

SHAPES

Smart and Healthy Ageing through People Engaging in supportive Systems

D3.8 –Draft User Requirements for the SHAPES Platform V2

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| 0.5 | 8/10/2020 | Gerald Walther (FhG) | Integrated links to other projects from the Health and Care Cluster |
| 0.6 | 23/10/2020 | Borja Arrue (AGE) | Feedback regarding end- user specification and |



| | | | involvement for validation and weighting |
|-----|------------|--------------------------|---|
| | | Tatiana Silver (TREE) | Suggestion on source specifications and integration of requirements overview into main document |
| 0.7 | 26/10/2020 | Claudia Berchtold (FhG) | Integration of Review Comments |
| 1.0 | 31/10/2020 | Michael Cooke (NUIM) | Executive summary and final version. |

Table of Contributors

Table 2 Deliverable Contributors

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Table of Acronyms and Abbreviations

Table 3 Acronyms and Abbreviations

| Acronym | Full Term |
|---------|--------------------------|
| AB | Availability |
| AC | Accessibility |
| AD | Adaptability |
| BR | Business Requirements |
| CO | Collaboration |
| CP | Capacity |
| CS | Cybersecurity |
| CS | Customer Service |
| ET | Ethics for Platform |
| FR | Functional Requirements |
| FT | Functionality |
| GE | General Ethics |
| GSA | General Security Aspects |



| HMS | Health Maintenance Support |
|-----|--|
| HS | Health Support |
| Ю | Interoperability |
| IS | Information Services |
| LER | Legal and Ethical Requirements |
| LS | Living Support |
| М | Marketplace |
| ME | Ethics for Governance, Business and Ecosystem Models |
| MN | Maintainability |
| OS | Openness |
| Р | Pricing |
| PE | Ethics for Processes and Support |
| PF | Performance |
| RB | Reliability |
| RC | Recoverability |
| RM | Rights Management |
| S | Sustainability |
| SC | Scalability |
| SR | Security Requirements |
| TR | Technical Requirements |
| US | Useability |
| PwM | People with Multimorbidity |
| WPs | Work Packages |

Keywords

SHAPES Platform, User Needs, Dimensions, Requirements

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Executive Summary

This Deliverable encompasses the 2nd iteration of the SHAPES platform requirements as enhanced between M9 and M12 of the project duration, i.e. July and October 2020. However, it describes the development process of the requirements starting with the 1st iteration (D3.7 Draft User Requirements for the SHAPES Platform V1) and can hence be read as a stand-alone document. This Deliverable describes the steps that have been taken in order to further develop the requirements. For the 2nd iteration, the adaptations to the requirements as a result of these working steps are furthermore specified. The requirements themselves are listed in an overview Section 4.

Section One presents the purpose, rationale, and objectives of this document, building on the initial draft requirements framework outlined in D3.7. and reporting on the validation activities of the requirements identified so far.

Section two outlines the validation methodology which includes comparisons with other EU projects and other health care cluster projects examining similar issues as examples of best practice. As well as this the requirements so far identified are linked with the needs and expertise available from other tasks throughout the project.

Section three details the process of requirements specification including coding as functional and validation phases and screening for additional requirements.

Section four summarises the currently list of requirements identified for the SHAPES platform including functional and non-functional requirements categorised as security requirements, ethical & legal requirements, health system requirements, business requirements, and technical requirements.

Section five present the deliverable conclusions and next steps towards the final iteration of the SHAPES platform requirements.



1 Introduction

1.1 Rationale and purpose of the deliverable

The rationale of Task 3.5 and the related Deliverables (3.7-3.9) is the development of the SHAPES platform requirements. Building on the 1st iteration which was submitted in June 2020 (Deliverable 3.7), interviews and small workshops were implemented between July and October 2020 to specify the subcategories and requirements for the platform. The overall structure for Task 3.5 including the 3rd iteration is detailed in the figure below.

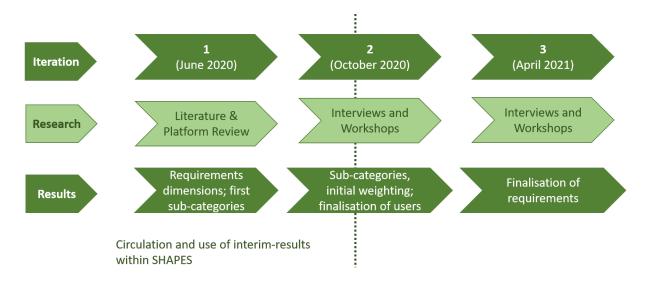


Figure 1: Iterations of SHAPES Platform Requirements, research conducted and results derived Source: own figure.

1.1.1 Deliverable Objectives

The main objective of Task 3.5 is the development of user-centred requirements for the SHAPES Platform, validated by the SHAPES Ecosystem of relevant stakeholders, in line with an agile, iterative co-design and co-development processes. This process ensures that care recipients' and care providers' needs, priorities, contexts, challenges and opportunities, as well as the specific gendered human factors and organisational aspects are taken into consideration in the development of the platform.

1.1.2 Key inputs and outputs

Figure 2 below specifies the links of Task 3.5 to almost every WP in SHAPES.



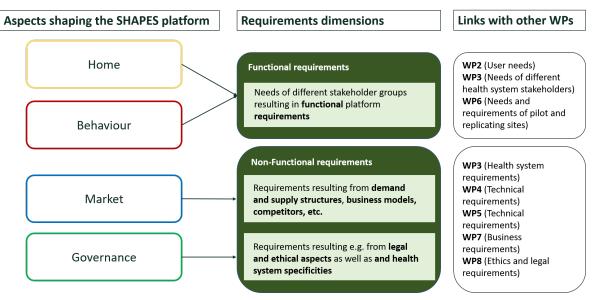


Figure 2: Task 3.5 Links with SHAPES WPs

Source: own figure.

Table 4 lists the most important tasks that provide input to the development of the platform requirements:

Table 4: Interaction with other SHAPES Tasks

| Task # | Title | Duration |
|-----------|--|----------|
| 2.1 | Understanding Older People: Lives, Communities and Contexts | M1-M24 |
| 2.2 | Accessing Physical Spaces | M1-M24 |
| 2.3 | Cultivating Age-Friendliness | M7-M36 |
| 2.4 | Empowerment of Older Individuals in Health and Care Decision-making | M13-M36 |
| 2.5 | SHAPES Personas and Use Cases | M1-M18 |
| 3.1 | Ecological Organisational Models of Health and Care Systems for Ageing | M1-M12 |
| 3.2 | Scaling-up Improved Integrated Care Service Delivery | M7-M30 |
| 3.4 | SHAPES Governance Model and Guidelines [| M7-M42 |
| 5.1 | Platform User Experience Design Guidelines and Evaluation | M4-M36 |
| 6.1 | SHAPES Pan-European Pilot Campaign Plan, Knowledge Model and Evaluation Methodology | M1-M6 |
| 8.1 | SHAPES Pan-European Pilot Campaign Plan, Knowledge Model and Evaluation Methodology | M1-M48 |
| 8.2 | Assessing the Regulatory Frameworks Facilitating Pan- European Smart Healthy Ageing | M7-M42 |
| 8.3 | Ethical Framework for SHAPES | M1-M6 |
| 8.4 | Privacy and Ethical Risk Assessment for the SHAPES Platform | M7-M42 |
| 8.5 | Privacy and Data Protection Legislation in SHAPES | M7-M48 |



The requirements provide input to WP4 and more particularly Task 4.1 "SHAPES TP Requirements and Mapping a Reference Architecture".

1.2 Structure of the document

The document specifies the methodology chosen for the development of the platform requirements (Section 2), and details the working steps and insights derived between July and October 2020 (Section 3). An overview of the requirements is given in Section 4. The complete list of requirements as a Living Excel Document (linked with relevant actors and ethnographic comments as well as open questions and remarks) is available in Annex I. Finally, requirements developed in the pilots as well as requirements stemming from other tasks (such as 3.1 and 3.4) have been mapped against the platform requirements. The respective results are also available in the Annexes.



2 Methodology

2.1 Distinguishing the SHAPES platform from product design

"Understanding user requirements is an integral part of information systems design and is critical to the success of interactive systems. It is [...] widely understood that successful systems and products begin with an understanding of the needs and requirements of the users" (Maguire und Bevon 2002, S. 133). The development of human-centred design processes for interactive systems is specified in ISO standard 13407:1999 that places the user needs in the centre of the design process. The process steps are usually the following:

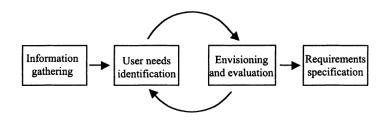


Figure 3: General process for user requirements analysis Source: (Maguire und Bevon 2002, S. 134)

Frequently, after the specification of the different user groups, their needs are identified by different methods such as interviews, focus groups or surveys (e.g. Maguire und Bevon 2002). This procedure is comparatively linear if it comes to concise products (for example Bruseberg und McDonagh-Philip 2001). A product can be defined as "something that is made to be sold, usually something that is produced by an industrial process or, less commonly, something that is grown or obtained through farming" (Cambridge Dictionary). The SHAPES platform, however, cannot be regarded as a product in this sense. It has to be understood as a vehicle to enhance health care for older adults and hence links (health) data and information management aspects with services (e.g. exercises and organisation of support) with dedicated tools such as sensors and robots facilitating certain aspects of health care. It thereby links a multitude of actors (ranging from care receivers to informal care providers, health professionals and health system administrators) in different EU countries with specific contexts. In order to take this diversity in context into consideration, to build on the work conducted under other SHAPES tasks and particularly to benefit from the trust that has been established between researcher and end-users, for example under WP2, Task 3.5 closely interacted with relevant tasks as specified in Table 4 above. This methodology is not unique to SHAPES. Other project in the health cluster, e.g. Vicinity (Open virtual neighbourhood network to connect IoT infrastructures and smart objects)¹ (D2.1 'Requirements specifications for ageing well'), adopt a similar approach for the same reasons.

¹ https://www.vicinity2020.eu/vicinity/ (27.10.2020).



Overall, the identification of functional and non-functional requirements phase was based on several steps as detailed in Figure 4. It included the review of projects similar to SHAPES and more in-depth literature review relating to the requirements dimensions identified in step one. The phase was complemented by discussions with project including WP2-WP8 partners representatives and the platform requirements Excel Sheet (Annex I of this Deliverable) was made available in the project platform for review to partners. The requirements specification and validation with stakeholder groups will be completed for the 3rd iteration.

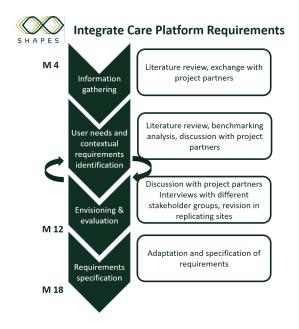


Figure 4: Overview of Task 3.5 Workflow. Source: own figure.

2.2 Building on existing knowledge and trust

2.2.1 Existing research and projects

A rich knowledge base on requirements for e-health systems and platforms already exists. For the SHAPES project, it was hence decided to build an initial version of the requirements on research and projects that have been implemented. In the first iteration of the SHAPES Platform Requirements, the requirements dimension and first differentiation of actors was therefore based on literature review and a project review, building on the CORDIS project results database². Using the search term 'platform' in the Cordis database yielded over 5,000 search results. This list of projects was screened for projects that develop a technology platform similar to the one envisaged by SHAPES. An initial ten projects were reviewed in detail, which entailed an analysis of how the project had developed their requirements and what types of requirements in general and what specific requirements they had identified.³ This relatively small sample size compared to the more than 5,000 hits from the search already yielded a plethora of requirements. It is interesting to note that with regard to the overall types of requirements, these were indeed quite congruent. In order to test if any projects that specifically work in the health sector developed completely different types of requirements, another Cordis search with the keywords 'platform AND health' was conducted. This search yielded over 1,460 hits for just H2020 projects. Another five projects were assessed in the same way as before. As was expected, these health

² https://cordis.europa.eu/ (30.09.2020).

³ The projects were: BONSEYS, PLUGGY, SoCaTel, SWAMP, PlatformUptake.eu, MetaPlat, openMOS, Mobile-Age, Vicinity, SIMPATICO.

⁴ The projects were: iManageCancer, Picaso, REACH2020, FrailSafe, i-PROGNOSIS.



specific projects utilised similar approaches to develop requirements and had identified similar categories of requirements.

2.2.2 Links to the "Health and Care Cluster Projects"

Similar projects to SHAPES are currently taking place within the Health and Care Cluster Projects (figure 5). These have progressed to various degrees with regard to the development of user requirements. Projects pharaon⁵, ADLIFE⁶, Gatekeeper⁷ and FAiTH⁸ are still in their planning phase or do not share their requirements in public deliverables. As mentioned above, ACTIVAGE⁹ uses the same approach as SHAPES. InteropEHRate¹⁰ has identified requirements, which pertain directly to scenarios and each of the technologies that they are developing and testing. SMART BEAR¹¹ also identified requirements for each of the specific applications that they are working towards (see D2.1 (D5) 'SMART BEAR requirements'¹²). In addition, they have identified technical requirements with regard to their platform and cloud and addressed general issues with regard to legal and ethical issues like data protection. In our next cycle, we will screen and map the SMART BEAR requirements in order to identify any further requirements.

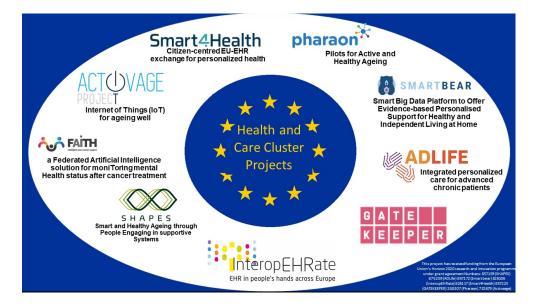


Figure 5: Overview of the Health and Care Cluster Projects Source: SHAPES Project (2020): Large Scale Pilots¹³



⁵ https://www.pharaon.eu/ (28.10.2020).

⁶ https://adlifeproject.com/ (28.10.2020).

⁷ https://www.gatekeeper-project.eu/ (28.10.2020).

⁸ https://www.h2020-faith.eu/ (28.10.2020).

⁹ https://activageproject.eu/ (28.10.2020).

¹⁰ https://www.interopehrate.eu/ (28.10.2020).

¹¹ https://www.smart-bear.eu/ (28.10.2020).

¹² https://www.smart-bear.eu/wp-content/uploads/2020/01/D5-D2.1.pdf (28.10.2020).

¹³ https://shapes2020.eu/projects/large-scale-pilots/ (28.10.2020).



2.2.3 Link with other SHAPES Tasks and user group interaction

In addition to this review, the development of the platform requirements was supposed to be linked closely with the SHAPES tasks as described above i) to ensure the integration of generated findings into the requirements development, ii) to exploit the established interaction and trust with actors in other tasks (and particularly under 2.1 Understanding Older People) as well as to iii) overcome language barriers existing with several pilot sites and use cases. Finally, this also eased the integration of a range of different views by limiting the number of personal contacts due to COVID-19.

The exchange with the different SHAPES Task for the 2nd iteration of the platform requirements is detailed in Section 3 below. During the 1st iteration, the main exchange took place with Task 2.5 (SHAPES Personas and Use Cases) to include the needs of the different care receiver personas and Task 3.1 (Ecological Organisational Models of Health and Care Systems for Ageing) to include the requirements dimension into the analysis of the different health care systems. In collaboration with Task 3.1, knowledge needs have been formulated by Task 3.5 for consideration in the review and interviews conducted under Task 3.1. They encompassed the following questions:

- 1. What digital technologies are you currently using as a care provider?
 - a. Briefly describe the most important ones (maximum of 3).
 - b. When did you introduce them?
 - c. What are the advantages of using these technologies?
 - d. What are the disadvantages of using these technologies?
 - e. While using these technologies, what are/were the major concerns and obstacles (i.e. personal skills, organizational problems, technical issues/limitations)?
- 2. If more digital solutions were to be introduced in your unit, what additional elements would you require (e.g. training for workers, more computers, high-speed internet access)?
- 3. Is there a way of linking any of these technologies?
- 4. With regard to the user experience of the platform, what information do you need to have in order to be able to use it?
- 5. Will the platform be used by every individual care giver?
- 6. How many users do you think will need to have access to the platform?
- 7. Will you have a single user of the platform (e.g. someone in management)?

