5. Internist clicks “Use my goals for simulation” button to tune the MT2D-MARVEL control variables to the target values set in the registered Treatment Goals and application tunes the variables accordingly*
- 6. Internist clicks the “simulate” button and the application sends a simulation query to POWER2DM Prediction Service with the supplied data (tuned parameters and latest neutral parameters)*
- 7. POWER2DM Prediction Service runs the MT2D-MARVEL model with the supplied data and return the results as Candidate New Reference Prediction*
- 8. The Candidate New Reference Prediction results (goal variables and impact on daily life) are visualized in comparison to previous predictions (existing Reference Prediction and Current Prediction) to show the improvement and effect of reaching those goals*
- 9. Internist clicks “Confirm updating the Reference Prediction” button to replace old Reference Prediction by Candidate New Reference Prediction*
- 10. Simulation results are stored as Reference Prediction in POWER2DM Personal Data Store*

### Alternative Flows

*4.1 Internist may tune the parameters manually to perform different simulations*

### Open Issues

- 1. Goal variables and impact on daily life need to be defined (see UC 4.1)*
- 2. Alternative flow 4.1. may result in wish to update the anamnesis (UC1.2) and/or treatment plans, how should this be handled?*

**2.3.4.4 UC4.4 Analyze outcome expectancies with Risk Score models in case goals are reached**

<b>Description</b>	<i>Internist show Patient how his/her risk of having complications (CVD, kidney related) may change if Patient can reach a specific goal (e.g. decrease HbA1C to ..., decrease cholesterol to ...) by using Risk Score models. The comparison of these (improvement if patient reaches the goals) with the expectations assuming that patient keeps his current lifestyle and status are also shown to the patient.</i>
<b>Parent</b>	<i>UC4</i>
<b>Included sub-use cases</b>	-
<b>Extended sub-use cases</b>	-
<b>Scope</b>	<i>POWER2DM Shared Decision Making Application (user interface for visualization) POWER2DM Prediction Service (to run Risk Engine models with the supplied data) POWER2DM Personal Data Store (data storage backend)</i>
<b>Actor(s)</b>	<i>Internist Patient</i>
<b>Goal</b>	<i>Show patient how his/her risk of having specific complication may change if he can achieve to reach the related goals</i>
<b>Trigger</b>	<i>Manually through POWER2DM Shared Decision Making Application</i>
<b>Frequency</b>	<i>For each shared decision making encounter if Internist decides this is necessary</i>

**Preconditions**

- 1. Internist is logged on the POWER2DM*
- 2. Internist is authorized to access/update the patient data in POWER2DM*
- 3. The required data for Risk Score Engine execution is ready in POWER2DM Personal Data Store*

**Success Postconditions**

- 1. Internist and Patient sees how the risk will change with the given simulation parameters*

**Main Flow**

- 1. Internist navigates to the Risk/Outcome Evaluation tab of POWER2DM Shared Decision Making Web Application*
- 2. Internist clicks "Simulate Risk Assessment" button and selects the risk assessment type (UKPDS Cardiovascular Risk Engine, ADVANCE Kidney Risk Engine, etc)*
- 3. Application shows sliders for the input parameters of the corresponding Risk Engine and retrieve latest values of these from POWER2DM Personal Data Store*
- 4. Internist clicks "Use my goals for simulation" button to tune some of the input variables (e.g. HbA1C) to the target values set in the registered Treatment Goals and application tunes the variables accordingly*
- 5. Internist clicks the "simulate" button and the application sends a risk assesment query to POWER2DM Prediction Service with the supplied data (tuned parameters and latest neutral parameters)*
- 6. POWER2DM Prediction Service runs the corresponding Risk Engine model with the supplied data and return the results*
- 7. Risk assessment results are visualized in comparison to previous prediction to show the improvement and effect of reaching those goals*
- 8. Risk assessment results are stored in POWER2DM Personal Data Store*

**Alternative Flows**

- 4.1 Internist may tune the parameters manually to perform different simulations*

## Open Issues

1. *If internist chooses different parameters (Alternative flow 4.1) and chooses an alternative scenario, this could require modification of treatment goals/plans in order to maintain consistency. How will this be handled?*

### 2.3.4.5 UC4.5 Update MT2D-Marvel personal model parameter settings periodically.

<b>Description</b>	<i>Supervised parameter optimization. The MT2D-Marvel model default starts with population-average model parameter settings. Depending on progress with time of the extent of data capturing for the individual patient as well as the total group of patients sharing their data, the parameter settings will be periodically updated to generate a more personalized forecast (similar to periodical updates of KADIS fingerprint).</i>
<b>Parent</b>	<i>UC4</i>
<b>Included sub-use cases</b>	-
<b>Extended sub-use cases</b>	-
<b>Scope</b>	<i>POWER2DM Prediction Service (to run MT2D-Marvel and Risk Engine models with the updated parameter settings) POWER2DM Personal Data Store (data storage backend) (POWER2DM Shared Decision Making Application (user interface for visualization) in case explicit notification is given to Internist and Patient)</i>
<b>Actor(s)</b>	<i>MT2D-Marvel Service Operator, Internist, Patient</i>
<b>Goal</b>	<i>Update MT2D-Model parameters to improve personal forecast</i>
<b>Trigger</b>	<i>Typically, when a new KADIS fingerprint has been performed/manually by TNO or PD</i>
<b>Frequency</b>	<i>Depending on judgment by MT2D-Marvel Service Operator, initially infrequent, later regularly e.g. once every 3 months</i>

## Preconditions

1. *The required data for MT2D-Marvel personal model parameter settings update is ready and available in POWER2DM Personal Data Store*
2. *Parameter updating is triggered*

## Success Postconditions

1. *MT2D-Marvel model parameters are updated*
2. *Internist and Patient see how the predictions made previously change with the new model parameters*
3. *Internist confirms parameter update*

## Main Flow

1. *A trigger for MT2D-Marvel parameter update is received*
2. *MT2D-Marvel Service Operator (@TNO or @PD) performs supervised parameter optimization using N=1 statistical analysis techniques (software in development @TNO)*
3. *Modified parameters are stored as candidate new settings in POWER2DM Personal Data Store*
4. *An attention flag is set to inform internist and patient at next visit, that MT2D-Marvel parameters have been updated with latest information and that predictions may deviate from previous ones performed during the last visit.*
5. *Internist and patient see the flag*

6. Internist clicks the “update simulations” button and the application sends two queries to POWER2DM Prediction Service with the supplied data, one with old and one with newly tuned parameters
7. POWER2DM Prediction Service runs the MT2D-Marvel model for the two cases
8. Results are visualized to learn how the new predictions deviate from the old ones
9. Internist clicks “Confirm” button to confirm parameter update.
10. New MT2D-Marvel model parameters are stored in POWER2DM Personal Data Store replacing the old ones.

**Alternative Flows**

9.1 Internist may refuse the parameter update in which case the old ones are kept and interaction with the MT2D-Marvel Service Operator is initiated

**Open Issues**

1. We here consider that parameter updating is performed in a supervised way, requiring a physical person called “MT2D-Marvel Service Operator” (like KADIS, and that the internist may refuse the update (typically if changes are substantial and felt to be unrealistic). Discussion is needed to decide on a protocol for this UC.

**2.3.5 UC5 – Finalizing and Registration of Treatment Plan and Goals into POWER2DM**

**2.3.5.1 UC5.1 Review planning summary (anamnesis, barriers, treatment goals and plans registered until that time)**

<b>Description</b>	<i>Internist and Patient reviews the summary of all decisions they take in the Shared Decision making phase in a dashboard view and also historical data.</i>
<b>Parent</b>	<i>UC5</i>
<b>Included sub-use cases</b>	<i>-</i>
<b>Extended sub-use cases</b>	<i>-</i>
<b>Scope</b>	<i>POWER2DM Shared Decision Making Application (user interface for visualization) POWER2DM Personal Data Store (data storage backend)</i>
<b>Actor(s)</b>	<i>Internist Patient</i>
<b>Goal</b>	<i>Show Patient and Internist the summary of all decisions and entries created in this Shared Decision making phase and also in the past</i>
<b>Trigger</b>	<i>Manually through POWER2DM Shared Decision Making Application</i>
<b>Frequency</b>	<i>For each shared decision making encounter</i>

**Preconditions**

1. Internist is logged on the POWER2DM
2. Internist is authorized to access/update the patient data in POWER2DM

**Success Postconditions**

1. Internist and Patient sees the summary of anamnesis, barriers, treatment goals and plans registered for patient until now

**Main Flow**

1. Internist navigates to the Patient Care Plan Summary tab of POWER2DM Shared Decision Making Web Application



2. *Application retrieves all related records from POWER2DM Personal Data Store*
3. *Application visualizes the followings in a summary view;*
  - i. *Basic information (demographic, diagnosis, etc.)*
  - ii. *Anamnesis(problem) of patient in categorical view*
  - iii. *Barriers identified for each problem*
  - iv. *Treatment Goals registered to address the problems and barriers*
  - v. *Treatment Action Plans registered to support in reaching the goal and to address the specific problems and barriers*
  - vi. *Prediction/Simulation/Risk Assessment results*

### Alternative Flows

None

### Open Issues

1. *(mentioned before) simulation results depend on chosen scenario's/ simulation parameters. They may differ for KADIS vs. MT2D-Marvel vs. Risk Scoring models. These again reflect potentially different treatment goals/ treatment plans. These again may differ from ones specified initially based on original anamnesis by the internist. A functionality must be implemented that warrants overall consistency of goals and plans. Maybe a separate use case (component running in the background) is required for that.*

#### 2.3.5.2 UC5.2 Register Treatment Goal

<b>Description</b>	<i>Internist registers a treatment goal into POWER2DM</i>
<b>Parent</b>	<i>UC5</i>
<b>Included sub-use cases</b>	-
<b>Extended sub-use cases</b>	-
<b>Scope</b>	<i>POWER2DM Shared Decision Making Application (user interface for data entry) POWER2DM Personal Data Store (data storage backend)</i>
<b>Actor(s)</b>	<i>Internist Patient</i>
<b>Goal</b>	<i>Register the identified Treatment Goal in Shared Decision making phase into POWER2DM</i>
<b>Trigger</b>	<i>Manually through POWER2DM Shared Decision Making Application</i>
<b>Frequency</b>	<i>For each shared decision making encounter for each identified Treatment Goal</i>

### Preconditions

1. *Internist is logged on the POWER2DM*
2. *Internist is authorized to access/update the patient data in POWER2DM*

### Success Postconditions

1. *The identified Treatment Goal is registered to POWER2DM Personal Data Store*

### Main Flow

1. *Internist initiate the Treatment Goal definition from POWER2DM Shared Decision Making Web Application*
2. *Application visualize the existing goals set for patient also showing the hierarchy among goals*

3. *Internist selects one of the goals and click to create a sub goal for it*
4. *Internist enters details of the Goal i.e. description, the target measure (e.g. HbA1c, Number of Blood Glucose Measurements per day, strenuous physical activity per week in hours etc.), duration to reach the goal (e.g. in 6 months), etc.*
5. *Internist relates the Goal with identified problems (anamnesis) to state that it is addressing those problems*
6. *Internist clicks the save button and all information is stored into POWER2DM Personal Data Store*

### Alternative Flows

3.1 *Internist may define goal which is in root level in goal hierarchy*

### Open Issues

*None*

#### 2.3.5.3 UC5.3 Register Treatment Plan

<b>Description</b>	<i>Internist registers a treatment plan into POWER2DM</i>
<b>Parent</b>	<i>UC5</i>
<b>Included sub-use cases</b>	<i>-</i>
<b>Extended sub-use cases</b>	<i>-</i>
<b>Scope</b>	<i>POWER2DM Shared Decision Making Application (user interface for data entry) POWER2DM Personal Data Store (data storage backend)</i>
<b>Actor(s)</b>	<i>Internist Patient</i>
<b>Goal</b>	<i>Register the identified Treatment Plan in Shared Decision making phase into POWER2DM</i>
<b>Trigger</b>	<i>Manually through POWER2DM Shared Decision Making Application</i>
<b>Frequency</b>	<i>For each shared decision making encounter for each identified Treatment Plan</i>

