Co-funded by the Horizon 2020
Framework Programme of the European Union

Deliverable 2.7
Update on Final version of User Requirements and Data Model

Work Package 2: Co-design Process

affecTive basEd iNtegrateD carE for betteR Quality of Life: TeNDER Project

Grant Agreement ID: 875325

Start date: 1 November 2019

End date: 30 April 2023

Funded under programme(s): H2020-SC1-DTH-2018-2020/H2020-SC1-DTH-2019

Topic: SC1-DTH-11-2019 Large Scale pilots of personalised & outcome based integrated care

Funding Scheme: IA - Innovation action

Disclaimer

The TeNDER consortium consists of the following Partners.

Table 1 - Consortium Partners List

No	Name	Short name	Country
1	UNIVERSIDAD POLITECNICA DE MADRID	UPM	Spain
2	MAGGIOLI SPA	MAG	Italy
3	DATAWIZARD SRL	DW	Italy
4	UBIWHERE LDA	UBI	Portugal
5	ELGOLINE DOO	ELGO	Slovenia
6	ETHNIKO KENTRO EREVNAS KAI TECHNOLOGIKIS ANAPTYXIS	CERTH	Greece
7	VRIJE UNIVERSITEIT BRUSSEL	VUB	Belgium
8	FEDERATION EUROPEENNE DES HOPITAUX ET DES SOINS DE SANTE	HOPE	Belgium
9	SERVICIO MADRILENO DE SALUD	SERMAS	Spain
10	SCHON KLINIK BAD AIBLING SE & CO KG	SKBA	Germany
11	UNIVERSITA DEGLI STUDI DI ROMA TOR VERGATA	UNITOV	Italy
12	SLOVENSKO ZDRUŽENJE ZA POMOČ PRI DEMENCI - SPOMINČICA ALZHEIMER SLOVENIJA	SPO	Slovenia
13	ASOCIACION PARKINSON MADRID	APM	Spain

Document Information

Project short name and Grant Agreement ID	TeNDER (875325)
Work package	WP2
Deliverable number	D2.7
Deliverable title	Update on Final version of User Requirements and Data Model
Responsible beneficiary	SPO
Involved beneficiaries	UPM, MAG, DW, UBI, CERTH, VUB, HOPE, SERMAS, SKBA, APM
Type[1]	R
Dissemination level[2]	PU
Contractual date of delivery	31. January 2023
Last update	17. January 2023

[1] **R:** Document, report; **DEM:** Demonstrator, pilot, prototype; **DEC:** Websites, patent fillings, videos, etc.; **OTHER**; ETHICS: Ethics requirement; ORDP: Open Research Data Pilot.

[2] **PU:** Public; **CO:** Confidential, only for members of the consortium (including the Commission Services).

Document History

Version	Date	Status	Authors, Reviewers	Description
v 0.1	18/10/2022	Draft	Špela Glišović Krivec (SPO)	Table of contents, structure
V 0.2	27/10/2022	Draft	Cristina Lozano (SERMAS)	Section 2.2
V 0.3	17/11/2022	Draft	Stefan Loureiro (UBI)	Inputs in Section 5, Data model
V 0.4	22/11/2022	Draft	Špela Glišović Krivec (SPO)	General inputs and edits
V0.5	9/12/2022	Draft	Jennifer Jiménez (APM)	Comments in section 1.2 and 2
V0.6	13/12/2022	Draft	Špela Glišović Krivec, David Krivec (SPO)	General edits and inputs for partners` review
V0.7	27/12/2022	Draft	Cristina Lozano (SERMAS)	Section 2.1.1 Social Impact
V0.8	03/01/2023	Draft	Špela Glišović Krivec, David Krivec (SPO)	General content edits, Inputs in section 2, edits on structure
V0.9	16/01/2023	Review 1	Vassilis Solachidis (CERTH)	Review
V0.10	17/01/2023	Draft	Špela Glišović Krivec, David Krivec (SPO)	Incorporating review changes and addressing the comments
V1.0	30/01/2023	Review 2 & Final formatting	Javier Serrano (UPM)	Review and version for submission

Acronyms and Abbreviations

Acronym/Abbreviation	Description
AD	Person with Alzheimer's Disease or other form of dementia or mild cognitive impairment
CRDe	electronic data collection notebook
CVD	Person with Cardiovascular Disease
PD	Person with Parkinson's Disease
QoL	(Health related) Quality of Life
TeNDER	affecTive basEd iNtegrateD carE for betteR Quality of Life
WPx	Work Package

Contents

1 INTRODUCTION 9
1.2 Contribution to other deliverables 9
1.3 Structure of the document 9
2 SUMMARY OF USER, FUNCTIONAL AND GENERAL REQUIREMENTS, addition to Deliverable 2.5 10
2.1 Additional requirements on TeNDER recommendation system 11
2.1.1 Social Impact 12
2.2 Focus group methodology 12
3 PRESENTATION OF REACHED OBJECTIVES 15
4 Summarized main findings from co-design process 16
5 Final TeNDER DATA MODEL 17
5.2 Practitioner resource 20
5.2.1 Formal Caregiver 21
5.2.2 Professionals 22
5.3 Related Person resource 22
5.4. Living Environment resource 23
5.5. Device resource 25
5.6. Organization resource 27
5.7. Observation resource 28
5.8. Group resource 30
5.9. Communication request resource 31
5.10. Questionnaires` resource 32
5.11. Questionnaires` response resource 34
5.12. Condition resource 35
5.13. Signal 36
6 Conclusions 38
7 References 39
ANNEX I 40
Script to be followed by the moderator: 40

List of Figures

Figure 1: Illustration: focus group 13
Figure 2: Data model for patient and relations to others 18
Figure 3: Patient`s model in JSON format 19
Figure 4: Codeable Concept 20
Figure 5: Practitioner`s data model 20
Figure 6: Practitioner`s model in JSON format 21
Figure 7: Code for the formal caregiver as a user 21
Figure 8: Related Person`s data model 22
Figure 9: Related Person`s model in JSON format 23
Figure 10: Location's data model 24
Figure 11: Association of the devices with a patient 25
Figure 12: Associations 26
Figure 13: Association of an Organization with a Contact 27
Figure 14:Association data model 27
Figure 15: Observation entity structure 28
Figure 16: Observation data model 29
Figure 17: Group entity and its secondary related entities 30
Figure 18: Group data model 30
Figure 19: CommunicationRequest entity and its secondary related entities 31
Figure 20: CommunicationRequest data model 32
Figure 21: Questionnaire entity and its secondary related entities 32
Figure 22: Questionnaire data model 33
Figure 23: Questionnaire response entity and its secondary related entities 34
Figure 24: Questionnaire response data model 34
Figure 25: Condition entity and its secondary related entities 35
Figure 26: Condition data model 35

List of Tables

Table 1 - Consortium Partners List 2
Table 2: Profiles of the participants in a focus groups sample 14
Table 3: Devices and signal entities connection 36

Executive Summary

This document serves as an update to the Deliverable 2.5 Final version of User Requirements and Data Model from July 2022 [6]. It is one of the output documents that have been creates in the co-design process with all relevant stakeholders (patients, carers, doctors and other professionals) in WP2 TeNDER tasks). Herein, the additional methodology is presented that TeNDER piloting partners will use within the piloting as for the evaluation of the usability and participants` perception, the summarization of the requirements and social impact is provided, and the Final TeNDER data model is presented.

1 INTRODUCTION

Co-design process is a non-linear process that involves multiple actors and stakeholders. We involved patients from different groups (people with dementia, people with Parkinson`s disease, people with cardiovascular diseases), their family members and informal carers, formal carers, health and social care professionals, and also other professionals and stakeholders from the field of care in the design process of TeNDER services. The aim was not only to improve the efficiency and effectiveness, but also to enhance the satisfaction of those who take part in the co-design process. The co-design process in TeNDER project allowed individual experiences of each potential user of TeNDER to be heard and framed the process by questions of acceptance, usability, human dignity, human rights, fairness, social inclusion, and emotional impact. The co-design process thus spans through several development phases, but also through the testing, as presented in Deliverable 2.5 Final version of User Requirements and Data Model in July 2022 [6]. Therefore, participants are included in feedback, gathering and providing their views and experience that allows participatory design of TeNDER services. Accordingly, the system architecture is being upgraded and tailored to serve potential users in the future.

1.1 Purpose and scope

The update of Deliverable 2.5 with the final report on the user requirements and the Final data model of the TeNDER system is closing the user requirement part of co-design process of the large-scale piloting phase of the project. The purpose is to allow the development of a solution that has the potential to be adopted in wider community by using person-centred approach, and also the professional driven approach. As the pandemic impacted this project, partners have been using an additional methodology in pilot definition in order to allow communication assessment, perception on the impact on visits to the professionals and general usability and experience collection during piloting, but also allowing the inclusion of large group of the participants.

1.2 Contribution to other deliverables

This deliverable is an update of Deliverable 2.5 and is closing the user requirement part and data model part in co-design process of TeNDER. As such will serve as additional guidance for the documents on piloting reporting in WP3, D3.3 Final version of Sensorial Subsystems, D3.4 Patient Interface Interaction Analysis and Pathway tracking; WP4, D4.2 Final version of Multi-Modal Fusion analysis, D4.3 Deep learning Based profile analysis and Recommendation System, D4.4 Personalised interactions and safety perception; WP5, D5.5 Final version of TeNDER Services; WP6, D6.5 Final Report on large scale Pilots.

1.3 Structure of the document

The document is presenting additional summarization of user requirements, the focus group methodology for the WP6 (Annex I) and the Final data model of TeNDER.

2 SUMMARY OF USER, FUNCTIONAL AND GENERAL REQUIREMENTS, addition to Deliverable 2.5

As described in previous deliverables, TeNDER partners performed co-design with various group of users in different phases of the TeNDER development and testing. In the first phase, partners jointly checked the existing provisions flow and together developed the service matching table (Annex I, Deliverable 2.5 [6]), that guided the partnership in the development of the tool. The existing situation in the different countries involved was summarized, the knowledge from previous projects and from the state-of-the-art relevant literature was integrated (reported in TeNDER Deliverable 2.1 [2]). Afterwards, the common approaches towards the potential users were defined. Use case stories reflected daily problems faced by a person with disease and his / her carers, and also support that can be provided by professionals (reported in TeNDER Deliverable 2.3 [4]). Accordingly, TeNDER partners framed the solutions and services that may be applied and technical integration happened. The key outcome was the report on existing service provision and guidance for conducting the study. The users` needs were investigated further on through the observational study that was presented in Deliverable 2.4. [5] Several domains were checked and through the reported needs, the customization was addressed. Partners also analysed the potential limitations for the use of the technology and the barriers were discussed to allow the user-friendly development of the TeNDER tool.

