



SHAPES

Smart and Healthy Ageing
through People Engaging in supportive Systems

D8.5– First Periodic Ethical Report

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|---------------------------|--|
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Revision History

Table 1 Revision History

| Revision # | Date | Editor | Comments |
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| 0.2 | 30/09/2020 | Sari Sarlio-Siintola (LAUREA) | Draft for reviewers and task leaders |
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| 1.0 | 30/10/2020 | Sari Sarlio-Siintola (LAUREA) | Final version including updates suggested by reviewers. |

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Table of Acronyms and Abbreviations

Table 3 Acronyms and Abbreviations

| Acronym | Full Term |
|---------|-------------------------|
| DMP | Data Management Plan |
| DPM | Data Protection Manager |
| EAB | Ethics Advisory Board |
| EM | Ethics Manager |
| ET | Ethics Team |

Keywords

ETHICS, PROGRESS REPORT

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Executive Summary

This report states the progress of addressing identified and newly-found ethical research issues during the first year of the project.

Ethical issues in the SHAPES project includes both SHAPES development work (process), as well as defining and implementing ethical requirements as features of the proposed SHAPES solution during that development and implementation work (outcome, solution to be created). SHAPES pilots are multifaceted from the viewpoint of ethics since they concern ethics of development work, validation of the ethical features of SHAPES and the use of SHAPES in real-time settings.

During the reporting period the ethics work has proceeded according to the original plans. No significant new ethical challenges have emerged during the reporting period. The ethics governance model has been taken into use, including ethical self-assessments and ethical requirements checks. The first version of the SHAPES Ethical Framework and ethical requirements have been defined and communicated to the partners. The Data Management plan has been provided and communicated to the partners. The Ethics Advisory Board has started its work and had its first annual meeting during the reporting period.

The design and preparation phase of the pilots has started, and the pilots have been provided with updated guidelines regarding ethical self-assessments. Information has been collected about data sets that will be gathered during the pilots in various phases.

1 Introduction

1.1 Rationale and purpose of the deliverable

1.1.1 Deliverable Objectives

This report states the progress of addressing identified and newly-found ethical issues during the first year of the project (SHAPES 2019).

Ethical aspects in the SHAPES project involve both the SHAPES development work (process), as well as defining and implementing the ethical requirements as features of the proposed SHAPES solution during that development and implementation work (outcome, solution to be created).

SHAPES focuses on the renewal of services providing assisted healthy ageing and fostering both dignity and independence according to the principles of autonomy and beneficence. Thus, the legitimacy of the SHAPES solution is based on ethical and societal grounds, and its outcomes and future impacts must be justified ethically following the principle of justice.

The SHAPES process in turn is ethically laden, due to the fact that the development of the SHAPES solution is based on: 1) research on older people's health and wellbeing, 2) active collaboration with various end-users and stakeholders, and 3) large-scale pilots with end-users in real time settings. In these pilots, we conduct a validation in an environment that expects the development version to be piloted fulfilling the minimum legal requirements.

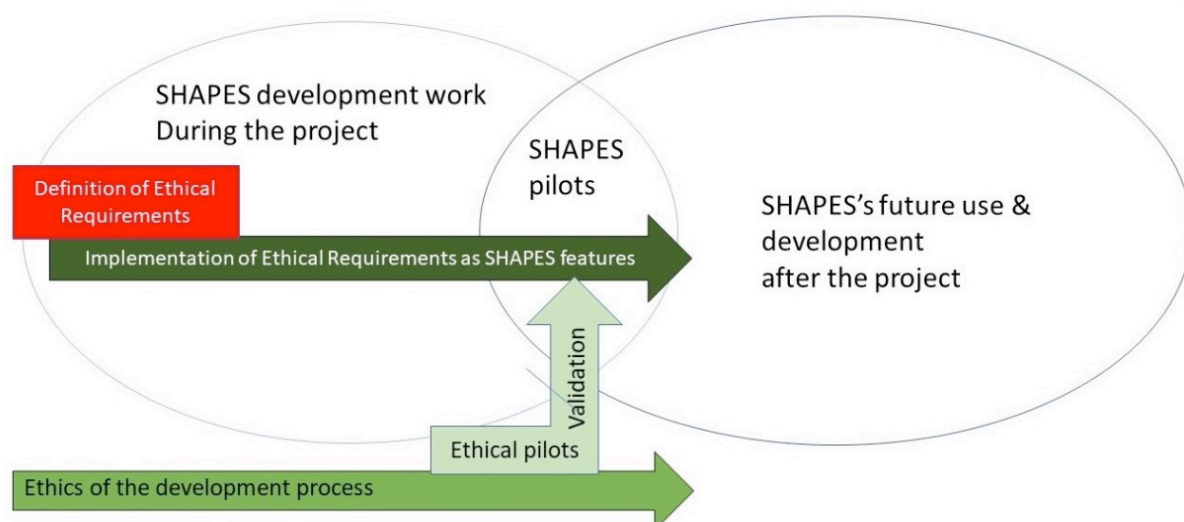


Figure 1: Ethical perspectives in the SHAPES project

1.1.2 Key inputs and outputs

The key inputs of this deliverable come from WP8 deliverables submitted, from ethics assessments and checks provided by partners, and from ethics guidance activities (meetings, emails).

1.2 Structure of the document

The contents of the document are organized by following the SHAPES Ethics Governance Model (see SHAPES 2020a).

- Section 2: SHAPES Ethics Governance model
- Section 3: Deliverables, meetings and workshops
- Section 4: Progress regarding the research integrity
- Section 5: Progress regarding definition & implementation of ethical requirements
- Section 6: Progress regarding the Ethics of SHAPES pilots
- Section 7: Progress regarding Data Management
- Section 8: Summary and conclusions

2 SHAPES Ethics Governance model

2.1 Introduction

(texts taken from D8.2 (section 2.1-2.4) and D8.13 (section 2.5))

The SHAPES Ethical Governance Model (based on systematic guidance, monitoring, and reporting on the implementation of ethical requirements and guidelines), is embedded in the structure of WP8 (see picture below).

