Acronym:	vINCI
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D3.2. Profile and Behaviour Models

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Project Partners:

[1] L = legal agreement, O = other, P = plan, PR = prototype, R = report, U = user scenario

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

Partner list:

No.	Partner name	Short name	Org. type	Country
1	National Institute for Research and Development in Informatics	ICI	R&D	Romania
2	Marche Polytechnic University	MPU	R&D	Italy
3	University of Nicosia Research Foundation	UNRF	R&D	Cyprus
4	National Institute of Telecommunications	NIT	R&D	Poland
5	Connected Medical Devices	CMD	SME	Romania
6	Automa Srl	AUT	SME	Italy
7	Optima Molliter (f. Salvatelli) Srl	SAL	SME	Italy
8	National Institute of Gerontology and Geriatrics “Ana Aslan”	NIGG	R&D	Romania
9	Comtrade Digital Services	CTR	Large enterprise	Slovenia

Revision History

Rev.	Date	Partner	Description	Name
1	05.12.2019	ICI	Created the template, added the sections and content	Lidia Bajenaru

1. Introduction

The main objective of the vINCI project is to propose and implement an integrated Internet of Things (IoT) framework that is able to improve professional healthcare by offering monitoring and support for the elderly. This naturally leads to a better quality of life (QoL) and increase in the active aging of the users of the platform. The beneficiaries of vINCI are mainly older adults with and without Mild Cognitive Impairments, which are clinically evaluated first through the DSM5 and ICD-11 criteria [Băjenaru, O., 2012].

The final goal of vINCI is to demonstrate a systematic approach to ensure the highest level of quality control, automated monitoring, and data governance. As such, in the vINCI platform, the older adult is monitored through a set of extensible technologies. Each individual recording is stored and analysed to automatic extraction of features (information) to be used in the detection of deterioration of symptoms associated with old age.

We introduce a novel approach for providing personalized assistance services for patients in an IoT-based eco-system. Our approach is based on an innovative study which uses a holistic view to assess the healthcare needs and preferences of selected elderly with chronic diseases.

1.1. The elderly patient profile in the context of preventive monitoring

The rapid global development of Internet and web technologies is a source of action for a new generation of healthcare applications, but providing systems that meet the needs of health stakeholders is still an open issue. One of the main issues in this area is the personalization of healthcare, i.e. enabling personalized healthcare services to be delivered to individuals at any place and any time.

With personalized healthcare, we can still get an early health system in which disease is approached as soon as possible, rather than a “late illness” model, where the focus is mainly on diagnosis and treatment. In order to get the personalization of healthcare, various factors, such as the individual’s lifestyle, surrounding situations, device capabilities etc., should be considered. Such personalization factors are known as the context, which refers to any information that can be used to characterize the situation of a person, a place or a computing object and the interaction between them. As a result, personalized healthcare request is contextual information on the provision of medical information based on the user’s changing context so that accurate information can be delivered to the right person at the right time and using the correct means. There is a necessity of deploying better assistive care for older people in order to create age-friendly environments, personalized treatments and support, appropriate medical devices and access to upgraded knowledge and information [Christensen, K. et al, 2009].

In this context, the new digital technologies have a critical role and the potential to sustain the implementation of new elderly-centred solutions. A digital ecosystem should be based on a holistic approach able to link and interconnect multiple healthcare domains, patient-centred insights, and technologies [Elissen, A. et al, 2016].

The old person must be seen from a new and comprehensive perspective that encompasses not only the improvement or preservation of their health, but also a continuous and personalized assistive care, active and preventative support from a broader range of healthcare specialists and informal caretakers, and, last but not least, digital technologies able to sustain the empowerment of the elderly and the management of the personal care and healthcare system. In the last years, there has been an increased use of assistive-based technologies to aid older people with cognitive impairments. These applications aim to enhance the patient's quality of life, but not many of them provide some form of personalized service.

1.2. Specific requirements for the elderly's healthcare and wellness

The elderly are much more likely to suffer from health deteriorations than other groups of population. Multiple chronic diseases and cognitive, physical and mobility impairments, lead to the necessity of increased access to healthcare services, personal assistance, environmental changes (like adapting the home to a specific dysfunctionality) or even a growing number of nursing homes and better ageing- specialized caretakers.

An integrated, personalized and elderly-centered assistive care provided by multidisciplinary healthcare specialists, supported by digital technology able to provide customized, in real-time assistance that is also focused on prevention and well-being of the elderly is the efficient solution to meet the needs and requirements of the ageing population at cognitive, physical, spiritual and social level.

In the same time, the health specialists have also new expectations for providing appropriate care for elderly, many of them being sustained by digital technology. Among the most important ones are: having access to updated health summaries (health data indicating the patient's current status, medical history), alarm triggers, analytics able to create a personalized predictive care model, evidence-based decision support etc.

It has become compulsory both for the elderly and healthcare professionals to be better engaged in identifying the most appropriate digital technology that can meet their personal needs for care, and not the average and perceive ones.

The health data associated with the elderly group is big, complex, diverse and usually, unstructured. Aggregating this data, processing and using it represent a challenge which can be tackled through an improved interoperability.

The growing use of wearable devices and the Internet of Things (IoT) for monitoring the elderly has demonstrated how valuable they are for a timely and accurate identification of health parameters, environmental indicators or safety marks. These already heterogenous measured issues can be colligated with data and information from personal health history or from other external sources and thus a manifold amount of data has to be analyzed and processed. Big Data and Big Data Analytics, cloud computing, machine learning, cognitive computing and blockchain technology are commonly used for dealing this type of data [Bessis, N. et al, 2014].

Health data rises important issues regarding data security and privacy. Moreover, the direct involvement of the elderly in the use of digital technology regarding the gathering and transmission of their personal data can induce greater risks. That is why a specific attention has to be put in designing health digital devices that can be personalized according to possible physical and cognitive impairments.

1.3. Specific needs for the elderly's healthcare

An elderly-friendly digital ecosystem can be defined as an infrastructure comprising healthcare taskforce (physicians, formal caretakers, pharmacists, or any health practitioner), health service and product providers involved in delivering healthcare for elderly, the entities to which they belong, direct or indirect beneficiaries of healthcare (elderly and their families, informal caretakers, organizational entities) and, moreover, the digital, legal and social environments that allow all the above to work and interact.

This type of ecosystem has as main core the elderly population in the context of the global ageing and it should support the hierarchical inter-connection, the data, information and knowledge sharing, the customization of assistive care and technology for an improved health service delivery, the continuous deployment of better healthcare models, the digital-based interaction and cooperation.

A properly established digital ecosystem has the potential of manipulating the health data at large scale, and, consequently, to better sustain early diagnosis, faster decision making and preventative measures.

An elderly-friendly digital ecosystem should also encompasses interoperable ICT systems that can address the consistent changing necessities of the older population and the implementing of an appropriate infrastructure prepared to support the real-time monitoring and care of the elderly, complex diagnosis, evidence-based decision making, health data and information processing.

A flexible, distributed and modular architecture of the digital ecosystem is a basic need for a scalable solution that allows new functionalities, like decision support tools.

A challenge that can no more be minimalized is the elderly patient involvement in the digital ecosystem. Firstly, he / she should have an easy and affordable access to digital tools that grant them a virtual connection with the healthcare providers, like setting an appointment in a hospital or a direct dialogue with the physician.

Secondly, elderly-cantered interoperable solutions should be implemented for providing assistive healthcare in terms on monitoring, support, prevention and alert.

Digital technology designed for a personalized assistive care for the elderly represents a reliable support designed to replace, supplement or recover the diminished or lost physical or cognitive functions and skills of the elderly, helping them to avoid many degradations related to the quality of life.

Being more accustomed with the daily use of digital technology, the nowadays the elderly are open to integrate diverse healthcare devices in their lives, as long as they are non-intrusive, affordable, easy accessible and, preferable, customized according to their own age-related dysfunctionalities.

A holistic approach for creating an elderly-centered digital ecosystem should lead to a new model of decentralized healthcare in which the quality of life of the older patients increases through a real-time access to medical services and monitoring in familiar and personalized environment, a prolonged independence and social involvement. The health organizations should become more efficient both from the point of view of provided medical services, but also from reduced costs.

Due to urbanization and the gap between generations, elders are ignored and face many problems and adaptation difficulties and adapt to them differently. Lack of social security, loss of social importance, lack of enough income to take care of health, are some of these issues. The needs and problems of the elderly vary significantly depending on age, health, social status and other background characteristics. Common problems for the elderly are: energy depletion and decreased mental abilities, physical weakness that leads to addiction to others. Support for the elderly involves both physical, mental, social and behavioral assistance that responds to the needs, frustrations and inner conflicts that can bring balance to them [Kotwal, N. et al, 2009].

The needs or essential requirements for health and wellbeing of older people can be classified as physical, intellectual, emotional and social needs.

The physical needs are: nutrition, medical care, mobility, safety. Stimulation, knowledge of illness, opportunities to learn new activities are the intellectual needs, and among the emotional needs: sense of belonging, sense of autonomy, feeling care for positive self-concept. The identified social needs are: communication, social interaction outside the family, relationships with family and friends.