### Preconditions

1. *Internist is logged on the POWER2DM*
2. *Internist is authorized to access/update the patient data in POWER2DM*

### Success Postconditions

1. *The identified Treatment Plan is registered to POWER2DM Personal Data Store*

### Main Flow

1. *Internist selects a registered Treatment Goal (e.g. 3 days per week of 30-minutes strenuous physical activity) and click to create an action plan related with it*
2. *Internist enter the details for the Treatment Plan i.e. type of action (e.g. Run), scheduling information for action (Mondays, Wednesdays after 22:00), details of action (e.g. 5km in 30 minutes)*
3. *Internist relate the Treatment Plan with registered barriers or problems*
4. *Internist click the save button and all information is stored into POWER2DM Personal Data Store*

### Alternative Flows

None

**Open Issues**

None

**2.3.5.4 UC5.4 Specify Treatment Goal and Plans to prepare patient for KADIS usage**

<b>Description</b>	<i>To use KADIS model for a patient whether in Shared Decision making phase or self-management, baseline data should be collected for patient. Furthermore, the KADIS should be introduced to the patient. In this use case, Internist recommend to use KADIS for patient and action plans and goals related with these preparation phase are registered into POWER2DM. Later, the POWER2DM Action Plan Engine and Mobile Application will guide patient to perform these actions based on these action plans.</i>
<b>Parent</b>	<i>UC5</i>
<b>Included sub-use cases</b>	<i>-</i>
<b>Extended sub-use cases</b>	<i>-</i>
<b>Scope</b>	<i>POWER2DM Shared Decision Making Application (user interface for data entry) POWER2DM Personal Data Store (data storage backend)</i>
<b>Actor(s)</b>	<i>Internist Patient</i>
<b>Goal</b>	<i>Register the necessary Treatment Goal and Action Plans to guide the patient to complete the preparations (baseline data collection for a week, educating patient, etc.) to use KADIS</i>
<b>Trigger</b>	<i>Manually through POWER2DM Shared Decision Making Application</i>
<b>Frequency</b>	<i>Once during shared decision making encounter if Internist suggests KADIS usage for patient and patient accepts it</i>

**Preconditions**

1. *Internist is logged on the POWER2DM*
2. *Internist is authorized to access/update the patient data in POWER2DM*

**Success Postconditions**

1. *All necessary Treatment Action Plans and Goals for preparation to KADIS usage are registered to POWER2DM Personal Data Store*

**Main Flow**

1. *Internist navigates to Daily Metabolic Management tab of POWER2DM Shared Decision Making Web Application*
2. *Internist activates the KADIS functionality for patient*
3. *Application lists all Action Plans needed to guide patient to complete the preparations for KADIS usage for the next week i.e.*
  - i. *Complete KADIS Introduction Tour*
  - ii. *Obtain a CGM or Use Glucometer to measure your blood glucose every ... hour*
  - iii. *Log calorie intakes for each of your meals*
  - iv. *Use Physical Activity Tracker to track your physical activity or log your physical activity*
  - v. *Log your insulin/medication intakes*
4. *Internist and Patient goes over the list and select the alternatives suitable to patient (e.g. CGM or Glucometer)*

5. *Internist clicks the “Save” button and all information is stored into POWER2DM Personal Data Store*

### Alternative Flows

None

### Open Issues

1. *KADIS Baseline Data Collection process will be defined as a set of Action Plans to guide the patient.*

#### 2.3.5.5 UC5.5 Select relevant JITAI(s) for patient

<b>Description</b>	<i>In POWER2DM, several JITAI's will be developed to deliver during self-management phase by the POWER2DM system (Communication Engine) based on the patient's changing context and behaviors. To assure clinical safety and effectiveness of interventions, in this use case Care Provider select the available POWER2DM JITAI types/mechanisms for patient that will be applied in self-management system. In this way, Care Provider has the chance to approve intervention delivery as well as tune the constraints or thresholds for the intervention delivery mechanism.</i>
<b>Parent</b>	<i>UC5</i>
<b>Included sub-use cases</b>	<i>-</i>
<b>Extended sub-use cases</b>	<i>-</i>
<b>Scope</b>	<i>POWER2DM Shared Decision Making Application (user interface for data entry) POWER2DM Personal Data Store (to store configuration for JITAI's)</i>
<b>Actor(s)</b>	<i>Internist Patient</i>
<b>Goal</b>	<i>Configure the JITAI intervention delivery mechanism to be applied in self-management phase by POWER2DM Communication Engine.</i>
<b>Trigger</b>	<i>Manually through POWER2DM Shared Decision Making Application</i>
<b>Frequency</b>	<i>For each shared decision making encounter</i>

### Preconditions

1. *Internist is logged on the POWER2DM*
2. *Internist is authorized to access/update the patient data in POWER2DM*

### Success Postconditions

1. *JITAI configurations for patient are stored in POWER2DM Personal Data Store*

### Main Flow

1. *Internist navigates to Self-Management Interventions tab of POWER2DM Shared Decision Making Web Application*
2. *Application lists all possible JITAI intervention mechanisms defined in POWER2DM with their descriptions*
3. *Internist selects a mechanism and approve it to apply in the next self-management cycle*
4. *Internist defines the constrains/thresholds if necessary*

### Alternative Flows

None

**Open Issues**

1. We need to agree on JITAI mechanisms/scenarios to define the detailed requirements
2. Too much burden on Internist.

**2.3.5.6 UC5.6 Establishing KADIS Metabolic Fingerprint**

<b>Description</b>	<i>Construction of KADIS Metabolic Fingerprint for each patient is computer-aided manual process where specialist analyze the collected required patient data and tune the Metabolic Fingerprint model accordingly. This use case describes this process by also describing the steps for data exchange and persistency of the constructed Metabolic Fingerprint in POWER2DM.</i>
<b>Parent</b>	<i>UC5</i>
<b>Included sub-use cases</b>	<i>-</i>
<b>Extended sub-use cases</b>	<i>-</i>
<b>Scope</b>	<i>POWER2DM Personal Data Store (to retrieve required data and store Metabolic Fingerprint)</i>
<b>Actor(s)</b>	<i>KADIS Specialist KADIS System (The system already used in IDK to help specialist to analyze patient data and tune the Metabolic Fingerprint)</i>
<b>Goal</b>	<i>Construct and persist Metabolic Fingerprint for a patient when his/her data is ready</i>
<b>Trigger</b>	<i>When the necessary data is collected and ready in POWER2DM Personal Data Store</i>
<b>Frequency</b>	<i>If Internist's request a new KADIS Metabolic Fingerprint identification</i>

**Preconditions**

1. Data required for KADIS Metabolic Fingerprint identification is ready in POWER2DM Personal Data Store

**Success Postconditions**

1. Metabolic Fingerprint for the patient is stored in POWER2DM Personal Data Store

**Main Flow**

1. When the required patient data is collected by the POWER2DM system and is ready in Personal Data Store, a Metabolic Fingerprint Identification order(notification) is sent to KADIS Specialist via the KADIS system he/she is using.
2. KADIS Specialist imports the anonymous patient data from POWER2DM Personal Data Store into the KADIS system.
3. KADIS Specialist works on the data and construct the Metabolic Fingerprint of the patient
4. KADIS Specialist clicks the "Save to POWER2DM" button and the model data for Metabolic Fingerprint is sent to POWER2DM Personal Data Store for persistency

**Alternative Flows**

*None*

**Open Issues**

1. Should we apply the same mechanism for QScore analysis or is it an automated process (in which case POWER2DM Prediction Service may include this calculation mechanism)

2. *Is there any way to do this before the consultation (nurse instructions, over phone, etc.)? (Ian's comment)*

## 2.3.6 UC6- Review/Adjustments of Self-Management Goals

### 2.3.6.1 UC6.1 View Treatment Goals and Plan

<b>Description</b>	<i>In this use case, the patient uses the POWER2DM Action Plan Engine to view the treatment goals and plan that have been specified during the Shared Decision making process. The original treatment goals and plans as specified during the Shared Decision making phase cannot be modified.</i>
<b>Parent</b>	<i>UC6</i>
<b>Included sub-use cases</b>	-
<b>Extended sub-use cases</b>	-
<b>Scope</b>	<i>POWER2DM Action Plan Engine POWER2DM Personal Data Store (data storage backend)</i>
<b>Actor(s)</b>	<i>Patient</i>
<b>Goal</b>	<i>Provide a view for the patient on treatment plans and goals that have been specified together with a Care Provider</i>
<b>Trigger</b>	<i>The patient can view the treatment goals and plan at any time. However, he/she will be notified whenever new or updated treatment goals or plans are available.</i>
<b>Frequency</b>	<i>After each change of treatment goals and plan.</i>

#### Preconditions

1. *Patient is logged in to the POWER2DM platform and has access to Action Plan User Interface.*
2. *Treatment Goals and Plans are available to the Action Plan Engine; event needs to be generated by the Shared Decision Making Application.*

#### Success Postconditions

1. *The treatment goals and plans are displayed to the patient.*

#### Main Flow

1. *Patient opens the Action Plan User Interface*
2. *The patient navigates to the menu item "Treatment Goals and Plans"*

#### Alternative Flows

1. *Patient gets a notification, that new or updated Treatment Goals or Plans are available.*
2. *Patient clicks (or taps) the notification and is able to view the current Goals/Plan*

#### Open Issues

1. *Event/Notification subsystem required*
2. *Push or pull notification from Shared Decision App to Action Plan Engine?*

### 2.3.6.2 UC6.2 Accept Treatment Goals and Plans

<b>Description</b>	<i>In this use case, the patient uses the POWER2DM Action Plan Engine, and accepts treatment goals and plans that have been specified during the Shared Decision making process. If a treatment plan needs no change, the patient can directly import</i>
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	<i>activities directly to his/her calendar.</i>
<b>Parent</b>	<i>UC6</i>
<b>Included sub-use cases</b>	-
<b>Extended sub-use cases</b>	-
<b>Scope</b>	<i>POWER2DM Action Plan Engine POWER2DM Personal Data Store (data storage backend)</i>
<b>Actor(s)</b>	<i>Patient</i>
<b>Goal</b>	<i>Patient commits himself/herself to the Treatment Goals and Plan – at home, after some time has been passed since the Shared Decision making.</i>
<b>Trigger</b>	<i>Whenever treatment goals or plans have been changed.</i>
<b>Frequency</b>	<i>After each change of treatment goals and plan.</i>

### Preconditions

1. *Patient is logged in to the POWER2DM platform and has access to Action Plan User Interface.*
2. *Treatment goals and plan have been specified and are available to the Action Plan Engine.*

### Success Postconditions

1. *Each treatment goal and plan has been reviewed by the patient. They should be marked accordingly in the POWER2DM Personal Data Store.*
2. *The accepted treatment goals are available as self-management goals and the accepted treatment plan is available as self-management activities are available in the Action Plan.*

### Main Flow

1. *Patient opens the Action Plan User Interface*
2. *The patient navigates to the menu item “Action Plan -> Goals”*
3. *Patient gets presented the Treatment Goals and Plans*
4. *Patient selects a treatment goal or plan*
5. *Patient accepts it as a self-management goal and the Action Plan Engine links it to the treatment goals resp. treatment plan*
6. *In case adaptations are needed the patient modifies it*
7. *In case a treatment plan is selected the patient import it as an activity to his/her calendar*