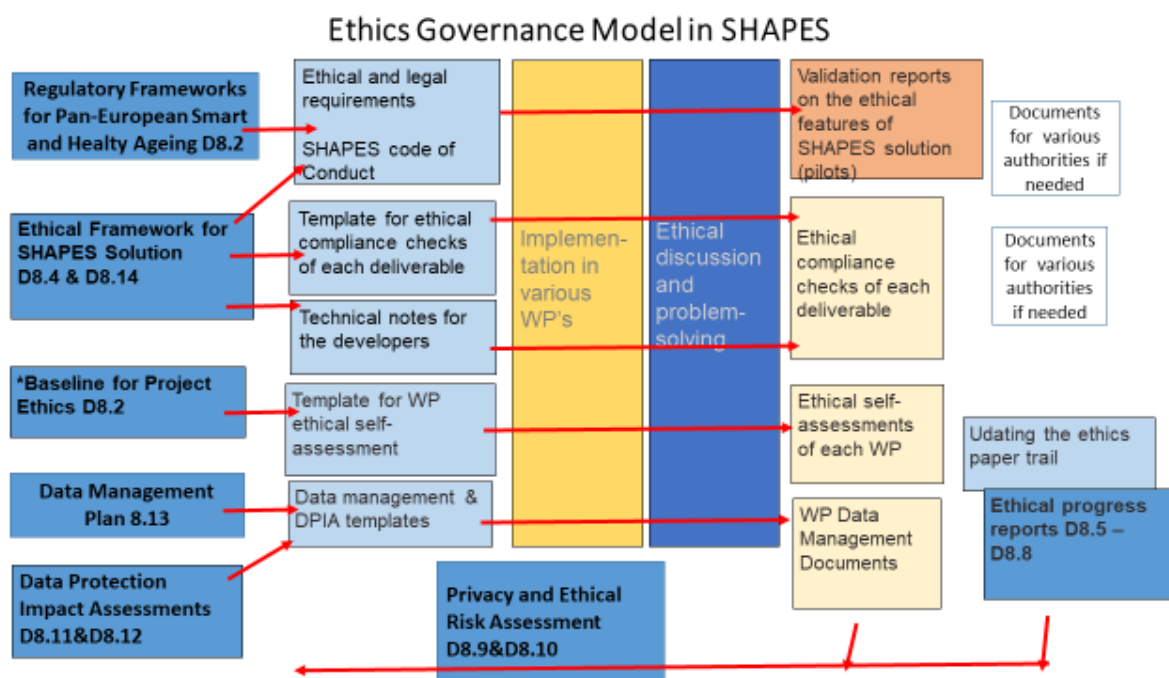


Figure 2: SHAPES Ethics Governance Model

From the viewpoint of ethics management, the key actors are the Ethics Manager (EM), the Data Protection Manager (DPM) and the internal Ethics Team (ET) as part of Task 8.1. The role of the internal Ethics Team is to review deliverables from the ethics point of view, as well as provide ad hoc consultancy on ethical issues that emerge during the SHAPES project. The Ethical Advisory Board (EAB) provides independent input to the Consortium on ethical compliance based on the reports and project meetings. Their comments will be included unabridged in the periodic ethics reports.

All the SHAPES project partners commit to upholding ethical research standards, including the European Code of Conduct for research integrity. They are committed to delivering high-quality scientific outputs and to be transparent, ensuring the

deliverables' reliability and impact. These features of the deliverables are validated as part of the quality management procedures.

2.2 Research integrity procedures

The principles of maximizing benefit and minimizing harm, social responsibility, dignity, fundamental human rights and other issues mentioned in the Horizon 2020 ethical self-assessment are supported during the R&D work by taking into use ethical self-assessment procedures as part of the SHAPES governance structure (appendix1)

This ethical self-assessment is based on the Horizon 2020 template, but it is further modified for the specific purposes of the SHAPES ethics governance. The process is as follows:

1. Each WP leader provides an ethical self-assessment (with necessary documents) of her/his WP and delivers it to the EM and uploads it to Teams.
2. If problems occur, they are to be discussed with the EM and in the EAB.
3. The EM will record the activities in the ethics paper trail and include it in the ethical progress report.

2.3 Definition and implementation of ethical requirements as SHAPES features

The ethical requirements for the SHAPES solution will be defined in the Ethical Framework for the SHAPES solution (D8.4 and D8.14).

To ensure that the ethical requirements are mutually understood, carefully prioritized and successfully implemented, the following activities are needed:

1. First, WP leaders and task leaders will familiarise themselves with the requirements by going through the list of ethical requirements defined in D8.4 and D8.14.
2. It is important to perceive whether we can accept differences (and mitigations) in the implementation of the requirements in the pilot version of the SHAPES solution, compared to the final version.
3. If clarification is needed, the EM and DPM are tasked with providing technical notes on the translation and implementation of the ethical requirements so that they can be taken into account in various tasks and deliverables. This work is carried out by providing the required documents and specifications and/or organising virtual meetings.

4. Task leaders are expected to conduct an ethical requirements check of their deliverables as part of the research work. In case clarification is needed about the requirements or if other ethical viewpoints emerge, the EM and DPM may be requested to provide help in the implementation of the ethical requirements.
5. The ethical requirement checks provided as an addendum to each deliverable are further reported in the ethics records and ethical progress reports by EM.

2.4 The pilots

2.4.1 Research integrity

The process regarding research integrity is based on the ethical self-assessment described above.

1. Each pilot organisation provides ethical self-assessment with attached documents and delivers it to the EM and upload to teams. It is essential to follow local guidelines and regulations regarding various piloting activities with citizens.
2. If problems occur, they are to be discussed with the EM and DPM.
3. The EM will record the activities in the ethics paper trail and submit it as part of the ethical progress report.

2.4.2 The validation/verification/assessment of ethical features of SHAPES

As the ethical requirements for the SHAPES solution (see D8.4 and D8.14) concern the SHAPES technology, its user processes and training, and future business/governance/ecosystem models, their verification/validation/assessment must be multifaceted.

