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Deliverable D2.2

FAITH Requirements, Methodology and MVP

Work package:	WP2 – Stakeholders identification, use cases definition, requirements specification, and architecture design
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FAITH Project Profile

Contract No H2020-ICT- 875358

Acronym	**FAITH**
Title	**a Federated Artificial Intelligence solution for moniToring mental Health status after cancer treatment**
URL	**https://h2020-faith.eu/**
Twitter	**https://twitter.com/H2020_Faith**
LinkedIn	**linkedin.com/company/faith-project**
Facebook	**https://fb.me/H2020.FAITH**
Start Date	**01/01/2020**
Duration	**36 months**

FAITH Partners

List of participants

Participant No	Participant organisation name	Short Name	Country
1 (Coordinator)	WATERFORD INSTITUTE OF TECHNOLOGY.	WIT	Ireland
2	UPMC Whitfield, Euro Care Healthcare Limited.	UPMC	Ireland
3	Universidad Politécnica de Madrid.	UPM	Spain
4	Servicio Madrileño de Salud.	SERMAS	Spain
5	UNINOVA, Instituto de Desenvolvimento de Novas Tecnologias.	UNINOVA	Portugal
6	Fundação D. Anna de Sommer Champalimaud e Dr. Carlos Montez Champalimaud.	CF	Portugal
7	Deep Blue.	DBL	Italy
8	Suite5 Data Intelligence Solutions Limited.	SUITE5	Cyprus
9	TFC Research and Innovation Limited.	TFC	Ireland

SC1-DTH-01-2019: Big data and Artificial Intelligence for monitoring health status and quality of life after the cancer treatment

H2020-SC1-DTH-2019

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Document Control

This deliverable is the responsibility of the Work Package Leader. It is subject to internal review and formal authorisation procedures in line with ISO 9001 international quality management system procedures.

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0.6	23/12/2020	Tom Flynn (TFC)	QA Review and ready for approval
1.0	31/12/2020	Giuseppe Frau (DBL), Ilaria Bonanno (DBL)	Final Version. Review. Executive summary and conclusions

Executive Summary

Objectives:

The aim of the D2.2 is to describe the user requirements for the FAITH trials as well as to outline the integrated methodology and the minimum viable product. The requirements described here, together with the technical requirements, described in D2.3, are being implemented for the execution of the trials, will be further refined based on the first trial results. This document focuses on the requirements of the first trial, namely the data collection trial. This set of requirements and methodology are highly dependent on the agreement of the Study Protocol and formal acceptance by the Ethical committees.

Results:

From a methodological point of view, the FAITH activities are divided in three main stages: the first stage has a data collection focus and aims at putting in place all the technologies and organizational procedures for acquiring the most valuable set of data from the first trials. The set of requirements for this stage is therefore oriented towards data acquisition (e.g., activity monitoring, sleep quality monitoring, nutrition questionnaires, medical assessments etc.), rather than data processing. It is the second stage of the methodology, instead, which is devoted towards the analysis of the data and the production of the AI models that, trained on the data collected, will be deployed for the third and last part of the study where the models are being validated through the second trials.

Four main actors were identified for the execution of the first trial. These actors are the patient, the doctor, the data scientist and the FAITH App (included as a technological actor functioning as the main link). All these actors contribute to the data collection and data processing stages fulfilling different roles: i.e. the patient mainly acts as a data provider, and the doctor monitors the patient status and produces clinical assessments that together with the "raw" data are organized and quality checked by the data scientist.

Requirements for the second trial have been identified from a high-level perspective; this is due to the fact that the development of the AI models includes functional uncertainties: it is not guaranteed that -for example- the voice data will provide valuable information in our case to detect depression; in this case the module wouldn't be included in the second set of requirements. Such considerations are part of the MVP definition and included in the second stage (processing and AI development) of our methodology.

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ABBREVIATIONS

Abbreviation	Description
AI:	Artificial Intelligence
D:	Deliverable
EAB:	External Advisory Board
EC:	European Commission
EU:	European Union
GDPR:	General Data Protection Regulation
HAM-D:	Hamilton Rating Scale for Depression
ICT:	Information and Communications Technology
IoT:	Internet of Things
ISO:	International Organization for Standardization
ISO9001-2015:	International Quality Management Systems.
IT:	Information Technology
KPIs:	Key Performance Indicators
ML:	Machine Learning
QoL:	Quality Of Life
WP:	Work Package
WL:	Work Package Leade
WHO:	World Health Organization

1 INTRODUCTION

The goal of the FAITH project is to provide an AI application that remotely identifies and analyses depression markers, using federated learning, to predict negative trends in people who have undergone cancer treatment. This concept would present healthcare providers with advanced warnings to allow timely intervention and to allow cancer patients to be more aware of their mental health situation and improve their quality of life. Such an application of AI requires the involvement of both patients and specialists (e.g., doctors and scientists) with different contributions to the concept study through the project execution driven by the overall project methodology. Due to the nature of the project, the FAITH methodology is highly centred on the hospital trials and on the agreed study protocol with the hospital partners.

The present document describes the user requirements identified for the actors of the FAITH concept focusing on the first part of the study represented by the first hospital trial that, from the methodology point of view, represents the data collection stage.

At the same time, technical requirements are described in D2.3 - *FAITH Framework Conceptual Architecture*. The results (both intermediate and final) of the first trial will affect the requirements of the second stage (i.e., validation), such requirements will be described in the second version of this deliverable (D2.2b - *FAITH Requirements, Methodology and MVP*) of this deliverable (only high-level requirements are described here for Trial2).

User requirements for the second trials will be described in the updated version of this deliverable, D2.2b - *FAITH Requirements, Methodology and MVP*.

1.1 Structure of the document

- Chapter 1 introduces the aims at framing the context of the deliverable; it also describes the concept map that summarizes the consortium's current vision of the concept shape and dynamics. It is important to highlight that such vision and concept maps are subject of iterative refinements and validation; however, it is a necessary asset to maximize awareness and internal agreement regarding the concept.
- Chapter 2 describes the overall methodology driving the FAITH project activities providing a summary description of the study protocol.
- Chapter 3 contains the user requirements of the FAITH project for the first trial, it is the core chapter of the deliverable and contains the main actors' descriptions, the user flows in the form of actor cards, user stories and use cases.
- Chapter 4 outlines the requirements for the second trial from a high-level perspective and focusing on the changes in the FAITH App.
- Chapter 5 presents a first version of the MVP and is described.
- Chapter 6 presents the conclusions.

1.2 Concept Map

FAITH will contribute towards the importance of monitoring mental health status after cancer treatment in cancer survivors, by providing an "AI-Angel" that remotely analyses depression markers and predicts negative trends in their disease trajectory providing doctors and patients with behavioural and sentiment information that will allow proper timely support.

The value proposition of FAITH, indeed, is to support the mental health of cancer survivors while reducing one of the most common comorbidities in cancer patients: depression. Within this aim, FAITH is aligned with the WHO agenda, in contributing to the creation of a healthier society.

On the other side, FAITH aims at supporting clinicians with valuable and systemic data that was not possible to obtain before. The decentralized digital eco-system will promote an improvement in the care of individuals, by enabling collaboration with

different healthcare stakeholders. Our Federated Learning AI Framework will contribute to the creation of better knowledge and predictive models to improve patients counselling and follow-up. The novel information on mental health's maintenance will ensure better prevention and treatment of the oncologic condition. Users are not required to trade their privacy for better services.

FAITH is strongly invested in safeguarding the privacy of sensitive data of the patients. Thanks to the Federated Learning approach, sensitive data never leaves the patient's phone, and the ethical respect of personal data protection is guaranteed. Artificial Intelligence transparency is indeed a common ground across the whole project and in the creation of FAITH AI- Angel. The design of the solution will be driven by three trials and pilot tests with real users who will help to build and improve the model. The three pilots will take place in Lisbon, Portugal, at the Champalimaud Centre for the Unknown; in Madrid, Spain at the Hospital General Universitario Gregorio Maranon (HGUGM); and in Waterford, Ireland at the Whitfield Hospital. Two pilot cycles with different purposes will involve practitioners and patients of these facilities and will allow to refine FAITH AI-Angel over the next two years.

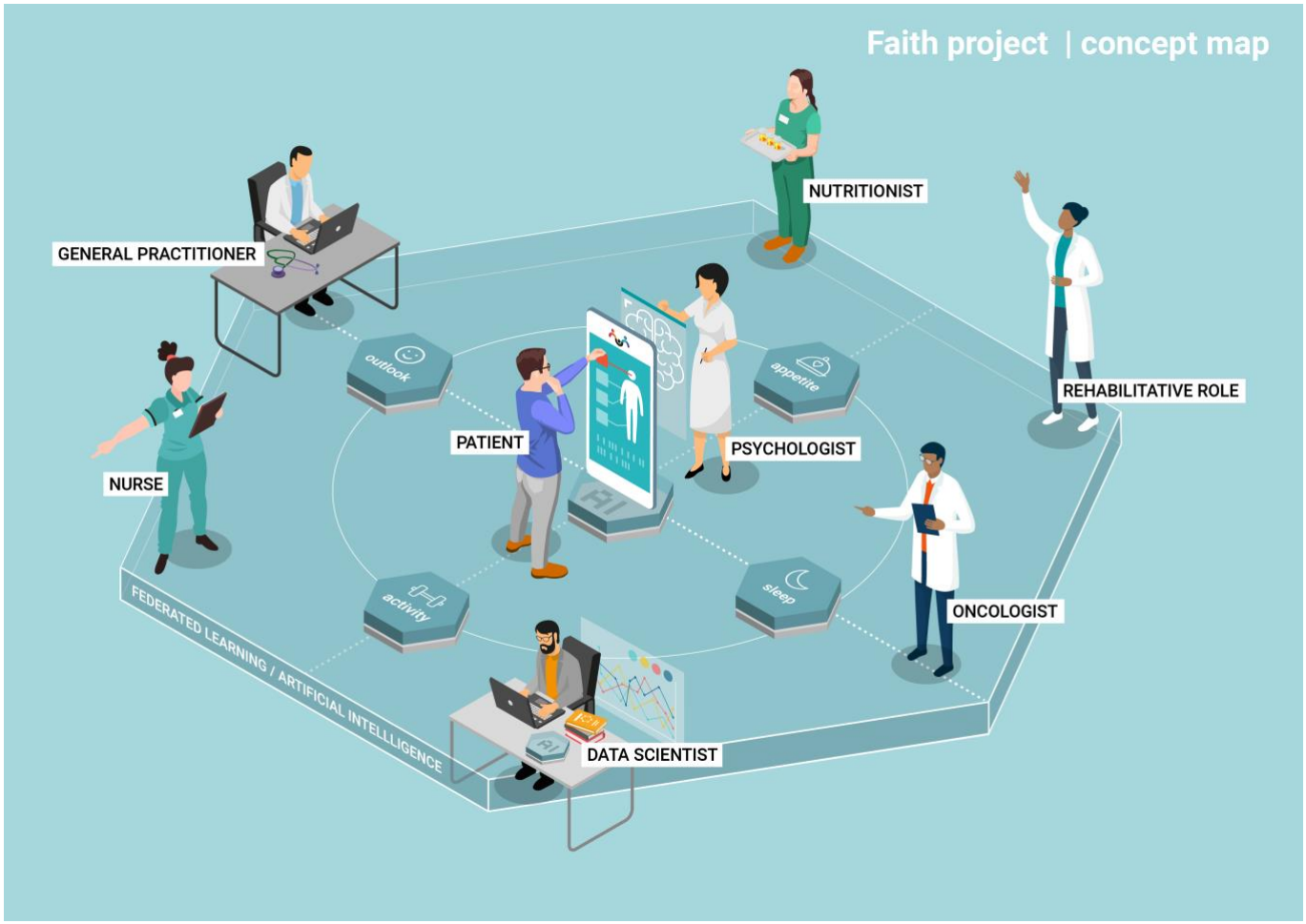

Figure 1 - Faith Concept Map

The FAITH Concept Map (Figure 1) provides a visual representation of the current vision of the concept. Our FAITH digital ecosystem makes it possible to support the quality of life of cancer survivors through their post recovery journey by enabling collaboration of different healthcare practitioners. The map outlines the main stakeholders involved in the system and their

interaction, highlighting the centrality of the patient in the solution. The FAITH App can act as the central junction between the medical environment and the private life of the patient. Here, supported by Artificial Intelligence, lies the data gathering and the interaction between the different roles that will lead to the proper support for the patient. The user-centric approach is a fundamental aspect towards the creation of FAITH and will ensure that our solution will fit the need of oncological patients in their life after treatment. The sourced data are shown as local AI models regarding Nutrition, Outlook, Sleep and Mental Health of the patient. Such models contribute to the elaboration of the central FAITH model, while the system and allow to forecast negative trends in the mental health of the patient based on it. This representation depicts the final formulation of FAITH, but in order to reach this results, previous trials and data gathering sessions are needed in a staged process. In the beginning, the role and contribution of the healthcare professionals will be mostly regarding support, collection and selection of data. Afterwards, the doctors will also become users and beneficiaries of the FAITH ecosystem. The end point of our trajectory, in fact, is the possibility to enhance the aftercare, well-being and quality of life of patients, also by bringing them closer to the medical team that cared for them during treatment.

2 METHODOLOGY

This chapter describes that FAITH methodology that drives the activity for the study and development of the concept. Dealing with cancer patients' data, and hospital partners, the FAITH methodology is greatly impacted and based on our study protocol, which is being defined by the hospitals in conjunction with the technical partners. It defines stages of the study, expected outcomes, data collection and usage as well as criteria for the participant's involvement.

2.1 Study Protocol

The Study Protocol is being refined on an ongoing basis; so while every effort has been made to capture the most important points from it here, it is subject to change. Follow-up versions of this deliverable will capture any changes (as will the final Study Protocol document). The FAITH study has both primary and secondary endpoints.

Primary Endpoints:

- To predict depression level changes in cancer patient survivors, correlating these changes with activity, outlook, sleep, and appetite measurements. Clinician-rated interviews will be run with the patients in parallel as a means of validating the correlations. These interviews will use the Hamilton Rating Scale for Depression (HAM-D).

Secondary Endpoints:

- Assess longitudinal progression of Quality of Life, using EORTC questionnaires.
- Describe the evolution of activity, outlook, sleep, and appetite measurements in cancer survivors throughout the study.
- To evaluate the feasibility and usability of the FAITH application on cancer care.
- To explore longitudinal evolution of primary outcome and predictors.
- To explore depression-related biomarkers.

2.2 Trial 1 Description

The study is being designed as a 12-month longitudinal observational and prospective study. This is not an interventional study. All the patients recruited will follow the therapy prescribed by their physicians according to their clinical practice. No additional treatment or change in treatment will be required by participation in this study. The study will require approval by the Ethical Committees of the participating institutions. Figure 2 gives an overview of the study design, though as highlighted already, this is subject to change e.g., the means and feasibility of running questionnaires every 3 weeks is currently being investigated.

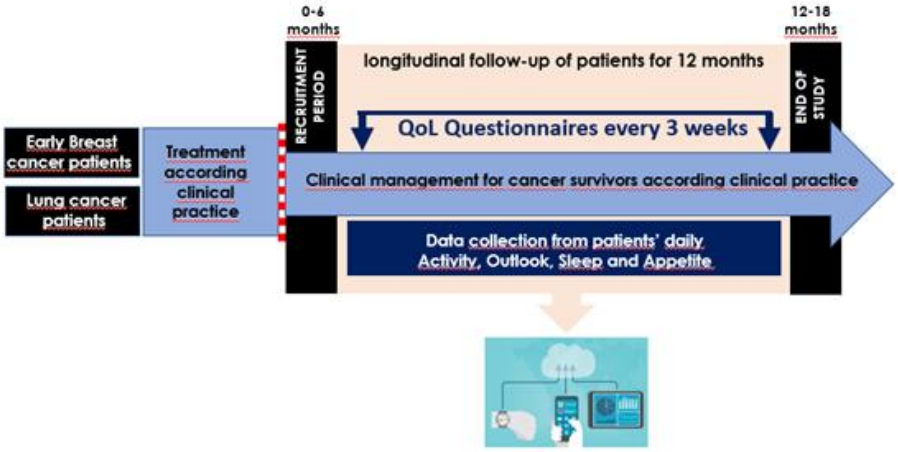

Figure 2 - Study Design

There are three trial sites corresponding to the three participant hospitals:

- UPMC Whitfield, Euro Care Healthcare Limited (UPMC), Ireland
- Hospital General Universitario Gregorio Marañón, (SERMAS), Spain
- Fundação D. Anna de Sommer Champalimaud e Dr. Carlos Montez Champalimaud (CF), Portugal

The study is framed in terms of Trial 1 and Trial 2, because each stage has different objectives. The aim of Trial 1 is gathering data i.e., the variables defined in the Study Protocol, and running the clinician-rated interviews. The questionnaires used as validation will be the same across both trials, and are:

- Depression:
    - Hamilton Rating Scale for Depression (HAM-D) to measure depression severity.
    - Hospital Anxiety and Depression Scale (HADS) allowing patients to self-rate levels of depression and anxiety.
- Quality of Life:
    - European Organisation for Research and Treatment of Cancer Quality-of-Life (EORTC) questionnaire EORTC QLQ-30 with extensions dependent on type of cancer.
        - EORTC QLQ BR-45 for breast cancer patients.
        - EORTC QLQ LC-29 for lung cancer patients.