To the extent possible, these were considered in the Task 3.1 analysis and interviews. Feedback was received from Task 3.1 in the form of requirements and needs extracted from the analysis of the different health care systems as detailed in section 3.2.1 and Annex II.

For the 3rd iteration, a *Requirements Board* will be set-up, being composed of selected SHAPES partners and external actors reflecting the different user groups for validation and weighting purposes. In addition, exchange with the pilot sites and use cases under WP 6 is currently being organised.



3 Process for specification of Platform requirements

3.1 Summary of 1st Iteration (D3.7)

3.1.1 Functional and non-functional requirements

As a result of the project and literature review that took place in the first iteration of this Deliverable, six requirements dimensions had been developed:

- Functional Requirements
- Non-functional requirements:
 - Security requirements
 - Ethical & Legal requirements
 - Health system requirements
 - Business requirements
 - Technical requirements

Each of the dimensions (functional and non-functional) was divided into several subcategories and exemplary requirements specifications. The dimensions, actors and requirements were refined and expanded during the 2nd iteration as described below.

3.1.2 Requirements coding

In order to be able to use and track the final platform requirements, they will each have a specific identification code. This code is made up of four sequences: <category>-<sub-category>-<number>-<user identification>.

Each category of requirements has a specific code, as follows:

Functional requirements: FR

Non-functional requirements:

Security: S

Legal and Ethical: LEHealth System: HS

Business: B

Technical requirements: TR

Similarly, each sub-category in every main category also has a unique code. For example, for the Legal and Ethical requirements there are the following sub-categories:

General Ethics: GEEthics for Platform: ET



- Ethics for Processes and Support: PE
- Ethics for Governance, Business and Ecosystem Models: ME

The third sequence element is a number, which starts at one for each sub-category.

Finally, the actor to which the requirement applies is given by the final element. The coding is as follows:

• Care Receiver: CR

Care Giver (formal): CGFCare Giver (informal): CGI

Doctors: D

Health administration / insurance: HAITechnology / Solution Provider: TP

A final requirement could, for example, look like this: FR-HS-1-CR (Functional Requirement; Health Services; First requirement; related to Care Receiver).

3.2 Working steps for 2nd Iteration

The interaction with the SHAPES WPs can be differentiated into two main building blocks: the interaction with WPs 2, 3, 7 and 8 and the exchange with the SHAPES pilot sites and solutions to be integrated into the platform through WP6 interaction.

3.2.1 Interaction with WPs 2, 3, 4, 5, 7 and 8

Interactions with multiple SHAPES partners from different WPs took place between July and October 2020. More particularly, the following telephone conferences and exchanges have been organised, mostly via Teams. The different actor groups are illustrated in the figure below and specified in Table 5.





Platform User Groups and WP Interaction under Task 3.5

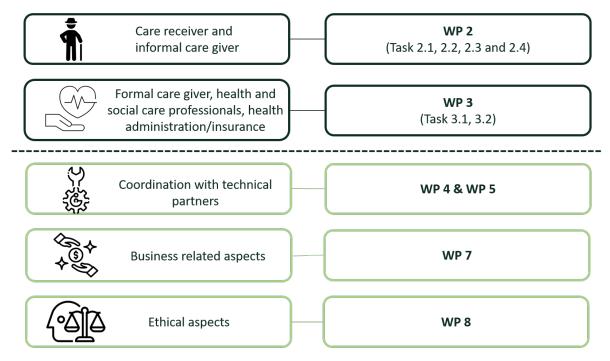


Figure 6: Interaction with SHAPES Platform User Groups and thematic experts through different WPs Source: own figure.

Table 5: Overview of exchanges with SHAPES partners and meaning for SHAPES platform requirements

| Date | Partners Involved | WP/Task Link | Discussion subject Conclusion |
|----------|--|--------------|--|
| 4.8.2020 | Tatiana Silva (TREE), Mark Donnelly (Ulster), Evert-Jan Hoogerwerf (AIAS), Victor Fernandez- Carbajales Cañete (TREE), Bettina Meeren (GEWI), Meftah Ghrissi (KOMPAI), Michael Scott (NHSCT), Andreas Andreou (UNRF), Fotis Gonidis (GNOMON), George Bogdos (FINT), Athanasios Tzikas (DYPE5), Waihang Shek (OMNITOR), Lucia D'Arino (WFDB), | WP4 and WP5 | Agreement on dimensions and revision/expansion of user groups; deleting of technology partners as users. |



| | Deirdre Desmond (NUIM), Valentina Fiordelmondo (AIAS), Oscar Villacanas (CH), Niamh Redmond (NUIM), Paul Isaris (SciFY), Maria Metaxa (AUTH), Dewar Finlay (Ulster), Christoph Kokelmann, Emma McEvoy, Claire Scullin (NHSCT), Tereza Norbertová (FNOL) | | |
|-----------|---|--|--|
| 12.8.2020 | Melanie Labor (NUIM) | Task 3.1 "Ecological Organisational Models of Health and Care Systems for Ageing" | First thoughts on how to integrate the findings of the Health Ecosystems into Task 3.5. |
| 26.8.2020 | Nicola Goodfellow (NHSCT) | WP2 | Health System Professional Requirements |
| 28.8.2020 | Evert-Jan Hoogerwerf | Task 3.2 "Scaling- up Improved Integrated Care Service Delivery" | Establishing a link with the ProACT project and more particularly its user requirements. |
| 1.9.2020 | Sari Sarlio-Siintola and Nina Alapuranen (LAUREA) | Task 8.4 "Privacy and Ethical Risk Assessment for the SHAPES Platform" | Integration and ranking/prioritisation of D8.4 findings. |
| 2.9.2020 | Exchange with Donal McClean and Matt McCann (Access Earth) | Task 2.2 "Accessing Physical Spaces" | Platform Requirements from Access Earth User perspective. |
| 3.9.2020 | Exchange with Lucia D'Arino (WFDB) and Frankie Picron and Mark Wheatley (EDU) | Accessibility Board | Platform Requirements from Accessibility perspective |
| 9.9.2020 | Ian Spero (AAA) | Task 2.3 "Cultivating Age- Friendliness" | Stressing the need for interoperability, scalability and |



| APES | | | |
|------------|---|---|---|
| | | | sustainability of the platform |
| 10.09.2020 | Melanie Labor (NUIM) | Task 3.1 "Ecological Organisational Models of Health and Care Systems for Ageing" | Submission of platform requirements extracted from Task 3.1. |
| 15.09.2020 | Barbara Guerra and Marco Manso (EDGE), Tatiana Silva (TREE), Alexia Zurkuhlen and Bettina Meenen (GEWI), Evangelos Markakis, Skepasia nos Iraklis and Yannis Nikoloudakis (HUM) | WP7 Meeting for the development of business requirements | Integration of business requirements for the SHAPES platform |
| 28.09.2020 | Katja Seidel, Jamie Saris and David Prendergast (NUIM), | Task 2.1 "Understanding older people" | Collaboration on the validation and weighting of requirements; integration of research results from Task 2.1 |
| 30.09.2020 | Borja Arrue (AGE) | Task 2.4 "Empowerment of Older Individuals in Health and Care Decision-making" | Synergies between 3.5 and 2.4, envisaging a joint consultation workshop to validate and weight the requirements. |
| 13.10.2020 | Nicola Goodfellow (NHSCT) | WP2 | Feedback on platform requirements (see also Annex IV) |
| 20.10.2020 | Óscar Villacañas Pérez | WP6 | Feedback on platform requirements (see also Annex V) |
| 21.10.2020 | Katja Seidel (NUIMI) | Task 2.1 | Feedback on the platform functionalities from an ethnographic point of view (see Annex I for their matching with functional requirements) |



3.2.2 Interaction with WP6 "Pan-European Pilot Campaign"

In terms of WP-6 interaction, an exchange took place during the WP meeting on 10th September 2020:

| Date | Partners Involved | WP/Task Link | Discussion subject Conclusion |
|----------|--|--|--|
| 10.09.20 | WP6 online meeting, Participants: Niamh Redmond & A. Jamie & Richard Lombard-Vance & Deirdre Desmond (NUIM), Corina Röllig (CCS), Bettina Meeren (Gewi), Michael Scott and Claire Scullin (NHSCT), Anabela Silva & Oscar Ribeiro (UAVR), Xavier del Toro Garcia (UCLM), Pedro Rocha (UPORTO), Vagelis Stamatiadis &Fotios Gio ulekas (5thYPE), Eduardo Carrasco & Mannex Serras (VICOM), Ioanna Dratsiou & Maria Metaxa (AUTH), Ronan O'Sullivan (UCC), Artur Krukowski (ICOM), Andreas Andreou (UNRF), Christoph Kokelman (MedicalSy n), Tereza Norbertova (FNOL), Yannis Nikoloudakis & Iraklis Sk epasianos (HMU), David Gonzalez Barrera (TREE), Dewar Finlay (ULS), Sarah Cooper (PAL), Paul Isaris (SkiFy), Mefthah Grissi (KOM), Oscar Villacans (CH), Lucia d'Arino (WFDB), George Bogdos (FINT), Barbara Guerra (EDGE) | Suggesting interaction process with pilots | Information requested with respect to platform requirements and requirements for digital solutions |

WP6, just as the above-mentioned WPs, has overlaps with the development of the SHAPES platform requirements. Most importantly, the *pilots* organise the interaction with the study sites and actors with respect to particular digital solutions and platform functionalities. In order to ensure that the needs of the actors in the different study sites are taken into consideration for the platform requirements, a two-way process was initiated. On the one hand, *pilot* sites were asked to develop requirements for the



platform with their end-user, i.e. the older people they are working with. More particularly, partners were asked to identify requirements with respect to including the below detailed guiding examples:

- **Functionalities** (for example measuring of nutrition intake, dedicated information spaces, etc.)
- Legal and Ethical aspects (for example data protection etc.)
- **Security** (for example cybersecurity, resilience of platform, etc.)
- **Technical aspects** (for example scalability, interoperability, etc.)
- Business aspects (for example, selection of cost-benefit effective devices, etc.)

On the other hand, pilot and replicating sites developed their own user requirements with respect to the adaptation of digital solutions that are to be tested. While the digital solutions are distinct from the platform, the requirements were scanned and mapped against the Draft version of the SHAPES platform requirements particularly with respect to the functionalities that the platform should encompass. Platform requirements were expanded accordingly. The mapping of the requirements is documented in Annexes IV-VI. At the current stage, the requirements of UC-PT2-001, UC-PT-3 and UC-PT-5-001 have been integrated into the platform requirements. This work is ongoing and all use cases have been asked to complete their requirements until February 2021 to allow for their review and integration into the platform requirements.

3.3 Results of the above interaction

The above detailed interaction can also be differentiated between the WP 2, 3, 7, and 8 interaction and the interaction with the pilot and replicating sites under WP6. The main results are summarised below.

3.3.1 Interaction with WPs 2, 3, 7, and 8

After the discussions with the project partners as sketched above, the following main adaptation were made:

3.3.1.1 Revision of dimensions, actors and requirements

- **Deletion of technical partner/technology providers as user group**. Although this group will interact with the platform, it is understood primarily as a service provider that needs to design the products and services according to the main actors, i.e. care receiver, care giver (formal and informal), health and social care professionals as well as health administrators and insurances.
- **Specification of actors**. The actors were further specified, reframing "doctors" to health care professionals and integrating social care professionals. In addition, the requirements were link with the actors for they are of relevance.
- Deletion of health dimensions. Since there were main overlaps with the functional requirements, requirements were integrated into the functional dimension.

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- Reorganisation and ranking of ethical and legal requirements. Jointly with WP8, ethical requirements were prioritised. Some aspects were moves to the technical and security dimensions (e.g. data protection aspects) where they seemed to fit more naturally.
- **Integration of accessibility requirement**. Accessibility was integrated as a high priority technical requirement for the platform to be inclusive. The VidAsor Project (Videoassistance and accompaniment for deaf seniors) can serve as an example on how to implement total conversation (see Annex X).

3.3.1.2 Integration of additional requirements

3.3.1.2.1 Task 2.1 Link: Insights from "Understanding older people"

In the exchange with Task 2.1 "Understanding Older People: Lives, Communities and Contexts" several requirements were formulated based on the in-depth interviews of which about 25 have been completed so far. The main requirements were:

- i) To design the platform in a way that resembles technologies that older people use in their every-day life. It was hence suggested to build on structures that are used for example in online-banking and
- ii) Allow for an easy to adjust appearance, i.e. contrasts, fonds, etc. Some older people may understand well how to adapt the appearance and it subsequently highly eases the use. Others may however not be familiar with adjusting respective appearances and might need support for this. Overall, the adjustability should also relate to the content of relevance since different people have different needs.
- iii) Stick to the "two-click-rule" and make use of a double menu at the top and on the side. If the platform is too difficult to navigate, it will not be used.

In addition to these requirements, the functional requirements were discussed by and linked with the ethnographic research conducted by Task 2.1. A respective column was inserted into the requirements (see Annex I). Overall, the requirements are hence linked with qualitative aspects that need to be considered when implementing certain functionalities of the platform. For the next iteration, Task 2.5 will review the requirements and link them with the insights from their research as well.

3.3.1.2.2 Task 2.4 Link: Aligning platform requirements and policy design

Task 2.4 "Empowerment of Older Individuals in Health and Care Decision-making" only starts in M13. However, Task leader AGE Platform Europe is "a European network of non-profit organisations of and for people aged 50+, which aims to voice and promote the interests of the 200 million citizens aged 50+ in the European Union (Eurostat, 2018) and to raise awareness on the issues that concern them most." In order to discuss certain aspects of ageing, AGE works with dedicated thematic *Task Forces* which are composed of representatives of organisations of older people based in different EU countries. While there are no results yet on which Task 3.5 could build



¹⁴ AGE Platform, About AGE, https://www.age-platform.eu/about-age (01.10.2020).



(as Task 2.4 begins only in month 13), it is envisaged to hold a joint workshop for the 3rd iteration of the requirements, involving the Task Force on *Dignified Ageing*.

3.3.1.2.3 Task 3.1 Link: Requirements relating to health system specificities

Task 3.1 "Ecological Organisational Models of Health and Care Systems for Ageing" extracted data from the CONOPS matrix which was created as part of the data gathering activities for D3.1. This data was partially gathered through interviews with relevant SHAPES partners, the WHO Health Systems in Transition Series¹⁵ and the Challenges in Long-Term Care series¹⁶. Task 3.1 thereby established the link to the health system models considered in SHAPES. The list of requirements derived can be found in Annex II. They were mapped against the Draft of the Platform requirements. Requirements covered or integrated are marked green; requirements neglected are marked yellow or red and linked with justifications.

3.3.1.2.4 Task 3.2 Link: ProACT project requirements

The integration of the ProACT requirements was suggested by Task 3.2 (Evert-Jan Hoogerwerf). The requirement study for the ProACT project¹⁷ was performed with the involvement of the most important public health and social care providers in Emilia-Romagna Region (Italy). The study design has followed the following steps:

- 1) Stakeholder groups and areas of need have been identified.
- 2) For each stakeholder group, focus group protocols have been co-designed, translated into Italian and used in focus groups.
- 3) All participants, with the exception of the managers in care have completed the standard demographic data questionnaire.
- 4) All focus groups have been audio recorded, transcribed and analysed using NVivo.