Some of these needs are common to most adults, but these needs can change over the various stages of life that the elderly go through. Some people have specific needs and may require support from health services and social services to meet these needs.

The process, in which users' needs, desires and limitations are investigated and analyzed helps to develop an in-depth understanding of the limitations and requirements of the age group of patients, leads to the development of the user profile [Elissen, A. et al, 2016].

The developers of healthcare products that meet the requirements of the elderly have to: analyze / understand the challenges and requirements of the elders, study and implement methods of making information communication technologies (ICT) accessible to elder user group, model and integrate preferences of the elder population segment into health technologies, and evaluate outcomes. The potential positive effects of a non-invasive IT solution include: better respect for recommended care, extensive health awareness, and increased awareness of the use of social support available by the elderly. These effects could improve clinical outcomes and improve the quality of life of older people.

In the last years, there has been an increased use of assistive based technologies to aid older people with cognitive impairments. These applications aim to enhance the patient’s quality of life, but no many provide some form of personalized service [Sposaro, F. et al, 2010].

1.4. Expectations for personalized healthcare

The nowadays elderly has improved IT and health literacy. That means they are more informed and interested in the management of their health, they have better access to up-to-date medical knowledge, they are familiar with digital technologies and more willingly to use them daily. Elderly persons have increased chances to reach the retirement age in good health and to preserve their independence and active life more time than 20 years ago. Therefore, they tend to invest in diverse means and devices able to sustain them in daily activities, social life, or healthcare support.

Ageing implies at different degrees the deterioration of health conditions in terms of cognitive, physical or mobility impairments. Every elderly person has specific particularities given by the

existing co-morbidities, the number and the level of the age-related degenerative issues. All these require assistive care which can be obtained through personal involvement, caretakers, institutionalization or assistive technologies. A personalized assistive care can support a minimal injury of everyday life, health and safety and has the potential to postpone a costly institutionalization. This type of care should consider both the transitory episodes and the permanent specialized healthcare requirements and should involve multiple medical disciplines.

Giving the uniqueness of each individual elderly, his / her empowerment regarding the personal involvement in the management of health conditions, the shift from the conventional healthcare model towards the preventative and elderly-centered one, a new personalized assistive care model should be implemented. Based on data and information acquired from daily activities, personal history and periodical health measurements, a patient profile can be created and updated continuously in order to provide personalized assistive care for improving the efficiency of the health services.

2. Patient profile to personalized assistive care

The elderly are the fastest growing segment today in our society. Performing a multidimensional geriatric assessment is the first step in the management of older patients in primary care practice. While geriatric conditions are considered by older patients and health professionals as particularly relevant for health and well-being, they remain too often overlooked due to many patient- and physician-related factors such as:

- Time constraints;
- Lack of specific training to undertake comprehensive geriatric assessment.

Comprehensive geriatric assessment involves the evaluation of the physical, psychosocial and environmental factors that impact on the well-being of older adults, respectively Quality of Life (QoL).

“Quality of life” has been defined in many ways [McSweeny, A. J. et al, 1995]. Our work for designing a patient’s profile, highly relevant for an ecosystem supporting people approaching old age, has been done in the framework of the vINCI AAL project.

vINCI is about holistic integration of AAL technologies. As a patient, you would be wearing a completely trendy and non-intrusive watch, THL One. Or, you will be monitored by depth-sensors for in-door situations. On the processing side, each patient is described by a cognitive profile or a model that we describe below.

Before enrolling into vINCI professional caregiving, you are first interviewed by your professional caregiver, with a series of questions, to construct your QoL profile, and establish a clear medical ground for delivering the most appropriate vINCI support (appropriate IoT kits for the prescribed QoL intervention). Next, in time, as you start using more vINCI, your data from the sensing device is put to use, such that vINCI automatically learns your personal preferences (e.g. daily walking routine). This personalized model is further used to establish a normal from a stressful activity. When EKG is monitored, if you are feeling lost, your heart rate gets off the charts, and so by comparison an alarm will be raised. When you are wandering from your typical daily walking routine, another alarm is raised. Such alarms are received by your caregiver, who will take the most suitable action: either phone you to see what happened, or in safety-related cases he can even alarm the closest rescuing / response units. And, in all this time, your caregiver

will, even if remotely, be able to know through a dedicated dashboard your current position and wellbeing.

The same model is delivered as objective evidence of whether a QoL intervention produces the desired QoL improvement, or it has to be adjusted. For these example scenarios, vINCI puts the patients entirely in control of their health data. The patient is able to specify what alarms can be seen by whom, what data is to be sent to whom. For example, as a patient you might feel more secure if you do not show your location to everyone in the family, but prefer to share it only with your caregiver. You might even specify that alarms should be triggered only to a professional medical caregiver (you might not want to alert your family of potential threats). The vINCI network ensures that all the data is secured, such that outside the caregiver nobody will be able to track your whereabouts. And, finally, as a patient you will not be bothered with a lot of annoying interface-related messages the data is collected automatically, and alerts are triggered for your caregiver.

This project aims, as such, to enhance older adults' active ageing and, as a result, their QoL through technology. The patient's profile design is very important as a strategy for designing the products and health care information technology systems [LeRouge, C. et al, 2013a; Elissen, A. et al, 2016]. Many health solutions require active participation by an informed patient for the treatment to be successful [LeRouge, C. et al., 2013a].

The patient' needs, requirements and capabilities in the development of the patient's profile model are obtained from multiple technics such as: professionals' observation, interviews, analyse context etc. Personalized applications for assisting the elderly are a challenge to meet the needs of patients [Skillen, K. et al., 2012; Nijland, N., et al, 2008].

2.1. The patient profile – first step

The attributes presented in this model are derived from the literature, description of our technology, health care literature, and data from this study.

The schema for identifying patient profile attributes that are important to reach our conceptual vINCI user model is shown in Figure 1.

Our model demonstrates that the technical, demographic, health issues and QoL domains must be considered to adequately capture the complete pattern of vINCI users.

The basic common demographic characteristics [Schwendeman, C., 2006] captured by a group of users of interest include:

- Contact information (Name, Phone, Address)
- Date of birth, gender
- Educational level
- Emergency contact information, family doctor, insurance provider data
- al.ergies, major diagnoses, major medical history, disabilities (if any)
- Living status (homeowner or renter)
- Visual, auditory, mobility condition.

Additional profile attributes that have been shown to be relevant to technology usability [Carpenter, B.D. et al., 2007, Helsper, E., 2009, Turner, P. et al., 2007, Charness, N. et al., 2009] and that we use in this study include:

- Environment of use (hospital, home)
- Computer skills
- Attitude towards technology
- Frequency of application use
- Other applications used.

"Traditional" user profile does not recognize psychological / psychosocial traits within people and their impact on health choices and outcomes.

Thus, they fail to recognize research that indicates that cognitive and behavioural patterns of perception and action can affect both short-term and long-term success with interventions directed to managing a disease or adopting health [Navarro, F., 1990].

Thus, the following features [van Dam, H.A. et al., 2003], [Barrera, M. et al., 2002], health issues have been added:

- Clinical data
- Chronic illness detection and diagnosis
- Knowledge of specific diseases
- Current practices in managing health care
- Behaviour
- Attitude towards providers.

According to the World Health Organization (WHO) definition [United Nations, 2015], Quality of Life represents the individual's perception of their position in life in the context of their culture and values systems and their goals, expectations, standards and concerns. It comprises a broad range of parameters reflecting from the person's physical health, psychological state, personal beliefs, social relationships, to his relationships and to main features of surrounding environment.

In the Quality of Life research, health is one of the most important social factor nominated by the population in setting their living standards [Baromètre santé, 2005]. Thus, based on this empirical evidence, it was considered justified to include health among the QoL dimensions or among the factors that decisively influence QoL [Bowling, A., 2004].

Health-related Quality of Life (HQRL) is a concept of Quality of Life related to health, pathology, illness or health model, including al. aspects of QoL that influence functional, physical and emotional health status [Beaumont, J. G., et al., 2004].

The objective of vINCI is to enhance older adults' active aging and, as a result, their QoL through technology.

With selected questionnaires, QoL will be measured for older adults without mild cognitive impairment over the project period repeatedly at set times.

The patient profile will be supplemented with QoL information on the following domains:

- Physical health
- Social interaction
- Psychosocial health
- Wellbeing
- Behaviour
- Environment interaction
- Spiritual beliefs
- Autonomy.

Quality of life provides a broad and flexible framework to identify common elements and factors that influence the quality of life of old age. From the studies so far, the following features of QoL can be distinguished: 1) QoL is multidimensional, there is no limit or convention in its specific fields; 2) It is a dynamic concept in which each dimension can be evaluated differently from one person to another, depending on the context, from where the measurement challenges. 3) The values attached to each dimension can change over time due to changes in life and life experience.

The patient data collection and monitoring devices (smartwatch, smart shoes, depth cameras) proposed in the project also provide specific information related to the patient.