Partners therefore collected requirements in different ways, for example: from literature, from previous experiences, from field of work, and from technical partners. According to the defined functionalities (Section 2.2, Deliverable 2.5, [6]), the technical development delivered modular services that were included in further co-design process through the testing and observation gathering. Further on, researchers were included in the survey and the general observations were framed and discussed in Internal reports (Report 1, 2 and 3 on Evaluation Strategy and Protocols, WP1 [7]) and Deliverable 2.5 [6]. Briefly, there was a variability observed on the personal level, according to the acceptance of the technologies. The best accepted functionality for people with dementia was the sleep tracker, that needs no personal interaction. Moreover, according to patients' opinion, the system should not be intrusive and should only report/notify the person if required. Furthermore, the patients' motivation can be enhanced if they are able to see their performance. Also, the carers accepted the technologies, but there were some expressed concerns about how care-recipients will accept it. The main requirement was that technological device and their interfaces need to be simple with big buttons/fonts/screens. There were some concerns reported in regards to the installation, usage and privacy, but also affordability of the system was questioned. Nevertheless, the patients commented that the developed system should be useful to patients. The usability perception for devices like the smart-watch was difficult sometimes, as patients often found difficulties to charge it, to put on and use a smartwatch by themselves. For patients living with dementia the usability assessment was difficult as they had some problems to understand the purpose of use. Mostly, the patients replied that they would need at least one person to be in charge of the system all the time (for example: checking data, charging devices, restarting devices...) [6,7].

Nevertheless, the user requirement that the professional might access the data and know if there are any health concerns was strongly present among patients and also carers. In

addition, some patients commented that they find useful that their data can be seen by their family member or carer in case there are any concerns. According to carers, there is a requirement to be supported by viewing night and daily activities and have a tool that would help with daily management accordingly. However, even some carers found useful to obtain information on how patients slept or how much they were active/moving around during the day, they reported that they found minor difficulties to have the App working (note: the TeNDER system was in the first development testing phase). The professionals` view was more focused on the accuracy and longitudinal visualisation of the data. They expressed that they found the provided data in the testing useful, but they wish that can it be evaluated and that it might give them additional information for better medical service or therapy.

2.1 Additional requirements on TeNDER recommendation system

In Section 2 of Deliverable 2.5 [6], the recommendation system requirements were added. The User Requirements, regarding the feedback mechanism and recommendations accordingly to the functionalities that are being used, were addressed as described in Table 2, Deliverable 2.5 [6]. Functional requirements that specify what the system should do were addressed jointly with work in WP4.

Partners developed separately three grouped types of the requirements: (1) for the patients, (2) for the carers, and (3) for the professionals. The system output is based on the inputs from the devices and functionalities of TeNDER that will be used by an individual, and according to his/her input into the questionnaires that will be provided thorough the TeNDER App. In this way the created recommendation events concerning the patient's wellbeing and are triggered according to specific or a combination of the system inputs. Partners developed recommendations that will be of a general type (like general recommendation for the activity to be a part of one's daily routine) and specific type (based of the trigger situations/events that will be detected through the TeNDER system). The users will therefore have the opportunity to receive general and personalized recommendations through the TeNDER App. The recommendations will fall into categories:

- social (based on the answers to the questionnaire on loneliness, needed help for house work, food preparation, daily management and similar);
- sleep habits (based on the quality of sleep and based on the answers to the questionnaire: regularity, interruptions of sleep, sleep latency, being tired during the day and similar);
- nutritional (based on the location functionality tested and daily habits, but also based on the answers to the questionnaire: general recommendations on healthy diet and cooking recommendations);
- environmental (based on the environmental monitoring functionality tested, the recommendations for maintaining health temperature and humidity will be triggered);
- emotional (based on the functionality for mood detection and based on the questionnaire);
- physical activity (based on the activity functionality);

- other (dedicated recommendations to follow the therapy and medication routine).

2.1.1 Social Impact

The study of social requirements involved the dedicated contribution from end-user entities and medical bodies in TeNDER as described in Section 2, Deliverable 2.5 [6]. It was decided to explore the opinion of key actors regarding the current situation of loneliness of patients living with chronical diseases and find out what they think about proposed measures.

Methodology

A qualitative phenomenological exploration was carried out through semi-structured interviews with local authorities, health professionals, carers and associations. A purposive sampling was carried out to select informants who met the selection criteria: professionals with a health care profile and professionals with a health management profile. Interviews on social impact were carried out according to the transcript provided in Annex 3, Deliverable 2.5 [6]. The interviews were telematic and collected the opinion and experience regarding loneliness of patients living with chronical diseases, public policies, need for care and their views about technologies as an assistive tool. The interviews were transcribed, organised and labelled by project researchers.

Results:

The sample consisted of 15 participants. The categories identified in the discourse were: loneliness at home, resources, informal carers and technology as an assistive tool. The participants recognised as problems: loneliness and social isolation of older people; existing policies regarding funding and resources; the role of the informal carer and their lack of recognition and training; and the digital divide and low funding in assistive systems. The opportunities identified were aimed at improving funding and setting up appropriate policy measures, in the recognition of carers and in the adaptation of new technologies as a tool to combat loneliness. The results with key words were presented in Table 3, Section 2 in Deliverable 2.5 [6].

Conclusions:

Health professionals with a care profile and management profile agree that tackling loneliness is a pending and priority issue. The funding and measures currently in place are insufficient and they agree that supporting the carer and designing technological systems aimed at helping people in loneliness will offer an effective solution.

2.2 Focus group methodology

The additional methodology was defined in order to be implemented in piloting definition and support the large-scale piloting. As such can be used in the pilot implementation in order to answer questions in a moderated setting. Partners decided to have a supporting methodology to explore why something occurs when limited information is available from the testing settings.

Moreover, while seeking the methodology that helps uncover new questions or future research ideas, and at the same time being focused on feelings or perceptions of the people, partners have chosen focus group methodology that can be used to look for explanation, and in-depth dialogue.

What is a focus group?

The focus group has its origins in an approach to group interviewing described in 50ies. Since then, it has gained increasing popularity within qualitative research and evaluation. A focus group can be defined broadly as 'a type of group discussion about a topic under the guidance of a trained group moderator'. Data collection and subsequent analysis take account of both the dialogue and the interaction that occurred within the group, and seek to capture the way in which meaning is negotiated and co-produced in the group context [1]. Therefore, a *focus group consists* of a group interview conducted by a moderator using a topic or interview script. Interaction among participants is sought as a method to generate information.

The focus group is made up of a limited number of people: between 4 and 10 participants, a moderator and, if possible, an observer (Figure 1). No figures or data are obtained that allow measuring any aspect. We work with the information that is expressed in the speeches and conversations of the groups.

Figure 1: Illustration: focus group

Sample selection of TeNDER focus group: the sample will be chosen through purposive sampling. This involves selecting specific groups of users with certain characteristics that are relevant to our study. Such as the role (patient, carer or professional), taking into account representativeness with respect to sex, age and the disease for which they have been included in the study.

It is proposed that the main variable for segmenting the groups be the role of the participant. In this way we will define 3 segments of the population to be studied: patient, carer and professional. The typical profiles to be chosen in each of the proposed segments are detailed in Table 2.

Table 2: Profiles of the participants in a focus groups sample

	Segment a (Group 1)	Segment b (Group 2)	Segment c (Group 3)
Role	Patient	Carer	Professional
Age	≥ 60 years.	≥ 18 years.	≥ 18 years.
Specific characteristics	AD, PD, CVD	Formal and/or Informal	Social professionals, Health professionals and/or other professionals

According to the Table 2, the proposal is to conduct 3 focus groups to achieve heterogeneity between groups:

1. Group 1: Patients
2. Group 2: Carers
3. Group 3: Professionals

Within each group, the aim is to achieve, on the one hand, homogeneous groups of people who have something in common (for example: the role they play) and whose personal and vital characteristics do not make them incapable of speaking freely and spontaneously in a discussion group. On the other hand, heterogeneity is sought among the members of a group, either by sex, age or specific characteristics. The script is presented in Annex I.

3 PRESENTATION OF REACHED OBJECTIVES

The main objective "Follow participatory design process" (Objective 6) covers the Co-design with relevant stakeholders (elders, carers, doctors) during all TeNDER stages and is described as presented in Deliverable 2.5 [6]. In this document it is presented:

- the definition of the functional specifications of the TeNDER ecosystem and services;
- the elaboration of the functional specifications into actual platform requirements;
- the design of the sub-goals that will drive the service recommendations;
- the current and realistic evaluation procedure, where elderly will use existing solutions (early in the project development to practically guide the functional specification gathering) and the TeNDER ecosystem with services;
- the assessment phases that will base on their feedback coming from the evaluations and use it to refine and improve TeNDER offerings.

The co-design process with all stakeholders was spanning through the pre-piloting phase, and the first two Waves of the piloting phase. As concerns the objective mentioned above, TeNDER measured its success through key performance indicators (KPIs) improvements, that were described and reached in the Table 5, Deliverable 2.5 [6].

4 Summarized main findings from co-design process

As stated in TeNDER Deliverable 2.5 [6], the focus of the TeNDER partners` team was on engaging diverse people in the process including individual and public engagement activities that were promoted from the beginning of the project. Partners recognized that there is a need to tackle stigmatization perceptions about the technology, but also what may work and for whom.

To make the complex health and wellbeing technologies more useful and applicable for people, it is crucial to involve all potential users, including staff, in the early phase of development of these interventions. Briefly, partners have found that it is better to include working prototypes for requirements gathering that paper prototypes. This was clearly detectable when different phases of the interfaces were tested. Moreover, the ability to observe real use provided us insights on the possibilities how to manage the tool. This way, partners got the insight on the steps that are needed to be taken, to design a friendly tool that can and will be used also without the presence of the researcher. Moreover, the interface design with possible dark backgrounds and customization of the fonts was also well acceptable.

As the TeNDER services are being designed for people that are facing daily challenges in a different way, the accessibility adaptations, customization of the contents and profiles was also needed.

One of the main findings was also that in order to enable people with cognitive disabilities to use the tools that they have, we need to involve carers and professionals in delivering interventions.

Finally, as we found that when people experienced technical problems, they were sometimes not able to provide useful feedback, the general requirement when testing innovative tools could be that the participant could have recurring pop-up or being asked to rate the design or system information.

5 Final TeNDER DATA MODEL

As we stated in the previous deliverable [6], in order to develop TeNDER data model, we used the HL7 FHIR resources, there is an obligation on using its data model. It's a verified and valid structure and cannot be changed but it's possible to create extensions.

All the resources are related between them by identifier keys, which are used as references. For our purpose, we used the resources that were better suited to the data that we need to store with the intent of future improvement, both in terms of the amount of information and its correct allocation. The following subsections refer to how resources are structured in the database and how they communicate with each other, providing examples as it will be shown to explain how the information can be requested.

