



# SHAPES

Smart and Healthy Ageing  
through People Engaging in supportive Systems

## D8.6– Second Periodic Ethical Reports

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0.2	01/08/2021	Sari Sarlio-Siintola (LAUREA)	First contents to be communicated to WP8 partners
0.3	01/10/2021	Sari Sarlio-Siintola (LAUREA)	Draft for peer-reviewers' information
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1.1	29/10/2021	Sari Sarlio-Siintola (LAUREA)	Version for submission

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## Table of Acronyms and Abbreviations

Table 3 Acronyms and Abbreviations

Acronym	Full Term
AC	Access Control
AI	Artificial Intelligence
BR	Business Requirements
DMP	Data Management Plan
DLM	Data Lifecycle Management (ISO 27050)
DLMP	Data Lifecycle Management Plans
DML	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 ( <a href="#">hyperlink</a> )
<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>ToC</b>	Table of Contents
<b>TP</b>	Technological Platform
<b>TRD</b>	Technical Requirements Document

## Keywords

ETHICS, PROGRESS REPORT

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## Executive Summary

This report states the ethics work and progress of addressing identified and new-found research ethical issues during the second year of the project.

Ethical issues in the SHAPES project during the reporting period have concerned both SHAPES development work (process), as well as the definition and implementation of ethical requirements as features of the proposed SHAPES solution during that development and implementation work (outcome, solution to be created).

In the previous reporting period, the ethics work focused on the development of ethical frameworks and guidelines in WP8, as well as ethical self-assessments of various work packages. Now, in the second reporting period, work on ethics has covered a wide range of work packages and their development activities. The earlier notion that SHAPES pilots in their real-time settings are complex from an ethical perspective has been strengthened.

During the reporting period, the ethics work in WP8 have proceeded mostly according to original plans, including the preparation of the Final SHAPES Ethical Framework (D8.14) and the SHAPES Privacy and Data Protection Legislation (D8.11). The preparation of the first SHAPES Privacy and Ethics Risk Management deliverable (D8.9) is still in progress, the original deadline D24 was postponed with two months due to DPIA and privacy risk timetables of pilots. Data Management plan (D8.13) has been updated based on EU review feedback.

Consultancy and guidance work on Privacy, Data Protection and Privacy and Data Protection Impact Assessments (DPIAs) have consumed more resources and time than expected. The secondary use of personal data, the SHAPES data model and the anonymisation and pseudonymisation on the SHAPES Platform, the collection and processing of harmonised data, and the use of external (non-EU) services have been discussed and aligned to be compliant with the General Data Protection Regulation (GDPR) and local regulations among other things.

Implementation of ethical requirements as SHAPES features has proceeded with WP3, WP4 and WP5 according to SHAPES methodology. SHAPES architecture in WP4 has frequently been discussed from the GDPR point of view. Collaboration has been intensive with the WP6 pilots, including provision of Ethics swim lanes and support for DPIAs. An ethics evaluation of the SHAPES first Open Call (OC) as part of WP9 has been performed.

The Ethics Advisory Board (EAB) has had two meetings 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 second year of the project (SHAPES 2019).

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 produce the ethical requirements and design ethical input for the SHAPES Platform and its solutions;
- 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 GA, 2019).

## 1.2 Key inputs and outputs

The key inputs of this deliverable come from WP8 and other deliverables submitted, from ethics assessments and checks provided by partners, from WP8, EAB and pilots and ethics meetings, and from ethics guidance activities (meetings, emails). Key outputs concern several SHAPES WPs (especially WP2, WP3, WP4, WP5, WP6, WP7) and their deliverables.

## 1.3 Structure of the document

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

- Section 1: Introduction
- Section 2: SHAPES Ethics in a nutshell
- Section 3: Overview of progress
- 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 of challenges and opportunities encountered
- Section 9: Conclusions

## 2 SHAPES Ethics in a nutshell

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.

We in SHAPES want not only to be compliant with regulations and rules, 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. The ethics perspective in SHAPES is, therefore, strongly focused on the future use of SHAPES after the project (see Figure 1).

The SHAPES research and development process 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 well-being, 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.

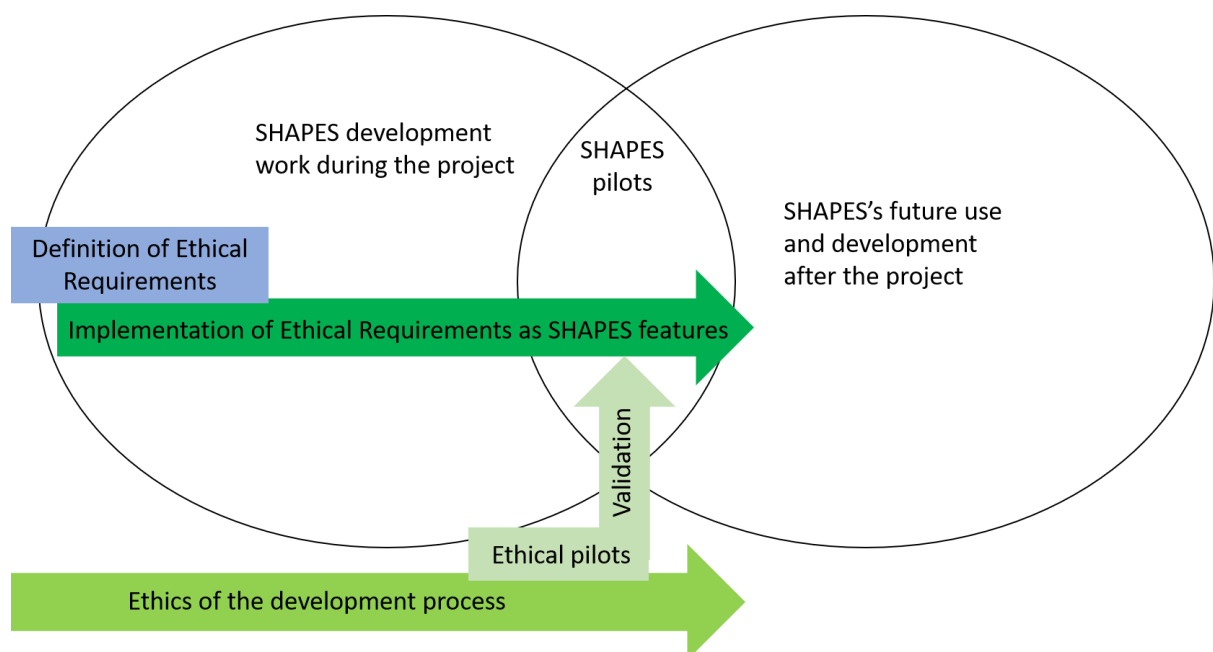


Figure 1 Ethical perspectives in the SHAPES project



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 Figure 2).

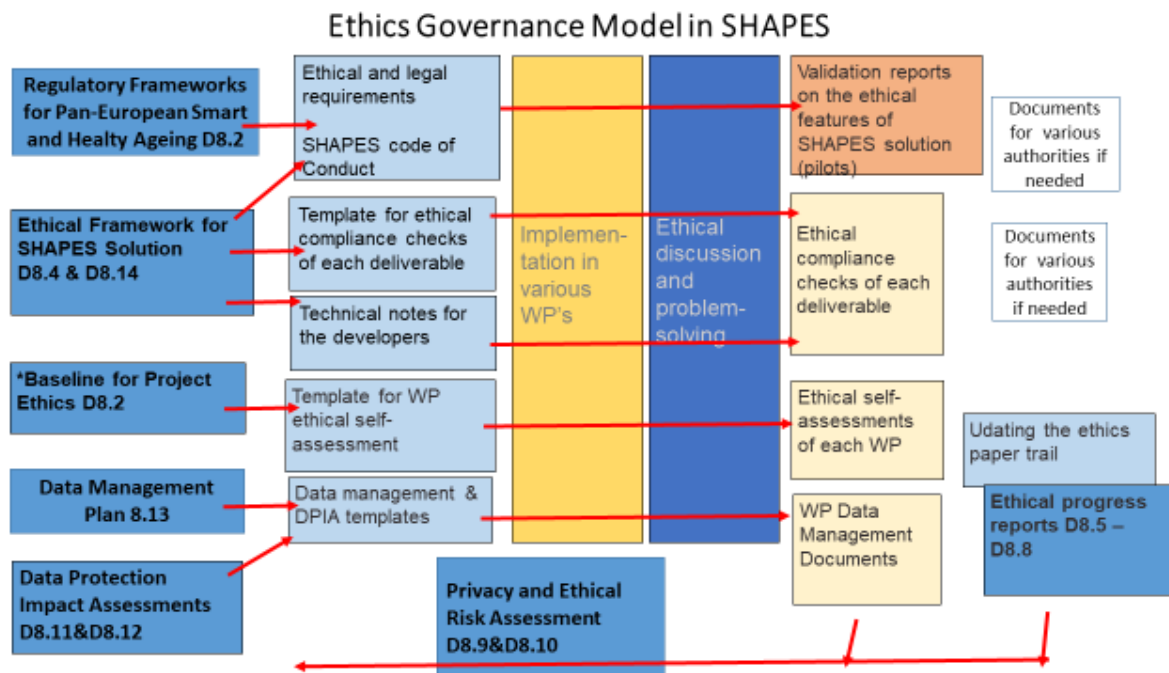


Figure 2 SHAPES Ethics Governance Model

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.