The patient is monitored via the smart watch and the smart shoes at predefined time intervals. Also, the patient has to visit a specially-designed room, where he needs to perform some activities in front of depth camera. The data provided by each of these devices complements the patient's profile. This is the dynamic component of the model.

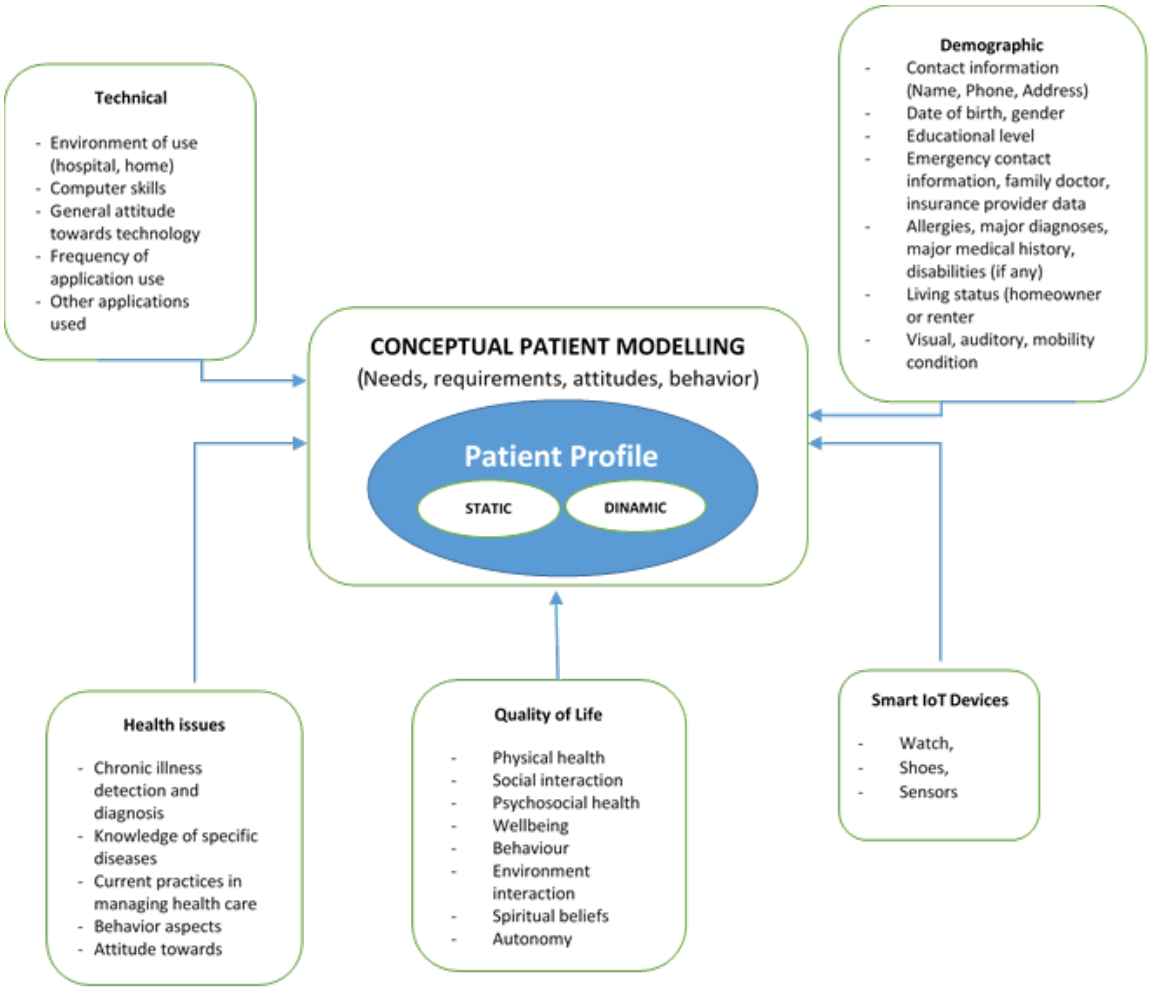

Figure 1. Conceptual model of the patient profile

2.2. The patient' requirements

The patient' needs, requirements and capabilities in the development of the patient's profile model are obtained from multiple technics such as: professionals' observation, interviews, analyse context, etc. (Figure 2).

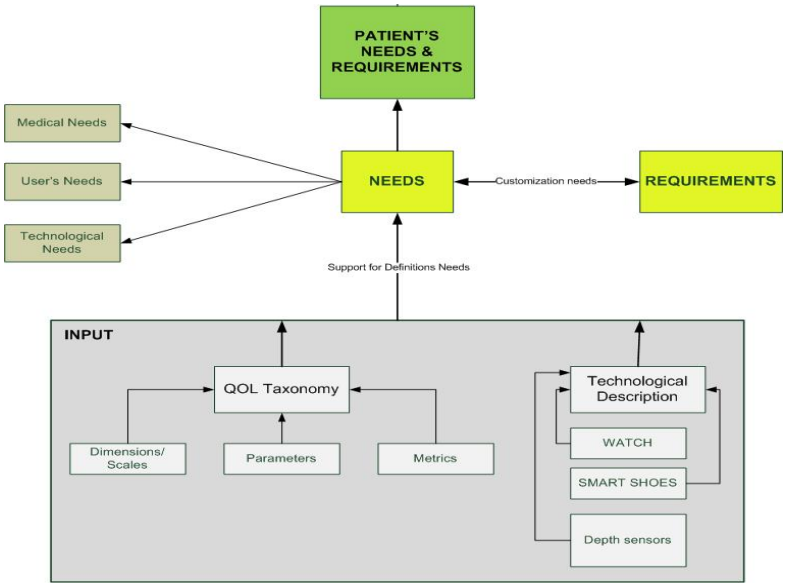

Figure 2. The patient's needs, requirements – a component of patient's profile

INPUT

- The static profile of the patient: Seniors without severe impairments
- QOL Taxonomy: Dimensions, Parameters, Metrics
- Technological Description for: Smart Watch, Smart Shoes, Depth Sensors

Steps for defining user's needs:

1. Definition of target group (identifying end - users)
2. Defining / establishing / understanding the context
3. Understanding and defining the needs of the target group

User needs can be structured in the following dimensions:

- Medical Needs: Identifying and understanding the medical needs for the target group by medical staff
  - Methods: Self-documentation, interviews, online survey
  - Target: Medical staff
- User's Needs:
  - Identification of the end user's subjective medical needs
    - Methods: Self-documentation, online survey, persona (profile of archetypical end-user), questionnaires, context analyse
    - Target: end user
  - Identifying how the user's medical needs can be met by the system
    - Methods: Self-documentation, online survey, questionnaires, context analyse
    - Target: end user
  - Technological Needs: Identifying technological needs
    - Methods: Self-documentation, questionnaires, context analyse

- Target: Technical staff.

The analysis and modelling of the captured information, using different techniques can provide descriptions about lifestyle, changes in clinical and behavioural dynamics of the patient and other complex information about each person.

The data analysis will lead to lifestyle description, information about changes in clinical and behavioural dynamics of the patient.

This analysis al.ows the building of formal model of the patient's lifestyle and of the patient's behavioural, clinical and biological dynamics, which will be integrated in the computer-based systems.

This contributes to improve the diagnosis and management of geriatric syndrome in primary care, as well as to increased levels of wellbeing, QoL and perceived health.

For vINCI care, the patient profile will be the input to provide personalized support for daily / medical activities. Finally, the patient profile will be used as evidence to evaluate the impact of vINCI on the perceived QoL level, allowing a proper adjustment (if needed) of the intervention support being provided by caregivers.

Studies and research have revealed the necessity of deploying better assistive care for older people that is up to create age-friendly environments, personalized treatments and support, appropriate medical devices and access to upgrade knowledge and information.

The patient's profile design is very important as a strategy for designing the products and health care information technology systems. Many health solutions require active participation of an informed patient for the treatment to be successful.

In the last years, there has been an increased use of assistive based technologies to aid older people with cognitive impairments. These applications aim to enhance the patient's quality of life, but no many provide some form of personalized service.

vINCI project proposes a novel approach for providing personalized assistance services for patients in an IoT-based ecosystem. For vINCI care, the user profile will be the input to provide personalized support for daily / medical activities. The profile will be used as evidence to evaluate the impact of vINCI on the perceived QoL level, allowing a proper adjustment (if needed) of the intervention support provided by caregivers.

In this study, we seek to investigate the utility of user profile as a methodological tool to develop an in-depth understanding of the limitations and possibilities of the aged patient population. The resultant conceptual model of the aged patients can be leveraged to inform design and development decisions of vINCI.

The patient profile attributes presented are derived from the literature, description of our technology, health care literature, and data from this project. At the same time, the attributes of the presented patient profile will form the basis of the VINCI conceptual model for user profile.

Our model demonstrates that the technical, demographic, health issues and QoL domains must be considered to adequately capture the complete pattern of vINCI users.