Based on this assumption, for continuity purposes we will report below the structure given in the previous deliverable, taking care to include appropriate updates.

The presented final data model has four new resources which are Communication request, Questionnaires, Questionnaires' response and finally the Condition. Based on the co-design process, the notifications to notify health professionals and practitioners were added within the Communication request. Moreover, in order to solicit information from the patients, carers or other individuals involved in the healthcare domain, Questionnaires and Questionnaires response data models are used for the health professionals. Finally, we added the data model Condition that has relevant information about a condition, problem, diagnosis, or other event, situation, issue, or clinical concept related with the patients in his diseases and comorbidities.

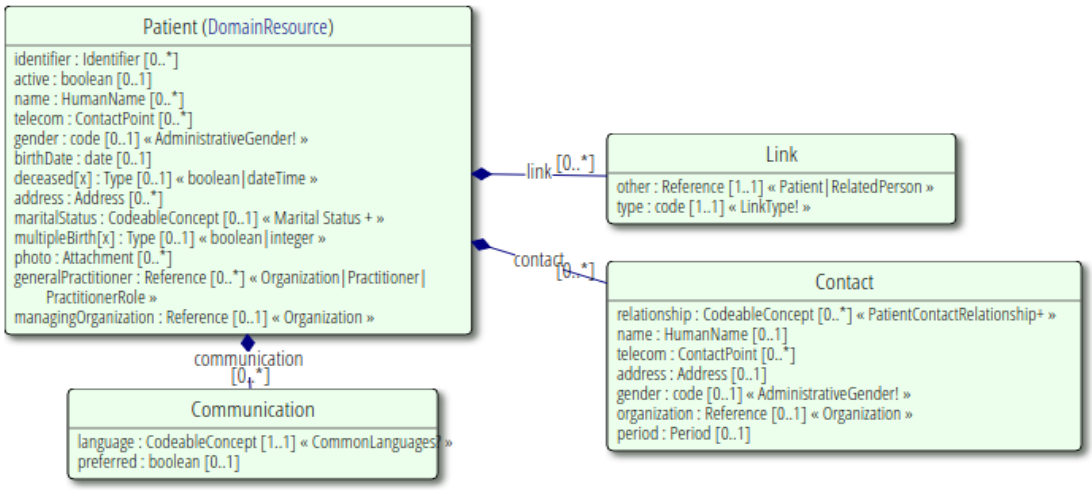
5.1 Patient resource

The following image shows the Patient's model where we can see several external references, which provides crucial connections.

In the image below (Figure 2), it's exposed the Patient's model domain resource and the integrated resources. In the Patient's model, we can verify several references values that can be defined like:

generalPractitioner: [{reference: "Practitioner/123123"}]

With the following reference, the patient will be related to the Practitioner with the unique identifier "123123".



(Source: https://www.hl7.org/fhir/patient.html)

Figure 2: Data model for patient and relations to others

The Patient's model can be better understood in the following JSON format (Figure 3).

```
{
  "resourceType" : "Patient",
  // from Resource: id, meta, implicitRules, and language
  // from DomainResource: text, contained, extension, and modifierExtension
  "identifier" : [{ Identifier }], // An identifier for this patient
  "active" : <boolean>, // Whether this patient's record is in active use
  "name" : [{ HumanName }], // A name associated with the patient
  "telecom" : [{ ContactPoint }], // A contact detail for the individual
  "gender" : "<code>", // male | female | other | unknown
  "birthDate" : "<date>", // The date of birth for the individual
  // deceased[x]: Indicates if the individual is deceased or not. One of these 2:
  "deceasedBoolean" : <boolean>,
  "deceasedDateTime" : "<dateTime>",
  "address" : [{ Address }], // An address for the individual
  "maritalStatus" : { CodeableConcept }, // Marital (civil) status of a patient
  // multipleBirth[x]: Whether patient is part of a multiple birth. One of these 2:
  "multipleBirthBoolean" : <boolean>,
  "multipleBirthInteger" : <integer>,
  "photo" : [{ Attachment }], // Image of the patient
  "contact" : [{ // A contact party (e.g. guardian, partner, friend) for the patient
    "relationship" : [{ CodeableConcept }], // The kind of relationship
    "name" : { HumanName }, // A name associated with the contact person
    "telecom" : [{ ContactPoint }], // A contact detail for the person
    "address" : { Address }, // Address for the contact person
    "gender" : "<code>", // male | female | other | unknown
    "organization" : { Reference(Organization) }, // C? Organization that is associated with the
contact
    "period" : { Period } // The period during which this contact person or organization is vali
d to be contacted relating to this patient
  }],
  "communication" : [{ // A language which may be used to communicate with the patient about his
or her health
    "language" : { CodeableConcept }, // R!  The language which can be used to communicate with
the patient about his or her health
    "preferred" : <boolean> // Language preference indicator
  }],
  "generalPractitioner" : [{ Reference(Organization|Practitioner|
   PractitionerRole) }], // Patient's nominated primary care provider
  "managingOrganization" : { Reference(Organization) }, // Organization that is the custodian of
the patient record
  "link" : [{ // Link to another patient resource that concerns the same actual person
    "other" : { Reference(Patient|RelatedPerson) }, // R!  The other patient or related person r
esource that the link refers to
    "type" : "<code>" // R!  replaced-by | replaces | refer | seealso
  }]
}
```

Figure 3: Patient`s model in JSON format

It's possible to visualize each key and its value's type, which can be a simple value like a boolean (true or false), a date, a code, or a more complex structure, *CodeableConcept*. Its structure is a collection of values that provides a more complete and flexible definition of the key. It can include anonymization codes, display text, etc.

The following image (Figure 4) exposes an example of a *CodeableConcept* object.

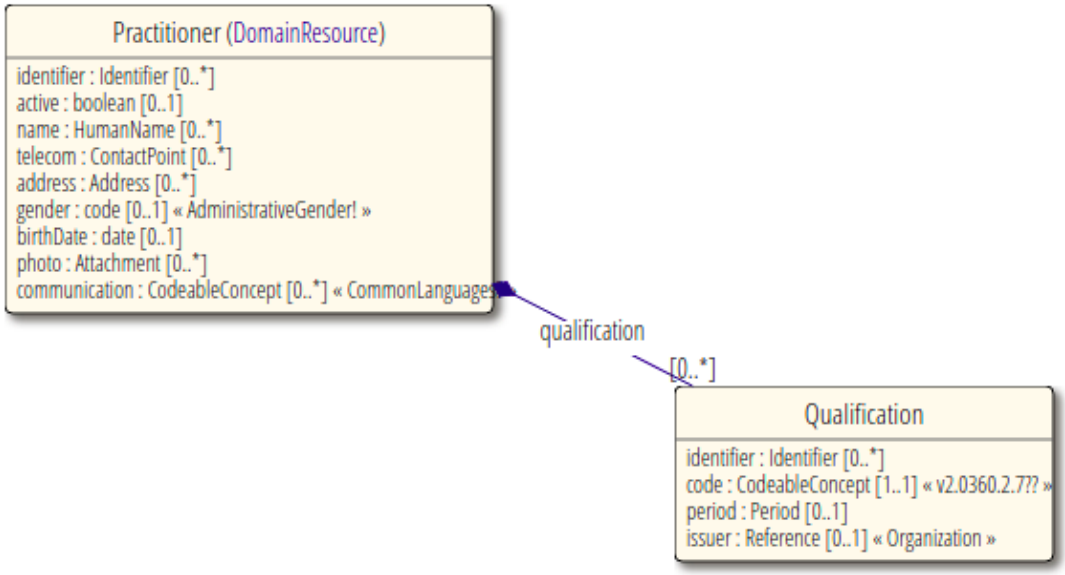
```
"valueCodeableConcept": {
        "coding": [
                {
                        "system": "http://snomed.info/sct",
                        "code": "260385009",
                        "display": "Negative"
                }, {
                        "system": "https://acme.lab/resultcodes",
                        "code": "NEG",
                        "display": "Negative"
                }
        ],
        "text": "Negative for Chlamydia Trachomatis rRNA"
}
```

(Source: https://www.hl7.org/fhir/datatypes.html#CodeableConcept)

Figure 4: Codeable Concept

5.2 Practitioner resource

The following image (Figure 5) exposes the Practitioner's data model.



(Source: https://www.hl7.org/fhir/practitioner.html)

Figure 5: Practitioner`s data model

In Practitioner resource (Figure 6), it's defined the general info of the user where its qualifications can be added, to validate its roles.

```
{
  "resourceType" : "Practitioner",
  // from Resource: id, meta, implicitRules, and language
  // from DomainResource: text, contained, extension, and modifierExtension
  "identifier" : [{ Identifier }], // An identifier for the person as this agent
  "active" : <boolean>, // Whether this practitioner's record is in active use
  "name" : [{ HumanName }], // The name(s) associated with the practitioner
  "telecom" : [{ ContactPoint }], // A contact detail for the practitioner (that apply to all ro
les)
  "address" : [{ Address }], // Address(es) of the practitioner that are not role specific (typi
cally home address)
  "gender" : "<code>", // male | female | other | unknown
  "birthDate" : "<date>", // The date  on which the practitioner was born
  "photo" : [{ Attachment }], // Image of the person
  "qualification" : [{ // Certification, licenses, or training pertaining to the provision of ca
re
    "identifier" : [{ Identifier }], // An identifier for this qualification for the practitione
r
    "code" : { CodeableConcept }, // R!  Coded representation of the qualification
    "period" : { Period }, // Period during which the qualification is valid
    "issuer" : { Reference(Organization) } // Organization that regulates and issues the qualifi
cation
  }],
  "communication" : [{ CodeableConcept }] // A language the practitioner can use in patient comm
unication
}
```

(Source: https://www.hl7.org/fhir/practitioner.html)

Figure 6: Practitioner`s model in JSON format

Since a *Practitioner* can have several roles in several organizations, to define them, the FHIR provides a resource already referred to, named *PractitionerRole*. This resource has the necessary fields to define which *Practitioner* will have a specific role in a specific organization.

For the *Practitioner's* users, we have professional's and formal caregiver's roles.

5.2.1 Formal Caregiver

For this type of user, the following code is used (Figure 6).

```
"coding": [
    {
        "system": "http://snomed.info/sct",
        "code": "133932002",
        "display": "Formal Caregiver"
    }
]
```

Figure 7: Code for the formal caregiver as a user

This 'coding' it's defined in the *PractitionerRole* and it's the value that enables the differentiation between roles. The 'system' and 'code' values are real values and are used for anonymization purposes.