Upon informed consent signature, at study entry each participant will fill in the baseline questionnaire. Throughout the trials these questionnaires will be repeated at regular intervals (the delivery method and intervals are still to be confirmed).

Figure 3 - Trial 1 Data Collection

Since the trials are exploratory i.e., we are trying to see if there are correlations between certain variables and changes in depression, anxiety and quality-of-life. Thereafter, it is vital that during the initial trial we capture as much data as possible. This will give us the best opportunity of uncovering the correlations we hope to discover. This being the case, a crucial component of our methodology, reflected in the study protocol, is an exhaustive detailing of variables to be recorded.

These variables will come from a variety of sources e.g., clinical records, oncology nurse consultations, FAITH application, and with some recorded as baseline variables at the outset of the trial, and other continuously monitored. Some examples are shown below in Figure 4 and Figure 5.

Timepoint	Variable name	Description	Possible Values	Data Source	Frequency of Acquisition	Interaction needed (passive or interactive)	Marker Category (nutrition, outlook, activity, sleep, Depression, QoL, All)	comments
General	Birth Date	Clinical variables	>18	Clinical record/ App	Only once	Interactive	All	update d birth date instead of age
Basal	PS	Clinical variables	ECOG	Clinical record	Only once	Interactive	All	
General	Gender	Clinical variables	Female for brast cancer patients. Male or Famale for Lung patients	Clinical record/ App	Only once	Interactive	All	
General	Age at diagnosis	Clinical variables	date	Clinical record	Only once	Interactive	All	new included
General	Type of Cancer	Clinical variables	Breast cancer/Lung cancer	Clinical record	Only once	Interactive	All	new included
General	Tumoral stage	Clinical variables	stage TNM	Clinical record	Only once	Interactive	All	new included

Figure 4 - Data Source Example 1

Timepoint	Variable name	Description	Possible Values	Data Source	Frequency of Acquisition	Interaction needed (passive or interactive)	Marker Category (nutrition, outlook, activity, sleep, Depression, QoL, All)	comments
								in detail at the Oncology nurse consultation
Continuously monitored	intake time			APP	daily	Interactive	Nutrition	To be excluded? Information from "food intake" could be enough for our purposes
Continuously monitored	Do you skip any food?		Yes/no	APP	daily	Interactive	Nutrition	
Continuously monitored	Liquid intake (quantity)		Litres per day (media)	APP	daily	Interactive	Nutrition	
Continuously monitored	Concommitant medications	Clinical variables	specify	APP	monthly	Interactive	All	new included. Concommitant medications can affect to patients status (deperssion leves, xe.)
Continuously monitored	Weight		Kg	APP	biweekly	Interactive	Nutrition, Outlook	

Figure 5 - Data Source Example 2

After this stage ends, the project partners will take time to analyse the data to see 1) if correlations indeed exist between the measured variables and the depression and QoL of the patient, and 2) if those correlations exist then algorithms will be developed to predict the changes in depression and QoL from the measured variables.

Figure 6 - Post-trial Analysis & Model Development

2.3 Trial 2 Description

The second trial represents the third stage of the methodology and will run across the same locations but this time rather than just collecting data, the models developed as a result of Trial 1 will be deployed on the patient devices. Our ambition is then that these models will predict changes in depression and QoL that will then be validated by the regular clinician-rated interviews.

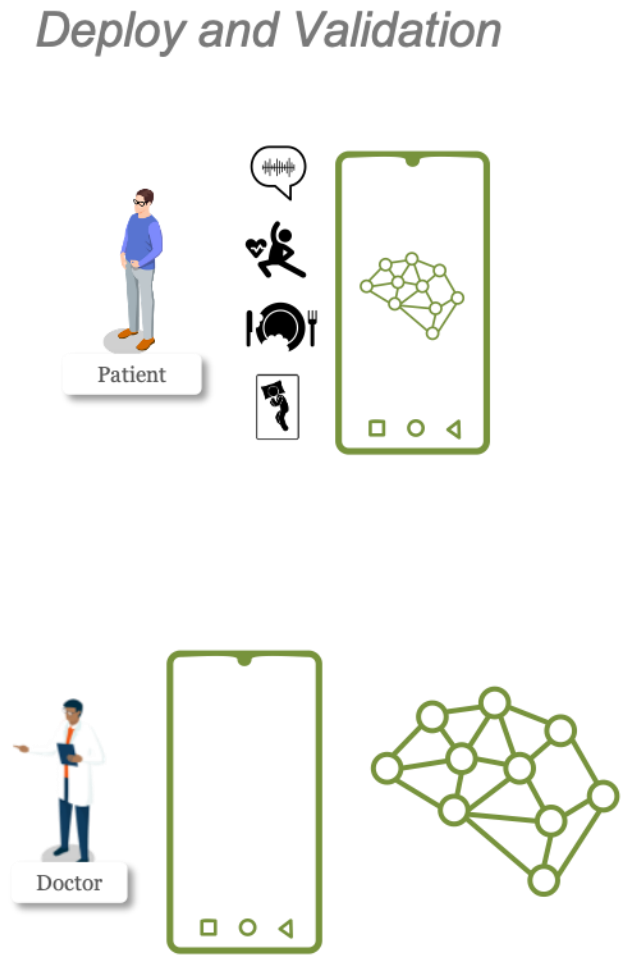

Figure 7 - Trial 2; Model Validation

3 TRIAL 1 USER REQUIREMENTS

The aim of this section is to identify both the functional and non-functional requirements to further translate them into technical requirements that will guide the development of the solution. The design and architecture of FAITH is conceptualized, detailing the specification of its main components and data. The user requirements are collected from our end users and organisations, as well as the relevant stakeholders and policy maker organizations. They drive the architecture specification, the data reference models, as well as real-life use case scenarios, which are then acted upon for the building of our platform components. They identify the needs of the main stakeholders of the FAITH framework and, on the base of that, envision scenarios of usage and adoption. Requirements ensure that real user needs are being addressed in the creation of the framework and in the definition of the Minimum Viable Product.

The first trial of FAITH will be aimed at data collection. It is designed as a 12-month longitudinal observational and prospective study. This is not an interventional study. All the patients recruited will follow the therapy prescribed by their physicians according to their clinical practice. In this timeframe, users will download the FAITH App on their personal smartphone and make use of it and a sleep monitoring device on daily basis. Through an iterative interaction and access to the smartphone sensors, the system will collect data in regards of the patient's nutrition, sleep, activity and outlook. Sleep will be passively monitored by the Sleep monitoring device during the night, while nutrition, physical activity will be investigated by direct inputs and vocal interactions with the app in several moments of the day. Iterated interview sessions with clinicians will be aimed at assessing the mental health status of each patient and at of validating the correlations with the physical monitoring.

The user will actively share personal information about their condition and will agree on the passive collection of data from the smartphone sensors. Federated machine learning will make it possible to direct access the personal treatment data and use them in machine learning, preserving the privacy of the patient. Instead of sharing their data, the device if the user' computers weight updates themselves using their locally available data. Data collected in Trial 1 will be used to train a model without directly inspecting users' data on a server.

This Chapter proposes the first stage of User Requirements, as emerged by the collaborative investigation with the technical partners of the consortium. According to the agile development of FAITH, further iterative sessions with real end-users will be conducted to confirm or redefine the actual criteria. The Chapter considers the different stakeholders involved in the process, in light of the needs in the use of the system. A detailed list of the actors involved is provided by Section 3.1 outlining their role, key characteristics and interactions. In section 3.2, description of actors is supported by FAITH Actors Concept Cards, illustrated tools picturing the interaction flows of each actor. Actors cards are provided for Patient, Doctor, Data Scientist and FAITH App.

In section 3.3 the requirements are distilled into user stories, which drive the formulation of a formal system architecture and the task required to deliver the system. The user stories also outline the needs and intentions of end-users derived from the user research and introduced the more detailed definition of Use Cases in section. 3.4. A general narrative scenario describing the end point of our system is provided in the final section of this chapter, 3.5.

3.1 Actors Description

This section describes the actors involved in the Trial 1 of FAITH. The term *actor* does not cover only users or practitioners, but it encompasses also tools and constitutive parts of the FAITH AI-Angel system. Initially, a systematic description of each actor is provided highlighting their goals, and interaction with tools and other actors. Subsequently, the role of each actor is outlined in detail with the support of the Actors Concept Cards. **FAITH Actors Concept Cards** are a user research tool that provides a visual depiction of processes and interactions concerning each actor. Focused on the role of the actor in the system, they depict all the possible interaction flows displaying the possible triggering events, the data produced by them, the subjects of the given actions, and final result achieved.

The actors involved in Trial 1 are: *Patient, Doctor, Data Analyst, FAITH APP, Sleep Monitoring Device and System Administrator*. Descriptions are listed below.

Name: Patient

Goals: Be physically and mentally healthy

Description: Patient is one of the main users and beneficiaries of the system. They are a cancer survivor who has undergone and completed the first phase of oncological treatment. They are returning to their daily lives after the period of treatment and may suffer the psychological consequences of the illness. What frightens the patient is the loss of contact with the medical support that has guided them through the treatment path.

Tool interaction: FAITH App, Sleeping Monitoring Device.

Other Interactions: Doctors, Family members, Other patients

Name: Doctor

Under the heading "Doctor" we cover different healthcare practitioners who can be part of the patient's therapeutic support, according to their needs. It may encompass: Oncologist, Psychiatrist, Psychologist, Psychotherapist, General Practitioner, Nutritionist, Dietitian, Physiotherapist, Radiologist and Surgeon.

Goals: Assure patient's mental health, prevent breakdowns in the patient's mental health, help creating the AI model.

Description: Doctor is a healthcare professional who is treating an oncological patient. Specifically, they can cover the role of Nutritionist, Psychologist, Psychiatrist, Psychotherapist, General Practitioner, Oncologist and Radiotherapist. Their role in FAITH is to take care of the patient's health according to their specific expertise. In the trial, they will help investigating the Patient's mental health and will help the Data Analyst in selecting the most valuable data.

Tool interactions: FAITH System, FAITH App.

Other Interactions: Other healthcare professionals (Nutritionist, Psychologist, Oncologist, General Practitioner, Other Therapist), Patient and Data Scientist.

Name: Data Scientist

Goals: Analyse the data regarding the patient's health in order to create the AI model.

Description: Data Scientist plays a fundamental role in the first trial of FAITH. Their work is to analyse all the raw data about Nutrition, Sleep, Outlook, Mental Health and Activity collected by the App, the Sleep Monitoring Device and the Doctor. Supported by Doctors, the Data Analyst selects the preeminent data in order to build an effective AI model.

Tool interaction: FAITH App, FAITH Central, Sleep Monitoring Device.

Other Interactions: Doctors

Name: FAITH App.

Goals: Actively interact with the Patient; Collect data from the Patient's Smartphone; Gather data from Sleep Monitoring Device

Description: The FAITH App is the interface between FAITH Central and the human actors in the system. It makes the Patient's phone work as a sensor suite, allowing to gather GPS and accelerometer data. It dialogs with the Patient both with UI and Vocal Interface allowing the collection of data about their health status. It sends the data collected to the Cloud.

Tool interactions: FAITH System, Sleep Monitoring Device, GPS and Accelerometer.

Other Interactions: Patient, Data Analyst.

Name: Sleep Monitoring Device

Goals: Collect data from the patient's sleep and send it to the App.

Description: Sleep monitor device is a wearable component of FAITH System. Worn by the patient during the night, it passively tracks their sleep. It tracks the amount of time spent asleep, the quality of the sleep, the duration of each stage of sleep, the sleep environment, and other physical health parameters and motions. It is connected via Bluetooth to the FAITH App to which it sends the data directly.

Tool interaction: FAITH App

Other Interactions: Patient (Passively)

Name: System Administrator

Goals: Support the User in case of need while using FAITH

Description: The System Administrator is a technical figure who provides support in case of need during FAITH trials.

Tool interaction: FAITH App, Sleep Monitoring Device.

Other Interactions: Patient, Doctor, Data Scientist.

3.2 Faith Actors Concept Cards

FAITH Actors Cards are research tools, designed to provide visual conceptualization of the user requirements and the interaction flows within FAITH. They constitute an agile and adaptable means of communication that allow to clearly identify the role of each component in the system and highlight its interaction with the other elements.

FAITH Actors Cards are based on a collection of graphic illustrations of all the elements involved in the system and a labelling system that highlights the types of relationships and actions. Every element is provided with an individual meaning and can be aggregated with other elements to build more complex processes of interactions.

The Card template (Figure 8) provides a matrix where to display the interactions.

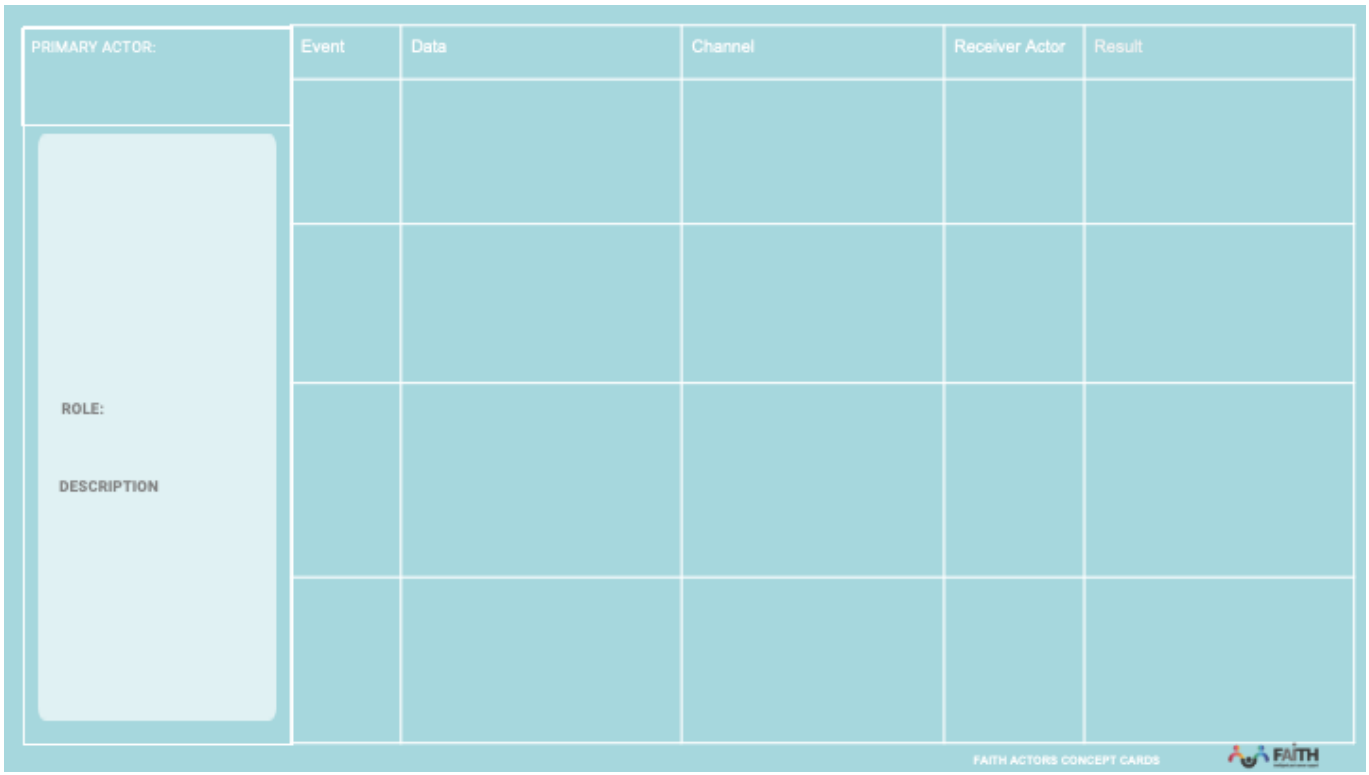

Figure 8 - Actor Card Template

The taxonomy on which the illustrative system is built is contained in the **FAITH Actor Cards Library** (Figure 9, Figure 10). Here, every element is displayed and labelled according to five main categories: *Actors/Channels*, *Events*, *Raw Data*, *Structured Data* and *Information.* A further *Data Catalogue* provides detailed information on the specific kind of data collected.

