



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 D4.5

Data Quality Analysis Framework I (D4.4.1 a)

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PP	Restricted to other programme participants (including the Commission Services)	
RE	Restricted to a group specified by the consortium (including the Commission Services)	
CO	Confidential, only for members of the consortium (including the Commission Services)	

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V0.2	12.08.2016	Comments and feedback from TNO in Excel.	TNO	PD
V0.3	04.10.2016	Further completion by PD and comments and feedback from PD in Excel.	PD	
V0.4	04.10.2016	Excel information transferred to project template for upload in ECAS. This deliverable needs to be updated at M10 and will then be finalized. Currently not all data types and quality are known that are needed for the first pilot.	PD	European Commission
V0.5	14.04.2017	Updated deliverable based on review comments by European Commission	PD	LUMC, TNO
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SRFG	Salzburg Research Forschungs Gesellschaft	Austria
PD	Prime Data B.V.	Netherlands
iHealth	iHealth EU	France

ROADMAP

Doc. Version	Due Date	Expected/Planned Actions	From
V0.4	M8	Publish the deliverable (DEADLINE) D4.5 (D4.4.1a Data Quality Analysis Framework I). This is a draft version that needs to be updated in M10.	PD, TNO
V0.6	M15	Finalisation of D4.5 (D4.4.1a Data Quality Analysis Framework I) as a baseline for the first prototype. Adjustments based on comments of intermediate review were made. Sections 3.3 and 3.4 were deleted in favour of adding additional information to the tables of section 3.2, such as extra parameter characteristics and the mapping to the data model of the Personal Data Store.	ALL
V2.0	M21	Publish the deliverable (DEADLINE) D4.6 (D4.4.1b Data Quality Analysis Framework II). This document will be a reference to a DEM: Demonstrator, pilot, prototype. It is part of Prototype and System Release 2. Final version	PD

OPEN ISSUES

No:	Date	Issue	Resolved
1	04.10.2016	Document is not reviewed yet by partners other than TNO. Document is currently based on the quantification protocol, which might not represent the complete scope for the POWER2DM prototypes.	M15
2	04.10.2016	Definitions and Acronyms have not been listed yet.	M15
3	04.10.2016	Sections 3.3 and 3.4 were deleted in favour of adding additional information to the tables of section 3.2, such as extra parameter characteristics and the mapping to the data model of the Personal Data Store.	M15

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1 PURPOSE

Data measured by devices or gathered through clinical questionnaires needs to be validated for correctness, accuracy and precision to ensure correct action plans for the patient as well as reliable modelling results for the models KADIS and MARVEL. Several quality checks and detections will be implemented in the POWER2DM Data Integration Platform, such as anomaly detection, outlier detection and min-max analysis, in order to overcome first order statistical issues within the datasets. Moreover, basic data processing will take place in order to guarantee data quality of the available data via API's. Both data quality analysis and basic data processing will be made configurable and changeable via a configuration management system.

Originally the quantification campaign is carried out with the existing functionality in PatientCoach. The PatientCoach functionality was the starting point for this deliverable: the Data Quality Analysis Framework. Afterwards, this deliverable has been updated with the adjusted scope for prototype 1, including an indication of which parameters will be in scope for prototype 1 and which are not, as well as updates on which devices will be used. This deliverable will be updated per following prototype.

In the Power2DM Quantification Campaign Protocol (v1_9 2016-07-21) it is described that the PatientCoach platform will be used to collect all patient input data, which will be installed on mobile devices by the POWER2DM research group or a research assistant who will help link the relevant apps. Besides this, the mobile PatientCoach platform can be used to communicate to the participants when needed, for example to send reminders if required input still needs to be filled in, or a warning when a value entered is outside the upper or lower cut-off ranges. If the required data is not corrected or not filled in at all, a notification message can be sent to the doctor in a similar way to prevent him/her from basing conclusions on incorrect or incomplete data. For prototype 1 this will be done using the Shared decision making application by patient and care provider, and using the mobile application and measuring devices the patient will wear as described in this document.

The purpose of this deliverable is to make an overview of data validation and data processing logic that is needed in the POWER2DM Data Integration Platform. This work is done in four steps. First measuring devices and questionnaire questions – both quantitative and qualitative data – are selected per prototype, based on the Quantification Campaign Protocol and general data quality criteria. Secondly, an inventory of all related data types and their characteristics is created. As a third step boundary conditions are determined for these data types, which can be translated to automated checks (business rules) in the POWER2DM Data Integration Platform. Finally, the fourth step makes the link between external data and the POWER2DM Personal Data Model (FHIR).