The patient' needs, requirements and capabilities in the development of the patient's profile model have been investigated in this phase also. They are obtained from multiple technics such as: professionals' observation, interviews, analyse context, etc

2.3. Medical Patient profile-finished model of pilot from Romania – second step

The Pilot Study will be performed on 60 persons 65 years of age and older, 30 for control group and 30 for test group. Before entering the Pilot Study a total of 140 patients will be screened using Recruitment Form and Digital Skills Questionnaire.

All consecutive patients 65 years of age and older admitted to NIGG - Geriatrics and Gerontology Inpatients Department on referral from general practitioners or other specialist for various chronic or subacute conditions will be considered for inclusion in the Pilot Study and then evaluated against exclusion criteria.

A questionnaire recruitment form was defined to establish the target group of the study for Data collection.

The **inclusion criteria** will apply to both acceptability and validation studies and both study and control groups and will be the following:

- age ≥ 65 years;
- presence of digital skills;
- signed Informed Consent;
- preserved basic functional independence;
- adequate compliance with study protocol.

All potential participants will fill in a Digital Skills Questionnaire (DSQ) to evaluate their computer and technological literacy. Seniors who will score low on the DSQ will be excluded from inclusion in the study group.

Prior to study initialization, all seniors will sign the Informed Consent form (Annex 7). The persons who do not sign the Informed Consent will be excluded.

The **exclusion criteria** will apply to both acceptability and validation studies and both study and control groups and will be the following:

- subjects not living in the catchment area (Bucharest);
- any acute medical condition;
- any surgery in the last 3 months;
- major neurocognitive disorder, moderate and severe depression;
- existing disability (needs human help in one or more basic activities of daily living);
- angina pectoris;
- uncontrolled high blood pressure;
- heart arrhythmias that could interfere with functionality;
- any terminal illness;
- frailty syndrome, risk of falls;
- any condition that might limit mobility (e.g. Parkinson disease, severe arthritis, stroke sequela);
- visual impairment (best corrected visual acuity of worse than either 20/40 or 20/60).

Exclusion criteria will be documented by medical examination, anamnesis and from patients' medical charts and documented medical history.

If person gives informed consent, person is included in study and continue with Compliance Form.

If person does not fully complete baseline questionnaires, person is excluded from study.

If person does not fully comply with vINCI instructions or does not appropriately use vINCI items, person is excluded from study.

Patient profile data

The information which define the static profile of the patient is structured in table 1.

Table.1 Patient Profile Data

Data category	Data	Values of data
	Date of recruitment (DD/MM/YY)	
Identification data	First name and surname	• First name • Surname
	Study number	
	Study type	
	Contact details	• Phone • Address
	Ward and room number	
	Group allocation	
Socio-cultural data	Date of birth (DD/MM/YY)	
	Gender	• Female • Male
	Formal education level	• *Not at all* • Primary school • High school (*Secondary school*) • College or university (*Tertiary school*)
	Living area	• Rural • Urban
	Living arrangements	• Alone • With someone • Nursing home
	Income	• Under medium monthly state pension • Above medium monthly state pension
Medical data	All documented diagnoses: documented medical history and	

Data category	Data	Values of data
	de novo diagnoses during hospitalization	
	• Catchment area (Bucharest)	• Yes • No
	• Acute medical condition	• Yes • No
	• Surgery in the last 3 months	• Yes • No
	• Major neurocognitive disorder (Montreal Cognitive Assessment MoCA <20)	• Yes • No
	• Moderate and severe depression (Geriatric Depression Scale – Short Form GDS-SF ›10)	• Yes • No
	• Existing disability (Needs human help in one or more basic activities of daily living)	• Yes • No
	• Heart failure functional class NYHA III-IV	• Yes • No
	• Angina pectoris	• Yes • No
	• Uncontrolled high blood pressure (>160 mmHg systolic)	• Yes • No
	• Heart arrhythmias	• Yes • No
	• Peripheral arterial disease	• Yes • No
	• Terminal illness	• Yes • No
	• Frailty syndrome (PRISMA 7 ≥ 3 “yes” answers)	• Yes • No
	• Risk of falls (Tinetti Tool Score < 24)	• Yes • No
	• Any condition that might limit mobility	• Yes • No
	• Visual impairment	• Yes • No
		If ALL answers are NO, Then DSQ!
Digital skills	DSQ score	If Low score: • Yes – Patient excluded from vINCI study

Data category	Data	Values of data
		• No – Informed Consent – If Yes, then Compliance Form

2.4. Digital skills data

Presence of digital skills for the elderly represents an inclusion criterion in study. Digital competence is the set of knowledge, skills, attitudes (thus including abilities, strategies, values and awareness) that are required when using ICT and digital media to perform tasks; solve problems; communicate; manage information; collaborate; create and share content, etc. All potential participants will fill in a Digital Skills Questionnaire (DSQ) to evaluate their computer and technological literacy.

The Digital Skills Questionnaires is based on DIGCOMP: A Framework for Developing and Understanding Digital Competence in Europe [Ferrari, A. et al., 2013].

Table 2 contains the Digital skills data corresponding to digital competence defined by European Union (EU) projects [https://ec.europa.eu/, accessed in 2019].

Table 2 Digital skills Data

Data category	Data	Values of data
Digital skills	DSQ score	
A. Critical questions		
	Types of ICT devices owned by the elderly: • desktop computer • laptop • smartphone • tablet • other ICT device	• Yes • No
	Level of knowledge in using a: • desktop computer • laptop • smartphone • tablet • other digital device	• Very low • Low • Well • Good • High
	Use on daily routine of: • desktop computer • laptop • smartphone	• Everyday • Often • At least once a week

Data category	Data	Values of data
	• tablet • other digital device	• At least once a month • Just once or sometimes • Never
	Internet access at home	• Telephone line • Cable • Satellite • Mobile • Other • NO
	Wireless access at home	• Full house coverage • Partial house coverage • NO
B. Digital skills / Competence areas		
• **Information**	I can look for information online using a search engine.	• Yes • No
	I know not all online information is reliable	• Yes • No
	I can save or store files or content (e.g. text, pictures, music, videos, web pages) and retrieve them once saved or stored	• Yes • No
• **Communication**	I can communicate with others using mobile phone, Voice over IP (e.g. Skype) e-mail or chat – using basic features (e.g. voice messaging, SMS, send and receive e-mails, text exchange)	• Yes • No
	I can share files and content using simple tools	• Yes • No
	I know I can use digital technologies to interact with services (as governments, banks, hospitals).	• Yes • No
	I am aware of social networking sites and online collaboration tools.	• Yes • No
	I am aware that when using digital tools, certain communication rules apply (e.g. when commenting, sharing personal information	• Yes • No

Data category	Data	Values of data
• **Content creation**	I can produce simple digital content (e.g. text, tables, images, audio files) in at least one format using digital tools.	• Yes • No
	I can make basic editing to content produced by others.	• Yes • No
	I know that content can be covered by copyright.	• Yes • No
	I can apply and modify simple functions and settings of software and applications that I use (e.g. change default settings).	• Yes • No
• **Safety**	I can take basic steps to protect my devices (e.g. using anti-viruses and passwords)	• Yes • No
	I am aware that my credentials (username and password) can be stolen	• Yes • No
	I know I should not reveal private information online	• Yes • No
	I know that using digital technology too extensively can affect my health.	• Yes • No
• **Problem solving**	I can find support and assistance when a technical problem occurs or when using a new device, program or application.	• Yes • No
	I know how to solve some routine problems (e.g. close program, re-start computer, re-install/update program, check internet connection).	• Yes • No
	I know that digital tools can help me in solving problems. I am also aware that they have their limitations.	• Yes • No
	When confronted with a technological or non-technological problem, I can use the digital tools I know to solve it.	• Yes • No

The text from tables are based on EC DG CONNECT “Digital Skills Indicator – derived from Eurostat survey on ICT usage by Individuals. Methodological note – 2015”.

Criteria to assign competence value for the area:

- BASIC: only one item in each COMPETENCE AREAS

- ABOVE BASIC: more than one item
- “LOW” (missing some type of basic skills) = one or more “none” in one to three domains (accomplished an activity at least in one of the four domains)
- Individuals with “no skills” = four “none” (no items ticked in all four domains)

All participants in the acceptability study will receive a semi-structured acceptability questionnaire adapted for each vINCI device and also an overall vINCI technology feedback questionnaire for self-completion. All acceptability and users feedback data will be recorded.

For all participants in the validation study the following data will be collected at follow-up:

- quality of life (WHOQOL-BREF) (Annex 2);
- physical activity level (IPAQ) (Annex 3).

Reasons for study attrition will also be recorded: death, worsening of health status during hospitalization, withdrawal of informed consent or misuse of any of the vINCI technological items.

The Quality of Life Questionnaire will be the Romanian language version of the World Health Organization Quality of Life Instrument, Short Form (WHOQOL-BREF). We have a legal agreement between us and World Health Organization for using the Licensed Materials subject to their terms and conditions. World Health Organization grants this license to us based on the representation and warranties we made in the license request we submitted through World Health Organizations online platform.