5.2.2 Professionals

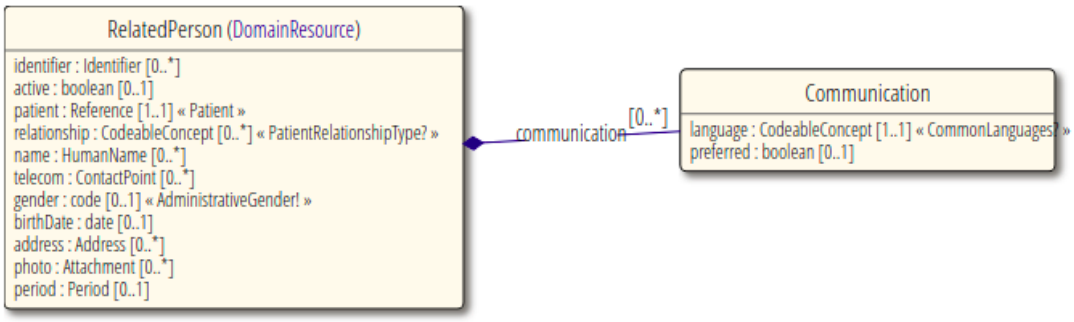
The professional's users have three types of possible roles:

- Health Professionals;
- Social workers;
- Other Professionals.

Each role has a specific code, like in the formal caregiver case. This is an important step to deferred all the possible roles and defines their permissions in the platform.

5.3 Related Person resource

This resource (Figure 8) is used to create users that are not associated with a specific organization. Their relation's only with the patient. The following image exposes the *RelatedPerson's* data model.



(Source: https://www.hl7.org/fhir/relatedperson.html)

Figure 8: Related Person`s data model

The 'patient' field will have the reference to a specific patient, using its identifier ('id') for the correct association (Figure 9). It's a simpler model since there are no additional resources for the role's definition or to the organization's association.

```
{
  "resourceType" : "RelatedPerson",
  // from Resource: id, meta, implicitRules, and language
  // from DomainResource: text, contained, extension, and modifierExtension
  "identifier" : [{ Identifier }], // A human identifier for this person
  "active" : <boolean>, // Whether this related person's record is in active use
  "patient" : { Reference(Patient) }, // R!  The patient this person is related to
  "relationship" : [{ CodeableConcept }], // The nature of the relationship
  "name" : [{ HumanName }], // A name associated with the person
  "telecom" : [{ ContactPoint }], // A contact detail for the person
  "gender" : "<code>", // male | female | other | unknown
  "birthDate" : "<date>", // The date on which the related person was born
  "address" : [{ Address }], // Address where the related person can be contacted or visited
  "photo" : [{ Attachment }], // Image of the person
  "period" : { Period }, // Period of time that this relationship is considered valid
  "communication" : [{ // A language which may be used to communicate with about the patient's h
ealth
    "language" : { CodeableConcept }, // R!  The language which can be used to communicate with
the patient about his or her health
    "preferred" : <boolean> // Language preference indicator
  }]
}
```

(Source: https://www.hl7.org/fhir/relatedperson.html)

Figure 9: Related Person`s model in JSON format

It's important to mention that only one patient can be related to the user-created through this resource.

Using the same object as mentioned in *Formal Caregiver,* the 'relationship' field it's used to define the specific role of each user. For the TeNDER case, there were defined two types of related persons: informal caregiver and family member. For now, both have the same permissions but they will be changed for the next pilot.

5.4. Living Environment resource

For the living environment, at least two resources are used.

Since each patient will have specific main environments associated, they are chosen on its registration process. The possible environments are:

- Home;
- Hospital;
- Day-care Center;
- Rehabilitation Room;

Each environment has its internal locations (Figure 10). For these locations, the *Location* resource it's used to enable the creation of locations and the association with the main environments. The following image it's related to the Location's data model.

```
{
  "resourceType" : "Location",
  // from Resource: id, meta, implicitRules, and language
  // from DomainResource: text, contained, extension, and modifierExtension
  "identifier" : [{ Identifier }], // Unique code or number identifying the location to its users
  "status" : "<code>", // active | suspended | inactive
  "operationalStatus" : { Coding }, // The operational status of the location (typically only for a bed/room)
  "name" : "<string>", // Name of the location as used by humans
  "alias" : ["<string>"], // A list of alternate names that the location is known as, or was known as, in the past
  "description" : "<string>", // Additional details about the location that could be displayed as further information to identify the location beyond its name
  "mode" : "<code>", // instance | kind
  "type" : [{ CodeableConcept }], // Type of function performed
  "telecom" : [{ ContactPoint }], // Contact details of the location
  "address" : { Address }, // Physical location
  "physicalType" : { CodeableConcept }, // Physical form of the location
  "position" : { // The absolute geographic location
    "longitude" : <decimal>, // R!  Longitude with WGS84 datum
    "latitude" : <decimal>, // R!  Latitude with WGS84 datum
    "altitude" : <decimal> // Altitude with WGS84 datum
  },
  "managingOrganization" : { Reference(Organization) }, // Organization responsible for provisioning and upkeep
  "partOf" : { Reference(Location) }, // Another Location this one is physically a part of
  "hoursOfOperation" : [{ // What days/times during a week is this location usually open
    "daysOfWeek" : ["<code>"], // mon | tue | wed | thu | fri | sat | sun
    "allDay" : <boolean>, // The Location is open all day
    "openingTime" : "<time>", // Time that the Location opens
    "closingTime" : "<time>" // Time that the Location closes
  }],
  "availabilityExceptions" : "<string>", // Description of availability exceptions
  "endpoint" : [{ Reference(Endpoint) }] // Technical endpoints providing access to services operated for the location
}
```

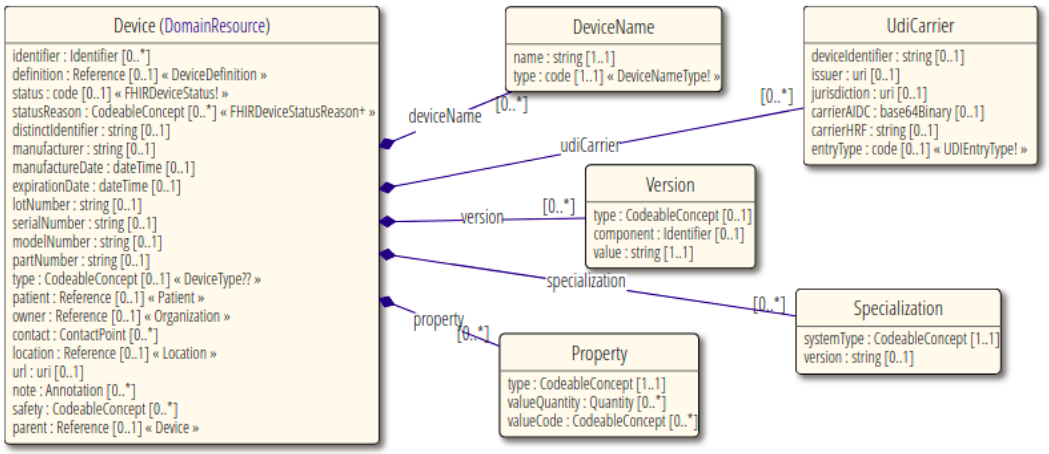
(Source: https://www.hl7.org/fhir/location.html)

Figure 10: Location's data model

In order to manage the correct organization and association, the main environments are defined as main locations as well. Then, the locations on each environment are created with the field '*partOf*', where the main location's identifier it's added. Through this step, all the locations are correctly set which enables the addition, edition, or even the removal of the child locations.

5.5. Device resource

Since the TeNDER solution includes the usage of several devices, they need to be registered and posteriorly associated with the patients (Figure 11).



(Source: https://www.hl7.org/fhir/device.html)

Figure 11: Association of the devices with a patient

By visualizing both data model structure and the fields' type and explanation (Figure 10 and 11), it's possible to see the complexity and the countless fields that this resource provides. Each Device can be associated with a specific user (patient) and still be related to an organization as its owner. It's even possible to define their location with the available locations previously created for each environment.

```
{
  "resourceType" : "Device",
  // from Resource: id, meta, implicitRules, and language
  // from DomainResource: text, contained, extension, and modifierExtension
  "identifier" : [{ Identifier }], // Instance identifier
  "definition" : { Reference(DeviceDefinition) }, // The reference to the definition for the dev
ice
  "udiCarrier" : [{ // Unique Device Identifier (UDI) Barcode string
    "deviceIdentifier" : "<string>", // Mandatory fixed portion of UDI
    "issuer" : "<uri>", // UDI Issuing Organization
    "jurisdiction" : "<uri>", // Regional UDI authority
    "carrierAIDC" : "<base64Binary>", // UDI Machine Readable Barcode String
    "carrierHRF" : "<string>", // UDI Human Readable Barcode String
    "entryType" : "<code>" // barcode | rfid | manual +
  }],
  "status" : "<code>", // active | inactive | entered-in-error | unknown
  "statusReason" : [{ CodeableConcept }], // online | paused | standby | offline | not-ready | t
ransduc-discon | hw-discon | off
  "distinctIdentifier" : "<string>", // The distinct identification string
  "manufacturer" : "<string>", // Name of device manufacturer
  "manufactureDate" : "<dateTime>", // Date when the device was made
  "expirationDate" : "<dateTime>", // Date and time of expiry of this device (if applicable)
  "lotNumber" : "<string>", // Lot number of manufacture
  "serialNumber" : "<string>", // Serial number assigned by the manufacturer
  "deviceName" : [{ // The name of the device as given by the manufacturer
    "name" : "<string>", // R!  The name of the device
    "type" : "<code>" // R!  udi-label-name | user-friendly-name | patient-reported-name | manuf
acturer-name | model-name | other
  }],
  "modelNumber" : "<string>", // The model number for the device
  "partNumber" : "<string>", // The part number of the device
  "type" : { CodeableConcept }, // The kind or type of device
  "specialization" : [{ // The capabilities supported on a  device, the standards to which the d
evice conforms for a particular purpose, and used for the communication
    "systemType" : { CodeableConcept }, // R!  The standard that is used to operate and communic
ate
    "version" : "<string>" // The version of the standard that is used to operate and communicat
e
  }],
  "version" : [{ // The actual design of the device or software version running on the device
    "type" : { CodeableConcept }, // The type of the device version
    "component" : { Identifier }, // A single component of the device version
    "value" : "<string>" // R!  The version text
  }],
  "property" : [{ // The actual configuration settings of a device as it actually operates, e.
g., regulation status, time properties
    "type" : { CodeableConcept }, // R!  Code that specifies the property DeviceDefinitionPropet
yCode (Extensible)
    "valueQuantity" : [{ Quantity }], // Property value as a quantity
    "valueCode" : [{ CodeableConcept }] // Property value as a code, e.g., NTP4 (synced to NTP)
  }],
  "patient" : { Reference(Patient) }, // Patient to whom Device is affixed
  "owner" : { Reference(Organization) }, // Organization responsible for device
  "contact" : [{ ContactPoint }], // Details for human/organization for support
  "location" : { Reference(Location) }, // Where the device is found
  "url" : "<uri>", // Network address to contact device
  "note" : [{ Annotation }], // Device notes and comments
  "safety" : [{ CodeableConcept }], // Safety Characteristics of Device
  "parent" : { Reference(Device) } // The parent device
}
```