### Alternative Flows

1. *Patient dismisses one or more goals/planned activities*
2. *Patient can comment the reason for any changes*

#### 2.3.6.3 UC6.3 Add or Modify Self-Management Goals

<b>Description</b>	<i>The patient uses the POWER2DM Action Plan Engine to add or modify self-management goals</i>
<b>Parent</b>	<i>UC6</i>
<b>Included sub-use cases</b>	-
<b>Extended sub-use cases</b>	-
<b>Scope</b>	<i>POWER2DM Action Plan Engine</i>

	<i>POWER2DM Personal Data Store (data storage backend)</i>
<b>Actor(s)</b>	<i>Patient</i>
<b>Goal</b>	<i>The patient is able to update, reschedule, delete or add new goals</i>
<b>Trigger</b>	<i>Whenever a patient wants to change the goal,</i>
<b>Frequency</b>	<i>Depending on the frequency of interventions</i>

### Preconditions

1. *Patient is logged in to the POWER2DM platform and has access to Action Plan User Interface.*

### Success Postconditions

1. *The self-management goals are available*

### Main Flow

1. *Patient opens the Action Plan User Interface*
2. *The patient navigates to the menu item “Action Plan -> Goals”*
3. *The Action Plan Engine presents all available self-management goals*
4. *In case a goals should be modified the patient selects the goals and clicks the Button “Modify”*
  - *The patient modifies the goal properties (e.g. description, etc.) according to the needs*
5. *In case a new goals should be added the patient clicks the Button “Add”*
  - *The patient describes the new goal including the goal properties*
6. *The modifications are stored in the personal data store POWER2DM Personal Data Store.*

### Alternative Flows

1. *In case a goals should be deleted the patient selects the goals and clicks the Button “Delete”*

#### 2.3.6.4 UC6.4 Specify personal value compass

<b>Description</b>	<i>The patient uses the POWER2DM Action Plan Engine to specify his/her personal values (value compass)</i>
<b>Parent</b>	<i>UC6</i>
<b>Included sub-use cases</b>	-
<b>Extended sub-use cases</b>	-
<b>Scope</b>	<i>POWER2DM Action Plan Engine POWER2DM Personal Data Store (data storage backend)</i>
<b>Actor(s)</b>	<i>Patient</i>
<b>Goal</b>	<i>The patient is able to identify what is important in his/her life</i>
<b>Trigger</b>	<i>Optional – when specifying self-management goals</i>
<b>Frequency</b>	<i>As needed</i>

### Preconditions

1. *Patient is logged in to the POWER2DM platform and has access to Action Plan User Interface.*

### Success Postconditions

1. *The personal values for the value compass are specified*

### Main Flow



1. *Patient opens the Action Plan User Interface*
2. *The patient navigates to the menu item “Action Plan -> Value compass”*
3. *The Action Plan Engine guides the patient through the different categories of the value compass, e.g. health, husband/wife/partner, family, friends, work*
4. *If applicable patient specifies personal values for a category*
5. *The value compass is stored in the personal data store POWER2DM Personal Data Store.*

**Alternative Flows**

1. *The patient can modify his/her personal values of the value compass*

**2.3.6.5 UC6.5 Identify barriers**

<b>Description</b>	<i>The patient uses the POWER2DM Action Plan Engine to identify his/her barriers for specific problems e.g. Low frequency insulin → Barrier: Fear injections</i>
<b>Parent</b>	<i>UC6</i>
<b>Included sub-use cases</b>	<i>UC6.3, UC7.2</i>
<b>Extended sub-use cases</b>	<i>-</i>
<b>Scope</b>	<i>POWER2DM Action Plan Engine POWER2DM Personal Data Store (data storage backend)</i>
<b>Actor(s)</b>	<i>Patient</i>
<b>Goal</b>	<i>The patient is able to identify barriers for a personal value</i>
<b>Trigger</b>	<i>Optional – when specifying self-management goals</i>
<b>Frequency</b>	<i>As needed</i>

**Preconditions**

1. *Patient is logged in to the P2DM platform and has access to Action Plan User Interface.*

**Success Postconditions**

1. *Barriers are identified for the specific problems of patient*

**Main Flow**

1. *Patient opens the Action Plan User Interface*
2. *If a problem is identified regarding a specific goal of patient, patient is asked to initiate a barrier identification process related with the problem*
3. *The Action Plan Engine guides the patient through a workflow for identifying barriers (interactive dialog with patient)*
4. *After identifying the barrier, patient is provided a set of interventions to overcome the barrier*

**2.3.7 UC7- View, Specification and Adjustments of Action Plan**

**2.3.7.1 UC7.1 View Action Plan**

<b>Description</b>	<i>In this use case, the patient uses the POWER2DM Action Plan Engine, to view the self-management activities of the Action Plan.</i>
<b>Parent</b>	<i>UC6</i>
<b>Included sub-use cases</b>	<i>-</i>
<b>Extended sub-use cases</b>	<i>-</i>
<b>Scope</b>	<i>POWER2DM Action Plan Engine</i>

	<i>POWER2DM Personal Data Store (data storage backend)</i>
<b>Actor(s)</b>	<i>Patient</i>
<b>Goal</b>	<i>Patient is informed about past, current and upcoming activities and related self-management goals.</i>
<b>Trigger</b>	<i>At any time, however the patient should be able to manage notifications about interventions.</i>
<b>Frequency</b>	<i>Depending on the frequency of interventions.</i>

### Preconditions

1. *Patient is logged in to the POWER2DM platform and has access to Action Plan User Interface.*
2. *Self-Management Goals and Action Plan are specified and available for this patient.*

### Success Postconditions

1. *All relevant information is correctly displayed to the user. This includes at least current goals and activities with the degree of fulfilment.*

### Main Flow

1. *Patient opens the Action Plan User Interface*
2. *The patient navigates to the menu item “Action Plan -> Calendar”*
3. *Patient gets presented the Action Plan (scheduled activities) in the calendar view*

### Alternative Flows

1. *Patient can switch between different views on planned activities (Weekly, Agenda view, etc.)*
2. *Patient can view the properties of an activity, e.g. values (e.g. glucose value), related self-management goal, comments*

#### 2.3.7.2 UC7.2 Add or Modify Self-Management Activities

<b>Description</b>	<i>The patient uses the POWER2DM Action Plan Engine to review or modify the self-management activities.</i>
<b>Parent</b>	<i>UC6</i>
<b>Included sub-use cases</b>	<i>-</i>
<b>Extended sub-use cases</b>	<i>-</i>
<b>Scope</b>	<i>POWER2DM Action Plan Engine POWER2DM Personal Data Store (data storage backend)</i>
<b>Actor(s)</b>	<i>Patient</i>
<b>Goal</b>	<i>The patient is able to update, reschedule, delete or add new activities on the action plan.</i>
<b>Trigger</b>	<i>Whenever a patient wants to change an activity.</i>
<b>Frequency</b>	<i>Depending on the frequency of interventions</i>

### Preconditions

1. *Patient is logged in to the POWER2DM platform and has access to Action Plan User Interface.*

### Success Postconditions

1. *The self-management goals are available*

**Main Flow**

1. Patient opens the Action Plan User Interface
2. The patient navigates to the menu item “Action Plan -> Calendar”
3. The Action Plan Engine presents a calendar with the current activities
4. Patient selects an activity and modifies the properties, e.g. time or duration
5. The modifications are stored in the POWER2DM Personal Data Store.

**Alternative Flows**

1. In case a new activity should be added the patient selects a date and a timeframe for the new activity
  - a. Patient can relate the activity to a self-management goal (optional)
  - b. The patient describes the new activity
2. In case a goal should be deleted, the patient selects the goals and clicks the Button “Delete”

**2.3.7.3 UC7.3 Manage the Action Plan using the Action Plan Dashboard**

<b>Description</b>	<i>This use case describes the Action Plan Dashboard, which allows the patient to review his/her daily progress and a summary of the past period (e.g. week). The dashboard is also the “home page” of the action plan and can be configured according to the needs of the patient.</i>
<b>Parent</b>	<i>UC7</i>
<b>Included sub-use cases</b>	-
<b>Extended sub-use cases</b>	-
<b>Scope</b>	<i>POWER2DM Action Plan Engine POWER2DM Personal Data Store (data storage backend)</i>
<b>Actor(s)</b>	<i>Patient</i>
<b>Goal</b>	<i>Patient is informed about the current state and upcoming activities. Patient can add missing values from daily observations.</i>
<b>Trigger</b>	<i>Triggered by the patient – maybe after reception of an intervention.</i>
<b>Frequency</b>	<i>Daily use – entry page of the Action Plan User Interface</i>

**Preconditions**

1. Patient is logged in to the POWER2DM platform and has access to Action Plan User Interface.
2. The self-management plan is available and active according to the needs of the patient.

**Success Postconditions**

1. The patient is informed about current state, like upcoming activities or missing results.

**Main Flow**

1. The patient opens the action plan user interface
2. The patient is able to see inbox messages (notifications and interventions), overall performance, upcoming activities and result charts – depending on the dashboard configuration (see UC7.4)
3. The patient reads and follows messages/interventions available in the inbox (if any)
4. The patient adds daily observations (measurement results) not yet automatically inserted by one of the medical devices (see UC8.2).
5. The patient may view one or more charts with results from recent observations.

**Alternative Flows**

None

### Open Issues

1. The “Action Plan Dashboard” can be an integral part of an “Overall POWER2DM Dashboard”, in the case that other components provide similar use cases.

#### 2.3.7.4 UC7.4 Configure the Action Plan Dashboard

<b>Description</b>	<i>The patient is able to configure the elements shown in the dashboard (see UC7.3)</i>
<b>Parent</b>	<i>UC7</i>
<b>Included sub-use cases</b>	-
<b>Extended sub-use cases</b>	-
<b>Scope</b>	<i>POWER2DM Action Plan Engine POWER2DM Personal Data Store (data storage backend)</i>
<b>Actor(s)</b>	<i>Patient</i>
<b>Goal</b>	<i>Patient can show/hide single elements (upcoming activities, inbox messages, result charts) from the dashboard.</i>
<b>Trigger</b>	<i>Triggered by the patient depending on the received user experience</i>
<b>Frequency</b>	<i>Seldom, whenever the patient needs to modify the user settings.</i>

### Preconditions

1. Patient is logged in to the POWER2DM platform and has access to Action Plan User Interface.
2. The dashboard view is available and functional but does not fit the users’ needs.

### Success Postconditions

1. The patient could change the elements (widgets) shown on the dashboard.

### Main Flow

1. The patient opens the action plan user interface
2. The patient navigates to “User Settings”
3. The patient sees the dashboard elements currently shown in the dashboard view
4. The patient selects/deselects the widget that should be shown or hidden.
5. The patient returns to the dashboard view (“home button”)
6. The dashboard view appears updated.

### Alternative Flows

None

### Open Issues

*This UC could be a sub-usecase of overall user profile settings (UC12).*

#### 2.3.7.5 UC7.5 Self-Management via Mobile Dashboard

<b>Description</b>	
<b>Parent</b>	<i>UC7</i>
<b>Included sub-</b>	-

<b>use cases</b>	
<b>Extended sub-use cases</b>	-
<b>Scope</b>	<i>POWER2DM Mobile Application POWER2DM Personal Data Store (data storage backend)</i>
<b>Actor(s)</b>	<i>Patient</i>
<b>Goal</b>	<i>Patient view a summary of the current day showing the planned actions, and observations and performance until now (and predictions for the future?)</i>
<b>Trigger</b>	<i>Triggered by the patient depending on the user experience</i>
<b>Frequency</b>	<i>Whenever the patient opens the Mobile Application</i>

### Preconditions

1. *Patient is logged in to the POWER2DM platform and has access to Mobile Application*

### Success Postconditions

1. *The patient can view the summary of current day*

### Main Flow

1. *The patient opens the Mobile Application and Mobile Dashboard is shown to patient*
2. *The patient sees the planned actions until the end of day*
3. *The patient sees the important results/observations until now (both manual entries and device collected data)*
4. *The patient sees the today's performance tips and suggestions*

### Alternative Flows

*None*

### Open Issues

1. It is not specified yet whether KADIS predictions will be shown to the patient. There are concerns regarding legal responsibility if they incorrectly use KADIS and there are negative consequences as a result. The Quantification Campaign will try to find the answers.

