



# SHAPES

Smart and Healthy Ageing  
through People Engaging in supportive Systems

## D8.7– Third Periodic Ethical Report

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## Revision History

Table 1. Revision History

Revision #	Date	Editor	Comments
<b>0.1</b>	20/06/2022	Sari Sarlio-Siintola (LAUREA)	Establishing updated ToC
<b>0.2</b>	21/09/2022	Sari Sarlio-Siintola (LAUREA)	Updated Toc and draft for partners comments
<b>0.8</b>	30/09/2022	Sari Sarlio-Siintola (LAUREA)	Version for the language check
<b>0.9</b>	07/10/2022	Sari Sarlio-Siintola (LAUREA), Tarja Laakkonen (LAUREA)	Version for the peer-review
<b>1.0</b>	21/10/2022	Sari Sarlio-Siintola (LAUREA)	Updated version including EAB input and modifications based on the first peer-review feedback.
<b>1.1</b>	27/10/2022	Sari Sarlio-Siintola (LAUREA), Tarja Laakkonen (LAUREA)	Final version for the submission, including also updates based on second reviewer's comments.

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<b>3 Overview of Ethics Governance and WP Collaboration</b>	Sari Sarlio-Siintola (LAUREA)
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<b>6 Summary</b>	Sari Sarlio-Siintola (LAUREA)

## Table of Acronyms and Abbreviations

Table 3. Acronyms and Abbreviations

Acronym	Full Term
<b>AC</b>	Access Control
<b>AI</b>	Artificial Intelligence
<b>BR</b>	Business Requirements
<b>DMP</b>	Data Management Plan
<b>DLM</b>	Data Lifecycle Management (ISO 27050)
<b>DLMP</b>	Data Lifecycle Management Plans
<b>DML</b>	Data Management Plan
<b>DPA</b>	Data Processing Agreement
<b>DPIA</b>	Privacy and Data Protection Impact Assessment
<b>DPM</b>	Data Protection Manager
<b>DPO</b>	Data Protection Officer
<b>DS</b>	Digital Solutions
<b>EAB</b>	Ethics Advisory Board
<b>HER</b>	Electronic Health Record
<b>EM</b>	Ethics Manager
<b>ET</b>	Ethics Team
<b>FAIR</b>	Findable, Accessible, Interoperable, Reusable
<b>FHIR</b>	Fast Healthcare Interoperability Resources
<b>FR</b>	Functional requirements
<b>FRIA</b>	Fundamental Rights Impact Assessment
<b>GDPR</b>	General Data Protection Regulation (EU) 2016/679
<b>FAIR</b>	Findable, Accessible, Interoperable and Reusable
<b>IP</b>	Intellectual Property
<b>ISO</b>	International Organization for Standardization
<b>IoT</b>	Internet of Things
<b>LER</b>	Legal and Ethical Requirements
<b>OC</b>	Open Call
<b>ORD</b>	Open Research Data
<b>PII</b>	Personally Identifiable Information
<b>PRH</b>	Personal Health Record
<b>QA</b>	Quality Assurance
<b>QMP</b>	Quality Management Plan
<b>RDA</b>	Research Data Alliance
<b>SDL</b>	Security Development Lifecycle (ISO 27034)
<b>STR</b>	Security and Technology requirements
<b>T</b>	Task (together with number, e.g., T8.4)
<b>ToC</b>	Table of Content
<b>TP</b>	Technological Platform
<b>TRD</b>	Technical Requirements Document
<b>WP</b>	Work Package

## Keywords

Ethics, Progress Report

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## Executive Summary

This report states the ethics work and progress of addressing identified and new-found ethical issues during the project's third year. This deliverable focuses on the ethics work among all the WPs, not only WP8. WP8 is responsible for Ethics, Privacy and Data Protection Management and Governance during the SHAPES project.

In the previous reporting periods, the ethics work focused on the development of the SHAPES ethical framework and ethical requirements, guidelines and tools for research integrity and ethical self-assessments of various work packages, the implementation of ethical requirements on the SHAPES platform, pilots' Privacy and Data Protection Impact Assessment (DPIA) work, as well as pilots' guidance related to ethics and compliance with regulations.

Now, in the third reporting period, ethics work has focused on pilots' ethical approvals, the finalisation of DPIAs, Data Processing Agreements (DPA), ethics risk workshops and on Artificial Intelligence (AI) ethics analysis, as well as on governance and business models (WP3, WP7) beyond the pilots and after the SHAPES project. The secondary use of personal data and the evolving European Health Data Space (EHDS) regulation and the secondary use of SHAPES personal data, as well as the collection and processing of harmonised data, have been discussed and aligned to be compliant with the General Data Protection Regulation (GDPR) and local regulations among other things during this reporting period. SHAPES Ethical Framework has also been an essential input into the ISO standard work performed under T2.3.

During the reporting period, the ethics work in WP8 has proceeded mostly according to plans both inside WP8 and in other WPs. The earlier notion that SHAPES pilots' real-time settings are complex from an ethical perspective has been reaffirmed.

WP8 monthly meetings were held until autumn 2022, when—thanks to the decreasing ethics workload—it was changed to every two months. The Ethics Advisory Board (EAB) met once during the reporting period.

# 1 Introduction

## 1.1 Deliverable objectives

This report states the progress of addressing identified and newly-found ethical issues during the project's third year.

The objectives of the WP8, on which this deliverable reports, are as follows:

- To ensure ethical innovation and development standards are met throughout the SHAPES Action
- To supervise the SHAPES IA's activities with respect to ethics and fundamental rights considerations
- To identify privacy, ethical, data protection and other legal concerns raised by the SHAPES Platform
- To identify the relevant regulatory frameworks facilitating pan-European smart healthy ageing. (SHAPES Grant Agreement, 2019).

## 1.2 Key inputs and outputs

The key inputs of this deliverable come from the following deliverables and documents:

- WP8 D8.2, D8.14, D8.3, D8.3.1, D8.9 and D8.12
- Other deliverables submitted during the reporting period: D2.4, D3.3, D4.2, D4.4, D4.5, D5.4, D6.4, D10.4, D10.6
- Privacy and Data Protection Impact Assessments (DPIAs) and Data Protection Agreements (DPAs) of pilots
- Ethics risk workshops with pilots
- AI ethics questionnaires for pilots
- Emails and meetings with pilots and other partners on ethics issues (including, e.g., Ethics Approvals, Consents, DPIA and DPA topics)
- WP8 meetings, pilots and ethics meetings
- Ethics Advisory Board (EAB) 2022 meeting

## 1.3 Document structure

The document's contents are organised following the SHAPES Ethics Governance Model (see SHAPES 2020a).

- Section 1: Introduction
- Section 2: SHAPES Ethics in a Nutshell
- Section 3: Governance and Collaboration with and for the other WPs
- Section 4: Progress Overview

- Section 5: Summary of Challenges and Opportunities Encountered
- Section 6: Conclusions



## 2 SHAPES Ethics in a Nutshell

SHAPES focuses on the renewal of services providing assisted healthy ageing and fostering 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.

We in SHAPES want not only to be compliant with regulations but to go beyond compliance. Ethics by design and a proactive approach to ethical challenges and opportunities are at the heart of SHAPES. Therefore, in the SHAPES project, the research component of ethics is essential alongside the ethics compliance component. Ethics in SHAPES is primarily a resource to create more value, not only a risk for non-compliance with regulations. Therefore, the ethics perspective on SHAPES is strongly focused on the future use of SHAPES after the project. Figure 1 illustrates the ethics work related to SHAPES during the project and pilots, as well as beyond the project. This work includes definition and implementation of ethical requirements as SHAPES features, ethics and research integrity of the development process, as well as piloting in real time setting with the validation of requirements.

The SHAPES research and development process is ethically laden since 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 validation in an environment that expects the development version to be piloted, fulfilling the minimum legal requirements.



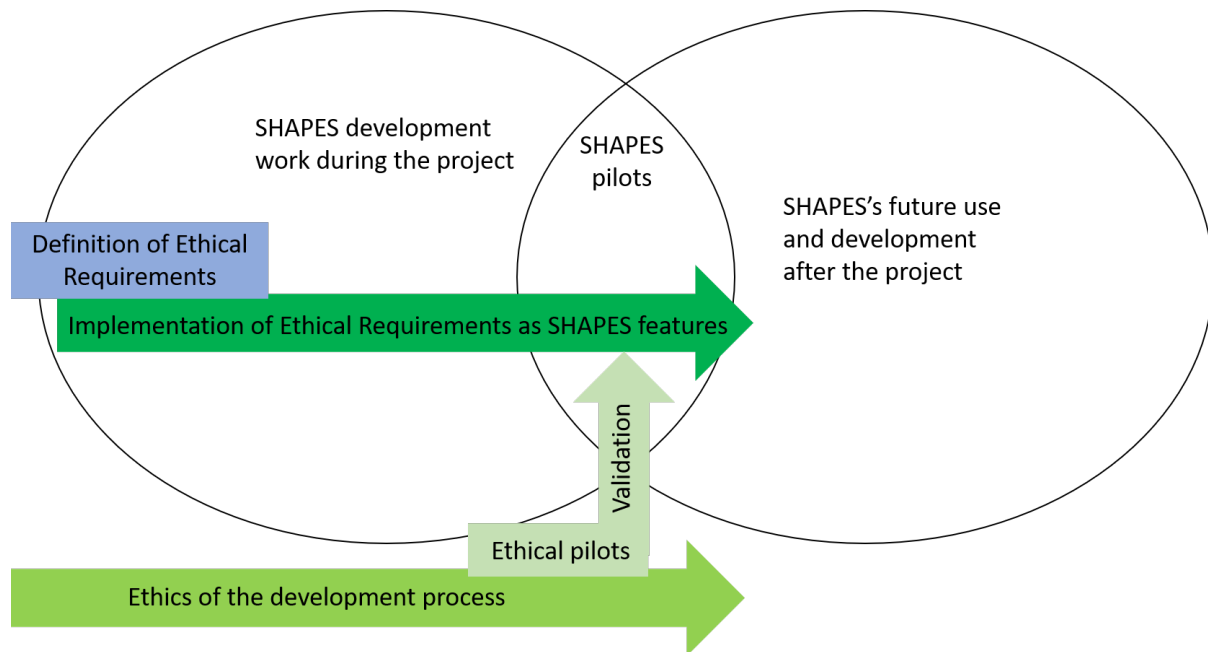


Figure 1. Ethical perspectives in the SHAPES project

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.

