Project: POWER2DM
Grant Agreement No.: 689444
Call: H2020-PHC-2015
Topic: PHC-28-2015

D5.1.1 Specific Requirements of Pilot Sites

Workpackage	WP5
Task	T 5.1
Due date	31.03.2016
Submission date	31.03.2016
Deliverable lead	IDK (SAS)
Version	1.1
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Dissemination Level		
PU	Public	x
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)	

EXECUTIVE SUMMARY

Task 5.1 of the POWER2DM project was designed to identify and anticipate any technical expected problems related with computer security and telecommunication in the different countries in which the Pilot Studies will be performed. It ranged from mobile companies to software installation problems derived from the security standards in the different clinical settings. In a large part, this task will depend on the final software solution implemented in POWER2DM, but the first deliverable 5.1.1. (Specific Requirements of Pilot Sites) was devoted to detect any overwhelming limitation to software access that could compromise the different options to be finally adopted in WP3 and WP4.

This document reviews the different problems anticipated when the project was drafted, how these have been discussed and the different conclusions obtained for any of the three different countries involved in the Pilot Studies.

This document does not serve as a guide for the election of the technical approaches for telecommunication and computer security, but is intended for showing up the *red lines* involving these factors in the different clinical settings (i.e. primary care, hospitals, outpatient clinics, etc) and in the different countries (Spain, Germany, The Netherlands), to serve as an aid to the technical partners of WP3 and WP4.

The information of any anticipated document as this one may be subjected to be modifiable in the light of non-expected problems during the advance of the final technical development of the Project.

1. PC-based security tasks

1.1 Permission to install and run programs within the health system framework.

The Pilot Studies of POWER2DM will be done in three different settings.

1.1.1 Specific Expected Scenarios in the three different Pilot Sites.

a) Institute of Diabetes "Gerhardt Katsch" at Karlsburg (IDK), Germany

IDK is the developer and owner of the patented KADIS® program. The KADIS program will be a cornerstone of POWER2DM. The program was created in 2007, and, since then, has been permanently and successfully used in Germany by about 300 physicians within routine diabetes health care for about 800 diabetic patients. In this case, permissions to install and run the POWER2DM platform will be easy to acquire, as it must be interpreted as the evolution of the KADIS program.

b) Leiden University Medical Center, Leiden, Netherlands

The Leiden University Medical Center (LUMC) is one of eight Dutch academic hospitals with approximately 7000 employees. It has a large experience in the developing of different initiatives similar to these, like **MYAIRCOACH:** Analysis, modelling and sensing of both physiological and environmental factors for the customized and predictive self-management of asthma. (Horizon2020, 2015-2017), **Innovation of diabetes outpatient clinic**: optimizing multidisciplinary self-management support for diabetes patients (LUMC, 2012-2015) or **TELEHYPE**: Trial of TELEmonitoring and self-management support of patients with newly diagnosed HYPErtension. (ZonMW: The Netherlands Organisation for Health Research and Development, 2013-2016). If required, it is expected that LUMC will provide authorization for installation of programs in the different clinical spaces destined to POWER2DM.

c) SAS, Hospital Universitario Reina Sofia at Cordoba, Spain.

Servicio Andaluz de Salud or Andalusian Health Service (SAS) is an autonomous body attached to the Ministry of Health of the Government of Andalusia in the South of Spain. There are 1,491 primary care centres, 29 hospitals and 84.706 employees. The Hospital Universitario Reina Sofia at Cordoba has a long trajectory of conducting research projects and clinical trials mainly in the area of the chronic diseases and human metabolism. SAS has a tight regulation for the installation and run of external programs in those terminals connected to those servers containing clinical information of the patients. However, specific terminals could be used to install and run the specific programs of POWER2DM.

1.1.2 Valuation as a whole

Although there is a plausible feasibility that local software could be installed and run in the different Pilot Sites, this Specific topic was discussed and addressed during the Kick-Off meeting of POWER2DM, and an initial preference for a web-based platform for POWER2DM was adopted.