Stakeholders were divided into the following groups: Adults with multimorbidity, Informal carers, Formal carers, Health professionals, Older people in situations of frailty, Managers in Health and Social Care, Social Workers, Adults with disabilities. Each group was composed by 4 to 8 people and was involved in two focus group sessions: the first one was focused on personal experiences in care, care pathways, self-management of conditions, challenges and expectation towards health and care services. The second meeting was focused on the use of technology and on the expectations regarding the benefits of the use of technology in the care system. All focus groups were transcribed, transcripts have been analysed both at single stakeholder group level and at cross stakeholder thematic level and results were crossed. Key findings identified led to the definition of requirements.

https://www.euro.who.int/en/about-us/partners/observatory/publications/health-system-reviews-hits/full-list-of-country-hits

¹⁶ https://ec.europa.eu/social/main.jsp?langId=en&catId=792

¹⁷ http://proact2020.eu/ (09.09.2020).



The ProACT platform requirements have been mapped against the SHAPES platform requirements as detailed in Annex III. Some of them had already been considered. Additional requirements were integrated into the platform requirements after assessing their applicability.

3.3.2 Interaction with pilot sites (WP6)

In addition to the exchange with the partners of WPs 2, 3, 7, and 8, exchange was sought with WP6, namely the pilot and replicating sites for two main reasons:

- i) Strengthening the link with the end-users in the pilot sites, represented by the care receivers, care givers as well as health and social care professionals in the study sites.
- ii) Ensuring that the requirements formulated for digital solutions to be tested are also aligned with the SHAPES platform requirements.

The WP6 telephone conference held on 10th September 2020 was therefore used to detail these objectives and Task 3.5 information requirements. Pilot sites were then asked to discuss with their sites the platform requirements and to formulate these along the following dimensions:

- **Functionalities** (for example measuring of nutrition intake, dedicated information spaces, etc.)
- **Legal and Ethical aspects** (for example data protection etc.)
- **Security** (for example cybersecurity, resilience of platform, etc.)
- **Technical aspects** (for example scalability, interoperability, etc.)
- **Business aspects** (for example, selection of cost-benefit effective devices, etc.)

In addition, each pilot and replicating site is developing a set of requirements for the digital solutions to be tested throughout the project lifetime. For example, pilot 3 "Medicine control and optimisation" deals with the monitoring of health data. While "Health data collection and management (and sharing) of health parameters" had already been defined as a requirement (FR-HS-3), specifications such as

- Measuring daily steps (to measure daily activity)
- Measuring Water uptake or
- Sleep tracking

were additionally integrated as specifications of requirements FR-HS-3 into the overview (FR-HS-3a-FR-HS-3g).

For all pilots, user requirements completed until 16th October 2020 were mapped against the platform requirements as detailed in Annex VI - IX. The overview of these pilots and replicating sites considered is detailed in the table below.



Table 6: Review and integration of user requirements from SHAPES use cases

| Pilot | Use case | Annex | |
|--|--|------------|--|
| PT1 - Smart Living ageing at Home | ng Environment for healthy | | |
| PT1-001 | Remote In-Home Wellbeing Monitoring and Assessment | Annex VI | |
| PT2 - Improving based Care | In-Home and Community- | | |
| PT2-001 | Monitoring of health parameters | Annex VII | |
| PT3 - Medicine Co | ntrol and Optimisation | | |
| PT3-general | Supporting multi-morbid older patients | Annex VIII | |
| PT4 - Psycho-soci Promoting Wellbei | ial and Cognitive Stimulation ing | | |
| To be integrated. | | | |
| PT5 - Caring f | or Older Individuals with | | |
| Neurodegenerative | e Diseases | | |
| PT5-001 | Online information and training for informal dementia caregivers | Annex IX | |
| PT6 - Physical Reh | nabilitation at Home | | |
| To be integrated. | | | |
| PT7 - Cross-borde | r Health Data Exchange | | |
| To be integrated. | | | |



4 Overview of SHAPES Platform Requirements

Building on the 1st iteration of the Deliverable (3.7) and the insights derived through the action specified above, the following requirements have been specified. A more encompassing overview including the relevance for different actor groups, comments, open questions, initial prioritisation as well as links with the ethnographic research can be found in Annex I.

4.1 Functional Requirements (Coding: FR)

| Sub-categories | Specification | Coding |
|-----------------------------|--|----------|
| Health support (Coding: HS) | An eHealth call centre to support platform users e needs to be available 24/7 for all users. | FR-HS-1 |
| | The platform should include tutorials and help cards regarding its use and the use of the devices connected to it. Also a glossary of terms should be available. | FR-HS-2 |
| | Health data collection and management (and sharing) of health parameters | FR-HS-3 |
| | Measuring daily steps (to measure daily activity) | FR-HS-3a |
| | Measuring daily exercises (time of exercise, intensity, objectives) | FR-HS-3b |
| | Measuring Water uptake | FR-HS-3c |
| | Sleep tracking (duration, begin/end; day time sleep; wake ups at night) | FR-HS-3d |
| | Nutrition tracking | FR-HS-3e |
| | Medication tracking | FR-HS-3f |
| | Monitoring of vital signs (weight, blood pressure, blood glucose, bioimpedance, heart rate, blood oxygen level, etc.) | FR-HS-3g |
| | Capability to enter manual data | FR-HS-3h |
| | Processing of health data: risk assessments, action plans | FR-HS-4 |
| | Recording the perceived state of well-being / self-assessment tool | FR-HS-5 |
| | Help for dealing with legal issues (e.g. advanced care plans; end-of-life care) | FR-HS-6 |
| | Medication reminder / support Reminder for clinical readings/appointments | FR-HS-7 |



| | Pain management system | FR-HS-8 |
|----------------------|--|----------|
| | Medical emergency alert system | FR-HS-9 |
| | Track and record clinical device characteristics regarding maintenance/calibration, make, model number | FR-HS-10 |
| | SHAPES platform should be explicit about the benefits of its use (prompts, feedbacks, rewarding messages, etc.) | |
| | Predictive Medicine (Predict risk of health events including decompensations in patients with heart failure, exacerabations of COPD, and hypo/hyperglycaemia in patients with diabetes. Using smart data analytics and predictive algorithms and Ambient Intelligence Health and Wellness Platform.) | |
| | Appliances Monitoring (on/off; duration of use) | FR-HS-13 |
| Information services | Easy to use communication systems | FR-IS-1 |
| (Coding: IS) | Video conferencing to complete medicines reviews (Remark: check inhaler technique) | FR-IS-2 |
| | Ability to provide questionnaires to monitor health-related quality of life, medicines adherence, symptoms etc | |
| | Easy to navigate dashboard and summary for healthcare professional review | FR-IS-4 |
| | Include fields of metadata that define the origin of a value | FR-IS-4a |
| | Ability to allocate tasks to specific healthcare professionals through the dashboard and mark as 'ongoing', 'complete', 'further follow-up required' or ability to leave notes e.g. handovers/updates | |
| | Scheduling of specific tasks for different users (care receiver, care giver, etc.) | FR-IS-5a |
| | Provide motivation/encouragement sentences to the care receiver: These set of sentences are to be provided on a regular basis or based on the values of other data, completion of tasks, etc. | FR-IS-5b |
| | Easy to navigate app/dashboard for service user/carer to review | FR-IS-6 |



| Relevant patient data: Age, gender, degree of dependence, individual top three challenges | FR-IS-6a |
|---|-----------|
| Relevant care giver data: Age, educational degree, distance to reach care receiver, access to internet, technological skills | FR-IS-6b |
| Caregiving data: type of care, duration and frequency of care Relevant caregiving data: delivery, number of caregivers, relationship | FR-IS-6c |
| Information about support services: peers and networks | FR-IS-7 |
| Information about support services: mental health | FR-IS-8 |
| Information about support services: physical help | FR-IS-9 |
| Create logs for personal data (e.g., who has seen/modified personal data and when). | FR-IS-10 |
| Permission/access privilege management | FR-IS-10a |
| Option of withdrawal from a pilot/ the platform | FR-IS-11 |
| Remove the study completely or the ability to use data up until the point of withdrawal providing consent is provided | FR-IS-11a |
| Allow the data subject to request a copy of the information held about them | FR-IS-11b |
| Provision of training material for care providers | FR-IS-12 |
| Training exercises are available as free text answer, drag & drop or check list. | FR-IS-12a |
| Training exercises and knowledge tests provide immediate feedback on answers. Feedback is provided using distinctive colours (red- incorrect, green-correct, blue- possible answer) and by offering detailed text-based explanations. | FR-IS-12b |
| The text contents in the programme adapt to users' information (e.g. name, gender/ name, gender of the person being cared for). | FR-IS-12c |
| The intervention plan (lessons to be performed) is chosen by the users according to their own needs and availability. | FR-IS-12d |
| The training plan set by the user can be modified at any time (lessons can be added or deleted). | FR-IS-12e |
| Quick overview of completed lessons | FR-IS-12f |
| Lessons start in the page where the users' left in his/her previous access. | FR-IS-12g |



| | A printout module is available to print personalized booklets of the sessions mirroring the user learning process. | |
|--------------------------|---|-----------|
| | Skills certificates are generated after lesson completion. | FR-IS-12i |
| | Realistic scenarios are used to train skills. | FR-IS-12k |
| | Satisfaction ratings (on usefulness and comprehensiveness) are available at the end of each lesson (star ratings). | FR-IS-12I |
| | Users can add new options to specific answer lists. | FR-IS-12m |
| | A button to start the lesson from the beginning could be added. | FR-IS-12n |
| | The printing option should be available directly when clicking at each lesson. | FR-IS-12o |
| | Drag and drop exercises should have the feedback displayed in the visible page area. | FR-IS-12p |
| | Information icons in check list exercises should be replaced by automatic display of information when the answer is selected. | FR-IS-12q |
| | The home page requires a visual lesson scheme. | FR-IS-12r |
| | Contents on legal aspects, social support mechanisms, disease progression and anticipatory grief should be added to the programme. | FR-IS-12s |
| Health maintenance | Mental exercises for care receivers and care providers | FR-HM-1 |
| support (Coding: HMS) | A mood assessment function is available for self-completion with ratings and free text assessment options. A mood graph/mood history is displayed to represent mood progress over time. | FR-HM-1a |
| | Mood ratings of x or lower should direct the users to relaxation and/or cognitive reframing lessons. | FR-HM-1b |
| | Various different relaxation exercises are available with options based on muscular relaxation and on imagery-based relaxation. | FR-HM-1c |
| | Relaxation exercises instructions are available in text and audio. | FR-HM-1d |
| | More than one mood status can be added per day. | FR-HM-1e |
| | The scale for mood assessment should discriminate the numbers from 1 to 10. | FR-HM-1f |



| | Physical exercises | FR-HM-2 |
|----------------|---|---------|
| | Support in maintaining good dietary balance; health literacy | FR-HM-3 |
| Living support | Assisted mobility at home | FR-LS-1 |
| (Coding: LS) | Assisted mobility and devices to monitor movement outside/ travel outside | FR-LS-2 |
| | Sensors to monitor falls | FR-LS-3 |
| | Sensor to monitor dangerous situation (fire, gas, electricity) | FR-LS-4 |
| | Home Monitoring (temperature; humidity; air quality) | FR-LS-5 |
| | Food shopping and similar support | FR-LS-6 |
| | Accessibility information for public spaces | FR-LS-7 |

4.2 Legal and Ethical Requirements (Coding: LER)

| Sub-categories | Specification | Coding |
|--------------------------------|--|---------|
| General Ethics (Coding: GE) | Maximise the level of fundamental rights of older persons and of care givers that SHAPES can promote | LE-GE-1 |
| | Ensure that SHAPES does not violate any fundamental rights of older persons and/or other stakeholders (e.g., non-discrimination, dignity, integrity and privacy when having robots, webcameras at home). (TBD) | LE-GE-2 |
| | Be aware of the four biomedical principles. Apply and promote those within SHAPES (justice, beneficence, non-maleficence and autonomy when using SHAPES services). | LE-GE-3 |
| | Be aware of the perspectives of care ethics. Apply and promote those within SHAPES (empathy, relationships, uniqueness of the case). | LE-GE-4 |
| | Maximise the level of human capabilities of older persons and caregivers that SHAPES can promote. | LE-GE-5 |
| | Ensure that SHAPES is not detrimental to any human capabilities of older people and/or other stakeholders. | LE-GE-6 |
| | Develop solutions that offer users different options to act according their own choice and practical reasoning. Be open to innovations that may not presuppose commercial commodities. | LE-GE-7 |



| _ | |
|--|----------|
| Note that the participation of older persons in the development of SHAPES can in itself be seen as a service that supports a person's human capabilities. Ensure that end-users have real power and impact in service development as part of the SHAPES ecosystem. | LE-GE-8 |
| Consider working methods and tools in the end- user collaboration so that they support a person's capabilities and ensure that essential information on end-users' needs is captured. (incl. the use of suitable service design tools in order to acquire and communicate properly end- users needs. | LE-GE-9 |
| Consider sustainable development goals in order to optimise the value SHAPES can bring to society. Work towards both the economic, social and environmental sustainability of the SHAPES Integrated Care Platform. | LE-GE-10 |
| Consider that the public sector, as part of the SHAPES ecosystem, plays a role as a bearer of political responsibility for ensuring the wellbeing of older persons. | LE-GE-11 |
| Be aware that the use of various digital solutions has an impact on the workload of caregivers but also their work displacement. | LE-GE-12 |
| Investigate improvements in the quality of work that the technology brings to homecare professions. | LE-GE-13 |
| Figure out opportunities to apply current services or implement new solutions to fight Covid-19. | LE-GE-14 |
| Consider and follow up technologies, scenarios and building blocks elaborated in the document "Blueprint on Digital Transformation of Health and Care for the Ageing Society". | LE-GE-15 |
| Ensure human agency and oversight in SHAPES Al solutions. | LE-GE-16 |
| Ensure technical robustness and safety of SHAPES AI solutions. | LE-GE-17 |
| Ensure privacy and data governance of SHAPES AI solutions. | LE-GE-18 |
| Ensure transparency of SHAPES AI solutions. | LE-GE-19 |
| Ensure the diversity, non-discrimination and fairness of SHAPES AI solutions. | LE-GE-20 |
| Ensure the societal and environmental wellbeing of SHAPES AI solutions. | LE-GE-21 |



| Ensure the accountability of SHAPES Al solutions. | LE-GE-22 |
|--|----------|
| Develop data protection and cybersecurity policies to be published on the SHAPES website. | LE-GE-23 |
| Data subject rights: right of access – define what data will be included. | LE-GE-24 |
| Data subject rights: right to rectification – define the process to correct information. | LE-GE-25 |
| Data subject rights: Right to be forgotten – define what data can be erased. | LE-GE-26 |
| Data subject rights: right to restriction – define the right level for restriction. | LE-GE-27 |
| Data subject rights: information to third parties – inform of data rectification/erasure to parties to whom data is disclosed. | LE-GE-28 |
| Data subject rights: right to data portability – define what data will be given to the data subject. | LE-GE-29 |
| Data subject rights: right to object: 1) define a process for manual processing instead of automated decision making + ensure information to the data subject; 2) ensure that the balancing test has been done when using profiling. | LE-GE-30 |
| Data protection principles: lawfulness – identify and document a lawful basis for processing data. | LE-GE-31 |
| Data protection principles: fairness – ensure that you use personal data so that it is fair from the data subject's point of view. | LE-GE-32 |
| Data protection principles: transparency – ensure that data subjects are informed about the usage of their data. | LE-GE-33 |
| Data protection principles: purpose limitation -1) ensure that the data is used only for a specified purpose and inform data subjects why and for what purpose the data is used; 2) ensure that if the data is used for a new purpose, there is a right to do so. | LE-GE-34 |
| Data protection principles: Storage minimisation – document how long data will be kept and justify it. Decide how the data will be processed when it is no longer required. | LE-GE-35 |
| Data protection principles: accuracy – create a process to check data accuracy and record the source of the data. | LE-GE-36 |