## 2.3.8 UC8- Collecting daily observations from patient

### 2.3.8.1 UC8.1 Transfer medical device measurement into POWER2DM

<b>Description</b>	<i>In this use case, measurement(s) from a medical device will be automatically and directly transferred to POWER2DM system via POWER2DM Mobile Application</i>
<b>Parent</b>	<i>UC8</i>
<b>Included sub-use cases</b>	-
<b>Extended sub-use cases</b>	-
<b>Scope</b>	<i>Medical Device &lt;&lt;system&gt;&gt; POWER2DM Mobile Application POWER2DM Sensor Processing Framework POWER2DM Personal Data Store (data storage backend)</i>
<b>Actor(s)</b>	<i>Medical Device &lt;&lt;system&gt;&gt;</i>
<b>Goal</b>	<i>Storing medical device measurements into POWER2DM Personal Data Store</i>
<b>Trigger</b>	<i>Triggered by the medical device when a measurement result is available and connection can be established with POWER2DM Mobile Application</i>

<b>Frequency</b>	<i>For each measurement</i>
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### Preconditions

1. *Measurement is done and temporarily stored in the Medical Device*
2. *Connection (e.g. bluetooth connection) is established between the Medical Device and the POWER2DM Mobile Application*
3. *Medical Device is linked with patient account in POWER2DM*

### Success Postconditions

1. *Measurement results are stored in POWER2DM Personal Data Store*

### Main Flow

1. *Medical Device sends the measurement(s) to POWER2DM Mobile Application*
2. *POWER2DM Mobile Application transfer the measurements to POWER2DM Sensor Processing Framework*
3. *POWER2DM Sensor Processing Framework analyses the quality of data and append the related metadata and save the records to POWER2DM Personal Data Store*

### Alternative Flows

*None*

### Open Issues

1. *This use case describes a direct data transfer from Mobile Application to POWER2DM over Internet when it receives measurement from device over Bluetooth connection. We should wait for the selection of sensors and devices to check for which ones this scenario is convenient.*
2. *We need to discuss the data quality assessment phase (T4.4) and the detailed scenario for the interaction of Sensor Processing Framework (PD) with Personal Data Store (SRDC)*

#### 2.3.8.2 UC8.2 Register daily observations manually

<b>Description</b>	<i>Patient manually register his/her daily observations, results, or log of his actions. The records include; body weight, complaints, mood, reporting of diabetic events, reporting of physical activities, reporting of dietary intakes, reporting of medication intakes, and acknowledgement of performed action (in relation to Action Plan)</i>
<b>Parent</b>	<i>UC8</i>
<b>Included sub-use cases</b>	<i>-</i>
<b>Extended sub-use cases</b>	<i>-</i>
<b>Scope</b>	<i>POWER2DM Mobile Application or POWER2DM Action Plan Engine POWER2DM Personal Data Store (data storage backend)</i>
<b>Actor(s)</b>	<i>Patient</i>
<b>Goal</b>	<i>Registering patient input regarding his/her daily observations, activities, results, or log of his actions.</i>
<b>Trigger</b>	<i>Manually triggered from POWER2DM Mobile Application or POWER2DM Action Plan Engine</i>
<b>Frequency</b>	<i>Depends on the logged data and patient's preferences</i>

### Preconditions

1. Patient is logged on the POWER2DM

### Success Postconditions

1. The record created by the patient input is stored in POWER2DM Personal Data Store

### Main Flow

1. Patient selects the type of record (e.g. complaint, body weight, etc) that he/she wants to log
2. Patient enters the required information
3. When patient saves the data, POWER2DM Mobile Application (or POWER2DM Action Plan Engine) sends the record to POWER2DM Personal Data Store to store it

### Alternative Flows

None

### Open Issues

1. We need to clarify how patient will log each type of record (dietary intake, physical activity, etc)

### 2.3.8.3 UC8.3 Transfer data from external self-management platforms (cloud services like iHealth Cloud or mobile applications that collect and store data on their own premises)

<b>Description</b>	<i>In this use case, we assume that device measurements or patient input (dietary or fitness management application) are collected and stored by the External Self-Management Platform and patient is already using these platforms. Also we assume that this platform provides a cloud service from which third party applications can access the data if patient allows it. In this use case, POWER2DM system periodically (daily, hourly, etc.) pulls information from these platforms and store them internally.</i>
<b>Parent</b>	UC8
<b>Included sub-use cases</b>	-
<b>Extended sub-use cases</b>	-
<b>Scope</b>	External Self-Management Platform <<system>> POWER2DM Sensor Processing Framework POWER2DM Personal Data Store (data storage backend)
<b>Actor(s)</b>	External Self-Management Platform <<system>> POWER2DM SMSS
<b>Goal</b>	Transferring external data from the self-management platforms that patient is already using into POWER2DM Personal Data Store
<b>Trigger</b>	Triggered periodically by POWER2DM SMSS
<b>Frequency</b>	Depends on the data type (daily, hourly, etc.)

### Preconditions

1. Automatic data integration is implemented between the platform and POWER2DM Personal Data Store
2. Patient has already linked his/her External Self-Management Platform and POWER2DM account and allows automatic data transfer (UC12.5)

### Success Postconditions

1. Related records are transferred and stored in POWER2DM Personal Data Store

### Main Flow

1. POWER2DM Personal Data Store query the External Self-Management Platform's corresponding service with the necessary credentials (obtained in UC12.5) and retrieve the latest records

2. *The records are converted to POWER2DM data model and stored in POWER2DM Personal Data Store*

### Alternative Flows

None

### Open Issues

1. *We should choose the applications that we will integrate with such a scenario.*

## 2.3.9 UC9- Delivering JITAI interventions at runtime during daily life

### 2.3.9.1 UC9.1 Deliver interventions based on patient's progress

<b>Description</b>	<i>Communication Engine analyses patient's progress in varying timeframes (hourly, daily batch analytics) and/or continuously (stream analytics) based on the collected patient data and if it detects patterns (suitable to the decision trees/rules identified for POWER2DM intervention set), it delivers a suitable intervention to patient relevant with the detected pattern considering also the burden on the patient and interruptibility of the patient. The intervention set and triggering conditions will be determined later in WP3 and this use case only describes the framework how these interventions will be delivered.</i>
<b>Parent</b>	-
<b>Included sub-use cases</b>	-
<b>Extended sub-use cases</b>	-
<b>Scope</b>	<i>POWER2DM Communication Engine POWER2DM Personal Data Store POWER2DM Mobile Application</i>
<b>Actor(s)</b>	<i>Patient</i>
<b>Goal</b>	<i>Delivery of an intervention to a patient based on the patient's self-management progress</i>
<b>Trigger</b>	<i>Periodic analysis patient's progress data by Communication Engine or after a new input related with a self-management activity is stored to the system</i>
<b>Frequency</b>	<i>As soon as a new data is received or after hourly/daily periodic analysis and the specified rules/decision flows are satisfied for the delivery of a specific intervention.</i>

### Preconditions

1. *Either a new information related with a self-management activity is stored in to Personal Data Store or the period to analyse patient progress is due.*
2. *Physician approves the JITAI to apply for patient during the Shared Decision making phase. See UC5.5.*

### Success Postconditions

1. *An intervention with suitable modality and content is delivered to patient*
2. *Statistics regarding the intervention delivery including delivery time, reaction of patient to intervention, reaction time is stored*

### Main Flow

1. *Communication Engine analyses patient progress for last day/hours considering various aspects of self-management including i) blood glucose management, ii) dietary/weight management, iii) physical activity management, iv) sleep/stress management and v) other aspects such as general diabetes progress, complications, action plan adherence, etc.*



2. *Communication Engine checks whether patient has preference for the self-management aspect of interest (e.g he/she has related goals or action plan).*
3. *Communication Engine analyses the interruptibility of the patient (e.g. what is the best time to show the intervention)*
4. *Communication Engine determines the suitable modality and content (e.g asking question for barrier identification vs. motivation by showing personal relevance vs motivation by showing outcome expectancies) for the intervention to be delivered*
5. *Based on the above decisions, Communication Engine either plans the intervention for immediate delivery or for a later suitable time and stores the intervention metadata (e.g. put the intervention plan to queue)*
6. *When the time comes for the planned intervention residing in the queue, a push notification for POWER2DM Mobile Application is prepared and send to the patient*
7. *POWER2DM Mobile Application signals (beeping and by led) the patient about the push notification and patient reads the message and click on it to get further information*
8. *POWER2DM Mobile Application shows the prepared content for the JITAI intervention on a specific user view*
9. *Intervention delivery is logged in Personal Data Store once the intervention is delivered*
10. *Whether the patient has reacted to intervention, if so, the reaction time, patient context is stored to Personal Data Store*

**Alternative Flows**

-

**Open Issues**

-

**2.3.9.2 UC9.2 Deliver reminders**

<b>Description</b>	<i>Communication Engine delivers an intervention before or after a planned activity.</i>
<b>Parent</b>	-
<b>Included sub-use cases</b>	-
<b>Extended sub-use cases</b>	-
<b>Scope</b>	<i>POWER2DM Communication Engine POWER2DM Action Plan Engine POWER2DM Personal Data Store POWER2DM Mobile Application</i>
<b>Actor(s)</b>	<i>Patient</i>
<b>Goal</b>	<i>Delivery of an intervention to a patient based on the action plan</i>
<b>Trigger</b>	<i>Activities planned in the action plan</i>
<b>Frequency</b>	<i>Each time an activity occurs in the action plan</i>

**Preconditions**

1. *An action plan including activities with a certain time is created by the patient*
2. *Adaptive reminding for this action plan is approved by the Physician during the Shared Decision making phase. See UC5.5.*

**Success Postconditions**

1. *An intervention with suitable modality and content is delivered to patient*

2. *Statistics regarding the intervention delivery including delivery time, reaction, reaction time is stored*

**Main Flow**

1. *Action Plan Engine triggers Communication Engine for the upcoming activity.*
2. *Communication Engine checks whether patient has preference for the self-management aspect of interest.*
3. *Communication Engine analyses the interruptibility of the patient*
4. *Communication Engine determines the suitable modality and content for the intervention to be delivered (e.g. simple reminder vs warning by presenting performance feedback, etc)*
5. *Based on the above decisions, Communication Engine either plans the intervention for immediate delivery or for a later suitable moment and stores the intervention metadata*
6. *When the time comes for the planned intervention residing in the queue, a push notification for POWER2DM Mobile Application is prepared and send to the patient*
7. *POWER2DM Mobile Application signals (beeping and by led) the patient about the push notification and patient reads the message and click on it to get further information*
8. *POWER2DM Mobile Application shows the prepared content for the JITAI intervention on a specific user view*
9. *Intervention delivery is logged in Personal Data Store once the intervention is delivered*
10. *Whether the patient has reacted to intervention, if so, the reaction time, patient context is stored to Personal Data Store*