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.



### 3 Overview of progress

This chapter provides an overview of WP8 and EAB ethics work, deliverables and meetings during the reporting period. It also clarifies how WP8 ethics deliverables and guidelines have enriched other work packages and deliverables of SHAPES, including the SHAPES Open Calls evaluation.

#### *3.1 Focus areas of the ethics work during the reporting period*

During the reporting period the ethics work has proceeded mostly according to the original plans in WP8, including the preparation of the Final SHAPES Ethical Framework (D8.14) and the SHAPES Privacy and Data Protection Legislation (D8.11). The preparation of the first SHAPES Privacy and Ethics Risk Management deliverable (D8.9) is in progress, the original deadline D24 was postponed with 2 months due to privacy risk timetables of pilots. The SHAPES Data Management Plan (D8.13) is also updated based on EU review feedback.

The ethics work with other SHAPES WPs has been especially intensive with pilots (WP6) and technology partners (WP4, WP5). Privacy and Data Protection Impact Assessment (DPIA) started in pilots in early summer and is almost finalised by M24. Implementation of ethical requirements as SHAPES features has proceeded with WP3, WP4 and WP5 according to the SHAPES methodology.

The SHAPES Ethical Framework (D8.14) has not only provided input to the design and implementation of the SHAPES Platform, but it has also nurtured the provision of Personas in WP2 and SHAPES governance modelling in WP3. During the reporting period, SHAPES WP9 also launched the first Open Call and ethics screening and evaluation of eight proposals were performed. The Ethics Advisory Board has had two meetings during the reporting period.

The Figure 3 illustrates how the ethics perspective and ethics deliverables produced in WP8 enrich other work packages and deliverables of the SHAPES project.



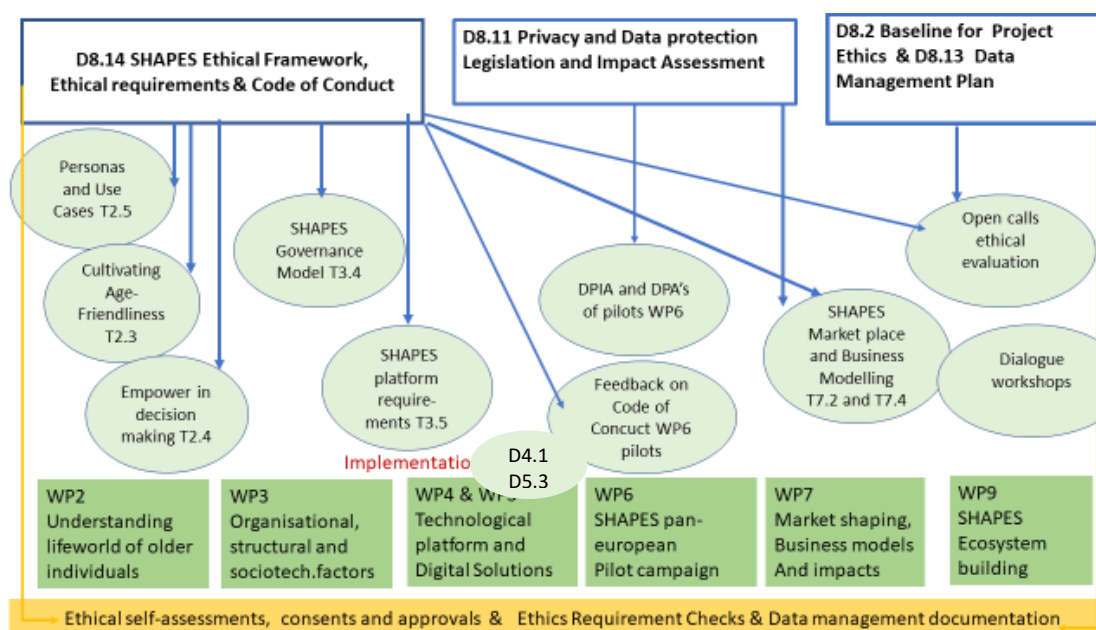


Figure 3 Ethics work in various SHAPES work packages

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

Table 4 Summary of ethics activities in the reporting period

WP	Ethics work in the WP	WP8 Supporting activities
<b>WP2</b>	<ul style="list-style-type: none"> <li>Research permits and consents collected for the research</li> <li>Embedding ethics viewpoint to T2.3 work on ageing-friendly neighbourhoods</li> <li>Creating ethics box to T2.5 work on personas</li> <li>Ethics requirements check of D2.1, D2.2 and D2.7</li> </ul>	<ul style="list-style-type: none"> <li>Support on research integrity issues</li> </ul>
<b>WP3</b>	<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>Organising workshop on ethical requirements as part of T3.5 and embedding the ethical requirements as part of the use requirements in D3.9</li> <li>Ethics requirements check of D3.2, D3.5 and D3.9</li> </ul>	<ul style="list-style-type: none"> <li>Participation in the workshop of T3.5</li> <li>Content provision to D3.9</li> </ul>
<b>WP4</b>	<ul style="list-style-type: none"> <li>Integration of D8.4/D8.14 aspects to architecture</li> <li>Ethics requirement check of D4.1, D4.3 and D4.6</li> <li>Participation in privacy risk workshop</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 and data protection</li> </ul>
<b>WP5</b>	<ul style="list-style-type: none"> <li>Ethics requirements check of D5.3</li> <li>Data Security Descriptions</li> <li>Participation to privacy risk workshops</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>
<b>WP6</b>	<ul style="list-style-type: none"> <li>Ethical self-assessments of each pilot</li> <li>Collection of research permits and consents</li> </ul>	<ul style="list-style-type: none"> <li>Intensive collaboration on a regular basis (pilots and ethics meetings)</li> </ul>



	<ul style="list-style-type: none"> <li>DPIA pilot (PT-3)</li> <li>DPIA each pilot/use Case.</li> <li>Feedback on SHAPES Code of Conduct</li> <li>Data Processing Agreements (DPA)</li> <li>Data Transfer Agreement (third countries)</li> </ul>	<ul style="list-style-type: none"> <li>Separate thematic meetings</li> <li>DPIA &amp; DPA support and meetings</li> </ul>
<b>WP8</b>	<ul style="list-style-type: none"> <li>Provision of SHAPES final Ethical Framework D8.14</li> <li>Provision of SHAPES Privacy and Data Protection Legislation D8.11</li> <li>Risk management work T8.4/D8.9 in close collaboration with other partners (privacy and data related risks, other ethical risks)</li> <li>Provision of D8.2 spin-off document on legal framework for SHAPES technology</li> <li>Ethics guidance regarding research integrity, including consents and permits</li> <li>Ethics work and collaboration with technology partners and pilots, especially related to Privacy and data protection</li> <li>Updating SHAPES Data Management Plan (DMP)</li> </ul>	
<b>WP9</b>	Ethics requirements check of D9.1 and D9.5	<ul style="list-style-type: none"> <li>Ethics evaluation of first open-call proposals</li> </ul>
<b>wp10</b>	Ethics requirements check of D10.2	<ul style="list-style-type: none"> <li>Dissemination activities in LAUREA from an ethics point of view.</li> </ul>

### 3.2 SHAPES Ethics Deliverables

During the second year, we have submitted three official ethics deliverables and communicated them to partners (see Table 5). The timetable of one deliverable (SHAPES Privacy and Ethics Risk Management D8.9) was postponed to M26, partly due the DPIA timetables in WP6, partly also due to personnel changes in LAUREA. In addition, an updated Data Management Plan (DMP) (D8.13) has been provided and the first version of the Legal framework was provided with its spin-off documents (D8.3.1).

Table 5 WP8 deliverables

Deliverable	Sub- mitted	Official timetable	Comments
<b>Updated D8.13 Data Management Plan</b>	internal updated version		The updated plan clarifies the implementation of FAIR principles in SHAPES, and provides further guidelines for Data Lifecycle Management Plans
<b>D8.14 Final SHAPES Ethical Framework</b>	M18	M18	In the final ethical framework both the contents and ethical requirements of the first SHAPES Ethical Framework D8.4 in M7 were updated. In addition an initial SHAPES Code of Conduct was provided.
<b>D8.6 Second Ethics Report</b>	M24	M24	This document
<b>D8.9 First SHAPES Privacy and Ethical Risk Management</b>	will be M26	M24	The timetable for the deliverable was postponed with 2 months due to the following reasons: <ul style="list-style-type: none"> <li>Pilots privacy and ethics risk work were completed not earlier than in M24. Analysis of the DPIA risk work took 2 weeks</li> <li>Other Ethics risk collection and analysis work were delayed due to several changes in the personnel at LAUREA</li> </ul>
<b>D8.3 Assessing Regulatory Frameworks</b>	M42	spin off document D8.3.1 was	The research regarding the regulatory frameworks has been under work during the reporting period





for smart and healthy ageing		released in M16	A spin-off document D8.3.1. investigating legal frameworks for the SHAPES technology platform was released first in M14 and then updated in M18
<b>D8.11 Privacy and Data Protection Legislation and impact assessment</b>	M24	M24	This first Privacy and Data Protection Legislation and Impact Assessment D8.11 focuses on the pilot phase of the SHAPES project, including challenges encountered, such as secondary use of personal data and use on external cloud services

### 3.3 Changes in the WP8 personnel

During the reporting period, there have been several changes both regarding WP8 task leaders and functional managers, well as in the EAB (see Table 6). This has caused smaller, but manageable, delays in the work.

