This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 857159

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<thead>
<tr>
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</tr>
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<td>48</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Work package</th>
<th>WP6 – Work Package Title</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead author</td>
<td>Sonja Grigoleit (FhG)</td>
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<td>Contributors</td>
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</table>
Peer reviewers | Wai Hang Shek (OMN), Maria Metaxa (AUTH), Barbara Guerra (EDGE)
Version | V1.0
Due date | M7 – 31/05/2020
Submission date | 14/05/2020
Dissemination | PU Public

Revision History

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<td>0.2</td>
<td>12/03/2020</td>
<td>Sonja Grigoleit (FhG)</td>
<td>Contribution from Gewi, UNRF, UPORTO, UAVR, AIAS, UCC, CCS, CH, FNOL, UP, NUIM, Access Earth</td>
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<tr>
<td>0.3</td>
<td>20/04/2020</td>
<td>Sonja Grigoleit (FhG)</td>
<td>Contributions from Laurea and NHSCT changes, amendments and reviews in various chapters, adding use cases, annex, Executive Summary and Conclusion</td>
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<tr>
<td>0.4</td>
<td>22/04/2020</td>
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<td>Contribution of final version from UCC; corrections of chapter 4.3.4; changes after review</td>
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<tr>
<td>0.5</td>
<td>08/05/2020</td>
<td>Sonja Grigoleit (FhG)</td>
<td>Changes in chapter 3; contribution of 5thYPE (chapter 2.4.7); gewi regarding data capture of pilot 2; contribution of UPORTO (chapter 2.4.5); contribution of NHSCT (changes to chapter 2.4.3); contribution from UCLM (chapter 2.4.6); contribution from NUIM (in chapter 2.1, 4.1.1.2 and 4.3.4); changes in</td>
</tr>
</tbody>
</table>
Table of Contributors

Table 2 Deliverable Contributors

<table>
<thead>
<tr>
<th>Section</th>
<th>Author(s)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction (chapter 1)</td>
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</tr>
<tr>
<td>Strategy of SHAPES pilot activities (chapter 2)</td>
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</tr>
<tr>
<td>Use cases to be tested within the SHAPES pilot campaign (chapter 3)</td>
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Table of Acronyms and Abbreviations

Table 3 Acronyms and Abbreviations

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<td>Use Case</td>
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<td>Model for ASsessment of Telemedicine</td>
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<td>Monitoring and Assessment Framework of the EIP</td>
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<td>NASS</td>
<td>Non-adoption, Abandonment, Scale-up, Spread, and Sustainability</td>
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Keywords

Evaluation methodology, large scale pilot campaign, healthy ageing
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Table of Contents

EXECUTIVE SUMMARY ........................................................................................................... XV

1 INTRODUCTION .................................................................................................................... 1

1.1 RATIONALE AND PURPOSE OF THE DELIVERABLE ................................................... 1

1.2 STRUCTURE OF THE DOCUMENT .................................................................................... 1

1.3 DEVELOPMENT PROCESS OF THIS DELIVERABLE ......................................................... 2

2 STRATEGY OF SHAPES PILOT ACTIVITIES ....................................................................... 6

2.1 OBJECTIVE OF THE PILOT CAMPAIGN ........................................................................... 6

2.2 SHAPES CO-DESIGN PROCESS TO DEVELOP PERSONAS, SCENARIOS AND USE CASES .................................................................................................................. 8

2.2.1 Methodology to develop personas in WP2 ................................................................... 10

2.2.2 Methodology to develop use cases within WP2 .......................................................... 11

2.3 STRATEGY OF THE DIFFERENT PILOT THEMES .............................................................. 12

2.3.1 Pilot Theme 1 - Smart Living Environment for healthy ageing at Home .................... 12

2.3.1.1 Objectives of pilot theme 1 ......................................................................................... 12

2.3.1.2 Overarching evaluation criteria – how is success defined? ...................................... 13

2.3.1.3 Which Use case will be tested in pilot theme 1? ....................................................... 14

2.3.2 Pilot Theme 2 - Improving In-Home and Community-based Care .............................. 14

2.3.2.1 Objectives of pilot theme 2 ......................................................................................... 15

2.3.2.2 Overarching evaluation criteria – how is success defined? ...................................... 16

2.3.2.3 Which Use case will be tested in pilot theme 2? ....................................................... 16

2.3.3 Pilot Theme 3 - Medicine Control and Optimisation .................................................. 16

2.3.3.1 Objectives of pilot theme 3 ......................................................................................... 17

2.3.3.2 Overarching evaluation criteria – how is success defined? ...................................... 17
2.3.3.3 Which Use case will be tested in pilot theme 3? ........................................... 18

2.3.4 Pilot Theme 4 - Psycho-social and Cognitive Stimulation Promoting Wellbeing .......... 18

2.3.4.1 Objectives of pilot theme 4 ................................................................................. 19

2.3.4.2 Overarching evaluation criteria – how is success defined? ................................. 19

2.3.4.3 Which Use case will be tested in pilot theme 4? ................................................. 20

2.3.5 Pilot Theme 5 - Caring for Older Individuals with Neurodegenerative Diseases .......... 20

2.3.5.1 Objectives of pilot theme 5 ................................................................................. 22

2.3.5.2 Overarching evaluation criteria – how is success defined? .................................. 23

2.3.5.3 Which Use case will be tested in pilot theme 5? ................................................. 24

2.3.6 Pilot Theme 6 - Physical Rehabilitation at Home ......................................................... 24

2.3.6.1 Objectives of pilot theme 6 ................................................................................. 25

2.3.6.2 Overarching evaluation criteria – how is success defined? .................................. 26

2.3.6.3 Which Use case will be tested in pilot theme 6? ................................................. 26

2.3.7 Pilot Theme 7 - Cross-border Health Data Exchange ............................................... 27

2.3.7.1 Objectives of pilot theme 7 ................................................................................. 28

2.3.7.2 Overarching evaluation criteria – how is success defined? .................................. 29

2.3.7.3 Which Use case will be tested in pilot theme 7? ................................................. 29

3 USE CASES TO BE TESTED WITHIN THE SHAPES PILOT CAMPAIGN ....................... 31

3.1 UC-PT1-001 WELLBEING MONITORING AND ASSESSMENT ............................ 31

3.2 UC-PT1-002 SOCIAL CONNECTION ........................................................................ 33

3.3 UC-PT1-003 COMPETENT USAGE OF DIGITAL TECHNOLOGIES ......................... 35

3.4 UC-PT2-001 MONITORING OF HEALTH PARAMETERS ........................................ 36

3.5 UC-PT2-002 COMMUNITY INTERACTION ............................................................... 39

3.6 UC-PT2-003 COGNITIVE AND PHYSICAL TRAINING ............................................. 41

This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 857159
3.7 UC-PT2-004 NIGHT SURVEILLANCE ROUNDS AT COMMUNITY CARE ........................................ 45
3.8 UC-PT2-004B NIGHT SURVEILLANCE ROUNDS IN THE HOME-SETTING ..................................... 46
3.9 UC-PT3-GENERAL DESCRIPTION “MULTI-MORBID PATIENTS” .............................................. 47
3.10 UC-PT3-001 (HEART FAILURE PATIENTS) ............................................................................. 50
3.11 UC-PT3-001B (UNRF VERSION) ............................................................................................ 51
3.12 UC-PT3-001C (OLOMOUC VERSION) ....................................................................................... 53
3.13 UC-PT3-002 (DIABETES PATIENTS) ......................................................................................... 56
3.14 UC-PT3-002B (VERSION UNRF) ............................................................................................ 58
3.15 UC-PT4-001 (PHYSICAL AND COGNITIVE TRAINING THROUGH DANCING) ......................... 59
3.16 UC-PT4-002 COGNITIVE TASKS ROBOT ................................................................................ 61
3.17 UC-PT5-001 iSUPPORT FOR DEMENTIA CAREGIVERS ............................................................ 66
3.18 UC-PT5-002 DIGITAL ASSISTANT FOR PEOPLE WITH MILD COGNITIVE IMPAIRMENT .......... 69
3.19 UC-PT5-003 MONITORING DIABETIC PATIENTS WITH MILD COGNITIVE IMPAIRMENT .......... 71
3.20 UC-PT6-001 TRAINING OF OROFACIAL MUSCULATION .......................................................... 74
3.21 UC-PT6-002 GAIT REHABILITATION ......................................................................................... 75
3.22 UC-PT6-003 3D DEPTH CAMERA REHABILITATION TOOL ...................................................... 77
3.23 UC-PT6-004 WEARABLE MOTION MONITORING DEVICES ..................................................... 79
3.24 UC-PT7-001 MONITOR OLDER PATIENTS WHEN TRAVELLING ABROAD ........................... 80
3.25 UC-PT7-002 IDENTIFYING ACCESSIBLE LOCATIONS AND ROUTES FOR OLDER PEOPLE ........... 82
3.26 UC-PT7-003 MONITOR SENIORS & PREVENT MEDICAL EMERGENCIES .............................. 83

4 EVALUATION METHODOLOGIES ......................................................................................... 86

4.1 EVALUATION METHODOLOGIES FOR LARGE-SCALE PILOTS – A LITERATURE RESEARCH .......... 88

4.1.1 Introduction - why are pilots important for health and care studies? .................................. 88

4.1.1 The difference between monitoring and evaluation for interventions ......................... 90

This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 857159
5 PLANNING OF THE SHAPES PILOT CAMPAIGN

5.1 DESIGN AND PREPARATION: PHASE 1-3

5.1.1 Phase 1: Plan, Design and KPI: Table-top Exercises

5.1.1.1 Objectives

5.1.1.2 Use cases

5.1.1.3 Scenarios

5.1.1.4 Evaluation Methodology

5.1.2 Phase 2: Prototyping and Mock-Up

5.1.2.1 Wireframe

5.1.2.2 Mock-Up

5.1.2.3 Prototype

5.1.2.4 Underlying findings on Usability engineering/Software ergonomics

5.1.3 Phase 3: Hands-on Experiments

5.2 PHASE 4-5: DEPLOYMENT AND EXECUTION

5.2.1 Phase 4 Small Scale Live Demonstrations

5.2.1.1 Methodology

5.2.2 Phase 5: SHAPES Deployments - large pan-European testing

5.2.2.1 Objectives of large-scale pilot campaign

5.2.2.2 Development of large-scale use cases protocols

5.2.2.3 Planning of large-scale piloting campaign activities

5.2.2.4 Design of Pilot Themes interventions in real life settings

5.2.2.5 Communication and Dissemination of pilot activities
5.2.2.6 Risk management ................................................................. 219
5.2.2.7 Ethical considerations .......................................................... 221
  5.2.2.7.1 Research integrity/action plan ........................................... 221
  5.2.2.7.2 The validation/verification/assessment of ethical features of SHAPES .... 221
  5.2.2.7.3 Data Lifecycle Management Plan (DLMP) to be created for each pilot ....... 222
  5.2.2.7.4 Ensuring ethics compliance of the SHAPES version to be used in pilots ...... 222

6 CONCLUSION .................................................................................. 223

7 REFERENCES .................................................................................. 224

ANNEX .............................................................................................. 240

ANNEX I: MATCHING OF PILOT THEMES AND TECHNOLOGIES ...................... 240
ANNEX II: MATCHING OF USE CASES AND PILOT THEMES ........................................ 270
ANNEX III: LIST OF PILOT SITES FOR EACH USE CASE ................................................. 284
ANNEX IV: ADAPTATION OF THE USE CASES TO COVID-19 PANDEMIC ................. 291

Pilot theme 1: .................................................................................. 291
Pilot theme 2: .................................................................................. 292
Pilot Theme 3: ................................................................................ 292
Pilot Theme 4: ................................................................................ 296
Pilot Theme 5 .................................................................................. 297
Pilot Theme 6 .................................................................................. 302
Pilot theme 7: .................................................................................. 305

List of Figures
This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 857159
Deliverable D6.1 SHAPES Pan-European Pilot Campaign Plan Version 1.0

<table>
<thead>
<tr>
<th>Figure</th>
<th>Description</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Process of Task 6.1; key input and output to other SHAPES work packages</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>The major impacts of the SHAPES project according to the DoA.</td>
<td>7</td>
</tr>
<tr>
<td>3</td>
<td>Use Case and Pilot Theme Use Cases (Pilot Cases) within SHAPES.</td>
<td>9</td>
</tr>
<tr>
<td>4</td>
<td>Personas development</td>
<td>10</td>
</tr>
<tr>
<td>5</td>
<td>The three main aspects of evaluation in the SHAPES project.</td>
<td>87</td>
</tr>
<tr>
<td>7</td>
<td>Schematic diagram of the interplay between monitoring and evaluation activities. .....</td>
<td>94</td>
</tr>
<tr>
<td>9</td>
<td>Linking stages of maturity with evaluation methods and claims [30]</td>
<td>95</td>
</tr>
<tr>
<td>10</td>
<td>MAFEIP combinations of Markov method [53]</td>
<td>107</td>
</tr>
<tr>
<td>11</td>
<td>MAST Assessment model [54]</td>
<td>109</td>
</tr>
<tr>
<td>12</td>
<td>Rainbow Framework Seven Clusters.</td>
<td>110</td>
</tr>
<tr>
<td>13</td>
<td>Conceptual model for the MAPS Toolkit, axes of scale and their definitions [57].....</td>
<td>113</td>
</tr>
<tr>
<td>14</td>
<td>Healthcare Innovation Cycle [58]</td>
<td>115</td>
</tr>
<tr>
<td>15</td>
<td>Process of the technical evaluation within the SHAPES project</td>
<td>124</td>
</tr>
<tr>
<td>16</td>
<td>Evaluation categories and selected evaluation models for SHAPES</td>
<td>128</td>
</tr>
<tr>
<td>17</td>
<td>Enabling service deployment - 4 conditions and 4 groups of CSFs [62]</td>
<td>130</td>
</tr>
<tr>
<td>18</td>
<td>The three steps in Model for Assessment of Telemedicine. [70]</td>
<td>132</td>
</tr>
<tr>
<td>19</td>
<td>MAFEIP Tool and its purpose [74]</td>
<td>141</td>
</tr>
<tr>
<td>20</td>
<td>Data Collection</td>
<td>148</td>
</tr>
<tr>
<td>21</td>
<td>Quantitative Data Collection Methods</td>
<td>149</td>
</tr>
<tr>
<td>22</td>
<td>Prospective and Retrospective Data Collection</td>
<td>162</td>
</tr>
<tr>
<td>23</td>
<td>The first &quot;Design and Preparation&quot; part of the pilot campaign.</td>
<td>188</td>
</tr>
</tbody>
</table>

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This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 857159

**List of Tables**

- **TABLE 1** REVISION HISTORY ................................................................. II
- **TABLE 2** DELIVERABLE CONTRIBUTORS ................................................ III
- **TABLE 3** ACRONYMS AND ABBREVIATIONS .......................................... IV
- **TABLE 4** DATA MODEL OF PILOT THEME 4 ............................................ 19
- **TABLE 5** PILOT STUDIES FUNCTIONS. [24, 25] ................................... 88
- **TABLE 6** QUESTIONS USED FOR MEASURING METRICS [30] ............. 93
- **TABLE 7** TYPOLOGY OF EVALUATION MODELS [34] ......................... 100
- **TABLE 8** THREE METHODOLOGIES ADOPTED IN LMIC COUNTRIES [36] ................................................................. 101
- **TABLE 9** EVALUATION APPROACHES BY BETTEREVALUATION .......... 102
- **TABLE 10** GLOBAL INNOVATIVE EVALUATION METHODOLOGIES [48] ................................................................. 104
- **TABLE 11** RAINBOW FRAMEWORK – CLUSTERS AND TASKS DESCRIPTIONS ................................................................. 110
- **TABLE 12** GUIDELINE FOR “NO / IN PROGRESS / PERFORMED / DOCUMENTED” ANSWERS [57] ......................... 114
- **TABLE 13** SCORING MECHANISM – QUANTITATIVE METHOD [57] ........ 114
- **TABLE 14** HEALTHTECH DELIVERABLES MATRIX (FOR EU) [58] ........... 116
- **TABLE 15:** OVERVIEW OF THE DIFFERENT EVALUATION TOOLKITS AND MODELS FOR SHAPES: ...................... 125

**FIGURE 24:** THE SECOND PART OF THE SHAPES PILOT CAMPAIGN. ................................................................. 189

**FIGURE 25:** ITERATIVE FEEDBACK LOOPS REGARDING THE USER EXPERIENCE OF SHAPES: ...................... 191

**FIGURE 26:** SHAPES SCENARIO BUILDING PROCESS ................................................................. 195

**FIGURE 27:** SHAPES SCENARIO DEVELOPMENT PROCESS ................................................................. 196

**FIGURE 28:** EXEMPLARY DEVELOPMENT PROCESS OF MOCK-UPS AND PROTOTYPES ................................................................. 197

**FIGURE 29:** SUMMARY OF THE INFORMATION IN THIS DELIVERABLE AND ITS FURTHER USE IN THE PROJECT.... 223
TABLE 16: DOMAINS AND QUESTIONS IN THE NASSS FRAMEWORK [63]. .................................................. 143

TABLE 18: DATA COLLECTION METHODS .................................................................................................. 150

TABLE 19: DATA COLLECTION METHODS FOR USE CASES AMONG THE PILOT THEMES ....................... 171

TABLE 17: TIME-PLAN FOR THE EVALUATION ACTIVITIES WITHIN THE SHAPES PROJECT ................. 181

TABLE 20: FUNCTIONAL GROUPS/ PERSONNEL ACCORDING TO THE ICS [143] ...................................... 183

TABLE 21: ATTRIBUTE LIST FOR MEDICAL PACT SCENARIO [146] .......................................................... 194

TABLE 22: FICS ELEMENTS OF THE SCENARIO [147, 151] ..................................................................... 195

TABLE 23: PILOT SITE CHECKLIST ........................................................................................................... 206

TABLE 24: STRUCTURE OF SHAPES LARGE-SCALE PILOT STUDY PROTOCOLS ........................................ 210
Executive Summary

This deliverable contains the strategy, evaluation methodology and planning of the SHAPES Pan-European Pilot Campaign. It builds on the persona and use cases developed in WP2 and is also the result of 33 teleconferences with the pilot leaders and replicating sites as well as the technical partners, numerous bilateral calls and hundreds of emails and chats to develop a clear picture of which technological tool or application will be tested under which pilot theme and at which pilot site to fulfil which need or objective and how this could be evaluated.

Thus, as result this report contains the following information:

1. A summary of the methodology, how the SHAPES consortium develops personas, general use cases as well as the specific use cases of the pilot themes
2. The background, objectives and overarching evaluation criteria of each of the pilot themes.
3. The use cases of each of the pilot themes (including a general description, the involved technical partner and technological tools and applications, the pilot sites and their plans for leading or replicating this use case)
4. An extensive literature review on evaluation methodologies in large scale pilot projects
5. The evaluation methodology of the SHAPES project
   • The technological evaluation of the digital tools and applications on the basis of the user requirements
   • An evaluation of the impact of the SHAPES solution using the methodologies MAST, MAFEIP, MOMENTUM and NASSS
   • An internal evaluation of the pilot activities of the SHAPES pilot campaign
6. Qualitative and quantitative data collection methods as well as an overview table which data collection method will be applied for which use case
7. The planning of the SHAPES pilot campaign
   • Phase 1: scenario development and testing with medical experts & technology developers
   • Phase 2: Mock-up/ prototype validation with users
   • Phase 3: Hands-on experiments with and training of the user
   • Phase 4: The planning of the small-scale live demonstration
   • Phase 5: The planning of the large pan-European testing including also protocols, communication and dissemination activities, risk management and ethical considerations
1 Introduction

1.1 Rationale and purpose of the deliverable

This report has the aim to define the high-level strategy, planning and methodology for the SHAPES Action’s Pan-European Pilot Campaign. In more detail this deliverable should include:

- **Objectives** for the selected persona-based use cases;
- The intent and the **nature of the different pilot activities** as well as the functional and quality characteristics;
- Specific and measurable **evaluation criteria** (to assess the impact of the SHAPES solution);
- The **roles and responsibilities** of the contributing entities.

To achieve these objectives this deliverable is embedded and based on the work of the other SHAPES work packages. Specifically, this deliverable is based on the input of WP2 (SHAPES persona and use cases), which is developed in parallel. Additionally, this deliverable also is based on the description of SHAPES digital solutions (WP4 and WP5). An overview of the key inputs and outputs is depicted in Figure 1.

![Figure 1: Process of Task 6.1; key input and output to other SHAPES work packages.](image)

1.2 Structure of the document

This report is divided into the following chapters:

*This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 857159*
• Chapter 1 - Introduction
• Chapter 2 – Strategy of the pilot activities (describing the objectives and overarching evaluation criteria of SHAPES in general and of the pilot themes)
• Chapter 3 – Use cases to be tested within the SHAPES pilot campaign (explaining the nature of the different pilot activities)
• Chapter 4 – Evaluation methodologies (describing the evaluation criteria as well as the evaluation methodology and process)
• Chapter 5 – Planning of Pilot campaign (containing the planning of the six phases of the SHAPES pilot campaign)
• Chapter 6 – Conclusion

1.3 Development process of this deliverable

To fulfil the objectives of this report at a rather early stage of the project (month 1 to month 6) it was necessary to set up a time-consuming, but very necessary communication process between all SHAPES partners to get a common understanding of the needs of the pilot sites, the opportunities of the technical solutions of the SHAPES project and of the pilot objectives – what we want to achieve with our pilot activities.

In more detail the process to reach this understanding was the following:

1. Telcos to explain the specific features and the functioning of the SHAPES technical solutions to the pilot leaders

We have performed a number of telcos with each of the pilot leaders and all interested technical partner to explain in more detail how the SHAPES technologies/tools/applications can be used in the respective pilot.

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<th>Topic</th>
<th>Participating partners</th>
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<td>FhG, TREE, VICOM, Access Earth, OMN, UPORTO, ULS</td>
</tr>
<tr>
<td>02.12.2019</td>
<td>Pilot theme 2a</td>
<td>FhG, PAL, Gewi, GNO, MedicalSyn</td>
</tr>
<tr>
<td>04.12.2019</td>
<td>Pilot theme 3</td>
<td>FhG, TREE, EDGE, OMN, NHSCT, ULS, GNO, UCLM</td>
</tr>
</tbody>
</table>
The minutes of each telco was uploaded to the SHAPES repository containing the needs and objectives of each pilot theme as well as the functions and features of the SHAPES technical solutions.

2. Second set of telcos with each of the pilot leaders in which the pilot leaders should decide which technologies/tools/applications are relevant for their pilot theme

<table>
<thead>
<tr>
<th>Date</th>
<th>Topic</th>
<th>Participating partners</th>
</tr>
</thead>
<tbody>
<tr>
<td>17.12.2019</td>
<td>Pilot 3</td>
<td>FhG, NHSCT</td>
</tr>
<tr>
<td>18.12.2019</td>
<td>Pilot 4</td>
<td>FhG, UAVR</td>
</tr>
<tr>
<td>18.12.2019</td>
<td>Pilot 6</td>
<td>FhG, SAL, VICOM, UCLM</td>
</tr>
<tr>
<td>19.12.2019</td>
<td>Pilot 7</td>
<td>FhG, 5thYPE, Gewi</td>
</tr>
<tr>
<td>20.12.2019</td>
<td>Pilot 5</td>
<td>FhG, UPORTO</td>
</tr>
</tbody>
</table>

The final result of this set of telcos was a table in which the different SHAPES digital technologies were matched with the pilot themes (see Annex I: Matching of pilot themes and technologies)

3. Bilateral communication with all other pilot sites and non-technical partners to clarify open questions regarding their contribution to the pilot campaign (January 2020)

4. In a further round of telcos with each of the pilot leaders the evaluation methodology and first use cases were discussed

<table>
<thead>
<tr>
<th>Date</th>
<th>Topic</th>
<th>Participating partners</th>
</tr>
</thead>
<tbody>
<tr>
<td>14.01.2020</td>
<td>Pilot 3</td>
<td>FhG, NHSCT</td>
</tr>
<tr>
<td>15.01.2020</td>
<td>Pilot 1 &amp; 2</td>
<td>FhG, Gewi, CCS</td>
</tr>
<tr>
<td>15.01.2020</td>
<td>Pilot 6</td>
<td>FhG, VICOM, SAL, UCLM</td>
</tr>
<tr>
<td>15.01.2020</td>
<td>Pilot 5</td>
<td>GNO, UPORTO, SciFy</td>
</tr>
<tr>
<td>16.01.2020</td>
<td>Pilot 4</td>
<td>FhG, UAVR, VICOM</td>
</tr>
</tbody>
</table>
Each of the pilot leaders explained with which evaluation methodology they have experience as well as the advantages and disadvantages of these methodologies. Additionally first ideas for use cases in each pilot theme were discussed. The first descriptions of use cases were uploaded to the SHAPES repository (see also chapter 3).

5. In the next round of telcos the use cases were discussed in more detail with the leader of WP 2

<table>
<thead>
<tr>
<th>Date</th>
<th>Topic</th>
<th>Participating partners</th>
</tr>
</thead>
<tbody>
<tr>
<td>04.02.2020</td>
<td>Pilot 1&amp;2 FhG, TREE, Gewi, CCS, UP, VICOM</td>
<td></td>
</tr>
<tr>
<td>04.02.2020</td>
<td>Pilot 5 FhG, TREE, VICOM, UPORTO, ICOM, UP</td>
<td></td>
</tr>
<tr>
<td>05.02.2020</td>
<td>Pilot 4 FhG, UAVR, ICOM, UP</td>
<td></td>
</tr>
<tr>
<td>05.02.2020</td>
<td>Pilot 3 FhG, ICOM, UP, NHSCT, VICOM, AIAS</td>
<td></td>
</tr>
<tr>
<td>06.02.2020</td>
<td>Pilot 7 FhG, 5thYPE, OMN, ICOM, UP</td>
<td></td>
</tr>
<tr>
<td>11.02.2020</td>
<td>Pilot 6 FhG, ICOM, OMN, UP, AIAS, VICOM, UCLM</td>
<td></td>
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</tbody>
</table>

The objective was to align the (technical) use case ideas which have been developed within WP6 with the leader of Task 2.5 (persona and use cases). Additionally, relevant technical partners participated in this telcos to be able to clarify open questions regarding the usage of the SHAPES technologies in the suggested use cases.

The result of the telcos was a table with a list of use cases for each pilot theme (including the necessary SHAPES digital technologies; see
Annex II: Matching of use cases and pilot themes).

6. **Telco with all pilot sites to discuss the use cases ideas also with the replicating sites**

The aim was to discuss the general interest of all pilot sites in the different use cases and also to clarify open general questions (e.g. organisation and management, timing, budget, equipment).

<table>
<thead>
<tr>
<th>Date</th>
<th>Topic</th>
<th>Participating partners</th>
</tr>
</thead>
<tbody>
<tr>
<td>28.02.2020</td>
<td>All pilot sites</td>
<td>FhG, CH, AIA5, TREE, 5thYPE, Gewi, UAVR, NUIM, AUTH, UP, UNRF, UCC, UCLM, FNOL, UPORTO, UCC</td>
</tr>
</tbody>
</table>

The result was a table with all use cases and the interested pilot sites (see Annex III: List of Pilot sites for each use case).

7. **Round of telco with each of the pilot leaders, all replicating pilot sites and relevant technical partners to discuss the use cases in more detail**

The aim of these telcos was to get a clear picture which replicating site is able to replicate which use case and also if it is possible to merge use cases, run them in parallel or to run them better separately (at a different time or with a different group of patients).

<table>
<thead>
<tr>
<th>Date</th>
<th>Topic</th>
<th>Participating partners</th>
</tr>
</thead>
<tbody>
<tr>
<td>10.03.2020</td>
<td>Pilot 3</td>
<td>FhG, UNRF, Gewi, SciFy, EDGE, CH, OMN, VICOM, NHSCST, FNOL</td>
</tr>
<tr>
<td>12.03.2020</td>
<td>Pilot 2</td>
<td>FhG, AIA5, SciFy, CH, OMN, FNOL, UCLM, NUIM, Gewi, VICOM, EDGE, 5thYPE, PAL, GNO</td>
</tr>
<tr>
<td>12.03.2020</td>
<td>Pilot 7</td>
<td>FhG, ICOM, UNRF, OMN, CH, NUIM, 5thYPE, GNO</td>
</tr>
<tr>
<td>17.03.2020</td>
<td>Pilot 1</td>
<td>FhG, EDGE, FNOL, AIA5, SciFy, GNO, FINT, CCS, VICOM, CH, UCLM, UCC</td>
</tr>
<tr>
<td>19.03.2020</td>
<td>Pilot 4</td>
<td>Suspended</td>
</tr>
<tr>
<td>19.03.2020</td>
<td>Pilot 6</td>
<td>Suspended</td>
</tr>
<tr>
<td>20.03.2020</td>
<td>Pilot 5</td>
<td>Suspended</td>
</tr>
</tbody>
</table>

These last telcos have been suspended due to the effect of COVID-19 (overloaded videoconference tools, difficulties with internet connection from participants working at home, difficulties to organise home office (e.g. accessing data, taking care of smaller children).
To mitigate this effect Microsoft Teams was used to set up chats for each pilot theme, in which the pilot leader, the replicating sites as well as technical partner can discuss open questions and exchange new ideas regarding the development of the use cases.

From **May onwards** telcos have been started again to discuss the detailed planning of the use cases for each pilot theme.
2 Strategy of SHAPES pilot activities

This second chapter summarizes the objectives of the pilot campaign in general as well as the more specific objectives of the seven pilot themes. Additionally it describes the overarching evaluation criteria for the pilots and gives an overview of the use cases to be tested in each of the pilot themes.

2.1 Objective of the pilot campaign

The overall objective of the pilot campaign is to implement the SHAPES Pan-European Pilot Campaign that demonstrates and validates the Platform in 36 pilot activities in 15 interconnected communities or pilot sites across 11 EU Members States. The SHAPES Pilot Campaign should

- include small-scale pilots and demonstrations and large-scale pilots to validate the SHAPES Platform capabilities and benefits to care recipients, caregivers and care service providers,
- be validated at the European scale, across different regions, cultures and health and care organisational models
- and assess the impact of the SHAPES Platform in supporting healthy ageing and independent living and the definition of improved integrated care policies and measures.

With this pilot campaign SHAPES aims to sustain and extend the healthy and independent living at home for older individuals facing temporary and permanent reduced functions or capabilities.
In more detail the expected impact of SHAPES on the care giver and the care recipient are listed in the figure above (Figure 2).

Thus, the evaluation process of SHAPES has to assess, if these defined and promised impacts of SHAPES can be reached during the course of the project. On the basis of the defined impacts the following evaluation categories have been developed:

1. **Technological evaluation**: In this category it has to be demonstrated that SHAPES is able to build and deploy a pan-European open Platform enabling the delivery of intelligent and personalised digital solutions sustaining and extending healthy and independent living at home (for details see chapter 4.2).

2. **Reduced costs and enhanced efficiency of health care services**: SHAPES should enhance the efficiency of in-home and community-based care, reduce hospitalisation and readmission rates and also reduces the number of visits and travel for medical appointments (for details see chapter 4.3.3).

3. **Improved quality of life and health status for involved users and carers**: This category covers the broad range of aspects pertaining to both the health status itself as well as the quality of life of the user and the carer (e.g. number of hospital admissions; health status using physiological metrics; physical, cognitive and social functioning; perceived well-being; health literacy; feelings of isolation). The different aspects of the health status and the quality of life to be evaluated in each of the pilot themes are described in chapter 2.3. The

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1 Not included are the impacts of the SHAPES project, which can’t be tested and evaluated during the pilots (e.g. synergies with EU-funded projects and EU associations, inclusion of open calls, the SHAPES Business plan, increased competitiveness of the European ICT industry). These impact success indicators will be evaluated by WP1.

This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 857159.
different data capture methods to assess the health status and the quality of life are summarized in Table 18.

4. **Usability and user-experience**: The satisfaction of the user with the SHAPES solution has also to be tested to make sure that the final solution is will be accessible to and accepted by the users. More details can be found in chapter 4.2.1.

5. **Demonstrate the scalability of SHAPES solution**: SHAPES aims to achieve a successful market deployment, uptake of the Platform and the digital solutions, promoting the co-creation of digital solutions that support active, healthy and independent ageing.

In chapter 4 several evaluation methodologies, which have been tested and reported in the literature, are described and analysed. A combination of well-tested methodologies have been selected which incorporate also these five essential evaluation criteria of SHAPES.

### 2.2 SHAPES co-design process to develop personas, scenarios and use cases

To understand and analyse the user needs for SHAPES the project applies a human-centred co-design process by developing personas, user stories and use cases. This process contains the following steps:
1. **Persona development (WP2):** The social scientists of the SHAPES consortium develop personas on the basis of mini-ethnographic studies, in-depth interviews with experts and focus groups. The personas will contain the attributes, attitudes, behaviours and characteristics of the user groups addressed by SHAPES.

2. **Use Cases (UC) (WP2):** General use cases will be developed on the basis of the needs of the persona. These use cases are aimed to illustrate the breadth and variability of the technology use for the improvements of the quality of life of older adults.

3. **Use Cases of Pilot Themes (UC-PT) (WP6):** On the basis of these more general use cases specific use cases are developed for each pilot theme. In these UC-PTs the needs of the users as well as the user stories are merged with specific digital tools and solutions of the SHAPES platform. This means that in comparison with the UC these UC-PT contain detailed information like the SHAPES digital solutions involved, equipment requirements and the general requirements (e.g. internet connectivity).

The methodology of the development of personas and use cases is described in chapter 2.2.1 and 2.2.2. The pilot theme use cases are summarized in chapter 3.
2.2.1 Methodology to develop personas in WP2

There is no set approach to developing personas, so they can be created at the beginning of a design process or emerge in the design and pilot process [1]. Many studies emphasize empirical nature of persona creation [2, 3], but some studies also recognize important input from designers experiences as well as other possibilities such as ad hoc assumptions [1]. Usual methods to create personas vary between studies, some studies use only qualitative methods [4], where data are gathered mainly using ethnographic techniques, interviews or focus groups, other studies use mixed methods [2] or purely quantitative methods, usually employing cluster analysis [1, 3].

Due to the limited time the methodology of creation of personas in SHAPES project was a combination of literature study and qualitative methods while making use of the rich experience with the target population of older adults within the UP and NUIM teams. The process of persona creation had three phases – see the schema below.

First draft of persona categories aimed at identifying the preliminary persona types and was based on the following data:

1. previous persona files, which were developed for the project submission – describe
2. data from DIPEx study on active ageing, from the Czech republic
3. literature review – case studies, qualitative studies on various types of older adults according to health status and behavioural patterns

4. expert interviews with four geriatric doctors (one of them leading a major geriatric clinic in Czech Republic) and two social workers who work with older adults.

5. discussion with some SHAPES team members, with long-term former experience in ethnographic study of older adults

At first the most common types according to health status and behavioural patterns were identified and the first draft of persona categories was prepared, followed by an extensive team discussion (within the UP team and later also with the expert team from NUIM). After the additional literature was reviewed, the draft personas were developed based on personas categories and sent to the team members for a second round of discussion, which led to the final personas. However, being so early in the project timeline, we consider these still preliminary as a basis for further discussion with other technological partners, designers, pilot leaders etc.

2.2.2 Methodology to develop use cases within WP2

Following the goals of Task 2.5, general use cases are aimed to illustrate the breadth and variability of the technology use for the improvements of the quality of life of older adults, rather than specific use cases developed for designing concrete digital solutions (this will be done in subsequent stages of SHAPES project, however). These use cases to be developed in Task 2.5 will address the persona’s needs. The aim of the use case is to support and ameliorate various aspects of persona’s life.

At the beginning, the rough forms of use cases were developed in a collaborative way by team members. Three main sources of available information was used for seeking the most suitable components and digital solutions for each of basic forms of use cases, a) components and digital solutions included in the available scientific literature (based on a literature review of papers published in relevant journals) b) components and digital solutions available in offer by providers; and c) components and digital solutions included in the SHAPES project proposal by SHAPES-partner providers.

We plan to insert use cases focused on the following general functions: Assistive Technology for Reading, Medication Reminder, Meal Ordering, Motor Exercising with Robot, Home Environment Monitoring, In-Home Post-Hospital Aftercare, In-Home Video-Monitoring, Digital Nurse, Location Tracking, In-Home Cognitive Training and remote wellbeing monitoring.
2.3 Strategy of the different pilot themes

This chapter contains a description of the objectives, evaluation criteria and use cases of the seven pilot themes.

2.3.1 Pilot Theme 1 - Smart Living Environment for healthy ageing at Home

2.3.1.1 Objectives of pilot theme 1

Pilot theme 1 is a demonstration for providing an environment for older individuals that contributes to a more independent, better and healthier living at home as well as keeping them integrated in an active and social life. The target group consists of older people (+65 years) living independently and displaying signs of reduced physical and/or cognitive capabilities and/or functions (physical and/or cognitive), but willing to maintain autonomy, independence and healthy living at home. It consists further of communities involved in activities for older individuals, care service providers and informal caregivers.

We aim for an improved wellbeing and independent living for older individuals, improved inclusiveness and social interactions between older individuals, care providers and their communities as well as an improved awareness of municipalities and care providers on the status of older individuals.

To achieve this aim, we will demonstrate and assess the impact of using smart person-aware environments, involving smart home solutions and wearable devices (e.g., smartwatches and smartphones) adapted for older individuals and their specific needs in terms of technology, usability and care processes. We also aim to establish tools to validate safety risk elements in the home environment and to propose how to make a friendly home environment to support friendly ageing.

A smart home provides a comfortable living environment for their users that is also aware of their status (e.g., presence, activity, safety alerts etc.). Where applicable, day-to-day digital assistant or Apps assist the individual to stay connected and aware of relevant events (e.g., medication reminder, medical appointment). Moreover, smart home involves information exchange to provide personalised recommendations about local social events for older individuals, news, notification of public works, garbage collection, local socio-cultural or educational activities, need for volunteers, delivery of support services (house cleaning, hairdressers, walking dogs), transportation, neighbouring networks, educational programmes and cultural events.

Current events show, that epidemics play an important role in the lives of older people. Thus, we aim for the involvement of local authorities or businesses to deliver food, medication, walk animals to the elders’ homes.
The target group of pilot theme 1 lives in rural areas of Saxony, Germany and are old people living alone. These old people are very reluctant to move somewhere else. They are healthy people and should not be seen as patients. The focus should be on “living” and not on “treating” them. The aim is that they should stay self-reliant. Thus, the technologies should be supportive – they should not take away their freedom to take decisions. The technologies should help them to communicate (easier) with their neighbours, e.g. to have tea together.

Expected challenges when conducting the pilot:

The technologies used in the smart home context should be easy to understand and as intuitive as possible. Technology also should not be intrusive. It is important to respect the privacy of the older individuals. Therefore, every solution including cameras is deemed difficult to use and integrate in the pilot.

Currently, we have no detailed information about housing of the older individuals. They usually live in 1 or 2 storey houses or in narrow flats. They probably have a phone, but not all of them have wifi in their home.

Digital connectivity will be likely challenge in this rural areas, both mobile connectivity as well as internet via landline. The other SHAPES partners suggested sat-connection (which is rather expensive) or boxes with SIM-cards. There are several infrastructure projects ongoing in the target region. However, for SHAPES we advise that the best solution is to select participants which have existing internet connectivity at home.

Opportunities of the pilot:

Pilot theme 1 poses exceptional opportunities for the community and the individual responsibility of older people. That is, through the use of challenge solving and generally supporting digital applications, older people are empowered to longer stay at home, independently. Independent living positively influences mobility, social activities, self-actualization and ultimately healthier and longer living.

As a result, the empowerment of older people and their increased wellbeing will lead to less burdening of their families, their social environment and the health system.

2.3.1.2 Overarching evaluation criteria – how is success defined?

We will evaluate the outcome of the implementation of SHAPES pilot theme 1 by close monitoring of the solution uptake and problem solving during and at the end of the pilot as well as surveys of the target group to gain direct feedback at the beginning and end of the pilot.
An initial recruitment questionnaire aims to address early adopters, in other words older individuals with a high digital affinity. The questionnaire leads to telephone interviews in which participants are directly recruited for the pilot and their wellbeing is addressed.

At the end of the pilot, we will address the participants with the same questions to qualitatively evaluate the pilot’s influence on their wellbeing. We regard increased wellbeing through the use of provided digital solutions as a critical success criterion of pilot theme 1.

Furthermore, our qualitative assessment will address (1) whether the participants fear to use digital solutions decreased, (2) if the provided solutions were used competently and (3) whether those solutions successfully solved specific problems of the older individuals. Positive results of all three assessments are interlinked success criteria of pilot 1.

2.3.1.3 Which use case will be tested in pilot theme 1?

The following use cases will be tested in a lead function:

- UC-PT1-001 Wellbeing Assessment Use Case
- UC-PT1-002 Digital Assistant to Support older people to live independently and remain socially connected

and:

- UC-PT1-003 Overcoming the fear of digital technologies – competent usage of technologies – problem solving in the community

Our aim is to reduce fear by increasing competent usage of digital solutions that solve specific problems of the target group.

2.3.2 Pilot Theme 2 - Improving In-Home and Community-based Care

Pilot theme 2 “Improving In-Home and Community-based Care” is centred on providing an appropriate home setting for older individuals needing care through a specialized nursing service, preferably in addition to care provided by informal caregivers. It aims at building a safe and caring environment to promote and maintain an individual’s autonomy at home, without forsaking the need for medical and nursing care. Digital solutions and smart home devices are deployed to obtain a person-aware environment and to infer the individual’s wellbeing based on relevant activity. Smart healthcare devices and wearables are integrated to frequently monitor the individual’s health parameters and health condition. Data analytics and Artificial Intelligence (AI) is used for early diagnosis and alerts.
The target group in pilot theme 2 is composed of +65 year old mostly living on their own, who are in need continuous health and care support due to permanently or temporarily reduced functions or capabilities because of chronic age-related illnesses. They are not particularly technology-savvy, struggling to maintain day-to-day communication with society as well as when reaching out in case of an emergency or a situation where they would require (medical) help.

The pilot theme will be implemented in rural (pilot lead) as well as urban areas.

2.3.2.1 Objectives of pilot theme 2

Pilot theme 2 aims to improve the overall well-being and health status as well as the integration into the community and providing a safe and supporting home or care setting.

The objectives of the pilot theme are therefore to:

- Improve the perceived well-being and quality of life of the older individual, reduce feelings of isolation
- Stimulate physical and cognitive health
- Increase communication and engagement with the community
- Support the older individual in day to day activities
- Alert the informal caregivers or selected persons when the health status assessment result is suspicious or action is needed
- Introduce new digital tools successfully in a non-tech-savvy, ageing population

In order to meet these objectives the following means will be used:

- Daily monitoring and assessment of the health status and well-being of the older individuals using wearables and/or digital devices and reporting the results to the individuals to convey a feeling of a functioning “safety net”.
- Allowing the measurement of the subjective health status by asking the individual to rate their well-being on a daily basis
- Tracking the performed cognitive and physical exercises via digital platforms
- Using smart home devices to monitor the older individuals and provide support to them
- Alerting the informal caregivers or selected persons in case of emergency or a potential need for help
- Monitoring the participation of the older individuals within the community-setting and providing prompts for enhancement Installing digital communication tools to enable contact with informal caregivers or family members to follow social care activities through remote channels
2.3.2.2 Overarching evaluation criteria – how is success defined?

In order to evaluate the outcome of the implementation of the SHAPES platform in pilot theme 2, several criteria will be analysed.

The acceptance rate of new technologies by the older individuals will be evaluated. It is expected that only older individuals who are willing to introduce digital solutions in their own home will participate in the pilot. However, the participants will be asked to rate their own acceptance of and feelings towards digital technologies before, during and after the pilot phase. An improved acceptance rate during and after the pilot phase is defined as a success factor.

Both the older individuals themselves as well as their informal care givers will be asked to rate the overall (perceived) well-being and quality of life of the older individual. An enhanced well-being during the pilot phase is defined as a success factor.

Increased communication and interaction with social contacts and the community (also regarding health and care issues) is defined as a success factor. When appropriate, an increased number of participations in community events will be included as part of the evaluation as well.

The amount of planned and performed activities such as going for a walk or exerting cognitive or physical exercises using the digital platform will be evaluated. An increased number of activities carried-out is defined as a success factor.

2.3.2.3 Which Use case will be tested in pilot theme 2?

The following use cases will be tested in pilot theme 2:

- UC-PT2-001 Delivering remote monitoring of key health parameters
- UC-PT2-002 Supporting the interaction of the individual with the community
- UC-PT2-003 LLM CARE Healthcare System for Cognitive and Physical training
- UC-PT2-004a Night surveillance Rounds at Community Care
- UC-PT2-004b Night Surveillance Rounds in the Home-Setting

More details on these use cases can be found in the corresponding sections that follow (Chapter 3 – Sections 3.4 – 3.8).

2.3.3 Pilot Theme 3 - Medicine Control and Optimisation

The primary objective of the Medicine Control and Optimisation pilot is focused on identifying, managing and improving deficiencies in adherence to medicines and treatments of older individuals living with permanent or temporary reduced functions or capabilities due to chronic, age-related illnesses and living at home. Digital
Solutions will be deployed to monitor the individual’s health condition(s), physiological parameters and medicine adherence. A personalised approach will be undertaken to enable early identification of side effects and the opportunity to adjust medicines and treatments so as to deliver safer and more effective use of medicines in-home, thus improving quality of life of the care recipients and reducing health care resource use.

The target population is composed of older individuals (+65 years) in domiciliary care with multiple chronic conditions typically respiratory, cardiac and endocrine conditions.

### 2.3.3.1 Objectives of pilot theme 3

The objectives of pilot theme 3 are:

- To improve the older individuals’ health outcomes and quality of life
- To reduce the workload of medical professionals
- To illustrate the capability of the SHAPES Platform and Digital Solutions to support older individuals with the management and control of chronic conditions
- To monitor and improve medication/treatment adherence and optimisation
- To assess attitudes towards medicines
- To assess attitudes towards the SHAPES platform and Digital Solutions
- To assess the user acceptance, accessibility and user experience of the SHAPES Platform and Digital Solutions
- To enhance health literacy and awareness of older individuals about their conditions
- To measure security and trust rate by users
- To illustrate the capability of the SHAPES Platform and Digital Solutions to provide real-time information to the care professionals about the older individuals’ physiological condition
- To illustrate the capability of the SHAPES Platform and Digital Solutions to deliver reminders, alerts and recommendations to older individuals, concerning the management and control of their conditions.

### 2.3.3.2 Overarching evaluation criteria – how is success defined?

To meet these objectives the following outcomes will be used:

- Measurement of health-related quality of life periodically throughout the pilot using the EQ-5D
- Measurement of healthcare resource utilisation e.g. hospital admissions, hospital length of stay
- Monitoring and assessment of the health status and wellbeing using physiological metrics
• Measure medication adherence and optimisation using e.g. smart inhalers, glucometers and the Medication Adherence Report Scale
• Monitor attitudes towards medication using the Beliefs about Medicines Questionnaire
• Interviews with participants, informal carers and healthcare professionals
• User experience evaluation will be completed using tools e.g. Momentum, MAST, MAFEIP, questionnaires and focus groups.

2.3.3.3 Which Use case will be tested in pilot theme 3?

Which Use case will be tested in pilot theme 3?

- Use case “Support Multi-morbid Older Individuals” will be tested in pilot theme 3.

This includes the following specific use case for pilot themes (UC-PT3-00x):

- UC-PT3-001 - In-home decompensation prediction for heart failure patients
- UC-PT3-001b - Prediction of stroke by home using blood pressure values
- UC-PT3-001c - Advanced telemonitoring of patients with heart failure in home environment
- UC-PT3-002 - Diabetes self-management, control and prevention
- UC-PT3-002b - Monitoring of blood glucose levels to older individuals with diabetes or pre-diabetic, abnormal glucose indications

2.3.4 Pilot Theme 4 - Psycho-social and Cognitive Stimulation Promoting Wellbeing

The aging process is usually associated with losses in several domains of daily functioning, including cognitive functioning, physical functioning, and social networks. Preventing these losses, delaying and ameliorating their progression, or attempting to revert them is essential to a strategy aiming to promote autonomous and independent aging in place and long and healthier lives lived with quality. Interventions combining a physical and a cognitive component are a means to achieve such goals and are likely to impact psycho-social functioning, particularly if delivered in structured group interventions. However, adhesion of older adults to this type of intervention is usually difficult. A way to overcome this limitation is to promote an intervention to which older adults relate and is simultaneously appealing. Dance has the potential to be attractive to older adults and can be adjusted according to individual characteristics (e.g., age, physical limitations, soundtrack preferences). Therefore, this pilot theme focus on the psycho-social and cognitive stimulation through a technological solution that engages older adults in a ludic activity (dance) that can be delivered in a one to one approach or a group approach, the latter a potential facilitator of interpersonal and social
relationships. The main technological solution that will be used is a mat dance exergame (StepMania), which includes a screen that presents the choreography that should be performed, dictating the body movements required to follow the music beat, and is likely to benefit balance, coordination, memory, and concentration. Furthermore, it requires the simultaneous execution of physical and cognitive tasks in a dual-task paradigm, which has a close association with daily life activities and has been shown to have increased benefits in comparison to mono-task interventions.

2.3.4.1 Objectives of pilot theme 4

The primary objective of the pilot run under the theme “Psycho-social and Cognitive Stimulation Promoting Wellbeing” is to assess the impact of technology on the psycho-social, cognitive and physical function and well-being of older adults.

Secondary aims are to:

- Evaluate the usability, accessibility and acceptability of the technological solutions used during the pilot.
- Evaluate user adoption and satisfaction with the technology and services.
- Evaluate experiences of using the SHAPES platform.

In addition, this pilot will also contribute to:

- Validate the overall SHAPES Platform.
- Assess the impact of the SHAPES Platform in supporting healthy ageing and independent living and the definition of improved integrated care policies and measures.

2.3.4.2 Overarching evaluation criteria – how is success defined?

Success for the primary aim will be defined considering statistical and clinical significance by comparing the group that uses technology against a control group that does not use technology for the measures detailed in the table below. These measures may need to be adjusted for specific use cases. Statistical significance will be defined at $p<0.05$. Clinical significance will be defined considering whether minimal detectable differences were attained and for how many variables assessed. Overall clinical significance of the intervention will be assessed using the Patient Global Impression of Change (PGIC) used to assess the patients’ perceived change in their condition as a result of the intervention.

<table>
<thead>
<tr>
<th>Measure</th>
<th>Domain</th>
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<tbody>
<tr>
<td></td>
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<tr>
<td>Test</td>
<td>Domain</td>
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<tr>
<td>Lubben Scale on Social Networks</td>
<td>Social Functioning</td>
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<tr>
<td>UCLA-6 Loneliness Scale</td>
<td>Social Functioning</td>
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<tr>
<td>Trail Making Test</td>
<td>Cognitive Functioning</td>
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<tr>
<td>Stroop Test</td>
<td>Cognitive Functioning</td>
</tr>
<tr>
<td>Gait velocity</td>
<td>Physical functioning</td>
</tr>
<tr>
<td>5 times sit to stand</td>
<td>Physical functioning</td>
</tr>
<tr>
<td>WHO Disability Assessment Schedule (WHODAS 12)</td>
<td>Physical functioning</td>
</tr>
<tr>
<td>Satisfaction with life scale- 5 items (SWLS - Diener)</td>
<td>Well-being (satisfaction)</td>
</tr>
<tr>
<td>EuroQoL EQ-5D</td>
<td>Well-being (quality of life)</td>
</tr>
</tbody>
</table>

Success in the secondary aims will be assessed with indicators of the performance of the technology used and satisfaction with the technology using a multi method approach (e.g. Usability Assessment scales Performance evaluation, Critical Incidents analysis, and/or qualitative reports on the use of the technology).

2.3.4.3 Which Use case will be tested in pilot theme 4?

The following use cases will be tested in pilot theme 4:

- Psycho-social and Cognitive Stimulation Promoting Wellbeing using StepMania.
- Cognitive training (Option 1: In-home cognitive activities for people with early-stage dementia; Option 2: Personalized cognitive activities in the context of a group activity for people with early-stage dementia

2.3.5 Pilot Theme 5 - Caring for Older Individuals with Neurodegenerative Diseases

Pilot theme 5 - Caring for Older Individuals with Neurodegenerative Diseases – is focused on the delivery of care to older individuals living with neurodegenerative diseases and their informal caregivers. Dementia was the fifth leading cause of death in 2016, with about 43 million people living with it in the world. The disability-adjusted life-years attributed to dementia was calculated in 28.8 million [5], which gives the idea of the relevance of this disease. As dementias are responsible for the greatest burden...
of neurodegenerative diseases [6], this pilot theme narrows its focus on dementia syndrome and mild cognitive impairment.

Informal caregivers are defined as individuals providing unpaid and ongoing assistance with basic or instrumental activities of daily living to a person with a disability or chronic illness. When compared with both the general population and informal caregivers of people with other chronic diseases, those caring for someone with dementia are at a greater risk of developing depression and anxiety disorders, as well as hypertension, digestive, and breathing problems [7, 8].

In 2019, approximately 463 million adults (20-79 years) were living with diabetes worldwide, where 1 in 5 diabetics are above 65 years old [9]. Although macrovascular and microvascular complications of diabetes are well recognized, there is a lack of awareness regarding other comorbidities such as cognitive impairment, depression and physical disabilities. We know that type 2 diabetes is associated with approximately a 1.5 to 2.5-fold increase in the risk of dementia [10]; the prevalence of dementia in type 1 diabetes is less clear. Cognitive dysfunction is an important condition to be recognized as it interferes with patient’s participation in their diabetes management. In addition, patients with cognitive dysfunction can be on a spectrum that extends from mild cognitive impairment (defined as cognitive deficit without difficulty performing daily activities) to severe impairment (commonly referred to as dementia). This condition has particular importance, because of its impact on self-care and quality of life [10, 11].

Within this reality this pilot theme envisions to build on digital tools to support individuals in this target group in managing their health, keeping independence, and improve their wellbeing.

The targeted groups in this pilot are composed of:

1. Older adults with mild cognitive impairment
   a. Aged 65 or older
   b. Able to provide informed consent;
   c. Living in the community (not in institutional care);
   d. Living independently in rural or urban environments;
   e. Digitally literate or benefit from support from others (e.g. to overcome minimal usage difficulties with the implemented technological tools).
   f. (Under the use case UC-PT5-005, an additional inclusion criteria is the diagnosis of type 2 diabetes, as the use case focus on the co-existence of the high prevalent disease with the condition of mild cognitive impairment.)

2. Informal caregivers of people with dementia
   a. Adult (18 years or older);
   b. Digitally literate;
c. Non-paid for the provision of care (support with basis or instrumental activities of daily living);
d. Supporting a person with formal diagnosis of dementia (regardless of the cause/type);
e. Supporting a person living in the community (not in institutional care);
f. Providing care for at least 6 months;
g. Experiencing caregiver burden (measured with Zarid Burden, cut-off ≥ 21);
h. And/or experiencing anxiety and/or depression symptoms (measured with HADS; cut-off ≥ 8).

2.3.5.1 Objectives of pilot theme 5

Pilot theme 5 aims to improve the delivery of care, the management of health conditions and of activities of daily living, and the communication and social well-being of individuals with mild cognitive impairment; as well as to minimize the negative effects of caregiving on the psychological health of informal dementia caregivers.

Specific aims under this pilot theme are listed below and are address by the three planned use cases and the technological solutions they resort to:

- Diminish the experience of burden as well as anxiety and depression symptoms of informal dementia caregivers (as self-reported) [UC-PT5-001]
- Improve quality of life, positive aspects of caregiving and general self-efficacy (as self-reported) of informal dementia caregivers [UC-PT5-001]
- Improve communication and social well-being of older adults with mild cognitive impairment [UC-PT5-002]
- Support an independent/ more independent performance of basic and instrumental activities of daily living by older adults living with mild cognitive impairment [UC-PT5-002]
- Improve disease and therapeutic plans (e.g. medication, food intake, physical activity) management in older adults with mild cognitive impairment and type 2 diabetes [UC-PT5-003]
- Improve well-being of older adults with mild cognitive impairment and type 2 diabetes [UC-PT5-003]

Research objectives of this pilot theme are:

- Evaluate the usability – efficiency, effectiveness, user satisfaction – of technological solutions embedded in the pilot theme and tested for the described use cases;
- Assess the user acceptability of technological solutions embedded in the pilot theme and tested for the described use cases;
• Explore the efficacy of technological solutions embedded in the pilot theme and tested for the described use cases in improving the defined outcomes (e.g. clinical, well-being).