All the SHAPES project partners commit to upholding ethical research standards, including the European Code of Conduct for research integrity. They are committed to being transparent and delivering high-quality scientific outputs, ensuring the deliverables' reliability and impact. These features of the deliverables are validated as part of the quality management procedures.

From the viewpoint of ethics management, the key actors are the Ethics Manager (EM), the Data Protection Manager (DPM) and the task leaders of WP8. The Ethical Advisory Board (EAB) provides independent input to the Consortium on Ethical Compliance based on reports and project meetings. Their unabridged comments will be included in the periodic ethics reports.

### 3 Overview of Ethics Governance and Collaboration with and for the other WPs

This chapter provides an overview of WP8 and EAB ethics work, deliverables and meetings during the reporting period. But more importantly, it also clarifies how WP8 ethics deliverables and guidelines have enriched other work packages and SHAPES deliverables.

#### 3.1 Collaboration with and for the other WPs

WP8 co-operation with other work packages has been close during the reporting period. Ethics deliverables, including Ethical Framework D8.14, Regulatory Frameworks D8.3, Privacy and Data Protection Regulation D8.11, Ethics and Privacy Risks D8.9 and Baseline for project ethics D8.2 produced in WP8 have enriched other work packages and deliverables of the SHAPES project, including both T2.3 Cultivating Age-Friendliness, T2.4 Empowerment of Older Individuals in Health and Care decision making, T3.4 SHAPES Governance Model, T3.3 Development of Policy Making Guidelines, D5.3 SHAPES Digital Solutions, T6.2-6.8 Pilots, T7.4 SHAPES Market Place, T7.2 SHAPES Socio-Economic Sustainability, T9.2 Ecosystem Building and T10.3 Dissemination. Figure 2 illustrates these interconnections between WP8 deliverables and work under various tasks in WP2, WP3, WP5, WP6, WP7, WP9 and WP10.

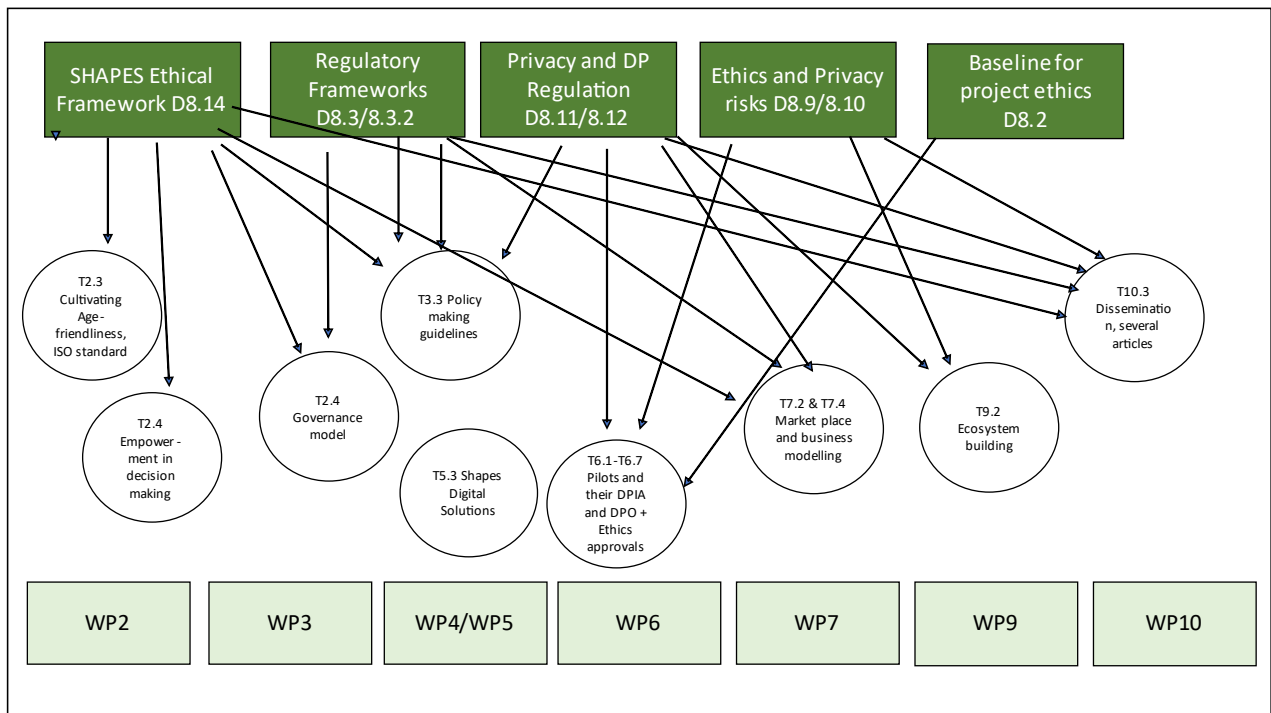


Figure 2. Ethics work with and for various SHAPES work packages



A more detailed summary of the ethics work inside each WP, as well as ethics work and guidance provided by WP8, is provided in Table 4.

Table 4. Summary of ethics activities in the reporting period

WP	Ethics Work in the WP	WP8 Supporting Activities
WP2	<ul style="list-style-type: none"> <li>• Research permits and consents collected for the research</li> <li>• Creating an initial Code of Conduct for multigenerational neighbourhoods as part of the ISO work in T2.3</li> <li>• Embedding ethics viewpoint in ATLAS game development in T3.4</li> <li>• Ethics requirements checks of D2.4</li> </ul>	<ul style="list-style-type: none"> <li>• Support for research integrity issues</li> </ul>
WP3	<ul style="list-style-type: none"> <li>• Research permits and consents collected for the research</li> <li>• Embedding ethics viewpoint to governance models (data governance, ethics governance, enterprise governance, privacy and data protection) in T3.4</li> <li>• Proposal for taking into consideration the following policy recommendations in the T3.3 (1) EHDS shortcoming from wellness data secondary use, (2) Need for harmonised ethics approval procedures</li> <li>• Ethics requirements check of D3.3</li> </ul>	<ul style="list-style-type: none"> <li>• Support for research integrity issues</li> </ul>
WP4	<ul style="list-style-type: none"> <li>• Ethics requirement check of D4.4. and D4.5 (D4.2 Not applicable)</li> </ul>	<ul style="list-style-type: none"> <li>• Discussions and meetings on SHAPES architecture, core and data lake, especially from the viewpoint of privacy, data protection and evolving EHDS</li> </ul>
WP5	<ul style="list-style-type: none"> <li>• Ethics requirements check of D5.4</li> <li>• Taking into account the ethical requirements in various digital solutions and technology</li> </ul>	<ul style="list-style-type: none"> <li>• Discussions on SHAPES digital solutions from the viewpoint of both technology and organisational arrangements</li> </ul>
WP6	<ul style="list-style-type: none"> <li>• Collection of ethics approvals and consents</li> <li>• DPIA each pilot/Use Case</li> <li>• Data Processing Agreements (DPA)</li> <li>• Data Transfer Agreement (third countries)</li> <li>• Ethics requirements check of D6.4</li> </ul>	<ul style="list-style-type: none"> <li>• Intensive collaboration on a regular basis (pilots and ethics meetings)</li> <li>• Separate thematic meetings</li> <li>• DPIA &amp; DPA support and meetings</li> </ul>
WP8	<ul style="list-style-type: none"> <li>• Organising WP8 monthly meetings (13)</li> <li>• Organising Pilots and Ethics meetings (5)</li> <li>• Organising EAB meetings (2)</li> <li>• DPIA and DPO meetings (10)</li> <li>• Participation in WP6 and WP7 monthly meetings (9)</li> <li>• Ethics risk workshops with pilots</li> <li>• AI ethics questionnaires work with pilots</li> <li>• OC1 deliverables' ethics reviews (6)</li> <li>• Contributions to the terms and conditions of the SHAPES marketplace (T7.4)</li> <li>• Cross-check of marketplace vs. organisational ethical requirements</li> <li>• Discussion and Guidance on implementation of those nontechnical ethical requirements not defined in D3.9 and D4.1</li> <li>• Ethics and data protection guidance, including ethics assessments, harmonised data processing, DPIA and DPO issues etc.</li> </ul>	