Actors/Channels encompass the individuals involved in FAITH, both as users and practitioners. They are Patient, Doctor and Data Scientist. Tool actors are *FAITH App*, *Doctor Web App* and *Sleep Monitoring Device* and *NLP Module* and technical components as *AI module* and *FAITH Central*. Channels to exchange data are intended as *Internet* or *Bluetooth.*

The Information Library (Figure 9) collects also the graphic icons for data representation. The section *Raw Data* includes *Sleep Data*, *Voice Data*, *Activity Data* and *Mental Health Data*. Structured Data includes *Mental Health Questionnair*e and *Nutrition Data.* Information produced refers to *Sleep Quality*, *Outlook Profile*, *Activity Profile*, *Nutrition profile* and *Mental Health Data.*

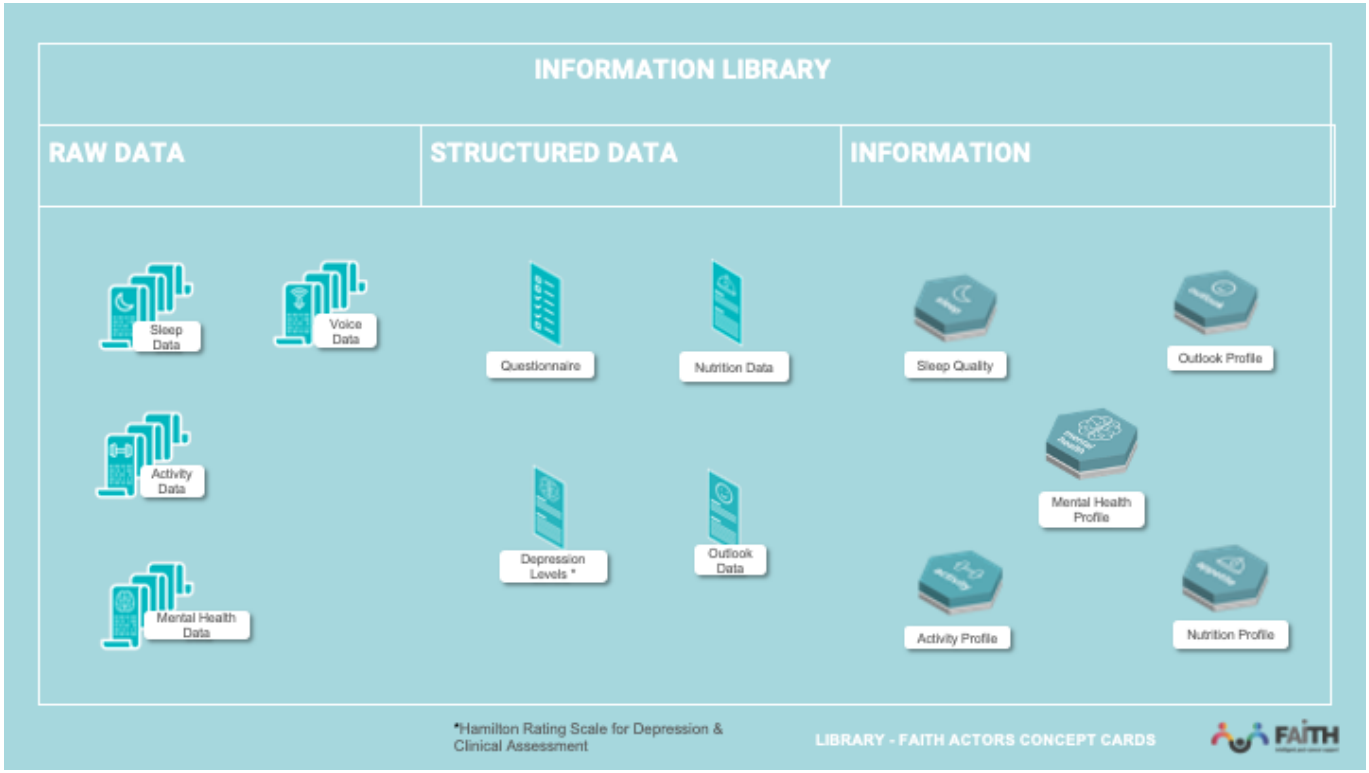

Figure 9 - Actors Cards Information Library, Data and Information Section

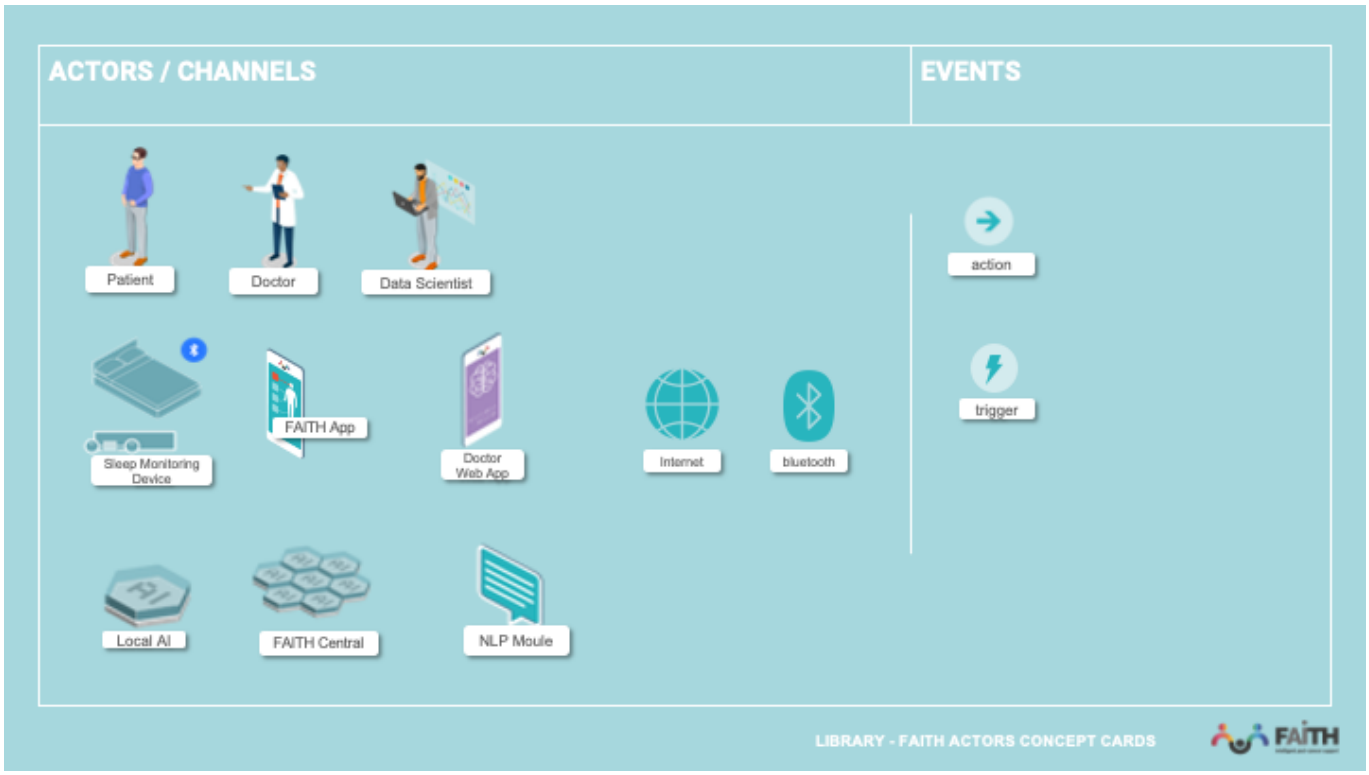

Figure 10 - Actors Cards Information Library, Actors/ Channels, Events Section

3.2.1 Patient

The **Patient Actor Card (Trial #1)** (Figure 11, Figure 12) is dedicated to the patient and its role in the Trial 1. During this timeframe, FAITH will gather information regarding the physical and mental condition of the patient in regards of different aspects to depict a frame of their psychological condition and build Local AI model to recognize it. The process will be supported by two professionals: Doctor and Data Scientist. Several flows will build the interactions between FAITH App, Sleep Monitoring Device and NLP Module.

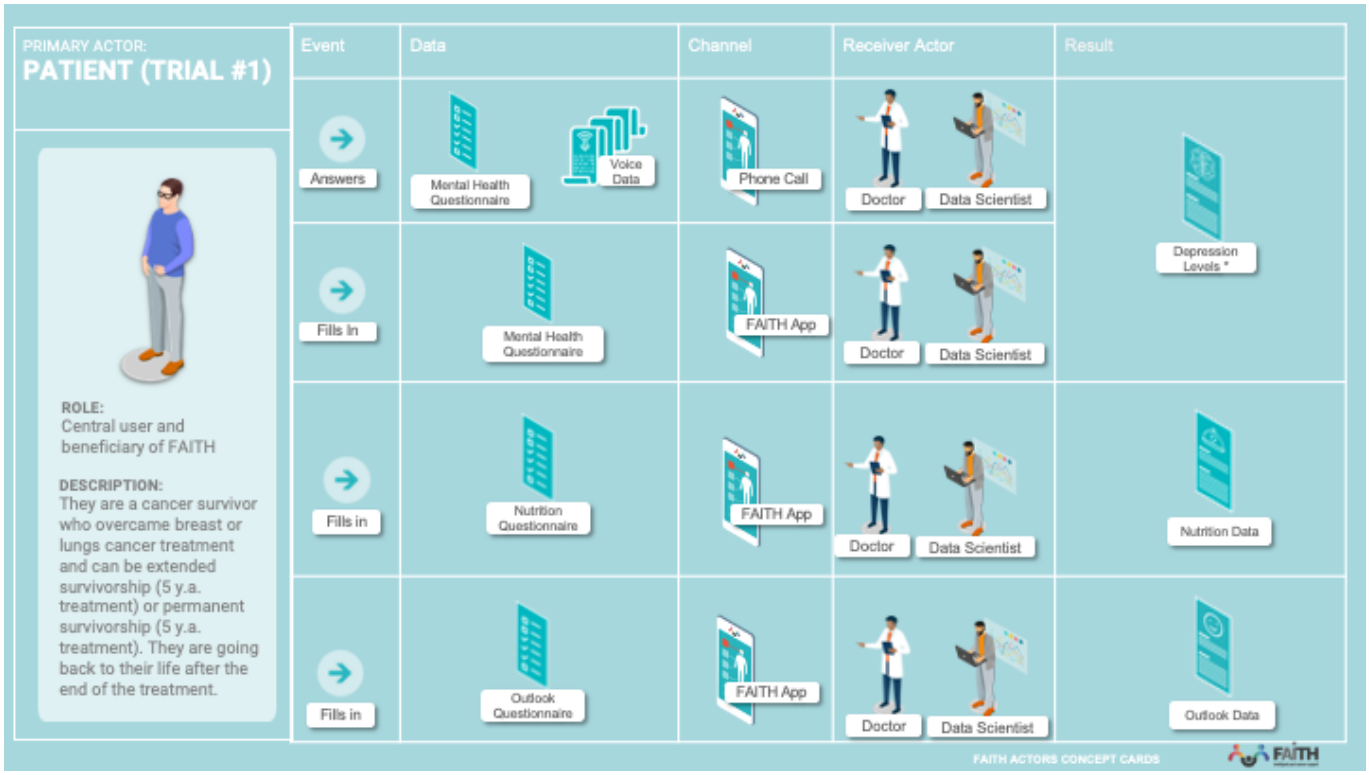

Figure 11 - Patient (Trial#1) Actor Card

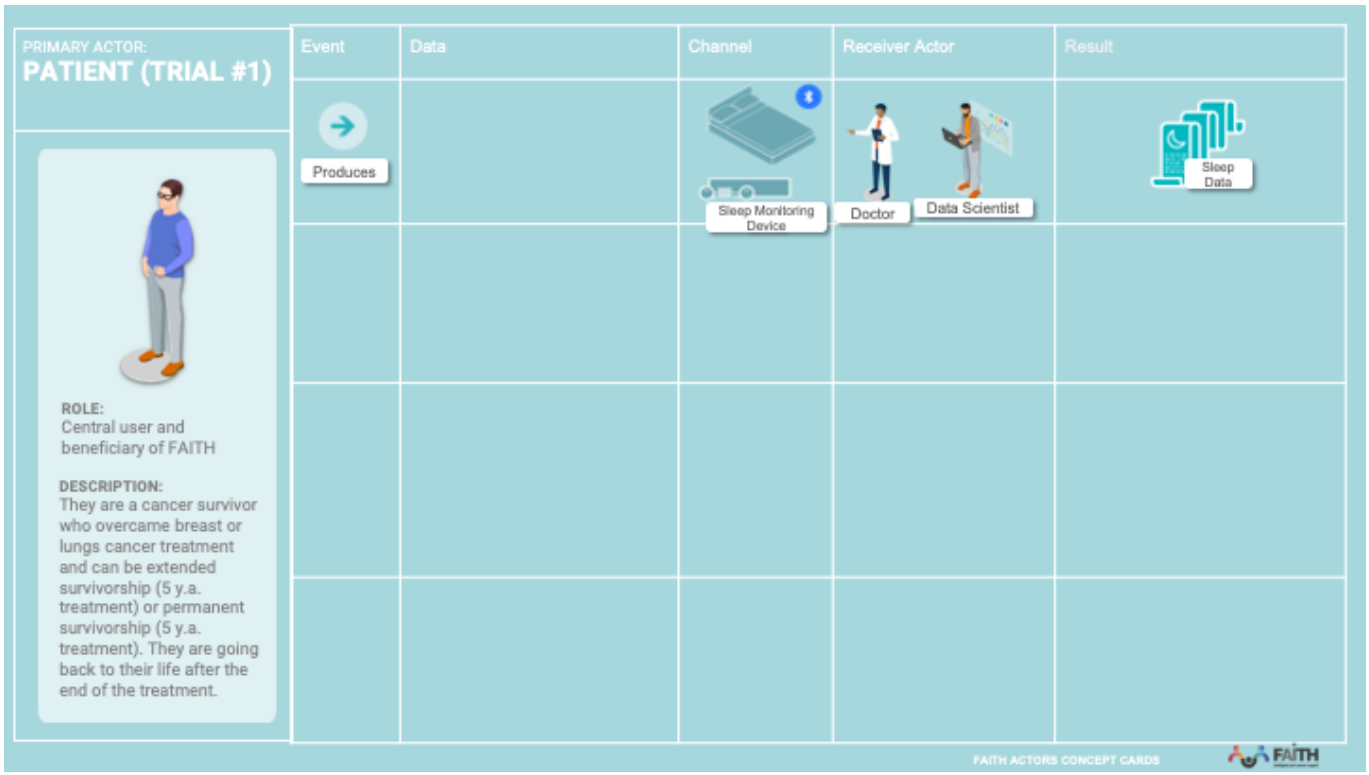

Figure 12 - Patient (Trial#1) Actor Card, Page 2

Patient is the central user and main beneficiary of FAITH. They can be a man or a woman who underwent oncological treatment and overcame (maybe partially) lungs or breast cancer. They have been enrolled in Trial 1 by their treating hospital and have accepted all the agreements to take part in the trial. They will adopt the solution initially for 1 year sharing their personal data in order to contribute building the FAITH AI-Angel.

They have downloaded FAITH App on their phone and connected it to the Sleep Monitor Device. During their everyday life the Patient interacts with the app in several different ways that can be spontaneous or prompted by FAITH. All the interactions can happen through vocal interface.