1. Ethical requirements related to SHAPES technology and its use should be validated as part of the general SHAPES validation approach during the pilot phase. 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.
2. Ethical requirements relating to privacy and data protection will be assessed as part of the SHAPES Privacy and Data Protection Impact Assessment (DPIA) (D8.10 and D8.11). Each pilot will carry out a DPIA before the pilots start.
3. The ethical requirements related to the business and governance model may not necessarily be validated as such during the project. On the other hand, by providing an ethics requirements check of each deliverable, it is possible to verify that the various ethical issues have been considered in various deliverables.
4. Feedback on the SHAPES Code of Conduct (see D8.14) will be collected via a questionnaire from the pilot participants. The EM and DPM will provide specific technical notes on the validation/verification of ethical requirements before pilots.

2.4.3 Ensuring ethics compliance of the SHAPES platform to be piloted

The minimum ethical requirements to be met by the pilot version of SHAPES itself concern legislation, namely data protection, IPRs, and local data information sharing regulation, including use of secondary data sources.

Minimum ethical requirements (ethical requirements, see D8.4 and D8.14) concerning the pilots can be defined after the data sources are defined in the Data Management Plan (D8.13) and when the Privacy and Data Protection Impact Assessment (D8.10 and D8.11) are completed. For the sake of clarity, each pilot needs to have its own data lifecycle management plan ready before the pilot starts. It might be that the pilots combine their plans so that there will be only one SHAPES data lifecycle management plan but that will be decided when all pilots have conducted their first versions of the plan. Technical notes will be provided for the work by the DPM.

2.5 Data management

1. Each WP will keep up to date their Data Management Plan originally provided as part of Data Management Plan D8.13.
2. Each pilot will provide input for the SHAPES Data Lifecycle Management Plan.
3. Each pilot will nominate a Data Manager for the pilots.

3 Deliverables, meetings and workshops

3.1 Deliverables

During the first year we have submitted five ethics deliverables and communicated them to partners. In addition, there are four more deliverables under work.

Table 4: Submitted deliverables

| Deliverable | Sub- mitted | Official timetable | Comments |
|---|----------------|-----------------------|---|
| D8.1 Ethics Advisory Board Set-Up | M6 | M4 | Recruitment took more time, as did administrative matters and discussion of fees. In addition, the main author was out of office 3 weeks in February/March because of her covid-19 infection. PO was informed on the situation. |
| D8.2 Baseline for Project Ethics | M6 | M6 | Templates provided are living documents. |
| D8.4 Ethical Framework for SHAPES Solution (first version) | M7 | M7 | In the amendment it was decided that there will be one more version of this deliverable in M18. This is needed in order to discuss and co-design the ethical requirements in collaboration with partner and WP3/T3.5. |
| D8.13 Data Management Plan | M6 | M6 | Data Management Plans of each WP are living documents. |
| D8.5 First Periodical Ethical Report | M12 | M12 | (This deliverable) |

Table 5: Other deliverables under work

| Deliverable | Official timetable | Comments |
|---|-----------------------|--|
| T8.2/D8.3 Regulatory Frameworks Facilitating Pan-European Smart Healthy Ageing | M42 | <p>The deliverable will discuss the EU legal framework, technology, and ecosystem relevant to the SHAPES platform in a critical fashion. The deliverable will analyse the extent to which the current legal framework facilitates the creation of pan-European systems for healthy ageing.</p> <p>Research has been undertaken (adopting a traditional legal methodology) on EU soft and hard law.</p> <p>An overview of the deliverable will be discussed with WP8 partners in October 2020 and with all WP leaders in December 2020.</p> |



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| T8.4/D8.9 First SHAPES Privacy and Ethical Risk Assessment | M24 | The approach and methodology to be used are already defined and discussed with WP8 partners. |
| T8.5/D8.11 First SHAPES Privacy and Data Protection Legislation and DPIA | M24 | The Personal Data Processing Description template has been designed and reviewed by partners. Collection of the data has begun. Please note that ethical requirements related to GDPR were already defined as part of T8.3/D8.4 work. |
| T8.2/D8.14 Ethical Framework for the SHAPES Solution (final version) | M18 | This final version of the SHAPES solution includes an updated Framework and updated ethical requirements, as well as the SHAPES Code of Conduct. The preparation of the deliverable started during the ethical requirements –implementation meetings in 6-9/2020. |

3.2 Ethics Advisory Board meetings

During the first year, the Ethics Advisory Board (EAB) established in D8.1 have had both a kick-off meeting (10th June) and an Annual meeting 2020 (1st September). Liisa Holopainen was elected as the chairperson of the EAB. In the Annual meeting the following topics were discussed:

Table 6: Topics discussed in EAB annual meeting 2020

| Topic | Current activities/plans | New activities needed |
|--|--|---|
| It may be reasonable to increase the number of external EAB members because not all members may be able to participate in each meeting or email discussion. | Comments and feedbacks of other EAB members (who were absent) will be asked on this topic. | |
| Possibilities for persons unable to give consent to participate in SHAPES project and to be users of SHAPES. | In the ethical requirements in D8.4 there is already a requirement for supported decision making (PE2) and consent (ET13). | EM will open discussion on this topic once again with WP6. (to discuss the possibility for those people to participate also in pilots etc.) |
| Incidental findings: we need more information about what the findings will be on the SHAPES | In the ethical requirements in D8.4 there is already a requirement to define the processes regarding incidental | |



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| platform. Partners should also be aware of negative and positive incidental findings. | findings on the SHAPES platform (ME6). Incidental findings on the SHAPES platform will be analysed more in detail as part of the risk management T8.4. | |
| The capabilities approach seems to be an interesting approach alongside fundamental rights. | In the ethical requirements there are several requirements related to capabilities (GE5-GE9, GE11, GE16 ET2, PE1, ME3). As part of the final version of the Ethical Framework for the SHAPES solution there will be an investigation of various digital solutions vs. capabilities and fundamental rights. | WP8 will take the idea into account to collect feedback on the use of SHAPES from the capabilities viewpoint. |
| Family caregivers/informal caregivers are essential end-users and stakeholders of the SHAPES solution. | Family caregivers and their capabilities and rights are also included in D8.4 ethical requirements (GE1-GE2, GE5-GE6). | A discussion of caregivers' rights in the context of free movement will be conducted under Task 8.2. |
| The level of accuracy of ethical requirements in D8.4 varies. | In the first version in D8.4 it was decided to focus on those requirements which are essential from the viewpoint of architecture. Other requirements will be defined more in detail in the final version D8.14. | |
| Find out how end users experience the processing of their own personal data | | A new ethical requirement will be included in the D8.14 "Find out how end users experience the processing of their own personal data" |
| Manage risks from the viewpoint of various SHAPES user groups, including also informal caregivers of SHAPES end-users | In the risk management T8.4 all the end-users/ stakeholders are taken into account. | |
| Facial recognition as part of SHAPES solution faces several ethical challenges. | This will be investigated as part of risk management T8.4. | |