2.3.5.2 Overarching evaluation criteria – how is success defined?

Success for usability evaluation is defined as favourable results on indicators of the technological solution performance and of the user satisfaction with such solution. A multi-method approach will be used, resorting to well-established qualitative and quantitative data collection techniques applied in usability study (e.g. think aloud protocol to collect verbal reactions, task analysis, task success, time on task, no. of errors, etc.), usability assessment scales (e.g. SUS) and qualitative reports, e.g. from semi-structured interviews, on satisfaction with the use of a technological solution.

Success for acceptability is defined as favourable results on indicators of use/non-use, dropout/retention rates, frequency of use and on qualitative reports (e.g. semi-structured interviews, focus groups) on how acceptable is the technological solution. In some cases, it might be possible to discern how acceptable each component of a solution is (e.g. for the iSupport platform one might be able to collect which parts of the programme are most used by caregivers).

Success concerning the efficacy of technological solutions will be defined by favourable (statistically significant at .05) changes in the defined outcome measures after using the intervention during a defined amount of time, from the baseline, and as compared to a control group (not using the technological solution and in a waiting list or receiving standard care). Some of the foreseen outcome measures are listed as follows, although requiring further adjustments to use cases. Qualitative methods and data collection techniques might be also employed to answer evaluation questions of a processual nature. While the counterfactual analysis from an outcome assessment should demonstrate if and to what extent the intervention works, a factual analysis based on qualitative data allows to address the how and why the intervention works/does not work. Exploring the quality of implementation, barriers to participation, and unmeasured perceived benefits, might be particularly useful in this pilot theme. This is particularly relevant if we consider the impossibility of measuring all outcomes of interest due to practical implementation issues, as well as the low sensitiveness of some outcome measures to change.

Foreseen outcome measures: Zarit Burden Interview (ZBI); Hospital Anxiety and Depression Scale (HADS); WHOQOL-BREF; Positive Aspects of Caregiving (PAC); Generalized Self-efficacy Scale;

In the case of UC-PT5-005, our experimental protocol will be a pilot study based on the methodologies of a randomized clinical trial and in strategies defined by WHO for monitoring and evaluating digital health interventions. Eligible participants will be…
randomly assigned and distributed by three study arms: G1 (diabetics with MCI), G2 (diabetics without cognitive impairment) and G3 (diabetics with MCI). Participants assigned to the intervention arm (G1 and G2) will receive access to the intervention eHealth tools and those assigned to control arm (G3) will receive standard care, without recourse to these tools. For planning the sample size, we will combine our outcomes and the results of the review of Task 1 and obtain these estimates from published full-scale studies of similar interventions in similar participants. Participants in the intervention arm will be provided with Bluetooth-enabled devices, as activity meter (smart bracelet) and smart pill box. Through wireless, will have available a blood glucose plus blood pressure monitoring system and a body composition scale. Through the Gnomon Informatics S.A. platform, we will have components related to the interaction between care/healthcare professionals and the patient, as well as sharing educational material. All components will be integrated in a wireless network to a cloud server, so that they work seamlessly and without interruption. Moreover, they will have access to scientifically approved education material, shared care plans (healthcare providers) and virtual patient scenarios to assist disease management. For the purpose of create reliable and realistic representations of the key audience segments for reference, we will develop personas/use cases. In terms of technology assessment, we will evaluate our analysis using quantitative tools based on clinical outcomes. We are developing 2 main lines of analysis: the effectiveness of the intervention in both intervention arms (G1 – G2); and compare the intervention with the standard of care (G2 – G3). The primary outcomes will be biologic indicators, such as HbA1c, urine protein test (including microalbumin), blood glucose, blood oxygen saturations levels, wrist-based heart rate, blood pressure and weight. Secondary outcomes will include activity (steps), sleep pattern, stress level, cognitive dysfunction (QMCI Screen), medication adherence (MAT scale), medical/nursing appointments, hospitalizations rates and mortality (all causes) quality of life (ADDQoL).

2.3.5.3 Which Use case will be tested in pilot theme 5?

To address the specific objectives of this pilot theme, there is a plan to test three use cases:

1. UC-PT5-001 – Online information and training for informal dementia caregivers (iSupport);
2. UC-PT5-002 – Digital Assistant for older people with mild cognitive impairment;
3. UC-PT5-003 – Technological resources for monitoring diabetic patients with mild cognitive impairment.

2.3.6 Pilot Theme 6 - Physical Rehabilitation at Home

Pilot Theme 6 “Physical Rehabilitation at Home” intends to provide the appropriate tools to safely conduct physical activity and physical rehabilitation routines. This Pilot
Theme will therefore address older individuals that need to recover from a certain accident or health issue (e.g.: stroke, fall, surgery, rheumatoid arthritis, osteoarthritis, orofacial disorder etc.) but also those who, without having to recover from a specific problem, benefit from physical activity, preventing or improving frailty conditions.

The realization of physical exercises, when not properly supervised by a therapist, could lead to injuries due to wrongly adopted postures or bad movements. Furthermore, supervision is also important for its intrinsic motivational aspect. However, access to a personal trainer or physical therapist is limited due to several reasons. On the one hand, the cost it entails is not always affordable. On the other hand, these sort of activities are carried out in specific facilities which are not always at hand to those who have limited movement or depend on others for transport, not to mention those that live in isolated areas who have no access at all to this type of facilities and professionals.

There is therefore a compelling a need for autonomously conducting physical activity and/or physical rehabilitation routines, while keeping a certain degree of supervision. This Pilot Theme will evaluate the convenience of a video-based system capable of catering for this need of supervision and motivation, while providing the advantages of having a personal contact with an expert who will be evaluating the evolution, based on the data gathered by the system and the analytics this will provide, along with a video-call system that will provide a one-click access to the expert supervising the conducted physical activity and rehabilitation process.

An RGB and Depth camera will be employed in combination with a screen displayer, like a smart TV. Older adults will face the screen or TV and they will be guided through the different exercises the physical therapist has prescribed them, receiving feedback regarding the performance and corrective instructions all over the routine performance. This pilot will also combine the adoption of other digital solutions such as wearable devices to monitor movement and robot assisted solutions for mobility.

The target group will be older adults that either have suffered a health issue or accident or just need to remain physically active to prevent frailty. Different contexts will be considered under this Pilot Theme. The context of a nursing home (like that provided by SAL) will be used to validate the benefits of overcoming the problems due to limited resources (in terms of access to a physical therapist) whereas the home context provided by AUTH and CH will enable us to evaluate the feasibility of exercising from home.

2.3.6.1 Objectives of pilot theme 6

The overall objective of Pilot Theme 6 is to improve the physical state and well-being of older adults that have either suffer from an accident or health issue, or just need to
keep active preventing frailty. This objective will be accomplished through the following specific objectives:

- Provide a list of exercises, wide enough, to treat the most common situations faced by older adults. This applies, but it is not limited to, the following conditions: strokes, falls, lower body joints surgery (hip or knee), rheumatoid arthritis, osteoarthritis, orofacial disorders and back pain.
- Provide real-time corrections during the exercise performance, preventing wrong postures and executions.
- Gather statistics about the routine performance. This information will be provided to both older adults and also to therapist supervising the process.
- Provide direct communication with the therapist in charge of supervising the process through a one-click video call system.

2.3.6.2 Overarching evaluation criteria – how is success defined?

The following KPI have been identified to evaluate the success of the proposed digital solutions:

- Minutes of physical activity. Each individual will be prescribed with a target value, depending on their condition and the goal towards which physical activity is intended to.
- Number of corrections. The number of corrections will decrease along time meaning the individual is gaining knowledge about how to properly perform the exercise.
- Number of exercises. There will be at least three exercises provided for each of the aforementioned conditions.
- User satisfaction. Appropriate tests will be designed to evaluate user satisfaction targeting a positive evaluation in 85% of the participants.
- Usability. Appropriate tests will be designed to evaluate the usability of the system targeting a positive evaluation in 85% of the participants.
- Condition improvement or maintenance. Therapist will evaluate the evolution of the individuals using the rehabilitation systems targeting a positive evaluation in 85% of all cases.

2.3.6.3 Which Use case will be tested in pilot theme 6?

The following use cases will be tested in Pilot Theme 6:

- UC-PT6-001 Training of orofacial musculature: This use case will involve individuals whose orofacial musculature needs to be improve or maintained.
• UC-PT6-002 Gait rehabilitation: This use case will specifically address those individuals going through a rehabilitation process involving gait, mainly due to accidents like falls, surgery or strokes.

• UC-PT6-003 Depth camera rehabilitation tool: This use case will be intended to provide a support system for rehabilitation and physical activity exercises.

• UC-PT6-004 Wearable Motion Monitoring Devices: This use case will be intended to provide additional information that can be used to assess the evolution of the rehabilitation process or just to assess the physical condition of the individual wearing the proposed devices.

2.3.7 Pilot Theme 7 - Cross-border Health Data Exchange
- Supporting Mobility and Accessibility for Older Individuals

Pilot Theme 7 addresses multiple aspects associated with the mobility and accessibility of older individuals - namely the availability of health and care data (exchange) across Europe – including those living with permanent or temporary reduced functions or capabilities, to access health and care services anywhere while traveling. Accessibility of older individuals, and of those experiencing physical disability, visual impairment (blindness) and hearing impairment (hard-of-hearing, deafness, deafblindness), is also addressed in the different piloting activities from the perspective of the accessibility level of buildings and outdoor environments, which tend to affect the older individuals’ mobility, and thus their decision-making process with respect to traveling.

The planning of PT7 focuses on delivering and demonstrating SHAPES’ two main capabilities:

A) To ensure continuous availability of health care data for both patients and their caregivers – safely and securely – wherever they may be

Older people suffering from chronic diseases (Heart Failure, Type II Diabetes, Chronic Obstructive Pulmonary Disease) need to be constantly monitored. This need becomes stronger when travelling to another country, adding up to the patients’, their relatives’ and their caregivers’ anxiety. Therefore, they must be empowered to efficiently manage their condition outside their “comfort zone”. Additionally, certain conditions carry the risk of resulting in critical events, often with life-threatening implications. Monitoring and analysing patient’s health and lifestyle data can act as a predictor of such events, thus triggering specific precaution measures to avoid those events from happening (or to give the patient enough time to reach an emergency room).

• measure vital signs
• GPS location tracking
- track activity levels
- evaluate behavioural and lifestyle patterns
- sustain medication adherence

In case of an emergency situation, it is of critical significance that access to the patients’ medical data (medication and patient summary) is available, as well as communication between the patient (and the patient’s accompanying relatives), the patient’s physician (back home) and the emergency physician (visiting destination), in order to perform the best informed medical practice.

Ensuring the above will increase the patient’s feeling of safety, preserving the feeling that the patient “never left home”.

B) To provide information and navigation for safe and accessible travelling sites and destinations

Older people with physical disabilities (including deafness, blindness and deafblindness) usually feel discouraged from selecting the recreational experience of travelling to other locations (abroad or domestic). Both the need for medical assistance (especially when a chronic disease is involved) and the little-to-no knowledge of the destinations’ accessibility and safety conditions act as a turn-off for any decision-making process for traveling and tourism activities. Assessing and identifying the safety / accessibility levels of potential destinations, as well as being able to navigate their way when they visit those destinations, can enhance their travelling decision-making capability and overall contribute to their active and independent living.

2.3.7.1 Objectives of pilot theme 7

The objectives of Pilot Theme 7 are:

- Improve the health outcomes, the perceived well-being and quality of life of the older individual
- Alert the formal (and informal) caregivers on suspicious patient signals or patterns when travelling
- Reduce the workload of medical professionals – increase their effectiveness
- Introduce new digital tools successfully in a non-tech-savvy, ageing population
- Illustrate the capability of the SHAPES Digital Ecosystem to support older individuals with the management and control of chronic conditions when travelling
- Assess attitudes towards the SHAPES Digital Ecosystem
- Assess the user acceptance, accessibility and user experience of the SHAPES Digital Ecosystem

This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 857159
• Measure security and trust rate by users
• Illustrate the capability of the SHAPES Digital Ecosystem to provide real-time information to the healthcare professionals about the older individuals’ physiological condition
• Illustrate the capability of the SHAPES Digital Ecosystem to access patient’s medical history (patient and medication summary)

2.3.7.2 Overarching evaluation criteria – how is success defined?

To meet the objectives above, the outcomes of following activities will be used:

• Measurement of health-related quality of life periodically throughout the pilot
• Monitoring and assessing the health status and wellbeing using physiological metrics
• Interviews with participants, informal carers and healthcare professionals
• User experience evaluation will be completed using tools e.g. Momentum, MAST, MAFEIP, questionnaires and focus groups.
• Application of Cross-border data exchange (Medical record and vital signal) using SHAPES platform

2.3.7.3 Which Use case will be tested in pilot theme 7?

The following use cases will be tested in pilot theme 7. More details of these use cases can be found in the corresponding sections that follow (Chapter 3 – Sections 3.24, 3.25, 3.26).

**UC-PT7-001:** Monitor older patient with chronic disease when travelling abroad

The rationale behind this use case is to demonstrate the capability of SHAPES Digital Ecosystem to support availability and access to physiological and medical data, for the patient and for the patient’s formal and informal caregivers, when the former travels abroad. Patient and health professional should be able, through SHAPES Ecosystem, to manage the disease and communicate face to face – as effectively as in a session conducted in the doctor’s office or patient’s home.

**UC-PT7-002:** Foster older people’s (with physical disabilities) independent living by identifying accessible locations and routes in other locations (domestic and abroad)

This use case shall be used to demonstrate that SHAPES Digital Ecosystem can identify travelling destinations and sites that are friendly and accessible to people with disabilities. SHAPES will access the safety and accessibility levels of potential destinations, suggest routes and sites, provide navigation and assistance, thus enhancing the individual’s confidence to make an informed decision in selecting a tourist destination and/or activity.
UC-PT7-003: Preventing and/or handling a medical emergency while visiting another country

The third use case in pilot theme 7 extends the capability of UC-PT7-001, by elevating on the features of data (availability / access / processing) and communication. Two major aspects of a medical emergency shall be put to test for the SHAPES Ecosystem: Prevention and handling.

The former relies heavily on data analysis and assessment. The SHAPES Ecosystem shall analyse and assess the patient’s health and lifestyle data so that it may detect anomalies and/or harmful patterns, thus predicting possible critical or life-threatening events. Consequently, it will generate the appropriate alerts (to the patient and accompanying family member), e.g. to take rest, medication, return to hotel, etc. or alert the patient’s doctor back home to initiate a videoconference for further advice. In addition, SHAPES can find and plot a route to the nearest health care facility (alerting the facility, as well) for the patient to seek immediate treatment.

The latter is based on sharing and exchanging the patient’s medical history between different systems. In case of a medical emergency, the SHAPES Ecosystem will be able to provide a medication and patient’s summary, along with the capability to establish a direct communication channel between the emergency physician, the patient’s physician and the patient, for further consultation and guidance, in order to perform the best informed medical practice.
3 Use cases to be tested within the SHAPES pilot campaign

This chapter contains the use cases of the specific pilot themes to be tested at the different pilot sites of the SHAPES project.

Of course these use cases of the pilot themes (UC-PTs) are just a first draft and will be finalized, corrected and amended during the course of task 6.2 to 6.8 together with the technical partner in WP4 and WP5. The first two tasks (6.2 and 6.3) will start in May 2020.

Not only the technical details (e.g. involvement of different digital solutions, necessary adaptions, interoperability) will have to be clarified in the upcoming month, also the participation of the different pilot sites will have to be verified, as necessary local administrative processes have to been undergone and the specific health situation (regarding COVID-19) has to be taken into consideration.

Additionally SHAPES aims to help addressing COVID-19 and further future pandemics by adapting the use cases so that they also help to reach this actual objective apart from the original SHAPES aims.

In Annex IV these changes to the pilot themes and use cases are summarized. For each pilot theme the

- Name and original objective of the pilot theme and use cases;
- the combination of digital solutions;
- the opportunities to do something with these or slightly modified versions or with some added technological solution to fight COVID-19;
- the objectives (regarding the pandemic), which can be reached with these (adapted) technologies;
- which additional evaluation steps have to be taken;

are listed.

3.1 UC-PT1-001 Wellbeing Monitoring and Assessment

<table>
<thead>
<tr>
<th>Code</th>
<th>UC-PT1-001</th>
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<tbody>
<tr>
<td>Title</td>
<td>Remote In-Home Wellbeing Monitoring and Assessment</td>
</tr>
<tr>
<td>Pilot Theme &amp; Task</td>
<td>PT 1 – Smart Living Environment for Active Ageing at Home (T6.2)</td>
</tr>
</tbody>
</table>
### Piloting Sites
|       | AIAS, CCS, CH, SAL |

### Description
In this use case we are addressing older people living independently in rural or urban environments. They usually live alone or with their spouse and are visited or supervised by a family member or caregiver on a regular basis.

In order to foster the early identification of risky situations at home and to detect signs of early physical or cognitive decline, tools that unobtrusively monitor the users are needed. These tools must monitor user’s lifestyle and the accomplishment of Daily Living Activities (DLA). Based on this data, normality patterns will be inferred. Once anomalies or risky situations are detected, an alarm will be triggered to the corresponding caregiver so that appropriate intervention is carried out.

### Digital Solution proposed
|       | Wellbeing Monitoring and Assessment solution |

### Technical partners involved
|       | OMN, EDGE, ICOM, FINT, VICOM, TREE, UNRF |

### Components
1) **Omnitron’s Notify system** – system that enables the monitoring of home appliances and electrical devices (such as TV, oven, microwave, home presence detectors …) that do not have built-in interoperability capabilities. Notify is simple to use, low cost and send messages to SHAPES TP once the device is turned on or off by the user.

2) **Home Platforms** – Home platforms / IoT platforms are needed to distribute sensors or IoT devices to capture information of the daily activities of the users at home, such as eCare from EDGE.

3) **Gateway** – the SHAPES Gateway collects the information at home and delivers to the SHAPES Cloud.

4) **Wellbeing analysis dashboard** – DLA patterns will be inferred; anomalies will be detected, and the corresponding alerts will be triggered.

Privacy will be preserved. Data flow will be maintained inside Shapes Technological Platform. No data sharing will be carried out in any form with third parties.

### Piloting summary
|       | CCS will test the system on 10 people in urban environments for 8 weeks (to be validated). |

SAL will test the system on 10 people in rural or urban environments for 8 weeks.

CH will test the system on 15-20 people (70-80 years old) in urban environments for 8 weeks. Rural environment could be included, but internet connection should be checked. These users live in their
Subject profile
Main persona of the use case: In this case of use, we address the elderly (65 years or older) who live independently or with sporadic supervision in rural or urban environments. Normally, they live alone or with their spouse.

Additional comments & bibliography
Previous pdf on Safe Digital Assistant.
Technical open issues:
- WiFi internet connection is needed at home.
- Integration with pre-existing home platforms has to be checked to ensure interoperability with SHAPES TP.

3.2 UC-PT1-002 Social Connection

<table>
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<th>Code</th>
<th>UC-PT1-002</th>
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<tbody>
<tr>
<td>Title</td>
<td>Digital Assistant to Support Older People to Live Independently and Remain Socially Connected</td>
</tr>
<tr>
<td>Pilot Theme &amp; Task</td>
<td>PT 1 –Smart Living Environment for Active Ageing at Home (T6.2)</td>
</tr>
<tr>
<td>Piloting Sites</td>
<td>CCS, CH, FNOL, SAL, AIAS, UCC</td>
</tr>
<tr>
<td>Description</td>
<td>In this use case we are addressing older people living independently in rural or urban environments. They usually live alone or with their wife/husband and are visited or supervised by a family member or caregiver on a regular basis. In order to remain independent, often they need assistance to remember appointments, or to make/solve certain basic situation such as cooking, take the medication, use home devices, etc. Another important issue is that they are at risk of isolation, and communication and social engagement must be reinforced/sustained. Hence, we are looking for an easy-to-use and intuitive communication solution that:</td>
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1. Provides timely reminders to a variety of situations (appointments, agenda, activity suggestions …)
2. Provides instruction on how-to-do situations (turn on new home device, …)
3. Foster communication with community (neighbours, friends, …). 
4. Engage in local cultural activities (optional)
5. Support for performing telephone calls (optional)
<table>
<thead>
<tr>
<th><strong>Digital Solution proposed</strong></th>
<th><strong>Digital Assistant for Older People with Mild Cognitive Impairment</strong></th>
</tr>
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<tbody>
<tr>
<td><strong>Technical partners &amp; tasks involved</strong></td>
<td>VICOM, TREE, CH, PAL</td>
</tr>
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</table>
| **Components** | 1) **Safe Digital Assistant** – we are thinking on a smart and safe digital assistant using Automatic Speech Recognition (ASR) and Natural Language Processing (NLP) technologies to provide timely reminders, instructions and communication suggestions. We will use an open source smart speaker (Mycroft) to be installed at the living room. The caregiver or a closer relative will be in charge of arranging the agenda for the older user with MCI and the digital assistant will be triggered correspondingly. In this use case, the interaction will always start from the Digital Assistant side, and it may involve a speech-based dialog with the user to retrieve him/her acknowledgement or to guide him/her through the actions to take. The assistant can include **ROSA Virtual Nurse (CH)** – Chatbot that can integrate nurse- and health-related protocols regarding, for example, medication and general evaluation of health conditions.  
2) **Caregiver administration panel** – As the caregivers need to plan a schedule for the user (cultural agenda, appointments with the doctor and so on), fill the user profile, and perhaps modify some behavioural aspects of the assistant, a proper interface should be defined.  
3) **Cultural and social agenda provider (optional)** – To foster communication and social well-being of the users, an API communication with a Knowledge Base which serves localised cultural and social activities would be a plus. Using the **Caregiver administration panel**, a set of pre-defined options can be selected regarding to activities that the user likes, so the assistant does the activity offering according to these. In addition, if some friends of the user -which also should be logged and registered in the SHAPES platform- are matched with the same cultural/social activity, the assistant should inform about it.  
4) **They might be two versions of this use case** – one with robots and another one without robots |

Privacy will be preserved. Data flow will be maintained inside Shapes Technological Platform. No data sharing will be carried out in any form.
with third parties such as Google or Amazon. Apart from the open-source smart speaker from Mycroft, only technology from Vicomtech and other SHAPES partners will be used in order to meet the privacy requirements of the users. ASR & NLP These components will be integrated in such a way that they work in an integrated and seamless way. The resulting digital tool will be integrated in the SHAPES Platform (gateway, cloud …). It also includes a control application to facilitate its use for the caregiver.

Piloting summary

SAL proposes to test the system on 10 people in rural or urban environments for 8 weeks.

CH will test the system on 15-20 people (70-80 years old) in urban environments for 8 weeks. Rural environment could be included, but internet connection should be checked. These users live in their houses or in sheltered housing. 10%-15% live with their spouse. The number of subjects may be split into UC-PT1-001 and UC-PT1-002 in case both use cases are undertaken.

AIAS will test the system with 5-10 people depending on the interoperability with PT1-001

Subject profile

Main persona of the use case: In this case of use, we address the elderly (65 years or older) who live independently or with sporadic supervision in rural or urban environments. Normally, they live alone or with their wife/husband.

Additional comments & bibliography

Previous pdf on Safe Digital Assistant.

Technical open issues:

- Accents. We agreed on selecting the candidates depending on their accent. No or soft accent candidates will be selected for the use case. This will reduce the Speech to Text module error, as the speech corpora used to train them has little-to-none accentuation. In addition, people with speech disabilities won’t be suitable for this use case.

- Internet connection. We need to specify, which are the minimum internet connection requirements for the use case for rural areas. A 10MB/s connection would be enough if it is stable enough (wired connections will be needed. 4G or satellite internet should be avoided for this use case).

3.3 UC-PT1-003 Competent usage of digital technologies

<table>
<thead>
<tr>
<th>Code</th>
<th>UC-PT1-003</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title</td>
<td>Overcoming the fear of digital technologies – competent usage of technologies – problem solving in the community</td>
</tr>
</tbody>
</table>
### Pilot Theme & Task

<table>
<thead>
<tr>
<th>Pilot Theme &amp; Task</th>
<th>PT 1 – Smart Living Environment for Active Ageing at Home (T6.2)</th>
</tr>
</thead>
</table>

### Piloting Sites

<table>
<thead>
<tr>
<th>Piloting Sites</th>
<th>CCS, OMN</th>
</tr>
</thead>
</table>

### Description

This use case contains three steps:

1. Overcoming the fear of digital technologies
2. Competent usage of technologies (e.g. receiving information)
3. Problem solving in the community

### Digital Solution proposed

Videocommunication

### Technical partners & tasks involved

OMN

### Components

- DigiRoom
- eCTouch

### Piloting summary

### Subject profile

Older people living at home.

### Additional comments & bibliography

#### 3.4 UC-PT2-001 Monitoring of health parameters

<table>
<thead>
<tr>
<th>Code</th>
<th>UC-PT2-001</th>
</tr>
</thead>
</table>

**Title**

Delivering remote monitoring of key health parameters

**Pilot Theme & Task**

PT 2 – Improving In-Home and Community-based Care T6.3

**Piloting Sites**

Gewi, AIAS, CCS, 5thYPE, FNOL, CH?, UAVR, UP?, SAL

**Description**

Health in old age is of great importance for each and every individual, but also for society. Although health problems and complaints increase with age, old age does not inevitably stand for illness, limitations and the need of care. Individual lifestyles and personal resources, social integration and the level of access to medical and social care greatly impact on the health status, quality of life and well-being of older individuals.

The aim of this use case is the remote monitoring of important health parameters of older individuals with the aim of maintaining or possibly even improving their health status thanks to preventive...
health and care measures. Wearables, sensors and other devices can enable individuals to remain independent for longer through the provision of specific tips and recommendations. Also, it should be possible to thereby showcase the so-called “feel-good effect” i.e. the power of knowing everything is – relatively speaking – in order. It is expected that recording a stable (good) health status will make older individuals feel safer and thus more secure in pursuing daily activities such as moving around the house or outdoors, engaging with family, friends and the community or committing to further hobbies.

Additionally to quantifiable health data, recording the perceived state of well-being should be included (“How do you feel today”) in order to enable reliable monitoring over time. 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…).

In case the system monitors unusual data, the informal caregiver/a predefined person of trust is informed/alerted.

In this sense, following tools are needed in order to:
1. Capture unobtrusively the relevant health parameters of the older individuals at home (i.e., blood pressure, saturation, weight variations, etc)
2. Report the health and well-being status in an tangible/understandable way
3. Give tips and prompts based on health and well-being needs

<table>
<thead>
<tr>
<th>Digital Solution proposed</th>
<th>monitoring of key health parameters and well-being</th>
</tr>
</thead>
</table>
| Technical partners & tasks involved | • EDGE (eCare)  
• CH (chatbot ROSA)  
• VICOM Safe digital assistant? (in case it is available in German for the pilot region Oberbergischer Kreis?)  
• TREE (DAPHNE Wellbeing app)  
• TREE, UNRF, VICOM (Data analytics & predictive algorithms) |

Need at least one more partner providing the necessary sensors for movements and/or falls in case the older individual is e.g. unable to move or/and speak.

| Components | 1. **eCare:** A smart ambient intelligence, health and wellness platform delivering remote monitoring of key health parameters of older individuals, including those with health problems requiring periodic or permanent monitoring. The platform registers vital signs, temperature, weight, heart rate, blood glucose level, blood pressure, weight (also fat mass & muscle |
Deliverable D6.1 SHAPES Pan-European Pilot Campaign Plan Version 1.0

mass) and respiration rate. Smart analytics (together with TREE and VICOM) enable the detection of anomalies and the generation of alerts that feed into the remote monitoring platforms of hospitals, clinics, nursing homes and care units.

2. **ROSA**: The chatbot is a digital nurse that monitors users at home, communicating in natural language and chat (“how do you feel”). Aside from assisting its users in the daily management of their care, ROSA is aware of the users’ medical conditions, medication and hospital history and can therefore provide an interactive dialogue, reminding the users of specific symptoms that they should be aware of. In case an alarm is raised due to unusual parameter readings, ROSA assesses the situation and gives it a level of priority and informs for instance the informal caregiver or a selected person such as a neighbour.

3. **Safe Digital Assistant**: friendly interaction mechanisms based on Automatic Speech Recognition & Natural Language Processing. Support the older people to remain independent and carry out with their daily activities at home.

4. **DAPHNE Wellbeing app**: uses information about anthropometrics, health markers, mental well-being, physical activity and nutritional data of the user and, using data processing and AI, creates personalised nutritional, activity and behavioural models, giving risks and recommendations for users and carers.

<table>
<thead>
<tr>
<th>Piloting summary</th>
<th>gewi envisions to test the above named combination of technologies for a total period of 2 months with 8 older persons (tbc) from the reference site. AIAS might consider testing these solutions with a max of 10 users.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject profile</td>
<td>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.</td>
</tr>
<tr>
<td>Additional comments &amp; bibliography</td>
<td>The access to WiFi or any other internet connection (3 or 4G) is needed at home. A tablet computer or smartphone is needed to give recommendations and show results of the health status assessment/ask about the perceived well-being.</td>
</tr>
</tbody>
</table>
3.5 UC-PT2-002 Community interaction

<table>
<thead>
<tr>
<th>Code</th>
<th>UC-PT2-002</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title</td>
<td>Supporting the interaction of the individual with the community</td>
</tr>
<tr>
<td>Pilot Theme &amp; Task</td>
<td>PT 2 – Improving In-Home and Community-based Care T6.3</td>
</tr>
<tr>
<td>Piloting Sites</td>
<td>Gewi, AIAS, CCS, UAVR</td>
</tr>
<tr>
<td>Description</td>
<td>The causes leading to loneliness can be very different and they change with age. Unfortunately, however, all people who suffer from loneliness for longer periods of time have one thing in common: their health, both physical and mental, suffers. Chronically lonely people have a high risk of developing depression, are more susceptible to cardiovascular disease and possibly have an increased risk of cancer – combating loneliness is therefore not only important for social cohesion, it is also an active health precaution. (BAGSO Bundesarbeitsgemeinschaft der Seniorennorganisationen e.V., 2019)</td>
</tr>
</tbody>
</table>

This use case aims therefore to support the interaction of the older individual with the community. If older individuals are already somewhat distanced from their community and they don’t take part in day to day activities within the community, they also don’t necessarily hear about new developments or opportunities for engagement, sports, educational or cultural events.

It needs to be ensured that they have easy access to suitable opportunities and developments in the community, such as specialized transport services, and are actively informed about e.g. weather conditions that allow for exercise outdoors but also activities such as readings, bingo, exhibitions and other opportunities to engage in activities taking place in local communities.

Based on an initial survey, only activities that align with the hobbies and interests of the older individual are suggested. The (machine) learning system notices which kinds of information and events are clicked on / not read or listened to entirely. Also relevant news items should be included in the platform - a balanced mix of articles must be provided that does not focus too much on negative developments.

The older individual should be reminded about activities that are taking place and informed on how to get there and what to bring.

If interested in participating in an event requiring the purchase of a ticket, an official registration or any other type of formal or financial transaction, the user should have the possibility to express his/her interest and this will be forwarded to the informal caregiver or a predefined person in charge of the older individual’s financial /
This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 857159

<table>
<thead>
<tr>
<th><strong>Deliverable D6.1 SHAPES Pan-European Pilot Campaign Plan Version 1.0</strong></th>
</tr>
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</table>

**Digital Solution proposed**

A digital platform that provides information about the community events and respective information and learns from the behaviour of the user.

The digital solution should run both on a tablet computer and a smartphone and inform the older individual via text and verbal messages, also when not actively used. (Pausing the app for a certain time /only allowing notifications during specific hours needs to be possible)

**Technical partners & tasks involved**

- FINT (FINoT platform & programmable cloud platform)
- OMN (DigiRoom)
- SciFy (NewSum)

It needs to be clarified how the information about community events and activities is fed into the system: can selected websites be scanned regularly to provide up to date news?

**Components**

1) **FINoT Platform**: A smart IoT-based living platform that leverages on the smart neighbourhood, smart community and smart city paradigms to deliver relevant information on weather, air quality, pollution, local public works, local transportation and local activities.

2) **DigiRoom**: a web-based, no-install communication tool for e.g. the communication with their informal caregivers or family members/friends who are not close/able to meet physically

**Piloting summary**

gewi suggests to test this combination of services with 5 older people living at home for three months.

If integrated with PT2-001 technology, AIAS might consider testing with max. 10 users.

**Subject profile**

Older individuals living at home by themselves at risk of isolation/loneliness, somewhat impaired by chronic conditions reducing their opportunities to meet others outside their home but willing to stay actively engaged in the community, with their peers and relatives.

**Additional comments & bibliography**

The access to WiFi or any other internet connection (3 or 4G) is needed at home.

A smartphone would be useful to make sure the older individual also has the necessary information with him/her when outside the home.

3.6 UC-PT2-003 Cognitive and physical training

<table>
<thead>
<tr>
<th>Code</th>
<th>UC-PT2-003</th>
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</thead>
<tbody>
<tr>
<td><strong>Title</strong></td>
<td>LLM CARE Healthcare System for Cognitive and Physical training</td>
</tr>
<tr>
<td><strong>Pilot Theme &amp; Task</strong></td>
<td>PT 2 – Improving In-Home and Community-based Care T6.3</td>
</tr>
<tr>
<td><strong>Piloting Sites</strong></td>
<td>AUTH, gewi</td>
</tr>
<tr>
<td><strong>Description</strong></td>
<td>Cognitive skills are considered key elements in the daily functioning of older adults. Although, for some of these cognitive skills (e.g. memory, problem-solving activities or speed processing), decline is inevitable in the process of ageing [1-4]. This kind of decline undermines older adults' ability to maintain an independent lifestyle [5, 6]. However, technology assisted solutions may facilitate older adults continued independent living [7]. In this vein, Lab of Medical Physics developed a service which is addressed to elderly users and integrates both physical and cognitive training through web service technologies [8, 9] aiming at improving their health condition, and thus their quality of life.</td>
</tr>
</tbody>
</table>

**The Integrated Healthcare System Long Lasting Memories Care (LLM Care)** is a successful example of commercializing the "Long Lasting Memories" research program ([http://www.longlastingmemories.eu/](http://www.longlastingmemories.eu/)), which was built on the broad foundations of long-term research (pan-European and initially funded by the European Commission under the coordination of Greece). LLM Care is an innovative social care service provided by the Laboratory of Medical Physics of the Department of Medicine of the Aristotle University of Thessaloniki.

Specifically, LLM Care is a certified ICT platform that combines state-of-the-art mental exercise with physical activity in an advanced ambient assisted living environment and offers an integrated solution for cognitive and physical health, providing effective protection against cognitive decline and, thereby, actively improving the quality of life.
This service is a **non-pharmaceutical** intervention against cognitive deterioration, qualitative results in the specific brain functions, affected by ageing, as well as the psychological state of the participants with a series of scientific contributions in *International and European Conferences and Journals*. The combination of physical and mental exercise reduces the risk of diseases and prolongs the time of **independent** and **autonomous** living. It also provides a **comprehensive solution** that has a direct impact on improving the quality of life of individuals, including elderly people or other vulnerable groups, Intellectual disabilities and Down syndrome, women with breast cancer, Parkinson’s disease patients, etc.

<table>
<thead>
<tr>
<th>Digital Solution proposed</th>
<th>LLM Care Healthcare System</th>
</tr>
</thead>
</table>
| Technical partners & tasks involved | • AUTH  
  • SciFy? |

**Components**: **COGNITIVE TRAINING SYSTEM**

**BrainHQ** is an interactive online environment consisting of cognitive training techniques that are particularly effective. It accelerates and sharpens the visual and hearing process – the brain hearing system. Improvement in the quantity and the quality of what the brain receives through image and sound, leads to a total improvement of thought, focus, observation, and memory, as well. The Cognitive Training System includes six categories with more than 29 effective exercises and hundreds of graded difficulty levels that focus on **attention, memory, brain speed, people skills, navigation and**
intelligence. Every exercise is dynamically adapted to the skill level of each trainee in order to produce true cognitive improvements. Concerning the utilization requirements a computer/ laptop/ tablet is needed.

PHYSICAL TRAINING SYSTEM

webFitForAll is an exergaming platform that helps elderly people physically train and maintain their fitness and well-being, through the use of an innovative, low-cost and widely accepted technology platform, like a motion detection device. The Physical Training System includes exercising protocols, especially designed for elderly people and vulnerable groups, from experienced scientists specializing in third age and its traits (e.g., dementia). These exercise protocols enhance aerobic capacity, flexibility, balance and strengthening of muscles. In addition, difficulty adjustment based on the trainee’s performance aims at the optimal function training. Concerning the utilization a computer and motion detection device are required, as well as some basic fitness equipment, such as 1kg or 2kg dumbbells and a mini bike. In addition, a blood pressure monitor is needed to measure pressure and pulses during physical exercise.

Talk and Play app (SciFy)?

Piloting summary

The ideal duration of the training program is 8-10 weeks long and includes physical training 3-5 times a week and cognitive training 4-5 times a week. After this period, it is suggested that participants should rejoin the program [10].

Subject profile

1. Older adults with or without Neurocognitive disorder
2. Older adults with Mild Cognitive Impairment and Mild Dementia
3. Patients with chronic and mental disorders (Schizophrenia)

Additional comments & bibliography

Details on https://www.llmcare.gr/en/home/

References:


7. Zarem J.E. Today’s Continuing Care Retirement Community (CCRC) LeadingAge; Washington, DC, USA: American Seniors Housing Association; Washington, DC, USA: National Investment Center; Annapolis, MD, USA: 2010


### 3.7 UC-PT2-004 Night surveillance Rounds at Community Care

<table>
<thead>
<tr>
<th>Code</th>
<th>UC-PT2-004a</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title</strong></td>
<td>Night Surveillance Rounds at Community Care</td>
</tr>
<tr>
<td><strong>Pilot Theme &amp; Task</strong></td>
<td>PT 2 – Improving In-Home and Community-based Care T6.3</td>
</tr>
<tr>
<td><strong>Piloting Sites</strong></td>
<td>Gewi, 5thYPE</td>
</tr>
<tr>
<td><strong>Description</strong></td>
<td>Nursing homes are often constrained to bring residents to their rooms quite early for evening retreat. The long evening shifts are often carried-out with a great reduction of staff. KOMPAI can help to « patrol » hallways and detect if anything is wrong providing a function of night-time surveillance. The connected cameras can help to facilitate to see if a resident is unexpectedly leaving his room, identify him, thanks to VICOMTECH recognition module – as can be common for disoriented patients – in the middle of the night, and be connected to alarms on corridor and main doors. If KOMPA is inside a resident’s room, he can also help to monitor how the patient is doing, detect a fall, and make it easier for them to alert in case of emergency. KOMPAI can also be connected to various sensors and detect for sudden changes in temperature or the appearance of smoke.</td>
</tr>
<tr>
<td><strong>Digital Solution proposed</strong></td>
<td>“Round” KOMPAÏ Robot</td>
</tr>
</tbody>
</table>
| **Technical partners & tasks involved** | KOM – T5.4 Robotic & Assistive Technologies?  
VICOM – T4.6 Authentication, Security & Privacy Assurance (Face identification & authentication) |
| **Components** | 1) **KOMPAÏ Robot** – Provides rounds (KOM)  
2) **Facial Recognition Module** – Authenticates the any person via facial image identification. (VICOM) |
| **Piloting summary** | To be completed |
| **Subject profile** | NC |
### Additional comments & bibliography


VICOM – Viulib computer vision library: [http://www.viulib.org/](http://www.viulib.org/)

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### 3.8 UC-PT2-004b Night Surveillance Rounds in the Home-Setting

<table>
<thead>
<tr>
<th>Code</th>
<th>UC-PT2-004b</th>
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</thead>
<tbody>
<tr>
<td>Title</td>
<td>Night Surveillance Rounds in the Home-Setting</td>
</tr>
<tr>
<td>Pilot Theme &amp; Task</td>
<td>PT 2 – Improving In-Home and Community-based Care T6.3</td>
</tr>
<tr>
<td>Piloting Sites</td>
<td>Gewi, 5th YPE</td>
</tr>
<tr>
<td>Description</td>
<td>Older individuals living at home by themselves are often cared for by an outpatient nursing service or informal caregivers during the day. During the night, however, they are often on their own. KOMPAI can help detect alarming signals providing a night-time surveillance service. If the robot is inside a the older individual's bedroom, it can also help monitoring how the person is sleeping, detect a fall, and make it easier for the older individual to alert someone in case of emergency. KOMPAI can also be connected to various sensors and detect sudden changes in room temperature or e.g. the appearance of smoke. The connected cameras can facilitate observing whether the older individual is unexpectedly leaving the bedroom or even the apartment/house and could alert a predefined person. KOMPAI can also assist the older individual in his/her necessary movements at night, such as going to the bathroom. Due to the integrated hand bar the older individual can hold on to the robot and safely be guided to the bathroom and back to bed.</td>
</tr>
<tr>
<td>Digital Solution proposed</td>
<td>KOMPAI Robot with hand bar</td>
</tr>
</tbody>
</table>
| Technical partners & tasks involved | • KOM – T5.4 Robotic & Assistive Technologies?  
• VICOM – T4.6 Authentication, Security & Privacy Assurance (Face identification & authentication) |
| Components | 1. **KOMPAI Robot** – Provides robot  
2. **Facial Recognition Module** – Authenticates the any person via facial image identification. (VICOM) |
These components will be integrated so that they work in an integrated and seamless way. The resulting digital tool will be integrated in the SHAPES Platform (gateway, cloud …). It also includes a control dash board to facilitate its use to the professional care teams.

<table>
<thead>
<tr>
<th>Piloting summary</th>
<th>Gewi suggests to implement this use case with 1 or 2 persons for at last 4 weeks per piloting site (depending on the availability of the robot).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject profile</td>
<td>Older individuals living at home by themselves, who are cared for either by an outpatient nursing service or informal caregivers during the day, but alone at night.</td>
</tr>
</tbody>
</table>
VICOM – Viulib computer vision library: [http://www.viulib.org/](http://www.viulib.org/) |

3.9 UC-PT3-general description “multi-morbid patients”

<table>
<thead>
<tr>
<th>Code</th>
<th>PT3</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title</td>
<td>Supporting multi-morbid older patients</td>
</tr>
<tr>
<td>Pilot Theme (Task)</td>
<td>PT3 – Medicine Control and Optimisation (T6.4)</td>
</tr>
<tr>
<td>Piloting Sites</td>
<td>NHSCT, CH, FNOL, Gewi, UNRF</td>
</tr>
<tr>
<td>Description</td>
<td>Older individuals tend to have a number of concurrent medical conditions resulting in the need to take a larger number of prescribed medicines to help control these conditions. There is a need to have a personalised approach to the safe and effective use of these medicines to ensure the best possible outcomes from their medicines. Specifically, the patients have been warned that they should monitor their glucose levels as the ability to adequately monitor the glucose levels ensures that the patients do not take medication they no longer require, preventing associated negative side effects. For respiratory conditions it is important that the patients are using their inhaler devices correctly for optimum effect. For cardiac conditions fluid change can be an indicator of decompensation in heart failure patients. Lifestyle measures including diet and physical activity and also important practices to promote to reduce the use of health service resources in the future.</td>
</tr>
</tbody>
</table>

**General purposes:**
- To validate the capability of the SHAPES Platform and Digital Solutions to support and extend healthy and independent living
Deliverable D6.1 SHAPES Pan-European Pilot Campaign Plan Version 1.0

for older individuals who are facing permanently or temporarily reduced functionality and capabilities;
- To validate the capability of the SHAPES Platform and Digital Solutions to improve the older individuals’ health outcomes and quality of life;
- To validate the capability of the SHAPES Platform and Digital Solutions to gain the older individuals’ trust and acceptance;
- To validate the capability of the SHAPES Platform and Digital Solutions to gain the care professionals’ trust and acceptance;
- To validate the capability of the SHAPES Platform and Digital Solutions to contribute for the reduction of the workload of medical professionals;
- To validate the capability of the SHAPES Platform and Digital Solutions to deliver efficiency gains in health and care delivery across Europe.

Specific purposes:
- To validate the capability of the SHAPES Platform and Digital Solutions to monitor medicine adherence;
- To validate the capability of the SHAPES Platform and Digital Solutions to deliver reminders, alerts and recommendations to older individuals, concerning the management and control of their medication;
- To validate the capability of the SHAPES Platform and Digital Solutions to empower older individuals in the management and control of their medication;
- To validate the capability of the SHAPES Platform and Digital Solutions to empower older individuals with the management and control of their medication;
- To validate the capability of the SHAPES Platform and Digital Solutions to improve medicine adherence rates;
- To validate the capability of the SHAPES Platform and Digital Solutions to contribute to medicine control and optimisation;
- To validate the capability of the SHAPES Platform and Digital Solutions to contribute to medicine control and optimisation;

<table>
<thead>
<tr>
<th>Proposed SHAPES Digital Solutions</th>
<th>Health and Wellbeing App for the registration of vital signs and physical measurements, diet and nutrition data and the intake of medication (based on eCare App from EDGE; Daphne App from TREE; Healthpass App from GNO);</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Health and Wellbeing System for the remote monitoring of patients by doctors (based on eCare Platform from EDGE; Healthpass System from GNO);</td>
</tr>
<tr>
<td></td>
<td>Digital Nurse Assistant for the engagement of patients concerning medication adherence (based on ROSA from CH);</td>
</tr>
<tr>
<td></td>
<td>Chatbot for the engagement of patients concerning medication adherence (based on Chatbot from Vicomtech);</td>
</tr>
<tr>
<td></td>
<td>Telemedicine System for remote consults (based on Telehealth System from CCS; Telemedicine System from FNOL)</td>
</tr>
</tbody>
</table>

This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 857159
- **Videoconference** (eCtouch System from Omnitor)
- **Analysis of medicine optimisation** for the automated decision aids on the medication adjustment required based on the health and wellbeing data collected (based on Big Data Analytics Platform from TREE; eHealth Software Toolkit from Vicomtech).

### Technical Partners

CH; EDGE; FNOL; GNO; OMN, TREE, VICOM

### Components

- **Health and Wellbeing App** for the registration of vital signs and physical measurements, diet and nutrition data and the intake of medication (based on eCare App from EDGE; Daphne App from TREE; Healthpass App from GNO);
- **Health and Wellbeing System** for the remote monitoring of patients by doctors (based on eCare Platform from EDGE; Healthpass System from GNO);
- **Digital Nurse Assistant** for the engagement of patients concerning medication adherence (based on ROSA from CH);
- **Chatbot** for the engagement of patients concerning medication adherence (based on Chatbot from Vicomtech);
- **Telemedicine System** for remote consults (based on Telehealth System from CCS; Telemedicine System from FNOL; eCtouch System from Omnitor).
- **Analysis of medicine optimisation** for the automated decision aids on the medication adjustment required based on the health and wellbeing data collected (based on Big Data Analytics Platform from TREE; eHealth Software Toolkit from Vicomtech).
- **Videoconference system**
- glucometers;
- scales with bio-impedance technology;
- tablets;
- smartphones.

### Piloting summary

n.a.

### Subject profile

80 multi-morbid older individuals (+65) who live alone

### Additional comments & bibliography

- Consider extending the number of older individuals in target group.

**Challenges:**

- The adoption of SHAPES Platform and Digital Solutions by older individuals;
- The high-level of reliability of SHAPES Digital Solutions for medicine management, control and optimisation;
- The trust and acceptance in digital solutions’ information, reminders, alerts and recommendations by older individuals and care professionals.

**General requirements:**

- The availability of Internet-enabled connectivity;
- Patient privacy and patient data protection.
### 3.10 UC-PT3-001 (heart failure patients)

<table>
<thead>
<tr>
<th>Code</th>
<th>UC-PT3-001</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title</td>
<td>In-home decompensation prediction for heart failure patients</td>
</tr>
<tr>
<td>Pilot Theme &amp; Task</td>
<td>PT 3 – Medicine Control and Optimization (T6.4)</td>
</tr>
<tr>
<td>Piloting Sites</td>
<td>NHSCT, CH, Gewi</td>
</tr>
<tr>
<td>Description</td>
<td>Older people suffering from heart failure have to be tightly monitored in order to avoid decompensations. When decompensations occur, these patients are normally transferred to hospitals incurring in high expenses for health systems, a decrease in quality of life for them and overall decrease of productivity for caring relatives. In this sense, tools are needed that</td>
</tr>
<tr>
<td></td>
<td>1. Capture unobtrusively the relevant health parameters of the patients at home (i.e., blood pressure, saturation, weight variations, etc)</td>
</tr>
<tr>
<td></td>
<td>2. Process the data captured and automatically predict when a decompensation is about to take place</td>
</tr>
<tr>
<td></td>
<td>3. Trigger an alarm to the corresponding care team so that they can intervene accordingly</td>
</tr>
<tr>
<td>Digital Solution proposed</td>
<td>In-home decompensation prediction tool for heart failure patients</td>
</tr>
<tr>
<td>Technical partners &amp; tasks involved</td>
<td>• VICOM, TREE - T5.5 Decision Support, Risk Assessment and Prediction Services</td>
</tr>
<tr>
<td></td>
<td>• EDGE</td>
</tr>
<tr>
<td></td>
<td>• CH</td>
</tr>
<tr>
<td>Components</td>
<td>1) <strong>eCare system</strong> – Health data capturing platform which includes several health sensors (BPM, scale, ...) to capture the needed measurements at home. (EDGE)</td>
</tr>
<tr>
<td></td>
<td>2) <strong>ROSA Virtual Nurse</strong> – Chatbot that is in charge of the follow-up of the patient. It reminds to the patient and caregivers when the measurements have to be taken, and it also provides the questionnaires that the patient has to complete. (CH)</td>
</tr>
</tbody>
</table>
3) **Heart Failure Decompensation Predictive Model** – Using the data captured by the health sensors of the e-care system and the questionnaire answers captured by ROSA it computes the decompensation probability for a given patient. (VICOM)

These components will be integrated so that they work in an integrated and seamless way. The resulting digital tool will be integrated in the SHAPES Platform (gateway, cloud …). It also includes a control dashboard to facilitate its use for the care teams.

<table>
<thead>
<tr>
<th>Piloting summary</th>
<th>CH proposes to test the system on 30 people (to be confirmed) for 4 weeks (to be confirmed).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject profile</td>
<td>Older individuals suffering from heart failure and living at their homes.</td>
</tr>
</tbody>
</table>

### 3.11 UC-PT3-001b (UNRF version)

<table>
<thead>
<tr>
<th>Code</th>
<th>UC-PT3-001b</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title</td>
<td>Prediction of stroke by home using blood pressure values</td>
</tr>
<tr>
<td>Pilot Theme &amp; Task</td>
<td>PT 3 – Medicine Control and Optimization (T6.4)</td>
</tr>
<tr>
<td>Piloting Sites</td>
<td>UNRF</td>
</tr>
<tr>
<td>Description</td>
<td>Auto-measurement of blood pressure at home will be highly reproducible, reliable and a useful clinical tool to prevent stroke incidents of older individuals. Also, by monitoring and analyse blood pressure measurements on a regular basis can provide fall prediction in hypertensive patients</td>
</tr>
</tbody>
</table>

Implementation:

1. Capture unobtrusively the relevant health parameters (blood pressure) of older individuals at home;
2. Process the visualizing data in a customizable client dashboard and automatically predict when the stroke or the fall will take place;
3. Trigger an alarm to the corresponding care team so that they can intervene accordingly

<table>
<thead>
<tr>
<th>Digital Solution proposed</th>
<th>In-home auto blood measurement tool connected with customizable client dashboard connected with measurements analyse and prediction tool that identify if systolic and diastolic pressure is out of normal</th>
</tr>
</thead>
</table>

**Components**

1. **eCare system** – Health data capturing platform which includes several health sensors (BPM, scale, etc) to capture the needed measurements at home (EDGE);
2. **DAPHNE Wellbeing App** – uses information about anthropometrics, health markers, mental wellbeing, physical activity and nutritional data of the user and with an intelligent data processing creates personalised nutritional, activity and behavioural models, giving risks and recommendations for each user. It requires data from wearables and sensors, including physical activity sensors, glucose sensors, blood pressure or sleep monitoring sensors (TREE);
3. **ROSA Virtual Nurse** is a digital nurse that monitors users at home, communicating in natural language and chat. It is used to improve the interactions with their customers, provide a better care and improving the awareness of their wellbeing. Aside from assisting its users in the daily management of their care, ROSA is aware of the users’ medical conditions, medication and hospital history and can therefore provide an interactive dialogue, reminding the users of specific symptoms that should be aware. In case an alarm is raised due to unusual parameter readings, ROSA assesses the situation and gives it a level of priority, calling for a rapid intervention team to visit the user and deliver prompt care (CH);
4. **HealthWatch™** – Newly introduced smartwatch with health data sensors including blood measurement;
5. **Support Vector Machines (SVM) & Support Vector Networks (SVN)** – supervised learning models with associated learning algorithms that analyse data used for classification and regression analysis.

Internet of Things (IoT), can provides an integration approach for all these devises that contain embedded technologies to be coherently connected and enables them to communicate and sense or interact.
with the physical world, among themselves and with a remote dashboard

**Piloting summary**

UNRF proposes to test the system on 10 people for 4 weeks

**Subject profile**

Older individuals suffering from hypertension and living at their homes

### 3.12 UC-PT3-001c (Olomouc version)

<table>
<thead>
<tr>
<th>Code</th>
<th>UC-PT3-001c</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title</strong></td>
<td>Advanced telemonitoring of patients with heart failure in home environment</td>
</tr>
<tr>
<td><strong>Pilot Theme &amp; Task</strong></td>
<td>Pilot Theme 3: “Medicine Control and Optimisation”</td>
</tr>
<tr>
<td><strong>Piloting Sites</strong></td>
<td>University Hospital Olomouc</td>
</tr>
</tbody>
</table>
| **Description** | The overall aim for implementing telehealth into the care management program for patients living with congestive heart disease is to support and improve the individual patient’s endeavors to self-manage and lead a lifestyle to reduce their risk of exacerbation and improve their quality of life. The practice will enable screening of common population in the Region with the disease; it will provide tools for remote control of patients with heart failure (HF):

1. Newly diagnosed patients with heart failure (NYHA class. I.-IV.) - up titration of medication
2. Patients with LVAD (left ventricular assist device) on destination therapy or candidates for transplantation
3. Patients with HF who are repeatedly decompensated – early palliative care

To select ICT-based available technologies and evaluate and demonstrate their ability to support the target group of patients at home in real conditions. The overall aim for implementing telehealth into the care management program for patients living with heart failure is to support and improve the individual patient’s endeavours to self-manage and lead a lifestyle to reduce their risk of exacerbation and improve their quality of life. |
In this sense, tools are needed that

1. Capture unobtrusively the relevant health parameters of the patients at home (i.e., blood pressure, pulse, weight variations, INR, liquids, steps)
2. Process the data captured and automatically predict when a decompensation is about to take place
3. Trigger an alarm to the corresponding care team so that they can intervene accordingly
4. Decision tree with symptoms - chatbot
5. Medication adherence – titration of medication – therapy optimization – maximum dose tolerance
   a. Pill intake confirmation
   b. drug level based on confirmation of use
   c. Integration with laboratory system
   d. Dosage confirmation by patients when it is changed
6. Better communication between patient and doctor/nurse
7. Safe videoconferencing - possibility to have recorded sessions with rehabilitation lessons or have a live session - gaming
8. Analysis of the text and voice during videoconference talk led by psychologist
9. Multidisciplinary communication between medical teams from different hospitals and social care centers
10. Communication and better connection among centers for heart failure – data sharing (echocardiography, lab results etc.)
11. Connection to the hospital information system in european standards e.g. IHE standards – FHIR
    a. Connection with laboratory system
12. Connection to 112 app
13. Increased security of existing telemedicine system (e.g., security SW for smartphones, VPN),
14. Patient empowerment – education
15. Online booking of visit for teleconference
16. Questionnaire QoL (The Minnesota Living with Heart Failure Questionnaire -MLHFQ)
17. Connection to ePrescription
18. Connection with smarthomes sensor or digital personal assistants
   a. smart home living platform – eCare
   b. Interconnection with informal carers

Patients are provided with a smartphone or tablet, blood pressure meter, and weight scales and are given training to use software application called Medimonitor on the smartphone. The smartphone or tablet acts as a gateway to upload the vital signs readings daily to the telemonitoring centre located in the hospital’s Cardiology
Clinic. Doctors, specialist nurses and biomedical engineers are able to access the telehealth portal with collected data via internet using a web browser with secure login. The Medimonitor system generates alerts in response to:

1. A patient’s vital signs readings are outside their threshold parameters. Patients will be contacted by a specialist nurse who will assess the severity of the situation. If the patient’s treatment and self management plan needs adjusting, the cardiologist will contact the patient to make the necessary adjustments and/or invite the patient to attend an unscheduled outpatient appointment.