**Alternative Flows**

-

**Open Issues**

-

**2.3.10 UC10- Self-evaluation with provided feedbacks**

**2.3.10.1 UC10.1 Review results of the recent period**

<b>Description</b>	<i>The patient is able to review the results for a specific period (usually weekly, but the period can be selected). The patient gets feedback from the system regarding the success of planned activities and overall performance towards the achievement of personal goals.</i>
<b>Parent</b>	<i>UC10</i>
<b>Included sub-use cases</b>	-
<b>Extended sub-use cases</b>	-
<b>Scope</b>	<i>POWER2DM Action Plan Engine POWER2DM Personal Data Store</i>
<b>Actor(s)</b>	<i>Patient</i>
<b>Goal</b>	<i>Patient should gain an overview of the achievements during the last period</i>
<b>Trigger</b>	<i>By an intervention or periodically</i>
<b>Frequency</b>	<i>Periodically, depending on the selected/agreed review interval.</i>

**Preconditions**

1. *Patient is logged on POWER2DM and has access to the Action Plan User Interface*

**Success Postconditions**

1. *The patient has an action plan for the upcoming week, which is realistic and achievable.*

**Main Flow**

1. *The patient navigates to the menu item “Action Plan -> Review”*
2. *The patient is requested to add missing results for past activities, if applicable (see UC8.2).*
3. *The patient gets feedback how successfully s/he has achieved the planned goals and activities from the previous week and sees health-related data and compares these with targets and/or simulated trajectories*
4. *If meaningful interventions are provided (e.g. tips or motivational messages) for fostering or improving self-management goals and activities*
5. *Patient may continue with UC6.3 (“Add or Modify Self-Management Goals”): Based on the evaluation of the achieved goals, existing goals may be modified or new goals may be added.*
6. *Patient may continue with UC7.2 (“Add or Modify Self-Management Activities”): Based on the evaluation of the previous period, the patient is able to decide whether planned activities for the upcoming period are realistic.*

**Alternative Flows**

1. *The patient is able to modify the period from “weekly” to “daily”, “bi-weekly” or “monthly”, etc.*

**Open Issues**

1. *It is not yet decided, whether the concept of “rewards” will be applied in POWER2DM.*

**2.3.10.2 UC10.2 Tips Personalized by the User**

<b>Description</b>	<i>The patient is able to manage and personalize selected categories of tips (e.g. sleep, stress). The patient can add, modify and delete tips and prioritize them.</i>
<b>Parent</b>	<i>UC10</i>
<b>Included sub-use cases</b>	-
<b>Extended sub-use cases</b>	-
<b>Scope</b>	<i>POWER2DM Action Plan Engine POWER2DM Personal Data Store</i>
<b>Actor(s)</b>	<i>Patient</i>
<b>Goal</b>	<i>The Action Plan Engine will preferably display the personalized tips with a high priority</i>
<b>Trigger</b>	-
<b>Frequency</b>	<i>As needed</i>

**Preconditions**

1. *Patient is logged on POWER2DM and has access to the Action Plan User Interface*

**Success Postconditions**

1. *The patient has specified and modified his personal tips*

**Main Flow**

1. *The patient navigates to the menu item “Action Plan -> Tips”*
2. *Patient select a tip category (e.g. stress tips)*
3. *Patient adds a new tip*
4. *Patient specifies the priority for the tip*
5. *The modifications are stored in the personal data store.*

**Alternative Flows**

1. *Patient modifies existing tips and if applicable change the priority for the tip*
2. *Patient deletes a tip*

**Open Issues**

1. *Tips need to be managed on two levels:*
  - *Expert tips using a general tip authoring tool. Those tips need to be categorized.*
  - *Users' personalized self-management tips*
2. *Maybe an additional UC is needed: Display Tip views according to the tip learning type.*

**2.3.11 UC11 – Introducing the POWER2DM system to patient**

This use case will be later specified (in the next version of deliverable) after the POWER2DM components and functionalities are fixed.

**2.3.12 UC12 – Configure SMSS****2.3.12.1 UC12.1 Customize user profile**

<b>Description</b>	<i>A patient configures his/her user profile.</i>
<b>Parent</b>	-
<b>Included sub-use cases</b>	-
<b>Extended sub-use cases</b>	-
<b>Scope</b>	<i>POWER2DM Mobile Application or POWER2DM Action Plan Engine POWER2DM Personal Data Store</i>
<b>Actor(s)</b>	<i>Patient</i>
<b>Goal</b>	<i>Updating the existing user profile</i>
<b>Trigger</b>	<i>Manually through POWER2DM Mobile Application</i>
<b>Frequency</b>	<i>Whenever the patients would like to update her profile information</i>

**Preconditions**

1. *Patient is logged on POWER2DM*

**Success Postconditions**

1. *The patient's user profile is updated.*

**Main Flow**

1. *The patient navigates to the Settings/User Profile page of POWER2DM Mobile Application*
2. *The patient updates data fields*
3. *The patient clicks to save to persist changes*

**Alternative Flows**

None

**Open Issues**

None

**2.3.12.2 UC12.2 Link medical device or self-management application to patient account**

<b>Description</b>	<i>A patient links an existing medical device or a self-management application with her POWER2DM account.</i>
<b>Parent</b>	-
<b>Included sub-use cases</b>	-
<b>Extended sub-use cases</b>	-
<b>Scope</b>	<i>POWER2DM Mobile Application POWER2DM Personal Data Store External Self-Management Platform &lt;&lt;system&gt;&gt;</i>
<b>Actor(s)</b>	<i>Patient</i>
<b>Goal</b>	<i>Linking patient account in external system with his/her POWER2DM account to handle the automated data integration</i>
<b>Trigger</b>	<i>Manually through POWER2DM Mobile Application</i>
<b>Frequency</b>	<i>Whenever the patients would like to update her profile information</i>

**Preconditions**

1. *The medical device or self-management application has an open Application Programming Interface (API) allowing external applications to connect.*

**Success Postconditions**

1. *POWER2DM has permissions to be able to query the external application or device API*

**Main Flow**

1. *The patient navigates to the Settings/Integration page of POWER2DM Mobile Application*
2. *The patient clicks the application/device to be integrated to POWER2DM*
3. *The patient confirms to giving permissions to POWER2DM to connect to the application's/device's API*

**Alternative Flows**

None

**Open Issues**

None

**2.3.13 UC13 – User and Security Management for POWER2DM****2.3.13.1 UC13.1 Create Patient Account**

<b>Description</b>	<i>Patient is registered to the POWER2DM Care Program and an account is created for patient to access POWER2DM SMSS.</i>
<b>Parent</b>	-
<b>Included sub-use cases</b>	-
<b>Extended sub-use cases</b>	-
<b>Scope</b>	<i>POWER2DM Shared Decision Making Application POWER2DM User Management, Authentication and Authorization Framework POWER2DM Personal Data Store</i>

<b>Actor(s)</b>	<i>Diabetes Nurse Patient</i>
<b>Goal</b>	<i>Creating an account for patient in POWER2DM SMSS system</i>
<b>Trigger</b>	<i>Manually through POWER2DM Shared Decision Making Application</i>
<b>Frequency</b>	<i>Once during the registration of patient</i>

### Preconditions

1. *Diabetes Nurse is logged on the POWER2DM*
2. *Diabetes Nurse is authorized to create a patient account*
3. *Patient signs the consent form to use POWER2DM SMSS*
4. *Other care providers accounts associated to the patient should have been created*

### Success Postconditions

1. *An account is created for patient with a valid username and password in POWER2DM User Management, Authentication and Authorization Framework*
2. *Patient's basic demographic data are stored in POWER2DM Personal Data Store*

### Main Flow

1. *Diabetes Nurse navigates to the Patient Registration page from POWER2DM Shared Decision Making Web Application*
2. *Diabetes Nurse enters the following information into the form;*
  - i. *Email address of the patient to be used as username*
  - ii. *Name, birth date, etc.*
3. *Diabetes Nurse selects other care providers that are associated with the patient*
4. *Diabetes Nurse clicks to register button and system creates an account for patient*
5. *POWER2DM User Management, Authentication and Authorization Framework sends an email to the patient's registered email address for the approval of registration with an automatically generated password*
6. *Patient opens his/her email account from his mobile phone and clicks on the link in the received email and approves the registration*

### Alternative Flows

None

### Open Issues

None

#### 2.3.13.2 UC13.2 Create Care Provider Account

<b>Description</b>	<i>A new account for a care provider is created by specifying the necessary credentials as well as the roles.</i>
<b>Parent</b>	-
<b>Included sub-use cases</b>	-
<b>Extended sub-use cases</b>	-
<b>Scope</b>	<i>POWER2DM Shared Decision Making Application POWER2DM User Management, Authentication and Authorization Framework POWER2DM Personal Data Store</i>

<b>Actor(s)</b>	<i>Care provider</i>
<b>Goal</b>	<i>Creating an account for a care provider in the POWER2DM SMSS system</i>
<b>Trigger</b>	<i>Manually through POWER2DM Shared Decision Making Application</i>
<b>Frequency</b>	<i>Once during the registration of the care provider</i>

### Preconditions

1. *Care Provider has the right to create account for himself/herself*

### Success Postconditions

1. *An account is created for the care provider*
2. *The care provider's registration data are stored in Personal Data Store*

### Main Flow

1. *The care provider navigates to care provider registration page from POWER2DM Shared Decision Making Web Application*
2. *The care provider specifies the necessary credentials, e-mail and role (e.g. nurse, dietician, etc.)*
3. *The care provider clicks to register button and system creates an account for herself*
4. *POWER2DM SMSS sends an email to the care provider's registered e-mail address for the approval of registration with an automatically generated password*
5. *The care provider opens his/her email account and clicks on the link in the received email and approves the registration*

### Alternative Flows

None

### Open Issues

None

#### 2.3.13.3 UC13.3 Sign-on to POWER2DM

<b>Description</b>	<i>A CareProvider is signing in to the POWER2DM system to use POWER2DM Shared Decision Making Application</i>  <i>or</i>  <i>A Patient is signing it to the POWER2DM system to use POWER2DM Mobile Application or POWER2DM Action Plan Engine</i>
<b>Parent</b>	-
<b>Included sub-use cases</b>	-
<b>Extended sub-use cases</b>	-
<b>Scope</b>	<i>POWER2DM User Management, Authentication and Authorization Framework POWER2DM Shared Decision Making Application POWER2DM Mobile Application POWER2DM Action Plan Engine</i>
<b>Actor(s)</b>	<i>Care provider or Patient</i>
<b>Goal</b>	<i>Authenticating Care Provider or Patient and starting a secure session for him/her in POWER2DM</i>
<b>Trigger</b>	<i>Manually through POWER2DM Shared Decision Making Application or POWER2DM Action Plan Engine or POWER2DM Mobile Application</i>

<b>Frequency</b>	<i>Every system access when previous session is expired</i>
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**Preconditions**

1. *User has a POWER2DM account*

**Success Postconditions**

1. *User is authenticated and logged on POWER2DM and ready to use the corresponding POWER2DM Application*

**Main Flow**

1. *User navigates to sign on page from corresponding POWER2DM Application (POWER2DM Shared Decision Making Application, POWER2DM Mobile Application or POWER2DM Action Plan Engine)*
2. *User enters the credentials and sign-in*
3. *POWER2DM User Management, Authentication and Authorization Framework authenticates the user and delivers the credentials to the client application which they will use to access the POWER2DM services on behalf of the user*
4. *User is navigated to the user interface of the corresponding POWER2DM Component*

**Alternative Flows**

None

**Open Issues**

None

**2.3.13.4 UC13.4 Configure access control settings**

<b>Description</b>	<i>A patient specifies data access permissions for the associated care providers.</i>
<b>Parent</b>	-
<b>Included sub-use cases</b>	-
<b>Extended sub-use cases</b>	-
<b>Scope</b>	<i>POWER2DM User Management, Authentication and Authorization Framework</i>
<b>Actor(s)</b>	<i>Patient</i>
<b>Goal</b>	<i>Updating the permissions for accessing the patient's data</i>
<b>Trigger</b>	<i>Manually through POWER2DM Mobile Application or Action Plan Engine</i>
<b>Frequency</b>	<i>Whenever the patients would like to update data access settings</i>

**Preconditions**

1. *Patient is logged on POWER2DM*

**Success Postconditions**

1. *Access permissions to the patient's data are updated*

**Main Flow**

1. *The patient navigates to the Access Control Settings from POWER2DM Mobile Application or POWER2DM Action Plan Engine*
2. *The patient updates data access permissions for the associated care providers*



3. *The patient clicks to save to persist changes*

**Alternative Flows**

None

**Open Issues**

1. We should clarify in which level patient can restrict Care Provider access to his/her records?

### 3 POWER2DM SMSS SPECIFIC REQUIREMENTS

#### 3.1 POWER2DM Shared Decision Making Application Requirements

<b>Related use cases</b>	UC1, UC2, UC3.1 UC3.2, UC 3.3, UC4.1, UC 4.2, UC4.3UC4.4, UC4.5, UC5.1, UC5.2, UC5.3UC5.4, UC5.5.
<b>User/Client characteristics</b>	This component shall provide a web-based user interface for the care providers to manage the treatment plan of patient and monitor patients during face-to-face encounters for Shared Decision making.