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| | See also GE57: investigate and collect user feedback related to services that may be considered intrusive (e.g., facial recognition), or may risk autonomy, depersonalisation or a threaten the sense of security (e.g., robots), or which may be associated with a surveillance type of service without own control (sensors at home). | |
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3.3 WP8 Meetings and workshops on ethics

WP8 has organized both monthly and specific meetings on ethical requirements. In addition, ethics was one theme on the first dialogue workshop. In the table below the topics and proceedings of those meetings are reported. All the documents are uploaded for the WP8 TEAMS.

Table 7: Meetings and workshops during the reporting period

| Time | Meeting | Topics |
|---------------------------------|---------------------|--|
| 18th December | WP8 Kick off | 1 W8 objectives and links to other WPs / Sari SS 2 Active tasks and their action plans for the M6 -T8.1 Project Ethics and Data Management Plan/ Sari SS -T8.3 Ethical Framework for SHAPES/Sari SS 3 Other tasks and their initial action plans from M7 onwards -T8.2 Assessing the Regulatory Frameworks for Facilitation Pan-European Smart Healthy Ageing/Delia F -T8.4 Privacy and Ethical Risk Assessment for the SHAPES platform/Sari SS -T8.5 Privacy and Data Protection Legislation in SHAPES/Nina AP |
| 30th January | WP8 Monthly meeting | 1 Minutes of the previous meeting 2 Data Management Plan D8.13 3 Baseline for Project Ethics D8.2 4 Ethical Framework for SHAPES D8.4 5 Ethics Advisory Board set-up D8.1 6 Discussion on ethical risks 7 Plan for the coming meetings |
| 24th February | WP8 Monthly meeting | 0. Minutes of the previous meeting (SSS) 1. Ethics Advisory Board D8.1 2. Data Management Plan (NAP) 3. Baseline for Project Ethics D8.2 (KN, SSS) 4. Ethical Framework for SHAPES d8.4 5. Other issues |



| | | |
|---|-----------------------------------|---|
| 3rd March 4th March 5th March 6th March | Data Management meetings | WP2, WP5, WP6, WP7, WP8, WP9, WP10 |
| 6th April | WP8 Monthly meeting | 1 Minutes of the previous zoom meeting 2 Situation with the WP8 deliverables Ethics Advisory Board D8.1 Baseline for Project Ethics D8.2 Ethics Framework for Shapes D8.4 Data Management Plan D8.13 3 Other issues |
| 27th April | WP8 Monthly meeting | 1 Minutes of the previous meeting 2 Deliverables due in M6 – final check before submission Ethics Advisory Board D8.1 Baseline for Project Ethics D8.2 Data Management Plan D8.13 3 Ethical self-assessments and Ethics compliance check procedures 4 Ethics Framework for Shapes D8.4 (M7) -situation & plan for the internal review 5 Ethics workshop in 12th May 6 Other issues |
| 12th May | Dialogue workshop | Fundamental rights, capabilities and ethics of artificial intelligence vs. the SHAPES Integrated Care Platform. Risks and challenges. |
| 28th May | WP8 Monthly meeting | 1 Minutes of the previous WP monthly meeting & snapshot regarding ethics work -D8.1, D8.2 and D8.13 submitted to ECAS -ethical self-assessments of each WP -first EAB meeting in June - D8.4 review situation 3 Ethical requirements and their implementation 4 Data protection descriptions and Data Protection Impact Assessments (DPIAs) 5 Other issues |
| 10th June | First ER – implementation meeting | Privacy and Data Protection, Cyber Security, AI ethics |
| 15th June | Second ER-implementation meeting | Fundamental rights, capabilities, ethics of care, bioethics, rights of persons with disabilities, blueprint for digital transformation |
| 28th August | WP8 Monthly meeting | 1) Minutes of the previous meeting & info slides 2) T8.1 situation (Sari) 3) T8.2 situation (Delia) 4) T8.3 situation (Sari) 5) T8.4 situation (Sari) 6) T8.5 situation (Nina) |



| | | |
|--------------------------------------|---|--|
| 31st August | Third ER– implementation meeting | Digital inclusion, moral division of labour, welfare technology and care work |
| 1st September | Meeting with T3.5 regarding the implementation of Ethical requirements | Periodization of the requirements |
| 7th September | Fourth ER – implementation meeting | Sustainable development and CSR, customer logic and Service design |
| 28th September | WP8 monthly meeting | 1) Minutes of the previous meeting 2) T8.1 situation (Sari) - EAB annual meeting – issues discusses - First Ethical Report 3) T8.2 situation (Delia) 4) T8.3 situation (Nina) 5) T8.4 situation (Sari) 6) T8.5 situation (Nina) |
| 13th October | WP6 meeting | Ethics and pilots -research integrity -validation of ethical requirements -compliance of the platform to be piloted -ethics research during the pilots -data management |
| 15th October | Meeting WP8, WP5, WP5 | Data storage and sharing solutions during the pilots and afterwards. |



4 Research integrity and guidance

4.1 Ethical self-assessments

All the work-packages have carried out their ethical self-assessments. No problems or challenges have been identified. Ethical self-assessments of each pilot site are underway. Assessments are archived in WP8 TEAMS.