2. If there is missing or incomplete measurement uploads twice in a row – either a biomedical engineer or nurse will contact the patient by telephone, SMS or Medimonitor message and provide additional training in the use of the smartphone or tablet if required.

The scheduled outpatient consultations are enhanced through the availability of the telemonitoring information which is also able to be accessed by hospital specialists in a patient’s symptoms worsen and they are admitted to hospital.

Smarthome solutions to improve life conditions in the homes, safety of the patients and quality of care by informal carers can be used as needed in concrete cases.

<table>
<thead>
<tr>
<th>Digital Solution proposed</th>
<th>In-home decompensation prediction tool for heart failure patients</th>
</tr>
</thead>
</table>

**Technical partners & tasks involved**

- EDGE: eCare Platform,
- OMN: videoconference solution.
- OMN: 112 App (medical information, emergency call to 112 or contact points)
- TREE: Care management platform, Big data and analytics

**Components**

- **eCare system** – Health data capturing platform which includes several health sensors (BPM, scale, …) to capture the needed measurements at home. (EDGE)
- **ROSA Virtual Nurse** – Chatbot that is in charge of the follow-up of the patient. It reminds to the patient and caregivers when the measurements have to be taken, and it also provides the questionnaires that the patient has to complete. (CH)
- **Heart Failure Decompensation Predictive Model** – Using the data captured by the health sensors of the e-care
system and the questionnaire answers captured by ROSA it computes the decompensation probability for a given patient. (VICOM)

- **Medimonitor** – Telemedicine system of UHO
- **Smart Living solutions** – SHAPES supported solutions optionally suitable for linkage of the patients and their homes with informal carers.
- **Videoconference (eCTouch, Digiroom, MEAS)**

These components will be integrated so that they work in an integrated and seamless way. The resulting digital tool will be integrated in the SHAPES Platform (gateway, cloud …). It also includes a control dash board to facilitate its use for the care teams.

**Piloting summary**
UHO proposes to test the system on 20 people (to be confirmed) for 12 months (to be confirmed).

**Subject profile**
Older individuals suffering from heart failure and living at their homes.

**Additional comments & bibliography**

### 3.13 UC-PT3-002 (diabetes patients)

<table>
<thead>
<tr>
<th>Code</th>
<th>UC-PT3-002</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title</strong></td>
<td>Diabetes self-management, control and prevention</td>
</tr>
<tr>
<td><strong>Pilot Theme &amp; Task</strong></td>
<td>PT 3 – Medicine Control and Optimization (T6.4)</td>
</tr>
<tr>
<td><strong>Piloting Sites</strong></td>
<td>NHSCT, Gewi</td>
</tr>
<tr>
<td><strong>Description</strong></td>
<td>Diabetes is a metabolic disease that causes high levels of sugar in blood and has relevant consequences in the organism. Therefore, its control and prevention are crucial to prevent health problems and stay healthy. Hence, we are looking for a solution that:</td>
</tr>
<tr>
<td></td>
<td>1. Monitors relevant information of users, such as weight and diet.</td>
</tr>
<tr>
<td></td>
<td>2. Helps the prevention of diabetes, especially in cases of high risk.</td>
</tr>
</tbody>
</table>
3. Supports patients with diabetes in the treatment adherence, diet and physical activity.
4. Support healthcare providers in managing their patients with intuitive tools.

<table>
<thead>
<tr>
<th>Digital Solution proposed</th>
<th>Diabetes app for self-management, control and prevention</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Technical partners &amp; tasks involved</th>
</tr>
</thead>
<tbody>
<tr>
<td>• VICOM, TREE – T5.5 Decision Support, Risk Assessment and Prediction Services</td>
</tr>
<tr>
<td>• EDGE</td>
</tr>
<tr>
<td>• CH</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>• <strong>eCare system</strong> – Health data capturing platform which includes several health sensors (glucometer, scale, …) to capture the needed measurements at home. (EDGE)</td>
</tr>
<tr>
<td>• <strong>Virtual Nurse ROSA</strong> – It reminds to the patient and caregivers when the measurements have to be taken, and it also provides the questionnaires that the patient has to complete. (CH)</td>
</tr>
</tbody>
</table>

4) **Decision Support System** – Using the data captured by the health sensors of the e-care system and the questionnaire answers it computes the rules entered by healthcare professionals and provides the recommendations to the patient. (VICOM)

5) Wellbeing recommendations, according to user’s habits (nutrition and physical activity)

6) **Clinical Expertise to formalize the protocols for Diabetes Management** – (NHSCT)

These components will be integrated so that they work in an integrated and seamless way. The resulting digital tool will be integrated in the SHAPES Platform (gateway, cloud …). It also includes a control dash board to facilitate its use for the care teams.

<table>
<thead>
<tr>
<th>Piloting summary</th>
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<tbody>
<tr>
<td>tbd</td>
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</table>

<table>
<thead>
<tr>
<th>Subject profile</th>
</tr>
</thead>
<tbody>
<tr>
<td>Older individuals suffering from diabetes or with risk of diabetes living at their homes and with smartphone.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Additional comments &amp; bibliography</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reference on Guideline-Based Patient-Oriented Gestational Diabetes Mobile App:</td>
</tr>
<tr>
<td>Artola, G., Torres, J., Larburu, N., Álvarez, R., Muro, N.: Development of a Gestational Diabetes Computer Interpretable...</td>
</tr>
</tbody>
</table>
### 3.14 UC-PT3-002b (version UNRF)

<table>
<thead>
<tr>
<th>Code</th>
<th>UC-PT3-002b</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title</strong></td>
<td>Monitoring of blood glucose levels to older individuals with diabetes or pre-diabetic, abnormal glucose indications</td>
</tr>
<tr>
<td><strong>Pilot Theme &amp; Task</strong></td>
<td>PT 3 – Medicine Control and Optimization (T6.4)</td>
</tr>
<tr>
<td><strong>Piloting Sites</strong></td>
<td>UNRF</td>
</tr>
<tr>
<td><strong>Description</strong></td>
<td>Older people suffering from diabetes have to be tightly monitored in order to avoid disruptions in a person's blood sugar levels. Data could be captured of transdermal glucose monitoring through computerized appliance-based virtual remote sensing and alert systems integrated with SHAPES.</td>
</tr>
<tr>
<td><strong>Implementation:</strong></td>
<td></td>
</tr>
<tr>
<td>1. The ongoing capture of data through continuous and automatic in monitoring of analyte levels, and its inclusion with a user-friendly computer interface, could be possible using a subcutaneous implanted sensor;</td>
<td></td>
</tr>
<tr>
<td>2. Process the data captured and automatically predict when a diabetic ketoacidosis or hyperosmolar hyperglycaemic nonketotic syndrome is about to take place;</td>
<td></td>
</tr>
<tr>
<td>3. Trigger an alarm to the corresponding care team so that they can intervene accordingly</td>
<td></td>
</tr>
<tr>
<td><strong>Digital Solution proposed</strong></td>
<td>Sensor for transdermal glucose monitoring integrated with analyse and prediction tool for disruptions in a person's blood sugar levels</td>
</tr>
<tr>
<td><strong>Components</strong></td>
<td></td>
</tr>
<tr>
<td>eCare system – Health data capturing platform which includes several health sensors (BPM, scale, etc) to capture the needed measurements at home. (EDGE);</td>
<td></td>
</tr>
<tr>
<td>Recurrent Neural Networks – Can provide blood glucose prediction with variance estimation [1]</td>
<td></td>
</tr>
</tbody>
</table>

These components will be integrated so that they work in an integrated and seamless way. The resulting digital tool will be
integrated in the SHAPES Platform (gateway, cloud, etc). It also includes a control dash board to facilitate its use for the care teams

Piloting summary

UNRF proposes to test the system on 10 people for 4 weeks

Subject profile

Older individuals suffering from prediabetes, diabetes type 1 and type 2 and living at their home

Additional comments & bibliography


3.15 UC-PT4-001 (physical and cognitive training through dancing)

<table>
<thead>
<tr>
<th>Code</th>
<th>UC-PT4-001</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title</td>
<td>Psycho-social and Cognitive Stimulation Promoting Wellbeing</td>
</tr>
<tr>
<td>Pilot Theme &amp; Task</td>
<td>PT 4 – Psycho-social and Cognitive Stimulation Promoting Wellbeing (Task 6.5)</td>
</tr>
<tr>
<td>Piloting Sites</td>
<td>UAVR, AUTH</td>
</tr>
<tr>
<td>Description</td>
<td>The aging process is usually associated with losses in several domains of daily functioning, including cognitive functioning, physical functioning, and social networks. Preventing these losses, delaying its progression or attempting to revert them is essential to a strategy aiming to promote autonomous and independent aging in place and long and healthier lives lived with quality. Combined interventions with a physical and a cognitive component are a means to promote physical and cognitive functioning and are likely to impact psycho-social functioning, particularly if delivered in structured group interventions. However, adhesion of older adults to this type of intervention is usually difficult and a way to overcome this limitation is to promote an intervention to which older adults relate and which is appealing. Dance has the potential to be attractive to older adults and can be adjusted according to individual characteristics (e.g. age, physical limitations, cognitive limitations). Therefore, a structured approach mediated by technological tools is needed that:</td>
</tr>
</tbody>
</table>
Deliverable D6.1 SHAPES Pan-European Pilot Campaign Plan Version 1.0

- Allows the combination of physical and cognitive training through dance (using StepMania);
- Is adaptable to the end-users physical and cognitive functioning, but also their culture and preferences;
- Captures data regarding users’ performance.

In addition to StepMania, the sites replicating this pilot may consider using other technological solutions that integrate a cognitive and a physical component.

<table>
<thead>
<tr>
<th>Digital Solution proposed</th>
<th>StepMania</th>
</tr>
</thead>
</table>
| Technical partners & tasks involved | • EDGE – interoperability between StepMania and SHAPES platform;  
| | VICOM – data analytics  
| | • TREE: motion detection  
| | • MedicalSyn – provide the platform to collect data on patients demographic and clinical characteristics as well as update the platform to include the measures that are going to be used in this pilot. |

| Components | • StepMania – a dancing surface and respective software that allows for the personalizing of dance choreographies and music and assesses the performance of the user during the choreography.  
| | StepMania allows for the choice of the music and the dancing movements (choreography) in line with users’ preferences and characteristics. It has a system of lights that prompt the user to perform a specific movement in a specific sequence and, therefore, requires the users’ attention and memory to identify and record patterns, i.e., StepMania integrates both a physical and a cognitive component into a ludic and appealing social activity (dancing). |

| Piloting summary | In Aveiro we propose to test the impact of using Stepmania in 25 individuals during 8 weeks. |
| Subject profile | Older individuals living in the community as defined in the first draft of the Personas 1 to 3:  
| | 1. Active, healthy older adults, satisfactory financial standing and social relationships  
| | 2. Older adults with mild chronic conditions, some reliance on spouses or children |
This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 857159

3. Older adults with chronic musculoskeletal disorders, risk of isolation

Additional comments & bibliography

Details on https://www.stepmania.com/

3.16 UC-PT4-002 Cognitive tasks robot

<table>
<thead>
<tr>
<th>Code</th>
<th>UC-PT4-002</th>
</tr>
</thead>
</table>
| Title      | Option 1: In-home cognitive activities for people with early-stage dementia  
            | Option 2: Personalized cognitive activities in the context of a group activity for people with early-stage dementia |
| Pilot Theme & Task | PT 4 – Psycho-social and Cognitive Stimulation Promoting Wellbeing (T6.5) |
| Piloting Sites | AIAS, AUTH, CH, UCC |

Description

Many elderly people with early-stage dementia can live independently. Studies have shown that cognitive training can have positive effects [1]. However, this type of interventions are sometimes not given or, in case they are, the procedure could be further improved to reach an optimal outcome. Some of the reasons that prevent an optimal implementation of cognitive training are:

- People need to go to the facilities were the training is given. This is an important issue for people with reduced mobility, low motivation or far from training centres.
- Caregivers (or care partners) who can help assisting during the cognitive tasks may not know how to follow directions or provide guidance properly.
- People participating in group activities may need a more personalized intervention to adjust difficulty level and have a greater motivation in the activity.

A social robot (such as ARI/TIAGo, from PAL ROBOTICS) can be an improved channel to give the cognitive tasks in a more personalized and motivating fashion by connecting ARI/TIAGo with:

- A set of cognitive tasks (diAnoia, Memori, developed by SCIFY)
  - A smart-phone app & marketplace (diAnoia & diAnoia marketplace) which provides a collection of non-pharmaceutical interventions and activities can be used.
This app, developed by SciFY is an educational application for family caregivers and health professionals in order to provide knowledge about simple techniques of non-pharmaceutical interventions will provide valuable insight and tools. The application is available for android and iOS smartphones / tablets and allows carers and health professionals to learn simple techniques of non-pharmaceutical interventions and use them to help people with dementia (at home or at non-specialized structures in the field of dementia, such as public structures for the elderly), when they cannot attend a Day Center for people with dementia for various reasons.

The marketplace app (web application) will serve as a way for users to upload and create their own set of mental exercises, which will then be available through the diAnoia smartphone app.

The smartphone application for the project "diAnoia" is useful for practicing the mental skills of people dealing with:

- Mild Cognitive Impairment with significant deficits
- Early-stages of dementia
- An electronic video-game called “Memor-i”. This game emulates the classic, old memory game with cards, and is an excellent resource to practice memory skills while playing. This game is offered as a desktop application for Windows and Linux platforms and does not require an Internet connection in order to be used. SciFY will incorporate new languages into the game and create a game variation suitable for people with dementia.

- A virtual assistant the provides guidance on how to perform the cognitive tasks (ROSA, from CLINICA HUMANA)
- Technologies which enable smooth interaction with humans (visual and speech recognition, VICOMTECH, PAL ROBOTICS)
- Emotion detection while making the exercises (TREE TECHNOLOGY)
- A recognition system of the reactions of the user to analyze acceptance and assist ROSA (TREE TECHNOLOGY)

The objective of the use case is to evaluate the integrated technologies in order to enhance engagement and facilitate the training with cognitive activities.
The use case can be implemented in 2 scenarios (which define the two title options):

- **Scenario 1:** Cognitive tasks will be given to the users in their own homes. If users live at different locations, the robot will stay with them 24/7. Alternatively, CLINICA HUMANA treats patients who live in sheltered apartments [2], all in the same building. In this case, it may be feasible that one robot can be shared by several users living in apartments located on the same floor.

- **Scenario 2:** People living in sheltered apartments have access to common areas in the building where group activities are given by a professional trainer. Some of these activities include cognitive tasks. In this second scenario, the robot could provide personalized training while the others are doing group-guided cognitive activities.

In order to equip ARI/TIAGo with the necessary features, the following developments will be carried out:

- User identification via facial recognition. It is very important that the robot authenticates the user, so that the session is delivered to the right person (identification of user in the activity group or within the family members or potential visitors in their own home).
- Speech Natural Language Processing to enable natural easy communication.
- Integration of dianoia/Memor-i in ROSA to equip ROSA with the capabilities to provide the cognitive tasks and evaluation of user’s health, motivation and engagement states.
- Integration and connectivity of the different technologies, including connectivity with ARI/TIAGo’s input/output devices: microphone, speakers, camera, table and social gestures features (eyes, head, arms, hands movement).
- Robot mobility features to go to user’s apartment (scenario 2): apartment localization, bell ringing.
- Identification of the emotions by facial recognition to have a non-intrusive monitoring of motivation.
  - Optionally, in addition to camera on robot, further cameras can be placed in the room/apartment to enhance recognition.
• Translation of diAnoia (currently in Greek only) into the users’ language (Piloting site CLINICA HUMANA, Spanish). Technical translation supervised by a medical doctor.


<table>
<thead>
<tr>
<th>Digital Solution proposed</th>
<th>Social robot adapted to provide cognitive tasks</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical partners &amp; tasks involved</td>
<td></td>
</tr>
<tr>
<td>• VICOM – T4.5 Human Interaction &amp; Visual Mapping. Speech-enabled ROSA</td>
<td></td>
</tr>
<tr>
<td>• VICOM – T4.6 Authentication, Security &amp; Privacy Assurance (Face identification &amp; authentication) / or PAL</td>
<td></td>
</tr>
<tr>
<td>• PAL – TX.X</td>
<td></td>
</tr>
<tr>
<td>• PAL – TX.X connectivity and coordination of components to robot and robot’s features</td>
<td></td>
</tr>
<tr>
<td>• VICOM / CH T6.6 – Integration of diAnoia in ROSA</td>
<td></td>
</tr>
<tr>
<td>• VICOM / CH T6.6 – ROSA questionnaires and evaluation of engagement and motivation</td>
<td></td>
</tr>
<tr>
<td>• TREE – T4.5/T5.5 Emotion recognition/engagement recognition (attention)</td>
<td></td>
</tr>
<tr>
<td>• CH/SciFy – TX.X Translation of diAnoia into Spanish and other necessary languages</td>
<td></td>
</tr>
<tr>
<td>• SciFY - Incorporation of Spanish and English Languages into diAnoia. New game development for “Memor-i video game”, with appropriate material and languages for people with dementia.</td>
<td></td>
</tr>
</tbody>
</table>

| Components |
|-----------------|-----------------------------------------------|
| 1. ARI/TIAGo – Channel for human interaction (PAL) |
| 2. ROSA Virtual Nurse – Chatbot that guides the user in the cognitive tasks and evaluates engagement and motivation. (CH) |
| 3. Facial Recognition Module – Authenticates the user via facial image identification. (VICOM/PAL) |
| 4. Natural Language Module – tool for implementing speech-enabled dialogs. (VICOM) |
| 5. Emotion recognition module – detects the mood of the user while doing the exercise (TREE) |
| 6. Engagement/User experience analysis (TREE) |
| 7. diAnoia & diAnoia marketplace – Cognitive tasks (SciFY) |
| 8. Memor-i Cognitive training through gaming (SciFY) |
These components will be integrated so that they work in an integrated and seamless way.

### Requirements

- All devices and implementations must consider potential users with multiple chronic conditions in addition to early stage dementia.
- Camera features (for emotion/engagement recognition)
- Microphone features (for speech recognition)
- Type of tasks (for ROSA integration), degree of integration of ROSA with ARI/TIAGo
- WiFi (ARI/TIAGo connectivity) + adjust network to enable door opening if necessary
- Ubuntu / Webpage based interface for robot tablet

- Smart doorbell or system for door knocking (if case 2), if there is budget and is necessary
- 3mx3m place for robot workstation (charging)
- ARI/TIAGo has 8h autonomy

- Details about the data coming from the APPs. User Experience (online time, time making the cognitive tasks, etc.)

- Data collection and storage (CH already has EHR -MySQL- which can host part of collected data)

### Piloting summary

**Scenario 1**, users in different locations: 1-2 people can be recruited (limited by the number of available robots). 8 weeks.

**Scenario 1**, users in sheltered apartments: CH proposes to test the system on 5-10 people (users living on the same floor) for 8 weeks.

**Scenario 2**: CH proposes to test the system on 6 people for 8 weeks. 6 people per activity session. It could be evaluated to use the robot in several activity sessions with other participants.

### Subject profile

People with early stage dementia. Independent or highly independent. They are frequently visited by caregivers, care partners or family members (scenario 1) who can assist with robot interaction and provide guidance during game directions. In group cognitive activities, there will be a professional who can provide such guidance.
Additional comments & bibliography

- PAL – TIAGo robot: https://tiago.pal-robotics.com/
- VICOM – Viulib computer vision library: http://www.viulib.org/
- VICOM – NLP library: https://www.vicomtech.org/es/id-tangible/libreriias-software

3.17UC-PT5-001 iSupport for dementia caregivers

<table>
<thead>
<tr>
<th>Code</th>
<th>UC-PT5-001</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title</td>
<td>Online information and training for informal dementia caregivers</td>
</tr>
<tr>
<td>Pilot Theme &amp; Task</td>
<td>PT 5 – Caring for Older Individuals with Neurodegenerative Diseases (T6.6)</td>
</tr>
<tr>
<td>Piloting Site</td>
<td>University of Porto (UPorto)</td>
</tr>
<tr>
<td>Description</td>
<td>Informal caregivers of people with dementia are at greater risk of developing physical and mental health problems when compared both to the general population and to informal caregivers of people with other chronic diseases. Those health problems include depression and anxiety disorders, as well as hypertension, digestive, and breathing problems. Psychoeducational and multicomponent interventions (including, e.g. skills training, psychoeducation, techniques for self-care, changes in the caregiver’s setting) have reunited favourable evidence with regards to its effects on subjective well-being, caregiver burden, depression and anxiety symptoms, skills/knowledge and self-efficacy. However, several reports have been stressing the existence of situational barriers impeding informal dementia caregivers of accessing interventions targeting them when delivered in its usual face-to-face format. Barriers may hamper the offer of those intervention programs (e.g. geographical inequalities, lack of trained workforce, infrastructures to scale up services, and/or funds); or may prevent IC from participating (e.g. social stigma, not managing to make a break from caregiving responsibilities or to arrange transport).</td>
</tr>
</tbody>
</table>
Internet-based interventions have been explored for their potential to minimize the negative effects of caring, accounting for their ubiquitous nature, convenient delivery, potential scalability and presumed (cost) effectiveness. Mirroring the encouraging evidence on online interventions, the World Health Organization’s (WHO) mental health action plan recommends the development of “comprehensive, integrated and responsive mental health and social care services” and “the promotion of self-care, for instance through the use of electronic and mobile health technologies” [12].

In this sense, a digital tool is needed that

1. Provides ubiquitous, accessible and convenient information and training to informal dementia caregivers;
2. Is able to reach informal dementia caregivers excluded, due to contextual barriers (e.g. inability to arrange transportation or delegate caregiving responsibilities) from usual care practices (i.e. face-to-face interventions).

<table>
<thead>
<tr>
<th>Digital Solution proposed</th>
<th>iSupport-Portugal training programme for informal dementia caregivers</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>iSupport is a self-help online program developed by the World Health Organization [13] to provide education, skills training and support to informal dementia caregivers. The programme sustains on the evidence-based guidelines for caregivers of people with dementia and is framed as a multi-component intervention, using problem-solving and cognitive behavioural therapy techniques.</td>
</tr>
<tr>
<td></td>
<td>In this pilot activity informal dementia caregivers will be provided with the opportunity to engage in individual, self-help and online activities (23 lessons distributed by 5 intervention modules). Engagement with iSupport will be carried in dementia caregivers’ preferred environments (e.g. at home) and by using their own technical devices (e.g. desktop, laptop, tablet), at a time of their convenience. The version of iSupport employed in this pilot activity is a culturally adapted Portuguese version by UPorto.</td>
</tr>
</tbody>
</table>

| Technical partners & tasks involved | UPORTO (iSupport) |

<p>| Components | Modules and lessons – 5 modules with 23 lessons approaching well-established thematic needs of informal dementia caregivers. Allows the collection of data on |</p>
<table>
<thead>
<tr>
<th>Piloting summary</th>
<th>UPorto proposes to test iSupport on 40 informal dementia caregivers for 3 months with a follow-up assessment at 3 months after the conclusion of the intervention. The details of the pilot, including the assessment methodology are described in additional internal documents.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Subject profile</td>
<td>Adult informal caregivers (non-paid) of people living with dementia facing caregiver burden and/or anxiety and depression symptoms. The profile considers informal caregivers regardless of specific diagnosis/dementia type of the care receiver, time since diagnosis, and level of dependence of the person with dementia. Individuals providing care for at least 6 months are the target of this pilot. Digitally literate and savvy caregivers, with permanent access to technical devices with internet connection (smartphone, tablet, desktop or laptop), younger (middle aged), employed and highly educated caregivers are expected to enrol in this pilot*.</td>
</tr>
</tbody>
</table>

- lessons accessed (when and which) and repeated by each user;
- A sub-component of each lesson is interactive exercises with immediate feedback (e.g. drag and drop, free text, checklist).
- **My plan** – functionality allowing the definition of a plan of lessons personalized to the convenience and needs of each informal dementia caregivers. Data on lessons added to the personalized plan by all users can be collected;
- **My mood**- module for a self-evaluation of the mood status (in a scale on 1 to 10) with the option of adding a description of the mood status. Quantitative and qualitative (text) data can be collected with this module concerning caregivers’ mood status.
- **My printouts**- module for a personalized printing of lessons that reflect the interaction of users with the system, i.e. each printable document results in the importation of interaction elements with the platform such as the answers to all exercises. Those printouts should then reflect the learning process per user.

* This assumption derives from previous user studies, but it needs to be tested in this pilot.
3.18 UC-PT5-002 Digital Assistant for people with mild cognitive impairment

<table>
<thead>
<tr>
<th>Code</th>
<th>UC-PT5-002</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title</strong></td>
<td>Digital Assistant for Older People with Mild Cognitive Impairment</td>
</tr>
<tr>
<td><strong>Pilot Theme &amp; Task</strong></td>
<td>PT 5 –Caring for Older Individuals with Neurodegenerative Diseases (T6.6)</td>
</tr>
<tr>
<td><strong>Piloting Sites</strong></td>
<td>UCC, AUTH, SAL, UPORTO (depending on the language availability of the NLP technology)</td>
</tr>
</tbody>
</table>
| **Description** | In this use case we are addressing older people (65 years or more) with mild cognitive impairment which live independently in rural or urban environments. Normally, they live alone or with their wife/husband. A caregiver visits them daily. The caregiver is in many cases a relative (daughter, son, …). Due to MCI, they tend to forget appointments, forget to turn on the oven before cooking food or how to make/solve certain basic situation such collecting medication from the pharmacy etc ... Another important issue is that they are at risk of isolation, and communication and social engagement has to be reinforced/sustained. Hence, we are looking for an easy-to-use and intuitive communication solution that:  

1. Provides timely reminders to a variety of situations (appointments, agenda, activity suggestions, …)  
2. Provides instruction on how-to-do situations (turn on new home device, …)  
3. Foster communication with community (neighbours, friends, …)  
4. Foster engagement and participation in social & cultural activity in the municipality. |
| **Digital Solution proposed** | Digital Assistant for Older People with Mild Cognitive Impairment |
| **Technical partners & tasks involved** | • VICOM – T4.5 Human Interaction and Visual Mapping  
• KOM (robots)?  
• CH (ROSA)? |
<table>
<thead>
<tr>
<th>Components</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Safe Digital Assistant</strong></td>
<td>– we are thinking on a smart and safe digital assistant using Automatic Speech Recognition (ASR) and Natural Language Processing (NLP) technologies to provide timely reminders, instructions and communication suggestions. We will use an open source smart speaker (Mycroft) to be installed at the living room. The caregiver or a closer relative will be in charge of arranging the agenda for the older user with MCI and the digital assistant will be triggered correspondingly. In this use case, the interaction will always start from the Digital Assistant side, and it may involve a speech-based dialog with the user to retrieve him/her acknowledgement or to guide him/her through the actions to take.</td>
</tr>
<tr>
<td><strong>Caregiver administration panel</strong></td>
<td>– As the caregivers need to plan a schedule for the user (cultural agenda, appointments with the doctor and so on), fill the user profile, and perhaps modify some behavioural aspects of the assistant, a proper interface should be defined.</td>
</tr>
<tr>
<td><strong>Cultural and social agenda provider (optional)</strong></td>
<td>– To foster communication and social well-being of the users, an API communication with a Knowledge Base which serves localised cultural and social activities would be a plus. Using the <strong>Caregiver administration panel</strong>, a set of pre-defined options can be selected regarding to activities that the user likes, so the assistant does the activity offering according to these. In addition, if some friends of the user - which also should be logged and registered in the SHAPES platform- are matched with the same cultural/social activity, the assistant should inform about it.</td>
</tr>
</tbody>
</table>

Privacy will be preserved. Data flow will be maintained inside Shapes Technological Platform. No data sharing will be carried out in any form with third parties such as Google or Amazon. Apart from the open-source smart speaker from Mycroft, only technology from Vicomtech and other SHAPES partners will be used in order to meet the privacy requirements of the users. ASR& NLP These components will be integrated in the SHAPES Platform (gateway, cloud …). It also includes a control application to facilitate its use for the caregiver.

| Piloting summary | UCC proposes to test the system on 12 people (10 people + 2 extra in case if illness/withdrawal) in rural or urban environments for 8 weeks. |

| Subject profile | Main persona of the use case: In this use case we are addressing older people (65 years or more) with mild cognitive impairment |
which life independently in rural or urban environments. Normally, they live alone or with their wife/husband.

Additional comments & bibliography

Previous pdf on Safe Digital Assistant.

Technical open issues:

- Accents. We agreed on selecting the candidates depending on their accent. No or soft accent candidates will be selected for the use case. This will reduce the Speech to Text module error, as the speech corpora used to train them has little-to-none accentuation. In addition, people with speech disabilities won’t be suitable for this use case.

- Internet connection. We need to specify which are the minimum internet connection requirements for the use case for rural areas. A 10MB/s connection would be enough if it is stable enough (wired connections will be needed. 4G or satellite internet should be avoided for this use case).

3.19 UC-PT5-003 Monitoring diabetic patients with mild cognitive impairment

Code: UC-PT5-003

<table>
<thead>
<tr>
<th>Title</th>
<th>Technological resources for monitoring diabetic patients with mild cognitive impairment</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pilot Theme &amp; Task</td>
<td>PT 5 – Caring for Older Individuals with Neurodegenerative Diseases (T6.6)</td>
</tr>
<tr>
<td>Piloting Site</td>
<td>UPORTO</td>
</tr>
<tr>
<td>Background</td>
<td>One of the challenges of managing older individuals with chronic diseases, such as diabetes, is the individualization of care in people with multimorbidity’s (co-occurring conditions). Diabetes affects currently 9.9% of Portuguese people, compared to 6.4% of the OECD [14]. Although macrovascular and microvascular complications of diabetes are well recognized, there is a lack of awareness regarding other comorbidities such as cognitive impairment, depression, and physical disabilities. We know that type 2 diabetes is associated with approximately a 1.5 to 2.5-fold increase in the risk of dementia [10]; the prevalence of dementia in type 1 diabetes if less clear. Cognitive dysfunction (also commonly referred to as cognitive impairment) is an important condition to recognized as it interferes with patient’s participation in their diabetes</td>
</tr>
</tbody>
</table>
management. In addition, patients with cognitive dysfunction can be on a spectrum that extends from mild cognitive impairment (defined as cognitive deficit without difficulty performing daily activities) to severe impairment (commonly referred to as dementia). This condition has particular importance because of its impact on self-care and quality of life [10, 11].

**Description**

Unlike other chronic diseases, diabetes self-care involves many behaviours that require cognitive capacity and insight to perform proper self-care, coordination and planning. Glucose monitoring, medications and/or insulin injections, medication adherence, and diet and exercise timing require participation from different domains of cognitive function. For example, a patient with memory problems may forget to take insulin doses, medications/insulin, or to eat on time. Besides that, patients with diabetes and cognitive impairment, seem to be “stubborn”, may refuse any new therapy, among others clinical issues, showing the usefulness of using these technologies to support health and well-being [10].

In this sense, a technological package will be useful to:

1. Provide accessible and convenient information to formal or informal caregivers;
2. Provide timely reminders to a variety of situations, namely for a correct management of therapeutic plans (e.g. medication, food, physical activity);
3. Data collection for research purposes in patients with diabetes and cognitive impairment, since more work is needed to more robustly identify the relationships between these two conditions.

For us, the use of a complete technological package consists of a new model of integrated health care, allowing patient follow-up using validity technology based on scientific methodologies.

<table>
<thead>
<tr>
<th>Digital Solution proposed</th>
<th>eHealthPassTM</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Technological package: smartphone, smart bracelet, blood glucose plus blood pressure monitoring system, body composition scale and smart medicine box</td>
</tr>
</tbody>
</table>

| Technical partners & tasks involved | Gnomon Informatics S.A. |
| Components | 1. **Activity tracker** that measures (steps, falls, sleep pattern, stress level).  
2. **Scientifically approved educational material** (articles, videos, etc) about how to handle the disease.  
3. **Questionnaires** (PROMS) that evaluate the condition of the subject. Further automatic actions can be triggered based on the answers. For example, if increased anxiety level is evaluated, then the solution may suggest a consultation with the healthcare professional (HCP) or exercise etc.  
4. **Shared Care Plans (SCP)**. This is in relation with a HCP. The HCP can prescribe certain medications, physical exercise, educational material etc. The SCP is then displayed on the mobile app of the patients who can follow it. The HCP and the caregivers can follow the progress and adherence to the SCP and receive relevant notifications.  
5. **Virtual Patient Scenarios**. The caregivers can run virtual scenarios that assist in the understanding of the disease and what actions to take depending on the given answers.  
6. **Community Portal/Chat option**. Caregivers and care receivers can participate in an online community related to degenerative diseases. The community can be operated and supported by a relevant patient association.  
7. **Blood Glucose Monitoring System**. Allows glucose to be monitored on the fly, with data sent to mobile phone.  
8. **Blood Pressure Monitoring System**. Allows blood pressure to be monitored on the fly, with data sent to mobile phone.  
9. **Smart Medicine Box**. By monitoring the dispensing of medications (especially solid dosage forms, such as pills and capsules), we can monitor medication adherence. |

These components will be integrated so that they work in an integrated and seamless way [15, 16].

| Piloting summary | UPORTO propose to recruit 10 individuals based on the inclusion criteria (subject profile below) for 6 months. The details of the pilot, including the assessment methodology are described in additional internal documents. |

| Subject profile | In this use case we are addressing older people (65 years or more) with mild cognitive impairment (tracked by QMCI Screen*) and diagnosis of type 2 diabetes at baseline. Other inclusion criteria are live in the community and have a formal or informal caregiver.  

*Quick Mild Cognitive Impairment Screen (available in Portuguese, Greek and Spanish)
### Technical open issues:

- We are waiting for more information from the technological partner and the companies that supply the devices/hardware;
- Technical issues related to interoperability between different devices are being evaluated.

### 3.20UC-PT6-001 Training of orofacial musculature

<table>
<thead>
<tr>
<th>Code</th>
<th>UC-PT6-001</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title</td>
<td>Training of orofacial musculature</td>
</tr>
<tr>
<td>Pilot Theme &amp; Task</td>
<td>PT 6 – Physical Rehabilitation at Home (T6.7)</td>
</tr>
<tr>
<td>Piloting Site</td>
<td>SAL</td>
</tr>
</tbody>
</table>
| Description | The loss of strength of the orofacial musculature is a common situation in the aging process. This process may negatively affect several basic activities such as swallowing, talking, and face-to-face communication. Additionally, it can be increased by several pathologies such as Parkinson, Stroke, and others. In this context, a set of exercises are normally prescribed by the speech therapists (logopedas) in order to recover or maintain as long as possible the oral agility, strength, speed and coordination of the orofacial musculature. In this sense, a digital tool is needed that
  1. Presents the face gestures to be carried out by the affected individual
  2. Measures the gestures carried out by the patient in real time and the overall performance
  3. Supports and motivates the patient to adhere to the treatment. |
| Digital Solution proposed | Orofacial musculature training tool |
| Technical partners & | VICOM |
This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 857159

<table>
<thead>
<tr>
<th>tasks involved</th>
<th>TREE</th>
</tr>
</thead>
</table>

| Components | 1. **Facial gesture detection system** – Computer vision component that captures and measures a predefined set of facial gestures and gaze in real time. (VICOM, TREE)  
2. **Emotion detection** associated to the rehabilitation exercise. (TREE) |
|-------------|---------------------------------------------------------------|

<table>
<thead>
<tr>
<th>Piloting summary</th>
<th>SAL proposes to test the system on 5-10 people for 4 weeks.</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Subject profile</th>
<th>Older individuals with symptoms of affected orofacial musculature. (to be revised)</th>
</tr>
</thead>
</table>

| Additional comments & bibliography | Example of orofacial musculature training session:  
https://www.youtube.com/watch?v=RBuKk-TQO-0  
Standardized scale to be identified. |
|-----------------------------------|---------------------------------------------------------------------------------|

### 3.21 UC-PT6-002 Gait rehabilitation

<table>
<thead>
<tr>
<th>Code</th>
<th>UC-PT6-002</th>
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</thead>
</table>

**Title**  
Gait rehabilitation

**Pilot Theme & Task**  
PT 6 – Physical Rehabilitation at Home (T6.7)

**Piloting Sites**  
CH, SAL, AUTH

**Description**  
After accidents, surgery, strokes, or other musculoskeletal diseases, older individuals require the delivery of at-home or at nursing home of physical rehabilitation services to recover/maintain physical condition. In particular, gait is a relevant task in which support is often needed. Several technological approaches can provide effective support for this task, such us the KOMPAÏ robot which integrates a walking assistance module. Additionally, to fully support the older patients in gait rehabilitation, new features have to be integrated in the robot such as:
1. Older person identification via facial recognition. It is very important that the robot authenticates the user, so that the physical session is delivered to the right person.

2. Integrate Speech-enabled ROSA in the robot so that ROSA can guide and motivate the user in a friendly and natural way during the gait rehabilitation session. ROSA can also assist to the prevention of the fear of falling during the session.

3. For security reasons, heart rhythm of the user must be monitored while performing gait rehabilitation sessions.

<table>
<thead>
<tr>
<th>Digital Solution proposed</th>
<th>Gait Rehabilitation KOMPÃÏ Robot</th>
</tr>
</thead>
<tbody>
<tr>
<td>Technical partners &amp; tasks involved</td>
<td></td>
</tr>
<tr>
<td>KOM – T5.4 Robotic &amp; Assistive Technologies?</td>
<td></td>
</tr>
<tr>
<td>VICOM – T4.5 Human Interaction &amp; Visual Mapping (Speech-enabled Rosa)</td>
<td></td>
</tr>
<tr>
<td>VICOM – T4.6 Authentication, Security &amp; Privacy Assurance (Face identification &amp; authentication)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Components</th>
</tr>
</thead>
<tbody>
<tr>
<td>KOMPÃÏ Robot – Provides gait rehabilitation session infrastructure. (KOM)</td>
</tr>
<tr>
<td>ROSA Virtual Nurse – Chatbot that guides the user in the gait rehabilitation session. (CH)</td>
</tr>
<tr>
<td>Facial Recognition Module – Authenticates the user via facial image identification. (VICOM)</td>
</tr>
<tr>
<td>Emotion detection (TREE)</td>
</tr>
<tr>
<td>Natural Language Module – tool for implementing speech-enabled dialogs. (VICOM)</td>
</tr>
<tr>
<td>Heart Rhythm Monitoring sensor - selects and provides the right sensor</td>
</tr>
<tr>
<td>Integration of the Heart Rhythm Monitoring – this sensor will be integrated in the handgrip of the Robot to monitor the heart rate of the user during the gait rehabilitation sessions. (KOM)</td>
</tr>
</tbody>
</table>

These components will be integrated so that they work in an integrated and seamless way. The resulting digital tool will be integrated in the SHAPES Platform (gateway, cloud …). It also includes a control dashboard to facilitate its use to the professional care teams.

<table>
<thead>
<tr>
<th>Piloting summary</th>
</tr>
</thead>
<tbody>
<tr>
<td>CH proposes to test the system on 10 people for 4 weeks.</td>
</tr>
</tbody>
</table>
SAL proposes to test the system on 10 people for 4 weeks.

<table>
<thead>
<tr>
<th>Subject profile</th>
<th>Older individuals in gait rehabilitation processes.</th>
</tr>
</thead>
</table>

**Additional comments & bibliography**

- **VICOM** – Viulib computer vision library: [http://www.viulib.org/](http://www.viulib.org/)
- **VICOM** – NLP library: [https://www.vicomtech.org/es/iditangible/libreries-software](https://www.vicomtech.org/es/iditangible/libreries-software)

### 3.22 UC-PT6-003 3D Depth camera rehabilitation tool

<table>
<thead>
<tr>
<th>Code</th>
<th>UC-PT6-003</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title</td>
<td>3D Depth Camera Rehabilitation Tool</td>
</tr>
<tr>
<td>Pilot Theme &amp; Task</td>
<td>PT 6 – Physical Rehabilitation at Home (T6.7)</td>
</tr>
<tr>
<td>Piloting Site</td>
<td>SAL</td>
</tr>
<tr>
<td>Description</td>
<td>Use of 3D Depth cameras for the supervision of exercise routines for rehabilitation purposes and maintain physical condition.</td>
</tr>
</tbody>
</table>

**Scenarios:**

- At-home
- Nursing-home

**Roles involved:**

- Monitor: Specialist devoted to user rehabilitation.
- User: Patient to be monitored in his/her rehabilitation process

**Usual user interaction:**

- The user stands in front of deep camera at the distance of X meters.
- The user/monitor turns on the system.
- The user/monitor initializes session/selects the user in the system (TBD).
- The user/monitor selects the exercise table.
- The system monitors the set of exercise. Provides appropriate instructions (visual/sound) per exercise. Provide feedback to the user.
- The user/monitor finalizes session.
- The system sends to the SHAPE’s platform (Cloud) the report about the session

Monitor key interactions:

- Create/Delete locations (e.g Residence, house, etc.).
- Create/Delete users.
- To relate users with locations.
- Create/Delete exercises (How are new exercises defined?).
- Create/Delete exercise tables, defined as a set of exercises related.
- Analyze summary reports per user/location.

Info required from other partners specialist on rehabilitation:

- 10-20 exercises classified per user profile.
- Use case focused on shoulder, hip and knee.
- User characterization.
- Tables of exercises that should be used together.

Digital Solution proposed

| 3D Depth Camera and software application for semi-supervised rehabilitation |
| Data analytics |
| Video conference system |

Technical partners & tasks involved

- UCLM: development of the 3D depth camera rehabilitation tool.
- VICOM: data analytics.
- TREE: possibility of making movement detection.
- OMN: video conference system.

Components

At-home:

- TV.
- 3D depth camera (Kinect).
- Computer (NUC).

Totem version:

- Size of screen > 42” (TV or Monitor).
- Touchable frame.
- Kinect III (adjustable).
- Laser/light to indicate the right position of the user in the floor.
- Microphone and Speaker/s.
- The totem should be mobile with locks to fix it in a specific position.
- With space for compact computer PC.
- RFID reader.
- External Bluetooth.

**Piloting summary**
SAL proposes 2 groups from 15 to 20 people.

**Subject profile**
To be defined by pilot sites.

**Additional comments & bibliography**
https://journals.sagepub.com/doi/full/10.1177/1550147719875649

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### 3.23 UC-PT6-004 Wearable Motion Monitoring Devices

<table>
<thead>
<tr>
<th>Code</th>
<th>UC-PT6-004</th>
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</thead>
<tbody>
<tr>
<td><strong>Title</strong></td>
<td>Wearable Motion Monitoring Devices</td>
</tr>
<tr>
<td><strong>Pilot Theme &amp; Task</strong></td>
<td>PT 6 – Physical Rehabilitation at Home (T6.7)</td>
</tr>
<tr>
<td><strong>Piloting Site</strong></td>
<td>SAL, AUTH</td>
</tr>
</tbody>
</table>
| **Description** | Use of wearable motion monitoring devices attached to the user’s shoes (both shoes) and in a wristband to track the evolution of rehabilitation processes and the condition of the user.  
Scenarios:  
- At-home.  
- Nursing-home.  
Roles involved:  
- User: Patient to be monitored in his/her rehabilitation process.  
- Therapeutic: Get periodically reports from wearables (number of steps, minutes of physical activity).  
- Psychologist; Get periodically reports from wearables (overall physicals KPIs).  
- Technical staff.  
User interaction: |
• The user wears the wearable device all day, technical staff periodically make data retrieval from sneakers.
  - Question: battery duration during data logging?
• The user carries mobile phone all day, an app collects and sends data about accelerometers, gyroscope, etc. periodically.
• The user carries smart band. The app of the app sends periodically data about accelerometers, number of steps, gyroscope, etc. periodically.
• Use of wearables during specific rehabilitation supervised routines. Data annotation by specialists supervising the sesión.

<table>
<thead>
<tr>
<th>Digital Solution proposed</th>
<th>Shoe-embedded Motion Monitoring Device based on IMU technologies and wristband.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Data Analytics</td>
<td></td>
</tr>
<tr>
<td>Technical partners &amp; tasks involved</td>
<td>UCLM: Device development and integration with SHAPES platform.</td>
</tr>
<tr>
<td></td>
<td>Vicom: data analytics.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Components</th>
<th>Wearables (Hardware):</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Microcontroller-based wearable with battery, sensors (IMU) and BLE connectivity. Connection through a bluetooth/wifi gateway.</td>
</tr>
<tr>
<td></td>
<td>Mounting case and body adjustment system (Shoe and Smart band).</td>
</tr>
<tr>
<td></td>
<td>Mobile phone, tablet.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Piloting summary</th>
<th>SAL proposes 2 groups from 4 to 20 people.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Group 1: people carrying out physical rehabilitation.</td>
</tr>
<tr>
<td></td>
<td>Group 2: people not carrying out physical rehabilitation.</td>
</tr>
<tr>
<td></td>
<td>(* groups will include user with dementia).</td>
</tr>
</tbody>
</table>

| Subject profile | To be defined yet in each pilot. |

| Additional comments & bibliography | |

3.24 UC-PT7-001 Monitor older patients when travelling abroad

<table>
<thead>
<tr>
<th>Code</th>
<th>UC-PT7-001</th>
</tr>
</thead>
<tbody>
<tr>
<td>Title</td>
<td>Monitor older patient with chronic disease when travelling abroad</td>
</tr>
<tr>
<td>Pilot Theme &amp; Task</td>
<td>Cross-border Health Data Exchange Supporting Mobility and Accessibility for Older Individuals (Pilot Theme 7, T6.8)</td>
</tr>
<tr>
<td>----------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Piloting Sites</td>
<td>DYPE, UAVR, UCC, UNRF</td>
</tr>
<tr>
<td>Description</td>
<td>Older people suffering from chronic diseases (Heart Failure, Type II Diabetes, Chronic Obstructive Pulmonary Disease) need to be constantly monitored. This need becomes stronger when travelling to another country, adding up to the patients’ and their caregiving relatives’ anxiety. To empower patients and their relatives to efficiently manage their condition outside their “comfort zone”, solutions / tools are required:</td>
</tr>
<tr>
<td></td>
<td>1. to measure vital signs, track activity levels and evaluate behavioural patterns</td>
</tr>
<tr>
<td></td>
<td>2. to remind of medication adherence</td>
</tr>
<tr>
<td></td>
<td>3. to enable patients’ caregivers (physicians, nurses) treat them from “back home”</td>
</tr>
<tr>
<td></td>
<td>thus, preserving the notion that the patient “never left home”</td>
</tr>
<tr>
<td>Digital Solution proposed</td>
<td>Assisted Living Solutions</td>
</tr>
<tr>
<td>Technical partners &amp; tasks involved</td>
<td>• GNO</td>
</tr>
<tr>
<td></td>
<td>• GNO</td>
</tr>
<tr>
<td>Components</td>
<td>• eHealthPass</td>
</tr>
<tr>
<td></td>
<td>• DM4all</td>
</tr>
<tr>
<td>Piloting summary</td>
<td>DYPE will test the system. The number of patients is yet to be decided.</td>
</tr>
<tr>
<td>Subject profile</td>
<td>Older individuals suffering from chronic diseases (mainly Heart Failure)</td>
</tr>
<tr>
<td>Additional comments &amp; bibliography</td>
<td>GNO Presentation</td>
</tr>
</tbody>
</table>
### 3.25UC-PT7-002 Identifying accessible locations and routes for older people

<table>
<thead>
<tr>
<th>Code</th>
<th>UC-PT7-002</th>
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</thead>
<tbody>
<tr>
<td><strong>Title</strong></td>
<td>Foster older people’s (with physical disabilities) independent living by identifying accessible locations and routes in other locations (domestic and abroad)</td>
</tr>
<tr>
<td><strong>Pilot Theme &amp; Task</strong></td>
<td>Cross-border Health Data Exchange Supporting Mobility and Accessibility for Older Individuals (Pilot Theme 7, T6.8)</td>
</tr>
<tr>
<td><strong>Piloting Sites</strong></td>
<td>DYPE, OMN?</td>
</tr>
</tbody>
</table>
| **Description** | Older people with physical disabilities (including deafness, blindness and deafblindness) are usually discouraged from choosing the recreational experience of travelling to other locations (abroad and domestic). Both the need for medical assistance (especially when a chronic disease is also involved) and the little-to-no knowledge of the destinations accessibility and safety conditions act as a turn-off for any decision-making process for traveling and tourism activities. To support this process and the activities that follow it, solutions / tools are required:  

1. to assess and identify the accessibility / safety levels of potential destinations  
2. to enable them to make their way once they have visited their selected destination  
3. to measure vital signs, track activity levels and evaluate behavioural patters  
4. to remind of medication adherence  
5. to enable patients’ caregivers (physicians, nurses) treat them from “back home”  

thus, contributing to their active and independent living in an assertive way. |
| **Digital Solution proposed** | Accessibility & Safety Assessment |
|                              | Assistive Technologies |
|                              | Assisted Living Solutions |
| **Technical partners &**    | ACCESS | Solutions for Active and Healthy Ageing and Independent Living | Task 5.3 |
### tasks involved

- SCIFY | Solutions for Active and Healthy Ageing and Independent Living | Task 5.3
- MedicalSyn | Solutions for Active and Healthy Ageing and Independent Living | Task 5.3
- GNO | Solutions for Active and Healthy Ageing and Independent Living | Task 5.3
- GNO | Solutions for Health and Care Service Providers | Task 5.6
- VICOM | Motivational Engine, Lifestyle Management and Wellbeing Assessment | Task 5.7

### Components

- AccessEarth
- ICSee
- DigiRoom
- eCTouch
- NOTiFY
- eHealthPass
- DM4all
- IT-Health Platform

### Piloting summary

DYPE will test the system. The number of patients is yet to be decided.

### Subject profile

Older people with physical disabilities (including deafness, blindness and deafblindness)

### Additional comments & bibliography

ACCESS, GNO, SCIFY, VICOM presentations

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**3.26 UC-PT7-003 Monitor seniors & prevent medical emergencies**

<table>
<thead>
<tr>
<th>Code</th>
<th>UC-PT7-003</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title</strong></td>
<td>Preventing and/or handling a medical emergency while visiting another country</td>
</tr>
<tr>
<td><strong>Pilot Theme &amp; Task</strong></td>
<td>Cross-border Health Data Exchange Supporting Mobility and Accessibility for Older Individuals (Pilot Theme 7, T6.8)</td>
</tr>
<tr>
<td><strong>Piloting Sites</strong></td>
<td>DYPE, UNRF, OMN?</td>
</tr>
<tr>
<td><strong>Description</strong></td>
<td>Older people suffering from chronic diseases (Heart Failure, Type II Diabetes, Chronic Obstructive Pulmonary Disease) need to be</td>
</tr>
</tbody>
</table>
constantly monitored. This need becomes stronger when travelling to another country, adding up to the patients’ and their caregiving relatives’ anxiety. Certain conditions carry the risk of resulting in critical events, often with life-threatening implications. Monitoring and analysing a patient’s health and lifestyle data can act as a predictor of such events, thus triggering specific precaution measures to avoid those events from happening (or to give the patient enough time to proceed to an emergency room).

If, however, such events do take place, it is of critical significance that access to the patients medical data (medication and patient summary) is available, as well as communication between the patient (and the patient’s accompanying relatives), the patient’s physician and the emergency physician, in order to perform the best informed medical practice.

Monitor & Care

- Measure vital signs
- Track activity levels
- Track location
- Detect shaking
- Detect fall
- Evaluate behavioral patterns
- Notify (patient, caregiver)
- Remind of medication adherence
- Enable remote treatment

Analysis, Assessment & Decision

- Analyze patient’s health & lifestyle data
- Detect anomalies
- Generate alerts
- Predict critical or life-threatening events

Emergency
This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 857159

<table>
<thead>
<tr>
<th>Technical partners &amp; tasks involved</th>
<th>Assistive Technologies</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACCESS</td>
<td>Solutions for Active and Healthy Ageing and Independent Living</td>
</tr>
<tr>
<td>SCIFY</td>
<td>Solutions for Active and Healthy Ageing and Independent Living</td>
</tr>
<tr>
<td>MedicalSyn</td>
<td>Solutions for Active and Healthy Ageing and Independent Living</td>
</tr>
<tr>
<td>GNO</td>
<td>Solutions for Active and Healthy Ageing and Independent Living</td>
</tr>
<tr>
<td>VICOM, TREE</td>
<td>Decision Support and Risk Assessment and Prediction Tools</td>
</tr>
<tr>
<td>GNO</td>
<td>Solutions for Health and Care Service Providers</td>
</tr>
<tr>
<td>VICOM</td>
<td>Motivational Engine, Lifestyle Management and Wellbeing Assessment</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>Components</th>
<th>DigiRoom</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>eCTouch</td>
</tr>
<tr>
<td></td>
<td>NOTiFY</td>
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<tr>
<td></td>
<td>Data Analytics</td>
</tr>
<tr>
<td></td>
<td>eHealthPass</td>
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<tr>
<td></td>
<td>DM4all</td>
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<tr>
<td></td>
<td>IT-Health Platform</td>
</tr>
<tr>
<td></td>
<td>eCare &amp; eHealth</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Piloting summary</th>
<th>DYPE will test the system. The number of patients is yet to be decided.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>UNRF proposes to test the system on 5 seniors travelling out of country or monitoring 5 seniors from other Europe countries</td>
</tr>
</tbody>
</table>
4 Evaluation methodologies

The original plan was to use only critical success factors to validate the SHAPES solution. According to Rockart [17] critical success factors (CSFs) could be defined as the ‘few key areas of activity where favourable results are absolutely necessary for a manager to reach his/her goals’ [18]. For example for business process management usually top management support, project management, project champions, communication and inter-departmental cooperation and end-user training are mentioned [19]. Identifying critical success factors is relevant to prioritise specific valuable resources in resource-constrained contexts [20].

These critical success factors will work very well, if we only want to validate the success of SHAPES as a project. However, after a series of teleconferences with all pilot leaders (see chapter 1.3) and an intensive literature research (see chapter Error! Reference source not found.) it was decided to expand the SHAPES validation to three different areas (see Figure 1) – evaluation of the technology, evaluation of the impact of the SHAPES solution and the evaluation of the organisation and management of the pilots. Only for this third part of the evaluation it makes sense to use critical success factors, for the two other parts of the evaluation better methodologies have been identified and analysed by the consortium.

The first area of evaluation is the performance of the platform/technology/application to be developed. This means the pure technological performance – do all technical tools work as they should and without any errors, are all system requirements fulfilled, are the tools interoperable with the local infrastructure, etc. (see chapter 4.2 for details).
The second one is more difficult. This type of evaluation refers to the **impact of overall solution** of the project. In this area several different methodologies exist (see chapter **Error! Reference source not found.**) and the different large scale pilot projects report about a bandwidth of different ways to perform this evaluation (see chapter **Error! Reference source not found.**). The SHAPES solution will impact the individual persons and the society at large in many different ways – the health status and the well-being of the persons, the satisfaction of the user with the SHAPES solution, the effect on the care-giver, organisational aspects for the health care community, economic aspects for the national health system as well as socio-cultural aspects for the society in general. Thus it is important to choose the evaluation methodology to assess the impact of the SHAPES solution wisely, so that all important aspects of regarding the impact of the SHAPES platform will be covered.