Table 6: Changes in the WP8 personnel

Role	Old resource	New resource
<b>SHAPES Data Protection Manager &amp; Task leader 8.5/Privacy and Data Protection regulation and impact assessment -leader</b>	Lawyer Nina Alapuranen left Laurea in June, 2021.	Lawyer Juhamatti Etuaro started his work in June, 2021. Responsible person for SHAPES Data Management is Rauno Pirinen.
<b>Task leader 8.4/SHAPES Privacy and Ethics risk management</b>	Nina Alapuranen left Laurea in June, 2021. Julia Nevmerzhtskaya left Laurea in April, 2021.	Sari Sarlio-Siintola took the responsibility as T8.4 leader. Harri Haapaniemi will be the main author of D8.9.
<b>EAB members</b>	Gerald Walther left Fraunhofer and EAB in late autumn, 2020. Eduard Fosch left EAB in late autumn, 2021.	Austin Tanney joined EAB in February, 2021. Lutz Kubitschke joined EAB in February, 2021.

### 3.4 Ethics Advisory Board meetings and EAB communication

During the second year, the Ethics Advisory Board (EAB) have had both the 2021 Annual Meeting and the meeting with new EAB members. There were also several participants from EAB in the Ethical Requirements implementation workshop organised by WP3, T3.5, and one participant in the SHAPES 3<sup>rd</sup> Dialogue workshop. In addition, several topics have been discussed informally with some members by email/phone calls (see Table 7).

Table 7: EAB collaboration during the reporting period

Time	Event	Topics discussed
<b>12/2020</b>	SHAPES 3 <sup>rd</sup> Dialogue workshop (WP9)	<ul style="list-style-type: none"> <li>The empowerment of older persons in SHAPES</li> </ul>
<b>13/01/21</b>	Workshop on ethical requirements (T3.5)	<ul style="list-style-type: none"> <li>Ethical requirements and their prioritisation</li> </ul>
<b>22/02/21</b>	Meeting with new EAB members	<ul style="list-style-type: none"> <li>AI ethical guidelines</li> <li>Code of conduct practices when new members join SHAPES</li> </ul>



		<ul style="list-style-type: none"> <li>Challenges with the anonymisation</li> <li>Transparent and traceable data processing</li> </ul>
28/02/21	Email	<ul style="list-style-type: none"> <li>The final SHAPES Ethical Framework D8.14 was sent for EAB members' information and comments</li> </ul>
02/21	Email discussions with Liz Mestheneos, Sari SS and Niamh R	<ul style="list-style-type: none"> <li>Are older persons really involved in the SHAPES development? How can it be ensured that their voices are heard?</li> </ul>
22/09/21	EAB Annual Meeting 2021	<ul style="list-style-type: none"> <li>SHAPES Ethical Framework D8.14 and Code of Conduct</li> <li>SHAPES Privacy and Data Protection Legislation D8.11</li> <li>SHAPES Ethical and privacy risks (&gt;input to D8.9) <ul style="list-style-type: none"> <li>digital inclusion</li> <li>lack of social support</li> <li>terminology</li> <li>automated care challenges</li> <li>business ethics and SHAPES</li> </ul> </li> </ul>

### 3.5 Open calls and new solutions from an ethics viewpoint

The first open call was organised during the first half of the year 2021. Ethics work concerned both ethical screening of the chosen proposal, as well as ethical evaluation of the proposals. The evaluation also included provision of guidelines for the ethical self-assessment (see Table 8).

Table 8: Open Call proposals' ethics evaluation

Proposal	Ethical self-assessment	Ethics deliverables needed + other activities needed
<b>Elliot</b>	ok	The gender dimension is insufficiently described. It should be specified which role gender (and other personal information) plays in developing recommendations. This is to be provided as a deliverable in M2. It should be explained how the data is analysed and how recommendations can be extracted and personalised if the analysis cannot be linked with personal information. This is to be provided as a deliverable in M3.
<b>CAPTAIN</b>	ok	
<b>BRAINCODE</b>	ok	<p>The following information is to be provided in M2 as a deliverable:</p> <ul style="list-style-type: none"> <li>What disease/ condition / disability do human participants have?</li> <li>Details of the recruitment, inclusion and exclusion criteria.</li> <li>What is your policy on incidental findings?</li> <li>Ethics approvals regarding the involvement of patients.</li> <li>Ethics approvals regarding the medical research with healthy volunteers.</li> </ul>
<b>Quafair</b>	ok	
<b>LogMeal</b>	ok	
<b>Liberty</b>	ok	Details of the technical and organisational measures to safeguard the rights of the research participants, as well as declaration





		confirming compliance with the laws of the country where the data was collected (confirmation that the company is allowed to use earlier collected data for a secondary purpose (SHAPES)) is to be provided as separate deliverable in M3.
<b>Myonabler</b>	ok	
<b>Caretechhuman</b>	ok	Standard contractual clauses of Commission have been utilised in data transfer to third countries (Ukraine).

### 3.6 WP8 Meetings and PMB meetings discussing ethics

WP8 has organised both monthly and specific meetings on ethical requirements during the reporting period. In addition, WP8 people have participated to several meetings of other WPs from the viewpoint of ethics. In the Table 9, the topics and proceedings of those meetings are reported.

*Table 9 Meetings and workshops during the reporting period*

Time	Meeting	Topics	Documents
<b>02/11/20</b>	WP8 Monthly	<ul style="list-style-type: none"> <li>D8.2 structure</li> <li>SHAPES Code of Conduct</li> <li>Pilots and ethics</li> <li>Common privacy policy</li> </ul>	Minutes and presentations in the WP8 TEAMS folder
<b>23/11/20</b>	WP8 Monthly	<ul style="list-style-type: none"> <li>EU review results + Findable, Accessible, Interoperable, Reusable (FAIR) principles</li> <li>Ethical self-assessment of pilots</li> <li>Data Protection Officer's (DPO) role</li> <li>Ethics swim lanes for pilots</li> <li>Consents, including recorded ones</li> <li>UK as third country</li> <li>Pilots and ethics meetings</li> <li>D8.14 updated Table of Content (ToC)</li> </ul>	Minutes, presentations and swim lanes in the WP8 TEAMS folder
<b>11/20</b>	PMB	<ul style="list-style-type: none"> <li>Clarification needed on the technologies to be used to guarantee FAIR data principles</li> <li>Nina/Sari to respond to queries over amount of data in the technical review action plan</li> </ul>	Minutes in the PMB TEAMS folder
<b>25/01/21</b>	WP8 Monthly	<ul style="list-style-type: none"> <li>New EAB members + next meeting</li> <li>Update Data Management plan (technology to guarantee FAIR)</li> <li>Legislative overview underpinning SHAPES Platform &gt; spin-off document of D8.2</li> <li>Current version of D8.14 + decision of peer reviewers</li> <li>Risk data from DPIA process &gt;D8.9</li> <li>Ethics risks of other WP's &gt;template to be used</li> <li>Need for pilot DPIA</li> <li>Data processing agreements</li> <li>Discussion on data pseudonymisation and sharing</li> </ul>	Minutes and presentations in the WP8 TEAMS folder
<b>22/02/21</b>	WP8 situation report	No monthly meeting in February	Presentation in the WP8 TEAMS folder