2 REFERENCE DOCUMENTS

The following documents were used or referenced in the development of this document:

- POWER2DM D4.1 Personal Data Model and Service API
- Devices used in the POWER2DM Quantification Campaign
- C.1 Power2DM Quantification Campaign Protocol LUMC v1_9 2016-07-21

The following websites were used or referenced in the development of this document:

- Use and Abuse of HOMA Modeling, American Diabetes Association, Diabetes Care via <http://care.diabetesjournals.org/content/27/6/1487>
- Mayo Clinic Cholesterol test Results via <http://www.mayoclinic.org/tests-procedures/cholesterol-test/details/results/rsc-20169555>
- Understanding Your Lab Values, National Kidney Foundation, via <https://www.kidney.org/kidneydisease/understandinglabvalues>
- Microalbuminuria from Wikipedia, the free encyclopedia, via <https://en.wikipedia.org/wiki/Microalbuminuria>
- Creatinine from Wikipedia, the free encyclopedia, via <https://nl.wikipedia.org/wiki/Creatinine>
- iHealth Wave - Activity, Swim and Sleep tracker, via <https://ihealthlabs.eu/en/48-ihealth-wave.html>
- iHealth Edge via <https://ihealthlabs.com/fitness-devices/ihealth-edge>
- The Science Behind Spire, via <https://spire.io/science>
- Fitbit HR Charge 2 heart rate + fitness wristband, via <https://www.fitbit.com/charge2>
- Fitbit Charge 2 Product Manual, via https://staticcs.fitbit.com/content/assets/help/manuals/manual_charge_2_en_US.pdf
- Target Heart Rates – American Heart Association, via http://www.heart.org/HEARTORG/HealthyLiving/PhysicalActivity/FitnessBasics/Target-Heart-Rates_UCM_434341_Article.jsp

2.1 Definitions and Acronyms

Table 1 List of Abbreviations and Acronyms

Abbreviation/ Acronym	DEFINITION
AS4	Axis IV: Psychosocial and environmental factors contributing to the disorder
BMI	Body Mass Index
HbA1C	Glycated hemoglobin; a form of hemoglobin that is measured primarily to identify the three month average plasma glucose concentration.
HDL	high-density lipoprotein cholesterol
LDL	low-density lipoprotein cholesterol
QoL	Quality of Life
T1DM	Type 1 diabetes mellitus
T2DM	Type 2 diabetes mellitus

3 DATA QUALITY ANALYSIS FRAMEWORK

3.1 Overview

The following section gives an overview of measured and registered data types and their characteristics. These data types are data that are – at first – external to the POWER2DM system. When these data types enter the POWER2DM system, they will need to be validated and mapped to the data types that were defined to be used within the POWER2DM system, see D4.1 Personal Data Model and Service API.

Our methodology is as follows:

1. Identification of measuring devices and questionnaire questions based on use cases and data quality criteria;
2. Definition of relevant parameters and their characteristics;
3. Definition of boundary conditions for these data types;
4. Mapping of these data types to the POWER2DM Personal Data Model.

The tables in the following subsections give a detailed overview of the results of each of the above steps.

3.2 Functional Description of Data Types

The key ID in the tables in this section is Parameter, which is listed in the first column. The Parameters have been clustered into 10 categories:

1. Patient Characteristics
2. Clinical Characteristics
3. Blood Glucose Level
4. Eating Behaviour
5. Exercise and Energy Expenditure
6. Sleep
7. Stress
8. Mood
9. Diabetes Medical Treatment
10. Questionnaire: Qualitative information

For each parameter the following characteristics have been inventoried:

1. Measuring device
2. More specific measuring device/method
3. Physical property to measure/register
4. Unit of measurement
5. Valid range lower cut-off
6. Valid range higher cut-off
7. Frequency and Timing of measurement/registration
8. (Expected) Data quality
9. Comments
10. Mapping of data type to Personal Data Store (PDS) data model (FHYR)

Please note for the following subsections that:

- Information in black is relevant for prototype 1;
- Information in blue is agreed to be nice to have for prototype 1 and is otherwise included in prototype 2;
- Information in grey is possibly interesting for later prototypes, but is not in scope for prototype 1.

3.2.1 Data Types of Patient Characteristics

Table 2 Parameters and measuring devices for category Patient Characteristics

Patient Characteristics										
<i>Parameter</i>	<i>Measuring device</i>	<i>More specific measuring device/method</i>	<i>Physical property to measure/register</i>	<i>Units</i>	<i>Valid range lower cut-off</i>	<i>Valid range higher cut-off</i>	<i>How often and when data is measured/collected</i>	<i>(Expected) data quality</i>	<i>Comments</i>	<i>Mapping data type PDS model</i>
Reason to start POWER2DM	Shared decision making application	All patient characteristics will be recorded and input into the patient data entry form at baseline (T0) by the diabetes healthcare provider or researcher.								
Age	Shared decision making application		Age	Years	10	111	1x baseline	Good, factual		Patient
Gender	Shared decision making application		Gender	Male or Female			1x baseline	Good, factual		Patient
Height	Shared decision making application		Height	cm	100	220	1x baseline	Good, provided it is measured correctly		SimpleQuantity Observation
Type Diabetes	Shared decision making application		Type Diabetes	T1DM or T2DM			1x baseline	Good, provided it is diagnosed correctly		Condition
Illness History	Shared decision making application		Illness History	diverse			1x baseline	Good, provided this is well done by healthcare provider or researcher		Condition
AS4	Shared decision making application	Diagnostic and Statistical Manual of Mental Disorders (DSM)	Axis IV: Psychosocial and environmental factors contributing to the disorder	diverse			1x baseline	Good, provided it is communicated truthfully		
Weight	Shared decision making application	Weight and BMI (calculated from Weight) will be reassessed at the end of Phase 1 and Phase 2	Weight	kg	10	250	1x baseline, 1x wk 11-12	Good, provided it is measured correctly		SimpleQuantity Observation
Waist	Shared decision making application		Waist	cm	40	175	1x baseline, 1x wk 11-12	Good, provided it is measured correctly		SimpleQuantity Observation
Waist-Hip ratio	Shared decision		Waist-Hip ratio		0.6	1.4	1x baseline, 1x wk 11-12	Good, provided it is measured correctly		