Therefore, in the next subchapter (**Error! Reference source not found.**) we have performed an intensive literature research regarding the different evaluation methodologies in other large scale pilot projects. Subsequently the recommended methodologies are explained in more detail in chapter **Error! Reference source not found.** and the final combination of methodologies used within the SHAPES project is explained and summarized in chapter **Error! Reference source not found.**.

The third aspect of evaluation refers to the **organisation and the management of the pilot activities** themselves. In most large-scale pilot projects there is a learning process from the first pilot activities to the last ones. The consortium has to get to know each other, the end-user organisations (here pilot sites) have to “learn” the new technological tools and applications of the technical partner and the technical partner have to understand the needs of pilot sites and their respective patients and older people. The different ways of planning and organization pilots in Europe have to be discussed and merged to a common planning process for the SHAPES pilots. The basis of a common planning of the SHAPES pilot campaign is described in this deliverable (see chapter 5). However, it is important to reflect after each individual pilot activity if problems or challenges have arisen or if the set up processes, templates and ways of communication needs to be improved. Therefore, after each pilot activity we...
will perform interviews with key personnel of the respective pilot sites to identify lessons learned and develop recommendations, so that the 36 pilot activities and learn from each other and build on the recommendations of the previous ones. The methodology to identify these lessons learned is described in chapter 4.3.6.

4.1 Evaluation Methodologies for large-scale pilots – a literature research

4.1.1 Introduction - why are pilots important for health and care studies?

On 4th Edition of Designing Clinical Research [21], a methodological compendium for clinical researchers (physicians, nurses, pharmacists, psychologists, and other health professionals / researchers), the category “Pilot Studies” is arranged in the section / chapter of “Alternative Clinical Trial Designs and Implementation Issues”, what shows the epistemological and methodological general status of pilots studies, namely its applicability: “Designing and conducting a successful clinical trial requires extensive information […]. Often, the only way to obtain some of this information is to conduct a good pilot study” [22].

This scientific status is not independent from two main applications of them, especially in social sciences, but also in clinical trials. First, the pilot study is adopted by researchers as a feasibility study, which means a “brief test […] with a small number of participants” [22], a “small scale version […] in preparation for the major study” [23]. And second, it is adopted as a testing study, which means a “pre-testing […] of a particular research instrument” [24].

According Teijligen et al. [24, 25] this dual perspective of Pilot Studies is also complemented by the several functions to run a pilot study evoked by researchers, and what they could improve the pilot’s scientific status. Curiously, all functions listed by the authors (Table 5) could be organized in two groups: methodological functions, which represent the main issues and challenges of feasibility study, and bureaucratic functions, which represent the main issues and challenges of testing study.

Table 5 Pilot Studies Functions. [24, 25]

<table>
<thead>
<tr>
<th>METHODOLOGICAL functions</th>
<th>BUREAUCRATIC functions</th>
</tr>
</thead>
<tbody>
<tr>
<td>○ Developing and testing adequacy of research instruments</td>
<td>○ Determining what resources (finance, staff) are needed for a planned study</td>
</tr>
<tr>
<td>○ Assessing the feasibility of a (full-scale) study/survey</td>
<td>○ Training a researcher in as many elements of the research process as possible</td>
</tr>
<tr>
<td>○ Designing a research protocol</td>
<td></td>
</tr>
<tr>
<td>○ Assessing whether the research protocol is realistic and workable</td>
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</tbody>
</table>
Recently, the digital and technological ‘revolution’ brings new issues and challenges for the health field, and pilots’ applications and functions were being analysed by researchers, in order to build a “large bodies of evidence required to support” [26] the digital health scaling-up [26–28].

In common, these literature reviews identified the main issues and challenges for digital health piloting, which, both directly and indirectly, could request an evaluation plan or / and monitoring process. They are:

- Despite digital health solutions having a positive impact to reduce the economic and social burden / budget in general (families, health systems, professionals), especially in societies and economies with low financial budgets, there are yet different accessibilities to eHealth ‘advantages’ and ‘innovations’; for instance, while the richest countries are able to scale digital health solutions with wireless technology, the poorest countries can’t because they have no basic support; nevertheless, the wireless technology would have the biggest impact on poorest countries, where there are no a strong health care system, than in the richest countries, where health and social systems works well (the same analyses fits for a single country or nation). In a global (European) and interconnected world, especially politically and economically (UN; WB; EU), evaluating digital health pilots for scale-up should adopt applications and functions, which are able to assess the impacts and results both globally (more than one country, region or state) and locally (country, community, society, individual) [27, 29].
- Despite the ‘futuristic promises’, eHealth solutions require, today, more investment in “evidence in e-health research”, “supervised training”, “semi-supervised techniques” and “expert clinicians”[26], at the same time ‘traditional’ Health Care Systems have to deal with ‘traditional’ problems and people. Facing these features, evaluating digital health pilots have to be understood as an “assessment and the ongoing collection of relevant data”, which need “purchasing and planning decisions” and “monitor[ing] and modify[ing]” technologies, a “broad description […] that covers technical, clinical, economic, ethical, legal and organizational issues”, such as “the availability of data, the
Digital health innovations in terms of devices and tools are having a greater impact on the monitoring performances, with gains in data collection and analysis, as well as the effectiveness and efficiency of health care. However, the literature emphasizes a set of challenges that should be consider on pilot studies and its evaluation, such as: “continually disturbing the patient with alarms generated by monitoring systems”, with unexpectable or unforeseen impacts and results; regarding only wireless technology, there are “phantom effects” into the signal when recording data less frequently than twice the fastest change in the data”; the lack of digital knowledge and skills on both health professionals and ‘patients’ could be wrongly interpreted and generating false-alarms, and unfeasibility tests and treatments; and the “new patterns in the data, with which clinical teams may not be familiar and which they may find difficult to interpret” [27].

This conjunctural scenario is now increasing the pressure under the pilot studies on digital health and under the effects of evaluation, both to validate devices, tools and programs scientifically, and to scale them [24–28]. In fact, the SHAPES Project aims to develop an evaluation methodology, which should ensure the scientific ‘prove’ for a range of eHealth “supporting Systems” addressed to “Smart and Health Ageing through People Engaging”.

However, despite the growing number of pilot studies in the digital health field, a sparse and scattered body of expert research regarding evaluation pilots in digital health field were evidenced by the literature review [30]. The literature also showed the lack of full and detailed reports and articles about evaluation issues and challenges, instead it showed the trends to only justify the methods or research tools, as well as to give a description of the pilot as whole [25, 28], for instance the Protocol as whole or just a resume.

Additionally, the evaluation field is shared by the scientific organizations (like research centres) and the consultancy expertise and companies. While the first often use the scientific methodologies in their evaluation’s activities; the second is building on evaluation programs or toolkits, which often improve the usability of scientific methodologies.

In conclusion, evaluating digital health pilots should to be strategically oriented by a ‘strong’ evaluation concept and definition, which are commonly recognised by different stakeholders, such as: researcher centres, companies, funders, governments, civil society, among others.
4.1.1 The difference between monitoring and evaluation for interventions - the maturity lifecycle

This section aims to conceptualize the differences and linkages between monitoring and evaluation within the “maturity life-cycle” of the interventions\(^2\) in Digital Health, based on WHO Guide [30], “Monitoring and Evaluating Digital Health Interventions. A practical guide to conducting research and assessment”. Three main criteria were adopted for this option\(^3\).

First, WHO is the most important global organization for health, and it is accepted by most health professionals and organizations around the world. Second, the Guide was developed on the basis of an accurate body of literature regarding digital health evaluation methodologies, which is largely accepted by researchers. Third, the Guide advocates an interactive model between monitoring and evaluation, in order to run a “maturity life-cycle” of Digital Health interventions.

\(^2\) For WHO, “interventions” means “projects, programmes, initiatives and other activities that are being monitored and evaluated” [30]. We also understand it as pilot studies.

\(^3\) In general, the Guide aims to give a practical and theoretical contribution for evaluation and monitoring of the Digital Health solutions, in order to “harmonize” methodologies for validation and scale-up, but also to “learn” from ongoing experiences. This Guide was a “collective learning […] with agencies working to strengthen their digital health deployments, develop robust evaluations, and scale up their activities nationally and regionally” [30].

This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 857159
Considering the innovative features of digital health interventions on the last decade, the WHO recognized a common “maturity life-cycle” (Figure 6) from prototype stage to scale-up goals, as well as it understood that “during this life-cycle, concurrent monitoring and evaluation activities should be planned, often in parallel, supporting each other” [30].

During this cycle, monitoring and evaluation activities are evolving from the initial point to the last (intervention maturity over time). In this timeline, variables like “functionality, stability, fidelity, quality” should be monitored, and, at the same time, the evaluation should assess outcomes and impacts, such as “usability, efficacy, effectiveness, implementation research, feasibility, economic / financial”. On this end, the issues addressed are concerned with a scale-up, such as integration, ethics, sustainability, by national and international policy actors, especially by health field (organizations, professionals, individuals) [30].

Regarding to monitoring, or the “monitoring process”, WHO defined it as a “routine collection, review and analysis data”. This process is critical to ensure the “course-
corrections” of the interventions, especially regarding “technical specifications”, “system stable and error-free”, “tasks consistently and dependably”, “variations in implementation across sites” and “benchmarks deployment”; moreover, monitoring should be an interactive process, which allows the entails’ collecting and analysing in “multiple time points” of the interventions, and giving critical information about optimization, “quality and consistency of the deployment” [30].

WHO understood the evaluation as a “systematic and objective assessment of an ongoing or completed intervention [which aims to determinate] the fulfilment of objectives, efficiency, effectiveness, impact and sustainability”. Nevertheless, this understanding of evaluation is only regarding, on the one hand, to the interactivity between users / health system and digital health solutions empowered; and on the other hand, the changes caused by digital health interventions [30].

Thus, the evaluation is suitable to assess metrics from the extrinsic / outward features of the intervention. In addition to those metrics previously identified (usability, efficacy, effectiveness, feasibility), “contextual readiness” of digital health interventions should be assessed by the evaluation plans; WHO identified the “connectivity, electrical grid stability, mobile phone access” [30]. In this particular, WHO provided a range of questions to support the evaluation of those metrics (Table 6).

The evaluation plan must be a ‘tool’ for “generating data” which allows “observed changes in behaviour, processes or health outcomes” attributed to the intervention; in other words, evaluation should be the process to “demonstrate attribution”, that is measure the change level from the external features. However, the “attributing change” is the most problematic challenge of evaluation plan, in terms of methodologies selected, quality of data collected and correctness of the “comparison” or “counterfactual” [30].

Table 6 Questions used for measuring metrics [30].

<table>
<thead>
<tr>
<th>METRICS</th>
<th>QUESTIONS</th>
</tr>
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<tbody>
<tr>
<td>Usability</td>
<td>Is the digital health system usable by the targeted end-user(s), and does it fit within their workflow?</td>
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<tr>
<td></td>
<td>How steep is the learning curve before a user can demonstrate proficient system use?</td>
</tr>
<tr>
<td></td>
<td>What are the rates of error – in using the system or in workflows – as a result of system use/misuse?</td>
</tr>
<tr>
<td>Efficacy</td>
<td>Has the digital health intervention changed processes (e.g. time between event X and response Y) in a research setting?</td>
</tr>
<tr>
<td></td>
<td>Has the digital health intervention changed outcomes (e.g. worker performance, such as guideline adherence, or patient health outcomes) in a research setting?</td>
</tr>
<tr>
<td>Effectiveness</td>
<td>Has the digital health intervention changed processes (e.g. time between event X and response Y) in a non-research setting?</td>
</tr>
</tbody>
</table>
Despite their differences, monitoring and evaluation could be understood by the “two faces” of the “maturity life-cycle” already presented. In fact, the evaluation works from monitoring performance, namely its data collection and analysis. Pritchett et al. [31] resumed this relationship with following sentence: “while monitoring asks: ‘is the project doing things right?’ evaluation asks: ‘is the project doing the right things?’”.

According to these authors, there are two methodological risks in the M&E approach. First, the risk of a “vicious circle” on the monitoring process, that is motivated by the emphasis on “[data] input utilization and process compliance” instead “date and reliable monitoring data”, which doesn’t feed the decision-making, thereby, there is not an effort on monitoring data “reliable or timely”. Second, the risk of “comparisons”, in other words, reducing the evaluation plan to a “crude ‘before and after’ comparison”, without a “coherent counter-factual” analysis which assess the causality between interventions’ inputs and the outcomes for target groups [31].

Facing these risks, the WHO Guide recommended the “seven-steps pathway” for monitoring and evaluating digital health interventions [30], based on “first generation of M&E approach”. In this generation, M&E is structured by a logical framework approach which ensure the rationality for internal and external metrics and measures, thereby, a logical interactivity between monitoring and evaluation [31] (Figure 7).

The “seven-steps pathway” should be understood as a methodological framework which organizes a plan for monitoring and evaluation a digital health intervention, from

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**Table 1.3**

<table>
<thead>
<tr>
<th>Dimension</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Cost</strong></td>
<td>Has the digital health intervention reduced costs associated with the delivery of health services? Has the digital health intervention introduced costs that are commensurate with benefits provided?</td>
</tr>
</tbody>
</table>

Has the digital health intervention changed outcomes (e.g. worker performance, such as guideline adherence, or patient health outcomes) in a non-research setting?

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**Figure 7** Schematic diagram of the interplay between monitoring and evaluation activities. Source: [30], adapted from [31].
the definition of initial stage of the intervention to development / running the monitoring and evaluation activities (Figure 8).

Framed by the logical approach, the ‘pathway’ should begin with the assessment of the initial stage of the intervention, the evaluation plan and the appropriate claims (Figure 9). Then, it's necessary defining “an underlying framework” (Step 2) and “evidence needs and evaluation objectives” (Step 3), which explain the theoretical rationality of the monitoring and evaluation objectives and its relationships, as well as the intervention outcomes and impacts, but also their indicators. The fourth step is the decision about the monitoring and evaluation design, optimal and appropriate [30].

The fifth and sixth steps are the selection of, respectively, the team to run the monitoring and evaluation activities, ensuring it independence; and the times and resources for developing the monitoring and evaluation, which should be suitable with the intervention “maturity life-cycle”. The last step is the design of implementation plan for monitoring and evaluation plan, which have to be “realistic”, thereby, includes: “a structured list of activities and sub-activities”, “responsible persons assigned to activities”, “a timeline and target dates”, and “the budget and details of other resources required” [30].
In conclusion, there are **three main lessons from WHO Guide** regarding to the evaluation of large-scale pilots which are integrated on pilots’ campaign. They are:

- Each single pilot should consider **two related processes for its evaluation**. First, a **monitoring process** which is regarding the data collection and analysis during the pilots’ activities. Moreover, this process should be running in order to understand the implementation of the pilots’ Protocol, but also to the “quality and consistency of the deployment” [30]. Second, an **evaluation plan** or program which aims, on the one hand, to run a “systematic and objective assessment of an ongoing [and] completed intervention”, as well as the users’
interactions with the digital solutions piloted; and, on the other hand, to understand “the changes caused by” the pilots’ use cases [30].

- The difference between monitoring process and evaluation plan could be adopted to differentiate the pilots’ research project, which also included an evaluation aim on their Protocols, from the evaluation of the pilots’ campaign as whole, which have to include the assessment of the outcomes from each pilot. Based on WHO Guide, it’s possible to conceptualize the evaluation of each pilot as a monitoring process of the evaluation of pilot’s campaign. This option is relevant to ensure the autonomy of each pilot and its research Protocol, as well as the pilots’ campaign. In other words, the pilots’ campaign is understood a complex and large-scale intervention [32] if each pilot project is being considered in its autonomy with their evaluation’s aims. In this sense, while each single pilot is relevant to assess the critical information about optimization and “quality and consistency of the deployment” of the digital solutions piloted; the evaluation of the pilots’ campaign is critical to determine “the fulfilment of objectives, efficiency, effectiveness, impact and sustainability” of the intervention as a whole [30].

- The monitoring and evaluation of pilots and pilot’s campaign could be developed based on the common “maturity life-cycle” [30], which starting on the prototype stage and finishing in scale-up goals. Under this maturity lifecycle, on the one hand, the pilots and the pilots’ campaign should be understood as a stage of the intervention as whole; on the other hand, the monitoring and evaluation plan should be especially related to the intervention as a whole, and not only the pilots itself. In this sense, there will be an evaluation plan common for all pilots, which clearly define the outcomes and impacts expected on the end of intervention, not only the pilots’ campaign, but the Project as whole. This evaluation plan should be integrating all the outcomes and impacts expected for each pilot, but also the outcomes and impacts expected by the Project, namely regarding the scale-up and integration or sustainability.

4.1.2 Monitoring & Evaluation paradigms: a multi-perspective overview

Globally, from classical scientific traditions, there are two dominant paradigms to give rationality for monitoring and evaluation programs: the Qualitative and the Quantitative paradigms. Both qualitative and quantitative paradigms represent the main scientific traditions in terms of epistemological and methodological theories and practices. Each approach has one perspective about reality (objective, subjective and intersubjective) and the best ‘ways’ to know them and to produce knowledge about them.

Furthermore, the relationships and interactions between both approaches - Triangulation - are often valued by researchers, mostly to deal with complex issues, such as a large-scale pilot or other complex and multi-national initiatives.
The **Qualitative paradigm** has no consensus in terms of its rigor and credibility for evaluation program, but, increasingly, there are qualitative dimensions of knowledge into an evaluation program, especially methods of data collection and analysis. For example: reflection and reflexivity; point of redundancy; accuracy of data collection; field-based and non-manipulative and non-controlled evaluation works; multiple views and perspectives about reality(ies); participation and participatory activities; unintended consequences; listening and learning; naturalistic inquiry; appreciative inquiry; and facilitating [32].

Two critical issues are addressed to this approach. First, the evaluation designers and staff and the stakeholders have to be aware that, in qualitative evaluation, the “evaluator” is an instrument of the evaluation. In other words, it’s the evaluator or evaluators who have the main role in data collection and, minor, on data analysis. Second, “there is a tendency to drift toward trying to explain qualitative data with quantitative language”, overvalue the numerical impacts / effects / outcomes (objective reality) than the significant and sensitive means (subjective / intersubjective reality) [32].

The **Quantitative paradigm**, on the contrary, is dominant and foundational in evaluation programs of large-scale, multi-national and complex initiatives. Traditionally, this approach is adopted because of its mathematical modelling tools, like systems of equations or statistical modelling. The mathematic modelling, into an evaluation quantitative approach, have many advantages as: to explain development chains; to control and monitoring rates; to measure impacts not directly (trends, predictions); to estimate / measure benefits, cost-benefit, cost-effectiveness and / or impact projections; to code models for data collection and analysis; to predict impacts and effects; and to move from small to large scale projections [32].

Some **issues and challenges** on these paradigms have been aware by experts, especially what they named a “black box” of evaluation program structure. The quality of the approaches depends on the **quality of a data collection** and analysis, and a **specific expertise** and experts (mathematicians, statistics staff, etc.). Moreover, the outcomes are often not measured on large-scale initiatives, what is expensive, but only through the intermediate process that it does not map the outcomes as a whole, for instance, pilots with **small samples** and controlled environment [32].

Facing these issues and challenges, [32] identified the **Triangulation paradigm** as a ‘third-way’, by the following critical features:

- “Triangulation is most commonly used in both situations where data are “unreliable or scarce”, and it’s “adopted an iterative and inclusive approach that engages stakeholders to help identifying and address information and data gaps”;
“Triangulation among multiple sources and multiple evaluators and stakeholders enhances the robustness, quality and credibility of evaluation conclusions and recommendations”;

“Triangulation reduces the risk of giving excessive importance to one method over the other methods”.

Considering these paradigms, the monitoring and evaluation **multi-perspective should be an option** for evaluator’s teams and experts. This standpoint was argued by Institute of Medicine [32], to explain that there are no equal monitoring and evaluation programs, and each one serves one specific purpose. Essential features of evaluation programs, like rigor, objectivity, feasibility and theory of change, are always dependent on strategic choices and their relationships with context and purposes.

For their evaluation experts, more than to know an monitoring and evaluation model or tool, it’s important to be aware of “transferable insights” gained across the spectrum of the scientific literature and practical experiences about them, but also of “benefits and limitations” of different epistemological and methodological options; they were also aware of stakeholders’ purposes [32].

In this regard, they defended that the **evaluation of complex initiatives requires trade-offs** (balance of independence, interdependence), as well as different options should be considered to improve the evaluation programs and their effects (scale-up, replication, contextual impacts). There are key features considering by monitoring and evaluation designing [32]:

- **“Multiple goals** for an evaluation may not be incompatible but often require different approaches”;
- “Evaluation can enhance their value by building in-country capacity and by involving more local participants in the evaluation”;
- “A large-scale data infrastructure that includes a wide variety of data sources could be a powerful research tool”;
- “The time frame and budget of an evaluation are critical factors in designing data collection and analysis for a complex evaluation”;
- **Financial data** can help assess the efficiency of a program and the return on an investment”;
- It is important to design the evaluation and interpret findings in the **context which initiatives are implemented by users and stakeholders**.

In resume, a **multi-perspective overview** should be understood as a critical standpoint to design the monitoring and evaluation program, without a ‘scientific obligation’ to adopt a specific paradigm, as well as ‘their’ methods and approaches. In other words, all the paradigms, which one with their ‘pros and cons’ could be integrated
in order to be able to foresee the expected impacts of the particular complex and large-scale intervention, the not expected impacts, as well as how and why achieve them.

4.1.3 From multi-perspective overview to evaluation methodologies

This section aims to provide a list of methodologies often adopted on monitoring and evaluation activities, which are strongly connected with traditional scientific research methodologies and tools to collect and analyse data, and/or to produce outcomes, results or recommendations. There are two main approaches suggested by scientific literature and institutional recommendations: the Logic Chain or Logic Model; and the Theory of Change [33].

The first, Logic Chain or Logic Model, describes, crisply, the expectations, conditions, problems, contexts, logic and sequential flow of the evaluation program, in order to be accessible and understandable to all stakeholders. The second, Theory of Change, provides an explanatory and predictive statement of how and why the component will perform, deliver and interface in achieving the program’s success. The last one, particularly, takes the components of model logic to construct a single theory of change for each evaluation program and its evaluative activity / methodology [33].

Under the question “how can evaluation sponsors and evaluators decide how to design evaluation with so many models to choose from?” [34], this evaluator expert conceptualized the evaluation methodologies into two different traditions: Programme Evaluation and Organization Evaluation or Organizational Effectiveness.

The first consists in a study which assesses an object’s merit and/or worth, but also a set of actions organized and planned to address a social problem. The second suggests that the evaluation is to increase the organizational efforts (administration performance, government interventions), to improve practical action situations in the future. Moreover, both traditions were dealing with how to conduct assessments (approaches, criteria and values), they are both applicable to organizations, and they are, often, overlapping on the same evaluation program or project.

In the same literature review, the author resumed different evaluation methodologies, into six categories: results models, process models, system models, economic models, actor models, and program theory models (Table 7). Based on this, the author underlined some critical features of evaluation models and methodologies [34], such as:

- All models have “their strengths and weaknesses” and “the choice of a model (or combination of models) thus entails that certain aspects fall into focus, while others are excluded”;
- Some models (goal-attainment model; economic models) are built on a notion of objectivity and with a notion that “evaluation can yield objective results”; while
others (stakeholder model) is based on a notion of the conflict and “the criteria for assessment are not clearly stated ex ante, but formulated in the evaluation process”;

- Despite the variety of evaluation approaches and models, from practical positions and perspectives, it’s difficult to mix them and to discuss theoretical, methodological principles and criteria for the choice of (combinations of) evaluation models.

Table 7 Typology of Evaluation Models [34]

<table>
<thead>
<tr>
<th>Evaluation Methodology</th>
<th>QUESTIONS</th>
<th>Criteria Evaluation</th>
</tr>
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<tbody>
<tr>
<td>Result Models</td>
<td></td>
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</tbody>
</table>
| a) Goal-attainment model | a) To what degree has the goal(s) been realized?  
  b) Which effects can be uncovered? | a) Derived from goal(s)  
  b) Open, all consequences should be uncovered |
| b) Effects model       |           |                     |
| Explanatory Process Model | Is the level of activity satisfactory?  
  Are there implementation problems? | Performance is analysed from idea to decision and implementation and to the reaction of the addressees |
| System Model           | How has performance functioned as a whole? | Realized input, process, structure and outcome assessed either in relation to objectives in same dimensions or comparatively |
| Economic Model         |           |                     |
| a) Cost-efficiency     | a) Is productivity satisfactory?  
  b) Is effectiveness satisfactory?  
  c) Is utility satisfactory? | a) Output measured in relation to expenses  
  b) Effect measured in relation to expenses  
  c) Utility measured in relation to expenses |
| b) Cost-effectiveness  |           |                     |
| c) Cost-benefit        |           |                     |
| Actor Model            |           |                     |
| a) Client-oriented model | a) Are clients satisfied?  
  b) Are stakeholders satisfied?  
  c) Is professional quality in order? | a) Formulated by clients  
  b) Formulated by stakeholders  
  c) Formulated by peers |
| b) Stakeholder model   |           |                     |
| c) Peer review model   |           |                     |
| Programme theory model |           |                     |
| (theory-based evaluation) | What works for whom in which context?  
  Is it possible to ascertain errors in programme theory? | Programme theory is reconstructed and assessed via empirical analysis |

Based on the “Evaluation Theory Tree” model [35], which purposed three models of evaluation programs (evaluation based on knowledge construction and their constraints; evaluation based on value judgment; and evaluation based on decision-making), Carden and Alkin [36] proposed three news evaluation methodologies to include the evaluation experiences from low and middle-income countries (LMIC) or ‘Global South’: adopted, adapted and indigenous methodologies (Table 8). They
argued that the “evaluation roots” of LMIC countries has been laid by ‘Global North’ agencies and “evaluation [methodologies] was developed and expanded by these agencies as a tool to support the delivery of their projects in developing countries”.

Table 8 Three methodologies adopted in LMIC countries [36].

<table>
<thead>
<tr>
<th>ADOPTED Methodologies</th>
<th>ADAPTED Methodologies</th>
<th>INDIGENOUS Methodologies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Methodologies transferred from systems developed in North America and Europe for use in LMIC through training activity, and without adaptation to the local context. To ensure a body of local evaluators and consultants who understood both the local cultural and political norms and the language. Logical Framework Analysis is one of the key adopted methodologies, but other methods are “adopted”: experimental and quasi-experimental methods and randomized controlled trials (RCT).</td>
<td>Methodologies designed by ‘Global North’ theorist but explicitly concerned with application in LMIC countries and its socio-cultural, political, economic, and ecological settings. To include significant engagement with the locals, they are built on practice, to assume context specificity and to expect modifications of the methodology. Participatory methodologies are the key adapted methodologies, like a rapid rural appraisal, participatory rural appraisal, outcome mapping, significant change.</td>
<td>Methodologies developed in the LMIC countries by locals’ specialists, but which are influenced by adopted and adapted methodologies and their tradition there. Example 1: The African Peer Review Mechanism, inspiring by OCDE Peer Review, is developed by Africans and is applied by indigenous teams and leads to African-based assessments. Example 2: The Sistematización (systematization) is a Latin-American methodology inspired by Paulo Freire and the participatory action research adapted the Latin American context.</td>
</tr>
</tbody>
</table>

In order to develop the Rainbow Framework Model (see next section), the BetterEvaluation agency made a wide review of evaluation approaches, which defined as an integrated package of options (methods or processes), to support specific evaluation questions or challenges, as well as to use a widely combination of the options (Table 9).

This review is an important literature review because it includes most evaluation methodologies adopted by scientific research, such as Developmental Evaluation [37–40], Collaborative Outcomes Reporting / Participatory Evaluation [41, 42], Qualitative Impact Assessment Protocol [39, 43–45], or Realist Evaluation [46, 47].

Table 9 Evaluation approaches by BetterEvaluation.⁴

<table>
<thead>
<tr>
<th>APPROACH OR METHODOLOGY</th>
<th>DEFINITION</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appreciative Inquiry</td>
<td>A strengths-based approach designed to support ongoing learning and adaptation by identifying and investigating outlier examples of good practice and ways of increasing their frequency.</td>
</tr>
</tbody>
</table>

| **Beneficiary Assessment** | An approach that focuses on assessing the value of an intervention as perceived by the (intended) beneficiaries, thereby aiming to give voice to their priorities and concerns. |
| **Case study** | A research design that focuses on understanding a unit (person, site or project) in its context, which can use a combination of qualitative and quantitative data. |
| **Causal Link Monitoring** | An approach designed to support ongoing learning and adaptation, which identifies the processes required to achieve desired results, and then observes whether those processes take place, and how. |
| **Collaborative Outcomes Reporting** | An impact evaluation approach based on contribution analysis, with the addition of processes for expert review and community review of evidence and conclusions. |
| **Contribution Analysis** | An impact evaluation approach that iteratively maps available evidence against a theory of change, then identifies and addresses challenges to causal inference. |
| **Critical System Heuristics** | An approach used to surface, elaborate, and critically consider the options and implications of boundary judgments, that is, the ways in which people/groups decide what is relevant to what is being evaluated. |
| **Democratic Evaluation** | Various ways of doing evaluation in ways that support democratic decision making, accountability and/or capacity. |
| **Developmental Evaluation** | An approach designed to support ongoing learning and adaptation, through iterative, embedded evaluation. |
| **Empowerment Evaluation** | A participatory approach designed to provided tools and knowledge so they can monitor and evaluate their own performance. |
| **Horizontal Evaluation** | An approach to learning and improvement that combines self-assessment by local participants and external review by peers. |
| **Innovation History** | A particular type of case study used to jointly develop an agreed narrative of how an innovation was developed, including key contributors and processes, to inform future innovation efforts. |
| **Institutional Histories** | A particular type of case study used to create a narrative of how institutional arrangements have evolved over time and have created and contributed to more effective ways to achieve project or program goals. |
| **Most Significant Change** | Approach primarily intended to clarify differences in values among stakeholders by collecting and collectively analysing personal accounts of change. |
| **Outcome Harvesting** | An impact evaluation approach suitable for retrospectively identifying emergent impacts by collecting evidence of what has changed and, then, working backwards, determining whether and how an intervention has contributed to these changes. |
| **Outcome Mapping** | An impact evaluation with theory of change, provides a framework to collect data on immediate, basic changes that lead to longer, more transformative change, and allows for the plausible assessment of the initiative’s via ‘boundary partners’. |
| **Participatory Evaluation** | To engage stakeholders (especially intended beneficiaries) in conducting the evaluation and/or making decisions about it. |
Participatory Rural Appraisal / Participatory Learning for Action

A participatory approach which enables farmers to analyse their own situation and develop a common perspective on natural resource management and agriculture at village level.

Positive Deviance

A strengths-based approach to learning and improvement that involves intended evaluation users in identifying ‘outliers’ – those with exceptionally good outcomes - and understanding how they have achieved these.

Qualitative Impact Assessment Protocol

An impact evaluation approach without a control group that uses narrative causal statements elicited directly from intended project beneficiaries.

Randomized Controlled Trials

An impact evaluation approach that compares results between a randomly assigned control group and experimental group or groups to produce an estimate of the mean net impact of an intervention.

Realist Evaluation

An approach specially to impact evaluation which examines what works for whom in what circumstances through what causal mechanisms, including changes in the reasoning and resources of participants.

Social Return on Investment

A participatory approach to value-for-money evaluation that identifies a broad range of social outcomes, not only the direct outcomes for the intended beneficiaries of an intervention.

Success Case Method

An impact evaluation approach based on identifying and investigating the most successful cases and seeing if their results can justify the cost of the intervention (such as a training course).

Utilization-Focused Evaluation

Uses the intended uses of the evaluation by its primary intended users to guide decisions about how an evaluation should be conducted.

In 2017, the Global Innovations in Measurement and Evaluation reported the methodological trends which have “potential to improve evaluation and program design” based on “cutting-edge technology” and “growing application of ideas that push practice beyond ‘traditional’ models of evaluation” [48].

This review paid especial attention to five innovative criteria for evaluation design and implementation: “overcoming previous barriers to good evaluation practice”; “providing more meaningful or robust data”; “using data to support decision-making, learning and improving practice”; “increasing equality between users, service deliverers and funders”; and “offering new contexts for collaboration that improve the utility of data” [48].

In Table 10, there is a summary of each methodology identified by the report.

Table 10 Global Innovative Evaluation Methodologies [48].
<table>
<thead>
<tr>
<th>USER-CENTRIC EVALUATION</th>
<th>Involve service users meaningfully in evaluation.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Consider user voice in all stages of evaluation.</td>
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<tr>
<td></td>
<td>Shift the power dynamic to a dialogue with users.</td>
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<tr>
<td></td>
<td>Facilitate by technological devices.</td>
</tr>
<tr>
<td></td>
<td>User feedback improves other data source.</td>
</tr>
<tr>
<td></td>
<td>Users’ perceptions as key indicators.</td>
</tr>
<tr>
<td></td>
<td>Make findings more compelling to decision-makers.</td>
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<tr>
<td></td>
<td>Robustness of evaluation by making the evaluation</td>
</tr>
<tr>
<td></td>
<td>design and implementation) relevant and meaningful.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>SHARED MEASUREMENT &amp; EVALUATION</th>
<th>For organisations with similar missions, programmes or users (same metrics).</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Strictly connected to systems change, collective impact initiatives and place-based approaches.</td>
</tr>
<tr>
<td></td>
<td>Building shared measurement methodologies, and pooling findings about needs and outcomes.</td>
</tr>
<tr>
<td></td>
<td>To create a bigger dataset that can support stronger conclusions (pooling information).</td>
</tr>
<tr>
<td></td>
<td>To understand the quality of their performance in relation to a sector-wide standard.</td>
</tr>
<tr>
<td></td>
<td>To enable organisations to better target interventions or plan services.</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>THEORY-BASED EVALUATION</th>
<th>Realistic evaluation which focuses on understanding how different contexts interact with mechanisms to lead to outcomes.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Focus the complexity of social systems, that it's not feasible to control.</td>
</tr>
<tr>
<td></td>
<td>Acquiring partial knowledge is the aim of evaluation, rather than seeking 'proof'.</td>
</tr>
<tr>
<td></td>
<td>Getting better at dealing with the complexity of social systems.</td>
</tr>
<tr>
<td></td>
<td>Replicate programs in a new context with different beneficiaries, understanding it.</td>
</tr>
<tr>
<td></td>
<td>Identify the mechanisms that are most instrumental to outcomes (based on theory of change), or the ones for which there is currently the least existing evidence.</td>
</tr>
</tbody>
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<table>
<thead>
<tr>
<th>IMPACT MANAGEMENT</th>
<th>Integrate impact assessment into strategy and performance management.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Evaluation activities are routine and aimed at learning, making corrections, and addressing uncertainties.</td>
</tr>
<tr>
<td></td>
<td>Facilitated by technologic devices and design principles (agile and lean), which emphasise testing and iteration.</td>
</tr>
<tr>
<td></td>
<td>The changes that many social purpose organisations seek are complex. Impact management allows organisations to test what is working, learn and adapt during programme delivery.</td>
</tr>
<tr>
<td></td>
<td>Help guide programmes towards better outcomes and better impact management (from small to large scale).</td>
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<table>
<thead>
<tr>
<th>DATA LINKAGE</th>
<th>Bringing together different but relevant data and creating more comprehensive datasets.</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Information about specified group of users from beyond a single organisation or sub-sector dataset.</td>
</tr>
<tr>
<td></td>
<td>Facilitated digital devices.</td>
</tr>
<tr>
<td></td>
<td>Identify trends or better understand the impact of specific interventions or populations.</td>
</tr>
<tr>
<td></td>
<td>Create comparison groups matched by characteristics, context and need, and add to pre-existing evaluation to provide more robust findings about impact.</td>
</tr>
</tbody>
</table>
BIG DATA
Harnessing the volumes of data that are all around us
- Data generated as a by-product of digital transactions and interactions (what people say or do online).
- Described as ‘real time’ although that doesn’t necessarily mean it is always immediately available.
- Sophisticated powers of prediction and generate new local, national and global insights, through technological and digital devices.
- Identify trends, patterns and behaviours, and understand what causes them using other information.

REMOTE SENSING
Having technology do the measuring for us
- Facilitate by digital and technological revolution (mobile phones, sensors placed in certain locations, or even satellites).
- Used both in the private and public spheres to map individual behaviours, in real time.
- Remote sensing can facilitate data collection from locations that are isolated or disparate, or in situations where data collection would not otherwise be possible or cost-efficient.
- New forms of data and new sources for collecting.

DATA VISUALISATION
Presenting information visually to uncover insights
- Practice of presenting data in a graphic, visual and engaging form.
- To see patterns that would not be obvious using conventional methods of data display.
- Facilitated by digital technology.
- More accessible to non-specialists.
- More attractive and accessible way.
- Encourage engagement and feedbacking.
- Communication of findings is more effective.

4.1.4 Evaluation toolkits and models

In this section, seven ‘toolkits or models’ are analysed in order to identify their scientific frameworks, as well as to understand their evidence-based and community-based focus. These models are widely adopted on active and healthy ageing pilot campaigns. They are the Monitoring and Assessment Framework for the European Innovation Partnership on Active and Healthy Ageing (MAFEIP), the Model for Assessment of Telemedicine Applications (MAST), the mHealth Assessment and Planning for Scale (MAPS), the Rainbow Framework, the Healthcare Innovation Cycle, the tools and techniques of the project MOMENTUM and the NASSS framework.

4.1.4.1 MAFEIP – theoretical background

The MAFEIP Model was developed under the European Innovation Partnership on Active and Healthy Ageing (EIP-AHA), by two consulting companies (Open Evidence and Empirica), funded by European Union. This model was a result of the study and training which included evidence-based data, users’ feedback, recommendations, in order to design and conduct an evaluation tool for EIP-AHA related initiatives [49–53].
For EIP-AHA, which was a funder-stakeholder, the MAFEIP Model should be able “to estimate the health and economic outcomes of a large variety of social and technological innovations in the health and care sector”, in order to “achieve the anticipated impact, and also help to identify what drives interventions’ effectiveness or efficiency in order to guide further design, development or evaluation” [53].

The MAFEIP tool rests on the principles of Decision Analytic Modelling (DAM), an approach that is commonly used in health economic evaluations to assess the health and economic impact of healthcare innovations. More precisely, MAFEIP is based on a generic Markov model, which provides the flexibility required to be adaptable to a large number of commitments within the six thematic Action Groups of the EIP on AHA. These Action Groups focus on a variety of objectives, implement different interventions and target different cohorts of individuals with different demographic or disease characteristics. The outcomes for the intervention and the control group are calculated by simulating the health status of the target population. This is done by simulating the transition of the target population between different health states defined in the Markov model. The MAFEIP tool has been upgraded to allow the user to choose the number of states of the Markov model, which varies from 3 to 5 i.e. there is a 3-state model, a 4-state model, and a 5-state model to choose from depending on which model best reflects the intervention to be assessed [53].

The combinations are depended on the interaction between, on the one hand, the “baseline” which represents “the general health status of the target population”, and on the other hand, the “disease / impairment health state”, which reflect a “health status of people” before and after intervention. There are three ‘crudes’ transition probabilities of combinations: the patient’s health condition gets worse; the patient’s health condition get better; the patient die [53].

Moreover, the incremental health gains of any intervention are estimated into a MAFEIP with both “parameter estimates for the respective intervention under assessment” and “parameters corresponding to the standard care scenario”. Nevertheless, these “scenarios may differ in terms of the transition probabilities (disease incidence, recovery and mortality), as well as the Health-related quality of life (HRQoL) weight, healthcare and societal costs attached to the health states” [53] (Figure 10).
The MAFEIP model is also a **web-based tool** for a large variety of ICT-enabled social and health innovations, including new care pathways, devices, surgical techniques, and organisational models, among others. Based on it, the ‘evaluators’ are able to simulate changes in the interventions and especially to detect the key determinants of their effectiveness and usefulness and guide further design, development or evaluation. The Model “has achieved a high level of maturity and has gone through a collaborative improvement and refinement process which makes it usable and flexible to adapt to different kinds of users far beyond the EIP on AHA context”⁵.

### 4.1.4.2 MAST – theoretical background

The MAST Model was developed within the **MethoTelemed Project** (Methodologies for Assessing Telemedicine Applications), which was funded by European Union through the “SMART 2008/0064: Assessing the effectiveness of telemedicine applications”⁶, in order to design a “new model for assessing the effectiveness and contribution to quality of care of telemedicine applications” [54].

In this context, MAST should be understood as a framework to support the decision-making from different stakeholders involved in telemedicine solutions and care systems (clinicals, managers, politics, hospitals, communities, regions, government department, biotech industry), in terms of “most appropriate technologies to be...
used in the most cost-effective way”; moreover, it’s understood as “a structure of aspects or outcomes of telemedicine applications that should be included” [54].

Within the MethoTelemed Project, the MAST Model was created by two ways related to each other: a review of the scientific literature [55] and two workshops with stakeholders and users of telemedicine [56]. As a result, the authors developed the theoretical and practical toolkit (Figure 11), which organize logically in three sets what should be “the different elements in the model for assessment of telemedicine”, that are: “preceding considerations”, “multidisciplinary assessment” and “transferability assessment” [54].

Based on MAST, evaluating / assessing telemedicine solutions have to start with preceding considerations, which aims to understand: the purpose of telemedicine solutions; if there are alternatives and how they can be compared with a main solution; the “level in the health care system (local, regional, national) at which the assessment should be produced and whether the telemedicine application is a mature technology” [54].

This initial stage is followed by a multidisciplinary assessment, which describes and assess “the different outcomes and aspects of the specific telemedicine application”, listed in the Figure 11. These outcomes were divided in seven groups that were built “based on the EUnetHTA core model and results from the two workshops with stakeholders” [54].

The last set of elements have a focus on the outcomes descriptions in order to understand “transferability of the results found”, in two different logics of scalability: from the literature review to the intervention, such as “the assessment of the results found in the literature”; and/or “from small scale to large scale and generalizability” [54].
According to their authors, the MAST Model is suitable for three main uses: “design of new studies of telemedicine”, “checklist for inclusion of domains and outcomes in new studies of telemedicine” and “assessment based on literature reviews and other existing information”. Nevertheless, they also warned for the model’s limitations: it’s only suitable for decision-making about new telemedicine solutions; it’s stress only “on the prerequisites for and consequences of use of telemedicine application”; it’s depended of others scientific studies that produce the information about the solutions’ specific features [54].

4.1.4.3 Rainbow Framework – theoretical background

The Rainbow Framework is a multi-perspective and interactive evaluation model, designed by BetterEvaluation agency7, because it organizes and mixes more than 300 methods and processes used in monitoring and evaluating, into seven clusters of

7 BetterEvaluation is “an international collaboration to improve evaluation theory and practice by sharing information about evaluation options (methods, strategies, processes) and approaches (collections of methods)”, as well as, to provide “an interactive and freely accessibly website and related events and resources”, which “supports individual evaluators, managers of evaluation and practitioners as well as organizations across disciplinary and organizational boundaries, sectors, languages and countries”. The agency was founded by “Institutional Learning and Change (ILAC) initiative of the Consultative Group on International Agriculture (CGIAR), Overseas Development Institute (ODI), Pact, RMIT University (Royal Melbourne Institute of Technology)”, and it is financial supported by “Australian Government Department of Foreign Affairs and Trade (DFAT), International Fund for Agricultural Development (IFAD), The Rockefeller Foundation, Netherlands Ministry of Foreign Affairs, International Development Research Centre (IDRC)”. In https://www.betterevaluation.org/en (acceded 27-02-2020).
tasks: Manage, Define, Frame, Describe, Understand Causes, Synthesize, and Report & Support Use (Figure 12).

![Rainbow Framework Seven Clusters](https://www.betterevaluation.org/en)

For BetterEvaluation, these clusters replicate the main activities (tasks) and purposes of the monitoring and evaluation enterprise. Under the same framework, which ensure a rational model, the clusters work as a **pre-packaged combination of options for evaluator’s teams**, encouraging evaluators’ reflexivity during the selection of methods, processes, approaches, among other features (Table 11).

In other words, the American National Academy of Medicine explained that the Rainbow Framework “help evaluators navigate the choices available at each stage of evaluation”, as well as “organizes clusters of tasks associated with each stage of the evaluation process” (the stage are not necessarily sequential), under the management stage “which acts as a sort of prism through all different stages are view” [32].

Moreover, BetterEvaluation agency provides an **interactive website** where they share information about evaluation options and approaches, themes and their specifications, and other resources (literature, events, agencies). It supports people to apply new knowledge to their particular situations, and to share their experiences and further contribute to learning how to do an evaluation better. There are three areas of support: evaluation practice, evaluation capacity strengthening and research and development in evaluation.

![Table 11 Rainbow Framework – Clusters and tasks descriptions](https://www.betterevaluation.org/en)

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| Define what is to be evaluated | 1. Develop an initial description | Develop an initial description of what is to be evaluated, to ensure agreement about the boundaries. |
| Frame boundaries of an evaluation | 2. Develop program theory / theory of change | Make explicit how activities are understood to contribute to the intended outcomes and impacts. |
| Describe activities, outcomes, impacts and context | 3. Identify potential unintended results | Consider possible negative impacts and how they can be identified before an intervention. |
| Understand Causes of outcomes and impacts | 1. Check the results are consistent with causal contribution | Check that the data are consistent with what would be expected if the intervention were contributing to producing the observed changes. |
2. Compare the results to the counterfactual | Develop an estimate of what would have happened without the intervention and compare that to the findings of what happened with the intervention.

3. Investigate possible alternative explanations | Identify other factors that might have caused the impacts and see if it is possible to rule them out.

**Synthesise data from one or more evaluations**

1. Synthesise data from a single evaluation | Decide how data will be combined in terms of the agreed evaluative criteria and standards to produce an overall judgement of merit or worth.

2. Synthesise data across evaluations | Decide how to find, extract and combine data from multiple evaluations to produce more general conclusions.

3. Extrapolate findings | Explain how findings from this evaluation might be more generally applied or translated to new sites and situations.

**Report and support use of findings**

1. Identify Reporting Requirements | Identify the primary intended stakeholders and determine their reporting needs, including their decision-making timelines.

2. Develop Reporting Media | Produce appropriate written, visual, and/or verbal products that communicate the findings.

3. Ensure Accessibility | Plan the reporting products to make sure they are accessible, including addressing issues such as limited time, low literacy, and disabilities.

4. Develop Recommendations | Draw on the findings and an understanding of the implementation environment to make recommendations (improvements, possible failures).

5. Support Use | Plan processes to support primary intended users to make decisions and take action on the basis of the findings.

---

### 4.1.4.4 MAPS – theoretical background

In the context of SHAPES Project, which aims to be a contribution for scale up digital health piloted solutions, the **MAPS Toolkit** could be a suitable methodology for assessing and planning the scale up of digital health solutions. Designed by the World Health Organization, the MAPS Toolkit is a “comprehensive self-assessment and planning guide designed to improve the capacity of projects to pursue strategies that increase their potential for scaling up and achieving long-term sustainability” [57].

This toolkit was developed to provide a theoretical and practical support for scaling up digital health solutions with sustainability, which it’s possible through three strategies: “government adoption”, including the solutions on public health and care systems; “commercial adoption”, developing business plans and market conditions; and “hybrid”, when entails both government and commercial strategies. Based on it, MAPS Toolkit provides “actionable information” relating to scaling up and sustaining [57].

This “actionable information” is produced within an “interactive cyclical process” composed by, on the one hand, the self-assessment goal / stage, which aims to “critically evaluate the progress of scaling up (pathway of scale)". and, on the other
hand, the plan goal / stage, which aims to define priorities, steps, strategies to scaling up based on the assessment’s outcomes. The “interactive cyclical process” also defines a structure for the “axes of scale”, which are the critical areas to support for scaling up digital health solutions with sustainability [57] (Figure 13).

The self-assessment could be driven through two approaches: first, the “individual assessment”, when different members of the intervention / project (e.g. pilots) answer the questions addressed; often the questions are delivered by the members, according their role on the intervention / project; it’s recommended a meeting with all team to review the answers; and second, the “team assessment”, when whole the team is engaging it, often “involve a series of meetings” [57].

These questions, which are already defined on the toolkit, are answered by two ways: there are questions for “no / yes” answers, and questions for “no / in progress / performed / documented” answers (Table 12). The several questions have also the option “not applicable” [57].

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115
Table 12 Guideline for “no / in progress / performed / documented” answers [57].

<table>
<thead>
<tr>
<th>RESPONSE OPTION</th>
<th>DEFINITION OF RESPONSE OPTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>No</td>
<td>You have not addressed this item at all.</td>
</tr>
<tr>
<td>In progress</td>
<td>You have begun to address this item, but further steps are needed.</td>
</tr>
<tr>
<td>Performed</td>
<td>You have addressed this item fully, leaving no remaining uncertainties.</td>
</tr>
<tr>
<td>Documented</td>
<td>There is written documentation or evidence demonstrating that this item has been completed. This may include a report or involve the development of standard operating procedures.</td>
</tr>
</tbody>
</table>

Both each answer and the whole answers should be calculated, adopting three score levels: “the overall score (total score combining all axes)”; the “axis scores (a separate score for each of the six axes of scale)”; and the “domain scores (specific scores for the domains within each axis of scale)”. This scoring mechanism will adopt a quantitative method (Table 13), which allows, on the one hand, measure an “overall progress” of the intervention / project, and, on the other hand, “to compare scores across axes and domains” [57].

The results from the self-assessment goal / stage should be applied on planning stage, ensuring “additional consideration, activities and strategies from project managers and teams”, as well as “tips, lessons from the field”. These results could be also applied “to assess and correct the course of progress”, regarding both “scaling up and the endgame” [57].

Table 13 Scoring Mechanism – Quantitative Method [57].

<table>
<thead>
<tr>
<th>SCORING MECHANISM</th>
<th>QUANTITATIVE METHOD</th>
</tr>
</thead>
<tbody>
<tr>
<td>Allocation of points</td>
<td>Points are allocated at the level of the sub-statements within each question. Each response option is worth a specific point value, as indicated in the check boxes. For example, No = 0 points, In progress = 1 point, Performed = 2 points, and Documented = 3 points.</td>
</tr>
<tr>
<td>Scorecards</td>
<td>Six scorecards – one for each axis of scale – are provided to help users calculate their scores. The specific steps entailed in the scoring process are detailed in these scorecards.</td>
</tr>
<tr>
<td>Final scorecard</td>
<td>Ultimately, the calculations will yield a percentage for each axis of scale as well as for each domain. The final scorecard will allow users to compare scores across the axes of scale and the domains.</td>
</tr>
</tbody>
</table>
4.1.4.5 Healthcare Innovation Cycle – theoretical background

The next model, **Healthcare Innovation Cycle**, is developed by Consortia for Improving Medicine with Innovation & Technology (CIMIT)\(^8\), to help the healthcare projects to “navigating a healthcare innovation cycle”. CIMIT approach argued that an innovation process is “learnable” and “teachable”, thereby project teams can use “the experiences of the others” in order to avoid “preventable mistakes”, as well as improving “speed and chances that promising innovations actually reach patients and improve care” [58].

This cycle was inspired by “US Department of Defense’s well-established Technology Readiness Level (TRL) framework”, and it aims to launch “a sequence of healthcare specific milestones that creates a roadmap […] from an unmet clinical need to becoming the standard of care” [58]. Globally, the cycle with a “clinical need”, which pushes for an “idea”. Based on this idea, a typical **maturity life-cycle** of the interventions in Digital Health [30] is started, from the “proof of concept” to “standard of care” (Figure 14).

![Figure 14 Healthcare Innovation Cycle [58].](image)

According CIMIT, the **Healthcare Innovation Cycle differs of Technology Readiness Level (TRL) framework, by three reasons**. First, it’s a process cycle rather a linear cycle, which “operates as a spiral, arriving at the end of each rotation at a higher standard of care, awaiting new medical insights and innovations for further

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\(^8\) CIMIT is “a network of world-class academic and medical institutions partnering with industry and government. Our mission is to foster collaboration among clinicians, technologists, and entrepreneurs to accelerate innovation and catalyze the discovery, development, and implementation of innovative healthcare technologies”. In [https://cimit.org/about](https://cimit.org/about) (acceded 27-02-2020).

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117
enhancement”. Second, it’s finished on “standard of care” rather on “clinical use”, in order to “disseminate innovations so that they are widely available”. Third, while “TRL framework only focuses on the technology”, the Healthcare Innovation Cycle requires a “constantly balancing the perspectives from four key domains critical to creating a successful healthcare solution: clinical, market/business, regulatory, as well as technical” [58].

Regarding these last four key domains, CIMIT proposes an example of key questions for each one, in order to clarify the milestones expected: for clinical risk, “Will the innovation be accepted and adopted in a workflow and produce real improvements in outcomes and/or lower costs?”; for market or business plan, “Is there a significant unmet need with enough buyers willing to buy the innovation at a sustainable price?”; for regulatory risk, “What claims will you need to prove and how long/ how much will it cost to get approval?”; for technical risk, “Will the technology be protectable as well as work better and be lower cost than alternatives?”[58].

Such as others, this model also defined deliverables, similar to outcomes, for each stage of the cycle, as well as key domains (Table 14). The implicit philosophy is capturing the experiences through a core set of deliverables: “CIMIT’s experience is that while each is journey is different, just as each ascent a mountain climber makes on a new peak is different, the underlying disciplines applied are the same”[58].

The model implementation is supported by a “Guidance and Impact Tracking System (GAITS)”, which is an on-line platform (GAITS Platform)9 used by teams and portfolio managers to provide “descriptions of the deliverables at the intersection of each milestone and domain along with resources to help teams complete them”. This platform was inspired by different fields, such as “HealthTech, Pharma, Health IT”, and it’s composed by open source “resources (e.g. descriptions, videos, templates, examples)” with peer rated [58].