<b>29/03/21</b>	WP8 Monthly	<ul style="list-style-type: none"> <li>• Open-call evaluation plans</li> <li>• Need for cybersecurity and GDPR and AI meeting related to ethical requirements</li> <li>• Discussion on D8.3.1 spin-off document legislation &amp; SHAPES Platform</li> <li>• The use of third-party cloud services (GNOMON/eHealthPass)</li> <li>• Updates to DPIA templates, including template for privacy risks</li> <li>• D8.14 SHAPES Ethical Framework status</li> </ul>	Minutes and presentations in the WP8 TEAMS folder
<b>03/2021</b>	WP cross alignment meeting	<ul style="list-style-type: none"> <li>• DPAs between pilots and technical partners Discussion</li> <li>• How is the SHAPES integrated care platform from the viewpoint of the end-user?</li> <li>• What are the needs for the big data analytics?</li> </ul>	Minutes in the PMB TEAMS folder
<b>26/04/21</b>	WP8 Monthly	<ul style="list-style-type: none"> <li>• OC1 evaluations and ethical self-assessments</li> <li>• Data Management Plan update, including FAIR</li> <li>• Personnel changes in NUIM</li> <li>• New personnel in LAUREA regarding Risk deliverable provision D8.9 (updated version of Toc in May)</li> <li>• Finalisation of D8.14 SHAPES Ethical Framework</li> <li>• Meeting with DPO</li> <li>• Data processing descriptions template under work</li> <li>• Discussing on DPAs and agreements in general</li> </ul>	Minutes and presentations in the WP8 TEAMS folder
<b>24/05/21</b>	WP8 Monthly	<ul style="list-style-type: none"> <li>• DMP updates, collecting comments.</li> <li>• Data Lifecycle Management plans (DLMP)</li> <li>• Proposal for AI regulation and Medical Device regulation added to D8.3.1</li> <li>• Discussion on risk deliverable D8.9 contents and division of labour among partners: <ul style="list-style-type: none"> <li>○ literature reviews</li> <li>○ workshops (privacy, other)</li> <li>○ mapping the risks against DS</li> </ul> </li> </ul>	Minutes and presentations in the WP8 TEAMS folder
<b>21/06/21</b>	WP8 Monthly	<ul style="list-style-type: none"> <li>• Plan for next EAB meeting</li> <li>• Implementation of DMP</li> <li>• The need for spin-off documents related to D8.3 Regulatory frameworks</li> <li>• Lawyer Juhamatti Etuaro has started his work as DPM and T8.5 leader</li> <li>• Risk data collection for the D8.9, partners contributions still partly open</li> <li>• Ethics support during the summer period</li> <li>• Contents of first SHAPES Privacy and Data Protection legislation D8.11</li> </ul>	Minutes and presentations in the WP8 TEAMS folder
<b>06/21</b>	WP Cross alignment meeting	DPIA process	Updated templates in the DPO TEAMS folder
<b>30/08/21</b>	WP8 Monthly	<ul style="list-style-type: none"> <li>• EAB meeting/topics to be discussed</li> <li>• Ethics progress report D8.6 situation</li> <li>• EU review results</li> <li>• Data Management Plan updates, procedures and collection of partners comments</li> <li>• D8.2 situation and links to WP3 work</li> <li>• D8.11 situation and focus</li> <li>• Privacy and data protection collective workshops</li> </ul>	Minutes and presentations in the WP8 TEAMS folder



		<ul style="list-style-type: none"> <li>Delays in collecting information to D8.9 &gt; need to postpone the delivery with 2 months</li> </ul>	
<b>23/09/21</b>	Cross alignment meeting	<ul style="list-style-type: none"> <li>Processing of harmonised data</li> </ul>	Minutes in the PMB TEAMS folder
<b>28/09/21</b>	WP8 Monthly	<ul style="list-style-type: none"> <li>Situation with the updated DMP and next steps</li> <li>Topics discussed in the EAB annual meeting on 22<sup>nd</sup> September</li> <li>Second Ethics Progress report D8.6 in M24</li> <li>Overview of progress D8.3</li> <li>Situation and next steps with the First Ethics and Privacy risk deliverable D8.9</li> <li>DPIA situation of pilots</li> <li>First Privacy Data Protection Legislation deliverable D8.11 in M24</li> <li>Contracts with Google / voice assistant</li> </ul>	Minutes and presentations in the WP8 TEAMS folder



## 4 Research integrity and guidance

### 4.1 SHAPES Ethical Self-assessments

The principles of maximizing benefit and minimizing harm, social responsibility, dignity, fundamental 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. 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.

All the work-packages have carried out their ethical self-assessments already during the first reporting period. During this second reporting period, each pilot provided its ethical self-assessment (see Chapter 6 on pilots). In addition, accepted open calls proposals provided their own ethical self-assessments (see Figure 4). They are archived in TEAMS under OC –folder. No critical issues were identified.






	SHAPES Open Call - Ethical Self-Assessment for...	26.8.2021 15.28	Microsoft Word Doc...	201 KB
	SHAPES Open Call - Ethical Self-Assessment for...	26.8.2021 15.26	Microsoft Word Doc...	225 KB
	SHAPES Open Call - Ethical Self-Assessment for...	26.8.2021 15.24	Microsoft Word Doc...	183 KB
	SHAPES Open Call - Ethical Self-Assessment for...	26.8.2021 15.27	Microsoft Word Doc...	180 KB
	SHAPES Open Call - Ethical Self-Assessment LIB...	26.8.2021 15.26	Microsoft Word Doc...	294 KB

Figure 4 Snapshot of open call ethical self-assessment documents

### 4.2 Guidance on ethics

The guidance and inquiries regarding ethical procedures have been focusing predominantly on pilots (see also Chapter 6). In addition, there has been discussion with WP2, WP3 and WP8 regarding research ethics, consents, research permissions and ethics approvals.

Due to the COVID-19 situation the collection of research data was organised predominantly by remote interviews. The possibility to also collect consent remotely was discussed. The conclusion was that consent can be collected orally by recording them and storing the files in a safe place, like written consents.



## 5 Progress regarding the definition and implementation of ethical requirements

This chapter reports how the SHAPES methodology regarding the implementation of the ethical requirements in D8.14 has proceeded during the reporting period. As the ethical requirements concern the SHAPES technology, user processes, and business/governance models, the implementation is multifaceted.

### 5.1 Updated SHAPES Ethical Requirements and Code of Conduct

In the final version of the Final SHAPES Ethical Framework (D8.14), an updated version of the ethical framework and ethical requirements was provided, including clarifications and specifications especially related to the responsibilities and processes related to ethical requirements (see Table 10).

Table 10 Snapshot from SHAPES Ethical Requirements in D8.14

Class	No	Requirement	Importance	Responsibility before the project	Responsibility after the project	Processes	More information in D8.14 section
General Ethical Requirements for the development	GE 1 (GE 2)	Maximise the level of fundamental rights of older persons and of caregivers that SHAPES and its digital services can promote. Ensure they do not violate any fundamental rights of older persons and/or other stakeholders (e.g., non-discrimination, dignity, integrity and privacy when having robots, web-cameras at home) (Fundamental Rights Impact Assessment FRIA)	Essential/Mandatory	WP2, WP3, WP6, WP7, WP9?	Marketplace, Service provider, Governance	Service joins, Service development, Platform development	Rights, Disabilities, AI Ethics, Privacy & DP, Lifelong Learning
General Ethical Requirements for the development	GE3 (GE4)	Be aware of the four biomedical principles and perspectives of care ethics. Apply and promote those within SHAPES (justice, beneficence, non-	Essential/Mandatory	WP2, WP3, WP6	Marketplace, Service provider, Governance	Service joins, Service development, Platform development	Bioethics, AI ethics, Cybersecurity
General Ethical Requirements for the development	GE5 (GE6)	Maximise the level of human capabilities of older persons and caregivers that SHAPES and its digital services can promote. Ensure that SHAPES is not detrimental to any human capabilities of older people and/or other stakeholders. Pay attention especially to those who are weaker or with disabilities.	Essential/Mandatory	WP2, WP3, WP6	Marketplace, Service provider, Governance	User joins, Service joins, Service development, Platform development	Disabilities, Capabilities, Lifelong Learning

In the D8.14, the initial SHAPES Code of Conduct was also provided (see Figure 5). The idea of the Code is to communicate the value base of the solution especially for end-users and other stakeholders. At the time of writing, the code is currently being commented on by pilots for updates.



## 4. Code of Conduct

### 1 Empowerment and inclusivity of end-users

Inclusivity and empowerment of end-users is the base of SHAPES culture. We create an atmosphere and environment where people can feel involved and have real possibility to empowerment. Cultural diversity is valued.

We understand participation and inclusivity of people in the development, actions and at the digital platform of SHAPES in itself being a service that supports the person's human capabilities. We ensure that the end-users have real power and impact in all SHAPES actions.

We support end-users to be empowered, active agents of change in their lives and in society. Instead of being merely inputs in the SHAPES project, end-users are themselves subjects of outcomes and impacts.



PHOTO: KRISTEN STURDIVANT

## 2 Privacy, data protection and cybersecurity

Privacy is a fundamental right. Both privacy and data protection are instrumental in preserving and promoting fundamental values and rights and are also important for SHAPES. The notion of data protection originates from the right to privacy. Data protection aims to protect information related to an identified or identifiable person. We are committed and promoting lawfulness, fairness and transparency.

The aim of cybersecurity is to make cyberspace safe from damage or threat. Cyber security is wider phenomenon as information security. We are committed to the principles of biomedical ethics also in the context of cybersecurity. In this context it means: efficiency and quality of services (Beneficence and Justice); Privacy of information and confidentiality of communication (Autonomy); usability of services (Nonmaleficence and Justice); Safety (Nonmaleficence and Beneficence). Risk management is built in in our cybersecurity management and we take it seriously. The overall goal of cybersecurity is that all systems and infrastructures are resilient.

**Q** Question?  
How can I evaluate my own actions in terms of maximizing benefit and minimizing harm, social responsibility, dignity of persons, fundamental human rights?

Question?  
Person wants to be forgotten in the data. Is that possible?

**Q**

Figure 5 Snapshot from the SHAPES Code of Conduct

## 5.2 Key deliverables regarding the implementation of SHAPES Ethical Requirements

### 5.2.1 SHAPES Platform Requirement D3.9

In accordance with the SHAPES methodology, ethical requirements defined in the D8.14 were further formulated, categorised and prioritised as part of the Final User Requirements for the SHAPES Platform (D3.9) (see Figure 6).