This model would lower the needs for permissions, and would increase the easiness of accession from different locations, health centres, etc.

1.2 Connections with external computers and servers

1.2.1 For local purposes

The three Pilot Sites and the secondary sub-sites (i.e. primary care, hospitals, outpatient clinics, etc) are web connected. Interconnectivity, is therefore assured.

1.2.2 For sharing data (central labs, clinical data, image testing).

These services will not be available in certain centres due to local laws. In these cases, specific software will be developed for exporting specific data to POWER2DM.

2. Technical issues

2.1 Operative systems

2.1.1 Operative Systems of the computer based POWER2DM software.

As defined above, the preferences for the development of the POWER2DM computer interfaces will be "web-based". Therefore, the underlying operative system of the computer would not be a threat for the Project, as it would run under the Internet browser.

In the case that WP3 and WP4 will finally decide by local software executable programs, preference will be given to Windows© Operative System.

2.1.2 Operative Systems of the Patients' Mobile Phone Apps

These will be developed for, at least, iOS and Android operative systems. There are no expected problems or Specific Requirements of Pilot Sites derived from this point, as the countries in which this project is being developed are members of the European Union, and they have access to upload and download mobile Apps from the two major App vendors AppStore and GooglePlay. The PatientCoach 'to do' list can also be accessed using an Android app or an iOS app on an iPhone or iPod touch 6th generation (© 2015 Apple inc). In addition, it is anticipated that a limited number of third party apps will need to be installed for connection with monitoring devices like e.g. Fitbit HR. Using Bluetooth the data stored on these devices will be regularly transmitted to their appropriate apps on the patients' mobile phone or iPod touch and will be subsequently send through wifi/internet to proprietary servers. If relevant and feasible, the PatientCoach system will send data requests to proprietary servers in order to build the research database.

2.2 Mobile phone company servers

There are no Specific Requirements of Pilot Sites concerning Telephone Company servers, as the three countries are within the European Union, and they all allow the connection of mobile phones to the web, and the installation of Apps.

3. Integration

Although some seminal programs will serve as cornerstones in POWER2DM, like KADIS, MARVEL or PatientCoach, specific integration of the PC-based and mobile-based systems with local pre-existing software, and the creation of any additional needed modules for those centres in which POWER2DM is installed "de novo" will be addressed.

Given the fact that two of the three Pilot Sites do not have any of the above programs, there are Specific Requirements of these Pilot Sites (SAS and LUMC) to develop "de novo" platforms based in the above referenced software. On the contrary, IDK will need a platform to contact KADIS and integrate it with the final POWER2DM software programs.

It is anticipated that the data collection in the Quantification Campaign as well as in the pilot phase and the Evaluation Campaign will be web-based. This includes the final POWER2DM system. For research purposes data entry of home measurements can be performed by the patient using the anonymized monitoring and research modules of the self-monitoring application PatientCoach. A 'to do' list will be available on a PatientCoach webpage specifically designed for this research and will provide links to questionnaires and data entry forms according to predefined personalized schedules.

In the Netherlands the PatientCoach system is to some extent integrated with the electronic health record of the LUMC and of the primary care practices, thereby offering professionals an overview of self-monitoring parameters of their own patients. For other countries, access to PatientCoach for professionals is facilitated by the internationally available authentication system myDigiPass. Only the involved POWER2DM professionals can generate PatientCoach access codes for their patients.

4. Abbreviation

This section contains the abbreviations used in this deliverable.

Abbreviation	***Definition***
SAS	Servicio Andaluz de Salud or Andalusian Health Service
IDK	Institute of Diabetes "Gerhardt Katsch" at Karlsburg
LUMC	Leiden University Medical Center

5. Change procedure and history

This section contains the procedures for modifying the deliverable and maintaining a history of the changes.

Version	***Date***	***Changes***	***From***	***Review***
V.01	*31-3-2016*	*Initial document*	*SAS*	*All partners*