<table>
<thead>
<tr>
<th>MILESTONE</th>
<th>Description</th>
<th>Clinical</th>
<th>Market / Business</th>
<th>Regulatory / Approvals</th>
<th>Technology</th>
</tr>
</thead>
<tbody>
<tr>
<td>NEED</td>
<td>Insights into unmet clinical needs and available solutions</td>
<td>Unmet needs defined</td>
<td>Needs screening &amp; selection</td>
<td>N/A</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Disease state characterized</td>
<td>Existing solutions characterized</td>
<td></td>
<td></td>
</tr>
<tr>
<td>IDEA</td>
<td>Potential solutions to unmet need developed</td>
<td>Clinical workflow description</td>
<td>Competitive landscape</td>
<td>Medical device intended use</td>
<td>Paper Prototype</td>
</tr>
</tbody>
</table>

9 In https://www.gaits.org (acceded 27-02-2020).
<table>
<thead>
<tr>
<th>Deliverable D6.1 SHAPES Pan-European Pilot Campaign Plan Version 1.0</th>
</tr>
</thead>
<tbody>
<tr>
<td>This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 857159</td>
</tr>
<tr>
<td>119</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PROOF CONCEPT</th>
<th>Key component concepts validated in models and value proposition articulated</th>
</tr>
</thead>
<tbody>
<tr>
<td>PROOF FEASIBILITY</td>
<td>Feasibility of whole solution demonstrated in models and in feedback from stakeholders</td>
</tr>
<tr>
<td>PROOF VALUE</td>
<td>The potential of the solution to work and create value for all stakeholders is demonstrated (Initial commercial investment)</td>
</tr>
<tr>
<td>CLINICAL TRIALS</td>
<td>Regulated production of prototypes and collection of clinical and economic data</td>
</tr>
<tr>
<td>VALIDATION OF SOLUTION</td>
<td>The solution is shown to be effective</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>and evaluated</th>
<th>Updated need description feedback from &gt;5 clinicians</th>
<th>Envisioned Value Proposition</th>
<th>Equivalent devices identified</th>
<th>Hypothesis &amp; experimental design idea screening &amp; selection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Feedback from clinicians in &gt;5 settings Updated need description and workflow</td>
<td>Competing solutions characterisation Preliminary Value Proposition Preliminary Path to Payment plan Stakeholder Map</td>
<td>Preliminary classification Preliminary intended use Preliminary regulatory pathway</td>
<td>PoC prototypes Demonstration results Institutional IP disclosure</td>
<td></td>
</tr>
<tr>
<td>Feedback from clinicians in &gt;20 settings Updated need &amp; workflow descriptions</td>
<td>Feedback from &gt;5 economic buyers Impact Plan (draft business plan) Advisory Board</td>
<td>Draft Essential Requirement Checklist Draft Instructions for use Institutional approval request(s)</td>
<td>“Works Like” &amp; “Looks Like” prototypes Freedom to operate review Provisional IP filing Killer Experiment</td>
<td></td>
</tr>
<tr>
<td>Feedback from &gt;100 clinicians and KOLs Animal/First-in-Man experiments Peer reviewed publication(s) Scientific Advisory Board</td>
<td>Investor ready business plan Feedback from &gt;20 economic buyers Key management team identified Initial seed investment</td>
<td>Application form to national competent authority Data requirements Clinical Investigation approval(s)</td>
<td>“Works Like/Looks Like” prototypes BOM, manufacturing plan, and costing Full IP application Killer technical experiment</td>
<td></td>
</tr>
<tr>
<td>Conduct Phase 0 and/or 1 clinical trial(s) Peer reviewed publication(s)</td>
<td>Economic data Feedback from &gt;50 economic buyers 1st Institutional Investment</td>
<td>Data requirements confirmation Pre-submission</td>
<td>Manufacture GMP-compliant pilot lots</td>
<td></td>
</tr>
<tr>
<td>The solution is shown to be effective</td>
<td>Clinical efficacy trials Purchasing intent from &gt;10 buyers Complete Technical File GMP Process Planning</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Updated need description**
**Feedback from >5 clinicians**
**Envisioned Value Proposition**
**Equivalent devices identified**
**Hypothesis & experimental design idea screening & selection**

**updated need description**
**feedback from >5 clinicians**
**envisioned value proposition**
**equivalent devices identified**
**hypothesis & experimental design idea screening & selection**
Comparing with the lasted models, this model is not a typical evaluation model. However, both its cycle (Figure 14) and deliverable matrix (Table 14) could be a critical tools for improve a final monitoring and evaluation plan, because its focus on innovation outcomes.

### 4.1.1.1 MOMENTUM – theoretical background

The **Momentum project** was a three-year initiative of European eHealth stakeholder associations and competence centres that was co-funded by the European Commission. It had the purpose to deliver a holistic European reference document for developing a telemedicine service framework and also a toolkit for capacity-building among telemedicine doers [59].

The Momentum blueprint offers **critical success factors** and performance indicators that help decision makers to scale up healthcare services from a distance through information technology. It also delivers a **self-assessment toolkit** that helps an organisation determine whether it is “ready” for telemedicine deployment [59].

**MOMENTUM** [60–62] three main aims and scope were as follows:

1. First, its consortium has aimed to understand the kinds of **challenges** faced by telemedicine doers when they work to implement telemedicine successfully as a part of a routine service.

This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 857159
• Second, as a result, the initiative has identified **18 critical success factors** needed to take telemedicine from a pilot phase towards large-scale deployment and thus integrate it into healthcare delivery systems.

• Third, MOMENTUM has delivered **tools and techniques** that support this movement, including materials for a self-assessment process that determines an organisation’s readiness to deploy telemedicine.

4.1.1.2 The NASSS framework – theoretical background

Especially interesting to capture the functional, behavioural, psychological, service usage and technology integration impacts of health and social care projects is an adapted version of the **Non-adoption, Abandonment, Scale-up, Spread, and Sustainability** (NASSS) framework, proposed by Greenhalgh et al [63].

The research project behind the NASSS framework aimed to explain the high number of **failed technology projects in health care**. On the basis of a systematic review and multi-site empirical case study they gathered enough empirical evidence to support this new framework, which is based on **seven domains** – the condition or illness, the technology, the value proposition (the initial assessment of whether the technology is worth developing), the actual or intended adopters (staff, patients, caregivers), the organisation, the wider system (e.g. policy, legal and regulatory context), and the process of adaptation over time [63, 64].

Each of these domains can be **simple, complicated or complex**. For example a broken ankle is “simple”, while cancer is a “complicated” illness. On the other end, a drug user from an immigrant group, who is also an alcoholic with a psychosis and hepatitis C would be a complex patient [64].

The same categories can be used for the technologies: a defibrillator is a rather simple technology, while a widely interoperable, multi-organisation technology platform is quite complex [64].

The **NASSS hypothesis** states that if all domains are in the ‘simple’ zone, the technology programme has a high chance of success. If some are complicated, there is still a good chance of success – but things will take a lot longer and be more expensive. But if the technology programme is characterised by multiple domains that are not just complicated but complex, such programmes have limited chance of ever being successfully implemented [63, 64].

4.1.5 Literature Review: specialized bibliography

Although the last chapter regarding the evaluation of large-scale pilots is quite extensive, there will still be other information, which may be critical for the SHAPES Project and their singular partners. Moreover, there is no single understanding of what is, how develop, why select, when start, who implement, where run… the monitoring and the evaluation programs. In this sense, the evaluation “could and should strive to be a cooperative, cumulative endeavour” [65]. From this standpoint:
“Enlisting and making better use of the body of knowledge produced and contained in these evaluations represent an opportunity for knowledge production that can and should be realized. As a self-proclaimed practice- and use-oriented field, whereby knowledge building becomes central, the pursuit of a cumulative impact of evaluation is only made all the more compelling, perhaps even called for” [65].

Based on this idea, Lemire & Christie [65] proposes the concept of “house of evaluation”, comparing the importance of the house for homeless individuals with the critical importance of a systematic literature review regards the evaluation studies for the evidence-based approach in evaluation. For them, among other evidences, the individual evaluation of the project or pilot is influenced by the individual knowledge of the specialised literature.

Instead of a final recommendation or conclusion about pilots’ monitoring and evaluation, this section lists a range of specialised literature, not used before, regarding evaluation, monitoring and large-scale pilots and their scale-up. Inspired by Ekeland et al. [55], developed as a first step of MAST evaluation model, the list is divided by topics:

### Transversal


### Developmental Evaluation / Formative Evaluation / Glocal Evaluation


Impact Evaluation


Large-scale and Scale Up Evaluation (pilots’ studies)


Deo, Sarang et al. (2019). What would it cost to scale-up private sector engagement efforts for tuberculosis care? Evidence from three pilot programs in India. PLoS ONE 14(6), 1-12. doi: https://doi.org/10.1371/journal.pone.0214928


Program Evaluation


Qualitative Evaluation / Mixed-methods Evaluation


Realistic Evaluation


Prictor, M. et al. (2019). Dynamic Consent: An Evaluation and Reporting Framework. Journal of Empirical Research on Human Research Ethics 00(0), 1-12. doi: //1d0o.i1.o1r7g/71/01.15157672/16545612694868179087873073


Theory based Evaluation


4.2 Technological evaluation

Within the SHAPES project the pure technological evaluation will be performed by the two technical tasks WP4 & WP5. The main task responsible for the technical evaluation of the platform is Task 4.8 “Integration and Testing of SHAPES TP”. However, this task builds on the tests and evaluation activities of the individual digital solutions to be performed within WP5.
The evaluation process will build on the functional and non-functional requirements, which are developed on the basis of the SHAPES user requirements and the use cases (see Figure 15).

4.2.1 User-experience evaluation

The Methodology of assessment for user-experience evaluation within the context of SHAPES will be defined in work package 5, task 5.1 within the “User experience and design guidelines and evaluation guide”. A scoping review of existing literature on best-practices will be performed and complemented with the procedures already used by the partners of the SHAPES project. This information will be merged and analysed so that best practices and standards of user experience are identified. Namely, we will identify:

- User-experience design guidelines
- International norms and guidelines for a range of technological solutions
- Applicable Accessibility Standards
- Good Practices targeting SHAPES users
- Specific Look and Feel Needs of SHAPES
- User-experience conformance
- Guidelines on conformance
- Current practices in conformance evaluation (models, instruments, …)
- User-experience evaluation with experts and users
- Guidelines on evaluation with experts and users
- Current practices of experts’ and users’ evaluation
The information collected will be further complemented with the outcomes of Tasks 2.1 - Understanding Older People: Lives, Communities and Contexts; Task 2.5 - SHAPES Personas and Use Cases, and Task 3.5 - User Requirements for the SHAPES Platform and with the results of actively engaging with users in co-creation activities and consultation sessions. This will lead to the definition of user-experience evaluation guidelines specific to the SHAPES project as well as procedures to assess whether SHAPES technological solutions met those guidelines. Aspects covered include protocol of assessment, sample size and characteristics, methods and instruments of assessment of effectiveness, efficiency and satisfaction, data analysis and report of results.

### 4.3 Evaluation of the impact of the SHAPES solution

Based on the literature review in chapter 4.1 the presented tools and models of chapter 4.1.4 have been evaluated regarding their advantages and disadvantages and their possible use within SHAPES. The results are presented in the following table (Table 15). The tools with special relevance for SHAPES are described in more detail regarding their practical implications for the SHAPES project in the following subchapters.

#### Table 15: Overview of the different evaluation toolkits and models for SHAPES:

<table>
<thead>
<tr>
<th>Advantage</th>
<th>Disadvantage</th>
<th>Usage in SHAPE</th>
</tr>
</thead>
</table>
| **MAFEIP** | - estimates health and economic outcomes;  
- includes a web-based tool with a high level of maturity  
- it represents one of the three cross-cutting initiatives that are open to any Partner to participate within the framework of the new 2017-2019 EIP on AHA cycle;  
- the user has to be qualified in health system statistics;  
- high quality quantitative and qualitative data related to the area and the new intervention is needed;  
- several pilot sites have reported that MAFEIP is difficult to use and may not be applicable to SHAPES (e.g. due to the relatively low number of participants for some of the use cases);  
- MAFEIP methodology is suitable particularly for high level decision regarding the introduction or deployment of the solution/ innovation;  
- it serves as a tool for modelling important population health and cost effectiveness parameters; |
<table>
<thead>
<tr>
<th>Methodology</th>
<th>Features</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>MAST</strong></td>
<td>multi-disciplinary assessment in seven categories; validated on many concrete services also outside the EU; focuses on the measurement of effectiveness and quality of care; includes a theoretical and a practical toolkit; can be time-consuming (if new empirical studies must be initiated); no information on why telemedicine works; does not include the working process (when introducing the application); only relevant for the assessment of matured telemedicine applications; MAST methodology can be applied in telemedicine and social care related intervention/services and it provides focused guidance on what everything and how to evaluate; particularly pilots that seek recognition by authorities and also healthy financing model should be evaluated by the multidisciplinary model; application of MAST for other areas outside of health and social carer need further study;</td>
</tr>
<tr>
<td><strong>Rainbow Framework</strong></td>
<td>multi-perspective and interactive evaluation model; provides an interactive website; Not specifically for technical evaluations in the health and care area designed; Not generally used in SHAPES</td>
</tr>
<tr>
<td><strong>MAPS</strong></td>
<td>methodology for assessing and planning the scale up of digital health solutions to achieve long-term sustainability; includes a toolkit; is suitable for the evaluation of projects after the pilots, as it includes e.g. future partnerships and financial plans for scaling-up; An alternative method to MOMENTUM, but MOMENTUM seems to be easier to use</td>
</tr>
<tr>
<td><strong>Healthcare Innovation Cycle</strong></td>
<td>was developed to help the healthcare projects to navigating a healthcare innovation cycle; included the online platform &quot;Guidance and Impact Tracking System (GAITS); was developed especially for clinical trials (and the innovation process from clinical needs to clinical use around it); Not generally used in SHAPES</td>
</tr>
</tbody>
</table>

This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 857159
The evaluation toolkits and models have been selected carefully, so that all evaluation categories, which have been defined in chapter 2 on the basis of the intended and promised impact of the SHAPES solution, are covered completely.

Figure 16 gives an overview of the matching of the different evaluation categories of SHAPES with the selected evaluation toolkits and models.
4.3.1 MOMENTUM - practical aspects

The MOMENTUM project has identified and validated eighteen critical success factors on the basis of the practical experience of telemedicine doers with projects that were successfully transferred from a pilot stage to their deployment in routine care and on a large scale [59].

The description of these critical success factors is followed by a relevant set of performance indicators. These indicators can be used by telemedicine doers to test out how important each critical success factor is to their specific deployment circumstances. There are 51 indicators in total. Each critical success factor has between 1-6 indicators associated with it [59].

These indicators are statements which telemedicine doers use to rate their telemedicine deployment initiative on a scale from 1 to 5. The overall scaling indicates the degree of readiness of a telemedicine solution for large-scale deployment [59].

Scalability of telemedicine services from pilots to large-scale deployment includes a wide variety of factors; many of these are not technological.
The critical success factors (CSF) defined by the project are laid out in four subgroups according to their content:

**The context**

1. Ensure that there is cultural readiness for the telemedicine service.
2. Come to a consensus on the advantages of telemedicine in meeting compelling need(s).

**People**

3. Ensure leadership through a champion.
4. Involve healthcare professionals and decision-makers.
5. Put the patient at the centre of the service.
6. Ensure that the technology is user-friendly.

**Plan**

7. Pull together the resources needed for deployment.
8. Address the needs of the primary client(s).
9. Prepare and implement a business plan.
10. Prepare and implement a change management plan.
11. Assess the conditions under which the service is legal
12. Guarantee that the technology has the potential for scale-up.

**Run**

13. Identify and apply relevant legal and security guidelines.
15. Ensure that telemedicine doers and users are privacy aware.
16. Ensure that the appropriate information technology infrastructure and eHealth infrastructure are available.
17. Put in place the technology and processes needed to monitor the service.
18. Establish and maintain good procurement processes.

The four groups of CSFs are to be assessed in four domains that have enabling role in the (new) service deployment. Each CSF belongs to one of the following conditions (see Figure 17):

- Strategy and management (yellow).
- Organisation and management (pale green).
- Legal and security (dark green).
- Technology and market (red).
The process of assessment of a new service according to MOMENTUM consists of survey performed with all stakeholders having decision role or influence in the environment of the new service and the service as such.

MOMENTUM is normally used for deployment of new service, which frequently follows a pilot, in which importance some of the CSF might by compromised. The pilot should demonstrate expected impacts or benefits under specific conditions that are intentionally helpful during the pilot period but such support may cease, which should be the impetus for assessment of CSFs according to MOMENTUM.

Ideally all stakeholders who have actively participated in a telemedicine pilot should be asked to contribute to the MOMENTUM survey. Representatives should be present in the procedure from all levels of the initiative from the steering committee to the health professionals who work with the telemedicine applications on a daily basis. Different professions, organisational and geographical affiliations should be reflected as well.

The assessment is based on assumption that experts, who are also familiar with the new service and its environment, should collectively provide opinion that is very close to real situation in which the new service is expected to run.

The survey can be organized either on paper or on line if there is an electronic tool located on a server. Each participant in the survey is to respond to a number of questions that can be answered using a five-point Likert scale ranging from “Agree” to
“Disagree”. Each CSF in such questionnaire has at least one but frequently more elementary questions, which then provide very detailed insight in what the stakeholders feel about the new service. The whole process is described in Deliverable 3.4 Personalised Blueprint for telemedicine deployment: validated and tested version of MOMENTUM project. The process may take as long as 8 weeks and includes evaluation of the response of the survey and a workshop with suggested agenda, group discussion of the results and conclusions, which will be based around a discussion or a decision on “The degree to which our organisation/region/country is ready for large-scale deployment of the telemedicine solution”.

Relevance to SHAPES

MOMENTUM [60–62] deals particularly with telemedicine service deployment, while SHAPES has broader scope, covers besides telemedicine also smart homes, medication, cognitive stimulation, in-home care and other activities or interventions. The conditions for success such services are very similar and still can be used with possible lower relevance if the area the new service is for example not so regulated as in case of medical services. The four groups of CSFs are very relevant for SHAPES pilots, just some of the CSF and obviously particular questions in the survey should be somewhat modified to reflect the pilot’s solution in question. The MOMENTUM CSF can be considered even during definition of a pilot as the new service is expected to be deemed after the pilots end. Similarly, MOMENTUM questions should be updated in line with new legislation that came into force since 2015. MOMENTUM assessment process with the survey and workshops can be recommended to be performed with relevant stakeholders at the end the SHAPES pilots and should beneficially provide relevant suggestions on how to improve conditions for the new services in order it can be sustainable.

Assessment using MOMENTUM methodology itself is not intended to guarantee success of deployed new service but apparent failing in compliance with any of the relevant CSFs is an indication that there may be issues that are necessary to resolve.

4.3.2 MAST – practical aspects

MAST (Model for ASsessment of Telemedicine) [54, 66–68] is an evaluation framework which focuses on the measurement of effectiveness and quality of care. In this context, the MAST represents a multidisciplinary process, evaluating the medical, social, economic, and ethical aspects of telemedicine in a systematic, unbiased, robust manner. This statement of principle is based on the definition of health technology assessment (HTA) in the EUnetHTA project [69]. MAST should be used if the purpose of an assessment is to describe effectiveness and contribution to quality of care by using telemedicine service and/or to produce a basis for decision-making (see chapter 4.1.4.2 for details on the theoretical background).
The use of MAST includes three steps as described in Figure 18. As a first step in the preceding assessment (Step 1) the maturity of the telemedicine technology and the organization using the service is assessed before the assessment of effectiveness is carried out. If the maturity of the technology needs to be developed further studies such as usability studies or feasibility studies must be carried out, and, similarly, if MAST is to be used to for development of the organization using the telemedicine, optimization studies needs to be performed.

Following implementation of the service or pilot, a multidisciplinary assessment (Step 2) of the effectiveness of the technology can be carried out using MAST. MAST encompasses seven domains including identification of the health problem and characteristics of the application; safety; clinical effectiveness; patient perspectives; economic aspects; organizational aspects; and socio-cultural, ethical and legal aspects.

Finally, an assessment should be made of the transferability of the results (Step 3) to other locations, regions or countries.

Figure 18: The three steps in Model for Assessment of Telemedicine. [70]

**STEP 1: Preceding considerations**

Before a health care institution e.g. a hospital begins assessing the different outcomes of a telemedicine application it is important that a number of preceding considerations are made in order to determine whether it is relevant for this institution to do the assessment at this point in time.
First, it is important to determine the aim of the telemedicine application and relevant alternatives to which the application must be compared in the assessment.

The description of the aim of the telemedicine application should include description of the patients, their health problem and the aim of using the technology. Thus, it should be described how this telemedicine application is expected to be an improvement compared to other technologies used for the same health problem. This is important, since these aims determine the primary outcomes that should be included in the assessment.

It is also important to describe the alternatives to which the telemedicine application should be compared. In general, the comparator will be status quo, i.e. the treatment used so far. However, making comparisons with an improved or upgraded system or other technologies should also be considered.

Secondly, as a minimum the following conditions need to be considered:

- Does the telemedicine service fit into the existing legislation?
- Is the telemedicine service reimbursed?
- How mature is the telemedicine application?
- What is the relevant number of patients expected to use the application?

**STEP 2: Multidisciplinary assessment - the domains in MAST**

In this section the content of the 7 domains in the multidisciplinary assessment is described in detail. For each domain the content is defined and the different topics are listed.

1. **Health problem and characteristics of the application**

This domain includes description of the health problem of the patients expected to use the telemedicine service or application and description of the application being assessed. The content of this domain serves as a description of the background for the assessment.

The topics within this domain include the epidemiology of the target health problem, the burden – both on individuals and on society – caused by the health problem.

Main question in this domain is a comprehensive set of pieces of information about the telemedicine application, how it addresses important issues, its general economic aspects, technical solution and necessary infrastructure for the service and its technologies.
This domain then includes the following topics (areas of question related to this domain):

- Clinical/health issues
- Description of the application
- Technical characteristics

2. Safety

Safety can be defined as the identification and assessment of harms. With regard to telemedicine applications issues of safety can be divided into clinical safety and technical safety.

Clinical safety includes mainly the assessment of harms for the patients using telemedicine, based on a description of the types of harms, their incidence and severity.

On the other hand, technical safety includes issues related to the technical reliability of the telemedicine application. This involves assessment of potentials with backup, interference and security of data, protection of personal data (GDPR) and also cybersecurity.

Many safety aspects are addressed in EU by MDR (Medical Device Regulation), however not all that may be relevant of given system used the intervention as MDR focuses (just) on general safety and performance requirements of the system or a device.

The following topics can be included in the assessment of safety (areas of question related to this domain):

- Clinical safety (patients and staff)
- Technical safety (technical reliability)

3. Clinical effectiveness

Efficacy of telemedicine refers to the health benefits of a telemedicine application for the patients under ideal circumstances (i.e. carefully controlled conditions). Effectiveness refers to the performance of a technology in regular clinical practice.

In practice efficacy is usually studied in controlled randomized trials (RCT) where all relevant conditions or aspects are held constant or controlled for and where patients are selected based on strict criteria. To determine the effectiveness one can either try to study the effects under more pragmatic circumstances (in pragmatic RCT) or make
judgements about the size of the expected effects under more ordinary circumstances based on RCTs.

In studies of effectiveness of telemedicine, it is often the case that the first studies by the inventors or early adopters show a higher degree of effectiveness than can be found in the following studies. This can reflect a difference between efficacy and effectiveness, and it underlines the fact that generally more than one study of a telemedicine application is needed before effectiveness can be said to be established.

The following topics can be included in the assessment of the clinical effectiveness:

- Effects on mortality
- Effects on morbidity
  - Physical health
  - Mental health
- Effects on health-related quality of life (HRQL)
  - Generic measures of quality of life
  - Disease specific measures of quality of life
- Behavioural outcomes (e.g. exercise)
- Utilization of health services (e.g. number of readmissions)

4. **Patient perspectives**

Patient perspectives are issues related to the perception and satisfaction of the patient or the relatives of the telemedicine application.

The patients’ perception and satisfaction of telemedicine applications are important aspects of telemedicine because telemedicine often affects the way health care is delivered to the patients and the way patients interact and communicate with the clinical staff. Telemedicine can be expected to affect the patients’ perception of the overall treatment process. Patient perspectives has many aspects that influence acceptability of the new application.

Measurement of outcomes within the domains of clinical effectiveness and patient perspectives are closely related and some outcomes e.g. the health-related quality of life can be said to include both clinical effectiveness and aspects of patients’ perception and views.

Telemedicine has strong potential in empowering patients, ability to handle the disease and the consequences of the disease by themselves and also increase interests in their own health.

The following topics can be included in the assessment of patient perspectives on telemedicine applications:
• Satisfaction and acceptance
• Understanding of information
• Confidence (in the treatment)
• Ability to use the application
• Access
• Empowerment, self-efficacy

5. Economic aspects

The economic aspects of new telemedicine applications are important because the cost of health care is rising and the need for prioritizing the limited resources is growing. This is relevant at the societal level, but also within the specific health care institutions who must decide whether or not to implement new technologies.

The economic aspects of a telemedicine application can be described in:

• A societal economic evaluation comparing a telemedicine application with other relevant alternatives in terms of both their costs and consequences.
• An analysis of the expenditures and revenues for the health care institutions using the telemedicine application.

Health economic evaluation can be divided into different types and corresponding types of analyses can be performed.

The following topics can be included in the assessment of the economic consequences of telemedicine applications in the economic evaluation or business case:

• Economic evaluation (societal perspective)
  • Amount of resources used when delivering the assessed telemedicine application and its comparators in the health care sector and other sectors. The different types of resources are:
    o Investments in equipment etc.
    o Training of staff
    o Maintenance
    o Use of staff (for each of the relevant type of staff)
    o Medication
    o Utensils
    o Patients’ use of time
    o Relatives’ use of time
    o Transportation
  • Unit costs or prices for each resource used
• Related changes in use of health care resources by different healthcare providers
• Clinical effectiveness of the telemedicine application and comparators (to be used in the cost-effectiveness analysis – see domain on clinical effects)

• Business case (institutional level)
  • Expenditures per year (including expenditures related to the resource use described in the cost estimation above)
  • Revenue per year:
    o Activity (number of patients or services)
    o Reimbursement (e.g. DRG-rate) per service or patient

6. Organizational aspects

The organizational domain considers what kind of resources have to be mobilized and organized when implementing a new application, and what kind of changes or consequences the use can further produce in the organization.

The organizational domain is crucial when it comes to evaluating telemedicine services because the implementation of telemedicine often changes the working routines or the distribution of tasks between health professions for health care providers. An important question to be asked is whether the telemedicine application will fit smoothly into the existing organizational framework.

The following topics can be included in the assessment of the organizational aspects of telemedicine applications:

• Process
  • Workflow
  • Staff, training and resources
  • Interaction and communication
• Structure
  • Spread of technology, centralization or decentralization
  • Economy (see domain on economic aspects)
• Culture
  • Attitude and culture
• Management

7. Socio-cultural, ethical and legal aspects

The social-cultural part of the domain focuses on more general socio-cultural implications of telemedicine applications. The focus of the domain is on the diverse social-cultural arenas where the patient lives and acts during use of the application. It
includes issues related to liability and responsibilities of patients and members of the clinical staff.

The life of a patient takes place in various arenas (hospitals, general practitioner, everyday life, homes, schools, workplace, etc.).

Topics:

- Changes in the patient’s role in major life areas (e.g. social life, working life)
- Patients’ relatives and others’ understanding of the telemedicine application
- Societal, political context and changes. Will the application influence the general model for the delivery of healthcare services if deployed?
- Changes in responsibility. Are the patients and/or relatives capable of handling the responsibility?
- Gender issues. Has the service any consequences on the position of gender?

STEP 3: Assessment of transferability

A new (successful) telemedicine intervention is useful to consider for scaling up to other healthcare providers, regions, countries, which require considerations of whether the results can be generalized from one setting to another. This consideration should be made within each of the seven domains.

There may be numerous differences between the originator and adopter of a telemedicine intervention. They may include:

- Difference in legal, regulatory and healthcare systems conditions
- Differences in basic demography and epidemiology of disease
- Differences in availability of health care resources and variations in clinical practice
- Differences in incentives to health care professionals and institutions, e.g. in reimbursement systems
- Differences in relative prices and costs e.g. in prices of different type health care professionals
- Differences in technological conditions for the service including networks
- Differences in population values

Strengths and weaknesses

The main strengths of MAST model are:

- It is based on the requests and comments from a large group of stakeholders and users of telemedicine. It is validated on many concrete services in many countries (not only EU).
• It is multidisciplinary and comprehensive
• It is based on scientific studies and criteria for quality
• Transferability of the estimated outcomes is described
• It is based on HTA and EUnetHTA and therefore familiar to stakeholders in the EU, national health authorities, industry, academics and health professionals.

The main weaknesses of the model can be described as:

• It can be time consuming if new empirical studies must be initiated
• It does not result in information on why telemedicine works. This information needs to be produced in other kinds of scientific studies.
• The model focuses on the outcomes of telemedicine (including organizational outcomes) and not the working processes when introducing the applications. Information about the process of implementation of telemedicine must be produced by using other kinds of assessments.
• MAST is only relevant in assessment of matured telemedicine applications. If the application is still being developed and still needs to be improved, other kinds of assessments should be carried out, e.g. in formative studies.
• The quality of the reports and publications based on MAST can vary because the model does not state a number of criteria to be fulfilled. However, the scientific criteria for quality of research within the different scientific disciplines can also be used as criteria for the quality of reports using the model.

Relevance to SHAPES

MAST is useful for evaluation of new services and advanced pilots. Its step 1 is useful to be considered even in the design phase of a pilot service but its major strength is in multidimensional assessment of the seven domains. The complex methodology may be useful for obtaining important evidence e.g. to prove benefits and/or assure sustainability of the new intervention, particularly if he pertinent decision process (e.g. reimbursement-related) recognizes HTA as suitable methodology.

Information to each selected topic in various domains are necessary to be obtainable. Many answers can be obtained from the stakeholders. It means that particular questions for each domain are necessary first to formulate and then organize the assessment e.g. by Surveys (on paper or on-line), Questionnaire and Focus group. The designed set of questions associated with the domains should be posed to stakeholders familiar with the new service and with the environment for the service. It is not always necessary to seek answer to all detailed questions, particularly if they are obvious in some domain, or their roles do not overweight benefits or impacts gained in other domains.
Amended MAST was used also in social care services, e.g. in project Connected for Health in simplified version. It was applied in assessment of a number of services in the area of Digital homecare. Its concrete use in smart homes interventions is not known but if strong kind of evidence is sought even in this and other areas of services based on ICT and used by people requiring care, an attempt to amend the domains of then model could be performed.

4.3.3 MAFEIP – practical aspects

The European Innovation Partnership on Active and Healthy Ageing (EIP on AHA), launched in 2012, is a European Commission led policy initiative to address the challenges of demographic change in Europe. Its overarching target has been to increase the average healthy lifespan by two years by 2020.

Thousands of entities and stakeholders are committed to EIP on AHA initiatives including monitoring the socio-economic impact of implementing innovative solutions for active and healthy ageing. A need for shared and reliable methodology to monitor impacts across the EIP on AHA domains and interventions has been identified.

The generic and flexible web-based monitoring and assessment tool called MAFEIP (Monitoring and Assessment Framework of the EIP) [53, 71–73] has been developed by the Joint Research Centre – IPTS - of the EU Commission in close cooperation with the Commission’s services and EIP on AHA partners (see chapter 4.1.4.1 for details on the theoretical background).
The tool is available online and after registration can be used by any subjects involved in monitoring impacts of health or social care-related innovations for making decisions. The tool can be used for either deterministic or probabilistic analysis.

The Deterministic Analysis module of the MAFEIP tool contains 5 steps: (1) Information, (2) Model Input, (3) Model Output, (4) Sensitivity Analysis, and (5) Model Output of the Sensitivity Analysis.

This probabilistic model enables the tool to account for the uncertainty with respect to the input model parameters and show the impact of this uncertainty on the outputs (incremental cost and Health Related Quality of Life). The uncertainty related to the input parameter values is represented by a probability distribution for each parameter.

The Probabilistic Analysis Module of the MAFEIP tool is designed for advanced users that have already gained prior experience in this field, are familiar with this type of analysis, or have already used the MAFEIP Deterministic Analysis Module and would like an additional, more precise analysis of their innovation.
Using the model requires relatively high-quality input information and data that is necessary to enter into the tool.

The outputs of MAFEIP in deterministic analysis include:

- Incremental cost and health-related quality of life, which refer to the difference between the cost that a person from a specific age and gender would have if he received the intervention minus the cost that would have if he followed current care.
- Cost-effectiveness, which represents the overall impact of the intervention on healthcare/societal cost and quality-adjusted life years (QALYs) for the total target population.
- Population impact, which represents incremental costs and incremental effects (QALYs) accumulated over the model time horizon for the whole population.
- Patient flow through model states, which is a probability that a patient would stay in a particular health state when using the intervention or standard care.

The model also enables to perform sensitivity analysis that allows the user of the model to assess the impact of different inputs for selected parameters on the outcome of the evaluation.

The model also enables to perform Output Sensitivity Analysis, in which e.g. relation of QALY and cost-effectives can be assessed.

Probabilistic Analysis can provide outcomes that show the total impact of the intervention on healthcare costs and health related Quality of Life for the total target population. The outcomes represent the weighted average of the outcomes for each age-gender combination, weighted by the distribution of age range in the specified target country and age range.

Other output can be cost-effectiveness acceptability curve (CEAC), which shows the probability of the intervention being cost-effective.

Relevance to SHAPES

MAFEIP is recommended tool to assess impact of innovations piloted in SHAPES. It should be noted, that users of the tool should be qualified in health system statistics and also have access to high quality quantitative and qualitative data related both to the area where the new interventions will act (e.g. health homecare, nursing houses) and the new intervention itself, including costs and also knowledge of the conditions on the side of clients/patients, such as willingness to share some costs. MAFEIP can be used in both health and social care. It was not designed intentionally for other ICT based systems such as smart homes, where e.g. relationship between health statues and the smart system at home is more difficult to qualify and quantify. Using not...
verified input data or particular model as well as uncritical interpretations of some outputs could mislead the user in decisions.

4.3.4 The NASSS framework – practical aspects

To assess the success of technology-supported health or social care programs an adapted version of NASSS framework, proposed by Greenhalgh et al [63] can be applied. Essentially, this framework comprises of a number of questions across 7 core domains (see Table 16). This way the core outcomes captured by the pilot sites can be reviewed in order to establish the functional, behavioural, psychological, service usage and technology integration impacts.

Table 16: Domains and questions in the NASSS framework [63].

<table>
<thead>
<tr>
<th>Domain/question</th>
<th>Simple</th>
<th>Complicated</th>
<th>Complex</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Domain 1: The condition or illness</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1A. What is the nature of the condition or illness?</td>
<td>Well-characterized, well-understood, predictable</td>
<td>Not fully characterized, understood, or predictable</td>
<td>Poorly characterized, poorly understood, unpredictable, or high risk</td>
</tr>
<tr>
<td>1B. What are the relevant sociocultural factors and comorbidities?</td>
<td>Unlikely to affect care significantly</td>
<td>Must be factored into care plan and service model</td>
<td>Pose significant challenges to care planning and service provision</td>
</tr>
<tr>
<td><strong>Domain 2: The technology</strong></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2A. What are the key features of the technology?</td>
<td>Off-the-shelf or already installed, freestanding, dependable</td>
<td>Not yet developed or fully interoperable; not 100% dependable</td>
<td>Requires close embedding in complex technical systems; significant dependability issues</td>
</tr>
<tr>
<td>2B. What kind of knowledge does the technology bring into play?</td>
<td>Directly and transparently measures [changes in] the condition</td>
<td>Partially and indirectly measures [changes in] the condition</td>
<td>Link between data generated and [changes in] the condition is currently unpredictable or contested</td>
</tr>
<tr>
<td>2C. What knowledge and/or support is required to use the technology?</td>
<td>None or a simple set of instructions</td>
<td>Detailed instruction and training needed, perhaps with ongoing helpdesk support</td>
<td>Effective use of technology requires advanced training and/or support to adjust to new identity or organizational role</td>
</tr>
<tr>
<td>2D. What is the technology supply model?</td>
<td>Generic, “plug and play,” or COTS&quot; solutions</td>
<td>COTS solutions requiring significant</td>
<td>Solutions requiring significant</td>
</tr>
<tr>
<td>Domain 3: The value proposition</td>
<td>3A. What is the developer’s business case for the technology (supply-side value)?</td>
<td>Clear business case with strong chance of return on investment</td>
<td>Business case underdeveloped; potential risk to investors</td>
</tr>
<tr>
<td>-------------------------------</td>
<td>-------------------------------------------------------------------------------------------------</td>
<td>-------------------------------------------------</td>
<td>-------------------------------------------------</td>
</tr>
<tr>
<td>3B. What is its desirability, efficacy, safety, and cost effectiveness (demand-side value)?</td>
<td>Technology is desirable for patients, effective, safe, and cost effective</td>
<td>Technology’s desirability, efficacy, safety, or cost effectiveness is unknown or contested</td>
<td>Significant possibility that technology is undesirable, unsafe, ineffective, or unaffordable</td>
</tr>
<tr>
<td>Domain 4: The adopter system</td>
<td>4A. What changes in staff roles, practices, and identities are implied?</td>
<td>None</td>
<td>Existing staff must learn new skills and/or new staff be appointed</td>
</tr>
<tr>
<td>4B. What is expected of the patient (and/or immediate caregiver)—and is this achievable by, and acceptable to, them?</td>
<td>Nothing</td>
<td>Routine tasks, eg, log on, enter data, converse</td>
<td>Complex tasks, eg, initiate changes in therapy, make judgments, organize</td>
</tr>
<tr>
<td>4C. What is assumed about the extended network of lay caregivers?</td>
<td>None</td>
<td>Assumes a caregiver will be available when needed</td>
<td>Assumes a network of caregivers with ability to coordinate their input</td>
</tr>
<tr>
<td>Domain 5: The organization</td>
<td>5A. What is the organization’s capacity to innovate?</td>
<td>Well-led organization with slack resources and good managerial relations; risk taking encouraged</td>
<td>Limited slack resources; suboptimal leadership and managerial relations; risk taking not encouraged</td>
</tr>
<tr>
<td>5B. How ready is the organization for this technology-supported change?</td>
<td>High tension for change, good innovation-system fit, widespread support</td>
<td>Little tension for change; moderate innovation-system fit; some powerful opponents</td>
<td>No tension for change; poor innovation-system fit; many opponents, some with wrecking power</td>
</tr>
<tr>
<td>5C. How easy will the adoption and funding decision be?</td>
<td>Single organization with</td>
<td>Multiple organizations</td>
<td>Multiple organizations</td>
</tr>
</tbody>
</table>
### Domain 6: The wider context

#### 6A. What is the political, economic, regulatory, professional (eg, medicolegal), and sociocultural context for program rollout?

| | Financial and regulatory requirements already in place nationally; professional bodies and civil society supportive | Financial and regulatory requirements being negotiated nationally; professional and lay stakeholders not yet committed | Financial and regulatory requirements raise tricky legal or other challenges; professional bodies and lay stakeholders unsupportive or opposed |

### Domain 7: Embedding and adaptation over time

#### 7A. How much scope is there for adapting and coevolving the technology and the service over time?

| | Strong scope for adapting and embedding the technology as local need or context changes | Potential for adapting and coevolving the technology and service is limited or uncertain | Significant barriers to further adaptation and/or coevolution of the technology or service |

#### 7B. How resilient is the organization to handling critical events and adapting to unforeseen eventualities?

| | Sense making, collective reflection, and adaptive action are ongoing and encouraged | Sense making, collective reflection, and adaptive action are difficult and viewed as low priority | Sense making, collective reflection, and adaptive action are discouraged in a rigid, inflexible implementation model |

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**Relevance for SHAPES**

This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 857159
Within SHAPES the employment of this approach to the pilot evaluation can be informed by the outputs of T3.1, including the CONOPS framework based on the integration of the IEEE [75] standard for the development of concepts of operations, along with cultural-historical activity theory (CHAT) [76], and Cognitive-Work Analysis (CWA) [77]. This allows for the broadening of the framework out from the clinical case view to include the point of view of other actors, such as care-workers and service providers, in an isomorphic way, that is, while still maintaining the overall nested ecological approach outlined above. CWA modelling emphasises the sociotechnical aspects of SHAPES including the human factors as well as the socio-organisational processes involved in system functioning along with the key mediating role of technology. CHAT emphasises in a critical way the interdependencies of people, tools, rules, motives, and objectives in achieving socially meaningful activity while also throwing light on the potential for conflict and contradiction within systems as key design challenges.

The combination of these approaches with the NASSS framework allows for a flexible overarching framework that accommodates the diversity of user categories, use cases, and objectives while maintaining overall coherence of the methodological approach. The SHAPES concept recognises that the technology platform for smart and healthy aging has to work in different ways for different people and that user needs evolve over time and context. A platform that facilitates cross-over of individual, community and clinical action taking i.e. integrating interactions, requires a complex systems analytic lens, provided by the NASSS framework to consider the influence of new technological solutions in the context of their integration into a dynamic network of people and other technologies. It is this dynamic network which generates particular activities in particular contexts; overall evaluation requires a rich, contextualised narrative of the multitude of interactions that help explain integration outcomes and unexpected effects of the technology-supported change efforts [78].

4.3.5 Quantitative and qualitative data collections methods

Stakeholders should start thinking about the data collection process as early as possible in order to gather information and develop health and wellness indicators to identify data collection needs. By health and well-being indicators we mean a measure that helps quantify health and quality of life overall. In addition, the indicator can be defined as a variable that measures the key elements of a health intervention. Some examples of the domains that an indicator can measure are: Health status; Risk factors; Service coverage; Health systems; etc. Indicators should be developed prior to data collection in order to incorporate monitoring procedures into the pilot activities and ensures that the information derived from the process is reviewed during policy-making cycles. We also need to consider the following:

- How the data collection methods are linked to indicators;
• Sampling plans. According to the sampling plan, we mean the process of determining how to obtain a sample from each EU pilot site during the implementation of the pilot activities;
• Frequency of data collection in during the pilot activities;
• Methods for collecting routine vital signs and health data;
• Techniques of recruiting potential participants for each use case among the pilot topics;
• Who will be responsible for collecting this data with respect and efficiency?
• How could registration/admission staff (hospitals and clinics) or call center staff (health plans) request this information?
• What are the legislations among pilot sites for collecting health data for each pilot activity?
• Are the quantitative and qualitative data collected simultaneously or sequentially and which has priority in each case [79, 80]?
• What is the procedure and duration of legislative bureaucracy for each National Bioethics Commission?

The process of data collection includes accumulating and counting of variable information within the field we are interested with respect to indicators have been developed for each method. Research oriented data collection methods are divided into the quantitative and the qualitative approach which includes several potential methods for collecting data. Comparing the quantitative and qualitative research methods we will realize that the main difference between them is that the data collected in case of quantitative method is numerical and during qualitative method not-numerical. Considerable importance has also the difference between the procedures applied within the two methods and the number of correspondents in each case. For example, sample is chosen randomly in order to collect quantitative data, while on the other hand during qualitative data collection random selection of participants is not appropriate.

Figure 20 presents data categories which are divided into primary data and secondary data. By primary data we mean new data collected for a specific research problem and with procedures that interpret the problem best. Data sets from document analysis that have been already collected for research activities, or any other related bibliography are called secondary data. However, we can consider as secondary data any clinical database that would be useful for our study. As we have already mentioned, data is divided into quantitative data that can be called objective and qualitative data that can be called subjective. The data are collected by various methods as shown in the following Figure 20.
Quantitative research approach focuses on testing theories and hypotheses, extracted data can be analysed through math and statistical analysis because mainly expressed in numbers, graphs and tables. In addition, the sample size of the respondents should be as large as possible in order to provide more accurate evaluation of the quantitative data. Quantitative research methods give more emphasis on the objective measurements and focuses on numeric data. Collected through quantitative data collection methods such as: Interviews with older individuals, caregivers and clinical experts by using rating scaled questions; Experimental studies like randomized controlled trials and quasi-experiments; or by manipulating pre-existing statistical data from clinical databases using computational techniques.

Figure 21 presents quantitative data collection methods which can be applied through data analysis or new studies. Both approaches are divided into sub-categories which integrate studies among the following three main methods: Observation; Experimental studies (RCT and Quasi-Experiments) and Questionnaires which include the methods that can be adapted in each case.
On the other hand, qualitative research focuses on exploring ideas and formulating a theory or hypothesis. Data that have been collected can be analyzed by summarizing and interpreting, mainly based on a descriptive, human-based narrative. More specifically qualitative research methods collect and work with non-numerical data. Usually, the purpose is to analyse this data through social sciences, seeking to interpret from these data the meaning of social life (e.g. the quality of life of a targeted population). Methods for collecting qualitative data include brainstorming [81] and interviews with focus groups (6 to 10 respondents), or dyads and triads (2 and 3 respondents, respectively), or face to face interviews with targeted participants from the field we are interested. Also, observational studies approach, where the astute observer describes events, e.g. case-control studies, cohort (a group of people who share a defining characteristic) studies offer endless possibilities for us to learn how humans interact by analysing the relevant document. Open-end surveys and oral history can be included too. In addition to traditional methods, new methodologies have been introduced in the main field of qualitative research. For example, in motivational research and attitude surveys which are also qualitative data collection methods, projective techniques play an important role to gather data from respondents. Also, projective techniques are useful because the interviewees have the opportunity to unconsciously express their true attitude and their true feelings on the subject under study through psychological methods, such as pictorial, verbal and expressive reading techniques.

Table 17 presents the different methods that can be used to gather quantitative and qualitative data through various techniques that will implement among pilot activities. Third column presents sampling method techniques of each case. In addition,
provides the amount of data that can be gathered and the domains of implementation of each method.

Another approach to provide data could be the combination of both quantitative and qualitative methodology, called mixed methods research, in a single study in order to have more comprehensive picture of health services and understanding of older people's quality of life. Mixed methods could be implemented in the following situations [82]:

- To gather data on the same topic with different methods to capture different dimensions of the same phenomenon (triangulation);
- If we need a complementary method to elaborate, illustrate, enhance, or clarify the results;
- In case the evaluation of the results of one method conclude to paradoxes and contradictions;
- In order to expand the breadth and depth of the study

Table 17: Data collection methods

<table>
<thead>
<tr>
<th>Methods</th>
<th>Variable</th>
<th>Sampling Method</th>
<th>Objectives</th>
<th>Volume of Data</th>
<th>Techniques</th>
<th>Domains</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brainstorming [83]</td>
<td>Qualitative</td>
<td>Clustered sampling/ Snowball sampling</td>
<td>Ideas for further exploration; Requirements gathering; Project planning; Focus on a particular issue</td>
<td>Small</td>
<td>Stakeholders gather to discuss intended to particular issues or areas of interest (contribute on trigger questions)</td>
<td>Challenges with Mobile Healthcare Applications; Social and Economic Aspects; Organisational aspects; Ethical, legal and socio-cultural aspects</td>
</tr>
<tr>
<td>Focus Groups [83]</td>
<td>Quantitative &amp; Qualitative</td>
<td>Stratified sampling</td>
<td>To collect data that are not typically contained in hospital/ambulatory care record. When data includes experiences, believes, views</td>
<td>Small to Large</td>
<td>Closed-ended or open-ended questions; Face-to-face or telephone interviews; Computer Assisted</td>
<td>Safety (Interview with manufacturers, clinical experts); Patient perspectives Organizational aspects; Socio-cultural,</td>
</tr>
<tr>
<td>Observation</td>
<td>Quantitative &amp; Qualitative</td>
<td>Clustered sampling/ Systematic sampling</td>
<td>To formulate framing and testing hypotheses about the observed older adult in each case; To collect data that cannot be collected through other methods such as interviews</td>
<td>Medium-Large (videos)</td>
<td>Track and record directly or with participation, specified events using cohort, cross-sectional, longitudinal study and case-control studies</td>
<td>Challenges with Mobile Healthcare Applications; Clinical safety (patients and caregivers); Quality and clinical effectiveness; Socio-cultural aspects</td>
</tr>
<tr>
<td>-------------</td>
<td>---------------------------</td>
<td>-----------------------------------------</td>
<td>-------------------------------------------------------------------------------------------------</td>
<td>----------------------</td>
<td>----------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Document analysis</td>
<td>Quantitative but mostly qualitative</td>
<td>Simple random sampling/ Clustered sampling/ Stratified sampling</td>
<td>To create a data collection form that summarize data gleaned from high-quality relevant evidence research document reviews</td>
<td>Medium to Large</td>
<td>Collecting data by reviewing existing hard copy or electronic document s that may include reports, program logs, performance ratings, meeting minutes, newsletter etc.</td>
<td>Every domain could implement document analysis in order to collect data</td>
</tr>
</tbody>
</table>
### Experiments/clinical trials

<table>
<thead>
<tr>
<th>Method</th>
<th>Characteristics</th>
<th>Description</th>
<th>Scale</th>
<th>Setting</th>
<th>Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Qualitative but mostly quantitative</td>
<td>Simple random sampling/Clustered sampling/Stratified sampling</td>
<td>Exporting data results from new intervention treatments about biomedical or behaviour in order to check safety and effectiveness of the proposed use cases among the pilot themes</td>
<td>Large</td>
<td>Experimental studies with (RCT) or without (quasi-experiments) randomization control groups</td>
<td>Clinical effectiveness; Medical signal processing and biomedical imaging; Economic and safety aspects</td>
</tr>
<tr>
<td>Quantitative</td>
<td>Clustered sampling/Systematic sampling</td>
<td>To improve the quality of patient care; To underpin our research; To improve cost-effectiveness; To provide information for regulatory purposes; To provide data on medication intensity and duration</td>
<td>Medium to Large</td>
<td>Compare data from prospective and retrospective recall of clinical daily diaries; Combine and analyse registered data and new entries in order to provide more accurate results</td>
<td>Health problem and description of the application; Safety; Clinical effectiveness</td>
</tr>
</tbody>
</table>

#### 4.3.5.1 Quantitative data collection methods

1. **Title**
   - Systematic Literature Review

2. **Definition**
   - Document analysis is a high-level overview of a specific research field from previous bibliography and research archives that uses systematic and accurate methods to identify, select, and critically examine data. These types of reviews can include knowledge generated through quantitative approaches derives from methods such as questionnaires, surveys, experimental trials, etc. [84]

3. **Domains**
   - Challenges with Mobile Healthcare Applications;
   - Clinical safety (patients and caregivers);
   - Quality and clinical effectiveness;
Patients and relatives' perspectives;
Social and Economic Aspects;
Organisational aspects;
Ethical, legal and socio-cultural aspects

**Implementation**

- Define topic of the research field;
- Formulate research questions;
- Identify keywords;
- Identify and search reliable databases;
- Read and assess reliability of published publications;
- Structure database;
- Produce and review summary table;
- Draft methods;
- Evaluate key results and draft results section;
- Draft introduction;
- Draft discussion and abstract;
- Revise document till ready for submission [85, 86]

**Advantages**

- Correct selection of studies reduce bias and produce reliable and accurate conclusions;
- Summary of several studies helps the reader to understand results easier;
- Enables the sparkle for research within the gaps of the existing knowledge

**Disadvantages**

- The combination of the results from research among several fields might be difficult and time-consuming;
- It might be difficult to decide how reliable is each source;
- If we use only published literature may lead to misrepresentation of the results because unpublished studies are not included

**Examples**

- [Cochrane library](https://www.cochranelibrary.com) which is a collection of databases in medicine and other healthcare specialties provided by Cochrane and other organizations;
- Database of Abstracts of Reviews of Effects ([DARE](https://dare.nihr.ac.uk));
- National Institute of Health Research ([NIHR](https://www.nihr.ac.uk));
- American College of Physicians [ACP Smart Medicine®](https://www.acpsmartmedicine.org);
- Agency for Healthcare Research and Quality ([AHRQ](https://www.ahrq.gov));
- [Evidence Updates Database](https://www.evidencedatabase.com);
- [Bandolier](https://www.bandolier.org)
<table>
<thead>
<tr>
<th>2. Title</th>
<th>Analysis of register data (Clinical registries)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Definition</strong></td>
<td>This method of collecting quantitative data focuses on clinical registries that can be used to improve the quality of patient care, underpin research, improve cost-effectiveness and provide information for regulatory purposes. The combination of clinical databases and medical registries emerge issues and opportunities that arise in order to study hypotheses or questions that are secondary from the original reason of data collection [87]</td>
</tr>
</tbody>
</table>
| **Domains** | • Health problem and description of the application;  
• Safety;  
• Clinical effectiveness;  
• Economic aspects |
| **Implementation** | • Subset of patient registries  
  ➢ Limit to records for patients 65 years or older;  
  ➢ Limit registries using inclusion criteria;  
• Link patient identifiers to link patient records  
  ➢ Link records between data sources on exact values of admission date, patient date of birth or age, patient sex etc.;  
  ➢ Use results from patient records to inform links;  
• Determine specifications for hospitalization-level linking  
  ➢ Choose rules to apply;  
  ➢ Decide whether records should be allowed to link to multiple registry records;  
• Link hospitalization records [88] |
| **Advantages** | • Readily available and contain much useful clinical information;  
• Can be linked to other follow-up information sources;  
• Can be used to characterize the medical history and clinical course of hospitalized and outpatient older adults;  
• Can provide data on medication intensity and duration |
| **Disadvantages** | • Sometimes data contained in medical records are not reliable;  
• Information is often incomplete and/or missing;  
• Checks on validity and reliability are not performed;  
• Information on etiologic or prognostic factors of importance is often either not obtained or asked about or recorded in a standardized manner [89] |
### Examples
- Cochrane library;
- Database of Abstracts of Reviews of Effects (DARE);
- Cloudpital is Electronic Medical Record (EMR) database in Cyprus;
- General Health System (GHS) database in Cyprus

### 3. Title Questionnaires using rating scaled questions

#### Definition
Questionnaire is a useful research form that contains a set of structured questions (e.g. Likert-type scale) or other types of prompts, in which the respondent is asked to answer. The purpose within SHAPES will be to gather information from elderly people and caregivers. Quantification of qualitative interview questions should provide graded scoring questions in order to convert qualitative data through questionnaires to quantitative data.

#### Domains
- Safety (Interview with manufacturers, clinical experts);
- Patient perspectives;
- Organizational aspects;
- Socio-cultural, ethical and legal aspects

#### Implementation
- Rating scaled questionnaires could be answered through interviews with focus groups (6 to 10 respondents), or dyads and triads (2 and 3 respondents, respectively), or face to face interviews with targeted participants from the field we are interested. Questionnaires could also be administered by mail or telephone survey to include people living in remote areas;
- Questionnaires should be complete in order to cover every aspect of the field we are investigating in each case;
- Clarity should refer not only to the content of the information but also to the responders

#### Advantages
- In terms of time, effort and cost questionnaires are economical;
- Because the target sample of the population is spread in geographically diverse locations is the easiest way to collect information, compared to the other methods like face to face interview or participant observation;
- Through questionnaires we will be able to collect personal and/or risk factor data that are not typically contained in clinical records;
The respondents have a greater confidence that they will not be identified compared with the other methods.

Disadvantages

- In case of mailed questionnaire method, if the respondent fails to understand some of the technical terms or he has any doubt, there is nobody to clarify these technical terms or doubts;
- If response rates are less than desirable, one may question the representativeness of the study sample and its generalizability;
- In questionnaire method, it is not possible on the part of the researcher to conduct an intensive or in-depth study of the feelings and reactions of the respondents.

Examples

- Questionnaire-based evaluation of everyday competence in older adults using rating scaled questions [90];
- Scaling analysis with questionnaires of attitudes to ageing [91];
- Measure Older People’s Quality of Life (OPQOL-bref) [92];
- Zarit Burden Interview (ZBI) is an example of rating scaled questionnaire with a structured verbal interaction which can be used in order to evaluate levels of stress of patients as well as for the caregivers;
- World Health Organization Quality of Life (WHOQOL-bref) is another example of mood and quality of life evaluation questionnaire that comprises the following broad domains: physical health, psychological health, social relationships, and environment;
- The construction of Hospital Anxiety and Depression Scale (HADS) will be another important tool of measuring well-being [93].

4. Title Quasi-experimental study designs

Definition

Quasi-experiments are studies that resemble experimental studies and aim to evaluate interventions without randomization. Often described as non-randomized, pre-post intervention studies and it is an approach to estimate causal effects of health care mediation. Credible quasi-experimental studies are able to estimate a causal relationship using exogenous variation in the exposure of interest which is not usually directly controlled by the researcher [94].