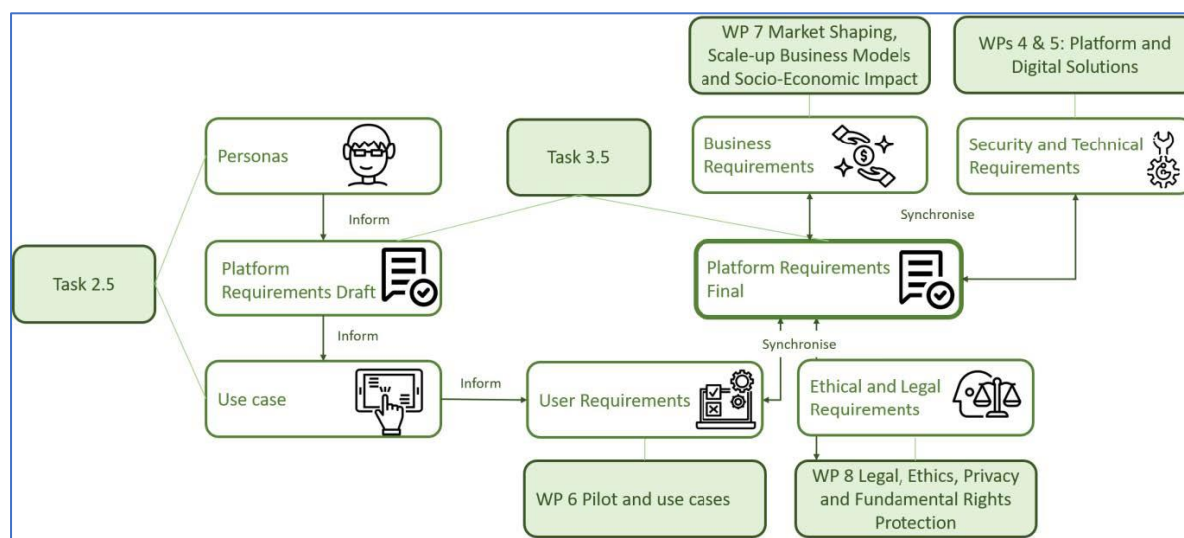


Figure 6 Task 3.5 Links with SHAPES WPs and Tasks (Adopted from D3.9)





In addition, conflicts between the Health Support Requirements (on the left) with Ethical Requirements (on the right) were visualised with the help of lines (see Figure 7).



Figure 7 Cross-checks of SHAPES Platform Requirements (Adopted from D3.9)



Overall, the SHAPES Platform Requirements in D3.9 encompass four dimensions: Functional Requirements (FR), Legal and Ethical Requirements (LER), Security and Technical Requirements (STR) and Business Requirements (BR). The ethical requirements defined in the D8.14 are mostly related to Legal and Ethical Requirements (LER) in D3.9 (see the table below), but also to Security and Technical Requirements and Business Requirements, where they seemed to fit more naturally. (see Figure 8).

Sub-category	Requirement	Coding	Ranking	General comments			
				Responsibility during the project	Responsibility after the project	Processes	More information in D8.4 sections
Platform Requirements (Coding: PT) (in distinction from more general requirements)	Ensure equal and non-discriminatory access to technology and its support services by using well-designed user interfaces, instructions and authentication.	LER-PT-1	Essential	WP2, W3, WP6, WP7, WP9?	Marketplace, Service provider, Governance	Service joins, Service development, Platform development	Rights, Disabilities, AI Ethics, Privacy & DP, Lifelong Learning
	Consider cultural diversity of users; for example, create avatars that represent different genders and cultures and let the user choose what to use. (TBD)	LER-PT-2	Mandatory	WP2, WP3, WP6	Marketplace, Service provider, Governance	Service joins, Service development, Platform development	Bioethics, AI ethics, Cybersecurity
	Create functionalities for the end-user to switch off/on various sensors and services whenever she/he want to do it.	LER-PT-3	Essential	WP2, WP3, WP6	Marketplace, Service provider	User joins, Service joins, Service development, Platform development	Disabilities, Capabilities, Lifelong Learning
	Data subject rights: right of access – provide a self-service portal where the data subject can get access to his/her data.	LER-PT-4	Essential	WP6, WP8	Service provider		Rights, Ethics of Care, Capabilities

Figure 8 Snapshot from the D3.9 LER requirements

## 5.2.2 SHAPES Technical Platform D4.1 and Digital Solutions D5.3

The SHAPES TP Requirements and Architecture (D4.1), elaborated in response to the user requirements acquired in WP3, use cases defined in WP2, pilot themes defined in WP6, as well as ergonomics and ethical recommendations produced in WP8. D4.1 translated requirements in D3.9 – also including ethical requirements having origin in D8.14) – into technical system specifications (see

ID	Specification	Priority	Applicability										Clarification	Reference
			Marketplace	symbolTe	ASAPA + biometrics	FHIR	FINoT	Gateway	Message Broker	Data Lake & Analytics	Digital Solutions	Front-End App		
												- Consent Document or "Patient Privacy Consent Acknowledgment Document"		
SPS-126	SHAPES shall offer traceability of personal data	High	X			X	X			X	X	Includes data mapping and data flows.	ET14 (D8.4 Privacy & DP 5)	
SPS-127	SHAPES shall support automated decision-making	High									X	Capability to re-direct the decision to a manual process.	ET15 (D8.4 Privacy & DP 5)	
SPS-128	SHAPES shall support "Privacy by design and by default"	High	X	X		X	X			X	X	Implement privacy enhancing technologies, e.g. encryption, anonymization etc.	ET16 (D8.4 Privacy & DP 5)	
SPS-129	SHAPES shall comply with trustworthy AI guidelines	High		X						X	X		ET21 (D8.4 AI Ethics 4.3)	
SPS-130	SHAPES shoulduse AI for self-diagnosis of SHAPES cyber-security protection	Medium		X							X		ET22 (D8.4 AI Ethics 4.3)	
SPS-131	SHAPES shall comply with common minimum cybersecurity rules for mobile and online services	High		X							X	X	ET23 (D8.4 Cybersecurity 6)	





Figure 9).

Secondly, D4.1 developed the concept architecture of the SHAPES system in response to the system requirements and specifications produced earlier. From the viewpoint of SHAPES architecture, the ethical requirements related to privacy and data protection and security were very relevant and also raised a lot of discussion (see Chapter 0).

The original ethical requirements in the D8.14 are in the D4.1 included in several different categories (Customer service, Pricing, Health support, Information services, Health maintenance support, Legal and ethical requirements, Data protection, Adaptability, Availability, Reliability, Usability, Core component operational specifications and IoT Cybersecurity for digital solutions).

ID	Specification	Priority	Applicability								Clarification	Reference
			Marketplace symbolTe ASAPA + biometrics	FHIR	FINoT	Gateway	Message Broker	Data Lake & Analytics	Digital Solutions	Front-End App		
											- Consent Document or "Patient Privacy Consent Acknowledgment Document"	
SPS-126	SHAPES shall offer traceability of personal data	High	X	X	X			X	X		Includes data mapping and data flows.	ET14 (D8.4 Privacy & DP 5)
SPS-127	SHAPES shall support automated decision-making	High							X		Capability to re-direct the decision to a manual process.	ET15 (D8.4 Privacy & DP 5)
SPS-128	SHAPES shall support "Privacy by design and by default"	High	X	X	X	X		X	X		Implement privacy enhancing technologies, e.g. encryption, anonymization etc.	ET16 (D8.4 Privacy & DP 5)
SPS-129	SHAPES shall comply with trustworthy AI guidelines	High	X					X	X			ET21 (D8.4 AI Ethics 4.3)
SPS-130	SHAPES should use AI for self-diagnosis of SHAPES cyber-security protection	Medium	X						X			ET22 (D8.4 AI Ethics 4.3)
SPS-131	SHAPES shall comply with common minimum cybersecurity rules for mobile and online services	High	X					X	X			ET23 (D8.4 Cybersecurity 6)

Figure 9 Snapshot of D4.1 requirements related to SHAPES Ethical Requirements

The requirements in the D4.1 – and including those related to the ethical requirements in D8.14 -were further analysed from the viewpoint of each digital solution as part of the SHAPES Digital Solutions (D5.3). In the Table 11, there is an example of this mapping.

Table 11 A snapshot of D5.3 mapping digital solutions and D4.1 requirements

System Specifications	Description	Fulfil (Y/N)	Comments
SPS-001	The SHAPES Platform shall adopt a customer logic (B2C and B2B) in its design and development.	Y	Adaptations to eCare consider the collected user feedback on design mock-ups and prototype.



<b>SPS-003</b>	The SHAPES Platform shall have its own Privacy Policy, observing applicable regulations, including the GDPR.	Y	eCare has its own privacy policy. For the SHAPES pilot activities, the privacy policy is defined by the pilot research protocol.
<b>SPS-018</b>	The SHAPES Platform shall comply with universal accessibility policies.	Y	eCare follows universal accessibility policies.
<b>SPS-023</b>	The SHAPES Platform shall support multilingual user interface.	Y	eCare has a multilingual interface and eCare adaptations benefitted from SHAPES partners' translation skills.
<b>SPS-027</b>	Digital Solutions shall provide usage tutorials and help cards, including on the devices they use.	Y	eCare provides a welcome guide. For the SHAPES pilot activities, a dedicated user manual has been created, including relevant instructions on the use of the devices.
<b>SPS-030</b>	The SHAPES Platform shall comply with private data protection of the GDPR regulation.	Y	eCare complies with GDPR regulations.
<b>SPS-031</b>	The SHAPES Platform shall ensure that private data is stored only within EU Member States and other countries considered as GDPR compliant.	Y	eCare storage is handled in EU Member States.