	<ul style="list-style-type: none"> <li>• Training material for end users on privacy and data protection</li> <li>• Governance model description of piloting phase from GDPR's viewpoint</li> <li>• SHAPES Privacy Policy updates</li> <li>• Analysis of the evolving EHDS regulation</li> <li>• Padlet-based tool for risk assessment and mitigation planning</li> <li>• Analysis of ethics risks and their mitigation plan among pilots</li> <li>• Ethics progress monitoring</li> <li>• Second and Third Ethics Progress Reports (D8.5 and D8.6)</li> <li>• Updated Data Management Plan D8.13, including FAIR and future guidelines regarding research and FAIR</li> <li>• First Privacy and Ethics Risk Assessment D8.9</li> <li>• Contributions to the paper "Applying the Human Rights Model of Disability to Informed Consent: Experiences and Reflections from the SHAPES Project" (this work was reported under WP8 and not WP10)</li> </ul>	
<b>WP9</b>	<ul style="list-style-type: none"> <li>• Networking with actors relevant from the viewpoint of EHDS regulations and its challenges (MEPs, TEHDAS project)</li> </ul>	<ul style="list-style-type: none"> <li>• Ethics reviews of OC1 deliverables</li> </ul>
<b>WP10</b>	<ul style="list-style-type: none"> <li>• Ethics requirements check of D10.4 and D10.6</li> <li>• Several articles in magazines and conferences</li> </ul>	

### 3.2 SHAPES ethics deliverables

During the third year, two ethics deliverables were submitted and shared with partners (see Table 5). In addition, two/three more deliverables (to be submitted later) are in progress.

Table 5. WP8 deliverables submitted and in progress during the reporting period

Deliverable	Sub- mitted	Official Timetable	Comments
<b>Submitted deliverables</b>			
<b>D8.9 First SHAPES Privacy and Ethical Risk Management</b>	M26	M24	This deliverable outlines the Ethics Risk Management Model for the SHAPES solution and provides the first inputs for risk identification and analysis.
<b>D8.7 Third Ethics Report</b>	M36	M36	This deliverable
<b>Other deliverables in progress during this reporting period</b>			
<b>D8.3 Assessing Regulatory Frameworks for Smart and Healthy Ageing</b>	-	M42	The full version of the deliverable and its spin-off D8.3.1 on Regulatory Frameworks for the SHAPES platform are almost ready. They will be updated and revisited in March 2023 with the view of having them prepared for internal review and ready for delivery in M42.
<b>D8.12 Privacy and Data Protection Legislation and Impact Assessment</b>	-	M48	The first contents have already been provided by the departing Data Protection Manager to ensure a smooth work transition to the new DPM.



### 3.3 Personnel changes in WP8

During the reporting period, there have been changes both regarding WP8 task leaders and functional managers (see Table 6). This has caused smaller but manageable delays and rescheduling of work. In addition, it has raised the amount of work to be done under WP8, especially in T8.5.

Table 6. Personnel changes in WP8

Role	Old Resource	New Resource	Challenges and How They Were Solved
<b>SHAPES Data Protection Manager and Task leader 8.5/Privacy and Data Protection Regulation and Impact Assessment</b>	Current SHAPES Data Protection Manager left the project and LAUREA in September 2022.	LAUREA DPO started her work as SHAPES Data Protection Manager in September 2021.	The preparation of the Second Privacy and Data Protection Regulation and Impact Assessment D8.12 started sooner than planned.
<b>T8.2 Key resource in the provision of D8.3 and D8.3.1</b>	The responsible person left the project in July 2022.		The full draft of D8.3 Assessing Regulatory Framework was already prepared in June 2022. Only minor updates are needed in M42.

### 3.4 Ethics Advisory Board meetings and EAB communication

During the second year, the Ethics Advisory Board (EAB) held the 2022 Annual Meeting on 20<sup>th</sup> October 2022. The discussion on SHAPES ethics was rich and versatile, including the earlier risks and challenges encountered, new perspectives of the SHAPES ecosystem risks, as well as EAB recommendations for the last year of the SHAPES project (the challenges identified, see the chapter 5.1).

During the reporting year, there was no need for other contact outside the annual meeting.

### 3.5 WP8, Pilots and Ethics, PMB/Cross alignment meetings discussing ethics

WP8 has organised monthly and specific ethics meetings during the reporting period. In addition, WP8 Ethics Manager and Data Protection Manager have also participated in several meetings of other WPs from an ethics viewpoint. In Table 7, the topics and proceedings of those meetings are reported.

Table 7. Meetings and workshops during the reporting period

Time	Meeting	Topics	Documents
<b>11 November 2021</b>	Pilots and ethics	DPIA and DPA contents and deadlines Data Sharing Agreements Consent and ethics approvals Mandatory ethical requirements Ethics risk workshop pilot TP3	TEAMS WP8/meetings with other WPS
<b>29 November 2021</b>	WP8 monthly	Pilots and ethics meeting 11 November Updated Ethics swimlanes for pilots Ethical requirements not included in D8.9/D4.1 AI ethics guidelines and AI assessments Cybersecurity requirements First ethics risk report D8.9 Risk processes with pilots DPIA situation Harmonised data and data sharing agreements	TEAMS WP8/monthly meetings
<b>16 December 2021</b>	PMB	WP update	TEAMS PMB
<b>22 January 2022</b>	PMB	WP update	TEAMS PMB
<b>31 January 2022</b>	WP8 monthly	Data management updates D8.3 and D8.3.1 drafts D8.10 Second ethics risk assessment plans Data Subject rights document updates Training material for end users regarding P and DP Governance model description for the pilot phase DSA and DPA, DPIA situation Privacy Policy update Discussion/brainstorming on conflicting ethical values	TEAMS WP8/monthly meetings
<b>22 February 2022</b>	PMB	WP update	TEAMS PMB
<b>28 February 2022</b>	WP8 monthly	FAIR principles in Data Management Terms and conditions for the marketplace Plan for AI ethics assessment work Data Subject Rights—document updates Harmonised data DPIA and open call topics Data security document	TEAMS WP8/monthly meetings
<b>22 March 2022</b>	PMB	WP update Deviations in PMs	TEAMS PMB
<b>24 March 2022</b>	Pilots and ethics meeting	Pilots and ethics risk workshops AI questionnaires DPIA situation and discussion	TEAMS WP8/meetings with other WPs
<b>28 March 2022</b>	WP8 monthly	Pilots and ethics meeting 24 March Padlet tool for ethics risk workshops Terms and Conditions first draft Slides on D8.3.1 How to utilise D8.3.1. Data/cyber risks, AI risks Open calls and P and DP DPIA situation, PDA discussion Consents	TEAMS WP8/Monthly meetings
<b>26 April 2022</b>	PMB	WP update	TEAMS PMB

<b>2 May 2022</b>	WP8 monthly	Marketplace cross-check of organisational ethical requirements Ethics risk workshops and AI assessments DPIA situation	TEAMS WP8/Monthly meetings
<b>26 May 2022</b>	PMB	WP update	TEAMS PMB
<b>30 May 2022</b>	WP8 monthly	The workload of pilots regarding ethics risk workshop WP8 situation with PMs consumed OC1 deliverables ethics reviews Preliminary analysis of EHDS Summary of D8.3 Situation with ethics workshops and AI DPIA with PT5, PT6 and PT7	TEAMS WP8/Monthly meetings
<b>27 May 2022</b>	PMB	WP update	TEAMS PMB
<b>27 June 2022</b>	WP8 monthly	TEHDAS forum presentation HIMSS presentation Table of Contents of the D8.7 Topics to be discussed in EAB Articles T8.2 Delays in ethics risk workshops and AI work DPIA EHDS analysis	TEAMS WP8/Monthly meetings
<b>29 August 2022</b>	WP8 monthly	Discussion of what has been challenging in ethics work Third Ethics Progress Report Plenary meeting Thessaloniki Situation in ethics risk workshops and AI questionnaires DPIA situation Next EAB meeting Personnel changes in T8.2 and T8.5	TEAMS WP8/Monthly meetings
<b>14–15 September 2022</b>	Pilots and Ethics meeting (during the Plenary)	Ethics risk workshop and AI ethics analysis situation First results of the analysis	TEAMS PMB
<b>14–15 September 2022</b>	SHAPES plenary meeting	Presentation of WP8 work progress and next steps Participation in several pilots' small group meetings	TEAMS/WP1

## 4 Progress Overview

### 4.1 *Research integrity*

The principles of maximising benefit and minimising harm, social responsibility, dignity, fundamental rights and other aspects mentioned in the Horizon 2020 ethical self-assessment are supported during the research and development work by using ethical self-assessment procedures as part of the SHAPES governance structure. This ethical self-assessment is based on the Horizon 2020 template, but it is further modified for the specific purpose of the SHAPES ethics governance. All the work packages, pilots and open-call solutions have already carried out their ethical self-assessments during the first reporting period. They are archived in TEAMS under the WP8 folder.

The guidance and inquiries regarding ethical procedures have focused predominantly on pilots (see Chapter 6).

### 4.2 *Progress regarding the definition and implementation of ethical requirements*

#### 4.2.1 Ethical requirements and their implementation

In D8.14, we provided the ethical framework for SHAPES. We defined the detailed requirements related to different ethical aspects (general requirements, technology requirements, user processes and governance/business models). D3.9/D4.1 defining user requirements for the SHAPES platform included only technology-related ethical requirements. Other types of ethical requirements were left out. Luckily, among other user requirements, there were already requirements which covered the topics of several mandatory nontechnical ethical requirements (e.g., requirements related to the training material).