Domains

- Economic and organisational aspects (e.g. An informatics technology group is introducing a pharmacy order-entry system aimed at decreasing pharmacy costs. The
intervention is implemented and pharmacy costs before and after the intervention are measured);

- Clinical effectiveness (e.g. A hospital introduces a new order-entry system and wishes to study the impact of this intervention on the number of medication-related adverse events before and after the intervention);

- Medical signal processing and biomedical imaging (e.g. Diagnostic errors measurement before and after the intervention of a system that could detect the abnormalities in commonly-ordered imaging tests, such as chest x-rays)

### Implementation

- Before the implementation of the quasi-experimental studies, we should consider the following:
  - Identify use cases of internet-based digital health interventions;
  - Identify effects that could be measured of internet-based digital health interventions;
  - Identify indicators that will be used to measure the effects of internet-based digital health interventions, and for whom will the effects be measured (patients, health care system, society etc.);
  - Natural changes over the passage of time may influence the study outcome (e.g. seasonality, fatigue, aging, maturity or boredom);
  - Instrumentation bias occurs when a measuring instrument changes over time (e.g. improved sensitivity of laboratory tests) or when data are collected differently before and after an intervention;

- Designs are divided into four study groups:
  - Without control groups. By control group we mean the group that does not receive the intervention in a study and is then used as a benchmark to measure how the group who receive the treatment react;
  - With control groups selected non-randomized and without a preliminary test;
  - With control groups selected non-randomized and with a preliminary test;
  - With interrupted time-series designs;

- In each case the depended variables will be extracted after the intervention;

- During the implementation of interrupted time series designs, a sequence of sequential observations equally spaced in time interrupts by the imposition of a treatment
or intervention, not just with individual measurements before and after an intervention [95]

<table>
<thead>
<tr>
<th>Advantages</th>
<th>Without randomize groups the process will be cheaper and less time consuming;</th>
<th>Even if policy implementation is out of our control quasi-experiments can retrospectively analyse policy changes;</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Quasi-experimental studies meet some requirements for causality including temporality, strength of association and dose response;</td>
<td>Designs can be strengthened with control groups, multiple measures over time and cross-overs</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Disadvantages</th>
<th>Need processes to assess availability, accuracy and completeness during baseline phase because retrospective data is often incomplete or difficult to be obtain;</th>
<th>Nonrandomized designs tend:</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>To overestimate effect size</td>
<td>To lack of internal validity [96]</td>
</tr>
<tr>
<td></td>
<td>Not to meet all requirements to determine causality;</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Examples</th>
<th>A quasi-experimental 12-month clinical trial conducted within a metropolitan-based healthcare system in the northeastern United States to prove that rehabilitative care is identified as the most efficacious treatment for maintaining physical function [97];</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>A quasi-experimental study of the effects of an integrated care intervention for the frail elderly on informal caregivers’ satisfaction with care and support [98];</td>
</tr>
<tr>
<td></td>
<td>A quasi-experimental observational study that investigates the potential fall injury reducing effect of a compliant flooring in a residential care setting [99].</td>
</tr>
</tbody>
</table>

---

5. Title

Observational study designs

**Definition**

Observation is the systematic monitoring and description of the events, behaviours, and artefacts [100]. There are two major types of observations. Participatory monitoring that implies researcher being in the studied environment as an observer and participant. Direct observation involves observing without interacting with the people which are under study.

**Domains**

- Challenges with Mobile Healthcare Applications;
- Clinical safety (patients and caregivers);
### Implementation

- Collecting data through observational studies could implement within cohort, cross-sectional, longitudinal and case-control studies as follow:
  - Cohort studies use a group of people with a common characteristic and they can be forward-looking (prospective) or backward-looking (retrospective) data as presented in Figure 22;
  - Cross-sectional studies implement when we want to compare data among different populations at the same point in time;
  - Longitudinal studies implement when we want to study a single population over an extended period of time;
  - Case-control studies compares people who have a common characteristic (e.g. disease) and people who do not have the characteristic, and looks back retrospectively to compare how frequently the exposure to a risk factor effect each group;
- We need to determine which observation method we will apply to collect data in a way that minimizes or eliminates unfamiliar devices into the environment we want to observe;
- In order to collect quantitative data, we have to develop a rating scaled debriefing to be filled in cases we examine well-being of elderly people (e.g. quality of life) or any other factor that can’t be translated numerically [101].

### Advantages

- Observational studies will be beneficial by formulating framing and testing hypotheses about the observed phenomenon in each case;
- Data collected through observation will in most cases be more accurate than data collected by other data collection methods (e.g. interviews, questionnaires) as we will be able to directly check and evaluate the accuracy from the observation;
- Observation will be the only appropriate tool for collecting data from older people who will not be able to express information about the fact we are examine for any reason, or simply non-cooperating individuals.
### Disadvantages

- In most cases the feelings and emotions cannot be reliably estimated by observational techniques and two researchers may judge the same phenomena differently;
- Additional limitations of the observational study would be that it requires high cost, time and effort;
- Lack of observer competence may impede the validity and reliability of the observation [102].

### Examples

- An example of observational case-control study was to explored the relationship between the use of antiplatelet and anticoagulant drugs (risk factor) and the risk of hospitalization for bleeding (outcome) in older people with a history of stroke [103];
- One prospective cohort study explored the relationship between the continuous use of antipsychotic drugs (exposure) and mortality (outcome) and hospitalization (outcome) in older people [104];
- A cross-sectional example took place in San Diego California and it was population-based observational study identifying prevalence of arterial and venous disease [105].

### 6. Title

**Randomized controlled trial (RCT)**

**Definition**

Randomized controlled trials are experimental study techniques for collecting data in which people are randomly allocated into two groups. In order to examine the effectiveness of the intervention, the first group will take the real treatment and the second a placebo [106].

**Domains**

- Clinical effectiveness;
- Economic aspects

**Implementation**

- First, we have to choose which of the following types of randomized controlled trials we want to use;
- Main types of RCT designs are:
  - Completely Randomized;
  - Stratified;
  - Cross-over;
  - Cluster-randomized;
  - Cluster-crossover;
  - Step-wedge;
- The process of this tests is to randomly recruit two groups of people, the experimental group and the control group;
The first will receive the intervention that we want to try and the second will receive an alternative (virtual) treatment (placebo) to test the effectiveness of the intervention.

### Advantages
- Randomization eliminates biased distribution and biased population recruitment and makes groups comparable according both known and unknown factors;
- Results can be analysed with well-known statistical tools;
- We will be able to establish superiority of two treatments for a certain intervention.

### Disadvantages
- Expensive in terms of time and money;
- We won’t be able to have the representative contribution of the whole population;
- May have lack of follow-up attributed to treatment [107].

### Examples
- RCT trials to test the efficacy of supplemental vitamin D and active forms of vitamin D with or without calcium in preventing falls among older individuals [95, 108];
- A study to investigate the effects of a structured 6-week neuropsychological course on the executive functioning of older adults with cognitive complaints through randomized controlled design trials [109];
- A randomized clinical trial comparing electrothermal arthroscopic capsulorrhaphy (i.e. the heat probe) versus open inferior capsular shift in patients with primary capsular redundancy was carried out in Canada [110].
4.3.5.2 Qualitative data collection methods

Elderly people usually live with comorbidities, and the existing conditions interfere with one another. In such complex situations, qualitative data collection methods can offer an affordable, convenient approach to evaluate the general health condition of a subject. Unlike quantitative methods, they do not need a fully defined, well-structured hypothesis, and, therefore, can be applied to explore and to gain information of complex scenarios. Qualitative methods also help determining the relationship between the subject and the care professional, which includes frequency of visits, main underlying disease and the symptoms which significantly impact quality of life, among others.

Most common types of qualitative data collection methods in clinical practice are: observational methods, (depth) interviews, storytelling, projective techniques and document analysis. In research, other options are brainstormings and focus group discussion [111].

Observational methods

A qualitative observational method elaborates a description of the topic of interest by observing the subject in their real environment without interfering.
In daily, current clinical practice, observational methods are carried out in an indirect manner. The description is based in recorded data collected in the standard routine of the treatment. For example, with non-hospitalized subjects, based on the case and their historic health record, the general practitioner or physician establishes a routine in health data collection to be done by the patient or the caregiver. Health professionals can also record measurements in scheduled visits, particularly when a biological parameter is measured or the environment is described (for example, flat with poor natural lighting). Although not currently implemented in standard clinical practices, new technologies can allow less intrusive measurements (for example, with cameras, sensors, wearable devices,...) and avoid daily life activity disruptions due to the measurement action. It is worth mentioning that, although the raw measurements may be quantitative, the final data is not, as it is defined as the description (not analysis) of the health professional after checking the data. In summary, collected measurements serve to describe the health state and quality of life of the patient in a qualitative fashion.

Examples of usual measurement types are: blood glucose, blood pressure, body temperature, weight, number of times the subject urinates/defecates, colour of urine, colour/consistency of feces, episodes of dizziness, episodes of disorientation, cough, skin colour, mucus, number of falls, appetite, nausea, diet, intensity of pain, mobility, physical/cognitive exercises, medication, socialization, habits (smoking, drinking,...) and so on. Measurements are usually recorded in a diary or formatted data sheets. The routine should be easily implemented in both the daily life of the subject and the scheduled visits of/to the health professionals.

The qualitative description of the collected measurements serves the health professional to evaluate the progression of the subject and define intervention actions, if necessary. After description (data collection), analysis effort is put into the finding of a rationale which can explain alterations from normal conditions and whether they are related to the current therapeutic treatment and/or life-style. Regarding chronic conditions in elderly people, a progression of the disease is always expected. Consequently, observational data is analysed to favour decision-making in providing the best possible quality of life. Aftermath of the analysis can lead to (always in agreement with the subject and/or the close family):

- No intervention, when parameters are stable, changes are considered inevitable or the state of the subject does not recommend so.
- Intervention to improve subject’s quality of life, when the intervention is backed up by the rationale deduced from the observations. Examples of interventions are change of medication, suggestions regarding life-style and physical/cognitive tasks, among others.

Clinical research

This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 857159
In clinical research, a more intensive observation is usually applied. Because of the research nature, reduced recruited population and the shorter time frame of the actions, continuous, long-time observations are feasible. Usual methods which are followed to describe the topic/subject under research are [112]:

- Researcher describes the subject in an overtly manner, usually when the subject is in a common/public area.

- Researcher describes the subject in an covertly manner:
  - By means of audio/video recording.
  - By means of a CCTV.

Some observational designs may include an active role of the researcher, for example, through the participation of mock patients [113].

**(Depth) Interviews**

Interview is a methodology in data collection in which a health professional interacts with the subject by asking questions in order to retrieve information [114]. Qualitative interviews are usually used when:

- The questions require complex answers. For example, interviews are useful when the variables included in the answer may vary from person to person, when guidance is needed to give a complete answer and when answers are detailed with experiences, believes, views and opinions.

- When an intimate relationship with the subject is needed to obtain certain information (to build a sense of trust).

- When the formulation of the questions and their order has to be adapted from person to person.

Questions in interviews take the form of:

- Open questions: they focus on the description of a situation without delimiting the parameters that are used in such. Example would be the description of “daily walks” or what “triggers anxiety”.

- Targeted questions: they focus on specific parameters but the answer is likely to be open. An interview with the question “how long do you walk a day?”, an interview allows answers of the type “usually five blocks” or “usually 30 min”. The health professional can homogenize answers with further questions.

Because of the more intimate nature of an interview, an interview-based method usually follows the next steps:
The health team defines the set of topics that will form the backbone of the interview. The questionnaire is thus a guide for the health professional to establish a conversation with the subject or care givers in order to extract relevant information.

To prepare the context of the interview, the stage.

To define the data collection methods (video, audio, phone call, writing, ...)

To select the right interviewer.

Define times in a flexible manner (to allow the subject to express for a long time, to tell stories, ...)

The objective of interviews is similar to the ones described for observational methodologies. However, due to the higher degree of interaction with the subject and the flexibility they allow, they are commonly used in three scenarios.

First visit. Relatively long interviews are common on the first time the physician meets the subject. It provides a holistic view of the general state of the subject which served to define therapeutic treatment or agree on the current one prescribed by a former professional.

Routine visits. Scheduled check ups follow a short interview model which, unlike the first visit, focuses on variations since last visit. They are oriented to introduce minor changes to the therapeutic treatment and suggestions regarding life-style.

Research studies. Medium/long-size interviews are usual when a research study is being carried out. While visits in clinical practice usually record data in writing, research studies incorporate other resources which allow a more detail recording and future revisions (video, audio, ...).

Scales

The scales are designed to be quantitative methods. The answers to the questions they include are categorized in order to compute the quantitative measure. However, the categorization is made by the health professional and may not reflect many details present in the answers given by the subject (or observations made by the professional). Thus, questionnaires of scales can be a source of well-established questions in the clinical practice that could be used in interviews. Several scales which are commonly used in the elderly are:

Barthel (Mobility, Dementia): to measure the performance in activities of daily living and degree of independence [115].
• Lawton’s and Brody’s test [116] (Dementia): to assess instrumental activities of daily life necessary for functioning in a community environment.

• Scales for disnea (Heart failure): Medical Research Council, New York Heart Association and Brog’s scale.

• ECOG [117] (Cancer): for the assessment of the progression of the disease and how it affects daily living abilities.

• Karnofsky [118] (Cancer): similar to ECOG but longer.

• Norton [119] (Ulcers): to assess the risk to suffer from ulcers.

• Pfeiffer’s test [120] (Cognitive): to assess the cognitive impairment.

Even though the high interaction between the subject and the health professional or researcher in interviews, the influence of the latter (reflexivity) should be minimal. A careful evaluation of such influence should be evaluated and minimised by design.

**Storytelling**

Storytelling is a narrative description of events and life experiences by a person who lived them [121]. Unlike interviews, there are much fewer questions which guide the conversation, and usually there is only one main question which helps setting the framework of the description. The stories allow the exploration of the complexity of experiences in real life and the meaning that they have on the subjects. Because the validation of facts is not possible, medical professionals usually focus on the meaning rather than the veracity of the story. For example, stories help understanding the perceived quality of life of people with chronic pain, independently of the accurate level of pain they suffer.

Usually, three dimensions are analysed within a story [122]:

• Interaction: both personal (feelings, hopes, …) and social (intentions of other people and their point of view).

• Continuity: remembering of past actions, how they affect present experiences and implication in the future.

• Situation/Place: physical environment and setting.

Storytelling is used in both clinical practice and research. In clinical practice, it is widely accepted that patient’s stories are an important part of professional’s training in order to know how the treatment affects the patient (not only in terms of the disease) and the appropriateness of treatment in each particular case. This is particularly useful in vulnerable people, such as the elderly and specific communities, when treatment may greatly affect the quality of life.
Storytelling is also a widely used technique in dissemination of medical conferences and group meetings. Medical cases are told under the experience of the health group involved to spread personal experiences and non-explicit knowledge.

**Projective techniques**

Commonly used in psychology, projective techniques collect responses from subjects exposed to ambiguous stimuli. The objective is to release thoughts or beliefs which are not consciously known or accepted by the individual and may have a strong relationship with emotion and irrational thinking. In addition to physiological treatment, projective techniques are also applied in marketing and product acceptance. Projective techniques can be useful while studying the acceptance of new technologies in groups of people with innovation resistance, lack of motivation and low literacy, aspects with higher prevalence within the elderly population.

**Document analysis**

Document analysis is the description of information gathered from already existing sources. In clinical practice, most common source of information is the Health Record of the subject. Other sources of information which are not directly linked to the subject are scientific literature, newspapers and so on. Sometimes, personal documents, such as pictures and life histories of any type, from the subject at different ages, can also provide valuable information.

**Brainstorming**

Brainstorming is also a group activity in which individuals interact with each other while generating responses to the research topic. Unlike focus groups, the objective is not to confront or consent ideas, but to generate as many thoughts, solutions and concepts as possible, regardless the critical evaluation of the generated ideas, even by the individual who has generated them.

In Brainstorming, the setting and the guidance have the objective to remove any critical observation or pressure. Brainstorming is usually applied to generate data and topics that will be evaluated with other methodologies in more focused research.

**Focus Groups**

Focus groups are a variation of interviews which take form of debates in order to capture shared descriptions. Focus groups are important when the scope of the answer requires interaction among subjects. For example, interaction among subgroups can emerge their differences on the topic.

**Combination of several methods**
In order to increase the credibility of any conclusion, several methods of qualitative data collection are used. Data triangulation is the concept of gathering data around the same topic with different methods. Similar conclusions achieved through different methodologies increase their reliability. Methods should be as orthogonal as possible, meaning that the information they gather do not overlap.

Quality procedures

Several criteria have been defined in order to raise the rigor of qualitative research [123].

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Strategies</th>
</tr>
</thead>
<tbody>
<tr>
<td>Credibility/ Internal validity</td>
<td>• Triangulation: the use of multiple data sources, investigators, methods or theories to provide corroborating evidence.</td>
</tr>
<tr>
<td></td>
<td>• Search for Disconfirming Evidence (“deviant” or “negative” cases): active search of cases which do not follow the theory to propose hypothesis to refine the theory. This process continues until there is no outliers.</td>
</tr>
<tr>
<td></td>
<td>• Subject Review ( “member checking” or “dialogue with participants”): the participants in the research or case study give their view on the interpretation of findings.</td>
</tr>
<tr>
<td>Transferability/ External validity</td>
<td>• Detailed Description of the Context and how the context affects external validation, reproducibility and, in general, the ability to answer the original research question.</td>
</tr>
<tr>
<td>Dependability/ Reliability</td>
<td>• Data Archiving/Creating an Audit Trail. In addition to data, all data collection and storing procedures has to be documented in a way that an external person with access to the primary documents can reproduce the supporting evidence of the findings.</td>
</tr>
<tr>
<td></td>
<td>• Skeptical Peer Review. An independent referee asks challenging questions regarding the methods, data collection and interpretations.</td>
</tr>
<tr>
<td>Confirmability/ Objectivity</td>
<td>• Triangulation.</td>
</tr>
<tr>
<td></td>
<td>• Skeptical Peer Review or Audits.</td>
</tr>
<tr>
<td></td>
<td>• Search for Disconfirming Evidence or Negative Cases.</td>
</tr>
<tr>
<td></td>
<td>• Reflective Journal Keeping by the Researcher. The narrative generated in qualitative data collection methods is intrinsically affected by the researcher who generates it. Therefore, the researcher state how their actions and decisions influenced the research.</td>
</tr>
</tbody>
</table>
personal characteristics, feelings and believes may have influenced. Furthermore, the researcher should described what points of the methodology were specifically incorporated to minimise the potential biases.

4.3.5.2.1 DIPEX

As the data from DIPEX study has a significant role in development of personas, we will shortly introduce the DIPEX and its methodology.

Developed in 2001 by the Oxford University Health Experience Research Group (HERG), the Database of Individual Patient Experiences (DIPEX) methodology uses rigorous qualitative research methods to collect interviews on patient experiences of selected health conditions. The data not only serve as basis for the analysis (usually qualitative thematic analysis [124], but also other methods are often used such as grounded theory or narrative analysis) and publication in scholarly journals, but also as a foundation for extensive online information for the lay public and also as a source of training materials for the medical staff training. Thanks to the inspiration by the success of the UK DIPEX site, up to date 12 other countries launched their own DIPEX chapters and joined with the UK to form DIPEX International.

DIPEX research is usually organized within individual modules, while each module presents a particular health condition of specified target group. In this project we use data from the module „Active ageing“ that was realized in Czech Republic in years 2014-2015. Within this active ageing project 50 in-depth interviews were conducted with older adults (age 65+) that explored several important aspects of ageing. Maximum variation sampling was employed, with the aim of approximating the sample to the demographic characteristics of the older Czech population. Despite the fact that we could not aim for representative sampling, our goal was to at least simulate a typical demographic distribution. For the recruitment of our participants, we employed a combination of the snowball technique, approaching older-adult organisations and advertising through social networks. Data were analysed using thematic analysis and narrative analysis [125].

4.3.5.2.2 EQ-5D

EuroQol group first introduced the EQ-5D in 1990 as a generic, non-disease specific tool to measure health-related quality of life [126]. Since then, several different versions of the EQ-5D have been developed as simple tools to describe and value health in both research and real-world settings to inform decision making in healthcare. Completion of the EQ-5D provides an indicator of health status at the time of completion, however, it can be administered at multiple time points to provide data on
There are two versions available to evaluate the health-related quality of life in older individuals: EQ-5D-3L and EQ-5D-5L. These have been used in many health conditions and populations [127]. Both questionnaires essentially consist of two pages; the EQ-5D descriptive system and the EQ-5D visual analogue scale (VAS). The VAS records the respondent’s self-rated health on a scale of 0 (worst health you can imagine) to 100 (best health you can imagine). The EQ-5D descriptive system assesses five health dimensions: mobility; self-care; usual activities; pain/discomfort; anxiety/depression. Each dimension has 3 or 5 levels of response depending on the tool used. The five level version (EQ-5D-5L) was introduced in 2009 to improve the instrument’s sensitivity and reduce ceiling effects compared to the EQ-5D-3L [128, 129]. The EQ-5D-5L is recommended for use across applications including economic evaluation, clinical studies, quality of care and in public health studies [129].

Economic evaluation of interventions is an important component for decision making in health systems. These economic evaluations usually take the form of cost-utility analyses where health benefits are expressed in terms of Quality Adjusted Life Years (QALYs) [130]. The EQ-5D descriptive system results may be assigned an index score, depending on societal preferences unique to each country, with higher index scores representing higher health utility. The EQ-5D is one of the tools recommended for cost utility analysis by a number of Health Technology Assessment bodies around the world.

The EQ-5D is available in over 200 languages and there are specific versions depending on the method (digital or paper) and mode of administration (self-complete, interviewer or proxy). The self-complete version is suitable for people with capacity to complete themselves. The interviewer completion version is for use either in face-to-face or telephone/computer interviews when participants are either unable to read or write or unable to be physically present for the interview. The proxy versions are either for use when patients are mentally or physically incapable of reporting on their own health-related quality of life, for instance because of severe intellectual disability or mental health problems or to assess caregiver’s own opinion of the patient’s health-related quality of life. There is currently insufficient evidence to support the aggregation of data collected via different modes of administration (self-complete, interviewer or proxy), however, there is substantial equivalence of responses between paper and electronic mediums using the same mode of administration [131].

More information on the use and access to the EQ-5D tools can be obtained from the EuroQol website https://euroqol.org/eq-5d-instruments/

Relevance to SHAPES

The EQ-5D instruments are routinely used in research and can be used at the individual level to monitor a patient’s health status over time for example before, during
and after an intervention has been applied. The EQ-5D is short, easy to complete and available in many different languages which is particularly relevant as it is likely to be one of several patient reported outcome measures used in SHAPES pilots. The use of the EQ-5D would provide consistency when assessing generic health-related quality of life across a broad range of diseases, patients and technologies in the SHAPES pilots.

4.3.5.3 Conclusion

The purpose of this deliverable is to identify and present all the relevant data collection methods for the various small-scale and large-scale pilot activities to be implemented within and between the different pilot topics. Data collection methods and techniques can be divided into two main categories if we consider the type of variable. As we already analysed if the variable can be measured, the method is called quantitative and if the variable is defined non-numerical, the method is called qualitative. However, both categories of data could be integrated to provide more accurate and reliable results through data analysis. Accurate data collection is extremely important to preserve the integrity of research. The main approaches that can maintain data integrity and validity are data quality assurance and data quality control [132]. The quality assurance approach is applied before data collection begins to avoid problems and errors during the process [133]. The development of quality control is implemented during and after data collection and combines control activities such as monitoring of personnel to identify and avoid inconsistent, extreme values or invalid data [134]. Measures should also be taken to correct faulty data collection practices and also minimize future occurrences. Through subparagraph 4.3.5.1 we aim to analyse the presentation of quantitative data collection methods including definition of each method, domains to be applied, implementation techniques, advantages, disadvantages and examples of usage from literature references. The importance of contribution within this deliverable is essential to understand the structure of implementation of activities among the pilot themes of SHAPES. Table 18 presents data collection methods that can be implemented during the proposed use cases between the pilot activities and the type of variable outcome data in each case. The deliverable will be beneficial for the project overall for the reason why data is the spine of a project in order to evaluate and conclude to reliable results.

Table 18: Data collection methods for use cases among the pilot themes

<table>
<thead>
<tr>
<th>Pilot Themes-Use Cases</th>
<th>Title</th>
<th>Methods/Time Points</th>
<th>Outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>UC-PT1-001</td>
<td>Remote in-home wellbeing monitoring and assessment</td>
<td>• Observation (constantly) by: Omnitor’s NOTIFY system that enables the monitoring of home appliances and electrical devices;</td>
<td>• Quantitative data; Nominal variables from multiple choice questions</td>
</tr>
</tbody>
</table>
### UC-PT1-002 Digital Assistant to Support Older People to Live Independently and Remain Socially Connected
- Face-to-face interview with questionnaires \((t_0: \text{baseline})\);
- Focus groups with the end users \((t_0: \text{baseline})\)

- Qualitative data;
- Quantitative data with scaled questionnaires;
- Answers characterized by dichotomy \((\text{yes/no})\)

### UC-PT1-003 Competent usage of digital technologies
- Face-to-face interview with questionnaires \((t_0: \text{baseline})\);
- Focus groups with the end users \((t_0: \text{baseline})\)

- Qualitative data;
- Quantitative data with scaled questionnaires;
- Answers characterized by dichotomy \((\text{yes/no})\)

### UC-PT2-001 Delivering remote monitoring of key health parameters
- Observation by chatbot (ROSA Virtual Nurse) which can measure the number and type of interactions it enables;
- Interviews with older individuals and informal caregivers regarding the level of quality of life (improvement) (physical, mental) during the key health parameters monitoring phase \((t_0: \text{baseline}/t_1: \text{post-intervention}/ t_i: \text{every 3 weeks } i\in\mathbb{N}-\{1\})\);

- Nominal or dichotomous variables;
- Quantitative data through OPQOL (Older People's Quality of Life)
- Qualitative data (open-ended interview questions)
<table>
<thead>
<tr>
<th>UC-PT2-002</th>
<th>Supporting the interaction of the individual with the community</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>•</strong> Communication with formal caregivers (tᵢ: monthly, i∈ℕ₀);</td>
<td><strong>•</strong> Observation by chatbot which can measure the number and type of interactions it enables and follow-up on which actions were taken</td>
</tr>
<tr>
<td><strong>•</strong> Interviews with older individuals and informal caregivers regarding (1) the preferred type of activities (t₀: baseline) and (2) the level of quality of life (bi-weekly-monthly)</td>
<td><strong>•</strong> Quantitative data based on chatbot observation</td>
</tr>
<tr>
<td><strong>•</strong> Communication with formal caregivers</td>
<td><strong>•</strong> Quantitative data through OPQOL (Older People’s Quality of Life)</td>
</tr>
<tr>
<td><strong>•</strong> Qualitative data (open ended interview-questions)</td>
<td><strong>•</strong> Qualitative data</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>UC-PT2-003</th>
<th>LLM CARE Healthcare System for Cognitive and Physical training</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>•</strong> Assessments of neurocognitive and physical condition of end-users before and after the intervention (t₀: baseline/t₁: post-intervention/ tᵢ: every 2 months after 24 interventions i∈ℕ-{1});</td>
<td><strong>•</strong> Quantitative data collected through the use of the assessments regarding the neurocognitive and physical condition;</td>
</tr>
<tr>
<td><strong>•</strong> Demographics data stored in LLM Care Platform (wFirForAll &amp; BrainHQ) (i.e. ID, gender, day of birth, residence, ZIP code, country, e-mail, credentials.)</td>
<td><strong>•</strong> Quantitative data of demographic characteristics;</td>
</tr>
<tr>
<td><strong>•</strong> Data stored in LLM Care Platform (wFitForAll) that are collected through motion detection sensor (i.e. scores, activities completed/skipped, hours of training, biometrics, etc.);</td>
<td><strong>•</strong> Quantitative data collected into a dashboard from the integrated sensors;</td>
</tr>
<tr>
<td><strong>•</strong> Data stored in LLM Care Platform (BrainHQ) (i.e. levels completed, days trained, progress made);</td>
<td><strong>•</strong> Quantitative data with Likert-scaled questionnaire;</td>
</tr>
<tr>
<td><strong>•</strong> Questionnaire addressed to trainees</td>
<td></td>
</tr>
</tbody>
</table>
who are trained in the use of LLM Care platform in order to evaluate the efficiency and the satisfaction in terms of training’s content, material amenity and services, and trainers.

<table>
<thead>
<tr>
<th>UC-PT2-004a</th>
<th>Night Surveillance Rounds at Community Care</th>
</tr>
</thead>
<tbody>
<tr>
<td>* Observation by robot which can measure the number and type of interactions it enables*</td>
<td></td>
</tr>
<tr>
<td>* Motion sensors integrated with robot and platform;*</td>
<td></td>
</tr>
<tr>
<td>* Interviews with care home residents as well as caregivers regarding the level of quality of life (improvement) (physical, mental) they encountered during the night surveillance phase*</td>
<td></td>
</tr>
<tr>
<td>* Debriefings from caregivers (t: monthly, i∈ℕ)*</td>
<td></td>
</tr>
<tr>
<td>* Quantitative data (robot, sensors; OPQOL-brief (Older People’s Quality of Life))*</td>
<td></td>
</tr>
<tr>
<td>* Qualitative data (open-ended interview questions)*</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>UC-PT2-004b</th>
<th>Night Surveillance at older individual’s home</th>
</tr>
</thead>
<tbody>
<tr>
<td>* Observation by robot which can measure the number and type of interactions it enables*</td>
<td></td>
</tr>
<tr>
<td>* Motion sensors integrated with robot and platform;*</td>
<td></td>
</tr>
<tr>
<td>* Interviews with older individuals as well as (in)formal caregivers regarding the level of quality of life (improvement) (physical, mental) they encountered during the night surveillance phase*</td>
<td></td>
</tr>
<tr>
<td>* Quantitative data (robot, sensors; OPQOL-brief (Older People’s Quality of Life))*</td>
<td></td>
</tr>
<tr>
<td>* Qualitative data (open-ended interview questions)*</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>UC-PT3-001</th>
<th>In-home decompensation prediction for heart failure patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>* Quasi-experiments to estimate causal effects of health care*</td>
<td></td>
</tr>
<tr>
<td>* Quantitative data;*</td>
<td></td>
</tr>
</tbody>
</table>

This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 857159.
<table>
<thead>
<tr>
<th>UC-PT3-002</th>
<th>Prevention for diabetes patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Collect data from <strong>clinical databases</strong> (to: baseline) using indicators related with diabetes patients (e.g. glycated haemoglobin, cholesterol, microalbuminuria etc) [137];</td>
<td></td>
</tr>
<tr>
<td>• Face to face interview to evaluate symptoms before failure (to: baseline/to: post-intervention/to: every 3 months in {1});</td>
<td></td>
</tr>
<tr>
<td>• Observation of health status with the same indicators from the clinical databases in order to implement prospective and retrospective study (constantly)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>UC-PT4-001</th>
<th>Psycho-social and Cognitive Stimulation Promoting Wellbeing (StepMania)</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Quasi-experimental to assess the effects of the intervention</td>
<td></td>
</tr>
<tr>
<td>• Survey to collect and cluster demographic and clinical characteristic data in order to develop structured groups (to: baseline);</td>
<td></td>
</tr>
<tr>
<td>• Capture data regarding users’</td>
<td></td>
</tr>
</tbody>
</table>

- **Observational studies** (e.g. case-control studies) by constantly monitoring the relevant health parameters (e.g. Heart Rate Variability (HRV) measures, blood pressure, saturation, weight variations, etc);

- Analysis of registered data from **literature review** and **clinical databases** (to: baseline) [135];

- **Zarit Burden Interview (ZBI)** from a longitudinal study involving both patients and caregivers [136];

- Nominal variables from (ZBI)

- Categorical variables can be described as percentages to quantify them;

- Quantitative data;

- Qualitative data;

- Quantitative data of demographic characteristics

- Quantitative data to evaluate the performance and impact of intervention;

- Qualitative data to evaluate the perception of
| UC-PT4-002 | Cognitive training/exercises | • Quasi-experimental to assess the effects of the intervention  
• Survey to collect and cluster demographic and clinical characteristic data in order to develop structured groups (t₀: baseline);  
• Questionnaires to evaluate the potential of the intervention to promote wellbeing (t₀: baseline/t₁: post-intervention/ tᵢ: every 3 months i∈ℕ-{1}; EuroQol)  
• Hospital Anxiety and Depression Scale (HADS)  
• Focus group to evaluate participants’ perceptions towards the intervention | • Quantitative data of demographic characteristics  
• Quantitative data to evaluate the performance and impact of intervention;  
• Qualitative data to evaluate the perception of participants towards the intervention;  
• Nominal variables to develop structured groups;  
• Data plan |
| UC-PT5-001 | Online information and training for informal dementia caregivers (iSupport) (Teles, Ferreira, Seeher, Fréel, & Paúl, 2020) | • Questionnaire for general data collection of caregivers and care receivers sociodemographic data, and data on context of care, attitudes towards online interventions, frequency of internet use and perceived dependence level of | • Categorical (nominal and ordinal) and numerical variables from questionnaires collected at baseline;  
• Quantitative data from questionnaires using Likert-type scales (total scores);  
• Data plan |
the care receiver (t0: baseline);
- **Zarit Burden Interview** (ZBI) to caregivers (t0: baseline; t1/post-intervention; and t2/follow-up, every 3 months until 6 months after baseline)
- Hospital Anxiety and Depression Scale (HADS) (t0: baseline; t1/post-intervention; and t2/follow-up, every 3 months until 6 months after baseline)
- **WHOQOL-BREF** questionnaire to evaluate mood and quality of life implement with method for converting raw scores to transformed scores (see WHQOL-BREF manual) (t0: baseline; t1/post-intervention; and t2/follow-up, every 3 months until 6 months after baseline)
- Positive aspect of caregiving questionnaire (PACQ) (t0: baseline; t1/post-intervention; and t2/follow-up, every 3 months until 6 months after baseline) (Abdollahpour, Nedjat, & Salimi, Positive Aspects of Caregiving and Caregiver Burden: A Study of Caregivers of Patients With Dementia, 2018), (Abdollahpour, Nedjat, Noroozian, Salimi, & Majdzadeh, 2017)
- **Generalized Self-efficacy Scale** [138] (t0: baseline; t1/post-intervention; and t2/follow-up, every 3 months until 6 months after baseline)

**UC-PT5-002** Digital assistant for older people with mild cognitive impairment
- Data collection from clinical registries of elderlies with mild cognitive impairment
- Dichotomous and nominal variables from questionnaires;

**Primary outcome is change in mean caregiver burden from baseline at t1.**

**Data Plan**
for the recruitment level \( t_0 \): baseline;  
- **Positive Aspects of Caregiving Questionnaire (PACQ)** in order to evaluate digital assistant caregiving over time \( t_1 \): post-intervention, \( t_2 \): every 3 months \( i \in \mathbb{N}-\{1\} \) [139, 140]  
- **Zarit Burden Interview (ZBI)** to caregivers \( t_1 \): post-intervention, \( t_2 \): every 3 months \( i \in \mathbb{N}-\{1\} \)  
- Cross sectional observational study among a group with physical assistant and a group with digital assistant (constantly)

| UC-PT5-003 | Technological resources for monitoring diabetic patients with mild cognitive impairment | • **Under development** | • **Under development** |
| UC-PT6-001 | Physical rehabilitation at home | • Data collection from the evaluation of robot assistant such as [KOMPAI Robot](#). Data should be exported from the monitoring (constantly) and be evaluated by focus groups of the key stakeholders \( t_1 \): post-intervention, \( t_2 \): every 3 months \( i \in \mathbb{N}-\{1\} \);  
• Data will be collected by a sensor that will be integrated in the handgrip of the Robot to monitor the heart rate of the user during the gait rehabilitation sessions (constantly);  
• Debriefings \( t_1 \): post-intervention, \( t_2 \): every 3 months \( i \in \mathbb{N}-\{1\} \) and related data collected from structured emotion detection and evaluation by (TREE) (constantly) | • Qualitative data in text form from the evaluation of the assistive technology with the robot;  
• Quantitative data of monitoring the heart rate during rehabilitation sessions;  
• Debriefings in questionnaire form in order to evaluate emotions such as joy, fear, disgust, anger, contempt, etc. Data will be in nominal or dichotomous form and in some cases quantitative with rated scaled questions |
| UC-PT6-002 | Wearable motion monitoring devices | • Investigate and collect data from state-of-the- | • Qualitative data collected from |
| UC-PT7-001 | Monitor older patient with chronic disease when travelling abroad | Collect data through sensors from smart-watch and smartphone integrated with SHAPES platform through IoT in order to measure vital signs, track activity levels and evaluate behavioural patterns (constantly) | Quantitative data from tracking the location and health condition signs | Qualitative & quantitative data on user experience and acceptance |
| UC-PT7-002 | Foster older people’s (with physical disabilities) independent living by identifying accessible locations and routes in other locations (domestic and abroad) | Interviews with participants, informal carers and healthcare professionals | Qualitative & quantitative data on user experience and acceptance |
| UC-PT7-003 | Preventing and/or handling a medical emergency while visiting another country | Medical data (medication and patient summary) should be collected from clinical | Qualitative data to summarize |
4.3.6 Steps to evaluation in the SHAPES project

On the basis of the analysis of the evaluation toolkits and models (described in chapter 4.3) a time-plan regarding the evaluation process of SHAPES has been developed and is described in Table 19.

As can be seen in the overview table of the different data capture methods within this project (Table 18), SHAPES sets a focus on the effects on health-related quality of life (HRQL) - both generic measures of quality of life as well as disease specific measures of quality of life. Apart from the general data capture methods to determine the quality of life of the participants like e.g. EQ5D also very specific methods to assess the neurocognitive condition, the depression scale, the caregiver burden or the self-efficacy scale are included. These methods will also be included into the MAST model - within the clinical effectiveness domain.
Table 19: Time-plan for the evaluation activities within the SHAPES project.

<table>
<thead>
<tr>
<th>Step</th>
<th>Description</th>
<th>Methodology</th>
<th>Time (Phase of Pilot Campaign)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>Training of all pilot sites regarding the evaluation methodology within SHAPES</td>
<td>All toolkits and models</td>
<td>From now on</td>
</tr>
<tr>
<td>1</td>
<td>Development of the use cases</td>
<td>NASSS (using the NASSS framework to detect risks in the use cases)</td>
<td>Before phase 1</td>
</tr>
<tr>
<td>2</td>
<td>Development of data plans for all use cases including the selection of data capture methods (see chapter 4.3.5)</td>
<td>MAST and MAFEIP (to be sure that all necessary data of the users are captured during the pilots – so that an evaluation with MAST and MAFEIP is possible)</td>
<td>Before Phase 1</td>
</tr>
<tr>
<td>2</td>
<td>Planning of small-scale and large-scale pilots</td>
<td>MOMENTUM (review if all CSFs can be met)</td>
<td>Phase 1</td>
</tr>
<tr>
<td>3</td>
<td>Planning of small-scale and large-scale pilots</td>
<td>MAST and MAFEIP (detailed planning of the evaluation with these two methods: collection of background data; review of data capture methods (if necessary); preparation of interview guidelines, questionnaires etc. in the local language)</td>
<td>Phase 1 – 3</td>
</tr>
<tr>
<td>4</td>
<td>Small-scale and large sale pilots</td>
<td>MAST and MAFEIP (evaluation of the outcome of the pilots)</td>
<td>Phase 4 and 5</td>
</tr>
<tr>
<td>5</td>
<td>Final evaluation</td>
<td>MOMENTUM (final evaluation regarding the scaling-up of the SHAPES solution)</td>
<td>After Phase 5</td>
</tr>
</tbody>
</table>
4.4 Lessons learned - internal evaluation of the pilot activities

Additional to the technical evaluation as well as the evaluation of the impact of the SHAPES solution, we will also evaluate each pilot activity internally to be able to adapt, improve and simplify the organisation and the management of the pilot activities.

The goal is to prepare a set of recommendations after each pilot activity, which helps to facilitate the management and organisation of the next one. After the last pilot activity these recommendations and lessons-learned will be published in D6.9 as input for future large scale pilots in eHealth or telemedicine.

In a literature research some reference projects have been identified which have published lessons learned or recommendation regarding the internal management of pilots of trials. For example the CYCLE project [141] has identified the following lessons learned:

1. Prepare and anticipate site needs
2. Communicate regularly with participating sites
3. Proactively analyse and act on process measure data
4. Develop contingency plans
5. Express appreciation to participating sites

The OCTET project [142] explored the acceptability of clinical trials management methods, focussing on study execution and monitoring. They reported about the following findings:

- **Clear, open, positive, but focussed communication**, through a variety of communication pathways, was noted as crucial to successful execution and monitoring of the study, as were prompt responses to queries.
- The importance of **trial managers having a friendly, personable nature** as a method of helping to forge bonds between the trial team, which can be critical to the successful management of the trial.
- **Enthusiasm and positivity from the trial managers** and chief investigator from the outset at study training and right through the trial, was seen to be effective at encouraging the wider research team to support the trial.
- **Maintaining a feeling of value, and so engagement**, is critical to ensuring that output improved through consistent quality of collected data and that sufficient quantity is collected to facilitate trial analysis.
- The provision of **clear and focussed procedures and resources** are important to both trial execution and monitoring (including intuitive documentation).
- The inclusion of robust safety procedures (also for the researcher) in addition to local employer lone-working arrangements are of particular importance.
- Identifying expectations of all involved parties at the earliest possibility is imperative to ensure a cohesive team and so links between involved parties are established early during study set-up, and built upon further as the trial progresses.

In the publication of the PUPTH trial [143] it is was recommended to use the Incident Command Structure (ICS) for clinical trial management. ICS is the “gold standard” for managing complex operations in the major incident and public health arenas. ICS is characterised by modular organisation and coordination of functional groups, but for pilots at the size of SHAPES the most important activities can be the responsibility of a few people.

The standard ICS model consists of five functional modules: Command, Planning, Operations, Logistics and Finance Administration. It can be modified to include also Regulatory Administration and Information.

Thus, according to ICS, the following roles should be allocated in the trial or pilot project:

*Table 20: Functional groups/ personnel according to the ICS [143].*

<table>
<thead>
<tr>
<th>Command</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Lead / principal investigator</strong></td>
<td>He/she is legally responsible for the pilot oversight.</td>
</tr>
<tr>
<td><strong>Safety oversight officer</strong></td>
<td>One or more physicians responsible for monitoring subject accrual, compliance with enrolment and eligibility criteria and adverse events.</td>
</tr>
<tr>
<td><strong>Public relations officer</strong></td>
<td>He/she is involved in the development, integration and management of effective communication – also with the public.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Planning</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Feasibility planning</strong></td>
<td>A realistic assessment of the capacity of the research team to successfully execute the proposed trial (e.g. subject availability, recruitment rates, personnel, resource capacity, budget)</td>
</tr>
<tr>
<td>Category</td>
<td>Description</td>
</tr>
<tr>
<td>--------------------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Long-range planning</td>
<td>Forecasts anticipated resource needs (e.g. supplies, personnel, staffing).</td>
</tr>
<tr>
<td>Contingency planning</td>
<td>Anticipate unexpected and disruptive changes (risks) in the pilot and identify alternative courses of action.</td>
</tr>
<tr>
<td>Analysis planning</td>
<td>Study experimental design (including randomisation and blinding), study sample size estimation, methods used to estimate treatment effects,..</td>
</tr>
<tr>
<td>Information</td>
<td></td>
</tr>
<tr>
<td>Data management and IT team</td>
<td>Variable identification and coding, data collection, data collation, matching of diverse databases, transfer, archiving, analyses, documentation, access, quality control and security.</td>
</tr>
<tr>
<td>Operations</td>
<td></td>
</tr>
<tr>
<td>Operational management</td>
<td>Developing guidelines how operations are to be conducted as well as expectations and requirements for all personnel when performing their job (standard operating procedures, SOPs).</td>
</tr>
<tr>
<td>Logistics</td>
<td></td>
</tr>
<tr>
<td>Logistic manager</td>
<td>Management of all support activities (equipment and supplies, movement of resources and personnel, processing of data, subjects, and staff, and technical services)</td>
</tr>
<tr>
<td>Regulatory administration</td>
<td></td>
</tr>
<tr>
<td>Manager of regulatory compliance tasks</td>
<td>Dealing with administrative tasks, like protocols, documentation, legal documents, ethical aspects,..</td>
</tr>
<tr>
<td>Finance</td>
<td></td>
</tr>
</tbody>
</table>
Although there are not so many publications regarding the internal management of large scale pilots in health care, there are many well founded and tested methodologies for the management of exercises and drills in the area of crisis management. Even though the area of expertise is different, the management or organisational part of crisis management exercises are similar to tasks we have to perform in SHAPES (e.g. different organisations with different backgrounds working together, playing a scenario, evaluation, implementing technology and equipment, recruitment of participants, communication and media, etc.).

For instance the World Health Organisation has published a guide for planning, conducting an evaluating simulation exercises for outbreaks and public health emergency preparedness and response [144].

In their guide they suggested to perform the following steps to prepare an exercise (as far as relevant and adapted to SHAPES):

- **Scoping** the project (e.g. objectives, outcomes, scenario, resources)
- Formation of an exercise management team
- Define the project management plan (e.g. budget, people, equipment)
- Identify participants
- Define the evaluation strategy and methodology
- Evaluation material
- Manage the admin & logistics
- Set the media, PR & communication strategy
- Safety & security (of participants and researchers)
- Context research & gathering reference materials (e.g. local environment)
- Developing the (pilot) handbook
- Venue(s) setup
- Test all equipment
- Run/control the pilot activities
- Capturing the outcomes
- Reporting about the pilot activities

On this basis a list of critical factors for the successful planning and organisation of SHAPES pilot activities has been developed.
| All important roles have been assigned (e.g. all functional roles in the areas command, planning, information, operations, logistics, regulatory administration and finance – see Table 20). |
| The leaders of the pilot have a friendly, personable nature and show enthusiasm and positivity. |
| Throughout the pilot there was a clear, open, positive and focused communication between all participants (also maintaining a feeling of value and engagement). |
| The objectives are clear to all participating members of SHAPES and the pilot site (the expectations of all participants are clear). |
| The pilot has a clear management plan (with clear and focused procedures). |
| The participants have been identified. |
| The evaluation methodology is clear and adapted to the local environment (necessary material, e.g. interview guidelines are prepared). |
| Administrative and logistic challenges have been solved. |
| The communications strategy for media, social media and website is been in place. |
| The safety and security of participants and researchers is taken care of. |
| Necessary background information about the venue and the environment is summarized for all participants. |
| A handbook for the pilot activities has been written. |
| The venue (hospital, residence, local homes) is prepared. |
| The technical SHAPES solution has been tested and adapted to the pilot needs. |
| The pilot activities have been run smoothly and according to plan. |
| The outcomes have been captured. |
| A report has been written about the results of the pilot activities. |
| A risk management is in place. |

After each pilot activity **interviews will be performed with 3 or 4 of the leading persons responsible** for the performance of the pilot activities at the local pilot site. In these interviews the persons will be asked, if these critical factors have been fulfilled.
satisfactorily or if they have recommendations on how the management and organisation of the pilot activities can be improved.

The results of these interviews will be published in deliverables 6.2 to 6.8 and distributed among all participants of the SHAPES work package 6 (pilot campaign).
5 Planning of the SHAPES pilot campaign

The SHAPES pilot campaign consists of two main parts: The design and preparation part and the subsequent deployment and execution part.

The first “design and preparation“ part of the pilot campaign has the following objectives:

- **Involve the user in the design process**, so that valuable feedback regarding mock-ups and prototypes can guide the technological development.
- **Train the user** on the different SHAPES solutions, so that they get accustomed to the digital tools and applications.
- **Develop a scenario for each use cases** (using the SHAPES persona presented in WP2), to be able to adjust the initial concepts, identify further technical, organisational, logistical or human requirements and set the basis for the planning of the demonstrations.
- **Specify and adapt the overall SHAPES pilot concepts** (e.g. recruitment, eligibility criteria) to the specific pilot theme and use case.
- Specify and **adapt the overall SHAPES evaluation methodology** to the specific pilot theme and use cases.

In more detail this first part is divided up in three phases:

![Diagram of the three phases](image)

**Figure 23: The first "design and preparation" part of the pilot campaign.**

The three phases are carried out in each pilot theme. The **first phase** has the aim to adapt the overall SHAPES concepts and evaluation methodologies to the specific regions involved in the respective pilot theme. This phase also includes the development and testing of a realistic scenario as a future base for the further planning of the pilot activities.
The **second phase** includes the validation of mock-ups or even prototypes, to be able to integrate this user feedback at an early stage of the technological development process.

In the **third phase** the users can try and test the SHAPES digital solutions of the respective use case in order to both accustom the user to the technical tool and also get further feedback regarding the functional elements of SHAPES.

The second “**deployment and execution**” part pursues the following objectives:

- **Deployment of the SHAPES platform**, associated concepts and digital solutions considering the socio-technical context, the specificities of the users
- **Evaluate the SHAPES solution in real-life conditions** to assess the platform’s performance, user acceptance and societal impact

This second part of the pilot campaign is divided up in two phases:

The **fourth phase** has the aim to test the SHAPES methods and solutions for later use in a large scale demonstration. This small scale demonstration will be performed with a smaller group of participants and/or with fewer SHAPES digital solutions to identify factors which could hinder the pilot site to organise and perform a successful large scale demonstration.

The **fifth phase** is the large scale demonstration of the SHAPES solution. In this phase the digital solutions, methods and processes will be tested under real-life conditions with the targeted users in the 15 European reference sites.
5.1 Design and Preparation: phase 1-3

The study “Impact of EU-Funded Research and Innovation on ICT for Active and Health Ageing - The Top 25 Most Influential Projects” prepared for the European Commission DG Communications Networks, Content & Technology [145] contains a list of lessons-learnt and recommendations for future ICT projects in the area of active and healthy aging. Regarding the planning of the pilot activities the following recommendations are relevant:

1. “The user should be placed at the centre of the design process through the adoption of tried and tested methodologies and sufficient, well-documented iterative cycles”

In more detail this means the following:

- The co-design and co-creation of solutions are extremely powerful tools to reduce resistance, increase engagement and ensure that the product or service is completely aligned with the real life needs of the user.
- The creators should work in direct contact with the users throughout the design process.
- A design thinking approach could be strongly encouraged.
- Exit interviews can be used at the end of the design process providing key insights for future developments (after the end of the project).
- Detailed documentation should be kept for each iterative cycle with clear mapping of the subsequent changes/modifications to the design process.

2. “Inclusion of counter-measures from early on in the project to help improve the digital skills of potential users for the pilot trials.”

- The differences in the level of ICT skills have to be taken into account from the start of the project with a plan in place for those users who have low or no digital literacy.
- Workshops to work with these users in the trail plan can be included.
- Various freeware apps exist on the market and can be used to help improve digital literacy (e.g. UISEL Game and Finger Touchscreen Training).

SHAPES will implement these recommendations in the planning process of the pilot campaign by:

- Including iterative feedback loops on mock-ups and prototypes
- Plan for a sufficient and clear documentation of the user feedback
- Plan for digital training of users with low ICT skills
The feedback loops and trainings of the users are included in the three phases as described in Figure 25. The methodology of the scenario testing, the mock-up/prototype validation and hands-on experiments are described in the following chapters.

![Figure 25: Iterative feedback loops regarding the user experience of SHAPES.](image)

### 5.1.1 Phase 1: Plan, Design and KPI: Table-top Exercises

The first phase of the pilot campaign has the following objectives:

- Adaption (if necessary) of the **objectives** of each pilot theme, which are already outlined in chapter 2.1 of this deliverable
- Adaption (if necessary) of the **use cases** for each pilot theme (the first use case ideas are described in chapter 3 and the final use cases are fully developed in WP2 and presented in D2.5, D2.6 and D2.7)
- Development of a realistic **scenario** for each use case using the SHAPES persona and user stories developed in WP 2
- Adaption (if necessary) of the **evaluation methodology** for each pilot theme (the overall SHAPES evaluation methodology is described in chapter 3.14, but it might be necessary to adapt e.g. the interview method to the specific type patient or user of the SHAPES solution)

#### 5.1.1.1 Objectives

The objectives of each pilot theme were already described in the SHAPES DoA and in more detail in chapter 2.1 of this deliverable. However, after a multitude of telephone conferences between representatives of the pilot sites and technical partners, the mutual understanding of the needs of the users on the one side and the technical opportunities on the other side increases and also leads to more clear-cut and focused objectives.
Thus, this first phase of the pilot campaign should be used to adapt (if necessary) and to set the final objectives of each pilot theme and disseminate them among all replicating pilot sites. The finalized objectives will be presented in D6.2 to D6.8.

5.1.1.2 Use cases

First ideas of use cases have already been described in chapter 3. The final version of the use cases are developed within WP2 and presented in Deliverable D2.7.

Within the first phase of the pilot campaign the pilot leader and the replicating sites have to finalize the plan which use case will be tested and run in which pilot site and which pilot site is the respective “leader” of the use case and the first to test it. A draft plan is presented in Annex III: List of Pilot sites for each use case.

The use case descriptions are the basis for the future planning of the pilot activities in each pilot site. Thus, it is important to have a clear plan which pilot site is involved in which use case and in which timely order at an early stage of the project.

The final plan should contain the following information for each pilot theme:

- which pilot site tests/ runs which use case
- Which pilot site is the “leader” and the first to test each use case
- How long is the time of intervention (how long are the technical tools needed at each pilot site)?
- In which timely order are the use cases replicated in the pilot sites
- When is the pilot leader (or “leader” of the use case) able to start with the intervention (earliest possible start date)
- A part from the technical readiness of the SHAPES platform – which other external factors have an influence on the possible start date (administrative or legal issues, procurement of equipment, input from external partners)

This deliverable already contains a draft version of this information, but as the final version of use cases will be delivered in month 18, this plan probably has to be adjusted or adapted.

This information is to be finalized as soon as possible and disseminated among the technical partner. The final version is presented in D6.2 and D6.8.

5.1.1.3 Scenarios

Scenarios provide a very good basis for strategic planning and are used in a broad area of different branches. They are for example used as a basis for table-top
exercises to plan for emergencies and disasters, but also military planners or business organisations use scenario techniques.

Also in the health sector there are a broad range of applications for scenarios. According to Huis in’t Veld et.al. [146] scenarios can be used to involve the users of telemedicine (both medical professionals as well as the patients) into the technical development process and thereby increase the user acceptance of the technical solution afterwards. It was reported that the lack of user acceptance of telemedicine services is an important barrier to deployment, so that an involvement of the users at an early stage of the development process was recommended. However, the involvement of users in the technical development process is difficult due to

- the knowledge gap between the expertise of medical and technical professions;
- the language gap, i.e. the use of different terminologies between the medical and technical professions;
- and the methodological gap in applying requirement methods to multidisciplinary scientific matters.

Therefore, Huis in’t Veld and her team [146] developed a guideline which can be used to develop a scenario from which important needs and requirements of the users (both medical professionals as well as patients) can be elicited already at an early stage of the development process.

A scenario is a detailed storyline that describes the user’s daily activity in the setting of the envisioned application of the system to be designed. These scenarios are to be developed following the PACT (People-Activities-Context-Technology) framework [147, 148]

Using this approach forces to think about all the relevant stakeholders that will be using the new system, the actions that they will perform and the (medical) context in which they perform them, as well as the technological innovations that are necessary for successful implementations [147].

Besides the user-centered perspective a designer-centric viewpoint was added to the scenario by applying the FICS (Function and events, Interactions and usability issues, Content and structure, Style and aesthetics) approach [147, 148].

The FICS approach is more system descriptive and provides insights for technicians to consider the technical specifications [147].

This way the approach includes both the user perspective (PACT framework) as well as the technical perspective (FICS elements). The scenario is developed in an iterative process:
In the first step the pilot leader (and medical experts) specify a “day in the life scenario” [149] in terms of the People-Activities-Context-Technology (PACT) framework [150].

Table 21: Attribute list for medical PACT scenario [146].

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Definition</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>People</strong></td>
<td>Roles and/or actors of typical users involved in delivering and receiving the telemedicine intervention</td>
<td>Patient: disabilities, educational/cognitive disabilities, age, gender, computer experience. Therapist: speciality, type and frequency of communication, computer experience; Goals and benefits of the outcome</td>
</tr>
<tr>
<td><strong>Activities</strong></td>
<td>Activities to be performed by the actors in order to successfully provide and receive the telemedicine intervention</td>
<td>procedures for the professional and the patient; Parameters that determine the measures used in the intervention</td>
</tr>
<tr>
<td><strong>Context</strong></td>
<td>Puts the telemedicine intervention in a health-care context.</td>
<td>Social-medical relevance of the telemedicine intervention; privacy issues; risks for the patient; locations</td>
</tr>
<tr>
<td><strong>Technology</strong></td>
<td>Typically, to realize telemedicine, technology needs to transform some input data into some output data which can be used by the medical expert and patient to support the activities defined earlier. The features of the technology are input, output, communication and content.</td>
<td>Type of information/parameter that are relevant in monitoring the health status; type and frequency of accessibility of information; feedback modalities (communication)</td>
</tr>
</tbody>
</table>

In the next step the technical partner provide feedback by proposing FICS extensions to the scenario. FICS elements describe how the intended system mediates actor’s activities and therefore form an operative service description of the intended system [151].
Deliverable D6.1 SHAPES Pan-European Pilot Campaign Plan Version 1.0

Table 22: FICS elements of the scenario [147, 151].