	making application								
BMI	Shared decision making application	Weight and BMI (calculated from Weight) will be reassessed at the end of Phase 1 and Phase 2	BMI	kg/m ²	10	75	1x baseline, 1x wk 11-12	Good, provided it is calculated correctly	SimpleQuantity Observation
Systolic Blood Pressure	Shared decision making application	Blood pressure will be reassessed at the end of Phase 2	Blood Pressure	mm Hg	60	200	1x baseline, 1x wk 11-12	Good, provided it is measured correctly	BloodPressure (systolic + diastolic)
Diastolic Blood Pressure	Shared decision making application	Blood pressure will be reassessed at the end of Phase 2	Blood Pressure	mm Hg	30	110	1x baseline, 1x wk 11-12	Good, provided it is measured correctly	BloodPressure

3.2.2 Data Types of Clinical Characteristics

Table 3 Parameters and measuring devices for category Clinical Characteristics

Clinical Characteristics										
<i>Parameter</i>	<i>Measuring device</i>	<i>More specific measuring device/method</i>	<i>Physical property to measure/register</i>	<i>Units</i>	<i>Valid range lower cut-off</i>	<i>Valid range higher cut-off</i>	<i>How often and when data is measured/collected</i>	<i>(Expected) data quality</i>	<i>Comments</i>	<i>Mapping data type PDS model</i>
HbA1C (glycated hemoglobin)	Clinical/Lab test, result uploaded to Shared decision making application	From lab	HbA1C	%	2	15	1x baseline, 1x wk 11-13	Depends on reliability of lab test	Primary outcome according to Power2DM Quantification Campaign Protocol (C.1 Power2DM Quantification Campaign Protocol LUMC v1_9 2016-07-21.pdf)	SimpleQuantity Observation
Fasting glucose	Clinical/Lab test, result uploaded to Shared decision making application	From lab, CGM	Fasting glucose	mmol/L	3	25	1x baseline	Depends on reliability of lab test		SimpleQuantity Observation
Fasting insulin	Clinical/Lab test, result uploaded to Shared decision making application	From lab, estimated from KADIS	Fasting insulin	pmol/L	15	250	1x baseline	Depends on reliability of lab test		SimpleQuantity Observation
Insulin sensitivity (%HOMA-2 S)	Clinical/Lab test, result uploaded to Shared decision making application	Based on fasting glucose/insulin	Insulin sensitivity (%HOMA-2 S)	%	0	100	1x baseline	Depends on reliability of lab test		SimpleQuantity Observation
Beta cell function (%HOMA-2-B)	Clinical/Lab test, result uploaded to Shared decision making application	Based on fasting glucose/insulin	Beta cell function (%HOMA-2 B)	%	0	100	1x baseline	Depends on reliability of lab test		SimpleQuantity Observation
Inflammation (mg/l hs-CRP)	Clinical/Lab test, result uploaded to Shared decision	From lab	Inflammation (mg/l hs-CRP)	mg/L	0	4	1x baseline	Depends on reliability of lab test		SimpleQuantity Observation

	making application									
Non-esterified fatty acids	Clinical/Lab test, result uploaded to Shared decision making application	From lab	Non-esterified fatty acids	mmol/L	0	1	1x baseline	Depends on reliability of lab test		SimpleQuantity Observation
Triglycerides	Clinical/Lab test, result uploaded to Shared decision making application	From lab	Triglycerides	mmol/L	0	7	1x baseline	Depends on reliability of lab test		SimpleQuantity Observation
Cholesterol	Clinical/Lab test, result uploaded to Shared decision making application	From lab	Cholesterol	mmol/L	1	10	1x baseline	Depends on reliability of lab test		SimpleQuantity Observation
HDL Cholesterol	Clinical/Lab test, result uploaded to Shared decision making application	From lab	HDL Cholesterol	mmol/L	0	3	1x baseline	Depends on reliability of lab test		SimpleQuantity Observation
LDL Cholesterol	Clinical/Lab test, result uploaded to Shared decision making application	From lab	LDL Cholesterol	mmol/L	1	7	1x baseline	Depends on reliability of lab test		SimpleQuantity Observation
Cholesterol Ratio	Clinical/Lab test, result uploaded to Shared decision making application	From lab	Cholesterol Ratio				1x baseline	Depends on reliability of lab test		SimpleQuantity Observation
Urine-Albumin	Clinical/Lab test, result uploaded to Shared decision making application	From lab	Urine-Albumin	mg/L	0	300	1x baseline	Depends on reliability of lab test		SimpleQuantity Observation
Creatinine	Clinical/Lab test, result uploaded to Shared decision making application	From lab	Creatinine	micromol/L	60	200	1x baseline	Depends on reliability of lab test		SimpleQuantity Observation
Cortisol	Clinical/Lab test, result uploaded to Shared decision making application	From lab, hair sample	Cortisol	pg/mg	3	30	1x wk 11-12	Depends on reliability of lab test		SimpleQuantity Observation