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| _ | |
|---|----------|
| Legal basis: define the legal basis for processing a) make a documented balancing test if needed (if processing is based on legitimate interest); b) if the legal basis is informed consent, ensure there is a proper documented process for asking consent. Note that there are also users who cannot give their own consent but whose consent is given by a legal representative. | LE-GE-37 |
| Automated decision-making: if processing contains automated decision-making, build a manual process to comply with art. 22 of GDPR. | LE-GE-38 |
| Data protection by design and by default: ensure data protection is taken into account when start planning for new services or processes. Adopt a "privacy first" approach. | LE-GE-39 |
| Risk management: conduct a DPIA for each pilot and for SHAPES Integrated Care Platform. | LE-GE-40 |
| Personal data breach: ensure that SHAPES has a consistent process for handling personal data breaches, including communication to the data subject and to the supervisory authority. | LE-GE-41 |
| Technical and organisational security measures: identify and document which roles need to have access to personal data. | LE-GE-42 |
| Create data protection-related templates: a) DPIA template b) personal data processing descriptions template c) personal data used in service xx d) template for balancing test. | LE-GE-43 |
| Obligations of the controller: fill the template "Personal data used in service xx" for each service. | LE-GE-44 |
| Ensure that privacy and data protection related responsibilities (e.g., NDAs, data processing agreements, data processing descriptions) are covered in service/technology agreements. The same applies to agreements with end-users. | LE-GE-45 |
| Investigate the ethical and legal aspects regarding the secondary use of personal data on the SHAPES for research purposes. | LE-GE-46 |
| Be aware of the importance and challenges with the terminology regarding older persons, also in your own language as well as the diversity of older persons as a group. Use non-stigmatising language. | LE-GE-47 |



| | Acknowledge the heterogeneity of older persons that materialise in the diversity of how older persons adopt and use digital devices (exclusion and inclusion). | LE-GE-48 |
|-----------------------------|---|----------|
| | Acknowledge the barriers and facilitators of older persons' usage of digital devices (perception of usefulness, user requirements, self-efficacy, sense of self, privacy and confidentiality, cost). | LE-GE-49 |
| | Acknowledge and understand the diversity and complexity of ageing and incorporate that gained understanding into the design process of health technology devices, including the realistic assessment or their usability. | LE-GE-50 |
| | Make sure that situational awareness is always up to date (cognitive domain). | LE-GE-54 |
| | Investigate and collect user feedback related to services that may be considered intrusive (e.g., facial recognition), risky for autonomy or for depersonalisation or for sense of security (e.g., robots), or associated with a surveillance type of services without one's own control (sensors at home). | LE-GE-55 |
| | Apply Design for All –approach in SHAPES development | LE-GE-56 |
| Ethics for Platform (ET) | Ensure equal and non-discriminatory access to technology and its support services by using well-designed user interfaces and authentication. | LE-ET-1 |
| | Consider cultural diversity of users; e.g., create avatars that represent different genders and cultures and let the user choose what to use. (TBD) | LE-ET-2 |
| | Create functionalities for the end-user to switch off/on various sensors and services whenever they want to. (TBD) | LE-ET-3 |
| | Data subject rights: right of access – build a self-service portal where the data subject can get access to his/her data. | LE-ET-4 |
| | Data subject rights: right to rectification – ensure that the data can be corrected in all places (incl. storage). | LE-ET-5 |
| | Data subject rights: right to be forgotten – build capabilities for deleting personal data. | LE-ET-6 |
| | Data subject rights: right to restriction – build a capability for restricting data processing. | LE-ET-7 |
| | | |



| r ii h | Data subject rights: information provided to third parties — create a functionality to easily get information about the third parties to whom data has been disclosed as part of robust data mapping and flows. | LE-ET-8 |
|--------------|---|----------|
| 5 | Data subject rights: right to data portability – create a capability to transmit data to the data subject/third party in a structured, commonly used and machine-readable format. | LE-ET-9 |
| t r s | Data subject rights: right to object: 1) ensure that he information about automated decision-making can be given to the user (the data subject) before the process starts; 2) create the capability to prevent the data subject's data to be part of profiling if a data subject has objected to profiling. | LE-ET-10 |
| - r v | Data protection principles: storage minimisation - ensure that there are technical capabilities to erase or anonymise personal data after the elevant data retention period. Ensure that data will be removed from all systems. Define automated functions if this is possible. | LE-ET-11 |
| | Data protection principles: accuracy – ensure hat the source of the data is recorded. | LE-ET-12 |
| t c r | Legal basis: a) ensure that there are sufficient echnical capabilities for asking consent as part of the service and that the consent is documented properly (obligatory); b) build up a epository where consents can be collected centrally (optional – to be defined if it brings value to SHAPES). Note that there are also users who cannot give their own consent but it is given by a legal representative. | LE-ET-13 |
| | Create traceability capabilities for personal data; data mapping/data flows. | LE-ET-14 |
| a | Automated decision-making: Ensure that there's a capability to re-direct the decision to a manual process. | LE-ET-15 |
| t v | Data protection by design and by default: ensure hat data-protection aspects are considered when designing and developing technological solutions by adding data-protection checkpoints to the development process. | LE-ET-16 |



| | _ | |
|---|--|----------|
| | Data protection by design and by default: add data protection section to "application portfolio" to describe if personal data is processed in the application and if yes, to add additional information such as sensitivity of the data, legal basis for processing data, retention period, link to data maps etc.; detailed information to be added will be defined with the WP8. | LE-ET-17 |
| Ethics for Processes and Support (PE) | Create a process for the implementation of services for single end-users (older persons) + and for the assessment of the suitability of the services from time to time (including a process to assess the digital literacy of the end-user and adapt the services according to end-user needs and capabilities). The process should include more time to discuss choices or have an advocate regarding important appointments in order to make notes and help the person understand or remember choices. | LE-PE-1 |
| | Create a detailed process to determine if the older person is able to decide on accessing the services and secondly if she/he is able to give informed consent for the collection of the information. | LE-PE-2 |
| | Provide for the end-user (older persons) plain language materials, information in visual form (including information on each service and how it operates and what data it collects.) | LE-PE-3 |
| | Create training material on data protection to end-users who need to understand data protection (older persons, caregivers). | LE-PE-4 |
| | Create a process for executing data subject rights in SHAPES (e.g., access to data). | LE-PE-5 |
| | Define skills and specific competences needed for the care givers using the SHAPES services and provide training materials. | LE-PE-6 |
| Ethics for Governance, Business and Ecosystem Models (ME) | Create the SHAPES Code of Conduct that outlines the value base and key principles of the SHAPES (to be utilised especially after the SHAPES project itself has ended and the exploitation begins). | LE-ME-1 |
| | Create a process to conduct SIA (Societal Impact) of the SHAPES Integrated Care Platform on a regular basis. | LE-ME-2 |



| Adopt customer logic in the building and expansion of the SHAPES Integrated Care Platform. Pay attention to the fact that even the most vulnerable should be able to use SHAPES (>also money needed for home equipment). Understand the different cultures of health assistance and modify the SHAPES Integrated Care Platform accordingly. | LE-ME-3 |
|--|----------|
| Create a process to ensure that members of the SHAPES ecosystem (during the open calls and after the project) have the capabilities to comply with mandatory ethical requirements. | LE-ME-4 |
| Define responsibilities regarding the SHAPES platform and each of its various services (e.g., if something goes wrong). This includes processes related to the personal safety solution that require organisational arrangements. | LE-ME-5 |
| Create processes and guidelines regarding the incidental findings when using or analysing SHAPES data. | LE-ME-6 |
| Establish a management model for Al governance. | LE-ME-7 |
| Define roles and responsibilities of controllers and processors in SHAPES. | LE-ME-8 |
| Define governance for handling requests of data subjects (rights). | LE-ME-9 |
| Organise Data Protection and Privacy Impact Assessment (DPIA) of each SHAPES configuration. | LE-ME-10 |
| Create and update "The Privacy Information" section in SHAPES website. | LE-ME-11 |
| Nominate a DPO (data protection officer) for each pilot (and after the project, for each SHAPES ecosystem). Pay attention; After the project, the individual SHAPES solutions are owned and governed by their respective providers that may not be SHAPES partners. This last part cannot be verified and therefore should not be a mandatory requirement. But it can be included in SHAPES Code Of Conduct. | LE-ME-12 |
| Nominate a data owner for each WP (see DMP). | LE-ME-13 |
| Create and implement the cybersecurity and resilience management of the SHAPES Integrated Care Platform (TBD). | LE-ME-14 |



4.3 Security Requirements (Coding: SR)

| Sub-categories | Specification | Coding |
|----------------------------|--|---------|
| General Security Aspects | Design and implement a Security Management Plan for SHAPES. | S-GSA-1 |
| (Coding: GSA) | Employ all appropriate security technologies. | S-GSA-2 |
| | Ensure the adequacy and quality of security information (suitability for AI). | S-GSA-3 |
| | Design and implement a Resilience Management Plan that covers all four event management cycles (plan/prepare, absorb, recovery, adapt) and interdependencies with other systems. | S-GSA-4 |
| | Personal data breach: create capabilities to identify potential personal data breaches and identification of personal data breaches. | S-GSA-5 |
| Cybersecurity (Coding: CS) | Deploy the functionalities related to cybersecurity (TBD later). | S-CS-1 |
| | Ensure that security protocols are in place and up to date to protect platform infrastructure | S-CS-2 |
| | Independent penetration testing | S-CS-3 |
| | Allow for the use of AI solutions to provide self-diagnosis of the SHAPES's security and other issues. | S-CS-4 |
| | Create a process for executing data subject rights in SHAPES (e.g., access to data). | S-CS-5 |
| Resilience (Coding: RE) | Ensure critical services are running 24/7 and are resistant to outside interference | S-RE-1 |
| | Security updates | S-RE-2 |
| | All data to be fully recoverable and attributable to individuals reviewing, amending, actioning tasks | S-RE-3 |
| | SHAPES should provide means to send notification in case selected security event occurs. | S-RE-4 |
| Rights management (RM) | SHAPES should provide capabilities to ensure that actors are prevented from gaining access to information or resources that they are not authorized to access. (Vicinity D1.5) | S-RM-1 |
| | SHAPES should provide capabilities to ensure the confidentiality of stored and communicated data. (VICINITY D1.5) | |
| | SHAPES should be able to guarantee the integrity of systems and stored and communicated data. (Vicinity D1.5) | |



| | SHAPES should provide means so that an entity cannot deny the responsibility for any of its performed actions as well as their effects. (Vicinity D1.5) | S-RM4 |
|--|---|--------|
| | SHAPES should provide a capability to track activities on the system with a record of individuals or entity that instigated the activity. (Vicinity D1.5) | S-RM-5 |
| | SHAPES should provide capabilities to establish and verify the claimed identity and integrity of any actor interacting with any external or internal interface of the SHAPES solutions. (Vicinity D1.5) | S-RM-6 |
| | Technical and organisational security measures: ensure that the IAM (identity and access management) can be used for limiting access to certain categories of personal data and the need to restrict access to certain data is taken into consideration in SHAPES architecture. | S-RM-7 |
| | Password management: Provide a mechanism to deal with forgotten passwords/ issuing new passwords | S-RM-8 |

4.4 Technical Requirements (Coding: TR)

| Sub-categories | Specification | Coding |
|------------------------------|---|--------|
| Scalability (Coding: SC) | Allow and support the scaling up of tools, i.e. does it allow tools to be used on a larger basis continuously (Wagner et al., 2016) | T-SC-1 |
| | Allow for different levels of complexity | T-SC-2 |
| | Cope with various operation levels and under strain conditions. (Vicinity D1.5) | T-SC-3 |
| Adaptability (Coding AD) | Platfo+C8:C13rm needs to adaptable in terms of relevant content to be displayed and appearence, i.e. fond size, contrast, etc. | T-AD-1 |
| Capacity (Coding: CP) | and retrieve large amounts of meta-data (Vicinity | |
| Availability (Coding: AB) | System is continuously available even in case of disconnections from the Internet and lack of access to any cloud data centre (Taumberger et al., 2018) | T-AB-1 |
| | SHAPES should support 24x7 service availability with acceptable downtime 2%. (Vicinity D1.5) | T-AB-2 |



| Principles for elimination of single point of failure should be applied during design SHAPES solutions. (Vicinity D1.5) | T-AB-3 |
|--|---|
| Means to recognize SHAPES components failure or other issues should be provided by SHAPES. (Vicinity D1.5) | T-AB-4 |
| If some parts of the network are unreachable/disconnected, the system should be able to manage the whole operation with historically stored/temporary data (Vicinity D1.5) | T-RB-1 |
| If one of the IoT Infrastructures transmits unreliable data due to issues with the connection or to a malfunction of a component out of the SHAPES framework, the system should be able to interpret (to a degree) the data using historically stored information to continue its operation. (Vicinity D1.5) | T-RB-2 |
| Sensors and measurement devices applied need to be validated | T-RB-3 |
| The integrated SHAPES framework as well as the SHAPES solutions should be able to perform with great stability and cohesion (Vicinity D1.5) | T-RB-4 |
| Frequent backups | T-RC-1 |
| If the SHAPES platform or one of its sub- systems comes back online after scheduled or unscheduled downtime, the users should be able to see/do everything they expect (system able to resume at the correct point) (Vicinity D1.5) | T-RC-2 |
| Platform needs to be accessible by different user groups including disabled (exchange with Accessibility Board) | T-AC-1 |
| Platform should resemble technologies that older people use in their every-day-lifes, for example online banking | |
| Platform should make information accessible with two klicks only; a double-menu (at the top and the side) should be used to navigate | T-AC-3 |
| The password registration field must be non-sensitive to spaces entered before and after. | T-AC-4 |
| Compatibility with IOS and android smartphones | T-AC-5 |
| Easy to update and maintain a tool once it is connected to the platform (Wagner et al., 2016); | T-MN-1 |
| | should be applied during design SHAPES solutions. (Vicinity D1.5) Means to recognize SHAPES components failure or other issues should be provided by SHAPES. (Vicinity D1.5) If some parts of the network are unreachable/disconnected, the system should be able to manage the whole operation with historically stored/temporary data (Vicinity D1.5) If one of the IoT Infrastructures transmits unreliable data due to issues with the connection or to a malfunction of a component out of the SHAPES framework, the system should be able to interpret (to a degree) the data using historically stored information to continue its operation. (Vicinity D1.5) Sensors and measurement devices applied need to be validated The integrated SHAPES framework as well as the SHAPES solutions should be able to perform with great stability and cohesion (Vicinity D1.5) Frequent backups If the SHAPES platform or one of its subsystems comes back online after scheduled or unscheduled downtime, the users should be able to see/do everything they expect (system able to resume at the correct point) (Vicinity D1.5) Platform needs to be accessible by different user groups including disabled (exchange with Accessibility Board) Platform should resemble technologies that older people use in their every-day-lifes, for example online banking Platform should make information accessible with two klicks only; a double-menu (at the top and the side) should be used to navigate The password registration field must be nonsensitive to spaces entered before and after. Compatibility with IOS and android smartphones Easy to update and maintain a tool once it is connected to the platform |