Each flow is described in detail below:

FLOW 1: Answering Mental Health Questionnaires

Data on the mental health of the patient are gathered through two different pathways: the appointment on the phone with the doctor and the Mental Health Questionnaire available on the App. In the former scenario, the patient talks with the doctor every three weeks to discuss their status. During the conversations held on the phone, the doctor investigates and assesses the mental health of the patient. The patient can share with the doctor details of their physical and mental outlook, and answers questions regarding their mental condition. Their tone of voice also constitutes a valuable data to their condition. Minor information regarding the emotional and psychological status of a person can be inferred from their speech. The NLP is activated on the Vocal Data and aims at extracting relevant information regarding the status of the speaker.

Meanwhile, the doctor administers to the patient a clinical Mental Health Questionnaire based on the Hamilton Rating Scale for Depression Assessment (HAM-D). On the results of the questionnaire, the doctor defines the clinical profile of the patient. Such assessment is then provided to the Data Scientist. The answers to the medical Mental Health Questionnaire and the Voice Data

are integrated to assess the mental condition. Data collected are received by the Data Scientist, who selects the proper patterns to build the AI model. The result of the flow is the newly detected Depression Levels, according to the HAM-D (Figure 13).

Similar data can be obtained also from the FAITH App. In the dedicated section, the App prompts the user with questions and the Mental Health Questionnaire to collect data about their mental status. The user can share their input spontaneously with the App. Even in this case, the data will be received both by the doctor and the data scientist, who will analyse the validity of the items in order to select appropriate ones. The result of the flow is the identification of the Depression Levels according to the HAM-D.

From this element, the Data Scientist will be able to build the Local AI model. (Fig.14). To read more details about the creation of the Local AI Model, check out the Data Scientist section (3.2.3).

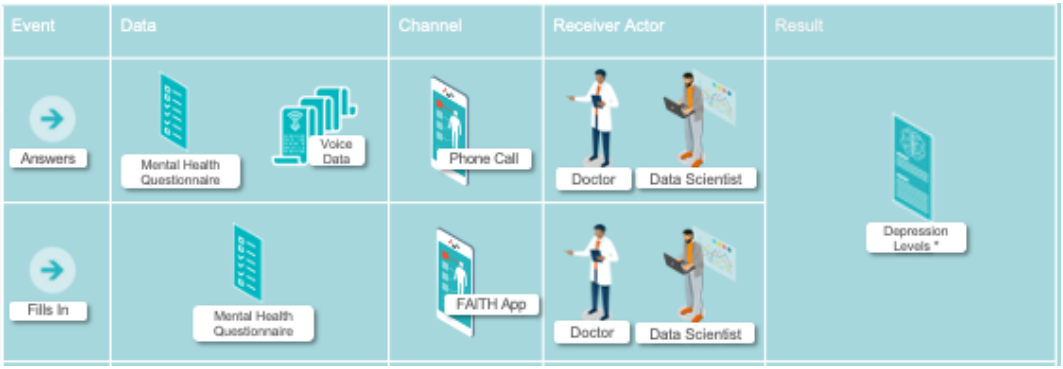

Figure 13 - Patient Actor Card, Answering Mental Health Questionnaire Flow

FLOW 2: Filling in Nutrition Records

During the day the patient is asked by the FAITH App to reply to some questions about their appetite and their meal. In the dedicated session of the App, the user can provide information about the meals there are going to consume during the day and their actual level of appetite. In the same area, it is also possible for the Patient to upload or take a picture of their meals. All this data is gathered and made available to the doctor who will assess their accuracy. Once the Doctor has confirmed their medical validity, they are sent to the Data Scientist who will translate them into Nutrition Data. Such elements will be the base for the creation of the Local AI Model by the Data Scientist (Figure 14). Such procedure is explained in section 3.2.3.

Figure 14 - Patient Actor Card, Filling in Nutrition Records Flow

FLOW 3: Filling in Outlook Data

During the day the patient is asked by the FAITH App about their outlook. In the dedicated section of the App, the Patient can fill in information regarding their outlook condition and reply to the QoL Questionnaire. The data will be made available to the Doctor who will confirm their validity and then to the Data Scientist who will analyse the items. The result of the flow is the Outlook data. From this outcome, the next stage will be the creation of the Local AI model (Figure 15). To know more about the creation of the model, see section 3.2.3.

Figure 15 - Patient Actor Card, Filling in Outlook Data Flow

FLOW 4: Collection of sleep data

During the night, the Patient does passively provide bio-metrical data about their sleep to the sleep monitoring device. The data collected are made available to the Doctor and the Data Scientist will analyse the outcome and select the appropriate data to build the AI model. The result will be the Sleep Data. (Figure 16) The creation of the Local AI Model from this data is illustrated in section 3.2.3.

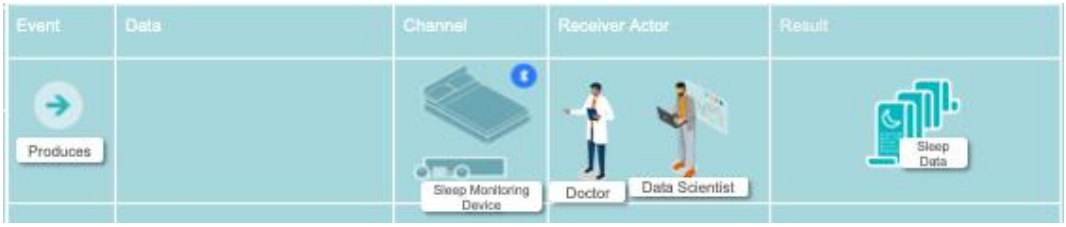

Figure 16 - Patient Actor Card, Collection of Sleep Data Flow

3.2.2 Doctor

The **Doctor Actor Card (Trial #1)** (Figure 17) is dedicated to the role of the Doctor in Trial 1. As previously stated, the term *Doctor* depicts a broader range including several healthcare professionals and can be referred to different clinical professions (e.g, psychologist, oncologist, nutritionist and more. See Sec. 3.1 for further details.).

In Trial 1, the Doctor plays two different active roles. On one side, he/she manages the iterative interviews with the patients to collect the first-hand data on their mental and physical outlook. On another hand, they provide validation and assessment of the data gathered by the App and the Sleep Monitoring Device. The contribution of the Doctor to Trial 1 has both to be intended as collection and validation of data patters. Such function is fundamental to provide proper data to the. Data Scientist who will lately select the more appropriate pattern to build the AI Model.

The two main action flow are described in detail below.

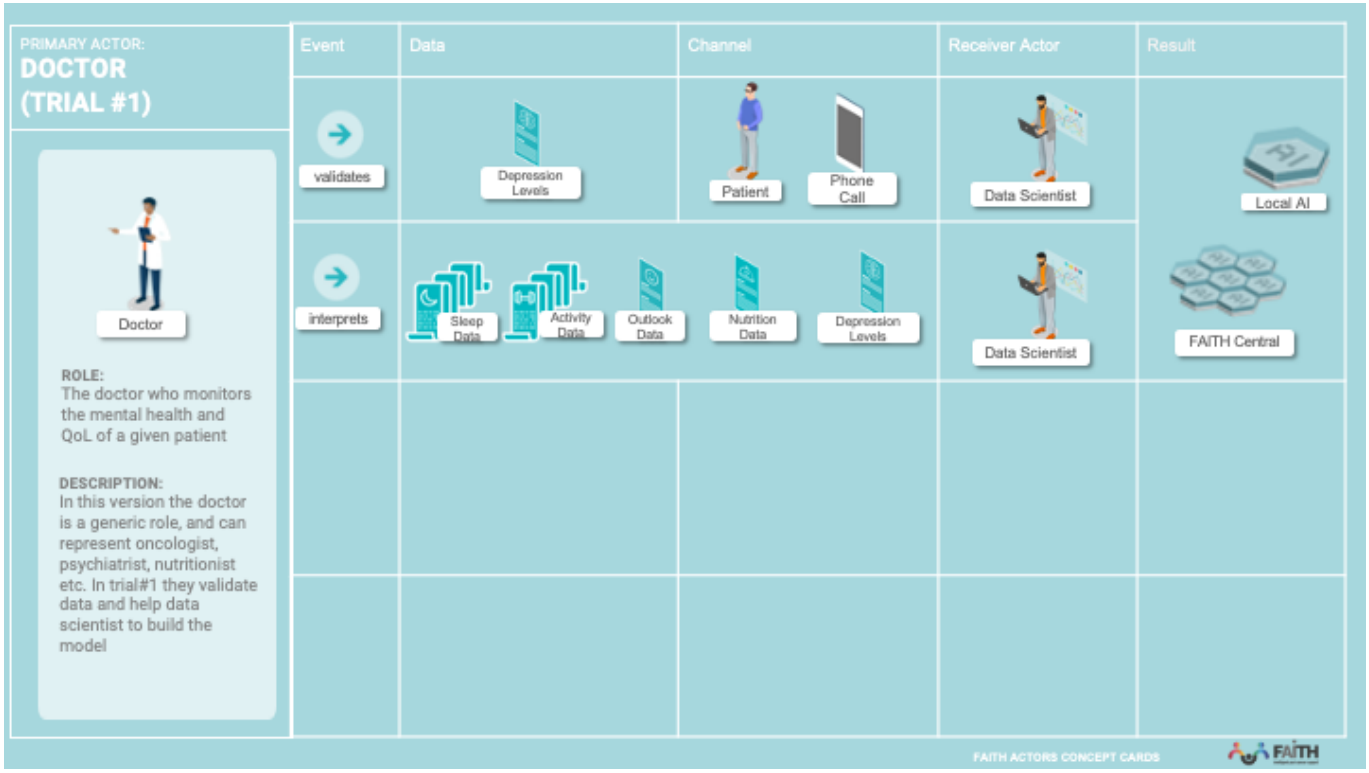

Figure 17 - Doctor (Trial #1) Actor Card

FLOW 1: Depression level validation

During the first Trial, the doctor plays an active role in the collection of information regarding the mental condition of the patient. Every three weeks the doctor meets their patients on a phone call to discuss their ongoing physical and mental condition. In particular, the doctor employs the HAM-D as certified tool to assess the mental condition and the QoL Questionnaire.

Hamilton Rating Scale for Depression (HAM-D) to measure depression severity, the Hospital Anxiety and Depression Scale (HADS) allowing patients to self-rate levels of depression and anxiety and the European Organisation for Research and Treatment of Cancer Quality-of-Life (EORTC) questionnaire EORTC QLQ-30 with extensions dependent on type of cancer (EORTC QLQ BR-45 for breast cancer patient, EORTC QLQ LC-29 for lung cancer patients) regarding the Quality of Life. Verified data are then made available to the Data Scientist (Figure 18).

FLOW 2: Depression level validation

Clinician-rated interviews will used in parallel with the sensor data collection to spot correlations. The doctor is in charge of checking the data collected through the App and their quality for the creation of the AI Model. Sleep Data, Activity Data, Outlook Data, Nutrition Data and Depression Level are assessed by the Doctor who will produce the Clinical Assessment of the patient on relevant links. Verified data are then made available to the Data Scientist, who will verify their employability for the creation of the AI Model (Figure 18).

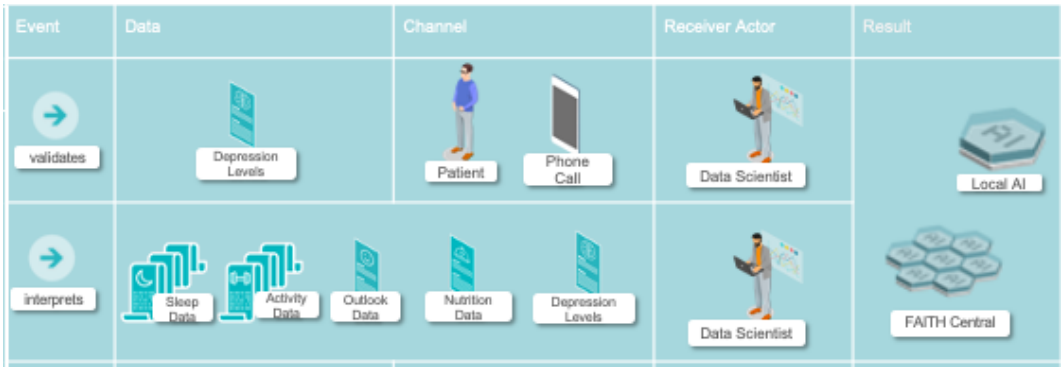

Figure 18 - Doctor Actor Card, Validation of Depression Levels Flow; Interpretation of data Flow

3.2.3 Data Scientist

The **Data Scientist Actor Card (Trial#1)**: See Figure 19, it is dedicated to the role of the Data Scientist in FAITH Trial 1.

The Data Scientist is a professional responsible for collecting, analysing and interpreting the amount of data gathered during the Trial by the interviews, the FAITH App and the Sleep Monitoring Device. In this stage, the Data Scientist collaborates with the doctor to obtain validated data and be supported in the selection of the most relevant correlations of data. The aim of the Data Scientist is the creation of the Local AI model on the most accurate and representative data. A Local AI model for each variable dimension will be created, specifically Nutrition Model, Outlook Model, Mental Health Model and Activity Model. The coordination of such local models will lead to the generation of the FAITH Central, with all the aggregated models.

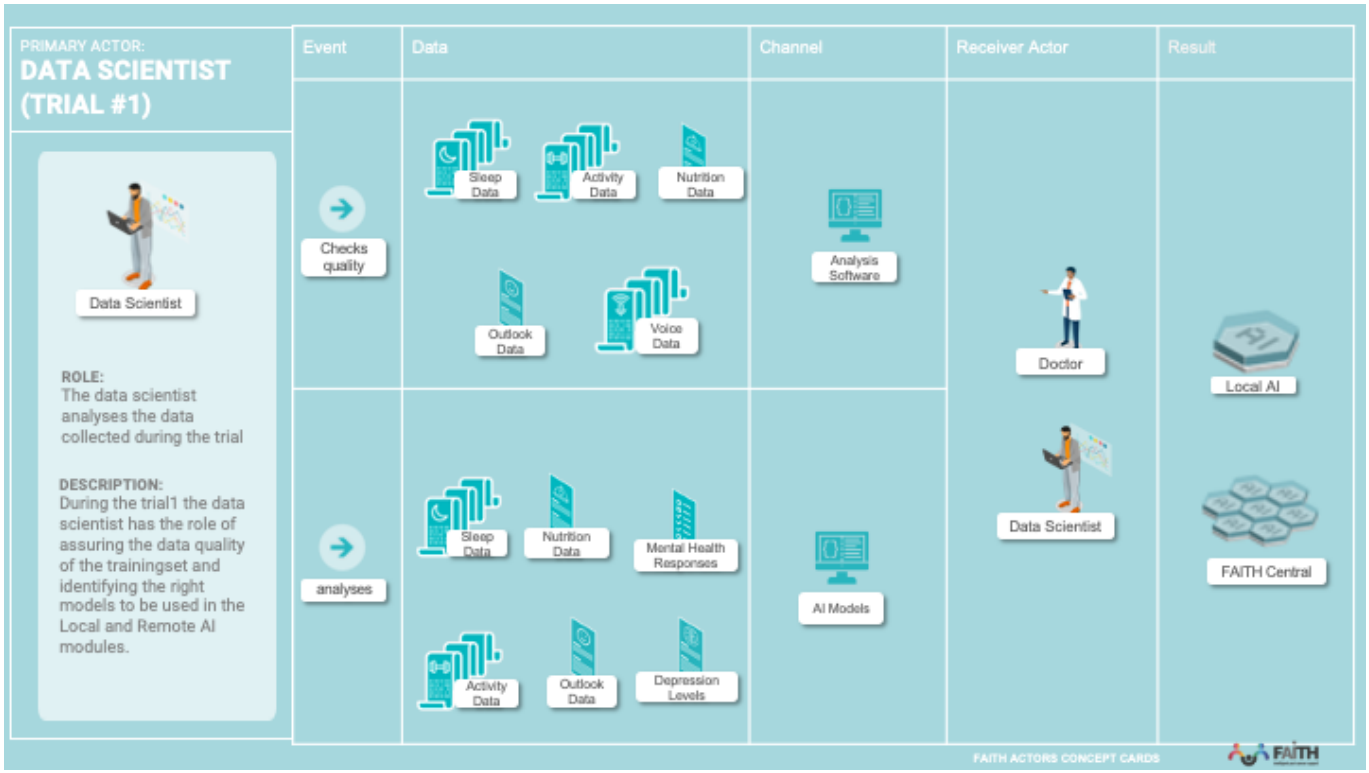

Figure 19 - Data Scientist (Trail #1) Actor Card

The main task covered by the Data Scientist are two: Data Quality Check and Data Analysis.