### 5.3 SHAPES Ethical Requirements –Check of each deliverable

The purpose of the SHAPES 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 considered the 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 12, the situation with the ethical requirements checks of each SHAPES deliverable submitted during the second year of the project are reported.

Table 12 SHAPES Ethical Requirements Checks of each SHAPES deliverable

Deliverable		Ethical req. check	Separate ethics section in the deliverable
<b>D1.8 SHAPES Action Report</b>	M18	N/A	
<b>D1.3 SHAPES Innovation and Knowledge Directory First Draft</b>	M24		
<b>D1.5 First report on SHAPES Advisory Board Activities</b>	M24	yes	
<b>D2.1 The SHAPES Platform Ethos</b>	M24		
<b>D2.2 Accessibility of Older Individuals to Physical Spaces</b>	M24	yes	
<b>D2.7 SHAPES Personas and Use Cases</b>	M18	yes	Separate ethics chapter, including ethics box for personas.
<b>D3.2 Scaling-up Improved Integrated Care Delivery V1</b>	M18	yes	



<b>D3.5 Initial SHAPES Collaborative Governance Model</b>	M18	yes	Ethics discussed in several sections, including IT-governance, Data Governance, Enterprise governance.
<b>D3.9 User Requirements for the SHAPES Platform</b>	M18	yes	Ethical requirements defined in D8.14 are included as part of the requirements for the SHAPES Platform.
<b>D4.1 SHAPES TP Requirements and Architecture</b>	M18	yes	Ethics viewpoint is clarified in several chapters.
<b>D4.3 Integration Plan and Test Cases v1</b>	M24		
<b>D4.6 SHAPES Interoperability Reference Testing Environment</b>	M24		
<b>D5.3 SHAPES Digital Solutions V.2</b>	M24	yes	Ethical requirement check provided. However the answer to several of ethical issues is simply given as “relevant for the Digital Solutions”.
<b>D8.6 Second Periodic Ethical report</b>	M24	yes	This deliverable
<b>D8.11 Privacy and Data Protection Legislation and Impact Assessment</b>	M24	yes	Deliverable is about privacy and data protection (>corresponding requirements in D8.14)
<b>D8.14 Final SHAPES Ethical Framework</b>	M18	yes	The whole deliverable is about ethics and ethical requirements related to the ethics requirement check –template
<b>D9.1 SHAPES Ecosystem Building, Findings and Breakthroughs V1</b>	M24	yes	
<b>D9.5 SHAPES Open Calls for Innovation and Collaboration - Publication, Evaluation and Selection Process</b>	M24		
<b>D10.2 SHAPES Outreach, Dissemination and Communication Activities V1</b>	M24		



## 6 Progress regarding the pilots & ethics

This chapter reports on the ethics work related to the SHAPES Pilots. The 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 work has been concentrated on general research integrity issues, as well as on conducting DPIA in order to ensure that pilots are compliant with GDPR, and to find out risks related to privacy and data protection of each pilot/use case.

### 6.1 Background

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). This work has been performed during the reporting period. 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).

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. In those pilots, we conduct a validation in an environment that expects the development version to be piloted itself, fulfilling the minimum legal requirements.

### 6.2 Meetings and discussions with pilots

During the reporting period, several “Pilots and Ethics” meetings with pilots regarding their DPIA work were organised. The SHAPES DPM and/or SHAPES EM have also attended several WP6 meetings. In addition, a lot of guidance and clarifications have been provided for pilots in order to support them in their DPIA work. The documentation related to the meetings is located under the TEAMS folder “Pilot DPOs.”

In discussions with the pilots, also the idea emerged that we would describe more in detail the tasks related to pilot phases 1-3 and 4-5, regarding research ethics and the



ethical requirements of SHAPES. We ended up using swim lanes as a means of presentation (see Figure 10). The purpose of these swim lanes is to figure out the complexity of the ethical procedures, and to help to keep in mind all the activities needed.

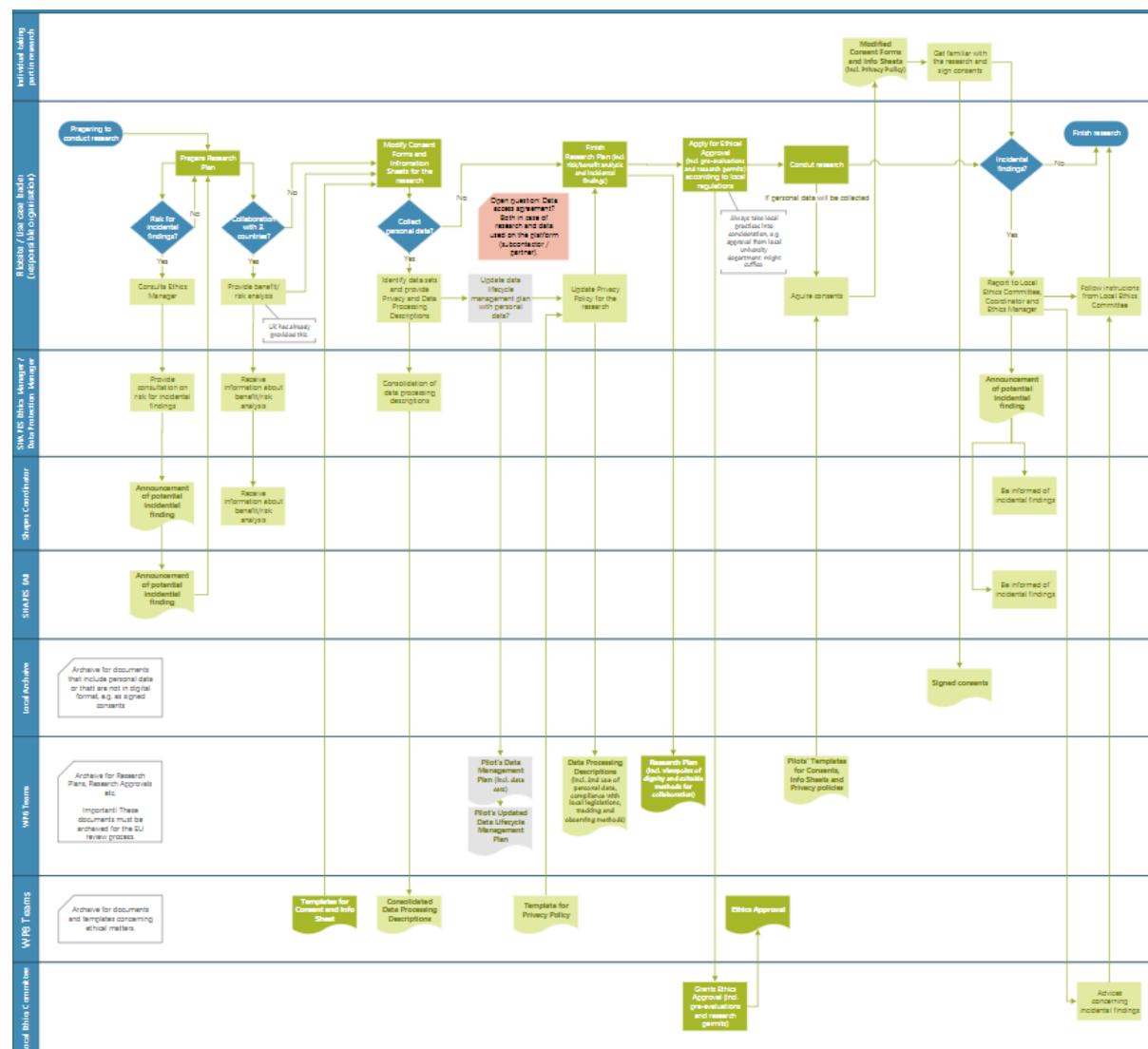


Figure 10 Snapshot of SHAPES Ethics Swim lanes for SHAPES Pilots

The Table 13 further illustrates the amount of interaction with pilots, and the topics discussed, such as consents, Data Protection Officer responsibilities, need for data processing agreements, and privacy risk identification.