3.2.3 Data Types of Blood Glucose Level

Table 4 Parameters and measuring devices for category Blood Glucose Level

Blood Glucose Level										
<i>Parameter</i>	<i>Measuring device</i>	<i>More specific measuring device/method</i>	<i>Physical property to measure/register</i>	<i>Units</i>	<i>Valid range lower cut-off</i>	<i>Valid range higher cut-off</i>	<i>How often and when data is measured/collected</i>	<i>(Expected) data quality</i>	<i>Comments</i>	<i>Mapping data type PDS model</i>
Blood Glucose Level	Abbot FreeStyleLibre Flash Glucose Monitor	Abbot FreeStyleLibre FGM measures blood glucose level with sensor	Interstitial fluid glucose levels (FSL)	mmol/L	1	20	Continuously	Depends of reliability of FGM	Primary outcome according to Power2DM Quantification Campaign Protocol (C.1 Power2DM Quantification Campaign Protocol LUMC v1_9 2016-07-21.pdf)	TimeSeriesObservation
Blood Glucose Level	iHealth Wireless Smart Glucose-Monitoring system (iHSGM)	Additional blood samples need to be drawn by means of a finger-prick	Interstitial fluid glucose levels (FSL)	mmol/L	1	20	8x a day for the first 72 hours, after that >= 2x a day	Depends of reliability of iHSGM	Primary outcome according to Power2DM Quantification Campaign Protocol (C.1 Power2DM Quantification Campaign Protocol LUMC v1_9 2016-07-21.pdf)	SimpleQuantityObservation
Date and time of hyperglycemic episodes	FGM, iHSGM	Times recorded when blood glucose level indicates hyperglycemic episode	Date time	dd-mm-yyyy hh:mm			Continuously	Good, easy to check correctness		Observation (may need a specific observation profile)
Frequency of hyperglycemic episodes	FGM, iHSGM	Number of times recorded when blood glucose level indicates hyperglycemic episode	Frequency	Number of hyperglycemic episodes			Continuously	Good, easy to check correctness		Observation (may need a specific observation profile)
Magnitude of hyperglycemic episodes	FGM, iHSGM	Blood glucose level when this indicates hyperglycemic episode	Interstitial fluid glucose levels (FSL)	mmol/L	10	20	Continuously	Depends on reliability of FGM/iHSGM		Observation (may need a specific observation profile)
Date and time of hypoglycemic episodes	FGM, iHSGM	Times recorded when blood glucose level indicates hypoglycemic episode	Date time	dd-mm-yyyy hh:mm			Continuously	Good, easy to check correctness		Observation (may need a specific observation profile)
Frequency of hypoglycemic episodes	FGM, iHSGM	Number of times recorded when blood glucose level indicates hypoglycemic episode	Frequency	Number of hypoglycemic episodes			Continuously	Good, easy to check correctness		Observation (may need a specific observation profile)
Magnitude of hypoglycemic episodes	FGM, iHSGM	Blood glucose level when this indicates hypoglycemic episode	Interstitial fluid glucose levels (FSL)	mmol/L	1	4	Continuously	Depends on reliability of FGM/iHSGM		Observation (may need a specific observation profile)