(Source: https://www.hl7.org/fhir/device.html)

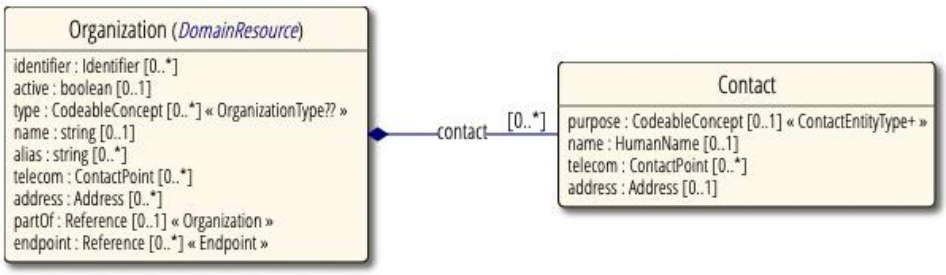
Figure 12: Associations

As explained earlier, most of the *Device* Resources is associated with one patient only. It could bring some problems to the creation of localization devices. These devices are in a room and collect data from several patients. To manage this specific case scenario, we create several *Devices* with the same name and serial number/MAC address, changing, of course, the patient identifier and associated them to a different location (markers have been put in the floor to

assist the patient being at the correct position). Having all the *Devices* created, depending on the user who is in the room at a specific time, the administrator needs to deactivate or activate them. It is a time-consuming process, but a task scheduler was developed to help with this type of management. It will provide the correct tools for each administrator to plan the activations and deactivations, which will occur automatically.

5.6. Organization resource

The organization entity is directly linked with entity contact (Figures 13 and 14), its domain is defined as Resource and contains relevant information about a specific organization and some relationship it could have like “partOf”.



(Source: https://www.hl7.org/fhir/organization.html)

Figure 13: Association of an Organization with a Contact

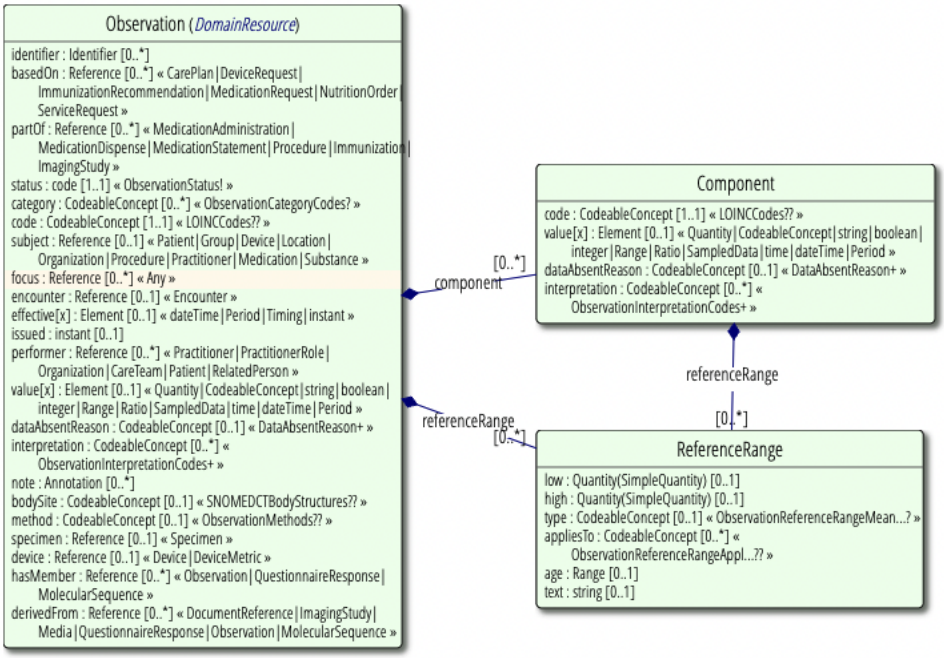
```
{
  "resourceType" : "Organization",
  // from Resource: id, meta, implicitRules, and language
  // from DomainResource: text, contained, extension, and modifierExtension
  "identifier" : [{ Identifier }], // C? Identifies this organization  across multiple systems
  "active" : <boolean>, // Whether the organization's record is still in active use
  "type" : [{ CodeableConcept }], // Kind of organization
  "name" : "<string>", // C? Name used for the organization
  "alias" : ["<string>"], // A list of alternate names that the organization is known as, or was
known as in the past
  "telecom" : [{ ContactPoint }], // C? A contact detail for the organization
  "address" : [{ Address }], // C? An address for the organization
  "partOf" : { Reference(Organization) }, // The organization of which this organization forms a
part
  "contact" : [{ // Contact for the organization for a certain purpose
    "purpose" : { CodeableConcept }, // The type of contact
    "name" : { HumanName }, // A name associated with the contact
    "telecom" : [{ ContactPoint }], // Contact details (telephone, email, etc.)  for a contact
    "address" : { Address } // Visiting or postal addresses for the contact
  }],
  "endpoint" : [{ Reference(Endpoint) }] // Technical endpoints providing access to services ope
rated for the organization
}
```

(Source: https://www.hl7.org/fhir/organization.html)

Figure 14:Association data model

5.7. Observation resource

The observation entity is linked to Component and ReferenceRange entities and it belongs to the domain Resource. It is an entity to insert specific data about a patient and annotation about its health condition.



(Source: https://www.hl7.org/fhir/observation.html)

Figure 15: Observation entity structure

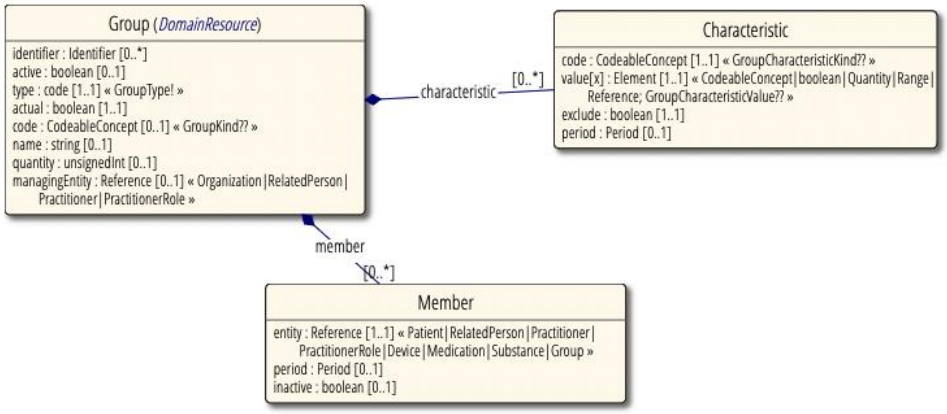
```
{
  "resourceType" : "Observation",
  // from Resource: id, meta, implicitRules, and language
  // from DomainResource: text, contained, extension, and modifierExtension
  "identifier" : [{ Identifier }], // Business Identifier for observation
  "basedOn" : [{ Reference(CarePlan|DeviceRequest|ImmunizationRecommendation|
   MedicationRequest|NutritionOrder|ServiceRequest) }], // Fulfills plan, proposal or order
  "partOf" : [{ Reference(ImagingStudy|Immunization|MedicationAdministration|
   MedicationDispense|MedicationStatement|Procedure) }], // Part of referenced event
  "status" : "<code>", // R!  registered | preliminary | final | amended +
  "category" : [{ CodeableConcept }], // Classification of  type of observation
  "code" : { CodeableConcept }, // R!  Type of observation (code / type)
  "subject" : { Reference(Device|Group|Location|Medication|Organization|
   Patient|Practitioner|Procedure|Substance) }, // Who and/or what the observation is about
  "focus" : [{ Reference(Any) }], // What the observation is about, when it is not about the sub
ject of record
  "encounter" : { Reference(Encounter) }, // Healthcare event during which this observation is m
ade
  // effective[x]: Clinically relevant time/time-period for observation. One of these 4:
  "effectiveDateTime" : "<dateTime>",
  "effectivePeriod" : { Period },
  "effectiveTiming" : { Timing },
  "effectiveInstant" : "<instant>",
  "issued" : "<instant>", // Date/Time this version was made available
  "performer" : [{ Reference(CareTeam|Organization|Patient|Practitioner|
   PractitionerRole|RelatedPerson) }], // Who is responsible for the observation
  // value[x]: Actual result. One of these 11:
  "valueQuantity" : { Quantity },
  "valueCodeableConcept" : { CodeableConcept },
  "valueString" : "<string>",
  "valueBoolean" : <boolean>,
  "valueInteger" : <integer>,
  "valueRange" : { Range },
  "valueRatio" : { Ratio },
  "valueSampledData" : { SampledData },
  "valueTime" : "<time>",
  "valueDateTime" : "<dateTime>",
  "valuePeriod" : { Period },
  "dataAbsentReason" : { CodeableConcept }, // C? Why the result is missing
  "interpretation" : [{ CodeableConcept }], // High, low, normal, etc.
  "note" : [{ Annotation }], // Comments about the observation
  "bodySite" : { CodeableConcept }, // Observed body part
  "method" : { CodeableConcept }, // How it was done
  "specimen" : { Reference(Specimen) }, // Specimen used for this observation
  "device" : { Reference(Device|DeviceMetric) }, // (Measurement) Device
  "referenceRange" : [{ // Provides guide for interpretation
    "low" : { Quantity(SimpleQuantity) }, // C? Low Range, if relevant
    "high" : { Quantity(SimpleQuantity) }, // C? High Range, if relevant
    "type" : { CodeableConcept }, // Reference range qualifier
    "appliesTo" : [{ CodeableConcept }], // Reference range population
    "age" : { Range }, // Applicable age range, if relevant
    "text" : "<string>" // Text based reference range in an observation
  }],
  "hasMember" : [{ Reference(MolecularSequence|Observation|
   QuestionnaireResponse) }], // Related resource that belongs to the Observation group
  "derivedFrom" : [{ Reference(DocumentReference|ImagingStudy|Media|
   MolecularSequence|Observation|QuestionnaireResponse) }], // Related measurements the observat
ion is made from
  "component" : [{ // Component results
    "code" : { CodeableConcept }, // R!  Type of component observation (code / type)
    // value[x]: Actual component result. One of these 11:
    "valueQuantity" : { Quantity },
    "valueCodeableConcept" : { CodeableConcept },
    "valueString" : "<string>",
    "valueBoolean" : <boolean>,
    "valueInteger" : <integer>,
    "valueRange" : { Range },
    "valueRatio" : { Ratio },
    "valueSampledData" : { SampledData },
    "valueTime" : "<time>",
    "valueDateTime" : "<dateTime>",
    "valuePeriod" : { Period },
    "dataAbsentReason" : { CodeableConcept }, // C? Why the component result is missing
    "interpretation" : [{ CodeableConcept }], // High, low, normal, etc.
    "referenceRange" : [{ Content as for Observation.referenceRange }] // Provides guide for int
erpretation of component result
  }]
}
```

(Source: https://www.hl7.org/fhir/observation.html)

Figure 16: Observation data model

5.8. Group resource

It contains information about different groups that a patient, a practitioner or Related person can be associated to; it is linked to Member and Characteriscs to define who is linked to a specific group (Figure 17).