The physical activity level subjective evaluation will be performed with the International Physical Activity Questionnaire (IPAQ). IPAQ underwent a translation and cultural adaptation process for Romanian users taking into consideration the principle of conceptual equivalence, metric equivalence and linguistic equivalence. Culturally relevant activities were identified and used as examples for applicable questionnaire items while the intensity of the physical activities (light, moderate, and vigorous) were retained.

2.5. Quality of Life and Lifestyle

According to the World Health Organization (WHO) “The Quality of Life is given by the perceptions of individuals about their social situations, in the context of the cultural value systems they live in and their own needs, standards and aspirations” [World Health Organization, 1997]. More specifically, the quality of life in medicine means physical, mental and social wellbeing, as well as the ability of patients to carry out their ordinary tasks in their everyday life.

Table 3 presents the WHOQOL-BREF Domains and Concepts considered for vINCI.

Table 3 WHOQOL-BREF Domains and Concepts

Physical health Determines / Influences the physical status	**Activities** of daily living
	Dependence on medicinal substances and medical aids-dependence on **medication**
	Energy and fatigue
	Mobility

	Pain and discomfort
	Sleep and rest
	Work Capacity
Psychological Determines / Influences the psychological / cognitive status	Bodily image and appearance – **body image**
	Negative feelings
	Positive feelings
	Self-esteem
	Spirituality / Religion / Personal beliefs
	Thinking, learning, memory and concentration- **cognition**
Social relationships Determines / Influences the social activity	**Personal relationships**
	Social support
	Sexual activity - **sex**
Environment Determines / Influences the Environment situation	Financial resources - **finance**
	Freedom, physical **safety and security**
	Health and social care: accessibility and quality
	Home environment
	Opportunities for acquiring new **information** and skills
	Participation in and opportunities for recreation / **leisure** activities
	Physical environment (pollution / noise / traffic / climate)
	Transport

2.6. Lifestyle concepts

Table 4 contains the Lifestyle concepts considered for vINCI.

Table 4 Lifestyle Concepts / Indicators

Lifestyle concepts / indicators
Work behavior pattern / occupation (office work, part-time work, self-employed, housework, none), excessive stress avoiding
Leisure behavior pattern / availability of leisure time, physical mobility
Activity / working, domestic and gardening activities, playing and participating in fun activities and learning, sleeping, exciting intellectual activities, participation in community activities, body mobility, sexual life
Attitude / enjoying intimacy, affection
Interest / hobbies and their satisfaction
Opinion / personal beliefs
Value / professional fulfilment
Allocation of income / appropriate income
Self-image / self-esteem
Self-concept / personal identity sense

Lifestyle concepts / indicators
Motivations / life satisfaction, well-being, optimal physical form, feeling of security, health insurance
Needs / moving, sleep and rest, appropriate nutrition (drinking and eating), discovering the satisfaction of curiosity, provision of good quality health care, property, possession of goods, housing
Wants / self-care, happiness, independence / autonomy (ability to make personal choices, ability to make decisions, personal self-control, presence of clearly defined values and goals, self-management in life)
Culture / spiritually / religion beliefs
Family / family structure, family relations, communicating with family members
Reference group / friends and friendships, social contacts, communicating with others, accessibility of social support
Social class / social status and role, acceptance in different social groups

2.7. QoL vs Lifestyle concepts

Table 5 presents a comparison between QoL concepts and Lifestyle concepts / indicators.

Table 5 QoL vs Lifestyle concepts/indicators

QoL Domains	QoL Concepts	Lifestyle Concepts / Indicators
Physical Status		
	Activities of daily living	physical mobility, optimal physical form, leisure behaviour pattern, availability of leisure time, physical autonomy
	Work behaviour pattern	occupation (office work, part-time work, self-employed, housework, none), excessive stress avoiding, ability to make decisions
	Medication	provision of good quality health care, appropriate medication and nutrition (drinking and eating)
	Sleep	optimal sleep
	Mobility	independence / autonomy
	Pain and discomfort	
	Energy and fatigue	appropriate nutrition (drinking and eating), provision of good quality health care
Phycological / cognitive status		

QoL Domains	QoL Concepts	Lifestyle Concepts / Indicators
	Cognition - Thinking, learning, memory and concentration	independence / autonomy (ability to make personal choices, ability to make decisions,)
	Spirituality	religion / personal beliefs
	Bodily image and appearance	self-image
	Positive / **Negative feelings** attitude	happiness / enjoying intimacy, affection, depression, hobbies and their satisfaction
	Self-esteem	professional fulfilment, self-image, self-care, discovering the satisfaction of curiosity, personal self-control, presence of clearly defined values and goals, self-management in life, ability to make personal decisions
Social relationships		
	Personal relationships	family structure, family relations, communicating with family members
	Social support	social status and role, acceptance in different social groups, friends and friendships, social contacts, communicating with others, accessibility of social support
	Sexual activity	enjoying intimacy
Environment domain		
	Finance resources	financially secure
	Safety and security	freedom, physical safety and security, health insurance, feeling of security
	Health and social care	accessibility and quality of health services
	Home environment	pollution / noise / traffic / climate
	Information	opportunities for acquiring new information and skills
	Leisure	availability of leisure time

3. Semantic Web and ontologies

The term *Semantic Web* reflects a new architecture of the *World Wide Web* (WWW), which enhances content with formal semantics, providing new navigation opportunities in the virtual space [Berners-Lee, T. et al, 2002].

The Semantic Web is a group of methods and technologies which allow machines to understand the meaning of information on the World Wide Web. It offers developers new web-based technology applications that provide a more intelligent access to information on the web. In the context of the Semantic Web, there are some aspects which offer reusability, sharing and interoperability among Web applications.

According to Berners-Lee, the *Semantic Web* structure is given by the existence of several layers of representation [Berners-Lee, T., 2006]:

- *Resource Description Framework* (RDF), represents a standard for describing information;
- *RDF Scheme* (RDFS), provides a data modeling vocabulary for RDF data;
- *Simple Protocol and RDF Query Language* (SPARQL), represents an RDF query language;
- *Web Ontology Language* (OWL), represents a family of languages for representing knowledge;
- *Rule Interchange Format* (RIF), represents a language dialect rules framework that supports the Web transfer rule.

Ontology is part of the Semantic Web structure and it is the explicit specification of a conceptualization of a knowledge domain which facilitates its sharing [Gruber, T. R., 1995]. The term ontology has been defined as the explicit specification of a conceptualization which facilitates the exchange of knowledge in a domain (that refers to the shared understanding of some domain interest). An ontology is used to describe the meaning of shared formal vocabulary used into an interest domain, and may be viewed as a declarative model of a domain that defines and represents the concepts existing in that domain, their attributes and relationships among them. It is typically represented as a knowledge base which then becomes available to different applications that need to use and/or share it. An ontology is mainly represented as a knowledge base available for different applications to use and share, being also used for modeling knowledge in a particular area of interest. It is a key issue for the integration of information from different sources, to meet the needs of patients and their profile.

An ontology can be defined as an explicit specification of the conceptualization of a problem domain, which consists of a number of classes (or domain concepts) and properties [Chandrasekaran, B. et al, 1999]. Nowadays, the development of a large number of applications in different fields, such as management, natural language processing, e-commerce, intelligent integration information, database design and integration, bio-informatics, education, etc., are all based on ontologies [Băjenaru, L. et al, 2015; Băjenaru, L. et al, 2016].

The vocabulary of terms and the relationships are used in a shared manner by all applications in a given domain, or even by different domains in a standard hierarchy. These standard descriptions are generally transposed on two levels, each having different powers of expression and calculation; it is about metadata and ontologies.

An ontology has the following components:

1. **vocabulary of terms** (as much as possible standardized);

2. **classes** that mean sets of objects (concepts) of the domain that contain individuals. The classes explicitly describe the concepts identified and they are usually organized into taxonomies, through which inheritance mechanisms can be applied;

3. **relationships** that represent a type of association between domain concepts; relationships are usually binary and are sometimes used to render the attributes or properties of the concept;

4. **properties** represent relationships and can be:
   - *datatype properties* - describe relationships between an individual and date values;
   - *object properties* - describe relationships between two individuals;

5. **individuals** are class instantiations, representing objects of the domain of interest;

6. **inheritance** from other ontologies;

7. *if-then-else* **inference rules**.

3.1. Methodologies and ontological tools

In the specialty literature, several methods and methodologies have been proposed for the development of ontologies. Choosing a methodology depends mainly on the characteristics of the ontology to be developed, including the domain in which it is developed, as well as the experience of the specialists in ontologies.

Among the methods and methodologies that were the basis for defining the own methodology for developing the ontologies of the vINCI system, we mention Methontology [Fernández, M. et al, 1997] and *Method 101* [Noy, N et al, 2001].

Protégé (http://protege.stanford.edu/), developed by *Stanford Medical Informatics* (SMI) at Stanford University, is a standalone, *open source* application with an extensible architecture, a popular tool in OWL modeling. Protégé, the ontology editor, was developed using a *plug-in* architecture, which allows the addition of new services.

The ontology is formally presented with the help of the *Protégé* platform, which has the ability to translate the ontology structure into the formal OWL language.