<table>
<thead>
<tr>
<th>Criterion</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Function and events</td>
<td>Functionality of the intended system which is capable to realize actor’s activities</td>
</tr>
<tr>
<td>Interactions and usability issues</td>
<td>User-system or system-component interactions mediating actor’s activities; Types of the interactions, e.g. unidirectional data streaming service or reliable messaging service</td>
</tr>
<tr>
<td>Content and structure</td>
<td>Variables of the interaction</td>
</tr>
<tr>
<td>Style and aesthetics</td>
<td>Look and feel of the system</td>
</tr>
</tbody>
</table>

Subsequently the pilot leader provides an updated scenario leading to a mixed form containing both PACT and FICS elements [150]. Ideally the scenario development process includes an offline or online meeting of pilot leaders, medical experts and technical partners to be able to go through the scenario step by step and reach a common multidisciplinary understanding.

This method to develop a scenario with multidisciplinary viewpoints from both medical experts as well as ICT developer to get a common and better understanding of the user needs of the system was already applied in several research projects, for example

- to develop a continuous care & coaching platform for patients with chronic diseases [147];
- in the MyoTel project for pain-teletreatment applications [146, 150];

This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 857159.
• for developing a nutrition education demonstrator [150];
• in the INTERACTION project to enhance the quality of movement in daily life after a stroke [152].

Within SHAPES the scenario development process is built on the results of WP2 as well as on the input of the technical partners in WP4 & 5 (see Figure 27).

5.1.1.4 Evaluation Methodology

The evaluation methodology of the SHAPES project is described in detail in chapter 4. In the first phases of the pilot campaign the pilot sites have to adapt the overall evaluation methodology to their specific pilot theme and patient group (see also the time-plan for evaluation in Table 19). This means that the following preparatory works for the evaluation process have to be done:

• revision (if necessary) of the data capture methods to be used as an input for MAST and MAFEIP;
• development of questionnaires, interview guidelines, etc. in the local language on the basis of the MAST and MAFEIP criteria;
• necessary background research (e.g. statistical data of the local area) as an input for MAST and/or MAFEIP.

5.1.2 Phase 2: Prototyping and Mock-Up

In phase 2, initial ideas are supposed to be put into a visual representation without actual function, called mock-up. Later in this phase, a prototype will be derived.
Mock-ups are a simplified representation of the actual design of a solution. Using exemplary templates, the positioning and size of individual elements of the solution can be worked out. The aim of wireframes is to arrange the individual functions or elements of a solution within the layout. Through the wireframe, the main elements of the content, the structure of the information and the basic visualization of the user interface are mapped. Based on the wireframes created, mock-ups will be designed in order to reflect the later appearance of the solution. Finally, these mock-ups will be transferred into a prototype.

Mock-Ups provide a basis for a first prototype of the portal to be developed. Figure 28 shows an example of the development process from the original idea to a prototype. Depending on requirements, existing knowledge base and project progress, it may make sense to omit or skip steps or to perform them more than once. Figure 28 therefore serves as a guideline:

![Exemplary development process of mock-ups and prototypes](image)

*Figure 28: Exemplary development process of mock-ups and prototypes*

### 5.1.2.1 Wireframe

Wireframes are created as a visual guide to transfer all defined elements and contents of the portal into a page layout, including interface elements, navigational systems as well as their interaction. Wireframes usually do without colour, graphics or design elements, as they are mainly intended to represent the targeted functions and content of the portal.
5.1.2.2 Mock-Up

The mock-up goes one step further and is a complete visual image of the portal, but without offering any functionality. It can be used for final demonstration and evaluation of the design and for advertising purposes. So, while the wireframing is primarily focused on functionality, the final mock-up also aims at the final layout and design including graphic elements.

Mock-ups should also be represented by a system architecture in the form of tree diagram. This enables the systematic and hierarchical capture of all levels of use and functions of the portal and more structured adjustment possibilities in the arrangement and range of functions.

Both wireframes and mock-ups are primarily used for visualization and evaluation of design and functions by developers and participants. Therefore, it can be very profitable to provide one or more feedback loops from participants, in which practicability and usability can be assessed and improved, as well as problems can be identified and subsequently solved. In addition, wishes or needs that have not been identified at the beginning of the development process can arise and be implemented later. It is therefore an iterative approach that can be used more or less frequently depending on the requirements and problems that arise.

5.1.2.3 Prototype

Based on the mock-ups and the feedback of the participants collected during the evaluation, the first prototype of the portal can be developed, which can be seen as the first functional model of the portal. It should then also be tested and evaluated extensively and in a structured manner (see next chapter about ISO standards) by developers and participants in order to assess and improve the usability, accessibility and functionality of the portal. Depending on requirements and problems that arise, this feedback loop should also be repeated so that an optimal result can be achieved.

5.1.2.4 Underlying findings on Usability engineering/Software ergonomics

Software ergonomics means the development towards easily understandable and quickly usable software, considering the available technical possibilities and the requirements resulting from the development of the portal. ISO 9241 has proven itself as an international standard. It addresses Ergonomics of Human System Interaction and defines some specific requirements that should be of interest for the development process of the SHAPES portal:

a) suitability for the task
Amount and type of the functions must be appropriate for the purpose of the portal. Unnecessary functions, interactions or designs must be minimized.

b) suitability for learning

The user should be able to learn how to use the portal quickly, e.g. with the use of a user manual.

c) suitability for individualization

Individualization for the user e.g. through user profiles or push up notifications.

d) conformity with user expectations

Consistency of functionality, design and structure and adaptation to the user model.

e) self-descriptiveness

The comprehensibility of the portal can be supported by help or feedback.

f) controllability

Controlling the dialogue/ the interaction through the user.

g) error tolerance

The system reacts tolerantly to errors or allows easy error correction by the user, if necessary.

ISO 9241 is supplemented by ISO 14915, which specifies four further design principles for the design of multimedia applications:

a) suitability for the communication objective

The presentation of the information is suitable for achieving the goals of the providers and visitors.

b) suitability for perception and understanding

The information transmitted is easy to understand and can be easily recorded.

c) suitability for exploration

The participant is able to find the desired information or complete his task without any previous knowledge or experience regarding the presentation or structure of the information offered.
d) suitability for user motivation

A participant must be encouraged to act. By focusing on the needs of the participants, an appealing presentation and goal-oriented guidance, the participant can be motivated.

5.1.3 Phase 3: Hands-on Experiments

Phase 3 is key to collecting the feedback from end-users and evaluating the performance of the digital solution in the actual setting. The end-users will be confronted with the tools that have been developed and improved during phases 1 and 2. In order to ensure the solutions actually took into account the feedback given in the previous phases, different types of evaluation need to be carried out. Ultimately, users need to be given the opportunity to be trained to use the digital solutions, challenge their functionalities and user-friendliness as well as indicate what changes still need to be made.

Participants

The pilot leaders will preselect potential end-users matching the profile and needs of the ageing population as described in the respective pilot themes and use cases. Gender equality should be reached in the pre-selected group of older individuals.

It is recommended that the testers already get in touch with the end-users before the hands-on experiments, e.g. by participating in events targeted at older individuals in the pilot region. This promotes a feeling of familiarity with the testers and increases the trust that the participants of the hands-on experiments will later place in them [153]. Informal caregivers or closely connected contact persons will be invited to be present during the hands-on experiments as well to provide reassurance to the older individuals.

Preparation for hands-on experiments

The preselected older individuals will be introduced to the digital and technical solutions using short introductory videos addressing the user in a dialogue, presenting the solution in a commercial way, with short messages about functions and exemplifying the use or implementation of the prototype in everyday life. This can either happen in a public space but preferably occurs at the older individual’s home. This way, certain obstacles or disturbing influences to implementing the platform or tools can already be examined and possibly counteracted.

Hands-on experiments
The hands-on experiments take place at the older individual’s home. The participants of phase 3 will be presented with the developed, close-to-final version of the SHAPES platform and the digital/technical solutions they will be testing. **They will be trained to use as many functionalities of the platform** fitting their needs. The encounters with the tools should be repeated for a number of days (depending on the solution tested). Whenever possible, the digital tools (e.g. a tablet) should remain in the older individual’s home during the remainder of phase 3.

**Monitoring & Observation**

The reaction to the training and first encounters with the solutions will be monitored both digitally as well as by an independent observer (different from the trainer instructing on the use of the tools). After a settling-in period the participants are given specific tasks within the tool. The process of accomplishing these tasks is monitored.

**Digital monitoring** includes:

- Counting the number of clicks and activation of functions
- Monitoring time gaps between clicks
- Collection of selected navigation paths
- Eyetracking to analyse parts of the screen that are hardly looked at

The **observer** will in particular detect hesitancies. In order to do so,

- the user is asked to “think out loud” when using the tools and thereby point out “stumbling blocks”
- facial expressions and movements of the user are observed and noted
- it is documented how often the participant asks for help and if there are specific points where many users need support
- it is observed whether the buttons or items on a touchscreens are found used easily and whether the response of the tool corresponds to what seemed to be expected by the user.

**Evaluation**

After the predefined number of days of testing the tools in phase 3, the observations are evaluated and interviews take place.

**Quantitative measures** are based on the digital monitoring and include the evaluation of the **success rate** of performed tasks as well as the **duration for the completion of the tasks** (how did these factors evolve over the number of days studied? Which differences exist in the participant-group?). The use of the search function versus the use of navigation is evaluated to assess user friendliness of the application.
Additionally to the **report of the observer**, **qualitative measures** include an **interview** the user about his/her experience. Interview questions are semi-structured, offering grading opportunities for the:

- **a. ease of use** (can I do it alone? Am I scared to break it? Is it intuitive enough?)
- **b. design** (is it nice to look at? Are the colours okay? Is the font size appropriate?)
- **c. utility** (does it answer my needs?)
- **d. gender equality** (is it too masculine? Too feminine? Does it look like it’s not of any use to my gender?)

**Moments of hesitancy** are reflected upon and analysed (was it due to the technology itself? Was it a lack of experience when using technologies? Was the test person too tired?).

Participants are asked to tell about their experiences made when nobody was around (what did they try on their own? Could the before completed tasks be repeated? Were there moments where they would have needed help? Could they ultimately accomplish what they tried to achieve?).

The older individuals are also asked to describe their **overall satisfaction** with the digital solutions as well as their **expectations** and the respective **performance** of the tools. Room for indicating wishes and suggestions for improvement is given. Would they like to continue using the digital solution?

Based on the evaluation of phase 3 the SHAPES platform and digital tools are adjusted for the following phases and deployment in the pilot regions. If necessary, usage- and instruction-guidelines are developed, explanatory videos for future users designed or support for critical points in using the tools, e.g. pop-up windows with tips, installed.

### 5.2 Phase 4-5: Deployment and Execution

#### 5.2.1 Phase 4 Small Scale Live Demonstrations

The objectives of small scale demonstration are similar to that of a pilot whereby a pilot is an experimental, exploratory, test, preliminary, trial or try out investigation [154]. It is a test of methods and procedures to be used on a larger scale if the pilot study demonstrates that the methods and procedures can work [155]. It is designed to test the feasibility of methods and procedures for later use on a large scale or to search for possible effects and associations that may be worth following up in a subsequent larger study [156].
A small scale demonstration will be the first step in the Shapes piloting process. It will allow the study group to identify a series of factors early on in the study which may hinder the ability of the study group to accurately design and conduct a successful larger pilot study. Factors which may be relevant to the Shapes Pan-European pilot are as follows;

- Measuring the effort required of the research team to source the requisite number of participants for a small scale live demonstration will determine the effort required for a larger pilot group thereby allowing the research coordinators put sufficient human and monetary resources in place for the larger group. E.g. identifying the availability of public transport links to participant sites can significantly reduce the costs of a study while also taking into account the environmental impact of singular passenger vehicle travel (relevant to all pilots).
- Difficulties recruiting a representative cohort can be identified early using a small scale live demonstration. Willingness to partake in research and the barriers to participation can be noted among the small cohort and results extrapolated to a bigger population. Marcantonio, Edward R., et al. note the willingness of older adults to participate in research but warned of several barriers to such willingness including but not limited to; disapproval of spouse/family or support network, participation necessitating travel outside their home, long interviews (90 minutes or longer) and long study duration. Approval of the research by a participant’s physician is also listed as a factor in willingness to participate in research studies [157]. (Relevant to pilot theme 3 - Medicine Control and Optimization)
- Accurate geographic segmentation of the participants in relation to one another allowing for relevant geographic separation to ensure an authentic sample while also being aware of the constraints on the research team travelling to the participant’s homes.
- Availability of reliable internet connection at the home of the participants where a digital component of the study exists including available bandwidth and whole home wifi network. It should be understood that people (65 years of age and older) are significantly less likely to use the internet than the average population [158]. Therefore the presence of internet in the homes of participants should not be assumed. (Relevant to pilot theme 3 – Medicine Control and Optimization, pilot theme 4 – In home cognitive training, pilot theme 4 - Psycho-social and Cognitive Stimulation Promoting Wellbeing, possible relevance to pilot theme 5 as the biggest cohort of carers in Ireland are aged between 55 and 59 [159].)
- Availability of the participant to contribute should also be taken into account. Willingness to participate will not always correlate with ability to participate. In cases where a caregiver is a research participant, inability to delegate caregiving responsibility even when the intervention is within the home of the
carer/care receiver is a concern. (Relevant to pilot theme 5 – Caring for Older Individuals with Neurodegenerative Diseases)

5.2.1.1 Methodology

How to organize a small scale live demonstration (participants and recruitment strategies, planning team, use cases, documentation, logistics, roles and responsibilities.

Recruitment of Participants

Fundamental to the worthiness and success of a small scale live demonstration is the ability of the research team to identify, investigate and authenticate the correct cohort of participants which accurately represents the wider population in the larger pilot. For the Shapes project, this process begins with detailed research and refinement of the correct cohort for each pilot use case. The factors outlined above help to examine some aspects relating to accurate participant identification. There are many others which relate specifically to each individual use case.

Recruitment Strategies

Recruitment Strategies for small scale live demonstrations are very similar to larger pilots however a smaller scale allows you to test more recruitment methods and therefore assess which have the greatest likelihood of accuracy and retention for the larger pilot study.

The following are examples of strategies which align themselves with smaller scale objectives for the Shapes project.

1. Hard Copy Advertisements

Hard copy advertisements in newspapers, flyers, leaflets, booklets, newsletters etc. are often used for recruitment of research participants but the Shapes small scale live demonstration will allow the study group to test, retest and refine;

a) the recruitment message, terminology and language in the advertisement based on the demographic metrics of the people who contact the study group as a result of the message

b) the geographic area the advertisement is available in
Critical to this process is the recording of all data arising from each recruitment advertisement (date advertisement was published, shelf life of advertisement, number of interactions as a result of the advertisement, reasons why an interaction was generated, method by which participants contact the research group as a result of the advertisement, geographic location of participant who interacted with the study as a result of the advertisement etc. Digital advertisements allow us to quickly see all this data with little effort therefore it is important to have resources and a policy in place to capture this data for hard copy. It is this data which will guide the recruitment for the larger pilot.

2. Face to Face Recruitment

Face to face recruitment is a good match for recruiting participants for small scale pilots as this type of recruitment will allow the Shapes research group to ensure there is no ambiguity among potential participants around the objectives of the study. Face to face recruitment also allows the researchers to ask more questions and therefore capture more data from the potential participant as often this type of recruitment takes place in a setting which is familiar to the participant thereby making them more comfortable and reducing the time pressure associated with a phone call.

It is worth noting that while SHAPES is a pan-European study, recruitment strategies should be unique to each individual site and take into account the environmental situation within that site. For example, the Irish healthcare system has recently introduced free general practitioner healthcare for all children in the state under 6 years old. This has increased the workload of general practitioners in Ireland therefore it can be assumed that cooperation from general practitioners for research studies will be less easily garnered than it has been in the past. Therefore, while the target cohort of participants for a pilot in two countries may be very similar, the methods by which that group is recruited may vastly differ.

Documentation

Small scale live demonstrations require more types of documentation than larger pilots due to their nature. Along with the normal study participant information, Shapes researchers will carry the site specific ethics approval letter and informed consent documentation. All research personnel will also have identification on their person as well as a copy of their country specific police clearance certificate for working with vulnerable groups. This is critical as not only will longer times will be spent in the participants homes for the live demonstrations but it is envisaged a larger number of people will be on site during the interaction (norm should be one research staff but for the live demonstration a second person may be necessary to record notes during the interaction between the primary researcher and the study participant.

Logistics

This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 857159.
By their nature, small scale demonstrations require more equipment than standard pilots. It is envisaged the shapes study will be no different. Small scale demonstrations are generally the first front line interaction with study participants therefore it is important for shapes research personnel to prepare for a variety of eventualities e.g. poor wifi signal. This will lead to the research staff carrying more IT equipment to diagnose issues therefore public transport is not always suitable. Planning for the visit to the participant’s home requires a high level of communication with the participant. Small things like the researcher planning and putting a protocol in place for an unannounced visit by a friend of the participant or an unfriendly animal in the home can pay huge dividends in terms of the success of the visit for both the researcher and the participant.

Roles and Responsibilities

The roles and responsibilities of a small scale demonstration are similar to that of a larger pilot however the smaller scale demonstration allows researchers to refine the roles and responsibilities if the workload requires. It should be noted that a larger pilot is focused on the evaluation of intervention data whereas the small scale demonstration must also focus on the delivery of the research interaction. Gathering this data during the small scale demonstration is fundamental to the success of the larger pilot. Therefore extra roles within the small scale demonstration are often necessary. The small scale allows this to happen. The roles that are extra for the Shapes small scale demonstration centre on the recording and analysis of the research interaction data.

Pilot Site Checklist

Table 23: Pilot Site Checklist.

<table>
<thead>
<tr>
<th>Criteria</th>
<th>Yes/No</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Ethical and Societal Requirements</strong></td>
<td></td>
</tr>
<tr>
<td>Has written approval of local ethics board been received?</td>
<td></td>
</tr>
<tr>
<td>If approval from local authority is needed, has it been given?</td>
<td></td>
</tr>
<tr>
<td>Have the local community health service team been notified?</td>
<td></td>
</tr>
<tr>
<td><strong>Recruitment of Participants</strong></td>
<td></td>
</tr>
<tr>
<td>Inclusion /Exclusion criteria guidelines have been adhered to?</td>
<td></td>
</tr>
<tr>
<td>Representative population cohort has been selected?</td>
<td></td>
</tr>
<tr>
<td>Consent</td>
<td></td>
</tr>
<tr>
<td>------------------------------------------------------------------------</td>
<td>---</td>
</tr>
<tr>
<td>Has informed written consent been received from participants?</td>
<td></td>
</tr>
<tr>
<td>Has a copy of the study information sheet been given to the participant?</td>
<td></td>
</tr>
<tr>
<td>Has training and information been offered to participants, family and friends?</td>
<td></td>
</tr>
<tr>
<td>Technical</td>
<td></td>
</tr>
<tr>
<td>Has the correct procurement procedure for SHAPES technology been followed and documented?</td>
<td></td>
</tr>
<tr>
<td>Has the selection of technologies been verified by the study participant as being the most beneficial for their lifestyle?</td>
<td></td>
</tr>
<tr>
<td>Has the technical partner confirmed the availability of the technological tools for the pilot starting date?</td>
<td></td>
</tr>
<tr>
<td>Where required, has transport of SHAPES technology been organized?</td>
<td></td>
</tr>
<tr>
<td>Has consideration been given to local technical requirements? E.g. country specific plug socket, adequate wifi, physical space at site for technology?</td>
<td></td>
</tr>
<tr>
<td>Documentation</td>
<td></td>
</tr>
<tr>
<td>Have you formally written to the participant with dates for all his/her study interactions?</td>
<td></td>
</tr>
<tr>
<td>Have you provided the participant with a copy of the ethics approval letter?</td>
<td></td>
</tr>
<tr>
<td>Have all individuals who will interact with the participant received appropriate police clearance?</td>
<td></td>
</tr>
<tr>
<td>Have you documented telephoning the participant the day before you visit them to remind them you are coming?</td>
<td></td>
</tr>
<tr>
<td>Have all researchers who will interact with participants university/organization identification?</td>
<td></td>
</tr>
</tbody>
</table>
Health/Medical Issues

Have you confirmed with the participant that they have made you aware of any health issues they may have?

Have you asked the participant for the telephone number of a next of kin and their doctor should they become unwell while you are in their home?

Evaluation

Have you considered how the participant will evaluate the technology?

5.2.2 Phase 5: SHAPES Deployments - large pan-European testing

This section provides a high-level view on how to plan the development of the protocols for each large-scale Pilot Theme study. Full protocols defining Pilot Theme-specific large-scale pilot objectives, target users, study design, procedures, and expected outcomes will be reported starting from M21 at the conclusion of Phase 3 (Tasks 6.2-6.8).

5.2.2.1 Objectives of large-scale pilot campaign

Overall, while in the previous Phases the focus was on the analysis of the technology (Phase 1,2) and the interaction of the users with the technology in controlled settings (Phase 3,4) to document its potential impact on specific user-related outcomes, in this last Phase the aim is to test the SHAPES TP at a larger level of scale in order to test its effectiveness in non-research settings, without strict controls on the delivery of the interventions with a view to contribute to identify challenges (e.g. organizational, policy-related) to scale-up between and within partners’ countries.

As such, the development of the present plan and related methodology for large-scale pilot design and implementation is based on the assumption that several steps in SHAPES TP development have been undertaken, that is, the platform (and related devices and products) will be mature enough to be implemented in different contexts, are usable by intended users and other stakeholders, and will be functional and stable.

Accordingly, the implementation of the SHAPES large-scale (Pan-European) pilot campaign meets the following objectives:
● to validate the SHAPES TP capabilities and benefits to care recipients, caregivers and care service providers.
● to validate the SHAPES TP at the European scale, across different regions, cultures and health and care organizational models
● to assess the impact of the SHAPES TP in supporting healthy ageing and independent living and the definition of improved integrated care policies and measures.

Specific objectives for all participants (older adults and people in their care network) include:

● evaluate the usability, accessibility and acceptability of the SHAPES TP.
● evaluate user adoption and satisfaction with the technology and services.
● evaluate experiences of using the SHAPES TP.

Additional objectives for target users include:

● evaluate the potential impact of the SHAPES TP on a range of health, well-being, psychological, and psychosocial outcomes for the older adults.
● evaluate the potential impact of the SHAPES TP on psychological and psychosocial outcomes for the care network professionals and informal carers.

5.2.2.2 Development of large-scale use cases protocols

The piloting campaign will be structured by themes (n = 7). Within each theme, use cases have been developed (see chapter 3 of this deliverable). Each use case scenario within each pilot theme will be conducted in one leading large-scale pilot site and replicated by other pilot sites. Accordingly, for each use case scenario within each Pilot Theme specific research protocols will be developed.

Each protocol will build on the results of the preceding Phases (1-4) outlined in the previous sections, and will be further informed by results from users requirements and ecosystems’ analyses reported in WP2 (D2.1) and WP3 (D3.1). Considering that (1) the pilots will take place over a period of 4 to 11 months, (2) pilots will take place in different cultural and organizational contexts, (3) participants will be provided with a set of solutions as various as e.g. eHealth applications, robotics, or assistive technologies, (4) different relevant people in participants’ care network will be involved, the leading large-scale pilot site will develop the main study protocol in strict connection with replicating sites in order to assure replicability and comparability of data collected.

Overall, based and the indications from both the WHO [30, 160] and the “Standard Protocol Items: Recommendations for Interventional Trials” (SPIRIT) [161] the protocol for each Pilot-Theme large-scale study will include:
• Measures to be taken and analysis to be performed to assess changes attributable to SHAPES TP *(Evaluation).*
• Strategies to assure implementation and replication fidelity *(Monitoring).*

The protocol should outline the rationale for the study, its objective(s), the methodology used and how the data will be managed and analysed. It should highlight how ethical issues have been considered, and, where appropriate, how gender issues are being addressed.

Accordingly, all protocols will follow a common structure outlined in Table 1. Protocols will outline both the scientific procedures for running the trial (e.g., eligibility, recruitment, design) as well as the practicalities of preparing for the trial, deploying technologies, engaging with participants and ensuring the smooth running of the pilot over the trial period (e.g. monitoring, pilot logistics).

An additional important aspect of the pilot study is to develop a **Standard Operating Procedure (SOP) manual.** This will include detailed instruction to the investigators to assure a uniform and standardized approach to carrying out the study with good quality monitoring.

*Table 24: Structure of SHAPES large-scale pilot study protocols.*

<table>
<thead>
<tr>
<th>Content of the protocol</th>
<th>Description</th>
<th>Considerations for SHAPES large-scale pilots development</th>
</tr>
</thead>
</table>
| 1. Eligibility criteria | Eligibility criteria [161] for potential trial participants **define the study population.** They can relate to demographic information; type or severity of the health condition; comorbidities; previous or current treatment; or other relevant considerations. | In this section, the following questions should be answered:  
1. What are the criteria for inclusion or selection?  
2. What are the criteria for exclusion?  
3. What are the criteria for discontinuation?  
4. *in case of involvement of a control group:* how participants will be allocated |
<table>
<thead>
<tr>
<th>2. Recruitment</th>
<th>This includes detailed descriptions of where participants will be recruited, by whom, when, and how (e.g., advertisements, review of health records)</th>
<th>Important for the scope of the SHAPES large-scale pilots is to develop common strategies for participants’ recruitment. If strategies differ by pilot site, such differences should be detailed to the extent possible.</th>
</tr>
</thead>
<tbody>
<tr>
<td>3. Study setting(s)</td>
<td>A description of the environment(s) in which a trial will be conducted.</td>
<td>To allow for a reliable interpretation of the applicability of the pilot study results, the type of settings (e.g., clinical; non-clinical), must be reported in the protocols.</td>
</tr>
<tr>
<td>4. Study design</td>
<td>This section refers to the type of research study conducted to assess benefit of SHAPES. The choice of the pilot studies design should be explained in relation to the study objectives</td>
<td>The aim of the large-scale pilot campaign is to assess whether SHAPES TP and its related products can achieve the intended results in a uncontrolled setting. As such, use case protocols should be developed considering research designs that are able to identify and quantify any changes connected to SHAPES TP use and implementation. Accordingly, a hybrid study design may be the most appropriate [162] by which the effects of both the intervention (i.e. effectiveness of SHAPES TP and related interventions) and the implementation process in real-world settings (e.g. experiences of stakeholders in adopting and using the SHAPES TP) are considered.</td>
</tr>
</tbody>
</table>
Such hybrid study design would benefit from a mixed-method approach to large-scale pilot evaluation, combining qualitative (in-depth interviews; focus groups) and quantitative (user satisfaction; system adoption/use rates; changes in outcome measures) data.

| 5. Intervention | Intervention refers to a specific clinical/therapeutic practice or delivery system/organizational arrangement, or health promotion activity (eg, self-management) being tested or implemented to improve health care outcomes. In our specific case, the devices deployed in each Pilot Theme and integrated in the SHAPES TP can be considered the interventions under investigation. | A description must be given of the:

1. **specific conditions** (use case scenarios) within which SHAPES (and its related products) will be tested within the facilities and environments made accessible by the piloting partners and involving the targeted users.

2. **devices to be used**, and whether they are already commercially available, or in phases of experimentation. For devices that are commercially available, the protocol must state their proprietary names, manufacturer. For devices that are still in the experimental stage (or that are commercially available but are being used for a different indication or in a different mode of administration), additional information should be... |
| 6. Primary and secondary outcomes | Following the SPIRIT guideline [161], for a given intervention, an outcome can generally reflect efficacy (beneficial effect) or harm (adverse effect). The outcomes of main interest are designated as primary outcomes, which usually appear in the objectives and sample size calculation. The remaining outcomes constitute secondary or other outcomes. | By the end of Phase 4, Pilot-them leaders will be able to identify benefits brought about the SHAPES ecosystem. Such benefits will be operationalized into clear value propositions i.e. statements describing the expected benefits to end users and other relevant stakeholders. Based on value propositions, measurable objectives for SHAPES TP use can be formulated and outcomes indicators selected that are able to assess whether the system is able to satisfy stakeholders' expectations. Indicators can be qualitative (e.g. user experience) and quantitative (e.g. number of daily steps). For the SHAPES purposes, particular attention should be put on expected outcomes valid for all pilot sites (e.g. usability, user acceptance, behaviour change or societal impact) and expected outcomes that may be specific for each pilot site (e.g. whether the system improves local health & social service delivery).

To ensure reliability and validity of measurements across pilot sites, the use of validated tools available in provided on any available pre-clinical investigations. |
| 7. Sample size | The protocol should provide information and justification about sample size. The basis on which sample size is calculated should be explained in the methodology section of each protocol. | When developing the research protocol, careful attention should be paid on the distinction between the “target” population and the “accessible” population. The sample has to be selected in order to be as representative as possible of the target population and large enough to provide valid answers. The exact number will be calculated on the basis of the pilot’s objectives and the resources available in each pilot site. |
| 8. Study procedure & data collection methods | This includes concise timeline of the study visits, enrolment process, interventions, and assessments performed on participants. It further includes strategies to assure consistency in data collection and procedures for obtaining Informed Consent from all participants in each pilot site. | A clear description of the data collection processes – including the personnel, methods, time points, instruments, and measures to promote data quality (see next section) – is warranted to ensure replicability across pilot sites. In-site or remote training events on a Standard Operating Procedure (SOP) manual (see next section) and involving research personnel are recommended to assure that data collection is identical for all pilot study groups. |
| 9. Monitoring | This section refers to the routinely collection, review and analysis of data which measure implementation | One of the main characteristics of the large-scale pilots is that they will be delivered in non-research (i.e. multiple languages is warranted. |
fidelity and progress towards achieving intervention outcomes [160].

real) settings. Nevertheless, researchers should be committed to assure that all users are using the system appropriately throughout the intervention period to ensure that any change in outcome measurements is attributable to SHAPES TP. In this view, monitoring activities will be performed for the whole duration of the pilots. Accordingly, each Pilot Theme will define a detailed monitoring plan to perform continuous checks of:

1. **Fidelity**: do the realities of pilot implementation alter the functionality and stability of the system, changing the intervention from that which was intended?

2. **Quality**: how well and consistently are the users within and between pilot sites delivering the intervention?

Monitoring may be performed using a variety of tools and strategies (e.g. periodical checklists; direct observations of system use). They will be developed by each Pilot Theme according to specific users’ and contexts’ requirements and described in a **Standard Operating Procedure** (SOP) manual.

The decision to have a data monitoring committee (DMC)
to further assure data quality will be based on the basis of studies’ objectives, resources and designs.

10. Pilot logistics

A detailed description of the logistics and planning required for various stages of the pilots – pre-deployment, deployment and maintenance during the pilot - should be provided in order to assure the proper use and functioning of SHAPES across pilot sites. Factors to be considered when planning pilot logistics include (but may be not limited to):

**Pre-deployment**
- Devices selection and purchasing
- Connectivity/Broadband
- Power

**Deployment**
- Device(s) calibration and set up
- Training of users and local staff

**Maintenance**
- Support desk
- Maintenance strategies

11. Analyses

The protocol should provide information on how the data will be managed, including data coding for computer

Depending on the study design, quantitative interval level data will be compared over repeated time points
| analysis, monitoring and verification. Information should also be provided on the available computer facility. The statistical methods used for the analysis of data should be clearly outlined. | using repeated measures ANOVA/ANCOVA and/or general linear models. Nominal and ordinal data will be compared with chi-square tests, Mann Whitney and Kruskal Wallis tests. Qualitative data will be analysed using thematic analysis in order to identify and understand emerging themes. |

5.2.2.3 Planning of large-scale piloting campaign activities

The planning of the large-scale piloting campaign for each pilot Theme will follow an iterative approach. In a first step, Pilot Theme leaders will coordinate the development of the SOP according to agreed pilot Theme’s objectives and expected outcomes. This phase will be performed over a series of telco with both technical and trial site partners in a manner similar to that followed for the development of the current high-level strategy report (and described in section 1.3). In this step, requirements from all pilot sites will be taken into account and a detailed SOP will be developed. In a second step, based on the procedure described in the SOP, all participating trial sites will apply for ethical approval in their respective contexts. Piloting will be commenced by the pilot leader in order to assure that the protocol and SOP fits the purposes of the trial. Once the pilot leader study is concluded, the other pilot sites can commence their pilot trials following a sequential or parallel approach. In the former, one pilot site starts the pilot study while the other sites wait until the leading pilot is over. In the latter, all pilot sites run their pilots in parallel. This flexibility in the study design will allow the transfer of technology from one pilot site to another if needed (e.g. the social robot). SOPs will have to be ready available at the end of Phase 3 in order to allow all pilot trial sites to prepare their documentation for ethical approval.

5.2.2.4 Design of Pilot Themes interventions in real life settings

Based on the specific aims of each Pilot Theme and related use cases, and in light of the results from the user requirements gathering process (D3.5), each Pilot Theme protocol will describe, in the Standard Operating Procedures (SOPs), the conditions within which the SHAPES TP will be tested. This will include a detailed articulation of the parameters required for implementation and evaluation.
Subsequent real world testing and validation of the platform, which may include full or partial replication of the leading pilots at other pilot sites, will require specification of the details articulated in Table 1, along with further consideration of influential contextual factors. This will also necessitate careful monitoring of the fidelity of the intervention and use characteristics. Any planned or unplanned deviations from the SOPs should be made explicit using a documented refinement process, such as RE-AIM (Reach Effectiveness - Adoption Implementation Maintenance) framework (Dzewaltowski et al. 2004). RE-AIM and similar frameworks encourage planners to examine reach, intervention effectiveness and contextual factors that can improve the sustainable adoption and implementation of interventions.

Specification and use of a core outcome set for SHAPES evaluations (i.e. an agreed standardised set of outcomes that should be measured and reported at a minimum) will allow for comparison and analysis of quantitative indicators of the Platform’s performance. This may also include comparable measures of user acceptance, and various societal impacts across participating sites. These data can be considered in tandem with qualitative RE-AIM assessments.

Extending replications to involve more of the participating facilities and environments made accessible by SHAPES partners, as well as involving a diverse set of targeted users in each replicating site, may facilitate scaling-up of the platform and the integration of new insights and knowledge. Scalability will largely be determined by effectiveness, likely reach and adoption of TP, the costs of operating pilots at a larger scale, and the acceptability and fit of the interventions within the local policy context (Milat et al., 2014). These activities will also contribute to the evidence-based decision making processes that will determine the adoption and market uptake of SHAPES solutions through classification of the scaling up pathways for a diverse range of real world settings. Strategies for de-implemention of ineffective interventions will also be specified.

5.2.2.5 Communication and Dissemination of pilot activities

Communication and dissemination of pilot activities will be done through the following external channels:

1. **SHAPES Website**

   This will be a relatively static location to explain what SHAPES is and highlight the core elements of the project. Categories such as ‘Gallery’, ‘Case Studies’, ‘White Papers’ and ‘Blog Posts’ will be present on the site so we can accurately communicate the rich body of work SHAPES is producing.

2. **Social Media platforms – Twitter, LinkedIn, Facebook and Instagram**
These will be updated as needed to highlight events, activities and outputs of the SHAPES project. Our goal here is to raise awareness and increase engagement with SHAPES pilots.

Throughout the course of the pilots, it will be the objective of SHAPES to promote awareness around the work being done and engage our target demographics. It is therefore paramount that updates and content are shared to the appropriate channels. The following are encouraged by all those in the pilots to generate for external communication:

- Hi-res images
- White papers
- Case studies
- Blog posts
- Flyers
- Infographics
- Testimonials
- Any other promotional materials or activities

By doing the above, we can create a rich repository of marketing materials which will also be able to feed into our reporting efforts down the line. While Access Earth LTD (AELTD) will seek to request the above types of materials as the project goes on, it is important that the pilot leads take a proactive approach in sharing this information with AELTD.

Please send any materials, requests or updates to ciara@accessearth.com who will ensure that the pilot in question gets highlighted on the appropriate platforms. Requests as such should include the following information:

- Title of project
- Activity time, date and location (if relevant)
- Date information needs to be published
- Target audience for message (if not general public)

Please note, all communications via the SHAPES website and social media platforms will be done in English.

5.2.2.6 Risk management

There are a number of risks associated with the implementation of the SHAPES pilot activities. In considering how best to minimise risks, it is important for those involved in the pilot activities to be aware of the nature of these risks, as well as their likelihood of occurring.
Based on consultation with the pilot sites, identified risks include those associated with the intended users, the design of the technology itself, as well as risks relating to the overall management and implementation of the project. One considerable risk that has recently emerged is the rapidly-evolving coronavirus (covid-19) pandemic. Given the current rate of growth in cases across Europe, covid-19 has the potential to impact considerably on the implementation and roll-out of pilot activities, in particular those which are planned in the earlier stages of the project. As ensuring the health and wellbeing of all project stakeholders is of utmost importance, contingencies may need to be put in place in order to minimise any risks to those involved in these activities.

Further risks include:

- **Risks associated with user recruitment and retention.** This may lead to an unrepresentative sample of older adults participating in pilot activities and/or a high attrition rate. This may be exacerbated by the current covid-19 crisis, where vulnerable adults with chronic conditions may be wary of engagement in certain pilot activities.
- **Risks associated with technology design.** This may occur should the roll out of digital solutions (1) lack user-centred requirements, or (2) be inappropriate for the needs and abilities of the users. Examples include barriers to the accessibility of technologies, or solutions that lack compatibility with the culture and values of users.
- **Risks associated with the overall usability or acceptability of technologies.** This may stem from a lack of appropriate training for users, a lack of trust in digital solutions, or a general lack of confidence in digital skills. Such risks may be more likely to occur in participants who are experiencing cognitive decline, and whose ability to engage in the pilot activities may, accordingly, be compromised.
- **Risks to the health and wellbeing of participants.** Separate to the aforementioned covid-19 pandemic which has the potential to put intended users at considerable risk, other risks to the health and wellbeing of users may include potential physical discomfort or psychological distress from participating in the pilot activities.
- **Risks associated with system failures, including, for example, a lack of technical capability, network failures, or an inability for technologies to predict adverse events.**
- **Risks associated with the reliability and validity of data stemming from the pilot activities.**
- **Sustainability risks relating to the long-term adoption of technologies across various social, economic, and political contexts.** This may also be influenced by the provision of financial resources.
- **Ethical risks, including a lack of compliance with the SHAPES ethical framework.**

This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 857159.
• Project management and organisational risks, including risks associated with coordination, communication, and deviations from budget and timelines.

Various ways of mitigating the above risks have been identified by partners, and ongoing consideration of these solutions will be critical in overall design of the pilot activities. This includes, for example, careful consideration of issues relating to participant recruitment and training, user-led design, and regular monitoring of identified primary and secondary outcomes via appropriate assessment tools. Mitigation of any legal and ethical risks, including any risks to the wellbeing of participants, are expected to be minimal, assuming compliance to the SHAPES ethical framework as specified in WP8. Given the present uncertainty in relation to the covid-19 crisis, it is unclear the extent that this will impact on the pilot activities. It is therefore paramount that risks are monitored and evaluated on an ongoing basis, with priority placed on ensuring the health and wellbeing on all involved.

5.2.2.7 Ethical considerations
5.2.2.7.1 Research integrity/action plan

All the SHAPES pilots commit to uphold ethical research standards, including the European Code of Conduct for research integrity. The principles of maximizing benefit and minimizing harm, social responsibility, dignity of persons, fundamental/human rights and other issues mentioned in the H2020 ethical self-assessment are supported during the pilots by taking into use ethical self-assessment procedure before each pilot. The process is as follows:

1. Each pilot organization provides ethical self-assessment with attached documents (see the template in the D8.2) and delivers it to EM and uploads to WP8 TEAMS. It is essential to follow local guidelines and regulations regarding various piloting activities with the citizens, including also practices with incidental Findings (see D8.2)
2. If problems occur, they are to be discussed with EM and in the EAB.
3. EM will record the activities in the ethics paper trail and finally report it as part of the ethical progress report.

5.2.2.7.2 The validation/verification/assessment of ethical features of SHAPES

As the ethical requirements for the SHAPES solution (see D8.4) concern both the SHAPES technology, its user processes and training, and future business/governance/ecosystem models, even their verification/validation/assessment has to be multifaceted.

i. The ethical requirements related to SHAPES technology and the use of it should be validated as part of the general SHAPES validation approach during the pilots. This includes not only ethical features of the various digital
services and data analytics, but also e.g. validation of consent to be collected on the SHAPES platform.

ii. The ethical requirements relating to privacy and data protection will be assessed as part of the SHAPES privacy and data protection impact assessment (DPIA) process (D8.10 and D8.11). Each pilot shall do a DPIA before the pilots start.

iii. The ethical requirements related to business and governance model may not necessary be validated as such during the project. On the other hand, by providing ethics compliance check on each deliverable it is possible to verify that the various ethical issues has been taken into account in various deliverables.

iv. Feedback on SHAPES Code of Conduct (see D8.4) will be collected via questionnaire from pilots participants.

The EM and DPM will provide a specific technical note on the validation/verification on the ethical requirements before pilots.

5.2.2.7.3 Data Lifecycle Management Plan (DLMP) to be created for each pilot

SHAPES Data Management Plan sets a framework for all data management activities in SHAPES. All SHAPES Pilots shall have an own Data Lifecycle Management Plan that describes how the data will be used in the pilot and how the general data management principles have been taken into account. The instructions for creating a DLMP are in the D8.13 SHAPES Data Management Plan. DLMPs will be stored in each pilots own Teams folder.

5.2.2.7.4 Ensuring ethics compliance of the SHAPES version to be used in pilots

The minimum ethical requirements to be met by the trial version of SHAPES itself concern the legislation, namely data protection, IPR’s and local data information sharing regulation, including also the use of secondary data sources.
6 Conclusion

The deliverable contains the necessary information for the further planning and evaluation of the SHAPES pilot campaign.

The information, methodology and planning protocols in this report will help both the pilot sites as well as the technical partners to advance with the further detailed planning of the different use cases for each pilot theme. It contains the necessary basis to

- adapt the SHAPES technical tools and applications to the needs of the pilot sites
- further develop the use cases of each pilot theme taking into consideration the specific needs of different involved pilot sites and the planned participants of the pilot campaign
- plan the detailed evaluation and data capture plan for each use case on the basis of the overall SHAPES evaluation methodology
- plan the pilot activities of each use case including scenario building, prototype testing, recruitment strategy, interventions, ethical issues, monitoring and analysis.

Figure 29: Summary of the information in this deliverable and its further use in the project.
7 References


Deliverable D6.1 SHAPES Pan-European Pilot Campaign Plan Version 1.0


This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 857159

227


[62] MOMENTUM, European Momentum for Mainstreaming Telemedicine Deployment in Daily Practice (Grant Agreement No 297320): Deliverable 3.4 Personalised Blueprint for telemedicine deployment: validated and tested

This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 857159.


This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 857159

233


[104] T.-C. Chan *et al.*, “Continuous use of antipsychotics and its association with mortality and hospitalization in institutionalized Chinese older adults: An 18-


Annex

Annex I: Matching of pilot themes and technologies

Pilot Theme 1: Smart Living Environment for healthy Ageing at Home

<table>
<thead>
<tr>
<th>Lead:</th>
<th>CCS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Recruitment levels</td>
<td>15</td>
</tr>
<tr>
<td>Replicated by:</td>
<td>AIAS, FNOL, OMN, SAL, UAVR, UCC</td>
</tr>
<tr>
<td>Recruitment levels</td>
<td>10, 5, 10, 10, 10, 10</td>
</tr>
</tbody>
</table>

General comments
Is it possible that some technical solution will be used only by some end-users? E.g., there are only 3 robots available - does this meant that only 3 persons test the robots and other persons test other technologies?
Everything which needs very good internet connection will be difficult to use and test in this pilot.
Before finally deciding which applications are useful for this pilot, the pilot leader would like to ask the end-users themselves.

<table>
<thead>
<tr>
<th>Number</th>
<th>Organisation</th>
<th>PM in Task 6.2 (pilot 1)</th>
<th>Pilot Activities</th>
<th>Tool/Application/ Solution</th>
<th>Applicable in this pilot</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>NUIM</td>
<td>4</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Access Earth</td>
<td>1</td>
<td>Access Earth App</td>
<td>??</td>
<td></td>
<td>CCS: Will ask the enduser if they consider this application to be useful for them</td>
</tr>
<tr>
<td>3</td>
<td>AGE</td>
<td>12</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>AIAS</td>
<td>12</td>
<td>Replicating</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>AUTH</td>
<td>36</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>6</td>
<td>CCS</td>
<td>36</td>
<td>Lead</td>
<td>Telehealth System</td>
<td></td>
<td>CCS’s Telehealth System provides remote applications for patient-centered care of in-home patients, under the supervision of trained tele-nurses.</td>
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</tr>
<tr>
<td>7</td>
<td>CH</td>
<td>18</td>
<td>Chatbot ROSA</td>
<td>Interesting</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>CCS: Very interesting. It could be very helpful for the end-user to have voice-controlled applications.</td>
<td></td>
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</tr>
<tr>
<td>8</td>
<td>EDGE</td>
<td>12</td>
<td>MAESTRA &amp; eCare</td>
<td>Interesting</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>CCS: Who will buy the sensors (e.g. smartwatches, sensors of smart-home applications). Do we have to use the open calls for these sensors? EDGE: It will be assessed the integration with CH ROSA chatbot.</td>
<td></td>
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<tr>
<td>9</td>
<td>EUD</td>
<td></td>
<td></td>
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<tr>
<td>10</td>
<td>FNOL</td>
<td>12</td>
<td>Replicating</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Telemedicine System</td>
<td></td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Operational telemedicine system comprising more than 20 sets of devices for chronic heart failure patients, over 60 glucometers, gateways based on tablets and smartphones, central system with database and portal located in a cloud.</td>
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<td>Fraunhofer</td>
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<tr>
<td>12</td>
<td>FINT</td>
<td>4</td>
<td>FINoT platform &amp; programmable cloud platform</td>
<td>Shapes overall platform</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Apply GW reference interoperable implementation and provide interconnectivity between the home/neighborhood environment utilising FINoT platform within SHAPES overall platform</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>13</td>
<td>GNO</td>
<td>2</td>
<td>eHealthPass</td>
<td>Not helpful</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>As the pilot leader does not have “patients” features like e.g. “care plan tools” are out of scope.</td>
<td></td>
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</tr>
<tr>
<td>14</td>
<td>gewi</td>
<td></td>
<td>Assisted Living Solutions</td>
<td>Not helpful</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>In Saxony they would prefer to use the panic or alarm button of a local provider (Better@Home Service GmbH). Is it possible to include this application in an open call?</td>
<td></td>
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<tr>
<td>15</td>
<td>ICOM</td>
<td>1</td>
<td>Technology leader</td>
<td>Shapes overall platform</td>
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<tr>
<td>16</td>
<td>KOM</td>
<td>4</td>
<td>KOMPAI-2 robot</td>
<td>Interesting</td>
<td></td>
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</tr>
<tr>
<td>17</td>
<td>LAUREA</td>
<td>8</td>
<td>IT-Healthcare Platform</td>
<td>Interesting</td>
<td></td>
<td></td>
</tr>
<tr>
<td>18</td>
<td>MedicalSyn</td>
<td>4</td>
<td>DigiRoom</td>
<td>Interesting</td>
<td></td>
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<tr>
<td>19</td>
<td>NHSCT</td>
<td>4</td>
<td>eCTouch</td>
<td>Interesting</td>
<td></td>
<td></td>
</tr>
<tr>
<td>20</td>
<td>OMN</td>
<td>Replicating</td>
<td>DigiRoom</td>
<td>CCS: very interesting.</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>eCTouch</td>
<td>CCS: very interesting.</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td>NOTiFY</td>
<td>Interesting</td>
<td></td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>eHealth platform</td>
<td>Not helpful</td>
<td></td>
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</tbody>
</table>

CCS: robots are very interesting. But the problem is that only few robots are available (how can we evaluate the impact?) - perhaps it is possible to use the robot one month in the first house and the second month the second house, etc.?

We would like to contribute with the MedicalSyn Healthcare-Platform to the pilot 1. If the pilot leader doesn’t want to use our tool, we will contribute with our technical and process know-how to this pilot.

CCS: they would like to platform for questionnaires (e.g. user requirements, evaluation); the database with medical data, insurance papers, etc. is not interesting (the end-user are elderly people not patients)

A new version is developed together with TREE and VICOM to analyse the behaviour of the user and rise an alarm if a risk is detected (e.g. the stove is on for 10 hours).

CCS: who pays for the sensors (e.g. door, window, oven)?

CCS: Privacy issues regarding the use of a camera in the bedroom.
<p>| | | | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>21</td>
<td>UP</td>
<td>4</td>
<td>TIAGo (mobile manipulator robot)</td>
</tr>
<tr>
<td>22</td>
<td>PAL</td>
<td>2</td>
<td>NewSum</td>
</tr>
<tr>
<td>23</td>
<td>5thYPE</td>
<td>6</td>
<td>Replicating</td>
</tr>
<tr>
<td>24</td>
<td>SAL</td>
<td>2</td>
<td>diAnoia App</td>
</tr>
<tr>
<td>25</td>
<td>AAA</td>
<td>2</td>
<td>Talk and Play</td>
</tr>
<tr>
<td>26</td>
<td>SciFY</td>
<td>2</td>
<td>DAPHNE Wellbeing App</td>
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<tr>
<td>27</td>
<td>HMU</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>28</td>
<td>TREE</td>
<td>2</td>
<td></td>
</tr>
</tbody>
</table>

**MEAS**

**Not helpful**

CCS: It is very difficult to include first responder organisations in the pilot activities. Not interesting for SHAPES.

CCS: interesting

It is only available in Greek and Spanish. It is not clear to us the comment "Not helpful" related to our tool NewSum, that we noticed in Pilot 1. NewSum is the tool we recommend, as it applies better for Pilot 1 than any other pilot. Do you have a different opinion on this?

But has to be translated into German and checked by a psychologist.

CCS: Difficult to apply (Translation, costs, (German) approval to use this app; difficult to evaluate the impact

CCS: interesting

activity recognition based on the data coming from the sensors?

CCS: is it available in German? How much input is needed from the elderly person (e.g. Do they have to provide a lot of text?)

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<table>
<thead>
<tr>
<th>Deliverable D6.1 SHAPES Pan-European Pilot Campaign Plan</th>
<th>Version 1.0</th>
</tr>
</thead>
</table>

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159.
### Pilot Theme 2: Improving In-Home and Community-based Care

**Lead:** GEWI

**Recruitment levels** 5/10

**Replicated by:**
- AIAS
- CCS
- CH
- DYPE
- FNOL
- SAL
- UP

**Recruitment levels**

<table>
<thead>
<tr>
<th>Number</th>
<th>Organisation</th>
<th>PM in Task 6.3 (pilot 2)</th>
<th>Pilot Activities</th>
<th>Tool/Application/ Solution</th>
<th>Applicable in this pilot</th>
<th>Comments</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>NUIM</td>
<td>4</td>
<td></td>
<td>Access Earth App</td>
<td>Not helpful</td>
<td>Gewi: Probably not helpful, but they will ask the end-user.</td>
</tr>
<tr>
<td>2</td>
<td>Access Earth</td>
<td>1</td>
<td>Access Earth App</td>
<td>Not helpful</td>
<td></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>AGE</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>4</td>
<td>AIAS</td>
<td>12</td>
<td>Replicating</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>AUTH</td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>CCS</td>
<td>12</td>
<td>Replicating</td>
<td>Chatbot ROSA</td>
<td>Not helpful</td>
<td>EDGE could provide more data from IoT devices (based on the eCare Platform) Gewi: Probably not interesting for gewi.</td>
</tr>
<tr>
<td>7</td>
<td>CH</td>
<td>12</td>
<td>Replicating</td>
<td>Chatbot ROSA</td>
<td>Not helpful</td>
<td></td>
</tr>
</tbody>
</table>

General comments:
Is it possible that some technical solution will be used only by some end-users? E.g. there are only 3 robots available - does this mean that only 3 persons test the robots and other persons test other technologies?

Everything which needs very good internet connection will be difficult to use and test in this pilot.
<table>
<thead>
<tr>
<th>#</th>
<th>Project</th>
<th>Number</th>
<th>Status</th>
<th>Description</th>
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<tbody>
<tr>
<td>8</td>
<td>EDGE</td>
<td>12</td>
<td>MAESTRA &amp; eCare</td>
<td>Interesting</td>
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<tr>
<td>9</td>
<td>EUD</td>
<td></td>
<td></td>
<td></td>
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<tr>
<td>10</td>
<td>FNOL</td>
<td>24</td>
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<td>Telemedicine System</td>
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<td>Fraunhofer</td>
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</tr>
<tr>
<td>12</td>
<td>FINT</td>
<td>4</td>
<td>FINoT platform &amp; programmable cloud platform</td>
<td>Shapes overall platform</td>
</tr>
</tbody>
</table>

EDGE provides a module (a digital solution inspired in the MAESTRA and eCare platforms) that aggregates information related with a person's vitals and home environment. It is planned to incorporate smart analytics (provided by TREE and VICOM) to enable the detection of anomalies and the generation of alerts that feed into remote monitoring platforms of hospitals, clinics, nursing homes and care units.

A virtual robot (e.g., ROSA) could also be integrated in order to provide deeper and more natural interaction with the user.

Note that the server hosting the SHAPES Platform and conducting advanced calculations (e.g., AI algorithms) can be installed at the premises of the pilot reference site.

We need to carefully plan the extent of the deployment and degree of local support (e.g., training and motivation, technical assistance) to be provided by pilot organisations in order to ensure the proper use of the SHAPES solution.

EDGE's module will be integrated in the overall SHAPES Platform solution, also incorporating other components (e.g., robots, medication control components, video calls, etc.).

Operational telemedicine system comprising more than 20 sets of devices for chronic heart failure patients, over 60 glucometers, gateways based on tablets and smartphones, central system with database and portal located in a cloud.

Apply GW reference interoperable implementation and utilise the capabilities of the IoT Accelerated GW for achieving interoperability and interconnectivity (EDGE & ICOM).
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<tr>
<td>13</td>
<td>GNO</td>
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<td>eHealthPass</td>
<td>Not helpful Gewi: Probably not helpful, the end-users are just elderly people, not patients.</td>
</tr>
<tr>
<td>14</td>
<td>gewi</td>
<td>18</td>
<td>Lead</td>
<td>Assisted Living Solutions Interesting In the Oberbergische Kreis they would prefer to use the panic or alarm button of a local provider (Better@Home Service GmbH). Is it possible to include this application in an open call?</td>
</tr>
<tr>
<td>15</td>
<td>ICOM</td>
<td>1</td>
<td>Technology leader Shapes overall platform</td>
<td>KOM needs a catalogue of requirements (e.g. in which areas the robot has to move around – flats or houses). Gewi: robots are very interesting. But the problem is that only few robots are available (who can we evaluate the impact?) - perhaps it is possible to use the robot one month in the first house and the second month the second house, etc.?</td>
</tr>
<tr>
<td>16</td>
<td>KOM</td>
<td>4</td>
<td>KOMPAI-2 robot Interesting, but issues have to be solved</td>
<td>Interesting Gewi: robots are very interesting. But the problem is that only few robots are available (who can we evaluate the impact?) - perhaps it is possible to use the robot one month in the first house and the second month the second house, etc.?</td>
</tr>
<tr>
<td>17</td>
<td>LAUREA</td>
<td></td>
<td></td>
<td>Interesting Gewi: very interesting.</td>
</tr>
<tr>
<td>18</td>
<td>MedicalSyn</td>
<td>4</td>
<td>IT-Healthcare Platform</td>
<td>Interesting We would like to contribute with the MedicalSyn Healthcare-Platform to the pilot 2. If the pilot leader doesn’t want to use our tool, we will contribute with our technical and process know-how to this pilot. Gewi: they would like to platform for questionnaires (e.g. user requirements, evaluation); the database with medical data, insurance papers, etc. is not interesting (the end-user are elderly people not patients)</td>
</tr>
<tr>
<td>19</td>
<td>NHSCT</td>
<td></td>
<td></td>
<td>Interesting Gewi: very interesting.</td>
</tr>
<tr>
<td>20</td>
<td>OMN</td>
<td>2</td>
<td>DigiRoom</td>
<td>Interesting Gewi: very interesting.</td>
</tr>
<tr>
<td>20</td>
<td>OMN</td>
<td>2</td>
<td>eCTouch</td>
<td>Interesting Gewi: very interesting.</td>
</tr>
<tr>
<td>20</td>
<td>OMN</td>
<td>2</td>
<td>NOTIFY</td>
<td>Interesting A new version is developed together with TREE and VICOM to analyse the behaviour of the user and rise an alarm if a risk is detected (e.g. the stove is on for 10 hours).</td>
</tr>
</tbody>
</table>
### Deliverable D6.1 SHAPES Pan-European Pilot Campaign Plan

#### Version 1.0

<table>
<thead>
<tr>
<th>21</th>
<th>UP</th>
<th>8</th>
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</thead>
<tbody>
<tr>
<td>22</td>
<td>PAL</td>
<td>4</td>
<td>TIAGo (mobile manipulator robot)</td>
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<td>25</td>
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<tr>
<td>26</td>
<td>SciFY</td>
<td>1</td>
<td>Talk and play app</td>
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<td>HMU</td>
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<td>28</td>
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<tr>
<td>29</td>
<td>UCLM</td>
<td>6</td>
<td>3D-depth video</td>
</tr>
</tbody>
</table>

**Gewi:** who pays for the sensors (e.g. door, window, oven)?

Privacy issues regarding the use of a camera in the bedroom.