(Source: https://www.hl7.org/fhir/group.html)

Figure 17: Group entity and its secondary related entities

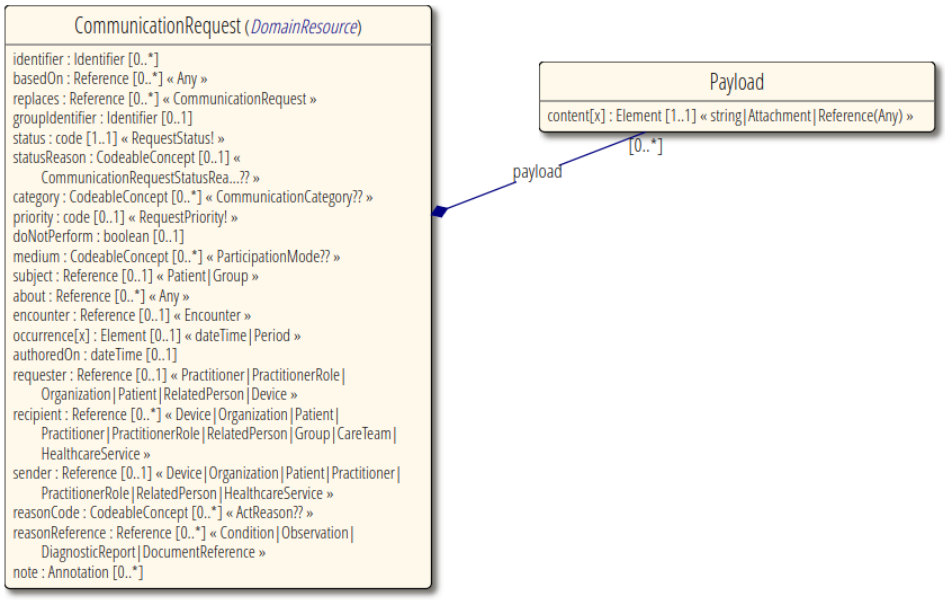
```
{
  "resourceType" : "Group",
  // from Resource: id, meta, implicitRules, and language
  // from DomainResource: text, contained, extension, and modifierExtension
  "identifier" : [{ Identifier }], // Unique id
  "active" : <boolean>, // Whether this group's record is in active use
  "type" : "<code>", // R!  person | animal | practitioner | device | medication | substance
  "actual" : <boolean>, // C? R!  Descriptive or actual
  "code" : { CodeableConcept }, // Kind of Group members
  "name" : "<string>", // Label for Group
  "quantity" : "<unsignedInt>", // Number of members
  "managingEntity" : { Reference(Organization|Practitioner|PractitionerRole|
   RelatedPerson) }, // Entity that is the custodian of the Group's definition
  "characteristic" : [{ // Include / Exclude group members by Trait
    "code" : { CodeableConcept }, // R!  Kind of characteristic
    // value[x]: Value held by characteristic. One of these 5:
    "valueCodeableConcept" : { CodeableConcept },
    "valueBoolean" : <boolean>,
    "valueQuantity" : { Quantity },
    "valueRange" : { Range },
    "valueReference" : { Reference },
    "exclude" : <boolean>, // R!  Group includes or excludes
    "period" : { Period } // Period over which characteristic is tested
  }],
  "member" : [{ // C? Who or what is in group
    "entity" : { Reference(Device|Group|Medication|Patient|Practitioner|
    PractitionerRole|RelatedPerson|Substance) }, // R!  Reference to the group member
    "period" : { Period }, // Period member belonged to the group
    "inactive" : <boolean> // If member is no longer in group
  }]
}
```

(Source: https://www.hl7.org/fhir/group.html)

Figure 18: Group data model

5.9. Communication request resource

The *CommunicationRequest* entity is directly linked with entity payload, its domain is defined as Resource and it's used for notifications in the application (Figure 19). The receivers of the notifications are the health professionals and practitioners.



(Source: https://www.hl7.org/fhir/communicationrequest.html)

Figure 19: CommunicationRequest entity and its secondary related entities

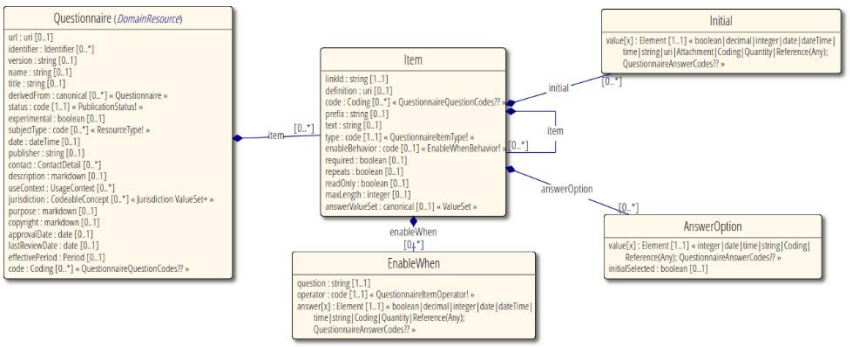
```
{
  "resourceType" : "CommunicationRequest",
  // from Resource: id, meta, implicitRules, and language
  // from DomainResource: text, contained, extension, and modifierExtension
  "identifier" : [{ Identifier }], // Unique identifier
  "basedOn" : [{ Reference(Any) }], // Fulfills plan or proposal
  "replaces" : [{ Reference(CommunicationRequest) }], // Request(s) replaced by this request
  "groupIdentifier" : { Identifier }, // Composite request this is part of
  "status" : "<code>", // R!  draft | active | on-hold | revoked | completed | entered-in-error
| unknown
  "statusReason" : { CodeableConcept }, // Reason for current status
  "category" : [{ CodeableConcept }], // Message category
  "priority" : "<code>", // routine | urgent | asap | stat
  "doNotPerform" : <boolean>, // True if request is prohibiting action
  "medium" : [{ CodeableConcept }], // A channel of communication
  "subject" : { Reference(Group|Patient) }, // Focus of message
  "about" : [{ Reference(Any) }], // Resources that pertain to this communication request
  "encounter" : { Reference(Encounter) }, // Encounter created as part of
  "payload" : [{ // Message payload
    // content[x]: Message part content. One of these 3:
    "contentString" : "<string>"
    "contentAttachment" : { Attachment }
    "contentReference" : { Reference(Any) }
  }],
  // occurrence[x]: When scheduled. One of these 2:
  "occurrenceDateTime" : "<dateTime>",
  "occurrencePeriod" : { Period },
  "authoredOn" : "<dateTime>", // When request transitioned to being actionable
  "requester" : { Reference(Device|Organization|Patient|Practitioner|
   PractitionerRole|RelatedPerson) }, // Who/what is requesting service
  "recipient" : [{ Reference(CareTeam|Device|Group|HealthcareService|
   Organization|Patient|Practitioner|PractitionerRole|RelatedPerson) }], // Message recipient
  "sender" : { Reference(Device|HealthcareService|Organization|Patient|
   Practitioner|PractitionerRole|RelatedPerson) }, // Message sender
  "reasonCode" : [{ CodeableConcept }], // Why is communication needed?
  "reasonReference" : [{ Reference(Condition|DiagnosticReport|
   DocumentReference|Observation) }], // Why is communication needed?
  "note" : [{ Annotation }] // Comments made about communication request
}
```

(Source: [https://www.hl7.org/fhir/communicationrequest.html)](https://www.hl7.org/fhir/communicationrequest.html)

Figure 20: CommunicationRequest data model

5.10. Questionnaires` resource

The Questionnaires entity is directly linked with entities Item, Initial, EnableWhen and AnswerOption, its domain is defined as Resource and is an organized collection of questions intended to solicit information from patients, providers or other individuals involved in the healthcare domain (Figure 21). The questionnaires are sent by the health professionals to the patients and caregivers.



(Source: https://www.hl7.org/fhir/questionnaire.html)

Figure 21: Questionnaire entity and its secondary related entities

```
{
  "resourceType" : "Questionnaire",
  // from Resource: id, meta, implicitRules, and language
  // from DomainResource: text, contained, extension, and modifierExtension
  "url" : "<uri>", // Canonical identifier for this questionnaire, represented as a URI (globall
y unique)
  "identifier" : [{ Identifier }], // Additional identifier for the questionnaire
  "version" : "<string>", // Business version of the questionnaire
  "name" : "<string>", // Name for this questionnaire (computer friendly)
  "title" : "<string>", // Name for this questionnaire (human friendly)
  "derivedFrom" : [{ canonical(Questionnaire) }], // Instantiates protocol or definition
  "status" : "<code>", // R!  draft | active | retired | unknown
  "experimental" : <boolean>, // For testing purposes, not real usage
  "subjectType" : ["<code>"], // Resource that can be subject of QuestionnaireResponse
  "date" : "<dateTime>", // Date last changed
  "publisher" : "<string>", // Name of the publisher (organization or individual)
  "contact" : [{ ContactDetail }], // Contact details for the publisher
  "description" : "<markdown>", // Natural language description of the questionnaire
  "useContext" : [{ UsageContext }], // The context that the content is intended to support
  "jurisdiction" : [{ CodeableConcept }], // Intended jurisdiction for questionnaire (if applica
ble)
  "purpose" : "<markdown>", // Why this questionnaire is defined
  "copyright" : "<markdown>", // Use and/or publishing restrictions
  "approvalDate" : "<date>", // When the questionnaire was approved by publisher
  "lastReviewDate" : "<date>", // When the questionnaire was last reviewed
  "effectivePeriod" : { Period }, // When the questionnaire is expected to be used
  "code" : [{ Coding }], // Concept that represents the overall questionnaire
  "item" : [{ // C? Questions and sections within the Questionnaire
    "linkId" : "<string>", // R!  Unique id for item in questionnaire
    "definition" : "<uri>", // ElementDefinition - details for the item
    "code" : [{ Coding }], // C? Corresponding concept for this item in a terminology
    "prefix" : "<string>", // E.g. "1(a)", "2.5.3"
    "text" : "<string>", // Primary text for the item
    "type" : "<code>", // R!  group | display | boolean | decimal | integer | date | dateTime +
```