3.2.4 Data Types of Eating Behaviour

Table 5 Parameters and measuring devices for category Eating Behaviour

Eating Behaviour										
<i>Parameter</i>	<i>Measuring device</i>	<i>More specific measuring device/method</i>	<i>Physical property to measure/register</i>	<i>Units</i>	<i>Valid range lower cut-off</i>	<i>Valid range higher cut-off</i>	<i>How often and when data is measured/collected</i>	<i>(Expected) data quality</i>	<i>Comments</i>	<i>Mapping data type PDS model</i>
Unixtime	POWER2DM mobile application	Determined at time of recording food/drink consumption by patients in POWER2DM mobile app	Unixtime	Seconds (10 digits)			Daily	Good, if correctly programmed		DietaryIntakeLog
Date	POWER2DM mobile application	Determined at time of recording food/drink consumption by patients in POWER2DM mobile app	Date	yyyy-mm-dd			Daily	Good, if correctly programmed		DietaryIntakeLog
Time	POWER2DM mobile application	Determined at time of recording food/drink consumption by patients in POWER2DM mobile app	Time	hhmm (hour, minutes)			Daily	Good, if correctly programmed		DietaryIntakeLog
Amount of carbohydrates	POWER2DM mobile application: manual input	Carbohydrate consumption recorded by patients in mobile app	Carbohydrates	grams	0	1000	Continuously	Depends on whether it is correctly filled in by patient(s)		DietaryIntakeLog
Type of food/drink	Not decided yet								Not decided yet	DietaryIntakeLog
Amount of bread units	POWER2DM mobile application: manual input	Bread units logged by patients	Bread units (carbohydrates)	Bread units (grams)			Continuously	Depends on whether it is correctly filled in by patient(s)		DietaryIntakeLog
Amount of calories	POWER2DM mobile application: manual input	Calorie consumption recorded by patients	Calories	kcal	0	5000	Continuously	Depends on whether it is correctly filled in by patient(s)		DietaryIntakeLog
Amount of calories	FatSecret	FatSecret calorie counter	Calories	kcal	0	5000	Continuously	Depends on whether it is correctly filled in by patient(s)		DietaryIntakeLog
Quality/Nutritional value	Not decided yet						Continuously	Depends on whether it is correctly filled in by patient(s)	Not decided yet	DietaryIntakeLog
Time of consumption	POWER2DM mobile application: manual input	Time of registering food consumption by patients	Time	hh:mm			Continuously	Depends on whether it is correctly filled in by patient(s)		DietaryIntakeLog
Water consumption	POWER2DM mobile application: manual input	Water consumption registered by patients	Water	litres	0	5	Continuously	Depends on whether it is correctly filled in by patient(s)		DietaryIntakeLog

3.2.5 Data Types of Exercise and Energy Expenditure

Table 6 Parameters and measuring devices for category Energy Expenditure

Exercise and Energy Expenditure										
<i>Parameter</i>	<i>Measuring device</i>	<i>More specific measuring device/method</i>	<i>Physical property to measure/register</i>	<i>Units</i>	<i>Valid range lower cut-off</i>	<i>Valid range higher cut-off</i>	<i>How often and when data is measured/collected</i>	<i>(Expected) data quality</i>	<i>Comments</i>	<i>Mapping data type PDS model</i>
Average resting heart rate	Fitbit HR Charge 2	Heart rate tracker in Fitbit	Heart rate	Number of beats per minute	60	100*	Continuously	***Depends on reliability of the Fitbit HR Charge 2 and on whether the patient wears the wristband continuously	*Maximum for heart rate when at rest	TrackerHeartRateSummary
Current heart rate	Fitbit HR Charge 2	Heart rate tracker in Fitbit	Heart rate	Number of beats per minute	60	220**	Continuously	Same as above (***)	**Maximum for heart rate during exercise	TrackerHeartRateSummary
Steps	Fitbit HR Charge 2	Accelerometer in Fitbit	Steps	Number of steps taken			Continuously	Same as above (***)		ActivityTrackerSummary
Distance	Fitbit HR Charge 2	Steps * average step-length	Distance	km	0	50	Continuously	Same as above (***)		ActivityTrackerSummary
Calories burned	Fitbit HR Charge 2	Calculated based on physical data, basal metabolic rate and exercise	Calories	kcal	0	5000	Continuously	Same as above (***)		ActivityTrackerSummary
Floors/Stairs climbed	Fitbit HR Charge 2	Altimeter in Fitbit	Elevation	Increments of 3,05m (10 ft)	0	50	Continuously	Same as above (***)		ActivityTrackerSummary
Duration	Fitbit HR Charge 2	Active time based on accelerometer measurement	Time active (duration) [hours, minutes]	hh:mm	0	10	Continuously	Same as above (***)		ActivityTrackerSummary
Steps	iHealth Wave		Steps	Number of steps			Continuously	Depends on reliability of the iHealth Wave	Source of information: https://ihealthlabs.eu/en/48-ihealth-wave.html	
Duration	iHealth Wave		Time (duration)	hh:mm			Continuously	Depends on reliability of the iHealth Wave		
Intensity	Not decided yet						Continuously	Depends on reliability of the iHealth Wave	Not decided yet	
Calories burned	iHealth Wave		Calories	kcal	0	5000	Continuously	Depends on reliability of the iHealth Wave		
Distance	iHealth Wave		Distance	km	0	10	Continuously	Depends on reliability of the iHealth Wave		

3.2.6 Data Types of Sleep

Table 7 Parameters and measuring devices for category Sleep

Sleep										
<i>Parameter</i>	<i>Measuring device</i>	<i>More specific measuring device/method</i>	<i>Physical property to measure/register</i>	<i>Units</i>	<i>Valid range lower cut-off</i>	<i>Valid range higher cut-off</i>	<i>How often and when data is measured/collected</i>	<i>(Expected) data quality</i>	<i>Comments</i>	<i>Mapping data type PDS model</i>
Duration	Fitbit HR Charge 2		Time (duration) [hours, minutes]	hh:mm	0	24:00	Continuously	Depends on reliability of the Fitbit HR Charge 2 and on whether the patient wears the wristband continuously		SleepQualitySleepSummary
Frequency	iHealth Wave	iHealth "Edge" and presumably the "Wave" measures number of times taken a nap, slept, woken up	Sleep frequency	Number of times slept			Continuously	Depends on reliability of the iHealth Wave	Source of information: https://ihealthlabs.com/fitness-devices/ihealth-edge	SleepQualitySleepSummary
Efficiency	iHealth Wave	iHealth "Edge" and the "Wave" measures "sleep efficiency"	Sleep efficiency	%	0	100	Continuously	Depends on reliability of the iHealth Wave		SleepQualitySleepSummary
Quality/Disturbances	Fitbit HR Charge 2	Time restless/awake in between sleep time	Time (duration) [minutes]	mm	0	60	Continuously	Depends on reliability of the Fitbit HR Charge 2 and on whether the patient wears the wristband continuously		SleepQualitySleepSummary
Quality/Disturbances	Not yet decided	A one item Visual Analogue Scale (VAS) (scale from 0 to 10) will be filled in daily during the monitoring periods	Sleep quality	Number on scale of 0 to 10	0	10	Daily	Good, provided it is correctly filled in by patient(s)		SleepQualitySleepSummary