The two main action flows are described in detail below.

FLOW 1: Data Quality Check

Several different raw data are collected by the FAITH App and the Sleep Monitoring Device. Other certified data are provided by the doctors during interviews. Through an analysis software, the data scientist checks the quality of all the different data (Figure 19).

The doctor provides a support in this operation, in order to guarantee the clinical validity of the outcomes. Once all the data have been selected and validated, it can be used as a training dataset by the data scientist for the creation of the different Local AI Model.

Each class of data can contribute to the creation of one or more specific models. For example, data regarding the appetite and the meals of the patients will created the Nutrition Model. The building of the model is a dynamic and continuative process that will be developed during the entire Trail 1.

FLOW 2: Data Analysis

As previously stated, the data collection will be ongoing throughout the entire duration of Trial 1. Once the Local AI model are built, the data collected by the App and the interviews will keep on training them. The data Scientist will constantly analyse the Sleep Data, Nutrition Data, Mental health Responses, Activity data, Outlook Data and Depression Levels collected by the AI Models. Together with the Doctor, the validity of the data will be always ensured in order to update the Local Models and build the general aggregated FAITH Central.

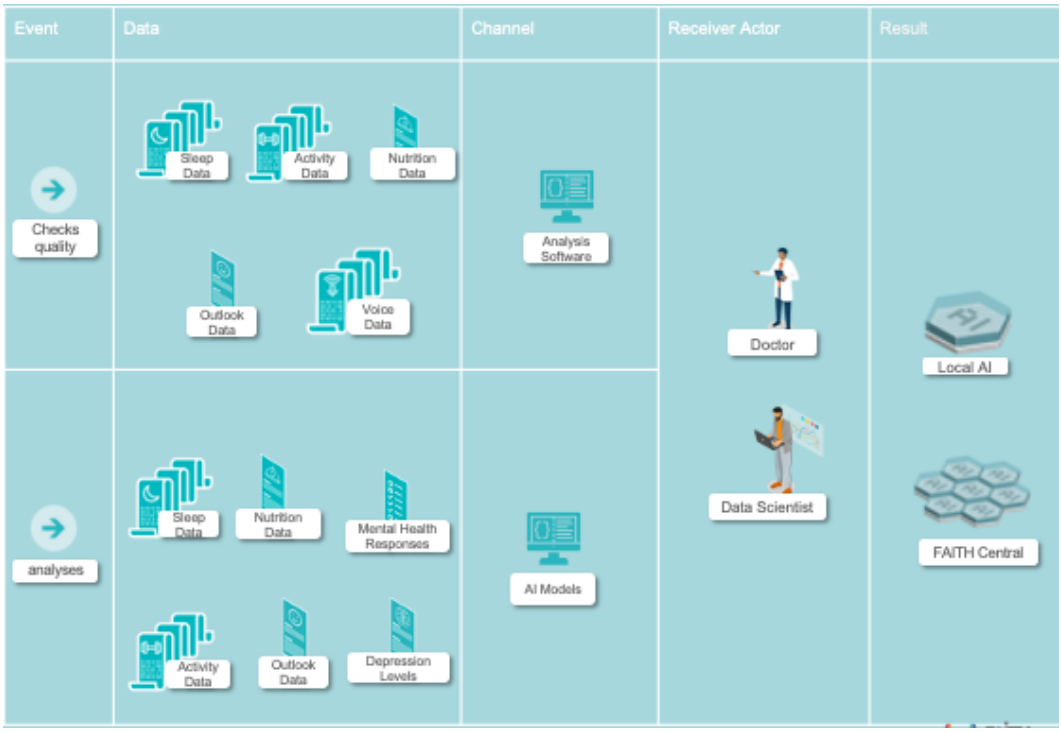

Figure 20 - Data Scientist Actor Card, Data Quality Check Flow, Data Analysis Flow

3.2.4 FAITH App

The FAITH App (Trial #1) Actor Card provides a clear representation of the features and User Interactions of the FAITH App.

The App is the main source of data gathering and has been designed to provide both active and passive tracking activities. The App has to be installed in the patient's phone and provided with the agreement to access data from the phone sensors. In particular, in order to be effective, FAITH App needs to have access to the accelerometer, GPS and position of the phone. Wi-Fi and Bluetooth have to be connected in order to ensure the connection with the Sleep Monitor Device and FAITH System and the efficacy of the NLP Module. In order to receive push notifications from the App, this mode has to be selected in the phone settings.

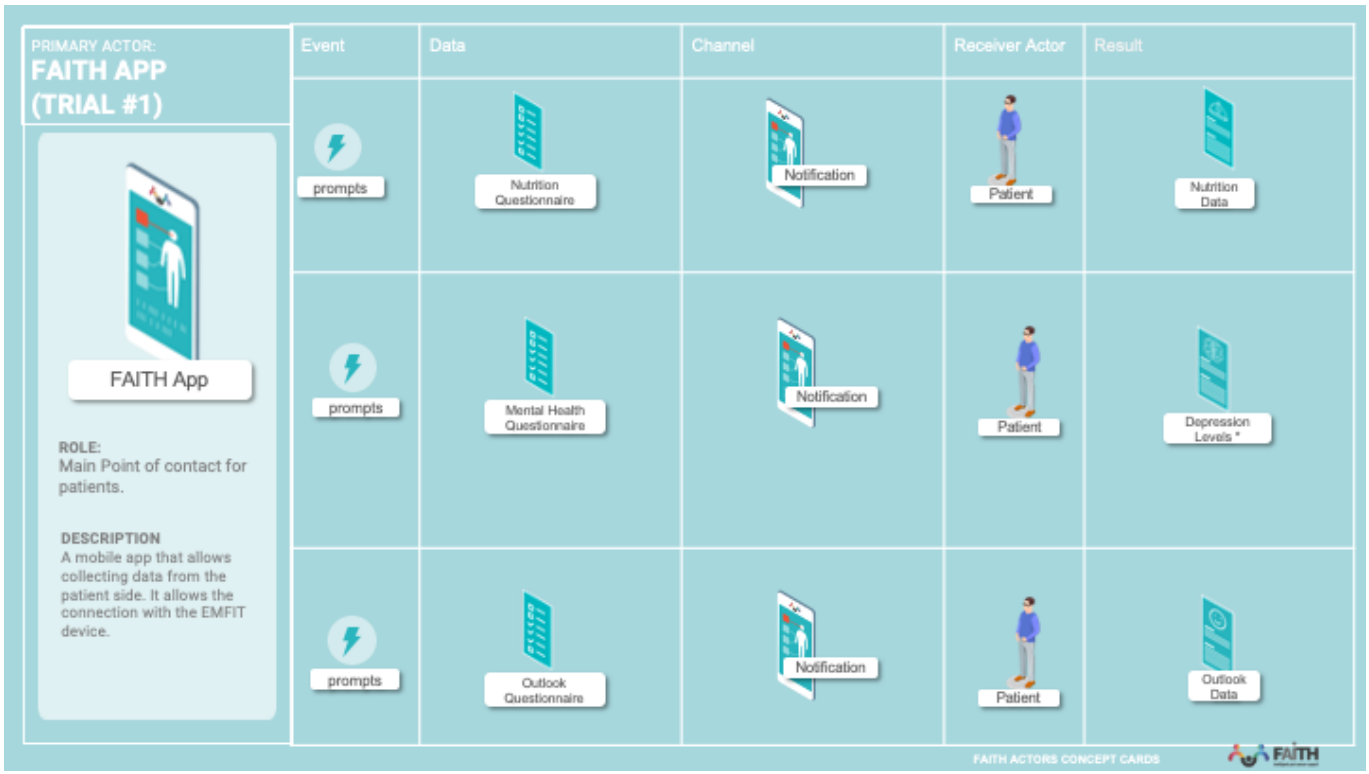

Figure 21 - FAITH App (Trial #1) Actor Card

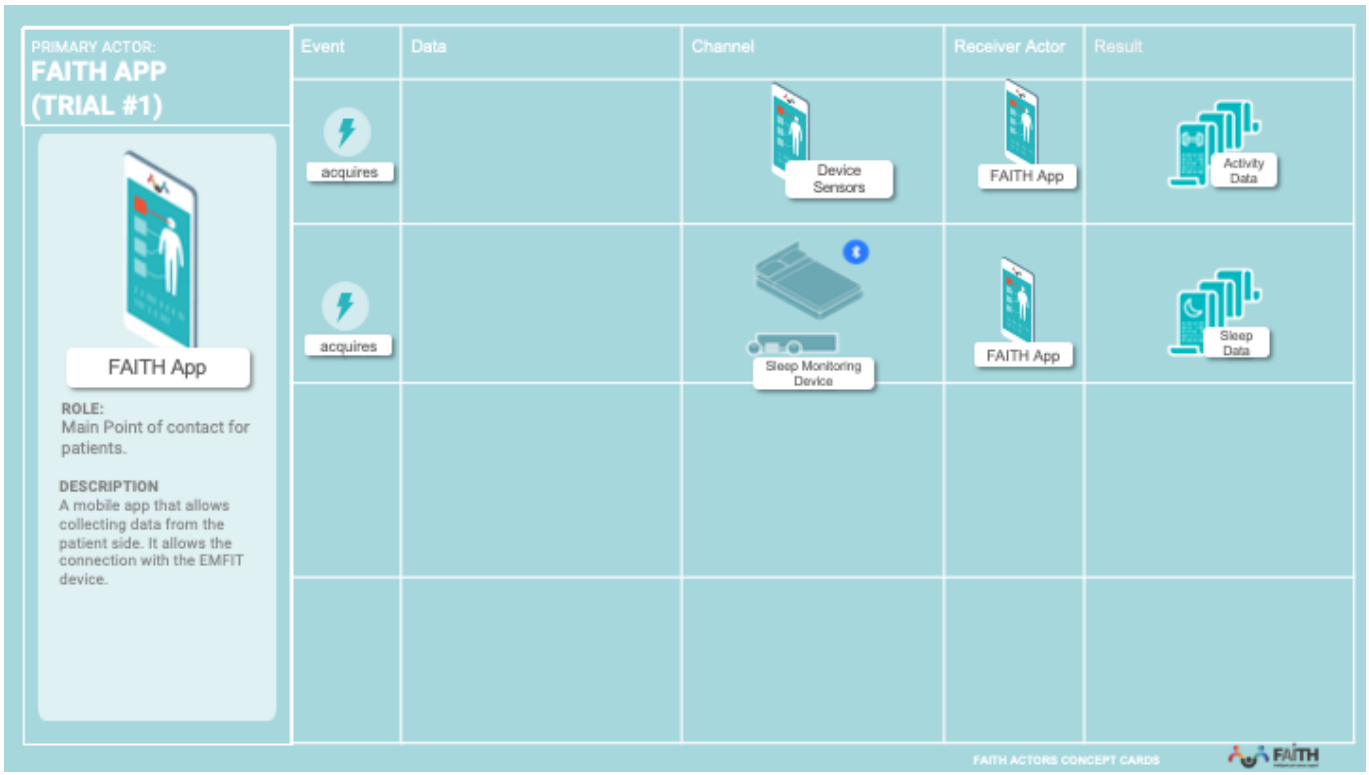

Figure 22 - FAITH App (Trial #1) Actor Card, Page 2

In Trial 1, the main user of the FAITH App is the patient who interacts with it on a daily basis for 12 months. The Actor cards shows four actions that are actively prompted by the App to request an interaction by the users (Figure 21) and two passive acquisition which runs in the background without requiring the user intervention (Figure 22).

Each flow is detailed below:

FLOW 1: PROMPTING NUTRITION QUESTIONNAIRE

When meal-time approaches, FAITH App prompts a push-up notification, asking the User questions regarding their appetite, nutrition and meals. Questions are different according to the moment of the day and can be here gathered under the general label *Nutrition Questionnaire*. The patient can provide data regarding their nutrition through several ways: typing, image uploads or vocal input. All these inputs are gathered by the App and falls under the description of *Nutrition Data.* (Figure 23)

Figure 23 - FAITH APP Actor Card, Prompting Nutrition Questionnaire Flow

FLOW 2: PROMPTING MENTAL HEALTH QUESTIONNAIRE

With frequency to be defined, FAITH App prompts push-up notifications to the user to start a conversation regarding their mental condition. Such interaction aims at the collection of fruitful data for the more general assessment of their mental health. Clinical tools are prompted by the App to help the User to self-evaluate their status and be conscious about it. The App prompts to the user the Hospital Anxiety and Depression Scale (HADS) allowing patients to self-rate levels of depression and anxiety.

Data collected are identified as Depression Levels. (Figure 24)

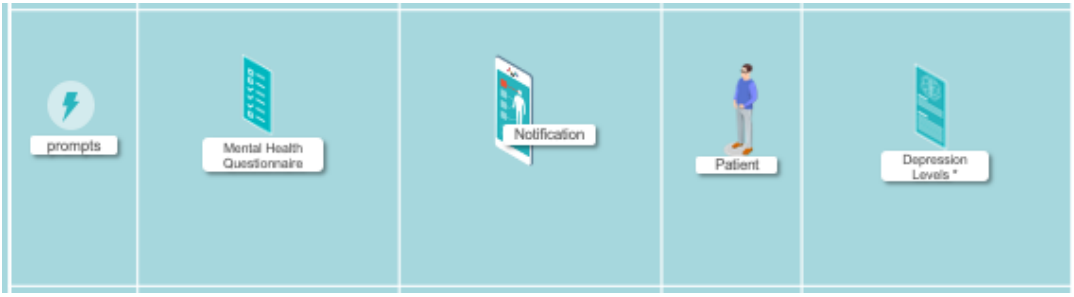

Figure 24 - FAITH APP Actor Card, Prompting Mental Health Questionnaire Flow

FLOW 3: PROMPTS OUTLOOK QUESTIONNAIRE

With frequency to be defined, FAITH App prompts push-up notifications to the user to start a conversation regarding their outlook. Such interaction aims at collecting fruitful data for the assessment of their mental condition. In order to do this, the App nudges an interaction with the users, trying to favour the sharing of their collection as text or vocal input. In case of vocal input, FAITH App activates the NLP Module to analyse it. Inputs collected falls under the description of *Outlook Data.*

Figure 25 - FAITH APP Actor Card, Prompting Outlook Questionnaire Flow

FLOW 4: ACQUIRING ACTIVITY DATA

FAITH App shares data with the phone in the background. After the access to the motion sensors and accelerometer are provided, the App collected this data in the background and integrate them with the ones actively collected from the interaction with the patient. Sensor data is acquired through the mobile OS frameworks.

Inputs collected falls under the description of *Activity Data.* (**Error! Reference source not found.**)

Figure 26 - FAITH APP Actor Card, Acquiring Activity Data from phone sensors Flow

FLOW 5: ACQUIRING SLEEP DATA

During the night the patient's sleep is monitored by the Sleep Monitoring Device. Several parameters are collected and sent to the App. The FAITH App stores this information and integrate it with the other monitored trends.

Figure 27 - FAITH APP Actor Card, Acquiring Sleep Data from phone sensors Flow

3.3 User Stories

User stories is an informal, natural language description of one or more features of a software system. This session is dedicated to the developing and reporting of respective sets of user stories initially inspired by the consortium healthcare trials partners and thereafter extended into the network of the consortium. The aim of the User Stories is to gather a point of view that takes all the relevant stakeholders into consideration. The User Stories outline the needs and intentions of end-users derived from the user research. Aims and goals have been identified in relation to the context of use and personal needs and formulated in a synthetic statement. Such outcomes have been distilled into user stories in order that will drive the further tasks required to deliver the project. The User Stories contain both functional and non-functional requirements. They will be used to build the user scenarios / use-cases and further define the user requirements. Their content is fundamental to the development of FAITH, since it shows data inputs and structures needed as well as the expected outputs for every possible process and interaction among the users and stakeholders.

User Stories are stated according to the following structure:

As a	<actor>
I want to	<task>
So that I can	<achieve goal>

All the User Stories are gathered by the User and collected in a table, highlighted as follows.