| | SHAPES platform should be implemented by below average software engineer (VICINITY D1.5) | T-MN-2 |
|-------------------------------|--|------------|
| | SHAPES platform should provide means to identify and resolve resource budget issues (Vicinity D1.5) | T-MN-3 |
| | SHAPES platform should be designed to anticipate most probable resource budget issues (Vicinity D1.5) | T-MN-4 |
| | SHAPES should adopt and use open & interoperable standards on internal and external interfaces or isolate dependencies by design to support reusability and portability. (Vicinity D1.5) | C-VIIVI- I |
| | SHAPES should provide means to migrate its components and data to different version. (Vicinity D1.5) | |
| | SHAPES should provide tools to simplify the installation of solutions (Vicinity D1.5) | T-MN-7 |
| Collaboration (Coding: CO) | Enable multiple developers to act as a team and work on the same application | T-CO-1 |
| Useability (Coding: US) | Collect analytics referring to public services usage (e.g. profiling on platform users and performance) for improvement | T-US-1 |
| | Make text content readable and understandable | T-US-2 |
| | Programme logos and the top of the page should have linking options to the landing page of the respective starting page/webpage. | T-US-3 |
| | Enable and support the exchange of information between different tools | T-IO-1 |
| | Allow for the use of mobile devices | T-IO-2 |
| | Facilitate mobile acces to health documents | T-IO-2a |
| | Link with existing patient profiles | T-IO-3 |
| Interoperability (Coding: IO) | Interconnecting patient data accross communities | T-IO-3a |
| (Coung. 10) | Retrieve patient data | T-IO-3b |
| | Retrieve identities/profiles | T-IO-3c |
| | Recording and retrieval of privacy consents | T-IO-3d |
| | Access control | T-IO-3e |
| | Exchange of documents | T-IO-4 |
| | | |



| | Compatibility with different browsers to be determined (NHSCT contribution) | | | |
|-----------------------------|---|--------|--|--|
| | Device Directive conform solutions (NHSCT contribution) | | | |
| Performance (Coding: PF) | Support multiple development environments in order to cover various development needs | T-PF-1 | | |
| | Response time of the SHAPES platform should be sufficient to support robust real-time operation with minimum latency. (Vicinity D1.5) | T-PF-2 | | |
| | Semantic search | T-PF-3 | | |
| | Data Prioritisation | T-PF-4 | | |
| Openness (OS) | Health and social care needs of citizens in different conditions are not static but develop over time, as well as the response to changing care needs that the institutions might wish to provide; the platform should take this into account | T-OS-1 | | |
| Functionality (FT) | The different functionalities of the SHAPES platform should respond to the care ecosystem analysis that identifies the functions performed by the different actors and personalises the functionalities of the system accordingly. | T-FT-1 | | |



4.5 Business Requirements (Coding: BR)

| Sub-category | Requirement | Coding |
|-------------------------------------|---|----------|
| Customer Service (Coding: CS) | The SHAPES Platform shall adopt a customer logic (B2C and B2B) in its design and development. | B-CS-001 |
| | The SHAPES Platform shall have its own Terms of Use and Services Policy. | B-CS-002 |
| | The SHAPES Platform shall have its own Privacy Policy, observing applicable regulations, including the GDPR. | B-CS-003 |
| | The SHAPES Platform should implement a customer support service. | B-CS-004 |
| Pricing (Coding: P) | The SHAPES Platform shall be cost-affordable based on the system's modularity and configurability. | B-P-001 |
| | The SHAPES Platform shall support various business models (e.g., direct sales, licensing, subscription, PaaS). | B-P-002 |
| | The SHAPES Platform shall support multiple subscription models (e.g., free, standard, premium). | B-P-003 |
| Marketplace (Coding: M) | The SHAPES Platform shall have an online marketplace. | B-M-001 |
| | The SHAPES Platform Marketplace shall support the registration of suppliers (supply) and of clients (demand). | B-M-002 |
| | The SHAPES Platform Marketplace shall select its suppliers based on their offer's effectiveness, affordability and added-value to the Platform. | B-M-003 |
| | The SHAPES Platform Marketplace shall contribute to the Platform's monetisation (e.g., fee per transaction). | B-M-004 |
| | Suppliers in the SHAPES Platform Marketplace shall abide and follow the SHAPES Platform's Terms of Reference, privacy policy and ethics. | B-M-005 |
| | The SHAPES Platform Marketplace should encourage transparent competitiveness. | B-M-006 |
| | The SHAPES Platform Marketplace should contribute to building economies of scale (e.g., create supply chains). | B-M-007 |
| | The SHAPES Platform Marketplace should contribute to remove existing vendor locks. | B-M-008 |



| | The SHAPES Platform Marketplace should contribute to the dynamics of local economies (e.g., aggregation of offers based on location and geographical reach). | B-M-009 |
|-------------------------------|---|---------|
| Sustainability (Coding: S) | The SHAPES Platform shall consider the sustainability of the Platform in its design and development (e.g., economic, financial, social and environmental). | B-S-001 |
| | The SHAPES Platform shall observe universal accessibility policies (e.g., consider the public authorities' role wrt subsidising schemes). | B-S-002 |
| | The SHAPES Platform should consider the adoption of standards in its design and development, from a business sustainability perspective. | B-S-003 |
| | The SHAPES Platform should foster corporate social responsibility (e.g., contribute to societal goals of a philanthropic, charitable or activist nature, by supporting volunteering or ethically-oriented practices). | B-S-004 |
| | The SHAPES Platform should observe a cradle-to-cradle approach. | B-S-005 |



5 Conclusion & Next steps

A lot of project interaction was organised under Task 3.5 for the 2nd iteration in order to take into consideration the needs of different actor groups from a range of different (country) contexts and to align the requirements development with all SHAPES partners and work conducted in other Tasks and WPs. This interaction informed the requirements development, as documented in a living Excel document. Overall, by October 2020 it has resulted in more than 200 requirements in the five dimensions:

Functional: 42

• Legal and Ethical: 89

Security: 20Technical: 56Business: 20

These requirements will be completed through interaction with the pilot sites. More importantly though, they will be validated and weighted in collaboration with the different user groups during the 3rd development iteration by the use of online workshop formats.

The development of the 3rd iteration of the Deliverable (due in M18) will encompass two main steps:

- i) **Specification**: The specification and more detailed description of the requirements
- ii) **Cross-check**: Requirements will be analysed in terms of inconsistencies and contradictions, particularly taking legal and ethical aspects into consideration. Therefore, information will be exchanged with WP8.
- Validation and weighting: processing and visualisation of requirements for further end-user interaction as well as the actual end-user interaction, particularly in collaboration with SHAPES WPs 2 and 6 for the end-user interaction but also WP 4, 5 and 7 for the technical and business specifications. Particular, interaction is envisaged with Task 2.1 "Understanding Older People" and Task 2.4 "Empowerment of Older Individuals in Health and Care Decision-making" as well as with the SHAPES pilot and replicating sites.

In order to ensure that all actor groups are considered for the validation and weighting process, a *Platform Requirements Board* will be involved in the above-mentioned steps. It should be composed of representatives of all groups will be designed in collaboration with the SHAPES project management. The suggested composition encompasses the following SHAPES partners:

- UCLM
- Clínica Humana
- Omnitor



- TREE
- INTRACOM
- NUIM
- UP
- EDGE

In terms of the methodology, comprehensive overviews will be created for the different requirements dimensions, most likely by the use of *mind maps* to facilitate the interaction with the different end-user groups and stakeholders. In addition, interactive online workshops will be designed during which the requirements will be discussed and weighted. The use of online polling systems is therefore envisaged.

Finally, interaction will be sought with Task 5.1 "Platform User Experience Design Guidelines and Evaluation" and the pilots to ensure that the platform requirements are considered in the evaluation methodologies.



Ethical Requirements Check

| Ethical issue (corresponding number of D8.4 subsection in | How we have taken this into account |
|---|---|
| parenthesis) | in this deliverable (if relevant) |
| Fundamental Rights (3.1) | Fundamental rights are part of the Ethics Requirements for the SHAPES platform. |
| Biomedical Ethics and Ethics of Care (3.2) | N/A |
| CRPD and supported decision-making (3.3) | N/A |
| Capabilities approach (3.4) | N/A |
| Sustainable Development and CSR (4.1) | N/A |
| Customer logic approach (4.2) | Business requirements including customer aspects are part of the requirements. |
| Artificial intelligence (4.3) | Al is part of the security and ethical requirements. |
| Digital transformation (4.4) | N/A |
| Privacy and data protection (5) | Part of the Security and Ethical Requirements. |
| Cyber security and resilience (6) | Part of the Security Requirements |
| Digital inclusion (7.1) | Part of the Technical Requirements: Accessibility |
| The moral division of labor (7.2) | N/A |





| Care givers and welfare technology (7.3) | N/A (indirectly) |
|--|------------------|
| Movement of caregivers across Europe (7.4) | N/A |

Comments: -



References

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Annex I – Mapping of requirements extracted from Task 3.1 "Ecological Organisational Models of Health and Care Systems for Ageing"

The below input was received from Task 3.1. The qualitative input was coloured according to the following coding:

Green = already covered in requirements list

Blue = newly integrated

Yellow = possible addition

Red = irrelevant

Technological Requirements

Electronic medical records (EMR) systems should be able to exchange information through the use of recently published international standards for their interoperability and clinically validated information structures (such as archetypes and international health terminologies), to ensure consistent and more complete recording and sharing of data for various patient groups. Such systems are counteracting the obstacles of differing clinical languages and styles of documentation as well as the recognized incompleteness of routine records: See T-IO-5

Health providers need support to use the information and technology system tool and the system itself undergoes continuous alterations to become more user friendly and fulfil the expectations of the providers: See FR-HS-2 and T-AC-1

Beneficiaries need continuous guidance to navigate correctly through the system. They also need to familiarize and adjust to the concept of personal doctor and what this entails: See FR-HS-2

Need to digitise healthcare processes and move away from paper-based processes: Too generic – many functional requirements deal with this digitalisation of healthcare processes

Unifying public and private outpatient provision of drugs created transient problems of entry and adequate circulation of drugs to pharmacies: Not clear how the platform could contribute here.



Providing facilities to patients to enable them to monitor their health or condition, and to participate in the development of their treatment plans. In part, this needs the integration of telemedicine which enables patients to take measurements, enter their health data into an individualised device, and to share their concerns with their GP: See FR-HS-3 and all subsections

ICT standardization: See technical requirements

Better communication with region – telemedicine should be a part of strategy for elderly people; Designing of system in cooperation with social care providers: This applies to the identification of requirements, i.e. our current work

Cooperation with professional associations, certification authority, insurance companies: What sort of cooperation? When?

Need for coordination and integration of the healthcare and social care sectors: We are trying to get their input for the platform development

Need digital tailored solutions to be able to properly communicate with older people: See T-AC-1

Need to digitally upgrade established healthcare services; Solutions and the platform need to be able to upgrade: healthcare services need to do this on their own, but also T-OS-1.

Achieve impact at scale: See T-SC-1 and T-SC-2

Telemedicine

Enable patients to communicate with the GP: See FR-IS-1 and FR-IS-2

Reduces need to come to the practice: See above

However, some problems cannot be resolved via telephone, e.g. control of blood pressure or measuring of glucose levels: See FR-HS-3 and subsections

Integrated national systems where different components "talk" to each other. Following criteria need to be fulfilled:

GDPR compliance: Covered in Legal and ethical requirements section

Data owned by patient who decides what data they want to share: See LE-ET-4 through LE-ET10

Greater levels of task-sharing between GPs, nurses (i.e. Advanced Nurse Practitioners (ANP)) and midwives:



e.g. prescription of certain medicines and diagnostics

provision of patient care

See FR-IS-5

A permanent helpline, technologies for tele-assistance and respite services should be created and/or developed: See FR-HS-1

Technological devices such as computers, tablets and smart phones are also perceived as too impersonal: Maybe LE-ET-2

Older adults need to be able to familiarise themselves with technological devices but USIDEC students are both reluctant and curious at the same time: See FR-HS-2

Older adults need to be able to understand the devices to lose their fear, and to understand what they can be used for. tactile approach very important: See FR-HS-2 and LE-ET-2

People are very curious about technology and they like it when they become more familiar with the devices and figure out how they work and what they are for: See above

Increasing need for the adoption of telemedicine and robotics to

be able to provide good quality care despite decreasing staffing numbers

FR-IS-5

keep cost down

B-CS-1

avoid having to cut time spent with care recipients

FR-IS-5

True co-design and co-production and allocate resources appropriately based on patient need: The pilots should help with this aspect.

Integrated national system: The encompass programme is a Northern Ireland-wide initiative that will introduce a digital integrated care record to Northern Ireland. This will support the HSCNI vision to transform health and social care in order to improve health outcomes and create better experiences for those receiving, using and delivering services: See T-IO-3



Telemedicine: Telemedicine to enable patients/HCP to monitor their conditions at home to prevent adverse health outcomes and reduce the pressure on healthcare system: See FR-HS-3 and subsection

Policy

Investment in the digital economy and in improvement of workers' digital skills is essential for bolstering productivity. Rather policy than platform aspect.

Increase in capacity of the business sector to innovate and boosting access to finance and investments that focus on well-defined areas of smart specialisation are crucial to improve Cyprus's competitiveness and that of its SMEs in particular. Rather policy than platform aspect.

Maximise investment in and prioritise digital technology. Rather policy than platform aspect.

Reconfiguration of services create a single accountable care organisation for Northern Ireland that can move money as is required. Rather policy than platform aspect.

True co-design and co-production and allocate resources appropriately based on patient need: Covered in pilots.

Long-Term-Care: prioritise healthy and active aging early on to reduce dependency on long-term care and find some way to fund appropriately: See Health Maintenance Support FR-HM-1, FR-HM-2, FR-HM-3

More intergenerational care and improvements in built environment: Rather policy than platform aspect.

Health providers need support to use the information and technology system tool and the system itself undergoes continuous alterations to become more user friendly and fulfil the expectations of the providers: See FR-HS-2 and T-AC-1

Human Factors

Horizontal integration in healthcare in the care of chronically ill. Rather policy than platform aspect.

Thorough education of patients and staff: FR-HS-2

More staff required to provide adequate care to patients. This does not necessarily mean an increase in GPs, but in community nurses that are trained to take on greater responsibilities, particularly routine tasks: Rather policy than platform aspect.



Cooperation with professional associations, certification authority, insurance companies: The platform will be available to them

Move away from a hospital-centred care model towards one where care is predominantly provided in the community: Rather policy than platform aspect.

Greater levels of task-sharing between GPs, nurses (i.e. Advanced Nurse Practitioners (ANP)) and midwives:

e.g. prescription of certain medicines and diagnostics

provision of patient care

FR-IS-5

Increase of number of ANPs and midwives from 328 (0.6%) to 700 by 2021: Rather policy than platform aspect.

Carers should have a support plan. Professionals from the health sector and from social care should be involved in the definition of such plan, which should include easy access to specialist consultations: FR-IS-11, FR-HM-1, FR-HM-2

Carers should have better access to information and capacity-building, through individual interventions and the establishment of self-help groups: FR-IS-7, FR-IS-8, FR-IS-9

Consideration should be given to using social benefits to reduce the risk of poverty for carers, and/or financial support compensating them for the loss of earnings resulting from taking on caring duties, for example part-time employment: Rather policy than platform aspect.

Giving carers the option of taking emergency leave should be considered: See above

Carers should be given incentives to engage in programmes of professional (re)qualification; and consideration should be given to ways of supporting them to remain in or re-enter the labour market and/or self-employment: See above

Social partners should be involved in the debate on how to reconcile caring duties and professional life in ways that avoid negative impacts and discrimination, especially in terms of gender: See above

The social value should be recognised of companies that promote good work practices and support for informal carers: Societal issue.