3.2.7 Data Types of Stress

Table 8 Parameters and measuring devices for category Stress

Stress										
<i>Parameter</i>	<i>Measuring device</i>	<i>More specific measuring device/method</i>	<i>Physical property to measure/register</i>	<i>Units</i>	<i>Valid range lower cut-off</i>	<i>Valid range higher cut-off</i>	<i>How often and when data is measured/collected</i>	<i>(Expected) data quality</i>	<i>Comments</i>	<i>Mapping data type PDS model</i>
Respiratory rate	The Spire		Respiratory rate	Number of breaths per minute	10	50	Continuously	Depends on reliability of The Spire	Source of information: https://spire.io/science	MindState
Unixtime	POWER2DM mobile application	Determined at time of recording stress level by patients in mobile app	Unixtime	Seconds (10 digits)			Daily	Good, if correctly programmed		MindState

Date	POWER2DM mobile application	Determined at time of recording stress level by patients in mobile app	Date	yyyy-mm-dd			Daily	Good, if correctly programmed		MindState
Time	POWER2DM mobile application	Determined at time of recording stress level by patients in mobile app	Time	hhmm (hour, minutes)			Daily	Good, if correctly programmed		MindState
Stress level	POWER2DM mobile application: manual input	A visual analogue color scale will be integrated into the app for completion with each insulin measure input.	Level of experiencing stress	Number on (colour) scale			6x a Day	Depends on patient (reliability, correctness)		MindState

3.2.8 Data Types of Mood

Table 9 Parameters and measuring devices for category Mood

Mood										
<i>Parameter</i>	<i>Measuring device</i>	<i>More specific measuring device/method</i>	<i>Physical property to measure/register</i>	<i>Units</i>	<i>Valid range lower cut-off</i>	<i>Valid range higher cut-off</i>	<i>How often and when data is measured/collected</i>	<i>(Expected) data quality</i>	<i>Comments</i>	<i>Mapping data type PDS model</i>
Unixtime	POWER2DM mobile application	Determined at time of recording mood by patients in POWER2DM app	Unixtime	Seconds (10 digits)			Daily	Good, if correctly programmed		MindState
Date	POWER2DM mobile application	Determined at time of recording mood by patients in POWER2DM app	Date	yyyy-mm-dd			Daily	Good, if correctly programmed		MindState
Time	POWER2DM mobile application	Determined at time of recording mood by patients in POWER2DM app	Time	hhmm (hour, minutes)			Daily	Good, if correctly programmed		MindState
Mood level	POWER2DM mobile application: manual input	A cartoon based pictorial will be used to assess affect. In this pictorial, different mood states are displayed on two axis with the y axis representing the valence and the x axis representing the arousal of the mood.	Valence and arousal	Numbers on scales/axes			6x a Day	Good, provided it is correctly filled in by patient(s)		MindState

3.2.9 Data Types of Diabetes Medical Treatment

Table 10 Parameters and measuring devices for category Medical Treatment

Diabetes Medical Treatment										
<i>Parameter</i>	<i>Measuring device</i>	<i>More specific measuring device/method</i>	<i>Physical property to measure/register</i>	<i>Units</i>	<i>Valid range lower cut-off</i>	<i>Valid range higher cut-off</i>	<i>How often and when data is measured/collected</i>	<i>(Expected) data quality</i>	<i>Comments</i>	<i>Mapping data type PDS model</i>
Unixtime	POWER2DM mobile application	Determined at time of recording medicine taken by patients in POWER2DM mobile app	Unixtime	Seconds (10 digits)			Daily	Good, if correctly programmed		MedicationAdministration

Date	POWER2DM mobile application	Determined at time of recording medicine taken by patients in POWER2DM mobile app	Date	yyyy-mm-dd			Daily	Good, if correctly programmed		MedicationAdministration
Time	POWER2DM mobile application	Determined at time of recording medicine taken by patients in POWER2DM mobile app	Time	hhmm (hour, minutes)			Daily	Good, if correctly programmed		MedicationAdministration
Type (oral/insulin)	POWER2DM mobile application: manual input	Type of medication taken recorded by patients in POWER2DM mobile app	Type of medicine	“Oral” or “Insulin”			Daily	Good, provided it is correctly filled in by patient(s)		MedicationAdministration
Name of medicine	POWER2DM mobile application: manual input	Name of medication taken recorded by patients in POWER2DM mobile app	Name of medicine	Text string			Daily	Good, provided it is correctly filled in by patient(s)		MedicationAdministration
Dosage/Amount	POWER2DM mobile application: manual input	Dosage of medication taken recorded by patients in POWER2DM mobile app	Dosage	mg	0	50	Daily	Good, provided it is correctly filled in by patient(s)		MedicationAdministration

3.2.10 Data Types of Questionnaires

As discussed during POWER2DM consortium meeting in Salzburg on 8 and 9 February 2017, the questionnaires for prototype 1 will be selected by LUMC.