**Functional Requirements:**

1. The application shall support the physician to enter patient input concerning:
  - a. Registration of anamnesis and problems;
  - b. Registration of barriers;
  - c. Enter treatment goals and committed actions;
  - d. Enter solutions to barriers.
2. The application shall support the physician to **visualize** the information of the patient.
3. The application shall support the physician to retrieve and visualize the information of the predictive engines (KADIS, MT2D-MARVEL, Risk-score).
4. The application shall support the physician to visualize the results to patients.
5. The application shall be able to convert the approved simulation parameters to treatment goals and treatment plan items.

**Data Requirements**

1. The input of the Shared Decision Making application shall be stored in the personal data store.
2. The Shared Decision application shall use the information in the personal data store.

**Software Interface Requirements**

1. The Shared Decision making application shall deliver the input data for the POWER2DM Action Plan Engine and store it into the POWER2DM Personal Data Store. This input consists of the treatment goals and the treatment plan.
2. The Shared Decision making application shall have an interface with the POWER2DM Prediction Services to get the short- , mid- and long term predictions.

**User Interface Requirements**

1. The Shared Decision making application shall have a user interface that supports the healthcare professionals in the Shared Decision phase to enter data to Power2DM SMSS.
2. The Shared Decision application is an end-user application with a user interface for physicians.

3. The Shared Decision application shall have a web-based user interface (web application).

### **Non-Functional Requirements**

1. The Shared Decision making functionalities shall be realized via an application.
2. The physician has the appropriate access rights to access and modify the data in the personal data store.
3. The data transfer to and from the Shared Decision and the personal data store shall be secure.
4. Non-functional characteristics:
  - a. functionality;
  - b. reliability;
  - c. usability;
  - d. efficiency;
  - e. maintainability;
  - f. portability.

These characteristics are broken down into sub characteristics.

#### *Functionality*

Functionality is the essential purpose of any product or service.

The relationship between software functionality within an overall business process is outside the scope and it is only the software functionality, or essential purpose of the software component, that is of interest for the functionality.

#### *Reliability*

Once a software system is functioning, as specified, and delivered the reliability characteristic defines the capability of the system to maintain its service provision under defined conditions for defined periods of time. One aspect of this characteristic is *fault tolerance* that is the ability of a system to withstand component failure. For example, if the network goes down for 20 seconds then comes back the system should be able to recover and continue functioning.

#### *Usability*

Usability only exists with regard to functionality and refers to the ease of use for a given function. The ability to learn how to use a system (learnability) is also a major sub characteristic of usability.

#### *Efficiency*

This characteristic is concerned with the system resources used when providing the required functionality. The amount of disk space, memory, network etc. provides a good indication of this characteristic. As with a number of these characteristics, there are overlaps. For example, the usability of a system is influenced by the system's performance, in that if a system takes 3 hours to respond the system would not be easy to use although the essential issue is a performance or efficiency characteristic.

#### *Maintainability*

The ability to identify and fix a fault within a software component is what the maintainability characteristic addresses. Maintainability is impacted by code readability or complexity as well as modularization. Anything that helps with identifying the cause of a fault and then fixing the fault is the concern of maintainability. Also, the ability to verify (or test) a system, i.e. testability, is one of the sub characteristics of maintainability.

#### *Portability*

This characteristic refers to how well the software can adopt to changes in its environment or with its requirements. The sub characteristics of this characteristic include adaptability. Object oriented design

and implementation practices can contribute to the extent to which this characteristic is present in a given system.

**Constraints**

1. All patient data must be stored in the POWER2DM Personal Data Store.

**Assumptions and dependencies**

1. Centralized Identity and management system for POWER2DM

**3.2 POWER2DM Action Plan Engine Requirements**

<b>Related use cases</b>	UC6, UC7, UC8.2, UC10, UC12, UC13.3
<b>User/Client characteristics</b>	This component shall provide a web-based user interface for the patient. Data exchange between Action Plan GUI and Action Plan Engine shall be done via HTTP-REST services using JSON. Interfaces to other System Components (Communication Engine, PDS) should be possible via internal API calls.

**Functional requirements**

1. The Action Plan Engine shall be able to import Treatment Goals and the Treatment Plan from the Personal Data Store.
2. The Action Plan Engine shall send push notifications (e.g. reminders for planned activities, motivational messages) to the patient
3. The Action Plan Engine shall provide a calendar view for planned and completed (matched observations) activities
4. The Action Plan Engine shall read and write daily observations to and from the Personal Data Store.
5. The Action Plan Engine shall read and write self-management goals to and from the Personal Data Store.
6. The Action Plan Engine shall read and write planned activities to and from the Personal Data Store.
7. The Action Plan Engine shall summarise recent results into a periodic review and into a dashboard view.
8. The Action Plan Engine shall read and write personalised tips for sleep and stress to and from the Personal Data Store.
9. The Action Plan Engine shall read and write personal health values (value compass) and barriers to the Personal Data Store.

**Data Requirements**

1. The interventions coming from the Communication Engine must be time & patient-oriented for correct delivery to the right patient.

**Software Interface Requirements**

1. The Action Plan Engine needs an interface (e.g. via an event messaging system) to receive JITAIs from the Communication Engine.
2. The Action Plan Engine needs to store different kinds of data (activities, goals, observations, etc.) to a persistence service (PDS).

**User Interface Requirements**

1. The Action Plan Engine shall provide user interfaces to display and manage daily observations, self-management goals, planned activities, personalised tips, personal health values and as well as identified barriers.
2. The Action Plan Engine shall show contextualised personalised tips (e.g. as part of the review and based on the collected patient data).
3. The Action Plan Engine shall provide different views on the data available in the Personal Data Store (Dashboard view, Periodic Review).
4. The Action Plan Engine shall guide the patient through a workflow for identifying barriers
5. The Action Plan Engine User Interfaces shall be usable on different kinds of devices (Desktop, Tablet, Smartphone) in both, online and offline mode.<sup>1</sup>

**Non-functional requirements**

1. The Action Plan Engine User Interface shall follow a responsive design

**Constraints**

1. The Action Plan Engine User Interface is limited to functionality possible to be implemented using HTML5/JavaScript.

**Assumptions and dependencies**

1. The Action Plan Engine receives interventions via some notification mechanism from the Communication Engine.

**3.3 POWER2DM Mobile Application Requirements**

<b>Related use cases</b>	UC6, UC7, UC8.2, UC10, UC12, UC13.3
<b>User/Client characteristics</b>	This component shall provide a native mobile application for the patient for self-management. It will be the communication medium for POWER2DM to interact with patient in his/her daily life. As the backend services to access to data (or store it), it will use the HTTP-REST services provided by other POWER2DM Components (Action Plan Engine, Personal Data Store, Communication Engine).

**Functional requirements**

1. The Mobile Application shall be able to retrieve patient data; daily observations, goals, action plans, etc. from Personal Data Store.
2. The Mobile Application shall be able to send obtained data from patient and medical devices (daily observations, answers to questions, etc.) to Personal Data Store for data persistency.
3. The Mobile Application shall be able to retrieve measurements from the medical devices (identified in POWER2DM Care Program) via suitable wireless protocol (Bluetooth connection or other protocols). The retrieved data from medical devices shall be securely transferred to Personal Data Store for persistency.
4. The Mobile Application shall log passive, on-mobile sensor data including; Wi-Fi context, location, device and application usage, etc. and transfer them to Personal Data Store.
5. The Mobile Application shall log the user experience data and his/her reactions to JITAI interventions; time to respond a push notification, spend time on a view, etc. and transfer them to Personal Data Store.

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<sup>1</sup> Action Plan GUI will be implemented as cross-platform HTML5 web application providing offline functionality by means of an *application cache* and exploiting *local storage*.

6. The Mobile Application shall implement the necessary security, authentication and authorization mechanisms to access the backend services provided by other POWER2DM components.

**Data Requirements**

1. The Mobile Application shall be able to process and render the patient records as specified in data exchanged format for Personal Data Store.

**Software Interface Requirements**

1. The Mobile Application shall implement the corresponding communication interface (if available) with the identified medical devices to be used in POWER2DM Care Program.
2. The Mobile Application shall be able to communicate with other POWER2DM components via their HTTP REST services.

**User Interface Requirements**

1. The Mobile Application shall provide user interfaces to visualise daily observations, treatment and self-management goals, planned activities (identified for POWER2DM care program).
2. The Mobile Application shall provide user interfaces that enable patients to create/modify, treatment and self-management goals, planned activities.
3. The Mobile Application shall provide user interfaces that enable patients to log their daily observations and completed activities in their action plan (for those that needs to be manually logged in POWER2DM Care program).
4. The Mobile Application shall provide user interfaces that enable patients to manage their user profile.
5. The Mobile Application shall provide user interfaces that summarizes the progress of patient for that day/week including blood glucose control, dietary and physical activity management, sleep/stress management, goals and planned actions.
6. The Mobile Application shall provide user interfaces to display JITAI interventions; warnings, motivations, reminders, questions, etc. including push notifications and views navigated from those push notifications.
7. The Mobile Application shall provide user interfaces to manage the connected medical device (only for medical devices to be used in POWER2DM care program) measurement process; displaying the connection and measurement status, result, etc.

**Non-functional requirements**

1. Note: Usability Requirements will be detailed in the next major version of the deliverable.

**Constraints**

None

**Assumptions and dependencies**

None

**3.4 POWER2DM Communication Engine Requirements**

<b>Related use cases</b>	UC9
<b>User/Client characteristics</b>	This component is not directly used by any actor. It basically composes JITAIs to be delivered to patients in various modalities such as push notification, SMS, e-mail, etc.