For ontology evaluation, there are tools, validators and interpreters, such as *RDF Parse Validation*, *DAML Validator*, *DAML + OIL Ontology Checker* and others. A framework for evaluating the ontologies was provided by Gomez-Perez et al. [Gomez-Perez, A. et al, 1995].

Also for checking the consistency of OWL ontologies, various reasoning tools, such as *Racer*, *Pellets* and *FaCT* ++, can be used to perform intelligent reasoning on OWL ontologies.

The ontology query is performed with tools such as *RDF Query Language* (RDQL) [Seaborne, A., 2004]. RDQL is an implementation of a SQL query language for RDF. It treats RDF as data and offers queries with triple models and constraints on a single RDF model. Another query language is *OWL-QL* [Fikes, R. et al, 2003], which has been designed to allow for dialogues / queries between agents using knowledge in OWL. Then, the OWL-QL is appropriate when it is necessary to do a inference in a query.

In order to understand the ontology, the graphical representations obtained with the specific tools [Swaminathan, V. et al, 2012] are needed, and for the ontology searches, with the extraction of useful information, semantic languages for databases such as SPARQL are used [Prud'hommeaux, E. et al, 2008].

Among the languages specially designed to represent knowledge for ontologies are: RDF and OWL. OWL is a *Semantic Web* language designed for the representation of semantically enriched knowledge and for complex representations of things, groups of things and the relationships between things [Allemang, D. et al, 2002]. OWL documents, known as ontologies, can be published in WWW. OWL allows, through XML, the description of classes that include specific components and properties.

4. Definition of the ontology of patient profile

The definition of the ontology of the patient's profile was made according to the recommendations of two of the methodologies recognized and validated by the specialty literature, namely the methodology of Noy et al., **Method 101** [Noy, N. et al, 2001] and the methodology of Fernández-López et al., **Methontology** [Fernández, M. et al, 1997]. These methodologies were the basis for defining a system own methodology.

The development of the ontology of the interest domain, respectively the development of a coherent conceptual model, are realized and developed. The development process comprised the following stages: knowledge acquisition, conceptualization, implementation and verification of the built ontology.

During the **knowledge acquisition phase**, information was collected on the target group, - patient profile, on the chosen domain - quality of life, as well as on the index of evaluation of the patient’s quality of life.

The knowledge acquisition was made in the first stage, simultaneously with the requirements specification stage and continued as the ontology development process progressed.

The knowledge base, thus acquired, consists of information about: the patient's profile, as well as the general and specific concepts about QoL.

Conceptualization of the ontology

The development of the ontology consisted of the following activities:

- identifying the concepts, their attributes and values;
- identifying the individuals of the concepts;
- arranging classes in a hierarchy;
- description of properties and attribution of their values;
- establishing the values for the instances;
- defining axioms.

In the conceptualization phase, the information collected during the acquisition phase has been organized and structured in a conceptual model that describes the identified solution.

In developing the ontology, the following requirements were considered:

- description of the basic concepts in relation to the purpose and role, proposed by the ontology;
- possibility to query the data stored in the knowledge base;
- the ontology to provide information necessary to the requirements.

4.1. Patient profile ontology

Modeling the patient profile using ontologies

The vINCI project proposes the provision of personalized care services for patients in an IoT-based ecosystem. The user profile will be used in assessing the impact of vINCI technology on the perceived QoL level, allowing for a proper adjustment of the intervention assistance provided by the family and caregivers [Marinescu, I. A. et al, 2018; Dobre, C. et al, 2019; Băjenaru, L. et al, 2018].

Some data about study's patients are obtained using selected questionnaires, interviews, clinical examinations, and observations. These data, which define a static profile of the elderly patient, are supplemented with data collected through smart IoT devices (non-intrusive watch, shoes, and sensors) proposed in the project. These personal data (Personal Data Records - PDRs) are to be used as a basis for tracking and profiling older adults. This data collection is the regular patient monitoring that will provide information in dynamics. The sum of these collected data defines the database with complete information about the studied person, information that can provide, following the interpretations using the tools, the analysis techniques, results like those in the schema presented in Figure 1.

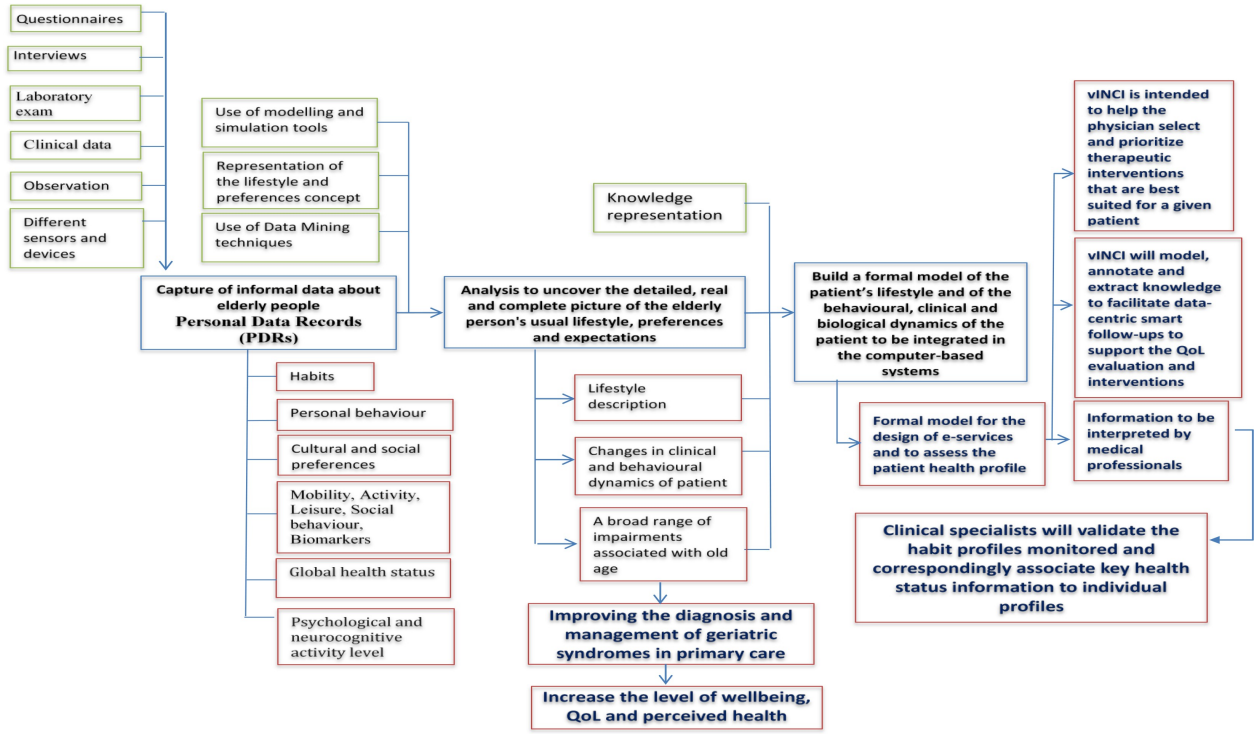

Figure 1 The patient's profile modelling process

The next step in patient's profile modelling is represented by the conceptual model of the profile. This is done by analyzing the captured information, using knowledge representation techniques that can provide descriptions of lifestyle, changes in clinical and behavioral dynamics of the patient and another complex information about that person. This contributes to improve the diagnosis and management of geriatric syndrome in primary care, as well as to increased levels of wellbeing, QoL and perceived health.

Building a formal model of the patient's lifestyle and of the behavioral, clinical and biological dynamics of the patient to be integrated in the computer-based systems, represents the next step in the modelling process of the patient profile. This formal model is used by the proposed platform to help the physician to select and prioritize therapeutic interventions that are best suited for a given patient. Also, vINCI will model, annotate and extract knowledge to facilitate multi-stakeholder data-centric smart follow-ups to support the QoL evaluation and interventions.

The formal model can assess the patient health profile and provide information to be interpreted by medical professionals.

For vINCI care, the profile will be the input to provide personalized support for daily / medical activities. Finally, the profile will be used as evidence to evaluate the impact of vINCI on the perceived QoL level, allowing a proper adjustment (if needed) of the intervention support being provided by caregivers.

Also, clinical specialists can validate the habit profiles monitored and correspondingly associate key health status information to individual profiles.

In figure from above we present the steps and tasks in the process of patient's profile modelling. The techniques used are marked with green, the particular tasks being performed are marked with blue, and the results obtained are marked with red.

4.2. Patient profile for vINCI

For all the patients of the vINCI study, the following data will be collected as baseline:

- identification data: first name and surname, study number, contact details, ward and room number, group allocation;
- socio-cultural data: date of birth, sex, formal education level (primary school, high school, college or university), living area (rural/urban), living arrangements (alone/with someone/nursing home), income (under or above medium monthly state pension);
- medical data: all documented diagnoses (documented medical history and de novo diagnoses during hospitalization);
- digital skills.

During the **knowledge acquisition phase**, information was collected on the target group, the selected old persons, on the chosen domain - quality of life, as well as on the index of evaluation of the patient's quality of life.

In the **conceptualization phase**, the information (collected during the acquisition phase) has been organized and structured in a conceptual model that describes the identified solution.