Number	As a …	I want to …	So that …
#1	Patient	Adopt FAITH AI Angel	I can have my mental health monitored
#2	Patient	Have my activity data captured	it can be analysed against historical activity data
#3	Patient	Have my appetite data captured	it can be analysed against historical appetite data
#4	Patient	Use conversation to have my mental outlook captured	it can be analysed against historical mental outlook data
#5	Patient	Upload pictures of my meals	it can be analysed against historical appetite data
#6	Patient	Wear Sleep Monitoring Device at night	Have my sleep data captured
#7	Patient	Have my sleep data captured	it can be analysed against historical sleep data

#8	Patient	Fill in mental health surveys with the doctor	Mental health can be monitored over time
#9	Patient	Contact System Administrator	I can have technical issues fixed
#10	Doctor	Assign a patient for monitoring	I can gather relevant information about them
#11	Doctor	Carry out mental health telephone surveys	I can capture mental outlook using traditional methods
#12	Doctor	Compare captured insights versus traditionally captured insights	I can validate the FAITH AI algorithms for depression detection
#13	Data Analyst	Analyse patient data	I can give informed decision on depression markers
#14	System Administrator	Assist a patient to set up the FAITH AI-Angel app	their data can be captured for analysis
#15	System Administrator	Support the patient requesting assistance	Fix any possible issue

3.4 Use Cases by Actor

In Trial 1, FAITH starts gathering information about the patients concerning specific domains: Nutrition, Outlook, Activity and Sleep. At this stage supplementary information about the Mental Health of the person are directly collected by the Doctor through the submission of certified Mental Health Questionnaires.

The section 3.4: Use Cases by Actor introduces the specific use cases of each actor happening during Trail 1. A use case is a description of how a person, or a subject interacts with other elements of the system to accomplish a goal. Each use case is identified with a number, a name, a short description including the primary actor and possible secondary ones; and provides preconditions, a basic flow, an alternate interaction flow and post-conditions.

All the procedures described in the Use Cases are covered by the FAITH Protocol.

3.4.1 Patient

During Trial 1, Patient shares data about their personal condition in regards of Nutrition, Physical Activity, Outlook and Mental Health. Since the main goal of Trial 1 is data collection, most of the use cases regarding the patient are aimed at the production of valuable data. Information regarding the patient's wellbeing, including both physical and mental condition, will be used by the Data Scientist to build Local AI models.

The main channel of information gathering are FAITH App, Sleep Monitoring Device and phone calls with the Doctor. Patient's use cases are listed below:

Use cases:

-Complete Mental Health Questionnaire

-Record Outlook entries

-Record Nutrition entries

-Post picture of meals on FAITH App

-Use of Sleep Monitoring Device

-Interaction with vocal interface

-Request of technical support.

Use Case Number	Patient-01
Use Case Name	Complete Mental Health Questionnaire
Actors	Patient (Primary) Doctor
Use case Description	Start when the doctor calls the patient to check on their mental health. Ends when the questionnaire and the call are over.
Preconditions	Doctor and Patient are part of the Trial 1.
Trigger	Scheduled Appointment.
Basic Flow	1. The Patient receives a call from the Doctor 2. The Patient is asked about different aspect of their mental outlook 3. The Patient replies to the questions 4. Answers are recorded in the questionnaire 5. The call is ended.
Alternate flows	3a. Patient doesn't fill like replying to some questions. 3b. Patient lies in replying to the questionnaire.
Post-conditions	Data about patient's mental health are collected.

Use Case Number	Patient-02
Use Case Name	Record Outlook entries
Actors	Patient (Primary) FAITH App
Additional Info:	None
Use case Description	Starts when the patient receives the input to insert information regard their outlook. Ends when the updated info is saved. The patient gets a notification on his smartphone that asking about their outlook. They open the app and provide information about their condition. They save the changes and upload them.
Preconditions	Patient is logged into FAITH App. Smartphone is connected to the internet. Patient has the appropriate time and space to complete the questionnaire. Patient feels like talking about his mental condition.
Trigger	The patient receives a reminder
Basic Flow	1. Gets reminder 2. Taps on reminder 3. Answers the questions 4. Saves changes
Alternate flows	1a. Patient deletes reminder and saves it for later 3a. Patient does not reply to the question. 4a. Smartphone is not connected to internet and the changes cannot be saved. 4b. Patient does not save the changes.
Alternate Interaction in the flow	I3a. Patient answers to the question through voice (NLP).
Post-conditions	Patient's outlook is recorded on the App. Patient's mental health trend is updated with new information.

Use Case Number	Patient-03
Use Case Name	Record Nutrition Entries
Actors	Patient (Primary) FAITH App
Use case	Starts when Patient opens the App and add entries to the nutrition area. Ends when the entries are saved and the Patient closes the page.
Description	The Patients records their nutrition entries on the FAITH App.
Preconditions	Patient is logged into the FAITH App.
Trigger	Reminder to fill nutrition tab sent by the App.
Basic Flow	1. Patients gets a reminder to fill nutrition tab 2. Patients opens the App and get into the Nutrition area 3. Records entries about the meal 4. Save entries about the meal 5. Close the area or the App.
Alternate flows	3a. Patient does not understand how to record entries. 3b. Patient attaches a picture of the meal (Use Case 3). 4a. Patient leaves the page without saving. 4b. Patient leaves the page without having completed the questionnaire.
Alternate Interaction in the flow	I3a. Patient fills in the nutrition entries by using their voice (NLP).
Post-conditions	Nutrition entries are recorded in the App Trends on Patient's health are updated.

Use Case Number	Patient-04
Use Case Name	Post picture of meals on the FAITH App
Actors	Patient (Primary) FAITH App
Use case Description	Start when the patient taps the button “attach a picture” Ends when the picture is sent. While recording the nutrition entries the Patients choose the option “Attach a picture of your meal”. They can take a picture or upload it from the gallery and save it in the nutrition tab.
Preconditions	Smartphone can take photos Smartphone is connected to the internet FAITH App has access to the galley and camera. Patients is able to send a picture.
Trigger	Notification “Would you like to attach a pic of your meal?”. The button “Attach a picture of your meal”.
Basic Flow	1.Patient Taps the “Attach a picture of your meal” button 2. Patient takes a pictures of their meal 3.Patient Uploads the photo.
Alternate flows	1a. Patient skip the attach a picture of the meal feature 2a. Picture is selected from the gallery 2b. FAITH App access to the gallery is denied 2c. FAITH App access to the camera is denied. 3a. Patient does not figure out how to attach the picture. 3b. Error in the connection cannot upload the photo. 3c. Photo format is invalid.
Post-conditions	Patient’s picture of the meal is recorded on nutrition tab. Patient’s trend is updated with new nutrition information.

Use Case Number	Patient-05
Use Case Name	Use of Sleep Monitoring Device
Actors	Patient (Primary) Sleep Monitoring Device
Use case Description	Starts when the patient goes to sleep wearing the Sleep Monitoring Device connected to the smartphone Ends when the patient gets up in the morning.
Preconditions	Sleep Monitoring Device is connected to the FAITH App. The Patient is wearing the Sleep Monitoring Device. Smartphone is connected to the internet.
Trigger	Sleep Activity
Basic Flow	1. Wears the Sleep Monitoring Device 2. Go to bed to sleep 3. Sleep Monitoring Device tracks the sleep of the patient 4. Sleep Monitoring Device sends sleep data to FAITH App 5. Patient gets up from bed 6. Sleep Monitoring Device pauses.
Alternative Flow	1a.
Post-conditions	Patient's Sleep trend is updated with new information. Patient can monitor their sleep quality and night time activity.

Use Case Number	Patient-06
Use Case Name	Interaction with Vocal Interface
Actors	Patient (Primary) FAITH App
Use case Description	Starts when the patient interacts vocally with the App Ends when the patient stops interacting vocally with the App.
Preconditions	The patient's phone can record audio.
Trigger	Patient wants to share information with FAITH App.
Basic Flow	1.Patient opens FAITH App

	2. Patient access the needed section 3. Patient interacts vocally with the App 4. NLP module activates and analyse the file.
Alternative Flow	2a. Patient records nutrition entry 2b. Patient records mental outlook 2c. Patient records new physical activity
Post-conditions	Information regarding patient's outlook are collected.

Use Case Number	Patient-07
Use Case Name	Request of Technical Support
Actors	Patient System Administrator
Use case Description	Start when the patient encounters a technical problem. Ends when the System Administrator solves the problem.
Preconditions	Patient knows how to contact the System Administrator Patient know how to recognize a technical problem.
Trigger	Technical issue
Basic Flow	• The Patient runs into a technical problem while using FAITH • The Patient contacts the System Administrator explaining the kind of issue. • The System Administrator identifies the nature of the problem • The System Administrator fixes the technical problem.
Alternate flows	1a. Patient does not identify the problem 2a. Patient has problem in reaching out the System Administrator 3a. System Administrator cannot recognize the problem 4a.System Administrator cannot fix the problem.

Post-conditions	Technical issue is solved.

3.4.2 Doctor

In Trial 1 the main role of the Doctor is to support data collection regarding mental health and to conduct regular meeting with the patient. During such occasion, the doctor will submit a certified medical questionnaire on mental health to the patient. The doctor also provides interpretation of the data collected both regarding the mental health and the other parameters (Nutrition. Sleep. Activity, Outlook) to identify the most representative values. This information will be made available to the Data Scientist who will select the most representative patterns to build the AI model. Doctor's use cases are listed below:

Use Cases:

- Conduct clinical assessment and depression questionnaire
- Help Data Analyst selecting the valuable data

Use Case Number	Doctor- 01
Use Case Name	Conduct clinical assessment and depression questionnaire
Actors	Doctor Patient
Use case Description	Starts when the doctor asks the questions from the mental health questionnaire to the patient when Ends when the doctor has collected all the answers.
Preconditions	Patient and Doctor have phone call meeting.
Trigger	Scheduled Appointment
Basic Flow	1.Doctor calls the patient 2. Ask questions part of the mental health and depression questionnaire 3. Records the answers 4. Produce clinical assessment and depression levels information according to used questionnaire.
Alternative Flow	N.A.
Post-conditions	Depression levels are collected. Clinical assessment is produced.

Use Case Number	Doctor -02
Use Case Name	Help Data Scientist selecting the valuable data
Actors	Doctor Data Scientist
Use case Description	Starts when the doctor analyses the data collected Ends when the doctor has identified most representative data.
Preconditions	Data regarding Nutrition. Activity, Sleep, Outlook, and Mental Health have been collected-
Trigger	New Data available
Basic Flow	1. Doctor interprets collected data about Nutrition, Activity, Sleep, Outlook, and Mental Health 2. Doctor looks for meaningful data 3. Doctor looks for representative patterns between meaningful data 4. Doctor indicates the appropriate values to the Data Scientist
Alternative Flow	1a. Data collected are not enough 2a. Quality of data collected is too low. 2b. Doctor cannot find meaningful correlations. 3a. Data does not allow to build representative patterns 4a. Doctor cannot indicate significant data to the Data Scientist
Post-conditions	Valuable data to build AI model are available

3.4.3 Data Scientist

In Trial 1, Data Scientist is responsible for selecting, supported by the doctor, the most valuable data to build the AI models. Data Scientist analyses all the data collected in order to select appropriate patterns.

Data Scientist's use cases are listed below:

- Analyse the Data Collected by FAITH App.
- Collect Depression levels and Clinical Assessment from Doctors' Interviews to build Local AI
- Build AI model on representative data.

Use Case Number	Data Scientist- 01
Use Case Name	Analyse the Data Collected by FAITH App
Actors	Data Scientist Doctor
Use case Description	Starts when the Data Scientist analyses the data collected Ends when the Data Scientist has identified most representative data
Preconditions	Data regarding Nutrition. Activity, Sleep, Outlook, and Mental Health was collected Data was verified by the Doctor.
Trigger	New Data available
Basic Flow	1. Data Scientist receives collected data regarding Nutrition, Activity, Sleep, Outlook, and Mental Health 2. Data Scientist receives feedback from the Doctor on their validity 3. Data Scientist select most appropriate data patterns to build the AI model.
Alternative Flow	1a. Data Scientist does not receive valid data 3a. Data Scientist cannot identify appropriate patterns
Post-conditions	Representative data patterns are identified.

Use Case Number	Data Scientist- 02
Use Case Name	Collect Depression levels and Clinical Assessment from Doctors' Interviews to build Local AI
Actors	Data Scientist

Use case Description	Starts when the Data Scientist receives Clinical assessment and Depression Levels by the Doctor. Ends when the Data Scientist uses Clinical assessment and Depression Levels to build Local AI.
Preconditions	Doctor produced Clinical Assessment and Depression Levels regarding the patient.
Trigger	New Interview was conducted
Basic Flow	1. Data Scientist receives Clinical assessment and Depression Levels by the doctor 2. Data Scientist analyses the data collected in relation to the other data available 3. Data Scientist selects valid data regarding Clinical Assessment and Depression Levels. 4. Data Scientist uses the valid data selected to build the Local AI.
Alternative Flow	1a. Data Scientist does not receive appropriate data
Post-conditions	Clinical Assessment and Depression Levels are used to build the Local AI.

Use Case Number	Data Scientist- 03
Use Case Name	Building AI model on representative data.
Actors	Data Scientist
Use case Description	Starts when the Data Scientist use the data collected to build the AI model. Ends when the local AI model is built.
Preconditions	Valid data regarding Nutrition. Activity, Sleep, Outlook, and Mental Health was previously selected. Data was verified by the Doctor.
Trigger	New Data available.

Basic Flow	1. Data Scientist selects the most representative data regarding Nutrition, Activity, Sleep, Outlook, and Mental Health. 2. Data Scientist builds the AI model on selected data.
Alternative Flow	1a. Data Scientist does not receive appropriate data.
Post-conditions	AI model is built.

3.4.4 FAITH App

During Trial 1, FAITH App main role is the collection of data regarding the patients' physical and mental wellbeing. The App has to be downloaded on the patient's phone and obtain access to the phone's sensors. This way, the patient's phone is turned into a sensor suit that allows to collect data through smooth interactions, both by using vocal and text interaction.

To collect data regarding the rest of the patient, FAITH App is paired with the Sleep Monitoring Device through Bluetooth.

The run FAITH App Bluetooth and Internet connection are required. For an optimal data collection, FAITH App has to be provided with access to GPS, accelerometer, push notifications, camera and microphone, in the phone's settings.

In Trial 1, FAITH App use cases regard the prompt of tools of data collection or the acquisition of data from other part of the ecosystem. Uses cases are listed below.

Use Cases:

-Prompting Nutrition Questionnaire

-Prompting Mental Health Questionnaire

-Prompting Outlook Questionnaire

-Acquiring Activity Data

-Acquiring Sleep Data

-Acquiring Vocal Data

Use Case Number	FAITH-APP - 01
Use Case Name	Prompting Nutrition Questionnaire
Actors	FAITH APP
Use case Description	Starts when the FAITH App prompts a notification inviting the User to add information about their nutrition Ends when Nutrition Data are produced.
Preconditions	N.A.
Trigger	Meal time
Basic Flow	1. FAITH App sends a notification on the Patient's phone 2. FAITH App asks the Patient about their appetite and their meal (Nutrition Questionnaire) 3. FAITH App invites the Patient to add more information about their meal 4. FAITH App collects Nutrition Data
Alternative Flow	3a. FAITH App invites the user to upload a picture of their meal.
Post-conditions	Nutrition Data are collected.

Use Case Number	FAITH-APP - 02
Use Case Name	Prompting Mental Health Questionnaire
Actors	FAITH APP
Use case Description	Starts when the FAITH App prompts a notification inviting the user to fill in Mental health Questionnaire Ends when Depression Levels are assessed.
Preconditions	N.A.
Trigger	N.A.
Basic Flow	1. FAITH App sends a notification to the user 2. FAITH App asks the Patient to fill in Mental Health Questionnaire 3. FAITH App collects compiled Mental Health Questionnaire 4. Depression Levels are assessed.
Alternative Flow	3a. Mental Health Questionnaire is not filled in.
Post-conditions	Depression Levels are assessed.

Use Case Number	FAITH-APP – 03
Use Case Name	Prompting Outlook Questionnaire
Actors	FAITH APP
Use case Description	Starts when the FAITH App prompts a notification inviting the user to add information about their outlook Ends when Outlook Data are collected.
Preconditions	N.A.
Trigger	N.A.
Basic Flow	1. FAITH App sends a notification to the user 2. FAITH App asks the Patient about their outlook 3. FAITH App invites the Patient to fill in Outlook Questionnaire 4. FAITH App collects filled in Outlook Questionnaire 5. Outlook Data are collected
Alternative Flow	3a. Outlook Questionnaire is not filled in

Post-conditions	Outlook Data are collected.