Data should be gathered regarding the effect of informal caring on the carers and on the persons cared for: FR-HM-1 and subsections; these data could be used for such a study

Benefits of informal care for the health and social systems should be analysed: Data in the project could be used for this study

Policy recommendations

Ensuring that formalising and improving the status of informal carers does not perpetuate the over-reliance on family members (especially women) for care provision: Data on informal health carers can be taken from FR-HM-1 and subsections

Widening access and affordability to formal LTC in order to ensure that large segments of the population are no longer excluded: Duty of national governments; SHAPES might lower costs

Revising entitlement to benefits, especially cash benefits, ensuring a closer linkage to the level of dependency rather than focusing excessively on means-testing criteria Rather policy than platform aspect.

Revising the amount of the cash benefits: Rather policy than platform aspect.

Granting tax benefits to those taking responsibility for caring for their relatives: Rather policy than platform aspect

Allowing time spent on care to count towards the workers' social security contributions record, e.g. for pensions: Rather policy than platform aspect

Assessing the constraints on the use of home-based care services that currently prevent them from representing a real alternative to institutional services: Rather policy than platform aspect

Allowing greater flexibility in working schedules (e.g. starting and finishing times, establishment of a bank of hours, concentrated working schedule, incentives for teleworking) in order to facilitate the caring needs of jobholders (bearing in mind possible gender impacts): Rather policy than platform aspect

Developing a process of systematic monitoring and evaluation of public policies in the field, including ex-ante assessments: Rather policy than platform aspect

People are fearful of using technology due to the perceived risks to their health. Technological devices such as computers, tablets and smart phones are also perceived as too impersonal: Maybe LE-ET-2



Workforce: Upskilling workforce to redirect work historically completed by one healthcare practitioner to other competent members of staff. Rather policy than platform aspect.

Use upskilling to optimise unit costs to the maximum level: Rather policy than platform aspect

Ethics

GDPR compliance: Covered in Legal and ethical section

Data owned by patient who decides what data they want to share: See LE-ET-4 through LE-ET10



Annex II – Mapping of ProACT Requirements against SHAPES platform requirements

| PeoACT Requirement | Explanation | SHAPES Link |
|---|--|---|
| [n° keyfinding linked] | | |
| R1 ProACT should be designed and implemented to support and empower human care, in all its aspects and not to completely substitute it. This might involve providing different types of support on demand. | For a successful implementation of the system in term of acceptance and trust by final users, technology should be clearly considered as a support for a better care and quality of life, and not as a competitor of human care. | Different supportive functional requirements have been formulated. |
| R2 The concept behind the design of the ProACT system and its end user interfaces should be that of the "supportive friend" that helps to cope with chronic conditions and the impact of these conditions on wellbeing and quality of life, including the overcoming of barriers. | Many PwM might feel more disabled by their pathology than they actually are. ProACT should help them to be reactive and find and use solutions for changing conditions. | Integrated into functional requirements → FR-HS-3 |
| R3 The architecture of ProACT should be open, modular and flexible allowing for the further development of the platform in order to respond to emerging health and social care needs at individual and institutional level. | The typical needs that ProACT aims to respond to are part of larger areas of health and social care needs of citizens in different conditions. These conditions are not static but develop over time, as well as the response to | Relates to the following technical requirements: - Scalability - Openness (introduced based on ProACT example) |



| | changing care needs that the institutions might wish to provide. | |
|---|---|--|
| R4 Any deployment of ProACT should be preceded by a care ecosystem analysis that identifies the functions performed by the different actors and personalises the functionalities of the system accordingly. | Care ecosystems are often complex and sometimes fragile with different actors performing different functions. It is important that ProACT adapts to this ecosystem and not that the ecosystem has to adapt to ProACT, unless there is consensus and clear benefits. | Technical requirement: T-FT-1 |
| R5 ProACT should take the role of the informal carer in very serious consideration as this "trusted" natural alley of the PwM will have a key role in the correct use of the system on the end user side. | The existence of a collaborative informal carer in the home care ecosystem is considered a key condition for success or, in case of serious health problems, even for intervention. | N/A since SHAPES will serve a multitude of stakeholders. |
| R6 ProACT should be predisposed to address different challenges related to independent living and personal safety. | ProACT should take into account the difficulty of many frail elderly to self-manage different aspects of daily life, including planning of activities, remembering appointments, controlling the environment (temperatures, humidity, presence of smoke, fire, water, etc.) | Respective functional requirements have been developed. |



| R7 The ProACT ecosystem should support activities and participation. | Many stakeholders have identified social isolation as an important factor for the development or worsening of chronic pathologies. Therefore, ProACT should actively stimulate users to get engaged in on & off line activities of social interaction. This might mean moving away from a predominantly medical connotation of ProACT towards a system that is also able to strongly support wellbeing and social interaction. | Functional requirements on communication have already been developed. |
|--|--|--|
| R8 ProACT should take into account various events that may disturb the self-management process and the system should be able to cope with them and be robust in case of critical ones. | Self-management is a complex process. Its success depends on many factors. These factors, together with unexpected events might disturb the self-management process. | Different functional requirements including health parameter observation, sensors to report falls, etc. have been developed. |
| R9 ProACT should be fully accessible for persons with disabilities and offer the possibility to personalise user interfaces in terms of complexity, accessibility and the number of functions available. | , , | Integrated into technical requirement: Accessibility (T-AC-1) |



| R10 ProACT should include applications that facilitate the communication between different actors in the care ecosystem. | | Respective functional requirements have been developed. |
|---|---|---|
| R11 In case of choice between two components having a similar reliability performance, ProACT should incorporate or be prepared to incorporate the cheapest solution available on the market. | In some cases patients might need to buy the equipment themselves, or contribute financially. In order to make the financial threshold as low as possible ProACT should be able to offer different options. | Business requirement B-CS-1 |
| R12 ProACT should be fully compliant with sensitive data treatment legislation. | Compliance with legislation in this field will be a prerequisite for the adoption of the system in any care context. | Is already integrated into Ethical and Legal requirements |
| R13 ProACT should provide facilities to store and retrieve data and to dialogue with other information management systems, using interoperable standards. | aiming to introduce eCare solutions, in | Interoperability = Technical requirement |



| R14 ProACT should use validated and reliable sensors and measurement devices. | ProACT will only be acceptable to clinical health professionals if data are reliable and the correct functioning of measurement devices is monitored over time. Has become a technical requirement RB-3 | |
|---|--|---|
| R15 ProACT should be able to display its services at different levels of complexity, allowing people to get gradually used to the system. | PwM that have to start to use ProACT might benefit from configurations with different levels of complexity, thus allowing the user to gradually move towards a more extended use. | Has become a technical requirement: T-SC-2 |
| R16 ProACT should be able to support therapy compliance, as this is one of the most critical issues identified in the self-management of care. | For many people taking medicines at the right moment of the day and in the right order and dosage is a real problem where ProACT could make the difference. | Medication reminder = functional requirements |
| R17 The focus of ProACT should be clearly directed to the management of single and multiple chronic conditions taking account the various implications of the conditions on the quality of life of the patient. | conditions and the mitigation of their the implications should be the core identity | |
| R18 ProACT should include tutorials and help cards regarding its use and the use of the devices connected to it. Also a glossary of terms could be helpful. | Many users might not be familiar with digital technology, including the interaction with menu's, icons and other aspects of the digital experience. | Has become a functional requirement: F-HS-2 |





| R19 In its interaction with the users ProACT should be explicit about the benefits of its use (prompts, feedbacks, rewarding messages, etc.) | reasons for not using ProACT unless | • |
|--|-------------------------------------|---|
|--|-------------------------------------|---|



Annex III Mapping of Feedback on Platform Requirements NHSCT and their processing

| | Action taken by Task 3.5 |
|---|--|
| Legal and ethical requirements | |
| a. LE-GE-26 Data subject rights to be forgotten. In addition to this we would like to see functionality that allows participant withdrawal from a pilot with a variety of options e.g. remove the study completely or the ability to use data up until the point of withdrawal providing consent is provided. | Additional functional requirement integrated: FR-IS-11 (new); previous FR-IS-11 now FR-IS-12 |
| b. The right for a data subject to request a copy of the information held about them. If participants take part in <1 pilot there will need to be a mechanism to link data/IDs and reduce duplication. | New Requirements: FR-IS-11b |
| c. LE-GE-38 ensure this is in line with EU medical device regulations | Comment added |
| d. LE-GE-40 DPIA for each pilot. Should this be for each use case or replicating site? | Should be conducted for each use case and replicating site Comment added. |
| e. Capability to enter manual data e.g. if there is a problem with a blood pressure device data transmission but device has displayed the results to allow these to be entered in manually | Requirement added: FR-HS-3h |
| f. LE-ME-12 nominate a DPO for each pilot- should this be for each site? | Question added → needs to be clarified. |
| Technical requirements | |
| a. Compatible with IOS and android smartphones | New requirement added: T-AC-5 |
| b. T10-14 ePrescription – this would not be compatible with the legal process in the UK at present | Comment added |





| 3. Business requirements | |
|---|---|
| a. Nothing to add at this point | N/A |
| 4. Security requirements | |
| a. Password management- mechanism to deal with forgotten passwords/ issuing new passwords | New Requirement added: S-RM-8 |
| b. Permission/access privilege management – should record who has access to what and when. Multi-level permissions overall>pilot level>site level and different stakeholder groups clinicians/service users/caregivers /inspectors/admin/service providers/technical partners etc. | New functional requirement added: FR-IS-10a |
| 5. Functional requirements | |
| a. A large number of the functional requirements are indicated as not available to the second/third pilot cycle Feb 22/Feb23. These functionalities are required for Pilot 3 which is due to begin Phase 4 in September 21. FR-HS-4, F-HS-5, FR-HS7, FR-HS-9, FR-HS-12, FR-IS-2, FR-IS-3, FR-IS-4, FR-IS-5, FR-IS-6 | Availability has been changed for most functional requirements to August 2021 |
| b. FR-HS-3a also applies to UC-PT3-001 | Added accordingly |
| c. FR-HS-3G also applies to Pilot 3 use cases | Added accordingly |
| d. FR-HS-3f will be used to a limited extent in pilot 3 i.e. a list of medicines will be managed and updated as required | Added accordingly |



Annex IV – Mapping of Feedback on Platform Requirements Clínica Humana and their processing

| | Action taken by Task 3.5 |
|---|---|
| Functional requirements | |
| Measuring daily steps (to measure daily activity) FR-HS-3a → Also for PT3-001 | Added accordingly |
| Sleep tracking FR-HS-3d → May be added to PT3-001 | Added accordingly |
| Medication tracking FR-HS-3f → Also for PT3-001 | Added accordingly |
| Monitoring of vital signs (weight, blood pressure, blood glucose, bioimpedance, heart rate, blood oxygen level, etc.) FR-HS-3g → Also for PT3-001 | Added accordingly |
| Sometimes, the parameter is measured more than once, if the first one gives and abnormal value. If values are collected automatically, a functionality to detect 'final' value would be nice. This may be specialist-dependent though. An example would be 'blood pressure', if it is high a second measure is recommended after 10-15 min of resting. Maybe it's difficult to implement as a functionality, as 'guidelines' are different at each site and a standard protocol does not exist. | Comment added |
| We are defining many more parameters to be monitored in the pilots we lead (PT3-001, PT4-002 and PT6-002). They are described in our data plans, however, they are not finished files and some of the parameters may drop out during the definition process. If you want to include them let me know and I can give you their localization in | Parameters need to be determined: comment added |



| Teams. But maybe you prefer to include them in the next iteration as if a parameter drops out, you will have gaps in the codes. | | |
|---|--|--|
| Recording the perceived state of well-being / self-assessment tool F- HS-5 → Related questionnaires applied to PT3-001 and PT6-002 | Comment added accordingly | |
| Medical emergency alert system FR-HS-9 → Considered in PT3-001 | Noted accordingly | |
| Ability to provide questionnaires to monitor health-related quality of life, medicines adherence, symptoms etc FR-IS-5 → We are still defining these type of requirements but I expect that it could be complemented with: On a regular basis (time frequency) Based on other data (for example, if older person is feeling worse than the previous days, to launch a set of questions) | Noted accordingly | |
| Same comment as Nicola (NHSCT): "A large number of the functional requirements are indicated as not available to the second/third pilot cycle Feb 22/Feb23. These functionalities are required for Pilot 3 which is due to begin Phase 4 in September 21. FR-HS-4, F-HS-5, FR-HS7, FR-HS-9, FR-HS-12, FR-IS-2, FR-IS-3, FR-IS-4, FR-IS-5, FR-IS-6" | | |
| New ones: | | |
| In PT4-002 and PT6-002, care receiver carries out exercises. The exercises can be scheduled beforehand by the care | The following requirement was added: | |
| provider (particularly in PT6-002). It would be good the platform allows the scheduling of specific tasks for each session and person, so the "digital solution" knows what to do at each session and to whom. | Scheduling of specific tasks for the care receiver FR-IS-5a | |
| | This functionality could support the implementation of the pilots. | |
| Data source: we are still defining this but it may be useful to include fields of metadata that defines the origin of the value (to be able to track back the origin at any time). The structure depends of the type of data. For example, in PT3-001 we will ask "the year of diagnosis of your heart failure condition". The | The following requirement was added: | |





| answer may be confirmed by 1) a medical report; 2) told by care receiver (who can be more or less sure); 3) told by the caregiver (again, who can be more or less sure). Our data plans will include these fields for our data (also finding a balance because filling all the info may imply very long | Include fields of metadata that define the origin of a value | FR-IS-4a |
|--|---|-----------------------------|
| interviews). That automatically loaded data (for example from blood pressure meters) can also be inserted manually by older | The following requirement was ad- | ded: |
| person/caregiver (connection may fail and they may have the necessary digital skill to do it on their own. Tracking who is inserting this should be added (device older person caregiver) | Capability to enter manual data | FR-HS-3h |
| To be able to provide motivation/encouragement sentences, pieces of information/educational information about the | The following requirement was ad- | ded: |
| condition, And in general, short sentences which are provided to the older person and no answer is expected. These set of sentences are to be provided on a regular basis or based on the values of other data. These sentences can be grouped, and the sentences in a group are interchangeable (providing variety to the information provided). | Provide motivation/encouragement sentences to the care receiver: These set of sentences are to be provided on a regular basis or based on the values of other data, completion of tasks, etc. | FR-IS-5b |
| Technical requirements | | |
| Some data may be stored at SHAPES platform and other must be stored at pilot sites | Comment was added to the following requirement: Data protection principles: lawfulness – identify and document a lawful basis for processing data. LE-GE-31 | |
| One person me be using different digital solutions. To avoid duplicities. | This should be covered by the Interoperability. | e Technical Requirements on |



Annex V – Mapping User Requirements PT-01-001

PT1-UC001 Remote In-Home Wellbeing Monitoring and Assessment

| Requirements | Mappin against Platform Requirements | |
|---|--|--|
| Wellbeing Assessment Score | Already considered: FR-HS-5 | |
| Home Monitoring (temperature, humidity, air quality) | New requirements: FR-LS-5 | |
| Appliances Monitoring (on/off; duration of state) | New requirement: FR-HS-13 | |
| Physical activity monitoring (daily steps, time of exercise, intensity, objectives, reminders) | Already considered: FR-HS-3 | |
| Sleep data monitoring (duration, begin/end; day time sleep; wake ups at night, tip on good night routine) | Already considered: FR-HS-3 | |
| Monitoring vitals (heart rate) | Already considered: FR-HS-3g | |
| Patient Data (Age, gender, degree of dependence, individual top three challenges) | Requirement specified under FR-IS-6 → FR-IS-6a | |



| Caregiver data (age, educational degree, distance to reach care receiver, access to internet, technological skills) | Requirement specified under FR-IS-6 → FR-IS-6b |
|---|---|
| Caregiving data (type of care, duration and frequency of care delivery, number of caregivers, relationship) | Requirement specified under FR-IS-6 → FR-IS-6c |
| Wellbeing Status (smiley card) | Already considered: FR-HS-5 |
| Data analytics (personalised recommendations, wellbeing assessment, anomaly detection) | Already considered: FR-HS-4, FR-HS-9 and FR-HS-12 |
| | |