An excel spreadsheet has been created which lists all the above ethical requirements and their definitions. Those missing ethical requirements in D3.9/D4.1 have been cross-checked with other user requirements in D3.9/D4.1.

Most of the mandatory ethical requirements not included in D3.9/D4.1 are related to the organisational arrangements for privacy, data protection and data security. Privacy and data protection requirements related to user processes and governance are covered in DPIA documents, data subject rights documents, data processing agreements and data sharing agreements. These documents include information about processes and responsible actors.

Several other mandatory ethical requirements related to user processes and the management model were not assessed as relevant in the pilot phase, but only when SHAPES is in actual use.

During the pilots, the collaboration with end users is very different from when SHAPES will be in the production phase. Requirements related to the business model/marketplace **to be piloted** have been considered in WP7 and cross-checked.

The remaining ethical requirements without integration to the SHAPES overall methodology are listed in Table 8 and how they are settled or confirmed to be in place (see also minutes of the Pilots and Ethics meeting 11/2021 and Pilot swimlanes in TEAMS).

Table 8. Ethical requirements outside D3.9 and their implementation

Ethical Requirements	How/ Where to be taken into account during the SHAPES pilots
<p>GE1 Maximise the level of fundamental rights of older people and caregivers that SHAPES and its digital services can promote. Ensure they do not violate any fundamental rights of older people and other stakeholders.</p> <p>GE3 Be aware of the four biomedical principles and perspectives of care ethics. Apply and promote those within SHAPES.</p> <p>GE5 Maximise the level of human capabilities of older people and caregivers that SHAPES and its digital services can promote. Ensure that SHAPES is not detrimental to any human capabilities of older people and other stakeholders. Pay special attention to vulnerable groups or with disabilities.</p>	<p>Ethics risk workshops with pilots and T8.5 Ethics risk management.</p> <p>Fundamental rights, biomedical principles, bioethics, human capabilities and rights of people with disabilities are frameworks for identifying and mitigating the ethics risks in pilots.</p>
<p><b>GE16 Ensure SHAPES AI solutions:</b></p> <ul style="list-style-type: none"> <li>• Human agency and oversight</li> <li>• Technical robustness and safety</li> <li>• Privacy and data governance</li> <li>• Transparency</li> <li>• Diversity, non-discrimination</li> <li>• Societal and environmental wellbeing</li> <li>• Accountability</li> </ul>	<p>Trustworthy AI questionnaires on pilots' AI solutions and their analysis.</p> <p>(Technical requirements are included in the D3.9/D4.1 and separately asked for from technology providers.)</p>
<p>PE2 Provide a detailed process to determine if the older adult is able to decide on accessing the services and secondly if they are able to give informed consent and re-consent for the collection of information. In that work, also consider local regulations.</p>	<p>This requirement is mandatory because it comes from the United Nations Convention of the Rights of Persons with Disabilities. At the moment, there are no pilots that have integrated people who cannot give consent. We need to keep this in mind and have a process for cases like this. The process doesn't have to be complicated; this requirement is more important in the SHAPES governance model after the project.</p>
<p>ME5 Deploy responsibilities/liability regarding the SHAPES and its various services (for example, if something goes wrong, if the data quality is poor and false positive and false negative situations). This includes processes related to the personal safety solution that requires organisational arrangements.</p>	<p>This process needs to be in place before phase 5 begins.</p>

ME6 Provide processes and guidelines regarding the incidental findings when using or analysing SHAPES data.	The process is already provided in the SHAPES Project Ethics and Data Management D8.2.
ME4 Create a process to ensure that members of the SHAPES Integrated Care Platform (during the open calls and after the project) have the capabilities to comply with mandatory ethical requirements.	During the pilot phase, this is integrated into the ethics screening and potential ethics deliverables to be provided.
G47 Be aware of the importance and challenges with the terminology regarding older people in your own language and the diversity of older people as a group. Use non-stigmatising language.	This has been taken into account also in the SHAPES quality process and the accessibility reviews of deliverables.
PE4 Provide training material on data protection and cybersecurity to end users who need to understand data protection (older people, caregivers and researchers).	Privacy and Data Protection materials are provided in the WP8 for pilots and their end users.
PE4 Update and publish data protection and cybersecurity policies.	Done in the WP8.
GE59 Ensure that legal frameworks related to the SHAPES Integrated Care Platform are taken into account.	A spin-off document D8.3.1 on the regulations relevant to the platform has been provided, including summary documents.  In addition, ethical approvals of pilots for their part ensure that local regulations are followed.
GE56 Ensure that penetration testing undertaken for software solutions is taken into account.	This was discussed with pilots in the pilots and ethics meeting.

#### 4.2.2 Ethical Requirements—checks of each SHAPES deliverable

The SHAPES Ethical Requirements Check template aims to ensure that all the deliverables related to the SHAPES Integrated Care Platform and its features, functionalities and operations have considered the ethical requirements for SHAPES technology and digital services for user processes and business/ governance/ ecosystem models.

Table 9 reports the situation with the ethical requirements checks of each SHAPES deliverable submitted during the project’s third year.

Table 9. SHAPES Ethical Requirements Checks of each SHAPES deliverable

Deliverable		Ethical Req. Check	Separate Ethics Section in the Deliverable
<b>SHAPES Action Report V3</b>	D1.9	OK	
<b>Empowerment of Older People in H&amp;C Decision-Making</b>	D2.4	OK	Ethics have been discussed widely in several chapters of the deliverable, especially Fundamental Rights, Rights of Persons with Disabilities, Capabilities Approach, Artificial intelligence, Digital Transformation, Privacy and Data Protection, Digital Inclusion and Caregivers and Technology.
<b>Scaling-Up Improved Integrated Care Delivery</b>	D3.3	OK	

<b>SHAPES Development Tools and Capabilities Toolkit</b>	D4.2	N/A	Deliverable provides source code and libraries so third-party developers can take advantage of the SHAPES Technological Platform.
<b>Integration Test Plan and Test Cases</b>	D4.4	OK	
<b>Test Case Results</b>	D4.5	OK	
<b>SHAPES Digital Solutions V1.3</b>	D5.4	OK	Ethical requirements related to technology are included in the reporting of each digital solution.
<b>Medicine Control and Optimisation—Pilot Activities Report</b>	D6.4	OK	The deliverable thoroughly describes issues concerning research integrity (ethics approvals, consents, etc.) and the ethical features of the solutions to be piloted (based on the ethical requirements originally defined in D8.4/D8.14).
<b>Third Ethics Progress Report</b>	D8.7	OK	This deliverable
<b>Awareness Campaigns for Citizens Engagement V1 D1.1</b>	D10.4	(N/A)	The deliverable only reports activities performed.
<b>SHAPES Dialogue Workshops V1</b>	D10.6	OK	The deliverable includes a separate section regarding the ethics workshop during the first dialogue workshop.

### 4.2.3 Ethics reviews of Open Call deliverables

The Open Call 1 (OC1) deliverables mentioned in Table 10 were ethics reviewed during the reporting period.

Table 10. Ethics review of Open Call deliverables

Open Call Solution	Deliverable	Review Time
<b>Braincode</b>	Braincode D2—Ethics Compliance and Pilot Study Design	25 May 2022
<b>Liberty</b>	D0.1—Ethics Compliance	23 March 2022
<b>CAPTAIN</b>	D1.1—Architecture and Data Management Plan D1.1	07 March 2022
<b>QUAFAIR</b>	D1.1—Solution Design and Validation	14 March 2022

## 4.3 Progress regarding the pilots and ethics

### 4.3.1 Overview

The earlier notion that SHAPES pilots in their real-time settings are complex from an ethical perspective has been reaffirmed. During the reporting period, the amount of ethics approvals and DPIA and DPO work have required a lot of resources from both pilots and WP8.

### 4.3.2 Research integrity

All the pilots already provided their ethical self-assessments during the previous reporting period. No critical issues were identified.

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





The ethics approvals related to phase 5 in real-time settings have consumed a large amount of pilots' resources and time—including the risk of delays. However, there have been only a few inquiries for WP8 consultancy regarding the ethics approvals.

### 4.3.3 Ethics risk identification and mitigation planning

Pilots have identified ethical risks beyond privacy and data protection in the ethics workshops. A separate online tool (Padlet) has been developed to facilitate the work and recording of results. The risks have been identified in accordance with the SHAPES Ethical Framework from the following perspectives:

- EU Fundamental Rights
- UN Convention on the Rights of Persons with Disabilities
- Human Capabilities
- Bioethics and Ethics of Care

Figure 3 illustrates the work with the help of the online tool. In the figure, there are examples on risks related to the principles of bioethics (Beneficence, Non-Maleficence, Justice) and to caring ethics (Empathy, Autonomy, Uniqueness of the case, Relationships).