Table 8: Ethical self-assessments of each WP

| Time | Work-package/pilot | Comments |
|----------------------|--------------------|--|
| 18 th May | WP10 | |
| 19 th May | WP1, WP6 WP8 | WP6: several issues will be specified more in detail later. Each pilot site will provide its own assessment. |
| 20 th May | WP5 | |
| 22 nd May | WP4 | |
| 25 th May | WP7 | |
| 26 th May | WP2 | |
| 28 th May | WP3, WP9 | |
| 21 st Oct | UCC | |
| 22 nd Oct | UNFR | |
| 23 rd Oct | AUTH | |
| 26 th Oct | DYPE | |
| 27 th Oct | UAVR | |
| 28 th Oct | CH | |
| 29 th Oct | CCS | |

4.2 Guidance on ethics

The inquiries regarding ethical procedures have been focusing predominantly on consent collection, regarding research and marketing activities. In the table below you can find a summary of the inquiries.

Table 9: WP8 Guidance on ethics procedures

| Topic | Time | Comments |
|--|-------------------------------------|---------------------------|
| WP11 support regarding the requirement 2 on recruitment and consents | 4/2020 | |
| WP11 support regarding the requirement 1 | 4/2020 | |
| WP11 support regarding the requirement 3 | 5/2020 and 10/2020 (several emails) | Provided content to D11.3 |



| | | |
|--|------------------------------|---|
| WP6 consents, information sheets and privacy notices | 5/2020 | |
| WP6/pilot 5 consent regarding the legal representatives | 4/2020 | |
| Discussions on the possibility for people unable to give consent to participate in SHAPES pilots and/or be users of SHAPES in the future. | 5-6/2020 (several emails) | In pilot theme 5 (Caring for Older Individuals with Neurodegenerative Diseases) people unable to give consent will not themselves be the end-users of the system. However in the ethical requirements there is a mandatory PE2 requirement on supported decision making and collection of consent. |
| Support and clarifications regarding the ethical self-assessments (WP3, WP7, WP5, WP6) | 5/2020 (several emails) | |
| WP10 consent for websites & contact lists | 4-5/2020 (several emails) | |
| WP, T3.2 consent, info sheet and privacy note for the research | 9/2020 | Additional research support was provided to D11.1 with regard to informed consent. |
| WP2 consent for the research | | Research support was provided to D11.1, assisting with the design of an informed consent guidance document which will be used by all SHAPES partners. |
| Discussions on data management categories and descriptions with several WPs. | 3/2020 | |
| Discussions on the idea to include the SHAPES ethics approach also in an ISO standard for ageing-friendly neighbourhoods. | 5/2020 | |
| WP5 D5.1 SHAPES Digital solutions & ethical requirement check | 10/2020 | How to apply the template? In this deliverable only general comments are OK. In the following versions more detailed information is needed regarding the ethical requirements vs. each digital solution. |
| | | |



5 Progress regarding the definition, implementation and validation of ethical requirements

5.1 Requirements in the D8.4

D8.4 the SHAPES Ethical Framework was provided and based on 102 defined ethical requirements. Some of the requirements are still on a general level and/or define only what is needed to do, whereas those requirements which have an impact on the SHAPES architecture have been defined in more detail (> features of the SHAPES Integrated Care Platform). In the final version of the Ethical Framework for SHAPES Solution D8.14 an updated version of the requirements will be provided, including clarifications and specifications.

Table 10: Ethical requirements in D8.4

| Type of requirement | Amount | Topics | Example |
|--|--------|---|--|
| General requirements | 58 | Rights, capabilities, ethics of care, persons with disabilities AI ethics, digital transformation sustainable development, customer logic privacy and data protection, cyber security digital inclusion, division of labour, caregivers | <i>GE1: Maximise the level of fundamental rights of older persons and of caregivers that SHAPES can promote.</i> |
| Requirements for technology | 23 | Rights, capabilities AI ethics privacy and data protection, cybersecurity | <i>ET6 Data subject rights: right to be forgotten – build capabilities for deleting personal data.</i> |
| Requirements for user processes and support | 7 | Capabilities, persons with disabilities, privacy and data protection, cybersecurity, customer logic, care workers | <i>PE2: Create a detailed process to determine if an older person is able to decide on accessing the services and secondly if she/he is able to give informed consent for the collection of the information.</i> |
| Requirements for business/governance models | 14 | Rights, capabilities, AI ethics, sustainable development, customer logic, privacy and data protection, cybersecurity | <i>ME2: Create a process to conduct an SIA of the SHAPES Integrated Care Platform on a regular basis.</i> |



5.2 New viewpoints emerged and discussed

D8.4, submitted in M7 was the first version of the SHAPES Ethical Framework and ethical requirements for the SHAPES Integrated Care Platform. ´

Since then those requirements have been specified and complemented in the ethical requirements implementation meetings, in the EAB annual meeting, when discussing WP11 deliverables, as well as part of the T8.4 risk management work. In the table below the updates are summarized.

Table 11: New viewpoints regarding ethical framework and requirements

| Topic | Location of discussion | Implications for the Ethical Framework & Ethical Requirements and other ethics work. |
|--|--|--|
| Possibilities of persons unable to give consent to participate in SHAPES project and to be users of SHAPES. | Ethics Advisory Board (EAB) meeting | In the ethical requirements in D8.4 there is already a requirement for the supported decision making (PE2) and for the consent (ET13). EM will open discussion on this topic once again with WP6. (on the possibility to those people to participate also to pilots etc.) |
| In the SHAPES project we could analyse both central human capabilities and EU fundamental rights vs. each digital solution in the SHAPES ecosystem. This could be a process to be performed on a regular basis after the project. | Second Ethical Requirements implementation (ER) meeting. EAB meeting. | Ethical requirements GE5-GE9, GE11, GE16 ET2, PE1, ME3 are now specified. In addition in the text part of the D8.14 Ethical Framework there will be a table mapping rights and capabilities vs. digital solutions. |
| First version of the SHAPES D8.4 Ethical Framework is based on desk-top studies. Best practices from the SHAPES pilots could also be provided. This | Fourth ER-meeting. | Embedding ethics in SHAPES ISO standard work is added as a new ethical requirement in D8.14. Collecting end-users feedback on SHAPES Integrated Care Platform and its ethical features |