Annex VI – Mapping User Requirements PT-02-001

UC-PT2-001 USER REQUIREMENTS

Remote monitoring of key health parameters

| # | User Requirement | Comments |
|-----------|--|---|
| UR- 01 | MAIN PERSONA: Older individuals living at home by themselves, insufficiently informed about the realm of their capabilities thus subject to suffer from isolation and associated risks such as loss of speech, vitality, and lack of general fitness. The individuals at stake are still rather agile but need to be somewhat motivated and/or informed about the variety of physical and mental activities at their disposal or within their reach in order to keep exercising regularly and/or entertain social contacts. The older individuals are inclined to stay "in touch" with others from the community as well as with virtual assistants to maintaining their mental and physical health. | |
| UR- 02 | SECONDARY PERSONA: the informal or formal caregiver/ a predefined person of trust. | |
| UR- | | Platform requirements FR- |
| 03 | AIM1: the remote monitoring important health and wellbeing parameters of older individuals | HS-3 |
| UR- | AIM2: to maintain or possibly even improve their health and wellbeing status thanks to | Platform requirements FR- |
| 04 | preventive health and care measures. | HS-4 |
| UR- 05 | AIM3: to remain independent for longer at home | This is more a goal/need than a requirement> not considered |
| UR- 06 | AIM4: to showcase the so-called "feel-good effect" i.e. the power of knowing everything is – relatively speaking – in order. | This is more a goal/need than a requirement> not considered |
| UR- | AIM5: to make older individuals feel safer and thus more secure in pursuing daily activities such | This is more a goal/need than |
| 0K- | as moving around the house or outdoors, engaging with family, friends and the community or | a requirement> not |
| 07 | committing to further hobbies. | considered |





| UR- 08 | HOW1: Capture unobtrusively the relevant health and wellbeing parameters of the older individuals at home (the parameters listed below). Using wearables, sensors and other devices. Recording quantifiable health data. Using Ambient Intelligence Health and Wellness Platform / | Platform requirements FR-HS-3 |
|-----------|---|--|
| UR- 09 | Smart Living at Home Platform. HOW2: Recording the perceived state of well-being should be included ("How do you feel today"). Recording a stable (good) health status will make older individuals feel safer and thus more secure in pursuing daily activities ("feel-good effect"). Using Ambient Intelligence Health and Wellness Platform | New Functional requirement integrated: FR-HS-5 |
| UR- 10 | HOW3: Report the health and well-being status in a tangible/understandable way to the main persona. Using dashboard, chatbot, safe digital assistant. Communicating in natural language. | Links mainly with FR-IS-1 and FR-IS-4 |
| UR- 11 | HOW4: Give personalized tips and recommendations based on health and well-being needs. Using a "personal coach"-concept, the older individuals receive tips to maintain their well-being and health status (e.g. reminders to drink water, walk a few steps, stand-up and sit-down, etc). Using Wellbeing and Lifestyle recommendations (physical activity and nutrition recommendations). | FR-HS-4 |
| UR- 12 | HOW5: In case the system monitors unusual data, the informal caregiver/ a predefined person of trust is informed/alerted. Using smart data analytics & predictive algorithms): analysis of anomalies and alert generation based on the data gathered from the different sensors. | FR-HS-4 |
| | | |
| | Parameter to be monitored | N 50: 1 50 HG 2 |
| UR- 13 | 1. Daily Steps MEASURE1: Daily steps (to measure daily activity). Steps should be counted using a pedometer, preferably one being worn on the wrist (it can be worn permanently). | New FR integrated: FR-HS-3a |
| UR- 14 | GOAL1: Daily steps target. It has to be set individually. A study has observed women over 62 years and correlated the number of daily steps with the mortality rate. It was found that up to a limit of 7,500 steps/day the mortality rate was reduced. Anything beyond this figure did not mean significant improvement in terms of reduced mortality. However, it is necessary to check individually whether this figure is a realistic daily goal and to adjust it if necessary. As this use case focuses on people in need of care, steps in the range of 1,000-4,000 steps should be aimed | |





| UR- 15 RECOMENDATIONS1: If at lunchtime 50% of the individual's number-of-steps target has not yet been reached, a reminder can be sent via the smartphone/tablet or a smart speaker. 2. Exercise New FR integrated: FR-HS-3b UR- 16 MEASURE2: Exercise GOAL2/RECOMENDATIONS2: • Older adults should preferably perform at least 150 minutes/week aerobic physical activity of moderate intensity (e.g. 5x30 minutes/week) or • perform at least 75 minutes/week aerobic physical activity of higher intensity, or • perform aerobic physical activity in appropriate combinations of both intensities (doing at least 10-minute intervals, e.g. at least 3 x 10 minutes/day or 5 x 30 minutes/week) • Older adults with mobility impairments should perform balance exercises to prevent falls at least three days a week • Older adults should avoid long, uninterrupted periods of sitting and, if possible, regularly interrupt sitting with physical activity • Older adults can attain further positive health benefits by increasing the amount and/or intensity of exercise beyond the minimum recommendations. • Older adults who cannot be physically active according to recommendations related to medical restrictions should exercise as much as their current health situation allows. | | for - depending on the individual physical condition. Above all, people who feel comfortable with a higher daily target should always try and match it. | |
|--|----|---|-----------------------------|
| 2. Exercise New FR integrated: FR-HS-3b UR- 16 MEASURE2: Exercise GOAL2/RECOMENDATIONS2: • Older adults should preferably perform at least 150 minutes/week aerobic physical activity of moderate intensity (e.g. 5x30 minutes/week) or • perform at least 75 minutes/week aerobic physical activity of higher intensity, or • perform aerobic physical activity in appropriate combinations of both intensities (doing at least 10-minute intervals, e.g. at least 3 x 10 minutes/day or 5 x 30 minutes/week) • Older adults with mobility impairments should perform balance exercises to prevent falls at least three days a week • Older adults should carry out muscle-strengthening physical activities at least two days a week • older adults should avoid long, uninterrupted periods of sitting and, if possible, regularly interrupt sitting with physical activity • Older adults can attain further positive health benefits by increasing the amount and/or intensity of exercise beyond the minimum recommendations. • Older adults who cannot be physically active according to recommendations related to medical | | | |
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| GOAL2/RECOMENDATIONS2: • Older adults should preferably perform at least 150 minutes/week aerobic physical activity of moderate intensity (e.g. 5x30 minutes/week) or • perform at least 75 minutes/week aerobic physical activity of higher intensity, or • perform aerobic physical activity in appropriate combinations of both intensities (doing at least 10-minute intervals, e.g. at least 3 x 10 minutes/day or 5 x 30 minutes/week) • Older adults with mobility impairments should perform balance exercises to prevent falls at least three days a week • Older adults should carry out muscle-strengthening physical activities at least two days a week • older adults should avoid long, uninterrupted periods of sitting and, if possible, regularly interrupt sitting with physical activity • Older adults can attain further positive health benefits by increasing the amount and/or intensity of exercise beyond the minimum recommendations. • Older adults who cannot be physically active according to recommendations related to medical | | | |
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| 3. Water uptake New FR integrated: FR-HS-3c | _ | Older adults should preferably perform at least 150 minutes/week aerobic physical activity of moderate intensity (e.g. 5x30 minutes/week) or perform at least 75 minutes/week aerobic physical activity of higher intensity, or perform aerobic physical activity in appropriate combinations of both intensities (doing at least 10-minute intervals, e.g. at least 3 x 10 minutes/day or 5 x 30 minutes/week) Older adults with mobility impairments should perform balance exercises to prevent falls at least three days a week Older adults should carry out muscle-strengthening physical activities at least two days a week older adults should avoid long, uninterrupted periods of sitting and, if possible, regularly interrupt sitting with physical activity Older adults can attain further positive health benefits by increasing the amount and/or intensity of exercise beyond the minimum recommendations. Older adults who cannot be physically active according to recommendations related to medical restrictions should exercise as much as their current health situation allows. | New FR integrated: FR-HS-3c |



| UR- 18 | MEASURE3: Water uptake. Smart drinking bottle. The bottle measures how much has been drunk and reports this to an app. Supplemented by manual entries (e.g. if the older person buys something to drink outside the home or prepares a cup of tea) the daily fluid intake can be documented. | |
|-----------|---|-----------------------------|
| UR- 19 | GOAL3: The German Society for Nutrition gives a reference value of 1.5L/day, which is increased | |
| UR- 20 | to 2L/day in summer RECOMMENDATIONS: Reminders are given if the person does not drink enough according to the following guidelines: • a glass of water immediately after waking up (stimulates digestion and circulation) • 3 hours into the day: drink at least 0.5L • 6 hours into the day: min. 0.75L • 9 hours into the day: min. 1 L • 12 hours into the day: min. 1.3 L • 15 hours into the day: min. 1.5L • Cap drinking 2 hours before bedtime in order not to interrupt the night's sleep | |
| | 4. Sleep | New FR integrated: FR-HS-3d |
| UR- 21 | MEASURE4: Sleep tracker (e.g. a fitness tracker on the wrist or a mobile phone app), sleep can be recordedg. sleep-app "Sleep Better" (Runtastic) or similar. Record sleep quality (how often awake/REM phases etc) and give tips on how to improve sleep the following day/evening | |
| UR- 22 | GOAL4: The duration of sleep should be between 7 and 8 hours for older people. However, there are also people who are completely satisfied with 5 hours of sleep and others who need 9 hours of sleep to recover. By surveying the test persons in the first two weeks of the use case duration, it can be determined at how many hours of sleep their individual optimum lies, at which they feel maximally recovered and satisfied. | |



| UR- 23 | RECOMENDATIONS4: On this basis, the app can give tips and recommendations as to when the person should ideally go to bed and when they should get up. It could also introduce a goodnight routine for people who do not sleep well, such as avoiding artificial "blue light" right before going to bed or recommending drinking a small cup of soothing herbal tea. Tips: → Reminder "good night routine, e.g. • Turn off TV at a fixed time (at least 30 minutes before bedtime) • Drink a small cup of herbal tea • Write a diary entry to remove recurring thoughts for the night • Opening bedroom windows for a few minutes | |
|-----------|--|--|
| UR- 24 | TEST1: How to determine individual sleep duration needs Sleep duration test 1 - Determine when you wake up: In Test 1, it is important to get up at the same time every day. What time that is isn't relevant, but you should not be woken up before that time or wake up too early by yourself. You get up as soon as the alarm clock rings at the same time every day or (ideally) you wake up by yourself, you go to bed as soon as you get tired. If you feel too awake, you should not go to bed, just as you should not force yourself to stay awake if tired. If this is maintained over a period of about two weeks, the body is used to getting up at the same time every day. At a certain time the body sends the signal to go to bed by the onset of fatigue. For example, if you get up at six o'clock every day and get tired at eleven o'clock in the evening, your individual sleep duration is about seven hours. | |
| UR- 24 | TEST2: Determine your daily sleep time Sleep duration test 2 - Determine your daily sleep time In the second test, it is the bedtime that must be determined. This point in time should be chosen so that it is possible to sleep for nine or ten hours. At best, one is already tired at this time so that one does not lie awake in bed for a long time. No alarm clocks should be set during the test phase. If there is a risk of oversleeping despite the sufficient time span of nine to ten hours, an emergency alarm clock can be set. However, since waking up by an alarm clock can falsify the test, in this case you should rather perform the first test. If the bedtime is observed, | |





| | you will always wake up at the same time after some time. If you go to bed at ten o'clock in the evening and wake up at six o'clock in the morning, the ideal sleeping time is about eight hours. | |
|-----------|---|-----------------------------|
| | 5. Nutrition | New FR integrated: FR-HS-3e |
| UR- 25 | MEASURE5: Nutrition. Tracking the meals is very complex and requires a lot of discipline, which makes the implementation massively more difficult. Since the test persons are in home care, one could assume that many at least get their lunch from external delivery services such as "meals on wheels". Together with these providers, a system could be designed in which the older persons could simply scan a barcode with their cell phone and the nutritional information from the delivery services would be taken over immediately. The system needs to allow the individuals to indicate whether everything was eaten or only partially / saved for later / shared with others. For many, breakfast and dinner are part of a fixed routine, which means that readymade standard meals to choose from a "menu" can be provided, making tracking much easier (such as: porridge / white bread with jelly / yoghurt / etc). | |
| UR- | | |
| 26 | GOAL5: Intake of all needed nutrients | |
| UR- 27 | RECOMENDATION5: Such documentation can be used to check whether all nutrients are supplied in sufficient quantities (e.g. based on recommendations by DGE) and whether there is a connection between certain foods and an increased or decreased well-being. Tips can then be given as to whether certain foods should rather be avoided or others should be consumed to a greater extent. | |



| UR- 28 | Problem: One problem frequently associated to tracking is that banning certain foods (e.g. the routinely consumed piece of cake in the afternoon or similar) can lead to frustration, which would not increase but rather worsen the well-being. An idea to solve this would not be to give the test persons a detailed overview of the nutritional values eaten, but rather a summary of the day in the form of a traffic light system with the recommendation to eat more fruit and vegetables the next day. | |
|-----------|--|--|
| UR- | | |
| 29 | Optional: Working together with the informal caregiver to document food intake. | |



Annex VII – Mapping User Requirements PT-03-General

PT3 - Medical Control and Optimisation

UC-PT3-general - Supporting multi-morbid older patients

| | | | | NHSCT | |
|-------|---|---------|-------------------------|---|--------------------|
| | | | | UC-PT3-general Supporting multi-morbid older | |
| # | Modules / Components | Partner | UR Code | patients | Comments |
| | Front-end app for target | | | | |
| 1 | users | | | | |
| 1.1 | eHealthPass App | GNO | | | |
| 1.1.1 | Self-assessment tool with personalised questionnaires (uses a text-based chatbot) | | UR-16 UR-25 UR-28 | HOW4: Main persona logs signs/symptoms. Using Health and Wellbeing Apps. MEASURE2: dizzy, shortness of breath, swollen ankles, cough, sputnum characteristics, etc. MEASURE4: Health-related quality of life (EQ-5D-5L questions, satisfaction with life scale) | Requirement F-HS-5 |
| 1.1.2 | Notifications | | UR-09 | AIM8: Deliver reminders, alerts and recommendations to older individuals, concerning the management and control of their medication | |
| 1.1.3 | Treatment plan | | | | |
| 1.1.4 | Control medication | | UR-15 UR-27 | HOW3: Tracking and registration of intake of medication. Using Health and Wellbeing Apps. MEASURE3: Medications (list of medicines, questionnaires) | |



| 1.1.5 | Register vital signs monitoring | | UR-13 UR-22 | HOW1: Tracking and registration of vital signs and physical measurements. Use sensors and other devices. Record quantifiable health data. Using Health and Wellbeing Apps MEASURE1: weight, blood pressure, blood glucose, bioimpedance, heart rate, blood oxygen level, etc. (smart glucometers, smart inhalers, smart scales, pulse oximeter, smart blood pressure measurements) | Requirement 3g | |
|-------|--|-----|----------------|--|--------------------------|---------|
| 114 | Manage diet and nutrition | | UR-14 | HOW2: Tracking and registration of diet and nutrition data. Using Health and Wellbeing Apps. | Requirement 3e | FR-HS- |
| 1.1.4 | ivianage diet and natrition | | OK 14 | indition data. Using Ficaltif and Weilbeing Apps. | 30 | |
| 3 | Health and Wellbeing Data Gathering / Remote Monitoring / Remote Consults via eHealth Apps & IoT Platforms | | | | | |
| 3.1 | eHealthPass - integrated care platform | GNO | | | | |
| 3.1.1 | Self-assessment tool with personalised questionnaires (uses a text-based chatbot) | | UR-16 | HOW4: Main persona logs signs/symptoms. Using Health and Wellbeing Apps. | Requirement & FR-IS-3 | F-HS-5 |
| 3.1.2 | Medication control | | UR-15 | HOW3: Tracking and registration of intake of medication. Using Health and Wellbeing Apps. | Requirement 3f | FR-HS- |
| 3.1.3 | Register health parameters. Synchronise with third- party medical devices (BPM, scale,) | | UR-13 | HOW1: Tracking and registration of vital signs and physical measurements. Use sensors and other devices. Record quantifiable health data. Using Health and Wellbeing Apps | Requirement I | FR-HS-3 |