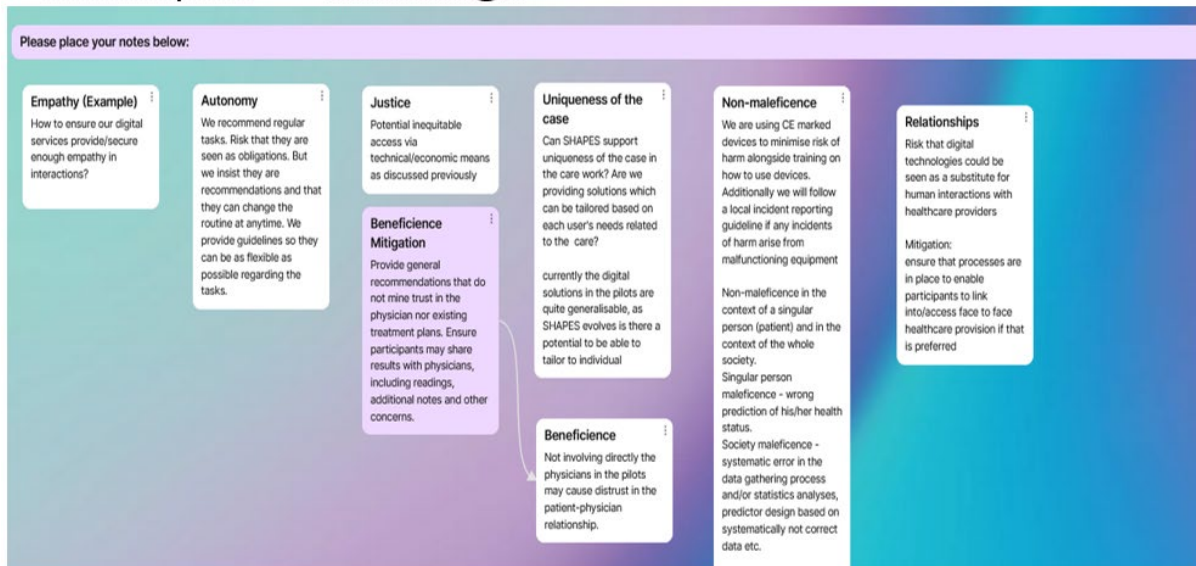


Figure 3. Snapshot of ethics risk workshop outcomes<sup>1</sup>.

Analysis and evaluation of these findings and the mitigation plan process are ongoing.

A questionnaire has been sent to each pilot using AI applications concerning ethical risks related to the use of Artificial Intelligence (AI) (technology providers have already answered these, but most of the AI ethical challenges are related to actual use cases).

The Assessment List for Trustworthy AI (ALTAI). ALTAI was developed by the High-Level Expert Group on Artificial Intelligence set up by the European Commission to help assess whether the AI system being developed, deployed, procured or used

<sup>1</sup> Examples in Figure 3:

**Empathy:** How to ensure our digital services provide/secure enough empathy in interactions?

**Autonomy:** We provide guidelines so they can be as flexible as possible regarding the tasks. We recommend regular tasks risking that they are seen as obligations. But we insist they are recommendations and they can change the routine anytime. **Justice:** Potential inequitable access via technical/economic means, as discussed previously.

**Beneficence Mitigation:** Provide general recommendations that do not undermine trust in the physician or existing treatment plans. Ensure participants may share results with physicians, including readings, additional notes and other concerns.

**Case Uniqueness:** Can SHAPES support case uniqueness in care work? Are we providing solutions that can be tailored based on each user's needs related to care? Currently, the digital solutions in the pilots are pretty generalisable. As SHAPES evolves, is there a potential to be able to tailor it to individuals?

**Beneficence:** Not involving the physicians directly in the pilots may cause distrust in the patient-physician relationship.

**Non-maleficence:** We are using CE-marked devices to minimise the risk of harm alongside training on how to use the devices. Additionally, we will follow a local incident reporting guideline if any incidents of injury arise from malfunctioning equipment.

Non-maleficence in the context of a singular person (patient) and the context of the whole society. Singular person maleficence—wrong prediction of their health status. Society maleficence—systematic error in the data gathering process or statistical analyses, predictor design based on systematically incorrect data etc.

**Relationships:** The risk is that digital technologies could be seen as a substitute for human interactions with healthcare providers.

complies with the seven requirements of Trustworthy AI, as specified in our Ethics Guidelines for Trustworthy AI. This work is in progress.

Figure 4 shows an example of this work performed in Pilot 3. The figure describes the artificial intelligence application used in the pilot from the following perspectives: Human Agency and Oversight, Technical robustness and Safety, Privacy and Data Governance, Transparency, Diversity, Non-Discrimination and Fairness, Societal and Environmental Well-being and Accountability.

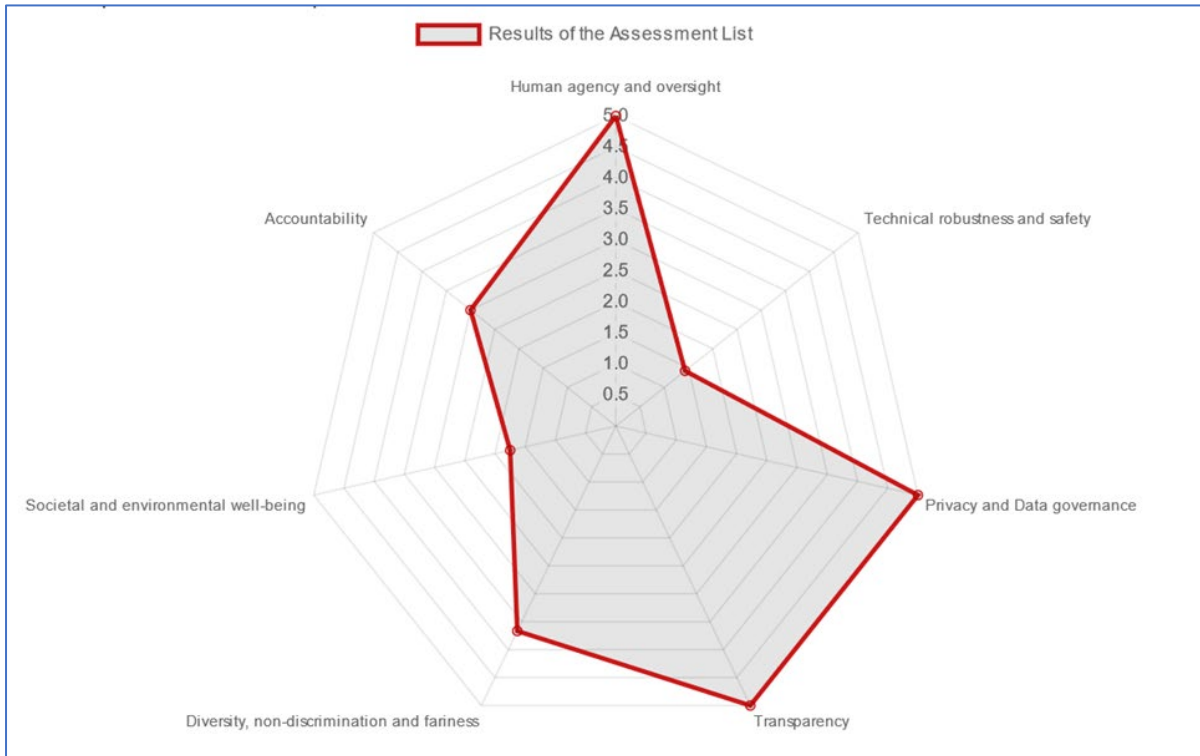


Figure 4. Example of AI ethics assessment using ALTAI

There were obvious challenges concerning timetables and participation in the workshop, but the flexible nature of the online workshop tool has mainly overcome this. So far, five out of seven primary workshops have been held and two more will be held within a month.

The participation of pilots and task members is a challenge and opportunity for analysing identified risks and is crucial for the SHAPES mitigation plan in the near future. LAUREA cooperates with pilots and other partners to have a process as flexible as possible. In Table 11, the current situation of this work per pilot is presented.

Table 11. Situation with pilot ethics workshops and AI questionnaires

Pilot	Ethics Workshops	ALTAI
1	October 2022	
2	Done by pilot	
3	14 June 2022	Done
4	22 July 2022	
5	17 June 2022	
6	4 October 2022	Done
7	8 September 2022	

#### 4.3.4 Privacy and Data Protection Impact Assessments (DPIAs) and their risk assessments

The obligation to conduct a data protection impact assessment (DPIA) is described in Article 35 in GDPR. Generally, a DPIA is required when a type of processing is likely to result in a high risk to the rights and freedoms of natural persons. Still, the European data protection authorities have emphasised that the controllers’ general obligation to implement measures to appropriately manage risks for the rights and freedoms of the data subject remains, even when the criteria for ‘high risk’ would not be met. Therefore, it has been agreed that every SHAPES pilot conducts a DPIA. It is decided within the Use Cases whether there will be a single DPIA that applies to all the pilot sites or whether the pilot lead and the replicating sites will make their own documents.

There are three primary documents used in the DPIAs:

- (1) General DPIA document, where for instance, it is described how the data protection principles (for example, lawfulness, fairness and transparency) are implemented in the pilot in question.
- (2) In the descriptions excel spreadsheet document, the general information of the partners involved, their contact information, personal data categories and their purposes are listed in a simple and accessible form.
- (3) Finally, there is the risk assessment document, where the partners involved must identify the risks, their root causes, and possible consequences, along with their probability and impact. The pilots need to plan and implement the mitigation actions in accordance with the risk severity.