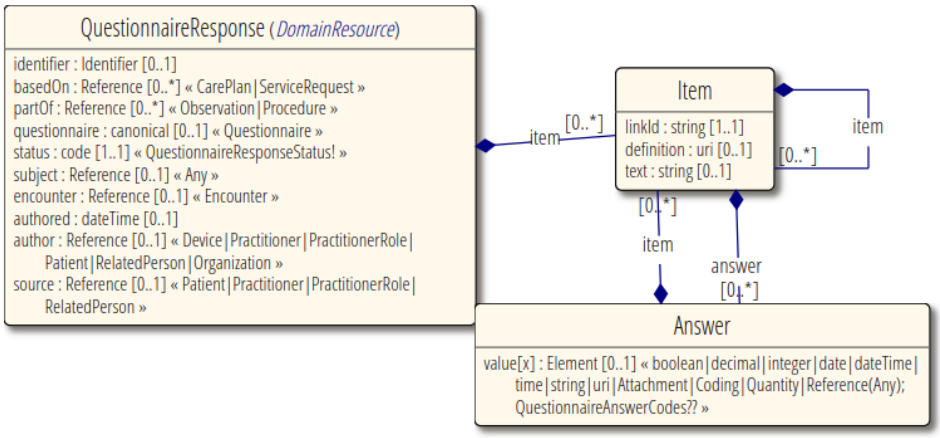
```
    "enableWhen" : [{ // Only allow data when
      "question" : "<string>", // R!  Question that determines whether item is enabled
      "operator" : "<code>", // R!  exists | = | != | > | < | >= | <=
      // answer[x]: Value for question comparison based on operator. One of these 10:
      "answerBoolean" : <boolean>
      "answerDecimal" : <decimal>
      "answerInteger" : <integer>
      "answerDate" : "<date>"
      "answerDateTime" : "<dateTime>"
      "answerTime" : "<time>"
      "answerString" : "<string>"
      "answerCoding" : { Coding }
      "answerQuantity" : { Quantity }
      "answerReference" : { Reference(Any) }
    }],
    "enableBehavior" : "<code>", // C? all | any
    "required" : <boolean>, // C? Whether the item must be included in data results
    "repeats" : <boolean>, // C? Whether the item may repeat
    "readOnly" : <boolean>, // C? Don't allow human editing
    "maxLength" : <integer>, // C? No more than this many characters
    "answerValueSet" : { canonical(ValueSet) }, // C? Valueset containing permitted answers
    "answerOption" : [{ // C? Permitted answer
      // value[x]: Answer value. One of these 6:
      "valueInteger" : <integer>,
      "valueDate" : "<date>",
      "valueTime" : "<time>",
      "valueString" : "<string>",
      "valueCoding" : { Coding },
      "valueReference" : { Reference(Any) },
      "initialSelected" : <boolean> // Whether option is selected by default
    }],
    "initial" : [{ // C? Initial value(s) when item is first rendered
      // value[x]: Actual value for initializing the question. One of these 12:
      "valueBoolean" : <boolean>
      "valueDecimal" : <decimal>
      "valueInteger" : <integer>
      "valueDate" : "<date>"
      "valueDateTime" : "<dateTime>"
      "valueTime" : "<time>"
      "valueString" : "<string>"
      "valueUri" : "<uri>"
      "valueAttachment" : { Attachment }
      "valueCoding" : { Coding }
      "valueQuantity" : { Quantity }
      "valueReference" : { Reference(Any) }
    }],
    "item" : [{ Content as for Questionnaire.item }] // C? Nested questionnaire items
  }]
```

(Source: https://www.hl7.org/fhir/questionnaire.html)

Figure 22: Questionnaire data model

5.11. Questionnaires` response resource

The questionnaire response entity is directly linked with entity Item and Answer, its domain is defined as Resource (Figure 23). It provides a complete or partial list of answers to a set of questions filled when responding to a questionnaire. It contains relevant information about the answers to the questionnaire's questions sent by the health professionals.



(Source: https://www.hl7.org/fhir/questionnaireresponse.html)

Figure 23: Questionnaire response entity and its secondary related entities

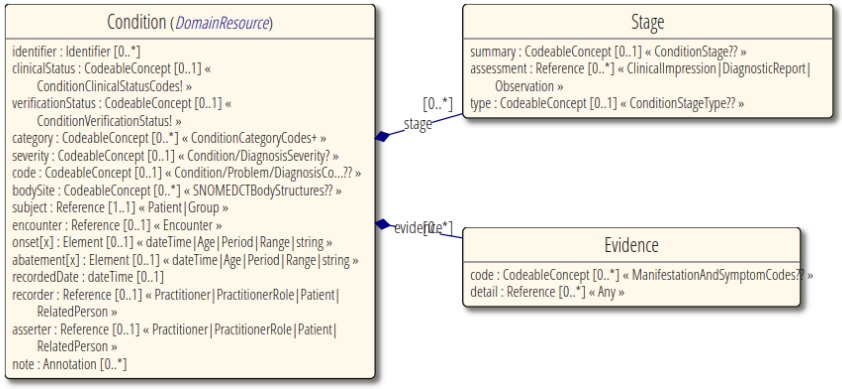
```
{
  "resourceType" : "QuestionnaireResponse",
  // from Resource: id, meta, implicitRules, and language
  // from DomainResource: text, contained, extension, and modifierExtension
  "identifier" : { Identifier }, // Unique id for this set of answers
  "basedOn" : [{ Reference(CarePlan|ServiceRequest) }], // Request fulfilled by this QuestionnaireResponse
  "partOf" : [{ Reference(Observation|Procedure) }], // Part of this action
  "questionnaire" : { canonical(Questionnaire) }, // Form being answered
  "status" : "<code>", // R!  in-progress | completed | amended | entered-in-error | stopped
  "subject" : { Reference(Any) }, // The subject of the questions
  "encounter" : { Reference(Encounter) }, // Encounter created as part of
  "authored" : "<dateTime>", // Date the answers were gathered
  "author" : { Reference(Device|Organization|Patient|Practitioner|
   PractitionerRole|RelatedPerson) }, // Person who received and recorded the answers
  "source" : { Reference(Patient|Practitioner|PractitionerRole|RelatedPerson) }, // The person who answered the questions
  "item" : [{ // Groups and questions
    "linkId" : "<string>", // R!  Pointer to specific item from Questionnaire
    "definition" : "<uri>", // ElementDefinition - details for the item
    "text" : "<string>", // Name for group or question text
    "answer" : [{ // The response(s) to the question
      // value[x]: Single-valued answer to the question. One of these 12:
      "valueBoolean" : <boolean>,
      "valueDecimal" : <decimal>,
      "valueInteger" : <integer>,
      "valueDate" : "<date>",
      "valueDateTime" : "<dateTime>",
      "valueTime" : "<time>",
      "valueString" : "<string>",
      "valueUri" : "<uri>",
      "valueAttachment" : { Attachment },
      "valueCoding" : { Coding },
      "valueQuantity" : { Quantity },
      "valueReference" : { Reference(Any) },
      "item" : [{ Content as for QuestionnaireResponse.item }] // Nested groups and questions
    }],
    "item" : [{ Content as for QuestionnaireResponse.item }] // Nested questionnaire response items
  }]
}
```

(Source: https://www.hl7.org/fhir/questionnaireresponse.html)

Figure 24: Questionnaire response data model

5.12. Condition resource

The condition entity is directly linked with entity stage and evidence, its domain is defined as Resource and contains relevant information about a condition, problem, diagnosis, or other event, situation, issue, or clinical concept related with the patients in his diseases and comorbidities (Figure 25).



(Source: https://www.hl7.org/fhir/condition.html)

Figure 25: Condition entity and its secondary related entities

```
{
  "resourceType" : "Condition",
  // from Resource: id, meta, implicitRules, and language
  // from DomainResource: text, contained, extension, and modifierExtension
  "identifier" : [{ Identifier }], // External Ids for this condition
  "clinicalStatus" : { CodeableConcept }, // C? active | recurrence | relapse | inactive | remis
sion | resolved
  "verificationStatus" : { CodeableConcept }, // C? unconfirmed | provisional | differential | c
onfirmed | refuted | entered-in-error
  "category" : [{ CodeableConcept }], // problem-list-item | encounter-diagnosis
  "severity" : { CodeableConcept }, // Subjective severity of condition
  "code" : { CodeableConcept }, // Identification of the condition, problem or diagnosis
  "bodySite" : [{ CodeableConcept }], // Anatomical location, if relevant
  "subject" : { Reference(Group|Patient) }, // R!  Who has the condition?
  "encounter" : { Reference(Encounter) }, // Encounter created as part of
  // onset[x]: Estimated or actual date,  date-time, or age. One of these 5:
  "onsetDateTime" : "<dateTime>",
  "onsetAge" : { Age },
  "onsetPeriod" : { Period },
  "onsetRange" : { Range },
  "onsetString" : "<string>",
  // abatement[x]: When in resolution/remission. One of these 5:
  "abatementDateTime" : "<dateTime>",
  "abatementAge" : { Age },
  "abatementPeriod" : { Period },
  "abatementRange" : { Range },
  "abatementString" : "<string>",
  "recordedDate" : "<dateTime>", // Date record was first recorded
  "recorder" : { Reference(Patient|Practitioner|PractitionerRole|
   RelatedPerson) }, // Who recorded the condition
  "asserter" : { Reference(Patient|Practitioner|PractitionerRole|
   RelatedPerson) }, // Person who asserts this condition
  "stage" : [{ // Stage/grade, usually assessed formally
    "summary" : { CodeableConcept }, // C? Simple summary (disease specific)
    "assessment" : [{ Reference(ClinicalImpression|DiagnosticReport|Observation) }], // C? Forma
l record of assessment
    "type" : { CodeableConcept } // Kind of staging
  }],
  "evidence" : [{ // Supporting evidence
    "code" : [{ CodeableConcept }], // C? Manifestation/symptom
    "detail" : [{ Reference(Any) }] // C? Supporting information found elsewhere
  }],
  "note" : [{ Annotation }] // Additional information about the Condition
}
```

(Source: https://www.hl7.org/fhir/condition.html)

Figure 26: Condition data model

5.13. Signal

With the explanation of some of the used resources and their internal relations, we can verify that the information is well related and organized, which provides correct and objective data when requested. Since the API provided by the HAPI FHIR is quite flexible (allows the use of several specific parameters to improve the filtering and search), all the data can be easily accessed (depending on the permissions), which enhances the data workflow.

It's important to mention that, first of all, all the data is verified before its storage, which prevents the storage of bad structured or duplicated data. In this case, signal entities are connected to devices, as in Table 3.