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| kind of SHAPES ethics approach could also be included in the T2.3 work regarding ISO standard. | | will be done to some extent during the pilots in phase 5. (e.g. capabilities approach) In addition feedback from SHAPES code of conduct will be collected already during earlier phases of pilots. (see the updated plan for pilots and ethics later in this deliverable) |
| The corporate social responsibility viewpoint vs. SHAPES needs to be clarified. The idea presented in D8.4 is that we could analyse SHAPES and its digital solutions from the viewpoint of UN Sustainable Development Goals. <i>(how the SHAPES ecosystem can support SDGs)</i> . In addition if SHAPES ethical requirements for technology and organizational arrangements are taken into account in the SHAPES platform and digital services, this can also show the responsibility <i>(how we have taken into account ethical viewpoints in our service development)</i> . | Fourth ER- meeting. | The Sustainable development and corporate social responsibility chapter in the Ethical Framework will be clarified in D8.14. D8.14 will also provide an analysis of the SHAPES platform and digital solutions vs. sustainable development goals. CSR will also be discussed in EAB. |
| The viewpoint of digital inclusion and exclusion concern not only older persons as SHAPES end-users, but also other users of SHAPES (e.g. family caregivers, care workers). | Third ER- meeting. | The digital exclusion topic in the Ethical Framework will be extended to other user groups also, including also new emerging ethical requirements. |
| AI is developing rapidly, and new ethical viewpoints may emerge in addition to those identified in the | EAB meeting | This expertise will also be taken into account when recruiting a new member to EAB. New sources of AI ethics will be added to the analysis of Ethical |



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| Guidelines for Trustworthy AI. | | <p>Framework D8.14, including possible updates of ethical requirements.</p> <p>Relevant legal profiles of AI (other than liability profiles) will be discussed in D 8.2.</p> |
| The customer logic approach using the term “customer” may not be suitable in all the SHAPES contexts. | Fourth ER meeting. | Texts in the Ethical Framework will be modified accordingly. |
| There is a need for agile and ethically justifiable co-creation/design tools in SHAPES with its various stakeholders. | Fourth ER meeting. | This can be added as new ethical requirement. Laurea can work on this topic as part of WP2 work. |
| Regulatory Framework which is under construction in T8.2 may also bring new ethical/legal requirements for the SHAPES Integrated Care Platform. | | Researchers will liaise within WP8 to align the legal research to the needs of other WPs |
| It is essential in ethics and in the whole SHAPES project to remember that in addition to older people, there are also other end-users and stakeholders, including family caregivers/informal caregivers | <p>EAB meeting</p> <p>Fourth ER- meeting.</p> | <p>Texts and ethical requirements in the Ethical Framework will be clarified from this viewpoint.</p> <p>Risk management in T8.4 will also to be performed from the viewpoint of various stakeholders.</p> |
| Incidental findings: we need more information on what kind of these findings could be on the SHAPES platform. Partners should also be aware of this kind of negative and positive incidental findings. | EAB meeting | <p>In the ethical requirements in D8.4 there is already a requirement to define the processes regarding incidental findings on the SHAPES platform (ME6).</p> <p>Incidental findings on the SHAPES platform will be analysed more in detail as part of the risk management T8.4.</p> |
| Consider mental exercises on the personal data | EAB meeting | A new ethical requirement will be included in the D8.14 “Find out how end users experience |



| | | |
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| processing from end-users point of view. | | the processing of their own personal data”. |
| Data storage and sharing solutions during the pilots and after the project. Can we use Amazon Web Services? | Meeting 15 th October and email discussion WP4, WP5, WP8 | Sensitive data cannot be stored in AWS/external non-EU cloud service. It is essential to think of the solution from the viewpoint of SHAPES future use: data as a strategic resource in the EU, trust among end-users, data availability in crisis situations. privacy and data protection risks. |

5.3 Ethical requirements –check of each deliverable

The purpose of the Ethical Requirements check template is to ensure that all the deliverables related to the SHAPES Integrated Care Platform and its features, functionalities and operations have taken into account ethical requirements for SHAPES technology and digital services for user processes and for business/governance/ecosystem models. This template was taken into use in M8 after the delivery of D8.4.

In the table below the situation with the ethical requirements check of each SHAPES deliverable submitted during the first year of the project are reported. The deliverables which have been submitted earlier (written in grey) and are relevant from the viewpoint of ethical requirements, will be filled in the template afterwards.

Table 12: Ethical requirements checks of each SHAPES deliverable

| Deliverable | | Ethical requirements check | Separate ethics section in the deliverable |
|---|----|---|---|
| D1.1 Project Handbook | M3 | N/A | Ethical self-assessment and Ethical requirements check templates will be added to the handbook. |
| D1.2 Quality Plan | M4 | N/A | Ethical self-assessment and Ethical requirements check templates will be added to the handbook. |
| D10.1 SHAPES Dissemination and Communication Plan | M4 | Ethical viewpoints of the SHAPES solution will be taken into the account of the deliverable: SHAPES adopts the “ethics by design” and “privacy by design” approaches in order to deliver an ethically, legally and societally sustainable solution. | |



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| D2.1 SHAPES Personas and Use Cases V1 | M6 | Ethical requirements check template will be taken into use in the next version M12 | |
| D8.1 Ethics Advisory Board set-up | M6 | Provided afterwards. See WP8 Teams. | |
| D8.2 Baseline for project ethics | M6 | Provided afterwards. See WP8 Teams. | Deliverable describes the procedures regarding the definition, implementation, and verification of ethical requirements in section 5. |
| D8.13 Data Management Plan | M6 | Provided afterwards. See WP8 Teams. | |
| D11.1 Ethics requirement 1 | M6 | Provided afterwards. See WP8 Teams. | |
| D11.2 Ethics requirement 2 | M6 | Provided afterwards. See WP8 Teams. | |
| 6.1 SHAPES Pan-European Pilot Campaign Plan | M7 | There is a separate section in the deliverable (5.2.2.7) about ethics and pilots. | |
| D8.4 Ethical Framework for SHAPES solution | M7 | This deliverable provided the ethical requirement check template. The whole contents of the deliverable are about the ethical requirements. | |
| D9.4: SHAPES Open Calls for Innovation and Collaboration – Rules of Participation | M7 | Ethical requirements regarding open calls will be communicated in D9.5: SHAPES Open Calls for Innovation and Collaboration – Publication, Evaluation and Selection Process (M24) | |
| D11.1 | M6 | Provided afterwards, see WP8 Teams. | The contents of the deliverable are related to research integrity during the SHAPES project but are also related to ethical requirements of consent collection and to the procedures regarding incidental findings on the SHAPES platform. |
| D11.2 | M6 | Provided afterwards, see WP8 Teams. | The contents of the deliverable are related to research integrity during the SHAPES project but are also related to ethical requirements of consent collection on the SHAPES platform. |