| 3.1.6 | Manage diet and nutrition | | UR-14 | HOW2: Tracking and registration of diet and nutrition data. Using Health and Wellbeing Apps. | Requirement FR-HS- 3e |
|--------|---|--------------------------------|-------|--|--------------------------|
| 3.1.9 | Connectivity to Electronic Health Records using eHealth standards (such as HL7, and even cross- border) | | | | |
| 3.1.10 | Connection with IoT devices (to be defined) | | | | |
| 3.1.11 | Synchronise with third- party Apps - Apple Health, | | | | |
| 3.2 | CCS - TeleHealth System | CCS | | HOW5: Remote monitoring of patients by doctors | Requirement FR-HS-3 |
| 3.3 | FNOL - Telemedicine System | FNOL | UR-19 | and montioring by other care givers. Using Health and Wellness Platform | Requirement FR-HS-3 |
| 3.4 | eCtouch System | OMN | | HOW7: Conduct remote consults. Using Telehealth and Telemedicine systems and eCtouch. | Requirement FR-HS-3 |
| | | | | | · |
| 4 | MCO Data Model (in SHAPES TP) | | | | |
| 4.1 | UC-PT3-general Supporting multi-morbid older patients | UC-PT3- general partners | | | issue is too general |
| | | | | | |
| 5 | Prediction of Health Events - AI modules (in SHAPES TP) | | | | |



| 5.1 5.2 5.3 | Remote Heart Failure Patients Decompensation Predictive Model eHST Library - Machine Learning Exacerbations in COPD Prediction Model Hypo/ hyperglycaemic events in T2D patients prediction model | VICOM VICOM TREE | - UR-21 | HOW9: Predict risk of health events including decompensations in patients with heart failure, exacerabations of COPD, and hypo/hyperglycaemia in patients with diabetes. Using smart data analytics and predictive algorithms and Ambient Intelligence Health and Wellness Platform. | Requirement FR-HS- 12 Requirement FR-HS- |
|-------------------|--|------------------|----------------|--|--|
| 6 | Dashboard for patients, caregivers and professionals | | | | Requirement T-AC-1 |
| 6.1 | eHealthPass (main interface to caregivers & professionals) Visual Analytics in | GNO | - UR-02 | AIM1: Support and extend healthy and independent living for older individuals who are facing permanently or temporarily reduced functionality and capabilities | solutions Requirement FR-HS- |
| 6.2 | Streaming and Batch. | TREE | UR-09 UR-17 | • | tracking |
| 6.3 | eHST Library - Visual Analytics (integrated in eHealthPass) | VICOM | | HOW5: Remote monitoring of patients by doctors and montioring by other care givers. Using Health and Wellness Platform | Requirement FR-HS-3 about collecting and sharing health data |



Annex VIII – Mapping User Requirements PT-05-001

FICS framework

Technical Perspective

Methodological note: The FICS framework was developed with basis on two focus groups with end users (8 professionals and 7 caregivers) and 5 usability test sessions. Literature review (e.g. on good practices for digital engagement was the origin for some requirements).

Focus groups = FG; Usability tests = UT; Literature review= LR; Priority level classified as: Must have (M), Should have (S), Could have (C) and Wish to have (W).

| Criterion | and | Function and events (F): Functionality of the intended system which is | | | | |
|------------|---|--|--|--|--|--|
| definition | definition capable to realize actor's activities. | | | | | |
| | | | | | | |

 $\underline{\text{Note:}}$ see UC-PT5-001 for iSupport programme components.

| ID | Priority level | Origin | Requirement | | Prigin Requirement Justification | | Comments | | |
|----|-------------------|--------|---|--------------------------------|----------------------------------|-----------------------------------|--------------------------|--------|-----------|
| F1 | M | LR | Skills training exavailable as free text. & drop or check list. | xercises are t answer, drag | | accommodate ning preferences a | different and styles. | users' | FR-IS-11a |



| F2 | M | LR | The drag & drop and checkbox exercises aimed at training skills and test knowledge present immediate feedback on answers. | | FR-IS-11b |
|----|---|----|--|---|--------------|
| F3 | M | LR | Feedback is provided by using distinctive colours (red- incorrect, green-correct, blue- possible answer) and by offering detailed text-based explanations. | To allow for a quick performance feedback and also for a full and detailed feedback. | FR-IS-11b |
| F4 | M | LR | The text contents in the programme adapt to users' information (e.g. name, gender/ name, gender of the person being cared for). | To increase personalization and mimic the targeted approach in face-to-face interventions (where the users is known, treated by his/her name); to increase the users' sense of engagement. | FR-IS-11c |
| F5 | M | LR | The intervention plan (lessons to be performed) is chosen by the users according to their own needs and availability. | To increase the sense of personalization and motivation towards the programme; to decrease dropout due to the perception of being trained on unsuitable topics to the users' particular case. | FR-IS-11d |
| F6 | М | LR | The intervention plan have by default the suggestion of five core | To increase the chance of users receiving training on most pressing | Too specific |



| | | | lessons, automatically added to 'my | topics for dementia caregivers; and to | |
|-----|---|----|-------------------------------------|---|------------|
| | | | plan'. | decrease the chance of dropping out | |
| | | | | before completing 5 core lessons. | |
| | | | | | |
| F7 | M | LR | The intervention plan set by the | To ensure personalization, users can | |
| | | | user can be modified at any time | update their training plans to changing | FR-IS-11e |
| | | | (lessons can be added or deleted). | needs. | |
| F8 | M | LR | A star icon marks lessons added to | Users must keep track of their training | |
| | | | my plan and a check icon marks | activities in the programme. | FR-IS-11f |
| | | | lessons already concluded. | | |
| F9 | M | LR | Lessons start in the page where the | Users must keep track of their training | |
| | | | users' left in his/her previous | activities; to avoid time spent on locating | FR-IS-11g |
| | | | access. | 'where they were' in the programme. | |
| F10 | M | LR | A mood assessment function is | To increase self-consciousness on | |
| | | | available for self-completion with | mood status; mood status monitoring is | |
| | | | ratings and free text assessment | relevant for burdened, anxious or | FR-HM-1a |
| | | | options. A mood graph/mood | depressed caregivers. | FR-HIVI-1a |
| | | | history is displayed to represent | | |
| | | | mood progress over time. | | |
| | | | | | |



| F11 | S | FG | Mood ratings of 4 or lower should | To increase the responsiveness of the | |
|-----|---|----|---------------------------------------|--|-----------|
| | | | direct the users to relaxation and/or | programme to the users' mood status. | FR-HM-1b |
| | | | cognitive reframing lessons. | | |
| F12 | M | LR | A printout module is available to | To cover diverse preferences for reading | |
| | | | print personalized booklets of the | programme's materials (online vs. | |
| | | | sessions mirroring the user learning | paper); to increase engagement by | FR-IS-11h |
| | | | process. | offering personalized booklets of the | |
| | | | | lessons. | |
| F13 | M | LR | Skills certificates are generated | To reinforce/motivate the user for the | 50 15 141 |
| | | | after lesson completion. | learning process. | FR-IS-11i |
| | | | | | |
| F14 | M | LR | 7 different relaxation exercises are | Relaxation exercises are important to | |
| | | | available with options based on | · | |
| | | | muscular relaxation and on | persons. To accommodate relaxation | FR-HM-1c |
| | | | imagery-based relaxation. | preferences (mental vs. physical based) | |
| | | | | and health conditions impeding e.g. | |
| | | | | muscular relaxation (e.g. paralysis). | |
| F15 | М | LR | Relaxation exercises instructions | To accommodate different preferences | |
| | | | are available in text and audio. | in learning the instructions of relaxation | FR-HM-1d |
| | | | | exercises. | |
| | | | | | |



| F16 | М | LR & | Realistic scenarios are used to train | To increase the degree of users' | |
|-------|----------|--------|--|--|-----------|
| | | FG | skills. | relatedness with the programme contents; to facilitate skills training | FR-IS-11k |
| | | | | through learning by modelling. | |
| | | | | | |
| F17 | M | LR | Satisfaction ratings (on usefulness | To increase users' awareness on the | |
| | | | and comprehensiveness) are available at the end of each lesson | usefulness and comprehensiveness of | FR-IS-11I |
| | | | (star ratings). | each lesson; to inform in the need to perform a lesson again (if not | FR-13-111 |
| | | | (Star ratings). | understood). | |
| | | | | andorotood). | |
| | М | LR | Users can add new options to | To increase accuracy and | |
| | | | specific answer lists. | personalization, option others than listed | FR-IS-11m |
| | | | | should be added by the users. | |
| Crite | rion | and | Interactions and usability issues | (I): User-system or system-component | |
| defin | ition | | interactions meditating actor's act | ivities; Types of the interactions, e.g. | |
| | | | unidirectional data streaming service | or reliable messaging service. | |
| ID | Priority | Origin | Requirement | Justification | Comments |
| | level | | | | |
| 11 | S | UT | The password registration field | Space sensitive password fields | T-AC-2 |
| | | | must be non-sensitive to spaces | increase the number of failures when | |
| | | | entered before and after. | looking to login into the programme and | |
| | | | | | |



| | | | | increase the number of contacts to the technical support. | |
|----|---|-----------|--|--|--------------|
| 12 | S | UT | The programme logo and the top of the page should have linking options to the landing page of the website. | | T-US-3 |
| 13 | С | UT | More than one mood status could be added per day. | Users may visit the programme more than once a day and experience different mood status in each visit. | FR-HM-1e |
| 14 | С | FG | The scale for mood assessment should discriminate the numbers from 1 to 10. | • | FR-HM-1f |
| 15 | С | UT& FG | The 'My mood' page should appear automatically at the beginning and end of each lesson. | To prevent underreporting of the users' mood status and to monitor the effects of the lessons on mood status. | Too specific |
| 16 | С | UT | The 'next' and the 'previous' buttons in each lesson should be both text based. | Users tend to use the 'next' button to advance in lessons but use the browser button to visit the previous page. | Too specific |



| 17 | С | UT | A button to start the lesson from the | While the programme memorizes and | FR-IS-11n |
|-----|---|------|---------------------------------------|---|-------------|
| | | | beginning could be added. | starts where the users left, some users | |
| | | | | would like to start the lesson from the | |
| | | | | beginning to remind the full contents. | |
| | | | | This is currently only possible by using | |
| | | | | the back button page by page. | |
| 18 | С | UT & | The printing option should be | In general, the option of printing was | FR-IS-11o |
| | | FG | available directly when clicking at | overlooked on the menu. The | |
| | | | each lesson. | participants suggested that a printing | |
| | | | | option/icon should be available directly | |
| | | | | on the lesson list. | |
| 19 | С | UT | Drag and drop exercises should | Feedback on answers given by the users | FR-IS-11p |
| 19 | C | O1 | have the feedback displayed in the | to drag and drop exercises is displayed | 1 (ζ-13-11) |
| | | | visible page area. | on the top of the page. When there are | |
| | | | visible page area. | several answers options the user may | |
| | | | | not note that the feedback is being given | |
| | | | | above. | |
| | | | | useve. | |
| l10 | С | UT | Information icons in check list | Information icons are sometimes | FR-IS-11q |
| | | | exercises should be replaced by | overlooked by users and the information | |
| | | | automatic display of information | is missed. | |
| | | | when the answer is selected. | | |
| | | | | | |





| 111 | С | FG | Professionals should be able to | While the programme is targeted at | Too specific |
|------------|----------|--------|-------------------------------------|---|--------------|
| | | | register in the programme in a | caregivers, professionals must be able | |
| | | | separate registration page. | to visit the programme in order to | |
| | | | | recommend it. A registration area for | |
| | | | | professionals would be relevant. | |
| Crite | rion | and | Content and structure (C): Variable | es of the interaction. | |
| defir | nition | | | | |
| ID | Priority | Origin | Requirement | Justification | Comments |
| | level | | | | |
| C1 | М | FG | The home page requires a visual | While lessons are listed, the users need | FR-IS-11r |
| | | | lesson scheme. | a visual representation of lessons | |
| | | | | structure to guide them. | |
| | | | | | |
| C2 | С | FG | The lesson 'Improve | Users believe that this is a core lessons | Too specific |
| | | | communication' should be added to | that should be included in the | |
| | | | the 5 core recommended lessons. | recommended list. | |
| C 3 | С | FG | Contents on legal aspects, social | Users have reported these needs in | FR-IS-11s |
| | | | support mechanisms, disease | terms of training contents. | |
| | | | progression and anticipatory grief | | |
| | | | should be added to the programme. | | |
| | | | | | |





| Crite | Criterion and Style and aesthetics (S): Look and fe | | | feel of the system. | |
|------------|---|------------|---|--|--------------|
| definition | | | | | |
| ID | Priority | Origin | Requirement | Justification | Comment |
| | level | | | | |
| S1 | С | FG | Illustrations can be remade. | Some users found the illustrations somehow puerile. | Too specific |
| S2 | С | UT & FG | The 'sad' and 'happy' faces in the 'My mood' evaluation should change colours according mood ratings. | | Too specific |
| S 3 | С | UT & FG | In drag & drop exercises the answer options should be in a neutral colour rather than in green, while unanswered. | Since correct answers are displayed in green, the fact that unanswered options are also in green is confusing for the users. | Too specific |
| S4 | С | FG | Fonts/colour fonts should be different for text containing general information and text for scenarios. | Different fonts/font colours for both types of texts would benefit the readability. | Too specific |
| S5 | С | FG | The landing page should have more visual elements (e.g. images, | Visual elements would benefit the comprehension of the platform's target | Too specific |



| | catchy sentences) clarifying who is | group immediately after accessing its | |
|--|-------------------------------------|---------------------------------------|---|
| | the platform target group. | landing page. | |
| | | | Ĺ |



Annex IX – VidAsor Project as example for the application of total conversation

The below is an embedded pdf:



VidAsor Videoassistance and accompaniment for deaf seniors

In 2017 the CNSE launched the VidAsor service, a service aimed at the assistance and accompaniment of the elderly deaf, a particularly vulnerable group with its own needs. Public administrations have detected a shortage of resources, programs and services that meet these needs.

This service aims to cover an important plot within the collective of deaf elderly people, accompaniment, taking advantage of the use of new technologies, and taking into account that it is a collective with little or no technological skills, the service is offered through conventional television, having internet connection and installing a specific equipment and with a web cam to the TV. The user will have the conventional channels and a specific channel of VidAsor, through which they will receive video calls from the video gamers for assistance and accompaniment.

The professional profile of video assist is that of ADECOSOR or communicative mediator, qualified personnel for the realization of this follow-up in deaf elderly people.

Communication between the professional and the deaf eldest person is made through the TELEVISION that the deaf eldest person has in his/her home to which this system has been connected in order to make that video communication with the professional who is in his/her workplace.

Being deaf people, in addition, communication with the deaf user is done directly, in sign language, without intermediaries, which offers complicity and trust to the user, important aspects also if it is an older person.

The service has 3 video speakers from 8:30 to 14.30 and from 16.00 to 20.00 from Monday to Friday, currently serving a total of 57 users.

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