Use Case Number	FAITH-APP – 04
Use Case Name	Acquiring Activity Data
Actors	FAITH APP
Use case Description	Starts when FAITH App access the GPS and accelerometer to get activity data. Ends when Activity data are collected.
Preconditions	Access to GPS and accelerometer is provided.
Trigger	Motion of the phone in the space
Basic Flow	1. FAITH App access device sensors data through the SDK of the operating system. 2 . FAITH App locally stores the data keeping track of the time.
Alternative Flow	
Post-conditions	Activity data are collected.

Use Case Number	FAITH-APP - 05
Use Case Name	Acquiring Sleep Data
Actors	FAITH APP Sleep Monitoring Device
Use case Description	Starts when FAITH App is connected to Sleep Monitoring Device. Ends when Sleep Data are collected.
Preconditions	Sleep Monitoring Device is connected to FAITH App through Bluetooth
Trigger	New Sleep Activity
Basic Flow	1. FAITH App connects to external monitoring device through Bluetooth connection

	2. FAITH App acquires the last recorded data regarding sleep quality 3. FAITH App locally stores the data keeping track of the time.
Alternative Flow	
Post-conditions	Sleep Data are collected.

Use Case Number	FAITH-APP - 06
Use Case Name	Acquiring Vocal Data
Actors	FAITH APP Patient NLP Module
Use case Description	Starts when the Patient provide vocal input. Ends when Vocal Data is collected
Preconditions	Access to the microphone is provided to FAITH App Patient records vocal input
Trigger	New vocal input
Basic Flow	1.FAITH App receives a new vocal input 2.FAITH App activates the NLP module 3. NLP Module analyses the raw vocal input 4. NLP Module translate raw vocal input in Voice Data 5. FAITH App saves Voice Data.
Alternative Flow	
Post-conditions	Vocal Data are collected.

3.4.5 Sleeping Monitoring Device

Sleep Monitoring Device is one of the technological components of the FAITH ecosystem. Its main role is to monitor biological condition of the person during the night to assess the quality of their rest. A good and healthy rest is of fundamental importance for the health and wellbeing of person. For this reason, FAITH aimed at collecting information regarding the patient's rest in order to provide a detailed wealth portrait of the person.

Data collected by the Sleep Monitor Device provide a strong contribution if cross-referred to other parameters of health collected by the App during the day.

The Sleep Monitoring Device has to be worn by the patient during the night-time and paired with the FAITH App. The data collection is automated and directly send to the App without direct intervention from the user.

Use cases are listed below:

Use Cases:

-Monitoring Patient's Sleep

-Sending Sleep Data to FAITH App

Use Case Number	Sleep Monitoring Device -01
Use Case Name	Monitoring Patient's Sleep
Actors	Sleep Monitoring Device FAITH APP
Use case Description	Starts when the Sleep Monitoring Device is worn by the patient during night-time. Ends when Sleep Data is updated
Preconditions	Patient is wearing Sleep Monitoring Device Sleep Monitoring Device is connected through Bluetooth to the FAITH App
Trigger	Night-time Nap
Basic Flow	1. Patient is wearing the Sleep Monitoring Device and goes to bed. 2. Sleep Monitoring Device tracks sleep activity. 3. Data is sent to the FAITH App 4. Sleep model is updated.
Alternative Flow	1a. Patient forgets to wear the device. 3a. The device.

Post-conditions	Sleep Data is collected

Use Case Number	Sleep Monitoring Device -02
Use Case Name	Sending Sleep Data to FAITH App.
Actors	Sleep Monitoring Device FAITH App
Use case Description	Starts when Data regarding rest are collected by the Device Ends when Sleep Data are received by FAITH App
Preconditions	Data regarding rest are collected by the Sleep Monitoring Device.
Trigger	N.A.
Basic Flow	1. Sleep Monitoring Device has new data regarding rest 2.Sleep Monitoring Device connect with FAITH App 3. Sleep Monitoring Device send data to the FAITH App 4.Sleep data are collected
Alternative Flow	N.A.
Post-conditions	Sleep Data are collected

3.5 Trial 1 Narrative Scenario

Narrative User Scenario are a research tool used to show how users might act to achieve a goal in a system or environment. Their main function is to allow stakeholders to understand the User's need and their context of use to improve the ideation and design of the system. In order to help identifying the feature of FAITH AI Angel, section 3.5 provides a Narrative Scenario describing the journey of 'Irene' - a fictional breast cancer survivor taking part in the Trial 1 of FAITH.

An Envisioning Scenario of Trial 2 is available in section 4.2

Preamble

'Irene' a 56-year-old lady found a breast lump and following an examination her GP referred her to the breast assessment clinic, Waterford. After diagnosis of a malignant tumour was confirmed and Irene underwent a series of treatments. The process lasted 15 months with Irene having 6 monthly check-ups with her GP following treatment. This journey had been both physically and mentally challenging for Irene, and even though Irene could be considered a 'survivor', research to date would indicate the next stage of Irene's journey is potentially challenging, on not just a physical but an emotional and social level.

Irene's Oncologist had heard about the **FAITH 'AI Angel'** through a colleague and was of the belief that the use of this new app, to monitor depression markers, would help towards maintaining holistic health. Through the use of this App downloaded to Irene's phone, and the support of one additional external sleep monitoring device, the Doctor explained to her that they would be in a position to monitor 4 depression markers (i.e., Activity, Sleep, Appetite and Outlook) and thus, be forewarned in the hospital of any downward trajectories in these depression markers, which would ultimately have an effect on her quality of life. Irene was shown the App and the sleep device, and she was shown how they work, how often she would need to engage as well as what to expect with regards to contact from the hospital. All of this made her comfortable that there would be minimum disturbance to her life, and that the promise of finally overcoming the aftereffects of her cancer ordeal would be worth this undertaking.

And so, Irene agreed to sign up for the **FAITH trial** and started the whole process of becoming a FAITH 'AI Angel' user. She was sent home with contact details of the UPMC-FAITH representative and informed that her sleep tracking device would be arriving in the post.

Setup

At a time that suited Irene, she made contact with the UPMC-FAITH representative, who walked her through the downloading of the App to her phone as well as installing the sleep monitoring device in a non-obtrusive place where it would not be noticed.

The FAITH Administrator then walked Irene through the setting up of her profile in the App, explained how it would work, as well as agreeing a regular slot for one of the UPMC clinicians to call and carry out a mental health/wellbeing survey questionnaire.

Usage Trial 1

Now that Irene had downloaded the FAITH App onto her smartphone, the app used the in-built motion sensors on her phone to monitor her movement activities and analyse these using the FAITH AI algorithms.

The sleep monitoring device also regularly synched its data to the app during the night, so that Irene's sleep data was also included as part of the analysis.

During mealtimes, Irene would take photographs of her food and complete a short in-app survey about her meal and this data is then analysed within the FAITH app.

On top of these inputs, the app would also engage with Irene through its voice interface, asking a short series of questions and recording the answers. These recorded answers were analysed for the content of the response as well as the pitch and speed of the voice, against predetermined markers, in order to gauge the level of mental wellbeing for Irene.

During Trial 1 Irene had also agreed to receive regular phone calls from a clinician whereby a normal phone interview will be carried out to survey, using Mental Health Questionnaire to get an indication of Irene's mental wellbeing. The results of these calls are cross-referenced by a Data Analyst with the FAITH app results to adjust the apps parameters to bring it closer in line with the live surveys.

All of the above inputs (Activity, Sleep, Appetite & Outlook) are fed into the FAITH apps machine learning algorithms to gather an overview on the current levels and compare these against historical values. The data collected through Mental Health Questionnaire are analysed by a Data Analyst supported by the expertise of the doctor and contribute as well to the creation of the AI model. During the entire pilot, in the background and unknown to Irene, the App is constantly improving on its models and analysis.

Conclusion

At the end of Trial 1, the data scientist gathered all the necessary data to build the Local AI Modules. Federated Artificial Intelligence is a fundamental part of FAITH since it allows to analyse the patient's data respecting their data protection. The second Trial will serve as a validation process of the AI model. Most of the interaction will remain unchanged but a great difference will regard the functioning of the FAITH App with the local AI module and data processing.

Envisioning Narrative Scenario of Trial 2, is provided in section 4.2

4 TRIAL 2 USER REQUIREMENTS

As stated in section 2, the study is framed in terms of Trial 1 and Trial 2, because each stage has different objectives. The aim of Trial 1 is gathering data regarding the variables defined in the study protocol through the first version of the FAITH App and with the support of the clinician-rated interviews. It is designed as a 12-month longitudinal observational and prospective study, during which users adopt the preliminary version of the App. Data collected through the App is validated by a data scientist and the clinicians.

Trial 2 will take place after the completion of Trial 1. The main purpose of Trial 2 is the validation of the local AI modules for depression forecasting. Trial 2 will run across the same locations but this time rather than just collecting data, the local AI models developed as a result of Trial 1 will be deployed on the patient devices. Our ambition is then that these models will predict changes in depression and QoL that will then be validated by the regular clinician-rated interviews.

Many aspects of Trial 2 will derive from the findings of Trial 1. As a consequence, planning of Trial 2 can only be approximate. For this reason, section 4 provides an exploration of the requirements of Trial 2 that will need to be confirmed in a second moment. None of these provisions should be considered binding for the development of further requirements. Several features, as well most roles of actors involved will remain unchanged between the two Trials.

The patients will still use the FAITH App and the Sleep Monitoring Device on a daily basis. They will actively share data about their health as in the first Trial and will held regular meeting with their doctor.

The doctor will keep on meeting the patient to assess their clinical condition and will contribute to the validation of the data collected in the process.

The main changes will concern the functioning of FAITH App and the data scientist's validation activity.

As described in section 3.2.3, part of the data scientist's role in Trial 1 regards the selection of the most appropriate data to build Local AI models. With a huge amount of data collected, it should be possible for the AI modules to recognize values that may be related to depression or negative mental conditions. Thanks to their implementation, FAITH App will automatically forecast changes in the patient's mental health. As a consequence, the data scientist will not validate raw data anymore but will monitor the outcome of the Local modules together with the support of a doctor.

This section introduces **FAITH App (Trial #2) Actor Card** to depict the forecasted role of FAITH App in Trial 2 and envision the new interactions with a narrative scenario. Since many features relies on the quality of data collected through Trial 1, this can only be considered an envisioning plan of the User Requirements for Trial 2. A more detailed deliverable will be produced for Trial 2 in a second moment.

4.1 FAITH APP (Trial #2) Actor Card

The main upgrade of FAITH technology in Trial 2 is regards to the functioning of FAITH App. During the first Trial, the FAITH App works both passively and actively to collect information regarding the status of the patient. The App accesses the phone's sensor and the Sleep Monitoring Device to collect data in the background and entertains active interactions with the user to investigate their status. These procedures allow the collection of a significant amount of data regarding the patient's Nutrition, Sleep, Activity, Outlook and Depression levels.

This database should make it possible to create 5 main Local AI modules: *Nutrition Modules, Sleep Module, Activity Module, Outlook Module* and a general *Mental Health Module* based on the cross-analysis of all the previous ones. Each module is of fundamental importance for the creation of a specific profile for each category of data that will result in the creation of a *Nutrition Profile, Sleep Quality Profile, Activity Profile and Outlook Profile.* The definition of the Local Modules relies on the quality of

data collected through Trial 1. For this reason, it is currently possible to provide only a prevision that may change with further development.

The most important contribution of FAITH App at this stage is the processing of all the different profiles through the local AI in order to create the all-embracing *Mental Health Profile*, and the update of the Local AI and the FAITH Central, where all the data are aggregated.

The cross-analysis of the patient's trend should make it possible to constantly monitor their general mental health condition and identify eventual emerging depression. If it is the case that a downward trajectory is noticed in Irene's depression levels, the App will identify the anomaly and create an alert. As described in the Concept Map (Section 1.5), on a higher maturity level, FAITH AI Angel could be provided with a messaging system to send alert to the reference doctor in order to inform them regarding the change in the trends. This feature will be verified during the Trial

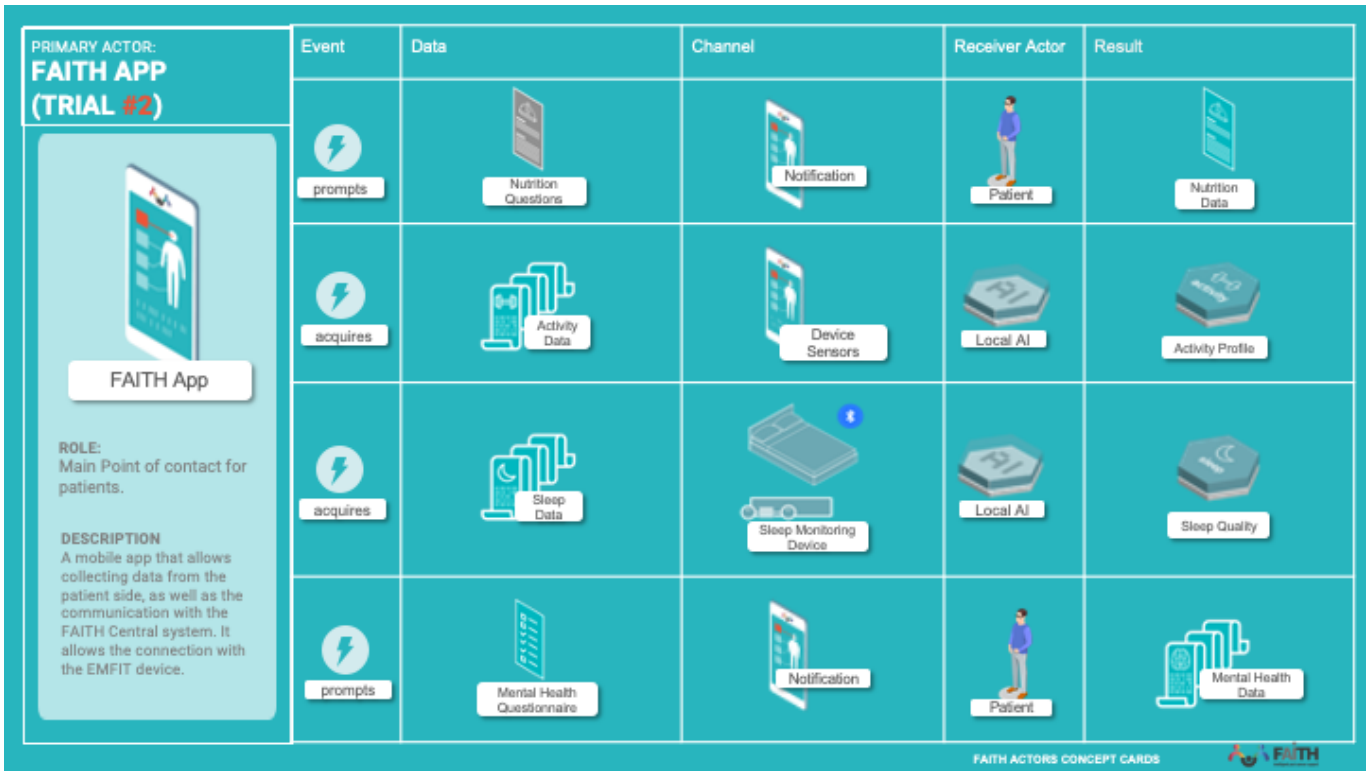

Figure 28 - FAITH APP (Trail#2) Actor Card, Page 1

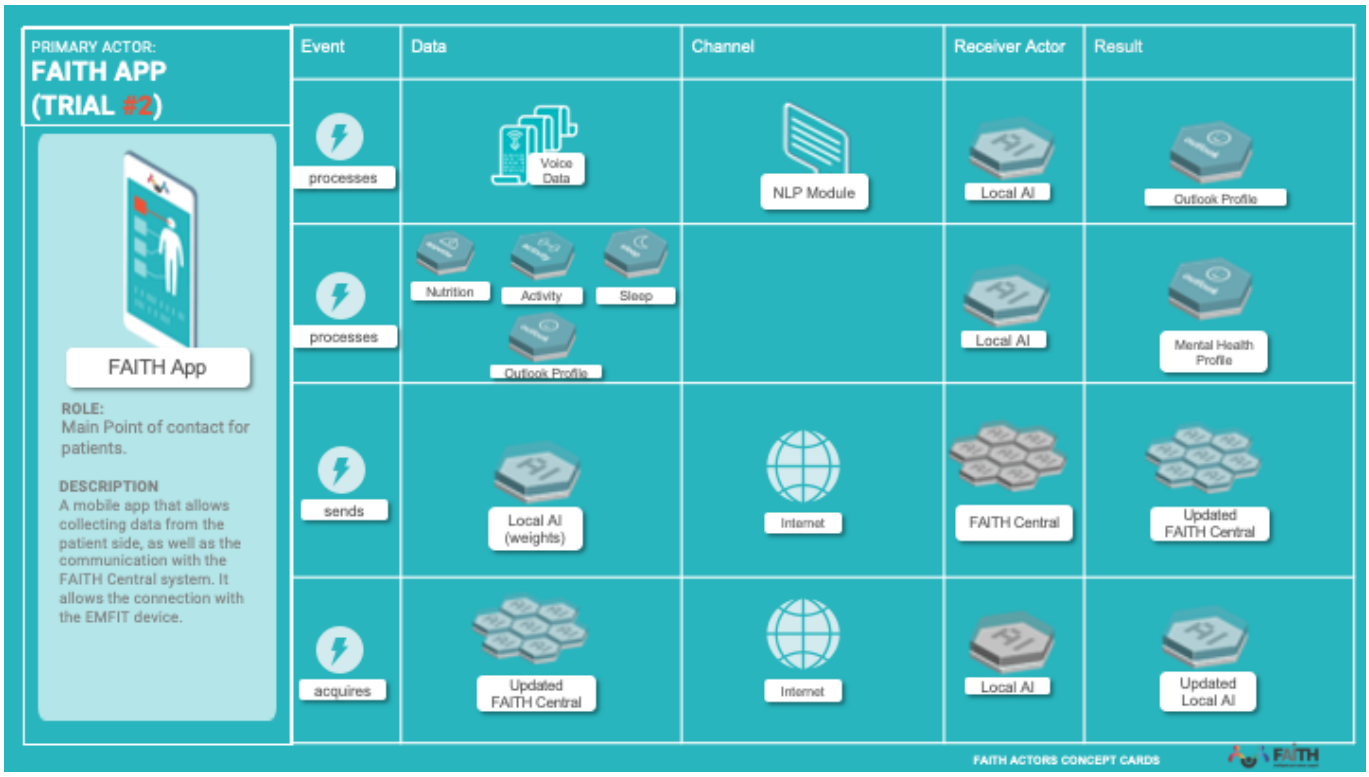

Figure 29 - FAITH APP (Trail#2) Actor Card, Page 2

Since the second Trial aims at the validation of the solution, it is important to note that the results of each module will be then validated by the Doctors and Clinicians in order to guarantee the efficacy of the model.