Table 13 Collaboration with pilots

Time	Meeting/ email	Topics	Documents	Sta- tus
02/11/20 24/11/20 27/01/20	Emails with several pilots	Consents, information sheets and privacy notes, contact persons	Templates are available in the WP8 TEAMS folder	ok



<b>07/01/21</b>	Emails with pilots	Discussion on DPO's roles and responsibilities		ok
<b>09/12/20</b>	Pilots and ethics - meeting	<ul style="list-style-type: none"> <li>• DPO responsibilities</li> <li>• Discussion on personal data processing</li> <li>• Pilots' ethical self-assessments</li> <li>• Ethics swim lanes</li> <li>• Ethics research during the pilots <ul style="list-style-type: none"> <li>○ Code of conduct</li> <li>○ Capabilities approach</li> <li>○ Vocational well-being</li> <li>○ Feedback on intrusive services</li> </ul> </li> </ul>	Notes + presentation in the WP8 TEAMS folder.	ok
<b>04/02/21</b>	Pilots and ethics meeting	<ul style="list-style-type: none"> <li>• Discussions/clarifications <ul style="list-style-type: none"> <li>○ Consents and contact persons</li> <li>○ Use of medical devices without CE</li> <li>○ Secondary use of personal data</li> <li>○ Personal data on the SHAPES core</li> <li>○ Updated swim lanes</li> <li>○ DPIA test with PT3</li> <li>○ DLMP and DMP</li> <li>○ DPAs/access to data</li> </ul> </li> </ul>	Notes + presentation in the WP8 TEAMS folder	ok
<b>12/02/21</b>	Email	Question regarding the insurances of robots to be used in pilots		ok
<b>02-06/21</b>	Several emails	Need for DPAs	Templates available in the WP8 TEAMS	ok
<b>06/21</b>	Several emails	The use of google analytics (google as processor, data transfer)	Updated DPIA guidelines in WP8 TEAMS folder	ok
<b>09/03/21</b>	Email	Discussion regarding <ul style="list-style-type: none"> <li>• CE marks</li> <li>• Medical Device Directive</li> <li>• Data Storage</li> </ul>		ok
<b>11/03/21</b>	Pilots and ethics meeting	<ul style="list-style-type: none"> <li>• Results of the pilot DPIA</li> <li>• Collective DPIA document on data subject's rights and on data security</li> <li>• Capabilities Approach -research</li> <li>• Validation of ethical requirements</li> <li>• Mandatory ethical requirements</li> <li>• Data access agreements</li> </ul>	Notes + presentation in the WP8 TEAMS folder	ok
<b>05/05/21</b>	Emails	Questions regarding sponsorship in using voice assistant		ok
<b>04/05/21</b>	WP6 meeting	Participation in the WP6 meeting		ok
<b>06/05/21</b>	Email	Clarifications regarding the use of open data		
<b>01/06/21</b>	Email	Case GNOMON/medical device		ok
<b>15/06/21</b>	T6.4 telco	<ul style="list-style-type: none"> <li>• DPIA, deadlines, Data Processing Description template updates, access of partners to SHAPES big data</li> </ul>		ok
<b>21/06/21</b>	Pilots and ethics meeting	<ul style="list-style-type: none"> <li>• DPIA situation of each pilot</li> <li>• Updating DPIA timetables</li> <li>• DPAs</li> <li>• DPA and Issues regarding internal and external transfer</li> <li>• Cybersecurity and joint data security document</li> </ul>	Notes + presentation in the WP8 TEAMS folder	ok



		<ul style="list-style-type: none"> <li>• Voice assistant and google translation services</li> <li>• DPIA validation during the pilots</li> <li>• First privacy and ethical risk management deliverable D8.9 + links to DPIA work</li> <li>• CA research will not be embedded in the pilot's harmonised research</li> <li>• SHAPES Code of Conduct and feedback collection</li> </ul>		
<b>24/06/21</b>	WP6 meeting	Discussion on anonymisation and pseudonymisation		ok
<b>26/06/21</b>	PT2/001, 002, 004 telco	General discussion on DPIA process		ok
<b>28/06/21</b>	Email PT1/001, 003	Privacy risk assessment and data processing descriptions		ok
<b>01/07/21</b>	Email	UK data protection act	Updated template for DPIA in the WP8 TEAMS folder	ok
<b>13/07/21</b>	PT2/003, 004, including open call	General questions regarding DPIA, DPA, data mapping		
<b>13/07/21</b>	PT2/001 telco	Privacy risks related to the use case + privacy risks in general		ok
<b>14/07/21</b>	PT3 telco	DPIA documentation		ok
<b>14/07/21</b>	email from PT3	Cancellation of consent		ok
<b>15/07/21</b>	Telco with several partners	Creation joint data security document needed in DPIA and for DPA		ok
<b>07/21</b>	several emails	Questions about data security document		ok
<b>19/07/21</b>	email from PT3	Questions of sub-processors		ok
<b>28/07/21</b>	Email	Updated versions of data security document for partners' comments	Internal confidential document in the TEAMS pilot DPO folder	ok
<b>29/07/21</b>	Privacy risk meeting	Discussion on privacy and data protection risks		ok
<b>07/21</b>	Several emails PT3	Storing place of harmonised data (further in the cross-alignment meeting 23rd September it was decided not to store in data lake)		ok
<b>07/21</b>	Several emails	Secondary use and pseudonymisation/ anonymisation (Secondary use of useful anonymised data is not possible)	D8.11 slide show in the WP8 TEAMS folder	ok





<b>05/08/21</b>	Several emails with PT3	Providing data to a person outside SHAPES who provides the template for data collection for SHAPES purposes  >This processing of personal data is added to consent (to avoid secondary use)		ok
<b>16/08/21</b>	PT5	General discussion on DPIA		ok
<b>21/08/21</b>	WP6 meeting	Harmonised data, agreements and GDPR  Mapping the situation of ethics work (consents, approvals) and data protection work (DPIA, agreements) performed in pilots/use cases		ok
<b>30/08/21</b>	Email with PT3 and technical partners	Data Processing Agreements, case UK Are the EU and UK DPA 2018 optional? Answer: GDPR is the basis, DPA2018 complements it.		ok
<b>02/09/21</b>	Email with PT2	Data Processing Agreements, case transfer to third countries (Ukraine) Standard contractual clauses to be utilised		ok
<b>02/09/21</b>	Telco with PT5	Going through PT5 DPIA, discussion especially related to the use of external services (google translator, bold by Devoteam)  Google does not make agreements directly, but for example via Devoteam). This topic is related to the use of unused travelling budget to buy translation services		ok
<b>13/09/21</b>	Privacy risk meeting with pilots	Discussion on general privacy & data protection risks, and how they may apply to various use cases	Minutes in the WP8 TEAMS	ok
<b>16/09/21</b>	Email with PT3	<ul style="list-style-type: none"> <li>Pseudonymisation from the GDPR viewpoint</li> <li>Privacy notice information</li> </ul>		ok
<b>20/09/21</b>	Telco with PT5	DPIA contents and agreements with Devoteam		ok
<b>29/09/21</b>	Telco with PT4	<ul style="list-style-type: none"> <li>DPIA contents</li> <li>Can own consent be used &gt; make sure that all the topics mentioned in the SHAPES consent template are included</li> <li>The use of anonymised data in secondary purposes than SHAPES (Not possible)</li> </ul>		ok
<b>30/09/21</b>	Telco with PT5	Google contract matters DPIA matters		ok
<b>30/09/21</b>	email	Guidelines to pilots regarding the harmonised data (DPAs, controllers, article 11, data subject's rights, DPIA)		
<b>12/10/21</b>	Emails	Retention of anonymised data > we need to define an exact time for the retention (Can be after the project, but has to be necessary for SHAPES purposes > is not secondary use)		ok





## 6.3 Current situation with SHAPES Pilots' DPIA and other ethics work

### 6.3.1 Research integrity

All the pilots have provided their ethical self-assessments. The assessments are archived in TEAMS under WP8 Folder (see Figure 11). No critical issues were identified.

	5th_Regional_Health_Authority_DYPE5_Ethi...	Fotios Gioulekas (D...	October 26, 2020	73.2 KB
	AUTH - Ethical self assessment template for...	varellaannita@gma...	October 23, 2020	69.7 KB
	CCS - Ethical self assessment template for p...	Stephanie.Ehrentraut	October 30, 2020	71.7 KB
	CH-Ethical self assessment template for pil...	oscar.villacanas@g...	January 12	76.2 KB
	Ethical self assessment template for pilots 2...	Sari Sarlio-Siintola	October 21, 2020	68.5 KB
	FNOL_Ethical self assessment template for ...	Tereza Norbertová	November 3, 2020	73.4 KB
	gewi_Ethical self assessment_PT2.docx	meen	January 25	77.5 KB
	NHSCT_Ethical self assessment_Phase 1-5_...	Nicola Goodfellow	December 3, 2020	78.2 KB
	UAVR_Ethical self assessment template for ...	Ana Martins	October 27, 2020	73.1 KB
	UC_PT5_001_Ethical_Self_Assessment_PH1-...	parocho	December 2, 2020	69.2 KB

Figure 11 Snapshot of pilots' ethical self-assessment documents in TEAMS

At the time of writing this deliverable, the pilots are gradually moving on to phase 4-5. Prior to the start of this phase, the necessary permits and ethical statements are under work in several pilots.

### 6.3.2 Privacy and Data Protection Impact Assessments (DPIAs)

DPIA work will identify risks related to the privacy and data protection, and ensure that all technical and organisational requirements related to privacy and data protection (> D8.14, D3.9, D4.1) are designed and implementable before the pilot in real-time settings begins. DPIAs (including also DPAs) have to be ready 2 months before the start of the pilot. This means that the DPIA work has been very intensive during the second part of the reporting period.