**Functional requirements**

1. Communication Engine shall provide metadata (i.e. description, triggering conditions, etc.) about complete list of JITAIs provided within POWER2DM

2. Communication Engine shall analyse patient's blood glucose data after a blood glucose measurement is registered.
3. Communication Engine shall evaluate adherence to action plan on particular measurement action basis, daily basis and consecutive days
4. Communication Engine shall analyse patient's dietary & weight data after a calorie intake is registered
5. Communication Engine shall evaluate adherence to action plan on particular meal basis, daily basis and consecutive days in terms of calorie intake entry and calorie intake
6. Communication Engine shall analyse patient's physical activity data after a physical activity is registered
7. Communication Engine shall evaluate adherence to action plan on particular physical activity action basis, daily basis and consecutive days in terms of duration and intensity
8. Communication Engine should analyse patient's sleep & stress data after a sleep measurement or mood entry is registered
9. Communication Engine should evaluate adherence to action plan on daily basis and on consecutive days in terms of sleeping time and sleeping quality
10. Communication Engine should correlate the patient's actions such as calorie intake entry, calorie intake, blood glucose measurement, physical activity with spatial and temporal context
11. Communication Engine should analyse self-management aspects such as adherence to overall action plan, general diabetes progress and complication risks periodically on daily, weekly or monthly basis
12. Communication Engine shall check the JITAI preferences of a patient
13. Communication Engine shall measure the interruptibility of a patient
14. Communication Engine shall consider phone usage statistics of a patient while measuring the interruptibility
15. Communication Engine shall evaluate whether the analysis results trigger a JITAI
16. Communication Engine shall utilize Prediction Services where prediction of blood glucose level changes on daily basis, BMI / Fasting Glucose, etc. and occurrence of complications on yearly (or longer) basis are required to evaluate JITAI conditions
17. Communication Engine shall compose a certain type of JITAI if conditions of that kind of JITAI are satisfied for a particular patient
18. Communication Engine shall consider delivering an intervention of which conditions are satisfied on hourly basis, before a planned activity in the action plan and after a planned activity in the action plan
19. Communication Engine shall store intervention delivery time, whether the patient has reacted to intervention or not, and the reaction time
20. Communication Engine shall analyse the patient's reaction to delivered interventions
21. Communication Engine shall correlate the patient's reaction data with spatial and temporal context
22. Communication Engine shall learn the patient's personal preferences in terms of intervention type, intervention modality and interruptibility

#### **Data requirements**

1. A JITAI should have trigger conditions that must be satisfied before considering to deliver that intervention

#### **Interface requirements**

None

#### **Non-functional requirements**

1. Communication Engine shall perform analysis operations in a reasonable time that is not exceed a minute

#### **Constraints**

None.

**Assumptions and dependencies**

None

**3.5 POWER2DM Prediction Service Requirements**

<b>Related use cases</b>	UC3, UC4, UC5.4, Possibly UC9.1, UC10.1
<b>User/Client characteristics</b>	This component shall provide a web-based user interface for the physician and patient for the Shared Decision Making Application. This component shall also provide a web-based user interface for the MT2D-Marvel Service Operator to perform supervised parameter optimization. System components may use the Prediction Services to retrieve stored simulation results. Data exchange between Prediction Service GUI and Prediction Service Engines shall be done via HTTP-REST services using JSON. Interfaces to other System Components (Shared Decision Making Application, PDS, Mobile Application) should be possible via internal API calls.

**Functional requirements**

1. The Prediction Service shall be able to import Personal Data relevant for KADIS from the Personal Data Store.
2. The Prediction Service shall be able to import personal parameter settings relevant for KADIS from the Personal Data Store.
3. The Prediction Engine shall supply Personal Data and personal parameter settings relevant for KADIS as input to the KADIS Prediction Engine
4. The Prediction Service shall invoke the KADIS Prediction Engine to calculate a KADIS glucose curve using the supplied Personal Data and personal parameters
5. The Prediction Service shall visualize a predicted KADIS glucose curve
6. The Prediction Service shall retrieve Personal Data for the KADIS scenario simulation that corresponds to the current Treatment Plan
7. The Prediction Service shall supply a GUI for KADIS scenario simulations
8. The Prediction Service shall write and read at least 1 simulated KADIS glucose curve for future reference to and from the Personal Data Store
9. The Prediction Service shall integrate the existing KADIS framework to perform Metabolic Fingerprint Analysis and Q-Score analysis including writing updated KADIS model parameter values to the Personal Data Store.
10. The Prediction Service shall be able to import Personal Data relevant for MT2D-Marvel from the Personal Data Store.
11. The Prediction Service shall be able to import personal parameter settings relevant for MT2D-Marvel model from the Personal Data Store
12. The Prediction Service shall be able to import Personal Data of multiple patients relevant for MT2D-Marvel model supervised parameter optimization from the Personal Data Store.
13. The Prediction Service shall be able to import personal parameter settings of multiple patients relevant for MT2D-Marvel model supervised parameter optimization from the Personal Data Store
14. The Prediction Engine shall supply Personal Data and personal parameter settings relevant for MT2D-Marvel as input to the MT2D-Marvel Prediction Engine
15. The Prediction Service shall invoke the MT2D-Marvel Prediction Engine to calculate MT2D-Marvel goal variables trajectories using the supplied Personal Data and personal parameters
16. The Prediction Service shall visualize predicted MT2D-Marvel goal variables trajectories
17. The Prediction Service shall retrieve Personal Data for the MT2D-Marvel baseline (current lifestyle and treatment) scenario simulation
18. The Prediction Service shall retrieve Personal Data for the MT2D-Marvel scenario simulation that corresponds to the updated Treatment Plan
19. The Prediction Service shall supply a GUI for MT2D-Marvel scenario simulations

20. The Prediction Service shall write and read at least 2 sets (corresponding to current and Treatment Goal scenario) of simulated MT2D-Marvel prediction trajectories of goal variables to and from the Personal Data Store
21. The Prediction Service shall include software components plus visualization features for supervised parameter optimization using N=1 statistical analysis techniques by a MT2D-Marvel Service Operator (@TNO or @PD)
22. The Prediction Service shall write updated MT2D-Marvel personalized model parameter values to a separate location in the Personal Data Store as candidates for replacing previous settings.
23. The Prediction Service shall be able to import Personal Data relevant for Risk Score models from the Personal Data Store.
24. The Prediction Engine shall supply Personal Data and personal parameter settings relevant for Risk Score models as input to the Risk Score Prediction Engines
25. The Prediction Service shall invoke the Risk Score Prediction Engines to calculate Risk Score Predictions using the supplied Personal Data and personal parameters
26. The Prediction Service shall visualize Risk Score Predictions
27. The Prediction Service shall supply a GUI for Risk Score scenario simulations
28. The Prediction Service shall write and read at least 1 simulated Risk Score Prediction per Risk Score Engine for future reference to and from the Personal Data Store

### **Data Requirements**

1. The MT2D-Marvel Service Operator (@TNO or @PD) shall set a MT2D-Marvel model parameter update flag to signalize changes in personal parameters to Internist and Patient.

### **Software Interface Requirements**

1. The Prediction Service needs a web accessible service API to interact with the KADIS Prediction Engine
2. The Prediction Service needs a web accessible service API to interact with the MT2D-Marvel Prediction Engine
3. The Prediction Service needs a web accessible service API to interact with the Risk Score Prediction Engines

### **User Interface Requirements**

1. The Prediction Service shall provide user interfaces to display and manage Predictions by KADIS
2. The Prediction Service shall provide user interfaces to display and manage Predictions by MT2D-Marvel
3. The Prediction Service shall provide user interfaces to display and manage Predictions by Risk Score models
4. The Prediction Service User Interfaces to display Predictions by KADIS shall be usable on different kinds of devices (Desktop, Tablet, Smartphone) in both, online and offline mode.
5. The Prediction Service User Interfaces to display Predictions by MT2D-Marvel shall be usable on different kinds of devices (Desktop, Tablet, Smartphone) in both, online and offline mode.
6. The Prediction Service User Interfaces to display Predictions by Risk Score models shall be usable on different kinds of devices (Desktop, Tablet, Smartphone) in both, online and offline mode.

### **Non-functional requirements**

1. The Prediction Engines calculation speeds for scenario simulations should be sufficiently fast to be considered real-time: 95% of calculations should require less than 1 seconds.



**Constraints**

1. none.

**Assumptions and dependencies**

1. It is assumed that the GUI to confirm parameter updates as proposed in UC4.5 is part of the functional requirements of the Shared Decision Making Application (partner PD)
2. MT2D-Marvel predictions may be driven not only by present Personal Data but also by KADIS predictions.
3. Risk Scores may be driven not only by present Personal Data but also by MT2D-Marvel and KADIS predictions
4. The Prediction Service shall use the Data Models defined by the Personal Data Store

**3.6 POWER2DM Personal Data Store Requirements**

<b>Related use cases</b>	UC1, UC2, UC3, UC4, UC5, UC6, UC7, UC8, UC9, UC10, UC13
<b>User/Client characteristics</b>	This component will mainly be used by other POWER2DM components; POWER2DM Shared Decision Making Application, POWER2DM Action Plan Engine, POWER2DM Mobile Application, POWER2DM Communication Engine, POWER2DM Prediction Service

**Functional requirements**

1. Personal Data Store shall implement a mechanism to create and store a patient record with the supplied data
2. Personal Data Store shall implement a mechanism to retrieve the content of a specific patient record instance given a unique identifier
3. Personal Data Store shall implement a mechanism to update the content of a specific patient record instance
4. Personal Data Store shall implement a mechanism to delete a specific patient record instance
5. Personal Data Store shall implement a mechanism to query a specific type of records (e.g. Barriers, Problems, Goals, etc.) based on some filtering parameters defined for each record type
6. Personal Data Store shall implement a mechanism to create several patient records in a batch way given the content of these records
7. For record creation and update mechanisms, Personal Data Store shall check the content of the record if it is conforming to the specified record model for that specific record type. If the content is invalid, it should reject the operation and return a suitable error to the client.
8. Personal Data Store shall implement a mechanism to access metadata definitions of data exchange record models for each record type as well as the metadata definitions for value sets defined
9. Personal Data Store shall implement bi-directional certificate-based node authentication mechanism for connections to and from each client system (e.g. other POWER2DM components) where only known clients are authorized to establish a connection and all exchange of data should be secured using certificates (SSL/TLS)
10. Personal Data Store shall implement an authentication mechanism for users that originate the transaction by using the client system
11. Personal Data Store shall implement an authorization mechanism for users and clients to support role based access control management in at most record type / record instance granularity

12. Personal Data Store shall implement an audit recording mechanisms for tracking the origins, authorship, status, and access of resources

**Data requirements**

1. Personal Data Store shall define data exchange model for different record types
2. Personal Data Store shall support JSON as data exchange serialization format which is suitable for mobile applications
3. Personal Data Store shall provide the metadata definitions for data exchange models defined for each record type
4. Personal Data Store shall provide the metadata definitions for value sets used for the data elements
5. Personal Data Store shall encrypt all patient data before storing it to the physical medium.

**Software Interface requirements**

1. Personal Data Store shall provide a web accessible service API for CRUD and query operations.

**User Interface requirements**

None

**Non-functional requirements**

1. Concurrent Usage:
  - i. Personal Data Store shall support at least 300 concurrent client connections
2. *Processing time Requirements:*
  - i. The Create Read Update Delete (CRUD) operations must be realized in a reasonable time; 95% of transactions must be performed less than one seconds
  - ii. Query operations must be realized in a reasonable time; 95% of transactions must be performed less than one seconds
3. *Space Requirements:*
  - i. Personal Data Store shall support at least 500 patient accounts to store at least 10 years of data

**Constraints**

1. Personal Data Store shall conform to HL7 FHIR standard as a “RESTful FHIR” service
2. Personal Data Store shall conform to HL7 FHIR Resource Definitions and may restrict or extend them if necessary

**Assumptions and dependencies**

1. D4.1 Personal Data Model and Service API defines detailed data requirements for Personal Data Store

**3.7 POWER2DM User Management, Authentication and Authorization Framework Requirements**

<b>Related use cases</b>	UC13
<b>User characteristics</b>	<p>For human users, this component will be used by Care Providers to register to POWER2DM, create patient accounts and authenticate to POWER2DM and by Patients to authenticate into POWER2DM and define access control settings</p> <p>For system users, this component will be used by other POWER2DM components as an authorization and authentication server</p>

### **Functional requirements**

1. A user registration mechanism should be provided for the registration of different user groups; patients, practitioners and other related persons
2. An authentication mechanism shall be provided for the authentication of users and allow clients (other POWER2DM components) to verify the identity of the end-user based on the authentication performed by this framework (single sign-on process).
3. An authorization mechanism shall be provided to handle the authorization requests of clients to access patient records.
4. Authorization mechanism shall decide on the authorization based on the rules specified in the combination of default POWER2DM access control policies and rules defined by patient him/herself.
5. Framework shall handle the corresponding authentication/authorization process of 3<sup>rd</sup> party applications/platforms/clouds where patient data will be integrated to POWER2DM

### **Data requirements**

1. User identity data including the secrets (password, authentication/authorization tokens,) shall be stored in encrypted secure storage
2. The patient identity data shall not be stored on the same machine, as the patient medical data
3. Audit logs shall at least include the timestamp, user requesting access/update to record(s), subsystem that the user is using to access/update to record(s), operation, details of query if it is a query, the identifiers(s) of the accessed/updated records.
4. Audit logs shall be stored in encrypted secure storage

### **Software Interface requirements**

1. Framework shall provide a software interface to pass the authentication tokens and user identity to client systems in a secure way after authenticating the user
2. Framework shall provide a software interface to request authorization grant for record access
3. Framework shall provide a software interface for other POWER2DM components to upload audit logs
4. All software interfaces shall be secured by node-to-node authentication (SSL/TLS)

### **User Interface requirements**

1. It shall provide a sign-in interface for users to authenticate the users into the POWER2DM
2. It shall provide a user interface for creating patient accounts and sign-up for care providers
3. It shall provide a user interface for patients to define access control settings for associated care providers
4. It shall provide a user interface for patients to access the audit logs related with the access/update of their personal records
5. It shall provide a user interface for patients to manage the permissions for POWER2DM to access data on 3<sup>rd</sup> party applications/platforms and medical devices that patient is using.
6. It shall provide a user interface for patient to abandon the POWER2DM Care program

### **Non-functional requirements**

1. User interfaces shall conform to responsive design principles

### **Constraints**

Standards and protocols will be decided and specified her in the next version.