Concerning the user experience, the second version of FAITH App does not provide any significance difference from the previous version. The App does still prompt interactive requests to the patients in order to obtain valuable information regarding their conditions. Most of the feature remained unchanged between Trial 1 and 2. The main difference concern the automation of the App based on the Local AI and its competence in creating a Mental Health Profile of the patient based on the data gathered and keep updated the FAITH central module.

In the next lines, each feature of the FAITH App is described as an interactive flow between the App and a receiver actor, aimed at the conversion of a data in a result through a specific channel.

FLOW 1 & 2: PROMPTING NUTRITION QUESTIONNAIRE AND MENTAL HEALTH QUESTIONNAIRE

During the day the App provides the same calls to actions as in Trial 1, asking the patient to fill in the Nutrition Questionnaire and the Mental Health Questionnaire (Figure 30). The values recorded by the patient results in the creation of Nutrition Data and Mental Health Data.

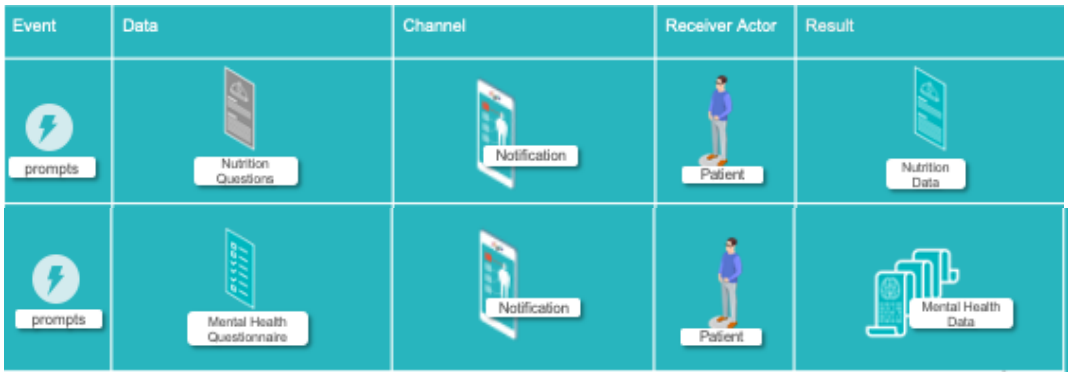

Figure 30 - FAITH APP (Trail#2) Actor Card, Prompt Nutrition and Mental Health Questionnaire Flow

FLOW 3 & 4: ACQUIRING ACTIVITY AND SLEEP DATA

In the same way as before, the FAITH App does also acquire information regarding the activity of the patient during the day (Physical Activity) and during the night (Sleep activity) (Figure 31). The acquisition is still mediated by the phone's sensors and the Sleep Monitoring Device. However, in this case such data are directly collected by the Local AI, which will contribute to the creation of the respective profile. Data regarding the activity will contribute to the update of the Activity Profile, while data regarding the night-time activity will be addressed to the Sleep Quality Profile.

Figure 31 - FAITH APP (Trail#2) Actor Card, Acquires Activity and Sleep Data Flow

FLOW 5: PROCESSING VOICE DATA

Another feature of the FAITH App, both present in the first and second trial, is the processing of the voice module through NLP. (Figure 32). Differently from the first Trial, at this stage the information is acquired in an automatic way (by voice interaction with the user in specific functions of the app) and received by the Local AI module that contributes updating the Outlook Profile.

Figure 32 - FAITH APP (Trail#2) Actor Card, Processes Voice Data Flow

FLOW 6: PROCESSING PATIENT'S PROFILES TO CREATE MENTAL HEALTH PROFILE

The processing of the patient's Nutrition, Outlook, Activity, Sleep Profile is the most important feature of FAITH App upgrade in Trail 2. With the data gathered in the first round, FAITH should be able to create more Local AI models to process each class of data collected. The number of Local AI module and their specific domain of analysis will strictly depend on the quality of the data gathered during the Trial 1. For this reason, it is only possible to provide a prevision of the flow.

In the optimal functioning, the Local AI modules should process all the profiles created on the data collected in order to generate the overall Mental Health Profile. Information collected in this profile will be then used to update the FAITH Central System and acquires new data from it. This interaction between the Local module and the FAITH Central is described in Flow 7 and 8 (Figure 33).

Figure 33 - FAITH APP (Trail#2) Actor Card, Processes Patient's Local Profiles Flow

FLOW 7 & 8: UPDATING FAITH CENTRAL AND LOCAL AI

The main activity of FAITH App relies in the AI functioning. In the second Trial, AI modules replace the role of the data scientist in Trial 1 and data selection and processing become automated and local. Since the system is built on Federated Artificial Intelligence, the AI is elaborated locally by the different modules created by the data scientist during Trial 1 (See Section 3.2.3).

According to the FAIIH principles, data should never leave the patient's phone, in order to ensure real data protection.

The local modules are directly connected to the FAITH Central, where data are securely aggregate, with no sensitive information regarding the patient. When data reaches this module, in fact, it is completely secure in term of personal data protection.

A dynamic and interactive dialog constantly happens between the Local AI and the Updated FAITH Central in order to keep both of them updated.

In FAITH Central all the modules are aggregated to generate a comprehensive frame of the patient's health. It constituted the core of FAITH since it provides an overall description of the patients' wellbeing and should make it possible to forecast negative mental conditions. In order to do so, FAITH App sends the Local AI module and their information to FAITH Central through Internet Connection. This process, indeed, requires Internet connection since FAITH Central is a cloud aggregated system. FAITH Central is then updated with the new model and can provide a more accurate depiction of the patient's condition.

Secondly, FAITH App acquires aggregated data from the updated FAITH Central through Internet in order to update the Local AI modules. The results are then updated at the Local AI.

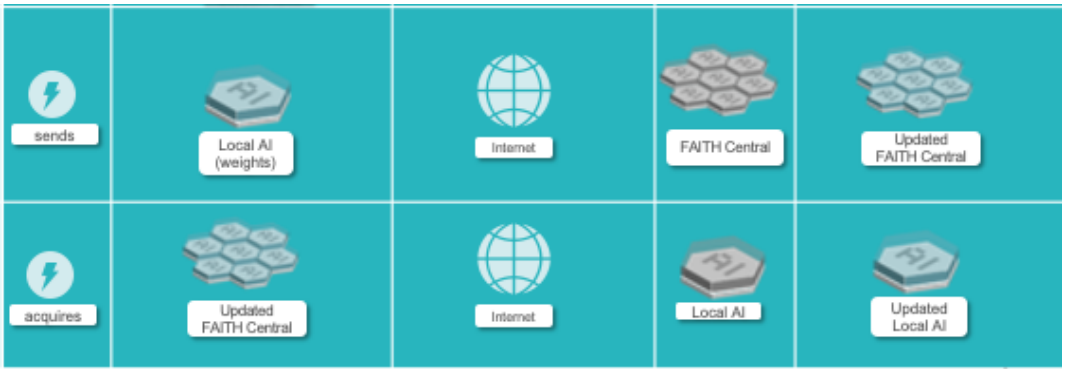

Figure 35: FAITH APP (Trail#2) Actor Card, Updating FAITH Central and Local AI Flow

4.2 Trial 2 Narrative Scenario (Envisioning)

Narrative User Scenario are a research tool used to show how users might act to achieve a goal in a system or environment. Their main function is to allow stakeholders to understand the user's need and their context of use to improve the ideation and design of the system. In order to help identifying the feature of FAITH AI Angel, section 3.5 provides a Narrative Scenario describing the journey of Irene, a fictional breast cancer survivor taking part in the Trial 1 of FAITH.

A Narrative Scenario (Envisioning) is an attempt to forecast the functioning of a product or system that has not been implemented yet. This section offers a Narrative Scenario envisioning the progresses of Trial 2, after the completion of Trial 1.

Trial 1 cannot be precisely planned since it will be defined on the outcomes of Trial 1.

The Narrative Scenario of Trial 1 can be found in section 3.5.

Preamble

'Irene' is a breast cancer survivor who joined the Trial of **FAITH 'AI Angel'**, referred by her oncological doctor at UPMC, Waterford. She took part in the Trial 1 for 12 months, using the FAITH App on her phone and meeting regularly with her Doctor.

In Trial 2, her role will remain unchanged. She will keep on using the App and meet with her doctor for another year. The main change is that FAITH App is updated to a new version and this year will be used to validate the new AI model.

Usage Trial 2

During the Trial 2, Irene normally keeps on using FAITH App and Sleep monitor device in her daily routine.

AI Model has been trained to collect data, so in this session are not processed by the data scientist anymore. She is still meeting regularly with her doctor to check on her mental condition and ensure that the results provided by the App are valid.

Data are constantly analysed by the local model.

A standard starting model has been downloaded to the device, which in turn learns and improves as the various modules on Irene's phone collect and analyse the data. This updated model is sent to the FAITH servers where it is averaged with models from other users and improved upon. An updated shared model is then downloaded to Irene's phone in order to provide a better analysis of her data, and the sequence is repeated. By doing so, Irene's data never leaves her phone, and her privacy is protected.

If it is the case that a downward trajectory is noticed in Irene's depression levels, then a message to indicate this is sent via the FAITH messaging system to the UPMC-FAITH representative for Irene.

Conclusion

After the end of the two-year trial period, Irene returned to the hospital to be informed that there were no longer any signs of depression, and that she was free to continue life as normal either with or without the AI-Angel app monitoring her wellbeing.

5 MVP DEFINITION

The term ‘MVP’ was first coined in 2001 by Frank Robinson but was subsequently popularised by Eric Ries through his book ‘Lean Startup’. Since then, it has come to mean many things to different people so for the sake of clarity we will treat it as defined there:

“The minimum viable product is that version of a new product which allows a team to collect the maximum amount of validated learning about customers with the least effort”

We believe this definition is the most useful, because the validated learning is the important part. An MVP is not about ‘hacking’ together a quick-and-dirty version of a product. It is about managing to learn something from the first iteration. Startups exist not to make stuff, make money, or serve customers. They exist to learn how to build a sustainable business. This learning can be validated scientifically, by running experiments that allow us to test each element of our vision. See Figure 34 - This is often referred to as the build-measure-learn feedback loop.

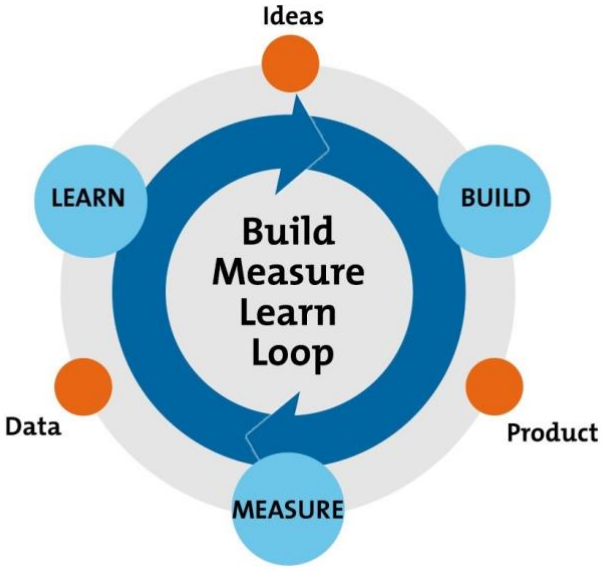

Figure 34 - Build Measure Learn Loop

Another crucial thing to define, particularly in an EU project, is the context within which we frame our MVP i.e. during the lifetime of the FAITH project an MVP will look significantly different to one post-project.

Additionally, describing an MVP at this stage of a three-year project built around an exploratory trial is problematic and our concept of an MVP is likely to change as the project, and trials, advance. All changes will be captured in future iterations of this deliverable.

5.1 Project MVP

An MVP in the lifetime of the project is markedly different to one that will exist post-project. For this project, the MVP is essentially a mobile application that can measure the variables defined in the study protocol. In terms of validated learning the single most important thing for us to learn is if a correlation exists between the measured variables and changes in depression and quality-of-life.

Validation in this sense is through the use of the patient questionnaires and clinician expertise. Only by uncovering these correlations, and consequently building algorithms to predict depression and quality-of-life changes based on them, can we then concern ourselves with other learning metrics.

5.2 Product MVP

If Trial 1 is successful and we then get to deploy models in Trial 2 to see if depression, anxiety and quality-of-life changes can be predicted, a significant part of validation will again be through the combination of questionnaires and clinical expertise i.e. are the model predictions in line with the expert assessments.

It is at this stage that we can also begin to broaden our application validated learning, to encompass more about how the patient experiences the FAITH application. If FAITH is successful in the trial stages, it becomes important then to prove that the concept has traction with its intended users. The importance of traction lies in the fact that it demonstrates that a business hypothesis is grounded in reality. Since the real business modelling of FAITH will be delivered in D8.2 in M18 (and updated later), it will be that work that then frames the metrics needed to satisfy validated learning. Consequently the ‘Product MVP’ will be defined more concretely in the M26 iteration of this deliverable.

6 CONCLUSIONS

This document focused on the user requirements of the first trial of the FAITH project. It has a strong focus on the data collection functions. The requirements of the overall concept are strongly dependent on the study protocol, which is being agreed by the hospital partners and then submitted for approval to the Ethical Committee. However, current user requirements were identified according to the:

- current knowledge regarding the study protocol definition.
- vision of the consortium regarding the overall form of the FAITH concept expressed in concept map.
- data needs for developing the AI models and validating them together with their usage (MVP).

Together with the technical requirements defined in D2.3, they form the core of the system, which is going to be deployed for the Trial 1 and partially for Trial 2.

User requirements for the second trial are also described in this deliverable. They serve mainly as a starting point for a more concrete definition that is possible only after the starting of Trial 1, therefore once the data collection capabilities and the first modelling attempts are in place.

The MVP definition at this stage is overlapped with the defined requirements as they specify exactly what are the functions used for the data collection that will be used both for development and validation.

The second version of this deliverable will focus on the clinical side of the concept, i.e., how the Doctors can benefit from the models' results, and on the implications of the concepts for the Users, namely how their daily life can be impacted in terms of awareness, usage, and relationship with the doctors involved.