Table 3: Devices and signal entities connection

Position-tracker	
Attributes	**Description**
Id	Patient's identifier. Type: text
Session	Session's ID code. Type: text
Client	Client's ID number. Type: integer
SensorID	Sensor's identifier. Type: text
Timestamp	Time-stamp in which data are transmitted. Type: datetime
Rssi	Received signal strength indicator. Type: integer
Mac	Medium Access Control address. Type: text
Location	Geographical location identifier. Type: text
last_time_ping	Date of the last ping received from the remote host. Type: datetime
Sleep-tracker	
Attributes	**Description**
Id	Patient's identifier. Type: text
Session	Session's ID code. Type: text
Client	Client's ID number. Type: integer
SensorID	Sensor's identifier. Type: text
Timestamp	Time-stamp in which data are transmitted. Type: datetime
heart_rate	Number of heart-beats per minute. Type: integer
respiration_rate	Number of breaths per minute. Type: integer
snoring_rate	Snoring intensity. Type: integer
sleep_state	Indicates the sleep state of the individual. Type: integer
device_name	Device's name. Type: text

Voice-tracker sub module	
Attributes	**Description**
id	Patient's identifier. Type: text
SensorID	Sensor's identifier. Type: text
predicted_class	Predicted voice's class. Type: text
timestamp	Time-stamp in which data are transmitted. Type: datetime
score	Voice-tracker's score. Type: float
features	Voice-tracker's features (e.g. MIC level, Frequency response, Physical dimensions). Type: list
Physical-tracking (wristband)	
Attributes	**Description**
id	Patient's identifier. Type: text
Band_ID	Band's identifier. Type: text
Client	Client's ID number. Type: integer
SensorID	Sensor's identifier. Type: text
timestamp	Time-stamp in which data are transmitted. Type: datetime
Move_evolution	Movement identifier. Type: text
Bio-measures	Biological measurements (e.g. blood pressure, height, weight). Type: text
Azure Kinect / Kinect v02	
Attributes	**Description**
id	Patient's identifier. Type: text
Skeleton ID	Skeleton's identifier. Type: integer
SensorID	Sensor's identifier. Type: text
timestamp	Time-stamp in which data are transmitted. Type: datetime
Move_evolution	Bodies' Coordinates. Type: float
Measures	Fall

6 Conclusions

In order to reach the true potential by technology-based services, people not only need to come to use it but also need to express their wishes and needs in order to allow the sustainable development of new tools and services by the use of those technologies. TeNDER user requirements were gathered throughout all system development phases, from the beginning of the project and continuous involvement has been enabled within the piloting testing phases. A common view of the user requirements was constantly collected by partners performing the fieldwork and the additional methodology for piloting with focus groups is presented as a part of co-design methodology. Moreover, several stakeholders were included in an observational study to collect further requirements and analyse the individualized needs and finally, the observations during the testing piloting phase have also been performed with individuals as primary and/or secondary users.

The TeNDER final architecture was released and herein we report the final data model for TeNDER. Dedicated contributions from patients with different neurological diseases, their carers, medical bodies, professionals, social workers and other relevant stakeholders were included in the requirements that were internally reported and discussed. This final data model has four new resources which are Communication request, Questionnaires, Questionnaires' response and the Condition. The Communication request was added to deal with notifications in the application to notify health professionals and practitioners. Questionnaires and Questionnaires' response data models are used for the health professionals to solicit information from the patients, carers or other individuals involved in the healthcare domain. To conclude, the data model Condition has relevant information about a condition, problem, diagnosis, or other event, situation, issue, or clinical concept related with the patients in his diseases and comorbidities.

7 References

1. Sim, J., Waterfield, J. Focus group methodology: some ethical challenges. Qual Quant 53, 3003–3022 (2019). https://doi.org/10.1007/s11135-019-00914-5
2. TeNDER Deliverable 2.1. 2020. First version of User Requirements and Data Model; affecTive basEd iNtegrateD carE for betteR Quality of Life: TeNDER Project, Grant Agreement ID: 875325, Funded under programme(s): H2020-SC1-DTH-2018-2020/H2020-SC1-DTH-2019, Topic: SC1-DTH-11-2019 Large Scale pilots of personalised & outcome based integrated care, Funding Scheme: IA - Innovation action. 24. March 2020.
3. TeNDER Deliverable 2.2. 2020. Report on TeNDER Services Provision; affecTive basEd iNtegrateD carE for betteR Quality of Life: TeNDER Project, Grant Agreement ID: 875325, Funded under programme(s): H2020-SC1-DTH-2018-2020/H2020-SC1-DTH-2019, Topic: SC1-DTH-11-2019 Large Scale pilots of personalised & outcome based integrated care, Funding Scheme: IA - Innovation action. 30 June 2020.
4. TeNDER Deliverable 2.3. 2020. First version of TeNDER Architecture Blueprint, Pilots definition; affecTive basEd iNtegrateD carE for betteR Quality of Life: TeNDER Project, Grant Agreement ID: 875325, Funded under programme(s): H2020-SC1-DTH-2018-2020/H2020-SC1-DTH-2019, Topic: SC1-DTH-11-2019 Large Scale pilots of personalised & outcome based integrated care, Funding Scheme: IA - Innovation action. 31. October 2020.
5. TeNDER Deliverable 2.4. 2021. Intermediate version of User Requirements and Data Model; affecTive basEd iNtegrateD carE for betteR Quality of Life: TeNDER Project, Grant Agreement ID: 875325, Funded under programme(s): H2020-SC1-DTH-2018-2020/H2020-SC1-DTH-2019, Topic: SC1-DTH-11-2019 Large Scale pilots of personalised & outcome based integrated care, Funding Scheme: IA - Innovation action. 31. May 2021.
6. TeNDER Deliverable 2.5. 2022. Final version of User Requirements and Data Model; affecTive basEd iNtegrateD carE for betteR Quality of Life: TeNDER Project, Grant Agreement ID: 875325, Funded under programme(s): H2020-SC1-DTH-2018-2020/H2020-SC1-DTH-2019, Topic: SC1-DTH-11-2019 Large Scale pilots of personalised & outcome based integrated care, Funding Scheme: IA - Innovation action. 29. July 2022.
7. TeNDER Report 3 Evaluation Strategy and Protocols; affecTive basEd iNtegrateD carE for betteR Quality of Life: TeNDER Project, Grant Agreement ID: 875325, Funded under programme(s): H2020-SC1-DTH-2018-2020/H2020-SC1-DTH-2019, Topic: SC1-DTH-11-2019 Large Scale pilots of personalised & outcome based integrated care, Funding Scheme: IA - Innovation action. 8. September 2022.

ANNEX I

Script to be followed by the moderator:

GROUP 1: Patients

Experience with the use of the TeNDER App. The objective is to briefly explore their experience of use, since they started using TeNDER App. To find out if they needed support from a carer and/or professional during the experience.

In order to do so, the following questions are proposed:

1. How would you describe your experience about using this tool? Have you found it difficult? Have you needed help to use it?

Skills needed. If they say that they have found it difficult or have needed help, explore which aspects of the use they have found more or less difficult.

To this end, we propose to ask the following question:

2. What did you find most complex about using the tool, and how could it be improved?

Communication with the carer and healthcare professional. To know their opinion and assessment of the communication.

In order to do so, the following questions are proposed:

3. How do you value the communication with your relatives or contact persons through the tool? And with your health professionals? Have you felt closer to them?

Connection with professionals. Explore the usability aspect of the connection, communication they have had with their professionals.

In order to do so, the following questions are proposed:

4. With the use of the tool, have you had more contacts with your health professionals than usual? How do you assess this result?

Contacts or consultations with care services. To know if during the time of using TeNDER they have visited the hospital, emergency or use other services more or less frequently than without the tool (compare before and during the use of TeNDER).

In order to do so, the following questions are proposed:

5. During the time you have used the tool, have you visited the hospital, emergency or other services? Do you think that the number of emergency and hospital consultations could be reduced with a sustained use of TeNDER? In what way?

Quality of life. Explore changes before and during the use of TeNDER.

In order to do so, the following questions are proposed:

6. What improvements in your quality of life has this tool brought? Do you think the tool could improve your quality of life? In what way?

GROUP 2: Carers

Experience with using the TeNDER App or platform (for formal carers). The objective is to briefly explore their experience of using it. To know if they needed support to manage it.

In order to do so, the following questions are proposed:

1. How would you describe your experience about using this tool? Have you found it difficult? Have you needed help to use it?

Skills needed. If they say that they have found it difficult or have needed help, explore which aspects they have found more or less difficult.

To this end, we propose to ask the following question:

7. What did you find most complex about using the tool, and how could it be improved?

Communication with healthcare professionals. To know their opinion and assessment of the communication.

In order to do so, the following questions are proposed:

8. How do you value the communication with the health professionals who take care of the person you care for? Have you felt closer to them?

Connection with professionals. Explore the connection, communication they have had with professionals.

In order to do so, the following questions are proposed:

9. With the use of the tool, have you had more contacts with health professionals than usual in relation to the person you care for? How do you value this result?

Contacts or consultations with care services. To know if during the time of use of TeNDER the people they take care of, have visited the hospital, emergency services or use other services more or less frequently than without the tool (compare before and during the use of TeNDER).

In order to do so, the following questions are proposed:

10. During the time you have been using the tool, has the person you are dealing with needed to go to hospital, emergency or other services? Do you think that the number of emergency and hospital consultations could be reduced with a sustained use of TeNDER? In what way?

Quality of life. Explore changes before and during the use of TeNDER.

In order to do so, the following questions are proposed:

11. What improvements has TeNDER achieved in the quality of life of the people you care for? Do you think that the continued use of the tool could also improve your quality of life and make your task as a carer easier? In what way?

GROUP 3: Professionals

Experience with using the TeNDER WebApp. The objective is to briefly explore their experience of using it. To know if they needed support to manage it.

In order to do so, the following questions are proposed:

2. How would you describe your experience about using this tool? Have you found it difficult? Have you needed help to use it?

Skills needed. If they say that they have found it difficult or have needed help, explore which aspects of the use of the platform they have found more or less difficult.

To this end, we propose to ask the following question:

12. What did you find most complex about using the tool, and how could it be improved?

Connections with patients and carers. To know their opinion and assessment.

In order to do so, the following questions are proposed:

13. How do you value the communication with patients and carers through the platform? How have you lived that experience? How could it be improved?

Contacts or consultations with health services. To know if during the time of using TeNDER your patients have visited health services more or less frequently than without the tool (compare before and during the use of TeNDER).

In order to do so, the following questions are proposed:

14. Do you think that the number of consultations has changed in those patients who used the tool? Do you think that consultations could be reduced with a sustained use of TeNDER?

Quality of life. Explore changes before and during the use of TeNDER.

In order to do so, the following questions are proposed:

15. Could you mention any improvement in the quality of life of your patients who have used TeNDER? Do you think that the sustained use of the tool could improve it?

Changes in working conditions: Explore changes before and during the use of TeNDER.

In order to do so, the following questions are proposed:

16. Do you think TeNDER has made it easier for you to care for this type of patient, and how could it be improved?