The patient profile is a conceptual model for the target groups, the selected old persons, which can serve to promote the common understanding underlying the process of analyzing, designing, developing and implementing of the informatics healthcare solution.

The patient's profile ontology, respectively the *Participant* profile, is developed with the open-source Protégé environment. The graphical representation of the identified concepts of the patient profile is presented in Figures 2.

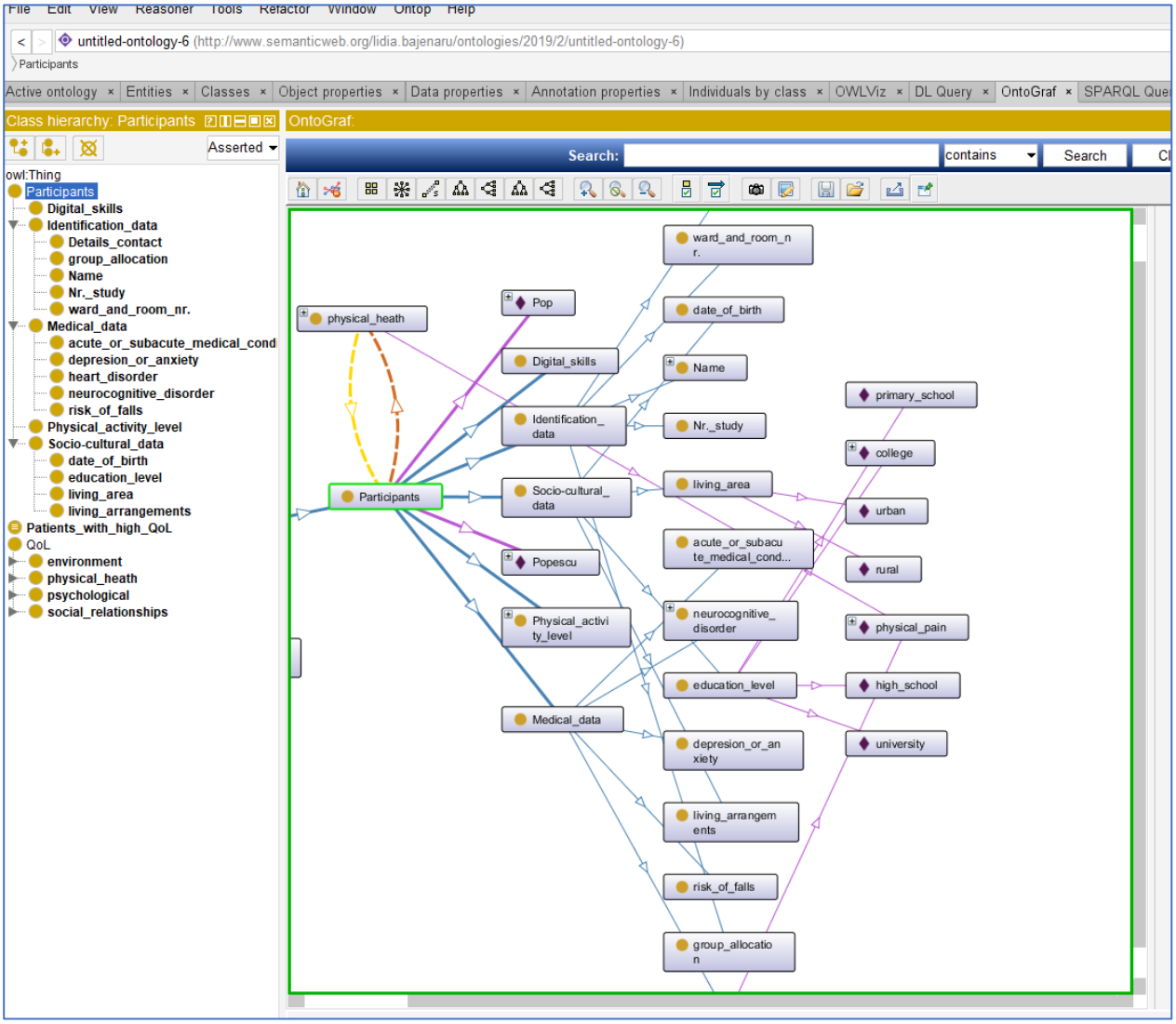

Figure 2 Hierarchical graphical representation of the medical patient profile ontology

The properties describe the characteristics and attributes of concepts and individuals. Relationships define properties and attributes that characterize classes.

The central concept of our ontology is the *Participant* (patient) class, which includes all of the patient's characteristics, respectively the subclasses *Identification Data, Socio-Cultural Data, Medical Data, Digital Skills, Physical Activity Level.*

4.3. Patient's lifestyle ontology

QoL ontology in conjunction with Lifestyle concepts / indicators

Our model demonstrates that the technical, demographic, health issues and QoL domains must be considered to adequately capture the complete pattern of vINCI users.

In the QoL research, health is one of the most important social factors nominated by the population in setting their living standards. Thus, based on this empirical evidence, it was considered justified to include health among the QoL dimensions or among the factors that decisively influence QoL [Bowling, A., 1991].

The ontology of the QoL domain is developed with *Protégé* and can be seen in Figure 3. The identified classes and subclasses of the QoL (*physical_health, social_interaction, psychosocial_health, environment_interaction*) are offered by the OWLViz application in this figure.

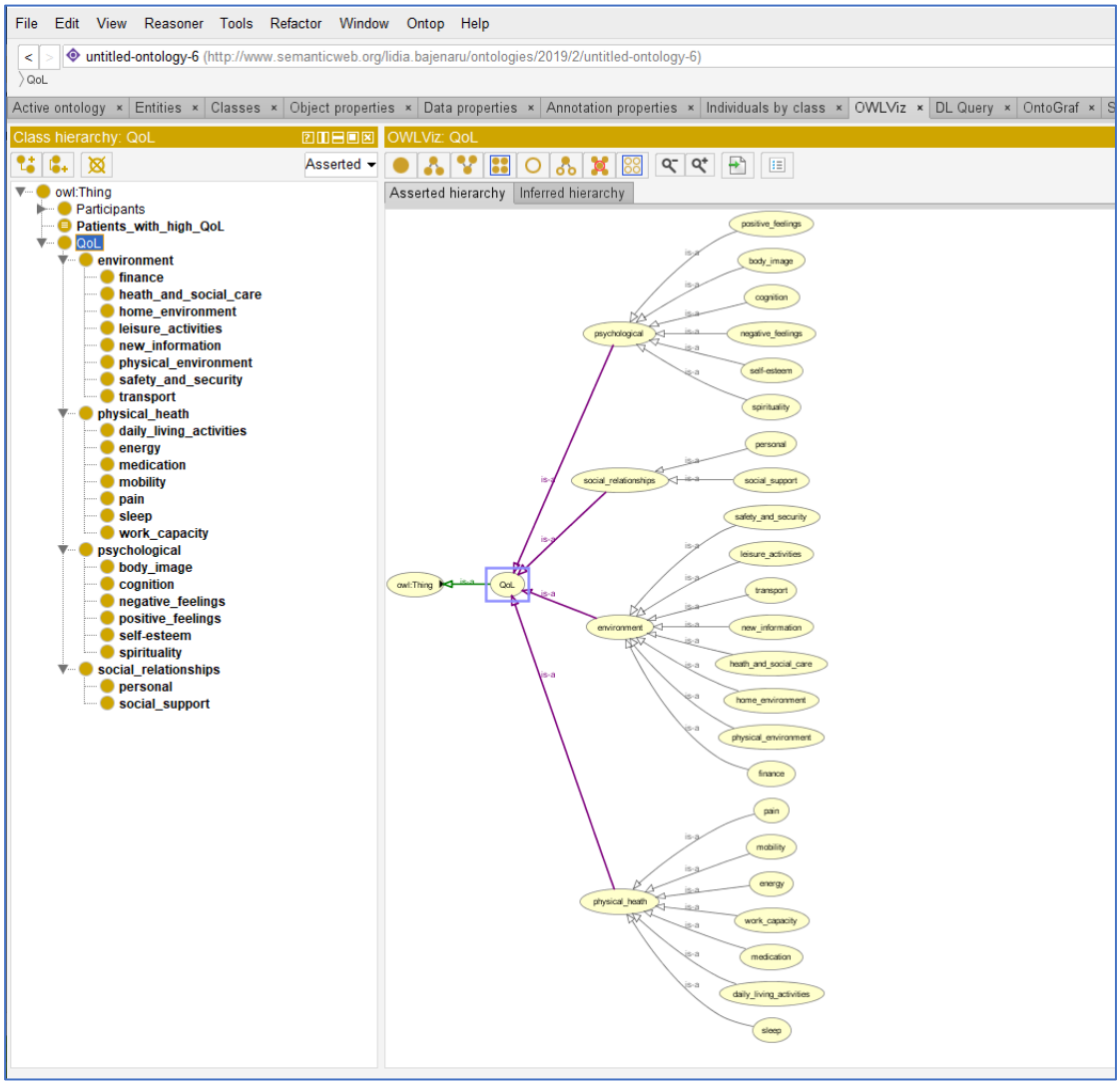

Figure 3 Hierarchical graphical representation of the QoL ontology

A hierarchical representation of the *QoL* class, respectively classes, subclasses and some individuals are offered by the OntoGraf application in Figure 4.