By the time this deliverable text is written, most of the DPIAs and their privacy and data protection, risk identification and mitigation planning will have been finished. Still,



while the most extensive work has been done, the documents are intended to be living documents in the sense that if any changes to the processing operation arise, the documents should be updated accordingly.

Consortium-wide risk workshops were arranged to support the risk assessment work of individual pilots. They were considered useful, as many types of risks similarly affect several Use Cases, and by sharing ideas, the chance that some risks are left unnoticed is minimised. The results of the risk assessments are discussed in more detail in Deliverable 8.9 (First SHAPES Privacy and Ethical Risk Assessment).

#### 4.3.5 Necessary agreements

According to Article 28(3) GDPR, any processing by a processor shall be governed by a contract or other legal act under Union or Member State law, which is binding on the processor with regard to the controller and that sets out the subject matter and processing duration, the nature and purpose of the processing, the type of personal data and data subject categories and the obligations and rights of the controller.

It has been decided to utilise the Commission's standard contractual clauses (Commission Implementing Decision (EU) 2021/915) in the SHAPES project to ensure compliance with the requirements of paragraph 3's subparagraphs (a)–(h). The data processing agreement (DPA) is thereby signed in every controller-processor relationship in the project. It mostly means that pilot sites as controllers sign DPAs with the technical partners acting as processors.

DPA is also used when harmonised data, i.e., used for evaluating the project's impact on end users, is collected. NUIM is the sole processor in this situation, as they will do the actual data analysis. Every pilot site in the project is a controller. They are not seen as joint controllers because they all make decisions for their own data sets, and their decisions on their collected data do not affect other controllers. In other words, if one controller decides to drop out of the project, others would not need to align their operations with it. Also, the pilots are mainly interested in evaluating the data that applies to their own pilots.

A data sharing agreement (DSA) has also been created for situations when different controllers within a single Pilot Theme want to share data for use in their own analyses. It has been planned that data subjects' rights can be provided in these situations, but consent must be requested in a way that covers this possibility as well. The data are not freely shared even after signing a DSA. The controllers must keep track of with which partners they have shared it.

### 4.4 Progress Regarding Data Management

The updated SHAPES Data Management Plan D8.13 in M36 involved practices, architectural techniques and tools for achieving open access and FAIR principles (Findable, Accessible, Interoperable, Reusable—see Table 12) for the delivery of data across the spectrum of data subject areas and data structure types in the SHAPES domain. Based on this, new guidelines are provided on utilising FAIR principles when publishing SHAPES research.

In addition, an introductory video was prepared for research data publication in one open repository, Zenodo. Zenodo is developed under the European OpenAIRE program and operated by CERN. It allows researchers to deposit research papers, data sets, research software, reports, and any other research related digital artefacts. For each submission, a persistent digital object identifier (DOI) is provided.

Table 12. FAIR principles in SHAPES

FAIR Principles in SHAPES		
<b>F</b>	<b>FINDABLE</b>	Data findability: making data and supplementary material as “findable”: improving the discoverability of data with metadata provision and standard identification mechanism, e.g., using of unique identifiers such as Digital Object Identifiers (DOIs) naming conventions, search keyword, and versioning.
<b>A</b>	<b>ACCESSIBLE</b>	Data accessibility: data and metadata are understandable to humans and machines. Used data is deposited in a trusted repository. Open access is ensured free of charge, and online access is created for users. The SHAPES deliverables and documents describes the data accessibility: how data is used and produced in the project and description of ways to made it openly available.
<b>I</b>	<b>INTEROPERABLE</b>	Data interoperability: metadata uses of a formal, accessible, shared, and broadly applicable language for knowledge representation. The SHAPES governance model establishes used data and metadata terminologies, standards, and methodologies to facilitate interoperability and inter-disciplinary. Providing mapping to commonly used ontologies, e.g., representation as an instance in European Health Care Data Space.
<b>R</b>	<b>REUSABLE</b>	Data reusability: data and metadata are well-described to allow data to be reused in future research and innovation action, allowing integration with other compatible data sources, facilitation of citations, references, and data interfaces.



## 4.5 Progress regarding the assessment of Regulatory Frameworks

The final draft of Deliverable D8.3 was completed at the beginning of July 2022.

This deliverable assesses the regulatory framework facilitating “Pan-European Smart and Healthy Ageing”, addressing the right to health of older people and people with disabilities and their free movement rights, as well as the freedom of caregivers and service providers to provide services across internal EU borders within the EU internal market. D8.3. also examines the legislative provisions underpinning the SHAPES Integrated Care Platform, which are discussed in further detail in D8.3.1. Deliverable D8.3. also includes a section on the Marketplace that explores the scope for the cross-border provision of the SHAPES Digital Solutions, taking into account the EU provisions that regulate the internal market and will underpin the SHAPES Platform governance models. The final section offers recommendations regarding the EU legal rubric required to support a large-scale, EU-standardised open platform for providing health and care services.

As part of WP8 and to complement D8.3., deliverable D8.3.1 (mentioned above) focuses on the various legal dimensions (excluding privacy which is addressed in deliverable D8.5) associated with features of the SHAPES platform and the SHAPES digital solutions. It builds on and complements the ethical analysis in D8.4 and D8.14. It focuses on EU legislation deemed relevant by the European Commission regarding AI and digital solutions. It identifies the most recent policy documents in the digital policy field, in particular, albeit not exclusively, the White Paper on Artificial Intelligence.

Given the evolving legal framework and the ongoing creation of the European Health Union, these deliverables will be updated later in year 2023 to incorporate new initiatives, references and up-to-date legislation.



## 5 Main ethical Challenges, Risks (and Opportunities) Emerged

This chapter summarises the main ethics topics and challenges discussed with partners, especially pilots. In addition, it reports separately the challenges discussed in EAB during the reporting period.

### 5.1 Risks and challenges discussed with EAB members during the reporting period

During the SHAPES project, the Ethics Advisory Board altogether has had five meetings, including one meeting during this reporting period.

In Table 13, ethics topics discussed in earlier meetings are in the left column, and the mitigation and status information are provided in the right-hand-side columns.

Table 13. EAB topics and risks identified earlier

Topic	Mitigation & status
<p><b>The viewpoint regarding the lack of social support of older people is essential in the SHAPES context.</b></p>	<p>The need for support services has been identified in several ethical requirements (ethical requirements for user processes PE1-PE7) in D8.14. The SHAPES governance and business model design in WP3 and in WP7 is in progress.</p> <p>In addition, a research paper is underway regarding the need for support services.</p>
<p><b>Ethics of the automatisisation of care, including responsibilities and liabilities, is a challenge recently discussed in academia and is very relevant in the SHAPES context.</b></p>	<p>There is an ethical requirement ME5 related to the liability issues. The SHAPES governance and business model design in WP3 and in WP7 is in progress</p> <p>The topic has also been taken into account in the AI ethics questionnaires as part of the T8.4 work. It is also an issue to be investigated by literature reviews in D8.10.</p> <p>Liability issues related to the piloting phase are taken into account in ethics approvals.</p>
<p><b>The use of terminology is essential. In SHAPES, we can impact how people talk about older people in the future.</b></p>	<p>The topic is discussed in the SHAPES Ethical Framework and there is the ethical requirement GE47 related to the topic (and further to be taken into account in the SHAPES governance/business models. SHAPES Code of Conduct also discuss this topic</p> <p>This is also taken into account in the SHAPES quality management, including the deliverable review templates</p>

<b>How SHAPES Digital Service providers operate and consider ethical requirements and the Code of Conduct?</b>	This is part of business modelling (WP7) and governance (WP3) which is under work.
<b>The use of external service providers as part of the current SHAPES Digital Solutions, such as Google Analytics, Google Translate and AI Ethics.</b>	This is to be included in the updated Code of Conduct.
<b>Business ethics may not be straightforward enough to put into practice holistically (without sub-optimisation).</b>	This is to be included in the updated Code of Conduct.
<b>How do we ensure that businesses and their solutions/data processing are transparent?</b>	This covered in the Privacy and Data Protection Impact Assessment -process and in the process related to the implementation of Trustworthy AI. (see corresponding ethical requirements GE16, GE24, GE31, ET4-5, ET9-10, ET12, ET 14, ET21. In addition, there are ethical requirements related to the training material about the features of the solution (PE3).  In addition, this will be added to the updated Code of Conduct.
<b>During the project, it is essential to investigate where this brand-new technology is needed from the viewpoint of older people.</b>	There will be a questionnaire asking the same kind of questions as part of the T7.2 and WP6.
<b>The tension between ethics and businesses is present in the SHAPES project.</b>	The purpose of SHAPES project is not to promote technology and digital services but to investigate their pros and cons critically, including ethical viewpoints. In the SHAPES project, there might be negative outcomes from the perspective of specific digital services.

In Table 14, there is a summary of the new topics discussed during the EAB annual meeting 2022.

Table 14. Topics discussed in EAB 2022 meeting

Topic	Challenge/Question	Discussion	To do
Ethics approvals	Procedures regarding ethics approvals varies from country to country and it is very time consuming. There is a need to harmonize the process.	In the USA there is a harmonized process.  In the context of EU, the harmonization is challenging since each country has its own practices and regulations.	This will be taken into account in T3.3 policy making guidelines.