Table 11 Parameters and measuring devices for category Questionnaires

Questionnaires										
<i>Parameter</i>	<i>Measuring device</i>	<i>More specific measuring device/method</i>	<i>Physical property to measure/register</i>	<i>Units</i>	<i>Valid range lower cut-off</i>	<i>Valid range higher cut-off</i>	<i>How often and when data is measured/collected</i>	<i>(Expected) data quality</i>	<i>Comments</i>	<i>Mapping data type PDS model</i>
WHO-5 Well-Being Index (WHO)	Questionnaire	WHO-5 Well-Being Index (WHO)	Well-Being Index	Number of points rated on (Likert) scales in questionnaire	0	100	1x baseline, 1x wk 11-12	Good, provided it is correctly filled in by patient(s)	Five items are assessed on a 6-point Likert scale ranging from 0 to 5 and the individual item scores are added together and transformed into a 100 point scale.	QuestionnaireResponse (holds the actual answers), QuestionnaireResult (the score calculated from the answers)
Patient Health Questionnaire (PHQ-9)	Questionnaire	Patient Health Questionnaire (PHQ-9)	Patient Health	Number of points rated on (Likert) scales in questionnaire	0	27	1x baseline, 1x wk 11-12	Good, provided it is correctly filled in by patient(s)	9 DSM-IV criteria for depression on a four point (0-3) scale. The sum of these scores (range= 0-27) is then used to assess the level of depression	QuestionnaireResponse (holds the actual answers), QuestionnaireResult (the score calculated from the answers)
Brief measure of Generalized Anxiety Disorder (GAD-7)	Questionnaire	Brief measure of Generalized Anxiety Disorder (GAD-7)	Measure of Generalized Anxiety Disorder	Number of points rated on (Likert) scales in questionnaire	0	21	1x baseline, 1x wk 11-12	Good, provided it is correctly filled in by patient(s)	A seven item anxiety scale (0-3) that measures how often the patient has been bothered by specific symptoms of anxiety over the previous two weeks. The sum of these scores (range= 0-21) is then used as an assessment of the presence of anxiety	QuestionnaireResponse (holds the actual answers), QuestionnaireResult (the score calculated from the answers)

Perceived Stress Scale (PSS)	Questionnaire	Perceived Stress Scale (PSS)	Perceived Stress	Number of points rated on (Likert) scales in questionnaire	0	40	1x baseline, 1x wk 4, 1x wk 11-12	Good, provided it is correctly filled in by patient(s)	10 item scale designed to measure the degree to which situations' in one's life are appraised as stressful on a 5 point scale. All scores are summed for an overall perceived stress score	QuestionnaireResponse (holds the actual answers), QuestionnaireResult (the score calculated from the answers)
Problem Areas in Diabetes (PAID)	Questionnaire	Problem Areas in Diabetes (PAID)	Problem Areas in Diabetes	Number of points rated on (Likert) scales in questionnaire	0	100	1x baseline, 1x wk 4, 1x wk 11-12	Good, provided it is correctly filled in by patient(s)	20-item measure of psychosocial adjustment to diabetes rated on a 5 point Likert scale (range = 0-4). Added together and multiplied by 1.25 to transform the raw score into a 0-100 scale with higher scores representing increased emotional distress	QuestionnaireResponse (holds the actual answers), QuestionnaireResult (the score calculated from the answers)
Diabetes Self-Management Questionnaire (DSMQ-R)	Questionnaire	Diabetes Self-Management Questionnaire (DSMQ-R)	Diabetes Self-Management	Number of points rated on (Likert) scales in questionnaire			1x baseline, 1x wk 4, 1x wk 11-12	Good, provided it is correctly filled in by patient(s)	20 items about self-management. These items can be grouped into four factors (glucose management, dietary control, physical activity, and physician contact) from which a sum score can be calculated for overall glycemic control. All subscales are highly correlated with levels of HbA1c.	QuestionnaireResponse (holds the actual answers), QuestionnaireResult (the score calculated from the answers)
Audit of Diabetes Dependent QoL (ADDQoL)	Questionnaire	Audit of Diabetes Dependent QoL (ADDQoL)	Diabetes Dependent Quality of Life	Number of points rated on (Likert) scales in questionnaire			1x baseline, 1x wk 11-12	Good, provided it is correctly filled in by patient(s)	The ADDQoL was developed to measure individuals' perceptions of the impact of diabetes on their quality of life in 13 domains on a 6 point scale for how much better this domain of their life would be if they didn't have diabetes and how important that aspect of their life is on a 4 point scale. Additionally, there are two items assessing perceived general quality of life and imagined general quality of life without diabetes.	QuestionnaireResponse (holds the actual answers), QuestionnaireResult (the score calculated from the answers)
Hypoglycemia Fear Survey (HFS)**	Questionnaire	Hypoglycemia Fear Survey (HFS)	Fear of Hypoglycemia	Number of points rated on (Likert) scales in questionnaire			1x baseline	Good, provided it is correctly filled in by patient(s)	37 item survey designed to quantify the fear associated with hypoglycemia in diabetes patients. The survey is divided into two sections assessing specific behaviours used to avoid low blood sugar and worry associated with low blood sugar. ** Only participants who use insulin, medication associated with hypoglycemic episodes, or those indicated as potentially having hypoglycemic related distress based on their responses on the PAID will be required to complete this questionnaire	QuestionnaireResponse (holds the actual answers), QuestionnaireResult (the score calculated from the answers)