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|---|-----|--|--|
| D3.7 Draft User Requirements for the SHAPES Platform | M8 | Ethical requirements are included in the requirements. | |
| D5.1 SHAPES User Experience Design and Design Guidelines | M9 | Provided. | D5.1 is related to several ethical topics and requirements. |
| D5.2 SHAPES Digital Solutions V.1 | M12 | Provided. | D5.2 is related to several ethical topics and requirements. More detailed analysis will be provided in the next versions of the deliverable. |
| D1.7 SHAPES Action Report V1 | M12 | N/A | |
| D2.6 SHAPES Personas and Use Cases V2 | M12 | Provided. | |
| D3.1 SHAPES Ecological Organisation Models | M12 | Provided. | |
| D3.8 Updated User Requirements for the SHAPES Platform | M12 | Provided. | |
| D8.5 First Periodic Ethical Report | M12 | This report. | |
| D11.3 POPD | M12 | Provided. | The deliverable is related to several ethical requirements regarding privacy and data protection. |



6 Progress regarding the pilots & ethics

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 is divided into three phases. The three phases are carried out in each pilot theme. (SHAPES D6.1, 2020).

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 user feedback at an early stage of the technological development.

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. (SHAPES D6.1, 2020).

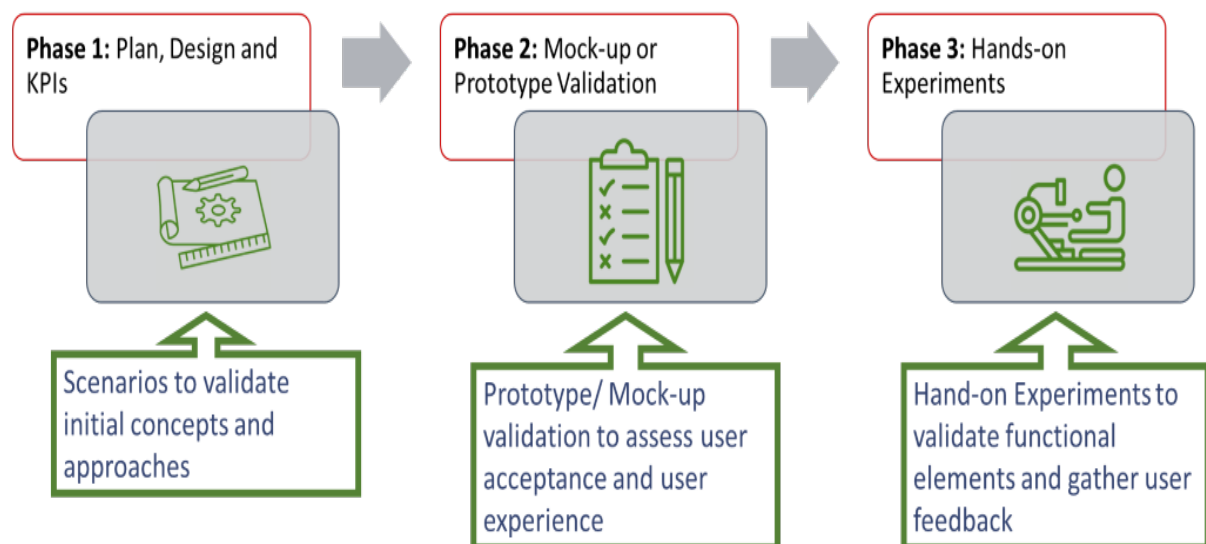


Figure 3 Design and preparation phases in SHAPES pilots (source SHAPES D6.1, 2020)

The second “deployment and execution” part is divided into two phases:

The fourth phase aims 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. (SHAPES D6.1, 2020)

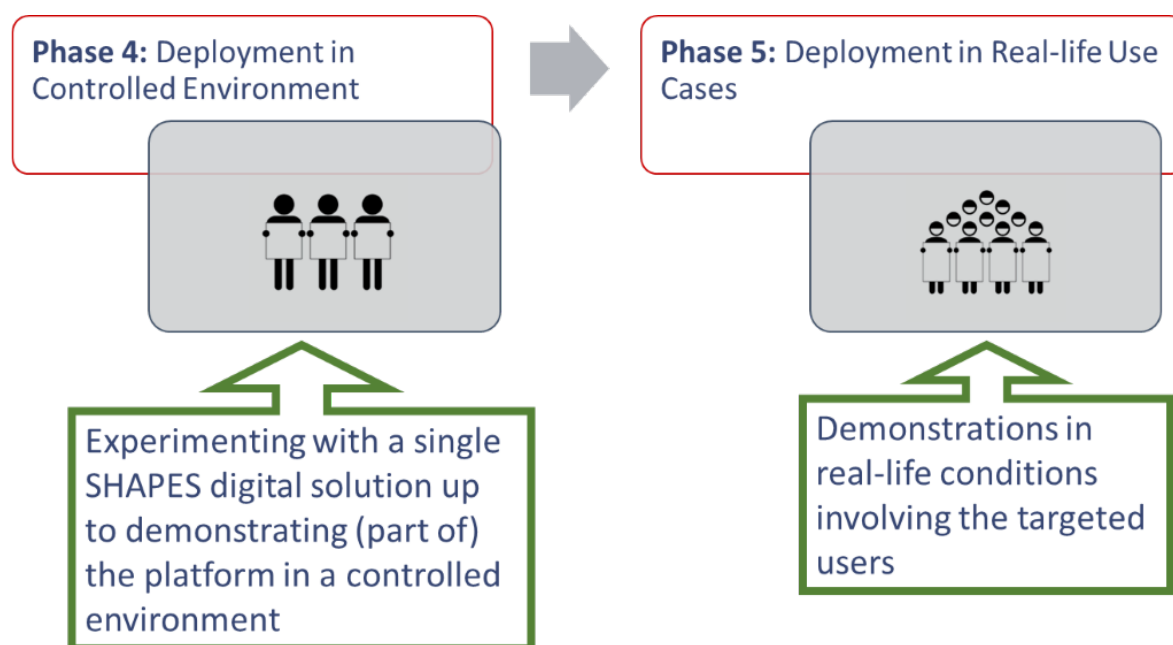


Figure 4 Deployment and Execution phases in SHAPES pilots (source SHAPES D6.1, 2020)

Ethical issues during the pilots are summarized in the table below.