	<p>As part of the T3.3 work, SHAPES is providing policy making guidelines - this topic could be added into those guidelines.</p>	<p>In the background of each country there is different politics, opinions and culture. EU does not have formal mandate for the harmonization.</p>	
<p>Time-consuming DPIA and DPO processes</p>	<p>DPIA process in SHAPES is based on the templates created based on GDPR requirements.</p> <p>The process is very time consuming. This was not taken into account in the project plan and resources needed in pilots.</p>	<p>There are common rules and harmonized regulation GDPR behind the DPIA process. However, interpretation of the regulation may vary.</p> <p>It is always challenging to estimate the time needed for ethics and DPIA work in the project proposal phase. And it is not necessarily possible to receive enough resources for this kind of obligatory work.</p>	<p>Such challenge with time-consuming DPIA and data protection work will be taken into account in the T3.3 policy making guidelines.</p>
<p>Secondary use of personal data</p>	<p>What are the possibilities for the secondary use of SHAPES personal data—both the data already collected during the SHAPES project and the data that will be collected in the future?</p> <p>It seems that European Health Data Space regulation may not solve the problems in wellness-type of applications (only EHR applications.)</p>	<p>The practices regarding the secondary use of data are fragmented at local levels.</p> <p>It is a risk if you rely too much on the consent as the legal basis of processing. Data subjects should really understand the processing of their data for secondary use. And the consent should be detailed enough to specify the purpose of the processing of data.</p> <p>One solution is related to “Data Stewardship” and someone’s mediator role (“trustworthy middleman”) regarding the secondary use. In Germany, there are several projects investigating this approach.</p>	<p>Lutz will provide information on the projects dealing with this issue.</p> <p>This will then be taken into account in the data governance modelling, as well as in the final ethics documents.</p>

Data transfers between EU and USA	There is no international agreement on the free movement of personal data between the EU and the US > Pilots have been instructed to seek devices from European manufacturers.	The commission has started its work on this topic in order to provide adequate decisions on the topic.	WP8 will follow up on this and updates to ethical requirements.
Co-creation as a solution to many problems	We should be critical on how we organize co-creation and recruit participants. Not everyone may be interested or capable of using digital services and/or develop them.	Participants co-creating should represent a variety of potential end-users – and not only the lead-users.  In addition, SHAPES should also collect feedback on the experiences of end-users regarding the co-creation.	Sari will contact WP6 in order to ensure that this kind of feedback is collected from end-users.
Ethics of R&D vs. ethics of deployment	Co-creation is related to R&D work. In what ways is it related to the future administration/business model?	In the SHAPES governance and business model the way the system will be developed with and for the end-users is an essential part of the ecosystem. Therefore, co-creation is an important part of the business/governance model. This is also a political topic: are citizens real agents of change or only object of development (and consumers of digital solutions)?	The importance of R&D practices as part of the business/governance model is to be underlined
What is a service in the context of SHAPES and its social-technical system?	Is a digital solution a service itself, or only a tool in the service provision?  Should the question in the SHAPES context be: “How to create services around the digital tools?” (instead of perceiving digital solutions as services as such)	This topic has been discussed in the context of ethical requirements in the D8.14 by emphasizing the need for end-user support services, as well as by discussing the viewpoint of care workers and their changing working practices.	This is a philosophical and strategic topic to be discussed more in detail in SHAPES context – including also terms to be used.
Ethical challenges related to the ecosystem-	Ethical challenges related to single stand-alone solutions are very different from those related to ecosystems. There	Challenges are related not only to big data, but also to distributional ethics.	Ethical challenges related to the ecosystem-type of innovations are to be investigated more in

type of innovations	is a need for new ethics frameworks for them.	<p>-Do people have real freedom of choice to also choose services other than a certain ecosystem?</p> <p>-Are the services designed to be of high quality and attractive for everyone, or only to be implemented cheaply for large masses?</p>	detail in WP8 risk work and WP3 governance modelling.
Technical platform as one outcome of SHAPES	Essential part of the SHAPES ecosystem is the technical platform enabling the SHAPES ecosystem. It is critical that the platform can be dynamic and that new services can be added into it. And that also other ecosystems may adopt the technical platform.	In the SHAPES project there are already Open Call -activities included. New services are evaluated from the viewpoint of SHAPES architecture, ethics etc, and added on the platform.	
SHAPES customers	Who are customers of a) platform b) digital solutions?	From the viewpoint of SHAPES platform, the customers are digital service providers. And customers of digital services are older persons using the solutions. On the other hand, it is essential that in order to ensure seamless services and end-user friendly customer service, it is also important to establish customer service for older persons also on the level of the platform.	
What is the value/utility of SHAPES for older people?	It is essential to find out how SHAPES and its digital solutions support wellbeing, diminish loneliness, etc. It is not sure that all of these solutions work and bring value.	<p>SHAPES pilots collect feedback from end-users with the help of various well-being indicators.</p> <p>It would be good if information could be collected about the benefits also after the project / after the use of the services ends</p>	Sari will discuss this topic with WP6/pilots.
Educational policy and the	We need political will to ensure that the expertise of	This is a key educational policy question and	This will investigated more in detail in T3.3



care professionals know-how on technology	professionals (nurses, doctors, social workers) is and remains up-to-date regarding the digitalization of the welfare sector.	therefore also an issue related to policy making guidelines.	policy making guidelines.
Welfare policy and SHAPES governance & business models	Somebody has to pay for the services, and the political approach may vary regarding the healthcare systems (public services, private services, welfare mix)	Key issue is to ensure the role of public sector are bearer of political responsibility regarding the citizens' wellbeing. (>second generation human rights, EU fundamental Rights, etc.)  See also corresponding ethical requirement in D8.14.	

### 5.2 Challenges (and opportunities) identified during the ethics workshops with pilots and AI questionnaires

Based on the preliminary analysis of the ethics risk workshop outcomes, the risks and challenges related to governance and business models are critical to SHAPES' sustainability. All the pilots raised these challenges. This provides input, especially for the T3.4 Governance model and WP7 Business model and sustainability. See examples of those risks in Table 15 (complementary risk reporting will be performed in D8.10).

Table 15. Examples of ethical risks identified in workshops

Risk (& consequences)	Mitigation
Feeling of being monitored beyond own control	Co-design  Right to disconnect systems when desired. Right to be reported about results
Risk of having the digital solution as a substitution of the regular healthcare system and human interactions with healthcare providers, reduction of human interaction.  Social robot may de-humanize the caregiver-caretaker relationship. In some occasions, there may be the risk that having a robot as the only interaction partner may exacerbate the feeling of loneliness	Ensure that processes are in place to enable participants to link into/access face to face healthcare provision if that is preferred  One possible way to avoid this is to use the robot also as a way for the older person to stay in contact with people  Human-centered design considering interaction with human-beings as an important part of the solution.

Governments often tend to force users (citizens) into a single type of digital solution without any possibility to use alternatives	
Burst of so-called "ehealth" digital solutions that have no solid scientific evidence.	Procedures for authentication and "certification" of digital solutions by public bodies.
Technologies might be intrusive in a way that may harm the participants or a non-adequate familiarity of older persons with the technology might cause accidents.	Design technologies with the aim not to cause pain or suffering, not incapacitate, not cause offense. Co-design and co-creation with and for the older individuals.
The digital solutions employed require a certain level of digital literacy and in some cases the use of personal tablets/smartphones and participant wi-fi.	Can overcome the problem of accessibility if everyone is provided with devices - but this is dependent on funding available - cost-benefit exercise.
Users being unable to understand the DS and critically think about them, thus not being adequately engaged.	User engagement from the early start of the DS; providing hands-on training and user feedback over time to improve functionality, friendliness and usefulness.

### 5.3 Discussion on secondary use of personal data

As it is known, consent is utilised as the legal basis for processing personal data in SHAPES. Although there are other legal bases for conducting research, consent can be seen as most appropriate for the context of SHAPES pilots, as the data is being collected directly from the data subject. However, collecting consent has raised questions about the possibility of requesting a “wide” consent because the data subject would also permit further unspecified processing. In the current legislative situation, this cannot be considered lawful.

For consent to be valid, it needs to be specific as per the requirements set in GDPR. Although Recital 33 states that data subjects should be allowed to give their consent to certain areas of scientific research, the European Data Protection Board’s (EDPB) view is that this does not disapply the obligations concerning the requirement of specific consent. Furthermore, scientific research projects can only include personal data based on consent if they have a well-described purpose. Also, quoting the EDPB, when special categories (such as health data) are processed, applying Recital 33 will be subject to a stricter interpretation, and GDPR cannot be interpreted to allow for a controller to navigate around the key principle of specifying purposes for which consent of the data subject is asked.

It can be argued that merely stating “scientific research purposes” is not specific enough, as the data subject would not know the actual research the data is handed out for.



On May 3<sup>rd</sup>, 2022, the European Commission published the Proposal for a Regulation of the European Parliament and the Council on the European Health Data Space (EHDS). Although much was expected from the proposal, it does not seem to change the situation of the secondary use of data in the SHAPES project. EDPB and European Data Protection Supervisor (EDPS) published a Joint Opinion 03/2022 on the proposal and presented a number of critiques. For example, the EHDS proposal sets its own definition for a “data holder”. It is unclear which type of entity this finally applies to, which differs from the Data Governance Act’s (DGA) definition. DGA applies to legal persons and data subjects who have the right to grant access to or share certain personal or non-personal data under its control. At the same time, in EHDS, it would mean an entity that (among other things) is a part of the health or care sector or performing research concerning these sectors.