Diabetes Eating Problem Survey (DEPS-R)*	Questionnaire	Diabetes Eating Problem Survey (DEPS-R)	Diabetes Eating Problem	Number of points rated on (Likert) scales in questionnaire	0	80	1x baseline	Good, provided it is correctly filled in by patient(s)	16 items (6 point Likert scale (0-5)) to assess the presence of eating related problems in T1DM patients. * This measure will only be used if a patient engages in an associated self-management task (e.g. only insulin users will be asked about anxiety related to using insulin) or they indicate associated problems in other questionnaires (e.g. DEPS-R will be administered if the patient indicates issues regarding eating)	QuestionnaireResponse (holds the actual answers), QuestionnaireResult (the score calculated from the answers)
Fear of Complications Questionnaire (FCQ)*	Questionnaire	Fear of Complications Questionnaire (FCQ)	Fear of Complications	Number of points rated on (Likert) scales in questionnaire	0	45	1x baseline	Good, provided it is correctly filled in by patient(s)	15 item questionnaire that evaluates patient fear surrounding long-term complications of diabetes on a four point scale. A sum score of all the items can be used to calculate overall fear of complications. * This measure will only be used if a patient engages in an associated self-management task (e.g. only insulin users will be asked about anxiety related to using insulin) or they indicate associated problems in other questionnaires	QuestionnaireResponse (holds the actual answers), QuestionnaireResult (the score calculated from the answers)
Diabetes Fear of Injecting and Self-Testing Questionnaire (D-FISQ)***	Questionnaire	Diabetes Fear of Injecting and Self-Testing Questionnaire (D-FISQ)	Diabetes Fear of Injecting and Self-Testing	Number of points rated on (Likert) scales in questionnaire			1x baseline	Good, provided it is correctly filled in by patient(s)	21 item questionnaire designed to assess fear of injecting insulin and fear of self-testing blood glucose in diabetes patients [62]. The patient reports on the frequency of given actions on a 4 point scale *** The questionnaire can be split into specific scales to measure the two individual factors of fear of injecting insulin and fear of self-testing blood glucose. Patients who indicate on the PAID that they may have anxiety related to self-testing will be required to complete the fear of self-testing blood glucose scale, and only those on insulin therapy or who indicate on the PAID anxiety related to insulin injections will be required to fill in the fear of injecting insulin scale.	QuestionnaireResponse (holds the actual answers), QuestionnaireResult (the score calculated from the answers)
After-Scenario Questionnaire (ASQ)	Questionnaire	After-Scenario Questionnaire (ASQ)	After-Scenario Questionnaire (ASQ)	Number of points rated on (Likert) scales in questionnaire			1x wk 1, 1x wk 4	Good, provided it is correctly filled in by patient(s)	The user rates their agreement with three satisfaction statements assessing ease, time, and support of use on a 7 point scale ranging from strongly agree (1) to strongly disagree (7) with the option of choosing not applicable.	QuestionnaireResponse (holds the actual answers), QuestionnaireResult (the score calculated from the answers)

Clarke score	Questionnaire	Clarke score	hypo-(un)awareness	8 multiple choice questions			1x baseline, 1x wk 4, 1x wk 11-12	Good, provided it is correctly filled in by patient(s)	Only for T1DM patient. Each one of these (Clarke score and Gold score) questionnaires has specific ways to calculate the cut-off scores to indicate the presence or absence of problems. Ideally, we would automate the calculations so only the indication is shown.	QuestionnaireResponse (holds the actual answers), QuestionnaireResult (the score calculated from the answers)
Gold score	Questionnaire	Gold score. Questions patient: "Do you know when your hypos are commencing?"	hypo-(un)awareness	7-point Likert scale, with 1 representing "always aware" and 7 representing "never aware".	1	7	1x baseline, 1x wk 4, 1x wk 11-12	Good, provided it is correctly filled in by patient(s)	Only for T1DM patient. A score of ≥ 4 implies impaired awareness of hypoglycemia.	QuestionnaireResponse (holds the actual answers), QuestionnaireResult (the score calculated from the answers)