- During the phases 1-3 where no real (personal) data is processed, the main issues are related to the research integrity (e.g. consent collection regarding the research participants). In addition some ethical research regarding SHAPES ethical features and code of conduct can be performed during these phases.
- During phases 4-5 in which the participants use SHAPES in real time settings, the ethics perspective is especially on the legal compliance of the SHAPES platform to be piloted, as well as on the validation of the ethical requirements.



Table 13: Ethics work and procedures during the pilots

| Phase | Research integrity and collaboration with users | Data Management | Compliance of the platform to be piloted | Validation of ethical requirement | Ethics related research |
|----------------|---|--|--|--|---|
| Phase 1 | Human dignity + use of suitable working methods. Consent. Research plan & research permits. | Avoid processing of any personal data. Data sets are to be identified before the pilot begins. | N/A | N/A | Feedback regarding the SHAPES Code of Conduct. |
| Phase 2 | | | | | |
| Phase 3 | | | | | |
| Phase 4 | Human dignity + use of suitable working methods. | Data processing descriptions and data lifecycle management plan (first version) ready before the pilot begins. | Privacy and data protection requirements (See D8.4). | Limited validation. | End-users feedback regarding the solution which might be intrusive. |
| Phase 5 | Consent. Permits regarding both research and processing of personal data. | | Local regulation regarding personal data processing + use of external sources of personal data. Procedures regarding incidental findings. | Full-scale validation, including Privacy and Data Protection Impact assessments. | Research regarding: 1) the capabilities approach vs. SHAPES. 2) care workers experience and opinions regarding SHAPES |



7 Progress regarding Data Management

The pilots have collected information about data sets that will be gathered during the pilots. While the planning is still ongoing, the data sets may be subject to change once the pilots begin. The pilots began the data set identification from personal data, and during the next months they will also add other data that will be collected and used as part of the pilots (see also previous section).

WP8, WP5 and WP6 had a status meeting on 09/2020 and the common understanding was that the data management planning is ongoing and on track. It was agreed that the Data Protection Manager will create a first draft of the data lifecycle management that will be then further developed together with the pilots. This activity starts on 10/2020. In addition WP8, WP4 and WP5 will have a meeting to discuss the cloud platform solution that relates to the big data platform.



8 Summary and conclusions

Ethics work has proceeded according to the original plans. No significant new ethical challenges have emerged during the reporting period. An ethics governance model has been taken into use. The first version of the SHAPES Ethical Framework and ethical requirements have been defined and communicated to the partners. A data management plan has been provided and communicated to the partners. The Ethics Advisory Board has started work.

Ethics is embedded in the work of each SHAPES work-package. During the reporting period this has been the case especially with WP2, WP3 and WP4. During the next period, ethics will be especially visible as part of the WP3, WP4, WP5 and WP6 work.



9 References

SHAPES D8.1 (2020) Ethical Advisory Board Set-Up.

SHAPES D8.2 (2020) Baseline for Project Ethics.

SHAPES D8.4 (2020) Ethical Framework for SHAPES Solution.

SHAPES D8.13 (2020) Data Management Plan.

SHAPES D6.1 (2020). SHAPES Pan-European Pilot Campaign Plan.

Ethical Self-Assessments of each WP

<https://teams.microsoft.com/#/files/WP8?threadId=19%3Abcea934935c74da5bd02c31abcea4e95%40thread.skype&ctx=channel&context=Ethical%2520self-assessments%2520-%2520%2520WP%2520level%2520documents&rootfolder=%252Fsites%252FSHAPEProject%252FShared%2520Documents%252FWP8%252FEthical%2520self-assessments%2520-%2520%2520WP%2520level%2520documents>

Ethical Self-Assessments of each pilot

<https://teams.microsoft.com/#/files/WP8?threadId=19%3Abcea934935c74da5bd02c31abcea4e95%40thread.skype&ctx=channel&context=Pilots%2520-%2520ethical%2520self-assessments&rootfolder=%252Fsites%252FSHAPESProject%252FShared%2520Documents%252FWP8%252FPilots%2520-%2520ethical%2520self-assessments>



Annex 1

ETHICAL REQUIREMENTS -CHECK OF EACH SHAPES DELIVERABLE

The focus of this compliance check is on the ethical requirements defined in D8.4 and which have an impact on the SHAPES solution (technology and related digital services, user processes and support, governance-, business- and ecosystem models). In the left column are the ethical issues identified and discussed in D8.4 (corresponding the D8.4 subsection in parenthesis). For each deliverable, report on how these requirements have been taken into account. If the requirement is not relevant for the deliverable, enter N/A in the right-hand column. Deliverable: D8.5

| Ethical issue (corresponding number of D8.4 subsection in parenthesis) | How we have taken this into account in this deliverable (if relevant) |
|---|---|
| Fundamental rights (3.1) | This deliverable reports the progress regarding the definition and implementation of ethical requirements in section 5. |
| Biomedical ethics and ethics of care (3.2) | |
| CRPD and supported decision-making (3.3) | |
| Capabilities approach (3.4) | |
| Sustainable development and CSR (4.1) | |
| Customer logic approach (4.2) | |
| Artificial intelligence (4.3) | |
| Digital transformation (4.4) | |
| Privacy and data protection (5) | |
| Cyber security and resilience (6) | |
| Digital inclusion (7.1) | |
| The moral division of labour (7.2) | |
| Care givers and welfare technology (7.3) | |
| Movement of caregivers across Europe (7.4) | |

Comments: _____