**MEAS**

Similar to an application in Germany “EmergencyEye”, which includes a live-video function and a precise localisation of the emergency. EmergencyEye has no log of the conversations – no tracking or traces are left after the conversation (to protect the emergency worker).

**gewi:** It is very difficult to include first responder organisations in the pilot activities. Not interesting for SHAPES.

**gewi:** interesting

**It can be translated easily by local partner. It is available in Greek, English and Spanish.**

**gewi:** Could be possibly useful. It depend on the amount of input which is need from the elderly person.

**The data analytics of the monitoring data could be used to provide additional information for the consultative care visits (Beratungsbesuche). Analyse data from the different devices for pattern analysis?**

---

This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 857159
<table>
<thead>
<tr>
<th>No.</th>
<th>Pilot Theme 3: Medicine Control and Optimisation</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lead:</td>
<td>NHSCT</td>
</tr>
<tr>
<td>Recruitment levels</td>
<td>30</td>
</tr>
<tr>
<td>Replicated by:</td>
<td>CH FNOL UNRF GEWI</td>
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This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159.
## Recruitment levels

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<th>Organisation</th>
<th>PM in Task 6.4 (pilot 3)</th>
<th>Pilot Activities</th>
<th>Tool/Application/Solution</th>
<th>Applicable in this pilot</th>
<th>Comments</th>
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<td>2</td>
<td>Access Earth</td>
<td>1</td>
<td></td>
<td>Access Earth App</td>
<td>Not helpful</td>
<td>Doesn't fit in this pilot. But at a later stage it might be useful to have it.</td>
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<tr>
<td>3</td>
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<tr>
<td>7</td>
<td>CH</td>
<td>Replicating</td>
<td></td>
<td></td>
<td>Interesting</td>
<td>Use case &quot;In-home decompensation prediction for heart failure patients&quot; with chatbot ROSA</td>
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<tr>
<td>8</td>
<td>EDGE</td>
<td>??</td>
<td></td>
<td></td>
<td>Interesting</td>
<td>NHSCT thinks that eCare and MAESTRA would be very useful for pilot 3 (e.g. including a smart living environment; smartwatches); their own platform should also be included in eCare/MAESTRA (via 5G or LoRa) EDGE: I am positive on the possibility to support pilot 3, but before we commit we need to assess the required involvement (and effort). It will also help if we can leverage our involvement from other themes where we are already involved with the specific partner (that is, where/if our technology - wearables, devices, ... - is already present).</td>
</tr>
<tr>
<td>9</td>
<td>EUD</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Telemedicine System</td>
<td>Operational telemedicine system comprising more than 20 sets of devices for chronic heart failure patients, over 60 glucometers, gateways based on tablets and smartphones, central system with database and portal located in a cloud.</td>
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<td>Shapes overall platform</td>
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<tr>
<td>13</td>
<td>GNO</td>
<td>2</td>
<td>eHealthPass</td>
<td>Interesting</td>
<td>NHSCT: Could be useful for the communication with the doctor.</td>
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<td>MedicalSyn</td>
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<td>IT-Healthcare Platform</td>
<td>We would like to contribute with the MedicalSyn Healthcare-Platform to the pilot. For this pilot 0 PM are requested. If the pilot leader decides to use the MedicalSyn Healthcare Platform, the redistribution of PM must be negotiated with the project partners, task leaders and pilot leaders. NHSCT: This would be interesting for the pilot. At the moment they are setting up a patient platform and it would be good to test one in this pilot.</td>
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</tr>
<tr>
<td>18</td>
<td>NHSCT</td>
<td>Lead</td>
<td>DigiRoom</td>
<td>NHSCT: useful for this pilot</td>
<td></td>
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<td>DigiRoom</td>
<td>NHSCT: useful for this pilot</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>eCTouch</td>
<td>It also might have other usages, e.g. the rehabilitation personnel could be alerted e.g. regarding an unusual usage of electric devices. This would also be useful for NHSCT.</td>
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<td>Interesting, but issues have to be solved</td>
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<td>HMU</td>
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<tr>
<td>No.</td>
<td>Partner</td>
<td>UCLM</td>
<td>3D-depth video</td>
<td>Smart bands</td>
<td>CHIPS installed in the shoe</td>
<td>Technology oriented assistance in combination with data analytics and predictive algorithms for assisted living solutions (together with TREE and VICOM)</td>
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<tr>
<td>28</td>
<td>TREE</td>
<td>1</td>
<td>data analytics</td>
<td>Interesting</td>
<td>TREE could provide this pilot with some predictive analysis/Decision support system they could develop with the data collected during Pilot 3 (they could use some of the EDGE devices). TREE will define together with Michael some interesting analytics mainly related to predictive tools. NHSCT: useful in combination with eCare/MAESTRA;</td>
<td></td>
</tr>
<tr>
<td>29</td>
<td>UCLM</td>
<td>6</td>
<td>3D-depth video</td>
<td>Not helpful</td>
<td></td>
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</tr>
<tr>
<td>30</td>
<td>UAVR</td>
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<tr>
<td>31</td>
<td>UCC</td>
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<tr>
<td>32</td>
<td>UPORTO</td>
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<tr>
<td>33</td>
<td>UNRF</td>
<td>6</td>
<td>Replicating</td>
<td>Interesting</td>
<td>They think that for this pilot the third option “chip in the shoe” would perhaps be interesting. This chip could be an additional sensor in this pilot. It could inform about differences in the behaviour of the patient, which might go back to differences in the medication or medication adherence. NHSCT: could be interesting, e.g. to see if the medicine has side effects or if the patient suffers pain.</td>
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<tr>
<td>34</td>
<td>ULS</td>
<td>2</td>
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</tbody>
</table>
If the patient fills out questionnaires before, the system could “learn” the behaviour and patterns of the patient and detect in advance if the patient is at risk or not feeling o.k. NHSCT: could be interesting (together with data analytics from TREE)

NHSCT is not sure where to apply this technology.

It has to be tested, if the patients accept a camera within the house.
NHSCT: it would be good to have a "virtual nurse" who could remind and reinforce the patient to take the medicine.

We need a data model / data provision plan (e.g. which type of data will we measure, how many people will participate). UAVR will provide this until End of January

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<tr>
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<td>NUIM</td>
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</tr>
<tr>
<td>2</td>
<td>Access Earth</td>
<td>1</td>
<td>Access Earth App</td>
<td>Not helpful</td>
</tr>
<tr>
<td>3</td>
<td>AGE</td>
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<td>4</td>
<td>AIAS</td>
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<td>5</td>
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<tr>
<td>8</td>
<td>EDGE</td>
<td>4</td>
<td>MAESTRA &amp; eCare</td>
<td>Interesting</td>
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<td>13</td>
<td>GNO</td>
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<td>eHealthPass</td>
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<td>Assisted Living Solutions</td>
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<td>17</td>
<td>LAUREA</td>
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</table>

EDGE will provide an interface with STEPMANIA (i.e., collection of performance data produced by STEPMANIA) to be sent to the SHAPES platform. Assess if UCLM can provide real-time activity data via the use of wearables. (add text to ULCM)
<table>
<thead>
<tr>
<th>No.</th>
<th>Participant</th>
<th>Contact No.</th>
<th>Comment</th>
<th>Observations</th>
</tr>
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<tbody>
<tr>
<td>18</td>
<td>MedicalSyn</td>
<td>3</td>
<td>IT-Healthcare Platform</td>
<td>Interesting We would like to contribute with the MedicalSyn Healthcare-Platform to the pilot 4. If the pilot leader doesn’t want to use our tool, we will contribute with our technical and process know-how to this pilot. UAVR: They would like to use a simplified version of the database just to capture the output of the pilot. VICOM could also use this database as an input for their data analytics. It has to be clarified if this database fits into the overall SHAPES platform (to be clarified with FINT).</td>
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<tr>
<td>19</td>
<td>NHSCT</td>
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<tr>
<td>26</td>
<td>SciFY</td>
<td>3</td>
<td>Dianoia app</td>
<td>Interesting The application will focus on mental and cognitive aspects. Will be available in Greek, English and one more. UAVR: Will it be easy to translate it into Portuguese (is it a text file?, can anybody translate it, or does he/she need a specific (medical/psychological) background?)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Memor-i</td>
<td>Interesting The application will focus on mental and cognitive aspects. Will be available in Greek, English and one more. VICOM: We have to integrate Memor-i into SHAPES. The output of the game has to be transferred to the SHAPES platform. We need to understand their data model (what is the result/output (type of data) of Memor-i?).</td>
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<tr>
<td>27</td>
<td>HMU</td>
<td>6</td>
<td>design and implementation of the SHAPES architecture, with emphasis on security.</td>
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<td>DAPHNE Wellbeing App</td>
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</table>

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To analyse the data of the different sensors (wearables, stepmania, SciFy applications) - and detect changes of behaviour and risks. Additionally, we are interested in the supporting the Pilot in the following task extracted from the pilot descriptions in the Grant Agreement: “the pilot theme’s implementation considers a large dataset for extracting knowledge and patterns of early decline symptoms, through data mining and analytics algorithms, and attempt predicting models of cognitive decline.”

UAVR: how large should the dataset be? (25 persons; 8-10 weeks and 3-6 month follow up); variables: cognitive functions, functioning, indicators of performance, questionnaires on quality of life; a problem is that we also need long-term data (what happens after 3-4 years?), because “decline” is a long time process; we need continuous data sets from STEPMANIA (e.g. weekly); also we want to check what else has an impact on the person (e.g. different songs or always the same song; should the person choose the exercise (personalization)); we also need medical information to evaluate “decline”; as a first step we have to define the outcome we want to achieve, then define the variable we will collect (data model) - we need to understand the data we capture (integer, float, ..)

<table>
<thead>
<tr>
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<th>Tool/Application/Solution</th>
<th>Applicable in this pilot</th>
<th>Comments</th>
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<tr>
<td>1</td>
<td>NUIM</td>
<td>1</td>
<td>Access Earth App</td>
<td>Access Earth App</td>
<td>Not helpful</td>
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<td>LLM Care (Integrated Healthcare System, which combines cognitive and physical training)</td>
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<td>Interesting</td>
<td>UPORTO: this could be interesting for pilot 5</td>
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This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159.
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<td>DigiRoom</td>
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<td>UPoro is worried that these technologies might be hard to use by persons with dementia.</td>
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<td>UPoro is mainly interested in NOTIFY, but asks OMN to provide more information regarding costs and practical issues regarding the eHealth platform (with the camera).</td>
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<td>eHealth platform</td>
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<td>UPoro is worried about practical issues like the costs, the maintenance, that several patients won’t have internet access and also about the user acceptance.</td>
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<tr>
<td>26</td>
<td>SciFY</td>
<td></td>
<td>diAnoia app</td>
<td>Interesting</td>
<td>SciFy: We could use diAnoia and Memor-i also in pilot 5, but, as I told you in a previous email, we think that these 2 projects don’t align strongly with pilot 5 goal: “Evaluate effective methods and solutions to monitor and evaluate older individuals facing neurodegenerative diseases.” So, despite the fact that diAnoia and memor-i could be beneficial for people with dementia, they don’t offer any evaluation or monitoring. UPORTO: these games have a good potential for this pilot</td>
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<td>Memor-i</td>
<td>Interesting</td>
<td>see above</td>
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<td>6</td>
<td>design and implementation of the SHAPES architecture, with emphasis on security.</td>
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Pilot Theme 6: Physical Rehabilitation at Home

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<td><strong>Not helpful</strong></td>
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<td>Replicating</td>
<td>LLM Care</td>
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<td>LLM Care (Integrated Healthcare System, which combines cognitive and physical training)</td>
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<tr>
<td>7</td>
<td>CH</td>
<td>6</td>
<td>Replicating</td>
<td>Chatbot ROSA</td>
<td><strong>Interesting</strong></td>
<td>SAL/UCLM: This might be useful - to guide the patients through the rehabilitation. It could also remind the patients when to go to the next session at the gym or to other appointments.</td>
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<td>12</td>
<td>FINT</td>
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<td>FiNoT platform &amp; programmable cloud platform</td>
<td>Shapes overall platform</td>
<td>Apply GW reference interoperable implementation and utilise the capabilities of the IoT Accelerated GW for achieving interoperability and interconnectivity (ICOM)</td>
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<tr>
<td>13</td>
<td>GNO</td>
<td>2</td>
<td>eHealthPass</td>
<td>Interesting</td>
<td>SAL/UCLM: This might be useful. When the patients have to see a medical specialist, it could be very helpful to have a videoconference and not having to travel quite far for a 5 minute appointment.</td>
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<tr>
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<td>Assisted Living Solutions</td>
<td>Interesting</td>
<td>SAL/UCLM: They are interested in fall-detection. This would be helpful especially during the night. They think that wearing a wearable is not a problem, because it is similar to a watch or a bracelet. A panic-button might be less useful, as people with dementia probably forget about it in an emergency situation.</td>
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<td>16</td>
<td>KOM</td>
<td>4</td>
<td>KOMPAl-2 robot</td>
<td>Interesting</td>
<td>overall KOM has 3 robots – 2 could be used for parallel evaluations within this pilot; the robot also has 3d video capabilities. SAL/UCLM: This is very interesting for the patients at the nursing home.</td>
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<tr>
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<tr>
<td>20</td>
<td>OMN</td>
<td>2</td>
<td>DigiRoom</td>
<td>Interesting</td>
<td>SAL/UCLM: This would be interesting for the people at the nursing home - this way they could talk to their family members far away. But perhaps it makes more sense to include it into pilot 1 or 2. The question is, if it is possible to integrate &quot;emotion detection&quot; into the videocamera system. But this might be too complex and should not be our first priority.</td>
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### Deliverable D6.1 SHAPES Pan-European Pilot Campaign Plan

**Version 1.0**

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<td>TIAGo (mobile manipulator robot)</td>
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<td>UCLM</td>
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**eCTouch**
- **Interesting**
  - UCLM already uses a small computer with Windows as an operating system; perhaps this remote communication tool could be installed there.
  - SAL/UCLM: They could also use this for the communication with the physiotherapist.

**NOTIFY**
- **Not helpful**
  - SAL/UCLM: This technology has not a high priority.

**eHealth platform**
- **Interesting, but issues have to be solved**
  - SAL/UCLM: It is probably not interesting to use the eHealth platform as it is, but they would like to use the videosurveillance system together with biometrics from VICOM as an (reverse) access control at the front door of the nursing home. This would be to avoid that people with dementia leave the building.

**MEAS**
- **Not helpful**
  - SAL/UCLM: This does not fit into this pilot.

**TIAGo (mobile manipulator robot)**
- **Not helpful**
  - SAL: This robot perhaps could be more useful in other pilots.

**Talk and Play**
- **Interesting**
  - Will be available in Greek, English and Spanish.
  - SAL: This is very interesting for this nursing home.

**emotion detection**
- **Not helpful**
  - The emotion detection can be used to supervise the „motivation“ of the patient (to improve the user-friendliness and usability).
  - They have to think about other possible use cases.

**data analytics**
- **Interesting**
  - Analysis of progress on the rehabilitation/activity recognition.

**3D-depth video**
- **Will definitively be used**

**smart bands**
- **Will definitively be used**

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<th>Chips installed in the shoe</th>
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</table>

Data analytics & predictive algorithms

Interesting

To analyse the data of the different sensors - and detect changes of behaviour and risks
SAL/UCLM: One possible use case would be the "**chip in the shoe**". With the help of this chip they could analyse the behavioural patterns, their daily life, activities and anomalies. Which **information** do we want to capture: depending on the illness the movement/activity of the two feet might be different; we can test the chip with "**healthy**" **people** (which are only impaired in their movement due to their age or which suffer general walking difficulties) or they can test the chip with specific diseases, which affect their legs or pies. Probably it will make sense to start with people without **pathology** and monitor their improvement. How much time do they have to monitor the patients? At least 6 month / 1 year. We have to create a **mini-Gantt** for this pilot. How many persons will **participate**? Perhaps 10 - but in the nursing home there will be 50-60 persons available.

**face recognition technology**

Interesting

It could be used for patients after a stroke;
SAL/UCLM: They can use it with patients with a **brain injury** or with **Parkinson**. Usually speech therapist work with these patients (e.g. to strengthen the musculature they work with gestures, vibrations, cold,...). A **face recognition technology** would be helpful - it might be complex, depending on the type of illness - if the entire face is paralysed or only half of it. They could start working with persons who still could move their face. VICOM will draft a use case for these orofacial movements.
### Pilot Theme 7: Cross-border Health Data Exchange Supporting Mobility and Accessibility for Older Individuals

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This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159
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This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 857159
It has to be decided, in which tool NLP could be integrated (neither ROSA nor the robots are included in this pilot).

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It has to be decided, in which tool NLP could be integrated (neither ROSA nor the robots are included in this pilot).
### Annex II: Matching of use cases and pilot themes

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| 17 | NOTIFY | dEHealth platform |
| 18 | MEAS |
| 20 | PAL | TIAGo (mobile manipulator robot) |
| 21 | SciFY | Talk and play app |
| 22 | Dianoia app |
| 23 | NewSum |
| 24 | Memor-i |
| 25 | ICSee |
| 26 | HMU | design and implementation of the SHAPES architecture, with emphasis on security. |
| 27 | TREE | data analytics |
| 28 | DAPHNE Wellbeing App |
| 29 | emotion detection |
| 30 | UCLM | 3D-depth video |
| 31 | smart bands |
| 32 | Chips installed in the shoe |
| 33 | UAVR | Stepmania |
| 34 | UPORTO | iSupport |
| 35 | UNRF | Data analytics & predictive algorithms |
| 36 | VICOM | Data analytics & predictive algorithms |
| 37 | multimodal biometrics/ face recognition technology |

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### Definiton

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Others: HelpCity: a local network of peers who can remain anonymous, chat and exchange news as well as meet virtually or in person.

This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 857159.
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**Processing (virtual nurse)**

- HealthWatch: Support Vector Machines (SVM) & Support Vector Networks (SVN)
- Medimonto - Telemedicine system of UHO
- Recurrent Neural Networks

**Definiton**

- "yes" technology included
- "perhaps" technology might be useful

- Psycho-social and Cognitive Stimulation Promoting Wellbeing (Stepmania)
- Option 1: In-home cognitive activities for people with early-stage dementia or Option 2: ...
- Online information and training for informal dementia caregivers (iSupport)
- Digital Assistant for Older People with Mild Cognitive Impairment
- Technological resources for monitoring diabetic patients with mild cognitive impairment

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### Pilot theme 6

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## Deliverable D6.1 SHAPES Pan-European Pilot Campaign Plan  
**Version 1.0**

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<td>30</td>
<td>UCLM</td>
<td>3D-depth video</td>
</tr>
<tr>
<td>31</td>
<td>smart bands</td>
<td></td>
</tr>
</tbody>
</table>

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<table>
<thead>
<tr>
<th>#</th>
<th>Organization</th>
<th>Technology</th>
</tr>
</thead>
<tbody>
<tr>
<td>32</td>
<td></td>
<td>Chips installed in the shoe</td>
</tr>
<tr>
<td>33</td>
<td>UAVR</td>
<td>Stepmania</td>
</tr>
<tr>
<td>34</td>
<td>UPORTO</td>
<td>iSupport</td>
</tr>
<tr>
<td>35</td>
<td>UNRF</td>
<td>Data analytics &amp; predictive algorithms</td>
</tr>
<tr>
<td>36</td>
<td>VICOM</td>
<td>Data analytics &amp; predictive algorithms</td>
</tr>
<tr>
<td>37</td>
<td></td>
<td>multimodal biometrics/ face recognition technology</td>
</tr>
<tr>
<td>38</td>
<td></td>
<td>chatbot with Natural Language Processing (virtual nurse)</td>
</tr>
<tr>
<td>39</td>
<td>Others</td>
<td>unlimited cloud storage;</td>
</tr>
</tbody>
</table>
Annex III: List of Pilot sites for each use case

Definition: L – leader of use case; R – Replicating site; X – interest in use case (leading or replicating site)

<table>
<thead>
<tr>
<th>Pilot theme 1</th>
<th>Use Case</th>
<th>AIAS</th>
<th>AUTH</th>
<th>CCS</th>
<th>CH</th>
<th>5th YPE</th>
<th>FNOL</th>
<th>GEWI</th>
<th>NHSCT</th>
</tr>
</thead>
<tbody>
<tr>
<td>UC-PT1-001</td>
<td>Wellbeing Assessment Use Case</td>
<td>x</td>
<td>L</td>
<td>x</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UC-PT1-002A</td>
<td>Digital Assistant to Support older people to live independently and remain socially connected</td>
<td>x</td>
<td>L</td>
<td>x</td>
<td>x</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UC-PT1-002b</td>
<td>Digital Assistant to Support older people to live independently and remain socially connected</td>
<td>x</td>
<td>L</td>
<td>x</td>
<td>x</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UC-PT1-003</td>
<td>Overcoming the fear of digital technology</td>
<td>L</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UC-PT1-004</td>
<td>competent usage of digital technologies (e.g. receiving information)</td>
<td>L</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>UC-PT1-005</td>
<td>problem solving in the community (e.g. video-communication)</td>
<td>L</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pilot theme 2</th>
<th>Use Case</th>
<th>AIAS</th>
<th>AUTH</th>
<th>CCS</th>
<th>CH</th>
<th>5th YPE</th>
<th>FNOL</th>
<th>GEWI</th>
<th>NHSCT</th>
</tr>
</thead>
<tbody>
<tr>
<td>UC-PT2-001</td>
<td>Delivering remote monitoring of key health parameters</td>
<td>x</td>
<td>R</td>
<td>?</td>
<td>x</td>
<td>x</td>
<td>L</td>
<td></td>
<td></td>
</tr>
<tr>
<td>UC-PT2-002</td>
<td>Supporting the interaction of the individual with the community</td>
<td>x</td>
<td>R</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>L</td>
</tr>
<tr>
<td>UC-PT2-003</td>
<td>Support of social interactions via companionship with a robot and impact on further engagement with the community</td>
<td>x</td>
<td>R</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>L</td>
</tr>
</tbody>
</table>

This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 857159
<table>
<thead>
<tr>
<th>Pilot theme 3</th>
<th>&quot;UC-PT4-002b&quot; = UC-PT2-003</th>
<th>LLM CARE Healthcare System for Cognitive and Physical training</th>
<th>X</th>
<th></th>
<th>X</th>
</tr>
</thead>
<tbody>
<tr>
<td>UC-PT2-004</td>
<td>Night surveillance Rounds at community care (suggestion KOMPAI)</td>
<td></td>
<td>?</td>
<td></td>
<td>X (contact with Mefta)</td>
</tr>
<tr>
<td>Pilot theme 3</td>
<td>UC-PT3-001</td>
<td>In-home decompensation prediction for heart failure patients</td>
<td>X</td>
<td></td>
<td>X (care team?)</td>
</tr>
<tr>
<td>UC-PT3-001b</td>
<td>Prediction of stroke by home using blood pressure values (merge with 001)</td>
<td></td>
<td>X (care team?)</td>
<td></td>
<td>L</td>
</tr>
<tr>
<td>UC-PT3-001c</td>
<td>Advanced telemonitoring of patients with heart failure in home environment</td>
<td></td>
<td>X</td>
<td></td>
<td>L</td>
</tr>
<tr>
<td>UC-PT3-002</td>
<td>Diabetes self-management, control and prevention</td>
<td></td>
<td>X</td>
<td>(internet?)</td>
<td>L</td>
</tr>
<tr>
<td>UC-PT3-002b</td>
<td>Monitoring of blood glucose levels to older individuals with diabetes or pre-diabetic, abnormal glucose indications (merge with 002)</td>
<td></td>
<td></td>
<td></td>
<td>L</td>
</tr>
<tr>
<td>UC-PT3-003</td>
<td>Wellbeing Assessment Solution adapted for patients with multimorbidities</td>
<td></td>
<td>?</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>UC-PT3-004</td>
<td>(Online) communication with a doctor</td>
<td></td>
<td></td>
<td>X</td>
<td>L</td>
</tr>
<tr>
<td>Pilot theme 4</td>
<td>UC-PT4-001</td>
<td>Psycho-social and Cognitive Stimulation Promoting Wellbeing (Stepmania)</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pilot theme 5</td>
<td>UC-PT4-002</td>
<td>In-home cognitive training for patients in early stages of neurocognitive deficits (merged with 002b)</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pilot theme 5</td>
<td>UC-PT4-002b</td>
<td>LLM CARE Healthcare System for Cognitive and Physical training</td>
<td>?</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pilot theme 5</td>
<td>UC-PT4-003</td>
<td>Option 1: In-home cognitive activities for people with early-stage dementia or Option 2: ...</td>
<td>x</td>
<td>x</td>
<td>x</td>
</tr>
<tr>
<td>Pilot theme 5</td>
<td>UC-PT4-003</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pilot theme 5</td>
<td>UC-PT5-001</td>
<td>Online information and training for informal dementia caregivers (iSupport)</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pilot theme 5</td>
<td>UC-PT5-002</td>
<td>Digital Assistant for Older People with Mild Cognitive Impairment</td>
<td>x</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pilot theme 5</td>
<td>UC-PT5-003</td>
<td>Voice reminders for Alzheimer’s disease and other dementia patients (to be merged with 002)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pilot theme 5</td>
<td>UC-PT5-004</td>
<td>In-home fall detection for Parkinson’s disease and other dementia patients (merged with UC-PT1-001)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pilot theme 5</td>
<td>UC-PT5-005 (now: UC-PT5-003)</td>
<td>Technological resources for monitoring diabetic patients with mild cognitive impairment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pilot theme 6</td>
<td>UC-PT6-001</td>
<td>Training of orofacial musculature</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pilot theme 6</td>
<td>UC-PT6-002</td>
<td>Gait rehabilitation</td>
<td>x</td>
<td></td>
<td>L?</td>
</tr>
<tr>
<td>Pilot theme 6</td>
<td>UC-PT6-003</td>
<td>3D Depth Camera Rehabilitation Tool</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pilot theme 6</td>
<td>UC-PT6-004</td>
<td>Wearable Motion Monitoring Device</td>
<td>x</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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| Pilot theme 7 | UC-PT7-001 | Monitor older patient with chronic disease when travelling abroad | | | | | L |
| UC-PT7-002 | Foster older people’s (with physical disabilities) independent living by identifying accessible locations and routes in other locations (domestic and abroad) | | | | | | L |
| UC-PT7-003 & UC-PT7-004 | Preventing and/or handling a medical emergency while visiting another country | | | | | | L |
| UC-PT7-005 | Monitoring seniors travelling through GPS tracking smartwatch | | | | | | L |
| UC-PT7-005 | Cloud-based electronic health record for cross-border health data exchange | | | | | | L |

| Pilot theme 1 | UC-PT1-001 | Wellbeing Assessment Use Case | OMN | SAL/UCLM | UP | UAVR | UCC | UNRF | UPORTO |
| UC-PT1-002A (with robots) | Digital Assistant to Support older people to live independently and remain socially connected | | | | | | | | x |
| UC-PT1-002b (without robots) | Digital Assistant to Support older people to live independently and remain socially connected | | | | | | | | x |
| UC-PT1-003 | Overcoming the fear of digital technology | | | | | | ? | | |

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<table>
<thead>
<tr>
<th>Pilot theme 2</th>
<th>UC-PT1-004 (merge with 003)</th>
<th>competent usage of digital technologies (e.g. receiving information)</th>
<th>x</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>UC-PT1-005 (merge with 003)</td>
<td>problem solving in the community (e.g. video-communication)</td>
<td>x</td>
</tr>
<tr>
<td></td>
<td>UC-PT2-001</td>
<td>Delivering remote monitoring of key health parameters</td>
<td>?</td>
</tr>
<tr>
<td></td>
<td>UC-PT2-002</td>
<td>Supporting the interaction of the individual with the community</td>
<td>x</td>
</tr>
<tr>
<td></td>
<td>UC-PT2-003</td>
<td>Support of social interactions via companionship with a robot and impact on further engagement with the community</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&quot;UC-PT4-002b&quot; = UC-PT2-003</td>
<td>LLM CARE Healthcare System for Cognitive and Physical training</td>
<td></td>
</tr>
<tr>
<td></td>
<td>UC-PT2-004</td>
<td>Night surveillance Rounds at community care (suggestion KOMPAI)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Pilot theme 3</th>
<th>UC-PT3-001</th>
<th>In-home decompensation prediction for heart failure patients</th>
<th>pilot theme in general</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>UC-PT3-001b</td>
<td>Prediction of stroke by home using blood pressure values (merge with 001)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>UC-PT3-001c</td>
<td>Advanced telemonitoring of patients with heart failure in home environment</td>
<td></td>
</tr>
<tr>
<td></td>
<td>UC-PT3-002</td>
<td>Diabetes self-management, control and prevention</td>
<td></td>
</tr>
</tbody>
</table>

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<p>| Pilot theme 4 | UC-PT3-002b | Monitoring of blood glucose levels to older individuals with diabetes or pre-diabetic, abnormal glucose indications (merge with 002) |  |  |  |  |
| Pilot theme 4 | UC-PT3-003 | Wellbeing Assessment Solution adapted for patients with multi-morbidities |  |  |  |  |
| Pilot theme 4 | UC-PT3-004 | (Online) communication with a doctor |  |  |  |  |
| Pilot theme 4 | UC-PT4-001 | Psycho-social and Cognitive Stimulation Promoting Wellbeing (Stepmania) | pilot theme in general | L |  |  |
| Pilot theme 4 | UC-PT4-002 | In-home cognitive training for patients in early stages of neurocognitive deficits (merged with 002b) | ? | x |  |  |
| Pilot theme 4 | UC-PT4-002b | LLM CARE Healthcare System for Cognitive and Physical training moved to pilot 2 | ? |  |  |  |
| Pilot theme 4 | UC-PT4-003 | Option 1: In-home cognitive activities for people with early-stage dementia or Option 2: … | ? | x |  |  |
| Pilot theme 5 | UC-PT5-001 | Online information and training for informal dementia caregivers (iSupport) | pilot theme in general | L |  |  |
| Pilot theme 5 | UC-PT5-002 | Digital Assistant for Older People with Mild Cognitive Impairment | ? | x(L or R) | x | (language?) |
| Pilot theme 5 | UC-PT5-003 | Voice reminders for Alzheimer’s disease and other dementia patients (to be merged with 002) | ? |  |  | ?? |</p>
<table>
<thead>
<tr>
<th>Pilot theme 6</th>
<th>UC-PT5-004</th>
<th>In-home fall detection for Parkinson’s disease and other dementia patients (merged with UC-PT1-001)</th>
<th>?</th>
<th></th>
<th>??</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>UC-PT5-005 (now: UC-PT5-003)</td>
<td>Technological resources for monitoring diabetic patients with mild cognitive impairment</td>
<td>L</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pilot theme 6</td>
<td>UC-PT6-001</td>
<td>Training of orofacial musculature</td>
<td>L</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>UC-PT6-002</td>
<td>Gait rehabilitation</td>
<td>R</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>UC-PT6-003</td>
<td>3D Depth Camera Rehabilitation Tool</td>
<td>L</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>UC-PT6-004</td>
<td>Wearable Motion Monitoring Device</td>
<td>L</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pilot theme 7</td>
<td>UC-PT7-001</td>
<td>Monitor older patient with chronic disease when travelling abroad</td>
<td>?? (difficult)</td>
<td></td>
<td>pilot theme in general</td>
</tr>
<tr>
<td></td>
<td>UC-PT7-002</td>
<td>Foster older people’s (with physical disabilities) independent living by identifying accessible locations and routes in other locations (domestic and abroad)</td>
<td>?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>UC-PT7-003 &amp; UC-PT7-004</td>
<td>Preventing and/or handling a medical emergency while visiting another country</td>
<td>?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>UC-PT7-005</td>
<td>Monitoring seniors travelling through GPS tracking smartwatch</td>
<td>?</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>UC-PT7-005</td>
<td>Cloud-based electronic health record for cross-border health data exchange</td>
<td>?</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
### Annex IV: Adaption of the use cases to COVID-19 pandemic

**Pilot theme 1:**

<table>
<thead>
<tr>
<th>Pilot Theme 1</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Name and original objective</strong></td>
<td>This pilot theme is centered on providing an environment for older individuals that contributes to a more independent, better and healthier living at home, as well keep them integrated in an active and social life. The target group consists of elders (+65 years) living independently and displaying signs of reduced physical and/or cognitive capabilities and/or functions (physical and/or cognitive), but willing to maintain autonomy, independence and healthy living at home. It consists further of communities involved in activities for older individuals, Care service providers and Informal caregivers.</td>
</tr>
<tr>
<td><strong>Combination of digital solutions</strong></td>
<td>• Health and Wellbeing App for the registration of vital signs and physical measurements, diet and nutrition data and the intake of medication (based on eCare App from EDGE; Daphne App from TREE; Healthpass App from GNO);</td>
</tr>
<tr>
<td><strong>Opportunities to do something with these or slightly modified versions or with some added technological solutions to fight covid-19</strong></td>
<td>Currently all people over 70 or those with certain underlying medical conditions are being recommended to stay at home and self-isolated. Some of them are inexperienced and afraid of using even simple digital services such as messaging and/or video chat. The originally planned use case PT1_03 even in an unaltered version provides immediate positive impact on the target group because it aims at reducing the fear of using digital services and increasing the competence at the same time.</td>
</tr>
<tr>
<td><strong>Which objective (regarding the pandemic) could be reached with this technologies</strong></td>
<td>Reduce fear of using digital services, increase competence and literacy, increase self-sustainability even in quarantine situations. No additional technologies would be required to answer this question.</td>
</tr>
</tbody>
</table>

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Pilot theme 2:

EDGE has developed a dedicated App (ONE, which states for Observation of National Epidemics) that supports the monitoring of the patients who are in active surveillance after being deemed infected or suspect of COVID-19. Because their condition does not warrant hospitalization, they remain in quarantine at their homes. The ONE App allows these patients to login their symptoms (selected to meet the COVID-19 requirements) and submit their vital signs (namely temperature) and well-being status to a platform that is handled by the Ministry of Health. Upon the severity of the symptoms and the decline of the health condition, the doctors in charge of accompanying them are able to act on real-time and determine their hospitalization for adequate treatment. The added-value of the App is to provide this information in real-time to the health authorities and the ability to scale for a large community, being able to accompany the disease evolution without being an added workload to the patient. In addition, it offers to those that remain in active quarantine the comfort of knowing that their condition is continuously being monitored and that, if needed, they will have the assistance they require.

We will be adding this App to the set of digital solutions available for the SHAPES pilots and hopefully it will be a good asset to combat not only this wave of COVID-19 but future waves and other epidemics that may rise in the future.

Pilot Theme 3:

<table>
<thead>
<tr>
<th>Name and original objective</th>
<th>The primary objective of the Medicine Control and Optimisation pilot is focused on identifying, managing and improving deficiencies in adherence to medicines and treatments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Combination of digital solutions</td>
<td>• Health and Wellbeing App for the registration of vital signs and physical measurements, diet and nutrition data and the intake of medication (based on eCare App from EDGE; Daphne App from TREE; Healthpass App from GNO);</td>
</tr>
</tbody>
</table>

This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 857159.
- Health and Wellbeing System for the remote monitoring of patients by doctors (based on eCare Platform from EDGE; Healthpass System from GNO);
- Digital Nurse Assistant for the engagement of patients concerning medication adherence (based on ROSA from CH);
- Chatbot for the engagement of patients concerning medication adherence (based on Chatbot from Vicomtech);
- Telemedicine System for remote consults (based on Telehealth System from CCS; Telemedicine System from FNOL; eCtouch System from Omnitor).
- Analysis of medicine optimisation for the automated decision aids on the medication adjustment required based on the health and wellbeing data collected (based on Big Data Analytics Platform from TREE; eHealth Software Toolkit from Vicomtech).

<table>
<thead>
<tr>
<th>Opportunities to do something with these or slightly modified versions or with some added technological solutions to fight covid-19</th>
<th>Currently all people over 70 or those with certain underlying medical conditions are being recommended to stay at home and self-isolate. Particular reference is made to the chronic health conditions of interest to this pilot theme. There may be scope to sample how participants medication management has changed over their self-isolation period and whether they used technology, particularly telemedicine, to assist with this.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Which objective (regarding the pandemic) could be reached with this technologies</td>
<td>How has the pandemic changed medication management in the population of interest? No additional technologies would be required to answer this question.</td>
</tr>
<tr>
<td>Which additional evaluation steps have to be taken</td>
<td>Change to planned interview questions Change to phone interviews to minimise contact</td>
</tr>
<tr>
<td>Any other comments regarding further necessary changes regarding the use case</td>
<td>It is difficult to predict what the coming months will bring in terms of covid restrictions, the SHAPES solution is needed now more than ever. Nevertheless the population we propose to sample are very vulnerable to covid, therefore a decision will need to be taken as to</td>
</tr>
</tbody>
</table>
whether our planned pilot could take place with an altered use case.

<table>
<thead>
<tr>
<th>Pilot Theme 3</th>
<th>UC-PT3-001c</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Name and original objective</strong></td>
<td>Promotion and maintenance of older individuals’ autonomy through digital solutions that provide a safe and caring environment for them at home, despite needing medical and nursing care/ Strengthening of informal care and expanding outpatient care/ Increase the involvement of older individuals and their families in the care situation and therapies/ Reduction of municipal rescue service and hospital admission rates, especially in the evening and on weekends. Added module for Viral disease (primarily COVID-19) symptoms resolution. (The whole pilot is described on a separate form.)</td>
</tr>
</tbody>
</table>
| **Combination of digital solutions** | • Telemedicine system (Medimonitor - FNOL) for remote interactive consults and support by cardiologist team and informal carers. (upgraded FNOL telemedicine system, Omnitor)….  
• Health and Wellbeing remote monitoring of patients by health professionals (based on eCare Platform from EDGE)….;  
• Digital Nurse Assistant for the engagement of patients concerning medication adherence (based on ROSA from CH);  
• Chatbot for the engagement of patients concerning medication adherence (based on Chatbot from Vicomtech);  
• Module in Medimonitor consisting of symptom checker, questionnaire and thermometer (other devices such as SpO2 meter as needed) to detect symptoms of viral disease. |
| **Opportunities to do something with these or slightly modified versions or with some added technological solutions to fight covid-19** | Specialists’ care of for chronic conditions (in the pilot: CHF) focuses on the disease in question and – as known in real world especially in countries with highly specialized care that does not regularly collaborates with primary care – do not support well patients in care of acute cases of other etiology, infections and other illnesses as this is subject of general practitioners. However: |
1. not all the patients and their informal carers are able to cope with fact that the telemedicine equipment and related intervention is not used to support them in complex sense of their healthcare status,
2. not all (chronically ill) patients are able to recognize new disease and then go immediately to their doctor in primary care,
3. and it is known that chronic condition of patients constitutes bad prediction of health development in case of infection, which is particularly truth in case of COVID-19.

Integrated, collaborating primary, specialized and hospital care might be a targeted vision, but its implementation may take in many countries a long time. In order to detect abnormal health status development due to viruses, minimum technologies and activities by the specialists is envisaged in addition to the distant chronic care support they normally provide. This added Virus module will also support self-care of patients as they will have some basic tools to recognize that “some (viral) illness is coming”. It should enable early detection of abnormal health development by the care professionals providing distant care and support via the telemedicine system. They will be able to early instruct the patients and/or informal cares to either visit primary healthcare centre or to make other action to resolve the status.

Current healthcare systems in many countries still do not enable sharing the telemonitoring data with general practitioners immediately from the beginning of pilots in the project but engaging GPs may be future enhancements of such telemedicine services for chronic care.

| Which objective (regarding the pandemic) could be reached with this technologies | Early detection of health issues (infection, virus) that can be revealed by temperature and symptom checking. The effect should result in better healthcare services and even lower mortality of the most vulnerable groups of patients. The Virus module does not replace any piece of primary care but can provide invaluable services to patients at home, particularly those who do not know what to do or for whatever reason cannot visit primary care in early stage and then the viral disease develops so that severely endangers their life. |
| Which additional evaluation steps have to be taken | Evaluation of frequency of the use of the module by patients, which indicates that the patients have a degree of confidence in such additional support.  
Evaluation of number of detected viral illnesses that has led to an action with the chronic patients related to viral disease. |
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<tr>
<td>Any other comments regarding further necessary changes regarding the use case</td>
<td>Support of chronic patients on distance alone may be very professional but the data available to the doctors (cardiologists) from measurements bioparameters purely focused on the chronic condition (e.g. weight development) and may not immediately disclose increased temperature and other symptoms of infection disease, which may ruin all the advanced (and expensive) care devoted to the patient for period of time. ICT technology allows to restrict the activity of specialists to minimum burden, not requiring significant extra effort. On the other hand, it can help as one step in integration of care, where multidisciplinary teams of doctors work together, sharing health data and other information about the chronic patients.</td>
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### Pilot Theme 4:

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<th>Pilot theme 4</th>
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<tbody>
<tr>
<td><strong>Name and original objective</strong></td>
<td>PT 4 (UC-PT4-001) – Psycho-social and Cognitive Stimulation Promoting Wellbeing</td>
</tr>
<tr>
<td><strong>Combination of digital solutions</strong></td>
<td>StepMania &amp; MedicalSyn</td>
</tr>
<tr>
<td><strong>Opportunities to do something with these or slightly modified versions or with some added technological solutions to fight covid-19</strong></td>
<td>Promote physical and cognitive wellbeing with less human resources and face-to-face interactions and monitor participants progression.</td>
</tr>
<tr>
<td><strong>Which objective (regarding the pandemic) could be reached with this technologies</strong></td>
<td>Maintenance of physical and cognitive stimulation during confinement.</td>
</tr>
</tbody>
</table>
Which additional evaluation steps have to be taken | Adapt the protocol and exclude the social face-to-face interaction that we aimed to include or create virtual communities that would facilitate this interaction.

| Any other comments regarding further necessary changes regarding the use case |

### Pilot Theme 5

### Pilot theme 5 | UC-PT5-001

| Name and original objective | Online information and training for informal dementia caregivers (iSupport)

Self-help online training and support program aimed at providing education, skills training and support to informal dementia caregivers. |

| Combination of digital solutions | iSupport digital platform |

| Opportunities to do something with these or slightly modified versions or with some added technological solutions to fight covid-19 |

- Dementia caregivers may experience increased stress due to social isolation and new challenges in care provision.
- We have identified new realities in care provision.
  - For a profile of younger, offspring, employed and mostly well-educated caregivers: Sons/daughters of community-dwelling individuals with dementia, working full time and caring at the end of the day/weekends have mostly seen the suspension of home help/formal care services. Remote working is frequently combined with supporting children in homeschooling and, for the first time, providing full-time support to a mother/father with dementia. Those caregivers lack practical skills to provide care and have limited time available for the learning process.
  - For a profile of sons/daughters coordinating the provision of care to a mother/father with a sibling, the decision of one of the siblings assuming entirely the care provision has been common, as a way to minimize social contact. In this situation, there is an increase of the number of hours providing care, a factor that research has shown...
to be associated with psychological distress (the higher the number of hours providing care, the greater is the likelihood of negative health outcomes).

- For a profile of caregivers caring full-time before the pandemic situation, attending to medical services and other support services in the community was perceived by those caregivers as a way to get out of the house and have some social time. Routine medical appointments have been postponed or provided by telephone, and community services such as support groups or ‘Memory cafés’ have been suspended, increasing the caregivers’ sense of isolation and psychological stress.

Overall, the breakdown of support services for both dementia patients (e.g. day care centres, home support services) and dementia caregivers (e.g. specialized counselling on dementia, psychological support) increases the chance of undesired upshots for both the caregiver and the care receiver.

The iSupport programme is fully provided online and is an already well adapted tool to provide remote alternative or adjunct care to informal dementia caregivers in a situation of social isolation and services restrictions. The use of this tool only requires the caregiver to have a device (computer/tablet/smartphone) with internet connection.

However, iSupport is a very comprehensive training tool and despite the fact that caregivers may decide to use only some contents, it still requires some available time to dedicate to the learning process.

The world health organization is planning iSupport Lite: a complement to the generic version of iSupport providing accessible public health messages aimed at reducing stress and improving mental health of informal dementia caregivers. This consists in an adaptation of iSupport contents to short, practical, support messages of psychological first aid.
If necessary, we can negotiate with WHO the integration of iSupport Lite in this pilot.

Another option is to negotiate the insertion of new contents in the comprehensive version of iSupport (e.g. a new training module), aimed at discussing and providing training on the new challenges emerging from the pandemic situation (e.g. manage the changes in routines of people with dementia; managing new and additional safety risks on wandering). This might require the conduction of a short needs assessment study to map some of the new pandemic-related challenges.

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<tr>
<th>Which additional evaluation steps have to be taken</th>
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<tr>
<td>No additional steps required for the already existing iSupport version.</td>
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<tr>
<td>Evaluation scheme should be adjusted in case iSupport Lite is tested (e.g. in terms of its time frame and outcomes).</td>
</tr>
<tr>
<td>Evaluation scheme can be kept for a possible new module in assessing the overall programme efficacy. New measures of self-reporting might be designed to specifically understand the utility of a new module in addressing COVID-related challenges.</td>
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<tr>
<th>Pilot theme 5</th>
<th>UC-PT5-002</th>
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<tbody>
<tr>
<td>Name and original objective</td>
<td>Digital Assistant for Older People with Mild Cognitive Impairment.</td>
</tr>
<tr>
<td>Provide timely reminders to a variety of situations (e.g. appointments, agenda, activity suggestions); Provides instruction on how-to-do situations (turn on new home device ...); Foster communication with community (neighbours, friends, ...); Foster engagement and</td>
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participation in social & cultural activity in the municipality.

| Combination of digital solutions | • Safe Digital Assistant  
|                                 | • Caregiver administration panel  
|                                 | • Cultural and social agenda provider |

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<th>Opportunities to do something with these or slightly modified versions or with some added technological solutions to fight covid-19</th>
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<tr>
<td>This case is already well-adapted to a situation of diminished social contact. The digital assistant might be used to broadcast public health messages; one possibility to be explored is to build on the reminders to broadcast COVID-19 specific measures (e.g. washing hands, monitoring usual symptoms of the virus).</td>
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<td>Provide timely reminders to a variety of situations (e.g. appointments, agenda, activity suggestions); Provides instruction on how-to-do situations (turn on new home device …); Foster communication with community (neighbours, friends …); Foster engagement and participation in social &amp; cultural activity in the municipality.</td>
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The assessment protocol needs to be adapted in order to minimize social contact when collecting data.

Eventually, new data needs to be collected on the effects of public health messages on behaviour changes.

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Pilot theme 5 | UC-PT-003 |
Name and original objective | Technological resources for monitoring diabetic patients with mild cognitive impairment.  
| Support management of diabetes in patients with mild cognitive impairment; |
Provide timely reminders to a variety of situations, namely for a correct management of therapeutic plans (e.g. medication, food, physical activity);

Provide accessible and convenient information to formal or informal caregivers.

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<tr>
<th>Combination of digital solutions</th>
<th>Gnomon Informatics S.A. platform eHealthPass™</th>
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<tr>
<td>Technological package: Smartphone, smart bracelet, blood glucose plus blood pressure monitoring system, body composition scale and smart medicine box</td>
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**Opportunities to do something with these or slightly modified versions or with some added technological solutions to fight covid-19**

Within Pandemic phenomenon (risk and emergency situations), there are new demanding for chronic diseases (such a diabetes), regarding health and care provision, both formal (hospitals, social support) and informal (families, caregivers), in terms of:

The offer: in those situations, the health and care systems may delay and defer provisions already scheduled (medical appointments, treatments, exams, visits, care), which will have non expected impacts for the individuals.

The demand: in those situations, people with chronic diseases (such a diabetes) may feel fear, stress and distrust in health and care systems, which may decrease aid requests in crises situations.

Moreover, the Pandemic phenomenon could decrease psychological well-being due to increased feelings such as fear, anxiety, frustration, impotence, loss of time, among others. This psychological (new) status could negatively affect the chronic illness of the person’s life.

Facing these predicted situations caused by Pandemic phenomenon (or similar phenomenon), the “UC-PT5-005” will improve the digital health and care remotely intervention, for older people with mild cognitive impairment and diagnosis of type 2 diabetes who lives in community (their homes), as well as their formal and
informal caregivers. There are three positive impacts foresee:

Digital Health and Care Solutions: the UC will provide the tested and personalized digital solutions for people with chronic diseases, which allow patient’s health and care monitoring and evaluating, remotely. This improvement is really suitable in the situations of social isolation and distance, as well as in the situations of rupture and pressure of health and care systems.

Digital Literacy: the UC will provide educational experiences of digital solutions, both for patients and caregivers (formal and informal), which could be useful to expand and evolve this new approach for health and care systems. In the future situations of social isolation and distance, this improvement could “smooth” the use of digital solutions by the patients.

**Public health messages:** monitor patterns of psychological well-being through data reported by devices (essentially, patterns of activity and sleep). Allowing permanent remote monitoring.

On the other hand, sharing of public health material validated by national authorities with generic information on health services and care.

| Which additional evaluation steps have to be taken | Adjustments to the assessment protocol may be required. |
| Any other comments regarding further necessary changes regarding the use case | |

### Pilot Theme 6

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<tr>
<th>Pilot theme 6</th>
<th>UC-PT6-001</th>
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<tbody>
<tr>
<td><strong>Name and original objective</strong></td>
<td>Training of orofacial musculature.</td>
</tr>
<tr>
<td></td>
<td>Orofacial musculature training tool</td>
</tr>
<tr>
<td>Combination of digital solutions</td>
<td>Webcam and VICOM software for facial expression recognition</td>
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<tr>
<td>Opportunities to do something with these or slightly modified versions or with some added technological solutions to fight covid-19</td>
<td>Could we identify mood? If so, how is the lockdown affecting individuals' mood. Maybe risk of depression due to isolation? Early detection could lead to early intervention.</td>
</tr>
<tr>
<td>Which additional evaluation steps have to be taken</td>
<td>Data should be collected and processed for this specific purpose.</td>
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<td>Any other comments regarding further necessary changes regarding the use case</td>
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<tr>
<th>Pilot theme 6</th>
<th>UC-PT6-002</th>
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</table>
| Name and original objective | Gait rehabilitation  
Supervision of exercise routines for gait rehabilitation. |
| Combination of digital solutions |  
- Gait Rehabilitation  
- KOMPAÏ Robot |
<p>| Opportunities to do something with these or slightly modified versions or with some added technological solutions to fight covid-19 | Under lockdown circumstances, the freedom of movements is restricted. Elder people can be easily affected by a long-lasting period of physical inactivity. Moreover, in-home walks can be appropriate for staying in shape but obstacles can cause falls. |
| Which additional evaluation steps have to be taken | No additional steps required. |
| Any other comments regarding further necessary changes regarding the use case | |</p>
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<tr>
<th>Pilot theme 6</th>
<th>UC-PT6-003</th>
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<tbody>
<tr>
<td>Name and original objective</td>
<td>3D Depth Camera Rehabilitation Tool</td>
</tr>
<tr>
<td>Supervision of exercise routines performed in front of a camera for rehabilitation of different conditions (or just to stay active).</td>
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<tr>
<td>Combination of digital solutions</td>
<td>3D Depth Camera and software application for semi-supervised rehabilitation, Data analytics</td>
</tr>
<tr>
<td>Opportunities to do something with these or slightly modified versions or with some added technological solutions to fight covid-19</td>
<td>A supervised routine of exercises, even without a specific rehabilitation purpose, could help individuals maintaining their shape.</td>
</tr>
<tr>
<td>Which additional evaluation steps have to be taken</td>
<td>Even if the system is not yet able to correct postures, exercise routines could be suggested, displayed in a tablet or TV screen.</td>
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<td>Any other comments regarding further necessary changes regarding the use case</td>
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<th>Pilot theme 6</th>
<th>UC-PT6-004</th>
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<tbody>
<tr>
<td>Name and original objective</td>
<td>Wearable Motion Monitoring Device</td>
</tr>
<tr>
<td>Monitor physical activity and identify gait patterns that might change over the time</td>
<td></td>
</tr>
<tr>
<td>Combination of digital solutions</td>
<td>Shoe-embedded Motion Monitoring Device based on IMU technologies and wristband. Data Analytics.</td>
</tr>
<tr>
<td>Opportunities to do something with these or slightly modified versions or with some added technological solutions to fight covid-19</td>
<td>This can help us track how active people is under lockdown circumstances</td>
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This project has received funding from the European Union’s Horizon 2020 research and innovation programme under grant agreement No 857159
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**Pilot theme 7:**

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<th>Pilot theme 7</th>
<th>UC-PT7-002</th>
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| Name and original objective | Foster older people’s (with physical disabilities) independent living by identifying accessible locations and routes in other locations (domestic and abroad)  
Identify travelling destinations and sites that are friendly and accessible to people with disabilities. SHAPES will access the safety and accessibility levels of potential destinations, suggest routes and sites, provide navigation and assistance, thus enhancing the individual’s confidence to make an informed decision in selecting a tourist destination and/or activity. |
| Combination of digital solutions | • ACCESS | Solutions for Active and Healthy Ageing and Independent Living  
• GNO | COVIDshield |
| Opportunities to do something with these or slightly modified versions or with some added technological solutions to fight covid-19 | Identify destinations according to COVID-19 and other epidemiological guidelines and statistics  
A European Vaccination card to record upcoming EU regulation for upcoming travelling guidelines and prove conformance to EU and other countries relevant legislation  
Assess travelling guidelines for contact tracing |
<p>| Which additional evaluation steps have to be taken | TBD |
| Any other comments regarding further necessary changes regarding the use case |                                                                    |</p>
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<tr>
<th><strong>Pilot theme 7</strong></th>
<th><strong>UC-PT7-003</strong></th>
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| **Name and original objective** | Preventing and/or handling a medical emergency while visiting another country

Availability and access to physiological and medical data, for the patient and for the patient’s formal caregiver, when the former travels abroad. Patient and health professional may manage the disease and communicate face to face – as effectively as in a session conducted in the doctor’s office or patient’s home.

Share and exchange medication and patient’s summary between systems, along with the capability to establish a direct communication channel between the emergency physician, the patient’s physician and the patient, for further consultation and guidance |
| **Combination of digital solutions** | • GNO | Solutions for Active and Healthy Ageing and Independent Living  
• GNO | Solutions for Health and Care Service Providers  
• GNO | COVIDshield |
| **Opportunities to do something with these or slightly modified versions or with some added technological solutions to fight covid-19** | Full patient summary with COVID-19 related data to be displayed at an unplanned care, compliant with the EU eHealth Digital Service Infrastructure (eHDSI) openNCP for cross border health care. |
| **Which additional evaluation steps have to be taken** | Data should be collected and processed for this specific purpose. |
| **Any other comments regarding further necessary changes regarding the use case** | |

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