The definition is an important matter because the proposal sets many obligations for an entity considered a data holder. For example, Article 33 lists minimum categories of electronic data that data holders must make available for secondary use. If some other entities than just the ones closely related to health or social care are considered data holders, such as some digital solution providers or even wellness applications (also defined in the proposal Article 2(2)(o)), according to the proposal, they should be made compatible with the national systems where the data is stored, and the secondary use would be facilitated through secure processing environments.

On the other hand, if an actor in the social or health care sector utilises a wellness application in their operations, they, as data holders, are obliged to make this data available for secondary use as well. However, this and what was described in the previous paragraph do not seem to be the case: EDPB-EDPS, in their Joint Opinion, ultimately suggested that the secondary use obligations regarding the data collected by wellness applications are removed from the proposal. This was, among other things, because of data quality requirements that did not apply to wellness applications.

The proposal did not present a new definition for anonymisation; hence, the rigorous interpretation of EDPB still stands. Working Party 29’s Opinion 5/2014 (later referred to by EDPB) on anonymisation techniques states that when a data controller does not delete the original data at the event level and the controller hands over part of this dataset, the resulting dataset is still personal data. In a literal sense, it means that even aggregated data could still be understood as personal data, as, according to some writers, some research outcomes should be reproducible.

It is important to add that EDPB-EDPS, in their Joint Opinion, recently stated that ‘the distinction between personal and non-personal data is difficult to apply in practice. From a combination of non-personal data, it is possible to infer or generate personal data, especially when non-personal data are the result of anonymisation of personal data and even more in the context of the processing of health data’. Indeed, it could

be argued that in the “consent or anonymise approach” for further use of personal data, the anonymise route is blocked.

Hence, in a nutshell, anonymising health data, means that the principles of GDPR would not apply anymore.

Due to the problems described above, in the SHAPES project, it has been recommended to ask for new consent from data subjects if a need for further use arises during the project. Creating a technical consent management tool for the SHAPES platform could be a solution. The discussion on these topics will continue.

#### *5.4 Data transfers into 3rd countries*

Some devices used in certain pilots have required the user to transfer the personal data in question to third countries, primarily the United States. There is no international agreement on the free movement of data between the EU and the US, so these devices have been ruled out of the project. Instead, in these situations, the pilots have been instructed to seek devices from European manufacturers. In order to transfer personal data outside of The European Economic Community (EEC), the data subject must be guaranteed the same level of data protection as inside EEC throughout the processing operation. It is well known that in many countries, data controllers are obliged by national law to hand over personal data to authorities when certain conditions are met. These rules mostly contradict GDPR.

#### *5.5 Changes in pilot work and DPIA work*

GDPR sets many requirements to be fulfilled by controllers and processors, which must be considered before the processing starts. For example, data protection agreements (DPA) must be in place before processing personal data to assign the roles and responsibilities of the parties in question. Also, the main aim of DPIA is to identify and assess the possible increased risks to the rights and freedoms of the natural persons that are part of the processing operation.

Still, the plans for the processing operation can change because, for instance, there is a shortage of some crucial tools or resources, as has been the case in some pilots. When changes occur, they need to be noted correctly in data protection documents, which creates a more significant burden for already burdened researchers working in Use Cases. This phenomenon does not primarily affect the obtained consent, except if the whole nature of the processing changes.

#### *5.6 General problems with data protection requirements*

Data protection requirements affect every phase of the processing operation. They could even prevent processing if the identified risks are too high and cannot be



mitigated to an acceptable level. Also, data protection must be considered after the most active phase of processing, guaranteeing that the data will be erased when the purposes of the processing have been fulfilled.

The requirements could easily surprise a data controller planning to process personal data. Fulfilling them requires many resources, and they cannot be at least wholly outsourced either. The controller must play an active role in filling in the documents and planning how the data is processed lawfully. In every project, the limited time and resources pose a challenge in planning the larger-scale instructions. DPIAs, DPAs, secondary use and data transfers (to name a few) must be thought through in the early phase, as they take considerable effort from those responsible. By planning the tasks early enough, revisiting them and duplicating work, data protection infringements can be avoided.

### *5.7 Ethics approvals and the need for harmonisation*

Obtaining ethical approvals from local ethics committees for pilot phase 5 has been a time-consuming process with many clarifications and documentation. This has been a common challenge with almost all pilots. In addition, obtaining the approvals related to the study, e.g., the life of older people, has been a time-consuming process.

Ethical approval processes vary in different countries. For example, processing biometric data (e.g., heart rate) in SHAPES applications or collecting health-related data for research analysis of older people can be perceived as medical research in many countries, which in turn means very demanding preparation of ethical papers to obtain permission.

From the point of view of SHAPES as an innovation activity—not just a research project—in many countries, these processes are heavy and unnecessary in all respects.

It is clear that it would be justified to harmonise research license practices—including consent required from users. At the same time, the different nature of innovation projects in the welfare sector should be taken into account vs traditional medical research.

Research permit practices that are harmonised and adapted to innovation activities would facilitate the smooth implementation of large innovation projects in several countries and focus on ethically essential—and only essential—matters.

- If possible, this idea of harmonisation will be discussed in more detail in the T3.3 policy guidelines.



## 6 Summary and Conclusions

During the reporting period, ethical work proceeded mainly according to plans in WP8 and other WPs.

This third ethics progress reporting period was very active, especially with WP6. The ethics work has had a strong impact on the timetables and workload of each pilot. Both Ethics approvals, Privacy and Data Protection Impact Assessments (DPIAs), Data Processing Agreements (DPA), Pilots and ethics workshops and AI ethics assessments have been conducted with pilots during this reporting period.

At the end of this reporting period, ethics work will significantly decrease both within WP8 and WP6, as well as among technology development in WP4 and WP5. The main focus of the ethics work during the last year of the SHAPES project is related to SHAPES Governance and Business modelling in WP3 and WP7, as well as on monitoring and managing ethical risks and following the evolving EHDS regulation.

Table 6, including partners’ authentic comments during WP8 August meetings on ethics work, nicely summarises what the work has been like so far.

*Table 16. Real comments from WP8 partners on ethics work in SHAPES*

<b>Comments from WP8 partners regarding the ethics work in SHAPES</b>
“From my point of view, mapping the possibilities of secondary use of personal data has been and will be a big challenge”
“The consortium has taken ethics work seriously and its importance from the viewpoint of both the SHAPES R&D process and the pilots in final SHAPES solutions”
“Development of DPA and DPIA was a bit challenging based on the content needed to be added, also the discussion conducted with regard to who will have access to data collected was challenging. A lot of questions and misconceptions have emerged with regard to the data controllers and those providing digital solutions”
“During the ethics workshops for the UCs, the topic of accessibility for people with disabilities has been discussed and considered a relevant topic, which hasn't been addressed that much before”
“The ethics aspect was quite important for SHAPES project, as it is a large-scale pilot project. A challenging part was to develop all necessary ethics documents.”
“It could be very interesting to have a slot for all the pilots to join and share their findings for the purpose of mitigation”



## References

SHAPES Grand Agreement (2019).

### **Deliverables**

SHAPES D2.4. (2022). Empowerment of Older Individuals in Health and Care Decision-making

SHAPES D3.3. (2022). Scaling-up Improved Integrated Care Service Delivery

SHAPES D4.2. (2022). SHAPES TP Development Tools and Capabilities Toolkit

SHAPES D4.4. (2021). Integration Testing Results (preliminary)

SHAPES D4.5. (2022). Integration Testing Results (final version)

SHAPES D5.4. (2021). SHAPES Digital Solutions

SHAPES D6.4. (2022). Medicine Control and Optimisation Pilot Activities Report

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

SHAPES D8.3 and D8.3.1 (versions 7/2022). Regulatory Frameworks Facilitating Pan European Smart Healthy Ageing + spin-off documents (not yet submitted)

SHAPES D8.9. (2021). First SHAPES Privacy and Ethical Risk Management Assessment

SHAPES D8.11 (2021). First SHAPES Privacy and Data Protection Legislation and Impact Assessment

SHAPES D8.12 (2020). Data Management Plan

SHAPES D8.14. (2021). Ethical Framework for SHAPES Solution

SHAPES D10.4. (2021). Awareness Campaigns for Citizens Engagement V1

SHAPES D10.6. (2021). SHAPES Dialogue Workshops – V1 – V1.0

### **Minutes (uploaded in WP8 teams)**

Minutes of WP8 meetings 11/21, 01/22, 02/22, 03/22, 04/22, 05/22, 06/22 and 08/22

Minutes of pilots and ethics meetings 11/21 and 03/22

## Minutes of Ethics Advisory Board (EAB) 2022 meeting on 20<sup>th</sup> October 2022

### **Other references**

Privacy and Data Protection Impact Assessments (DPIAs) and Data Protection Agreements (DPAs) of pilots

Ethics risk workshops with pilots

AI ethics questionnaires for pilots

Emails and meetings with pilots and other partners on ethics issues (including, e.g., Ethics Approvals, Consents, DPIA and DPA topics)



## Annex 1: Ethical Requirements check

### 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 D8.14 subsection in parenthesis)	How we have taken this into account in this deliverable (if relevant)
Fundamental rights (3.1)	<p><b>This deliverable reports the progress regarding the definition and implementation of ethical requirements in section 5.</b></p>
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: \_\_\_\_\_