### **Assumptions and dependencies**

## 4 POWER2DM SMSS PATIENT RECOMMENDATIONS

### 4.1 Introduction

The POWER2DM SMSS design was presented to a patient panel during a project meeting in Leiden, The Netherlands on Oct 18, 2016. A highly interactive session was held during which the patients discussed the scientific work, and shared their daily life experiences. All participants, scientists and patients, subsequently wrote down their TIP (main recommendation) and TOP (main appraisal) for the Power2DM project team. In a very lively discussion, these TIPs and TOPs were then ranked according to importance. The results are given in the next section.

### 4.2 Results

The ranked items were categorized into 5 main categories, and for each category a typical quote was added as follows:

#1 TIP/TOP: Patient & care giver participation in Power2DM (8 items). “We felt the added value of patients' daily life experiences in the meeting. Our top: keep talking to patients! And our tip: broaden these user experiences panels with GP's, diabetes nurses and specialists”.

#2 TIP: Personalised advice, tailored to the patient (6 items). “The major added value of Power2DM is that it integrates patient data and uses this to do something 'extra'. In our view, this 'extra' is the most important and adds value to the existing 'support' tools. In daily life, we experience quite a lot of decision points. For example: should I eat at this party, and if so - what? Real time advice would be a great 'extra!'”

#3 TIP/TOP: User friendliness of the system (6 items). “Keep the system simple to use. For example: integrate glucose and physical activity measurements from other devices, design an easy to use dashboard - both for patients and for care givers”.

#4 TOP/TIP: Combine 1) High level evidence & 2) National implementation (5 items). “The scientific possibilities are huge, and lots of evidence supports and feeds your work. Implementation in EU countries will be a challenge and is very important to make patients benefit from the scientific progress”.

#5 TIP: Focus on motivating patients and care givers (3 items). “Throughout the development and implementation phase, think about the motivation of patients and doctors to use the system. Patient and care giver participation in the Power2DM project is a way to do this during the project, but motivation can also be built into the system (motivational messages) and the implementation plan”.

The individual items are all listed, together with implementation expert comments (TNO) and suggestions for implementation (including links to the different use cases described in this deliverable) in Table 1.

Table 1. Patient recommendations, comments and suggestions for implementation in the POWER2DM SMSS

Recommendation category		Comments	Suggestions for implementation in POWER2DM
<b>I. Patient &amp; caregivers participation in the project</b>			
I.1	Focus on integration of GP's, specialist and patients	Focus on integration but especially for GP's / specialists focus on protocols to be used: during a visit as well as when patients contact GP's / specialists online, the GP's / specialists should not only discuss the clinically registered data / results but also the data / results registered by patients themselves	A possibility is to integrate the functionality to give warnings from the system to care providers in UC9-Delivering JITAI interventions. Certain conditions once detected by the system could trigger such a warning. For this a protocol is needed as part of the scenario. See for instance Peter scenario step Month 1 (wks 2-4 step 4) in D1.1
I.2	Make sure that during the whole project period you use the experiences of real patients.	Besides workshops, also directly measure the acceptance, system use and the trust in the system. Such measurements for patients and GP's can be done at the start and further periodically (e.g. every three months). High acceptance / trust/ usability leads to more motivation using the system.	One possibility is to include distrust in the system as a possible barrier for self-management, and integrate this in UC2-Register barriers in POWER2DM, and UC 6.5-Identify barriers. This could be done in several ways: <ul style="list-style-type: none"> <li>• Questionnaires module</li> <li>• Algorithm to identify barriers for self-management</li> <li>• Visual presentation of patient barrier profile</li> </ul> Alternatively, the trust in the system could be assessed in UC10 as part of the self-evaluation cycle.
I.3	Take the patient attitude into account ("Feel / Think like a patient")	For looking at Patients' attitude it helps to consider his typo. There are 3 typos: simplistic, more empathic and the empowered. Simplistic typo needs more short / direct advices: just tell them what to do. Well educated typo needs simplicity: straight-forward advices but the option of getting more background information about the protocol behind the advices if they want. Empathic typos need or expect more guidance.	It is difficult to detect which communication style preference a patient has therefore the applications should have as default a communication style for short and direct advice and offer the option to see details of the background of advices. For non-experienced or empathic patients, an avatar is a solution. The preferred communication style could be set in UC12 – customize user profile.
I.4	On-going communication and training to the professionals and patients.	Necessary because patients' needs can change during the time of using the system.	Similar to I.2, in UC9 we can integrate the possibility to give, and regularly update, some information about patient's experience level from the system to care providers. For this a protocol is needed as part of the scenario. The experience

			level can be based on factors measured.
I.5	Patient reviews	Patient reviews as defined in I.2.	See I.2
I.6	Talk to patients more frequently while developing the system.	Show the latest version and let them play with that version.	Communicate via the system about the latest technical changes and updates. This could e.g. be integrated in UC9.2 - Deliver reminders
I.7	Keep listening to patients in the design phase, and also to GP's, diabetes nurses and specialists!	See I.6.	See I.6.
I.8	Add functionality that enables patients to advice / learn from the other patients	Take for instance the "face book" functionality for that task.	Communicate via the system about this possibility. This could be integrated in UC 9.2 – Deliver reminders, or in a separate UC that provides links to information that is relevant for diabetes patients (e.g. websites of patient organizations).
		Comments	Suggestions for implementation in POWER2DM
<b>II. Personalized advice, tailored to the patient - if possible even real time. Don't forget positive feedback ("good job!").</b>			
II.1	Advice that is really to the point for the individual patient	Tailored advices based on a <i>combination</i> of lifestyle results and diabetic values.	This will form part of UC9.1-Deliver interventions according to patient's progress. As mentioned there, the protocol (decision tree) will be defined in WP3. The tailored advice can be delivered in a simple visual format (e.g. Traffic Light symbols) as alternative to text.
II.2	Personalized daily support covering complex cases.	Does that support: real time, online, automated advice? Make sure that GP's / specialists take responsibility for these advices !!!	Personal coaching is needed for complex cases. Business rules should be established that decide whether a patient is referred to a healthcare professional, or is sufficiently educated and experienced to try a set of automatically generated solutions first. See also II.1.
II.3	Provide a tool that enables the user to improve his/her condition and make changes to own behavior.	Combine this with KADIS functionality based on patients' profile. Show the consequences of behaviour in KADIS.	UC9-Delivering JITAI interventions could be partially based on the KADIS profile (UC3-KADIS) to generate personalized suggestions for e.g. meal intake, medication intake, sports/activity streaks for instance to avoid hypo's. However, proper risk management is essential for such an application and a strict protocol has to be developed together with clinical partners. Only well-trained patients

			may be able/qualified to use such a functionality.
II.4	Define what functionality of KADIS can be made available <i>after</i> the initial 3 days: important potential for added value!	See II.3	See II.3
II.5	The device should give feedback, tips and information, also positive, and should have the possibility to give feedback from users (patients, doctors) back to the system / provider.	Take information and tips based on the real situation and context around the patient. Make it possible for patients to respond on the feedback to GP's / specialists.	The intervention set will be determined later in WP3
II.6	Reminder about goals, positive feedback ('reward' when goal is reached or everything is fine - and not only warn when things are about to go wrong)	Positive feedback is important. Patients must also have the possibility to disable specific (categories of) reminder functions or to change their goals.	In "UC9.1-Deliver interventions according to patient's progress", positive feedback must be included. Patients may indicate their preferences also with respect to their interruptibility (i.e. what is the best time to show the intervention) in UC10.2- Tips Personalized by the User.
		<b>Comments</b>	<b>Suggestions for implementation in POWER2DM</b>
<b>III. Userfriendliness of the system, easy to use</b>			
III.1	User-friendly interface, depending on user-group (patients, nurses, GP's, specialists).	Not necessary to have different interfaces. Better make one good basic interface: simple in use, intuitive and technical with a fast response time (system speed). Content must be easy to understand for both patients and GP's / specialists.	This is covered in Deliverable 2.5
III.2	Personal profile: selection of desired / non-desired features.	Give in one interface three communication levels as described in III.1.	See I.3 recommendation
III.3	Do not forget that diabetic persons often already use instruments and there may be limited physical options to add further devices.	The devices must communicate automatically with software apps. Don't patients let register output from devices by hand in the system. Only let patient register his own behaviour and feedback to GP's etc.	For UC8.1-Transfer medical device measurements into POWER2DM we need to consider this limitation. WP4 can strive to include devices that integrate multiple functionalities as opposed to single functionalities
III.4	User friendly, for example: the prints of the insulin pump and glucose measurements connecting to KADIS.	Result from different devices / apps must always be shown in the same format. See also III.3	Consider this for the Data display formats defined in Deliverable 2.5.
III.5	Make / Keep it simple!	See II.1	See II.1
III.6	Keep it simple to use!	See II.1	See II.1

		Comments	Suggestions for implementation in POWER2DM
<b>IV. Combine 1) High level evidence with 2) National implementation</b>			
IV.1	Translate techniques to real world benefits for patients. Advices must stay available for both patient and GP.		WPs 5,6 and 7
IV.2	That the Power2DM system will not only use glucose measurements but a lot more than that (exercise, food intake, stress, etc.).	See II.3and II.4	See II.3and II.4
IV.3	Keep up integrating international expertise and local implementation.		
IV.4	Keep including evidence / proven medical knowledge to keep trust of patients and doctors (scientific basis).	The more acceptance / trust, the more motivation and willingness to use the system.	
IV.5	Combine online tool with offline (real life) support for motivating patients.		
		Comments	Suggestions for implementation in POWER2DM
<b>V. Motivation of patients and care givers - adoption &amp; usage</b>			
V.1	Motivate both doctors and patients to use Power2DM	Motivation is based on acceptance of the system by patients and care givers. Adoption is based on evidence and the expectance of a well-working system (easy to use and easy to understand)	
V.2	Reminder about goals, activity links to overcome problems, to reach goals	See II.6	See II.6
V.3	Provide motivational messages rather than raw data without interpretation.	Interpretation with easy-to-understand signals such as a traffic light can be given, combined with possibility to get information on the reasons underlying the signals.	