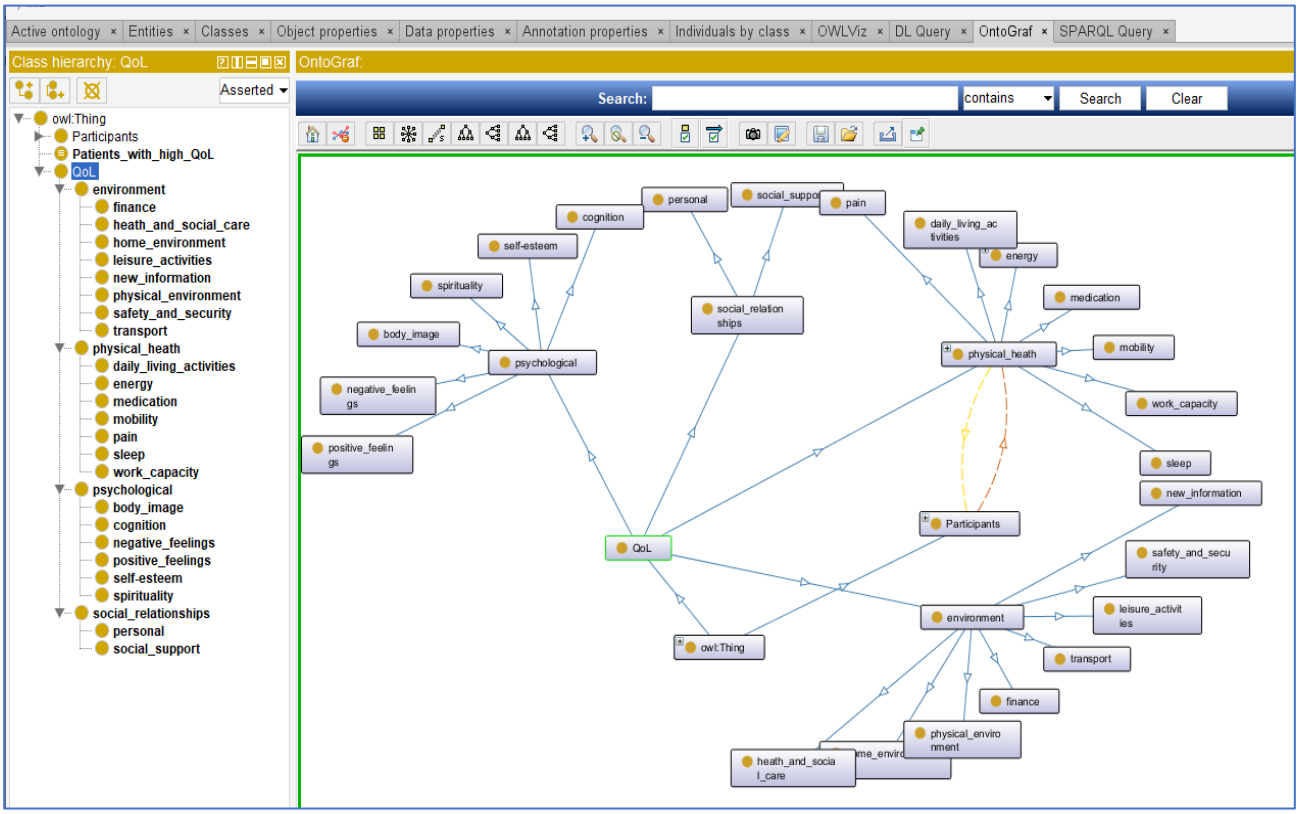

Figure 4. The QoL ontology

4.4. Relationship between medical patient profile ontology and QoL domain ontology

In Figure 5 we can see the hierarchy of the *Participants* and *QoL* classes, respectively the relations between the individuals of these classes, such as *Popescu has high energy*, *Popescu has physical pain* (*Popescu* is a *Participants* individuals and *high energy* and *physical pain* are QoL individuals). The relationships between the concepts of the two classes, *Participants* and *QoL*, can provide information about the QoL level that an individual in the first class has, respectively, which are the recommendations for improving the quality of life.

Also, individuals in the *Participants* class can be grouped according to the level of quality of life achieved, for example in *Patients_with_high_level* superclass.

The relationships between the participants' individuals and the QoL entities can be identified in the right panel of Figure 5.

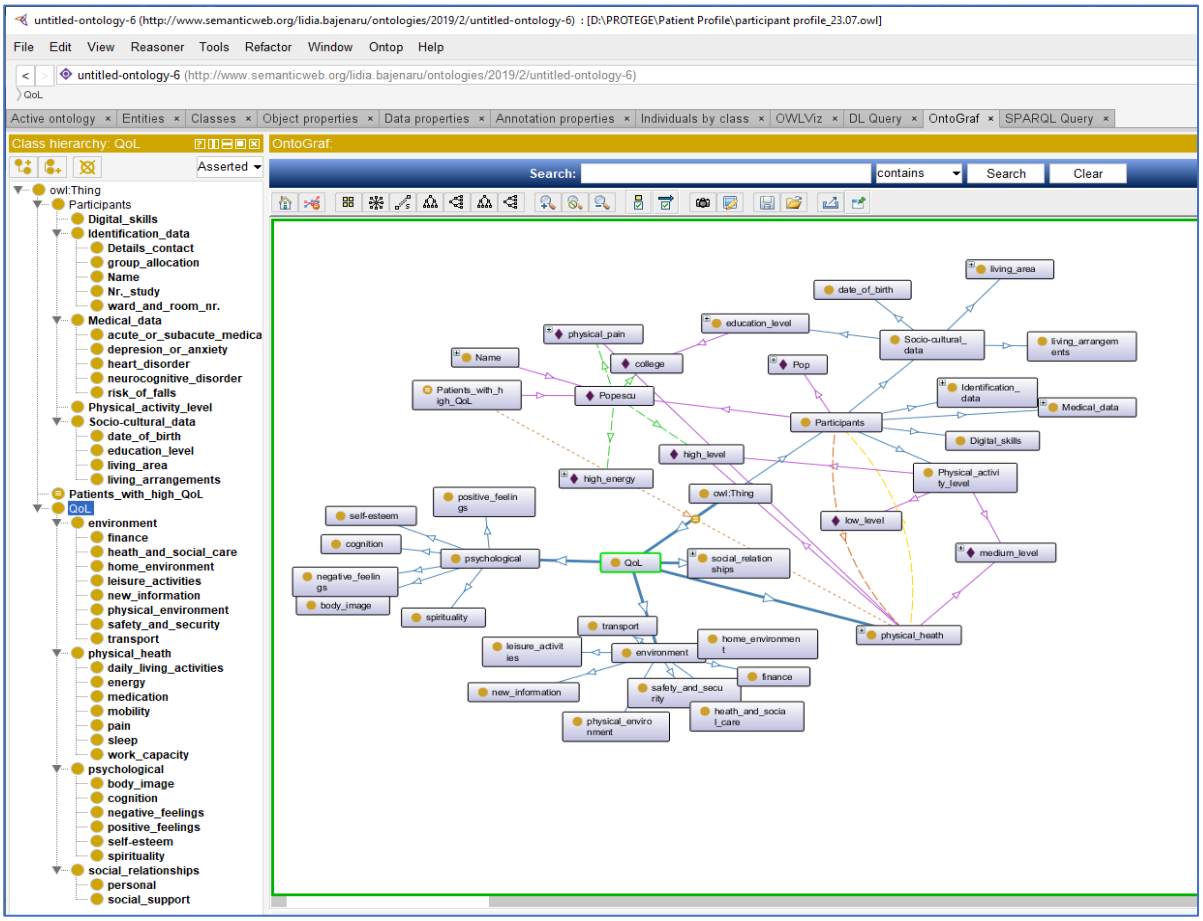

Figure 5 Relationship between patient profile ontology and QoL domain ontology

The relationships between the concepts of the two classes, Participants and QoL, can provide information about the QoL level that an individual in the first class has, respectively, which are the recommendations for improving the quality of life. Also, individuals in the Participants class can be grouped according to the level of quality of life achieved, for example in Patients_with_high_level superclass.

The modelling of a profile for older adults are used as support for understanding a user's health/QoL conditions monitored using IoT technologies. The model is part of the vINCI project, which proposes a novel approach for providing personalized assistance services for patients. Like with many other similar projects today, our challenge was to find a solution to understand and model the older adult being monitored by the set of IoT technology. As such, we presented the design considerations for a profile of an elderly patient, that we model in vINCI using ontologies. For vINCI care, the patient profile will be the input to provide personalized support for daily / medical activities. The profile is used as evidence to evaluate the impact of vINCI on the perceived Quality of Life (QoL) level, allowing a proper adjustment of our technologies (calibration) and the intervention support provided by caregivers.

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