During the DPIA process, a number of complex issues have arisen regarding the organisation of harmonised data processing, the use of external (non-EU) services, the SHAPES data model and personal data, and the secondary use of personal data (see Chapter 8). This work has consumed a lot of resources from both WP8 and WP6



pilots. On the other hand, this work has systematically reviewed the SHAPES solution from mandatory ethical (data protection) requirements point of view.

DPIA is also one of the core processes providing inputs to the First SHAPES Privacy and Ethics Risk Management deliverable (D8.9) in M26.



## 7 Progress regarding Data Management

This chapter focuses on SHAPES Data Management, including the updates to the SHAPES Data Management Plan (D8.13), and its implementation during the SHAPES Project. SHAPES Data Management is a large entity covering both the research data, deliverables and dissemination, as well as the SHAPES Data Model and architecture.

### 7.1 Updated Data Management Plan and its implementation

The original Data Management Plan (D8.13) submitted in M6 described methodologies that will be used to store and manage data, and the types of data that will be managed. However, the amount of data that will be collected and managed during the project and the technologies that will be used to guarantee the FAIR data principles were not specified (SHAPES Review report, 2020).

The updated SHAPES Data Management Plan D8.13 involves practices, architectural techniques and tools for achieving open access and FAIR principles (Findable, Accessible, Interoperable, Reusable - see Table 14) for delivery of data across the spectrum of data subject areas and data structure types in SHAPES domain. The current SHAPES DMP is expanded with remarks for furthering its collective data management view as “a common point of reference” including 1) uniformity, 2) accuracy, 3) stewardship, 4) semantic consistency, and 5) accountability of the data assets towards to harmonisation of the SHAPES data as an instance in European Health Care Data Space. The DMP document is updated continuously over the course of the project whenever significant changes occur, as a minimum in time with the periodic evaluation or assessment of the project as well as for the final review.

Table 14 FAIR Principles in SHAPES (Adopted from updated SHAPES D8.13, 2021)

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 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 data and access are ensured, that is 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>INTER-OPERABLE</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 interdisciplinary. 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 for integration with other compatible data sources, facilitation of citations, references, and data interfaces.
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At the time of writing, the implementation (actualisation process) of the updated plan is currently being planned, including the following:

1. **Open Data Issues:** How open and FAIR are the “raw research data” and “analysed research data” as well as possible “fused data (such as middle-range outcomes of data fusion processes)” on “non-personal data sets and gathered data views” in SHAPES?
2. **Actualisation of FAIR:** How are the current data sets of WPs updated (including FAIR Principles, Data Lifecycle Management Plans, and new Data Sets (DS))?
3. **Data Privacy Impacts:** How can current descriptions with FAIR and DLMP in the DPIA documents (data processing descriptions, data sets, and data flows) and WP6 Use Cases data plans progress (complement)?
4. **Categorisation of SHAPES Data Sets:** How are the different categories of SHAPES data described, processed and managed in the perspective of Data Management? (see Figure 12 as a first-draft description)

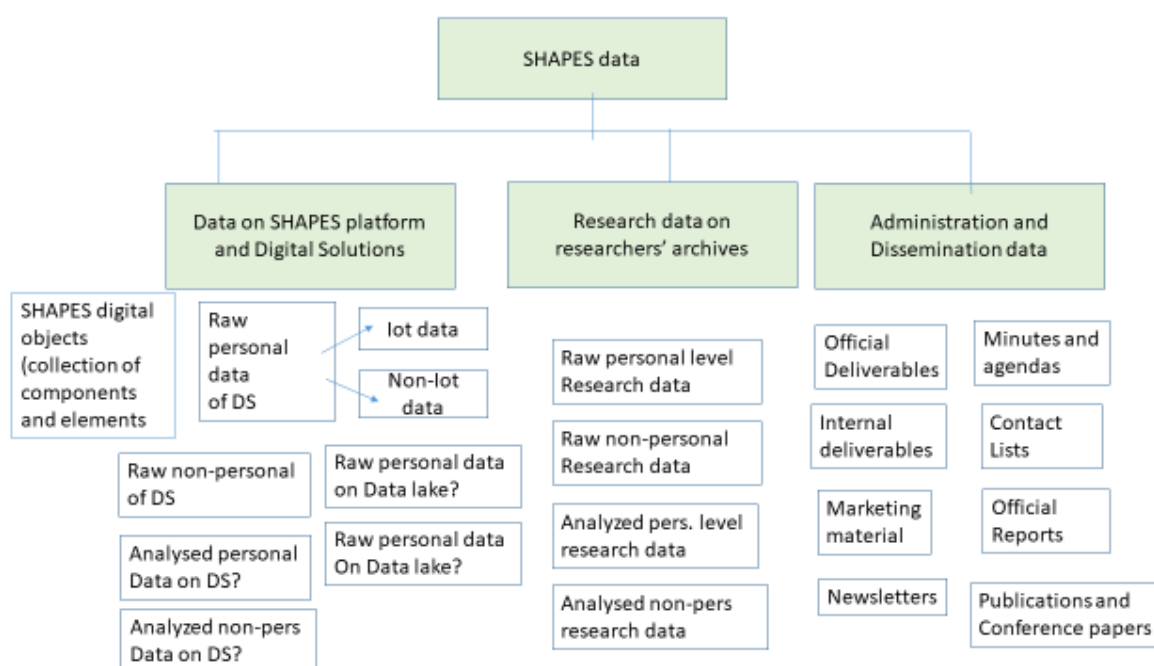


Figure 12 Categories of SHAPES datasets (to be updated)



## 7.2 Data Management on the SHAPES Platform

The SHAPES Platform will provide a **federated data model approach** for information sharing, as in the Figure 13. Within WP4 data models and WP8 DMP each Digital Solution (DS) retains the “data owning” and “access control” (AC) of their own data as well as management and rights of the digital suites. Hence the symbloTe platform functions as a mediator between Digital Solutions for IoT types of medical data while FHIR Interoperability, see (Fast Healthcare Interoperability Resources (FHIR)) in where a component offers similar translations for exchanging medical information among interconnected systems.

The current plan of the SHAPES interoperability mechanisms is as follows:

- 1) no identification-related data is transmitted to the core of the SHAPES Platform;
- 2) a necessary metadata needed to align diverse data models and interface development and configuration is being provided;
- 3) after that, both actors can bilaterally develop the data exchange, data security issues, such as encryption used, and information exchange processes. The purpose of this proposed plan is that the data privacy and coherence requirements are reduced to a minimum, in such manners as there is no personal identifiable data sent to interoperability mediation components in the SHAPES core.

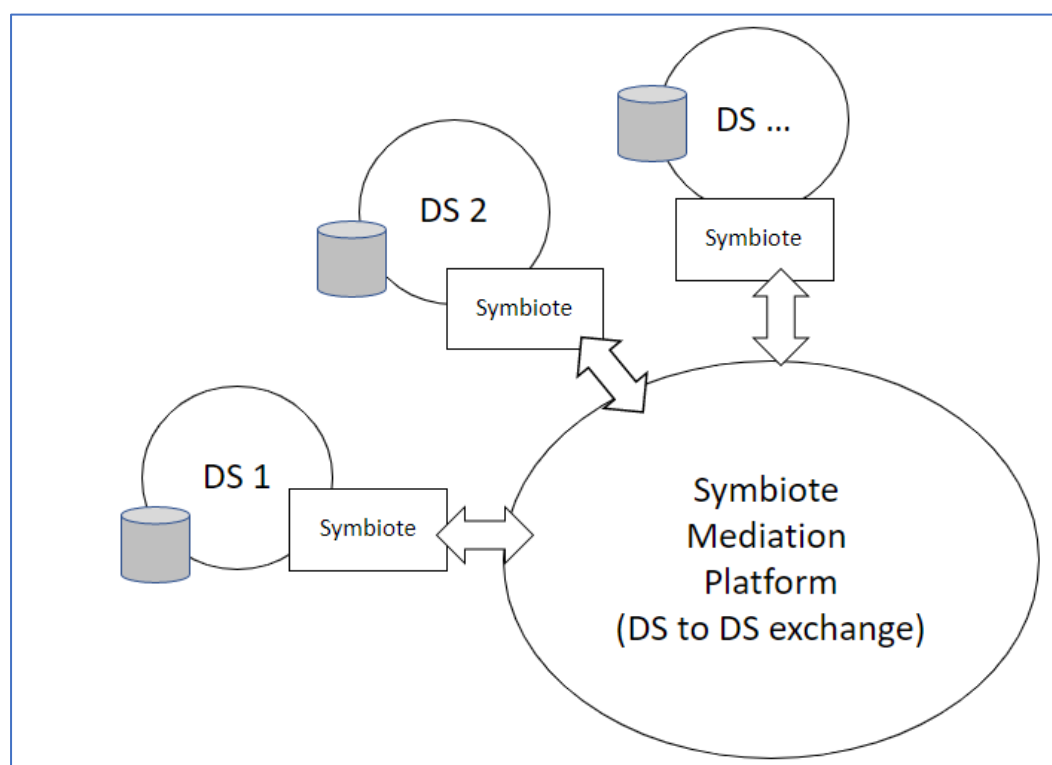


Figure 13 SHAPES Federated Data Model - approach (adopted from SHAPES D4.1, 2021)

A current summary of data management strategies and implementation guidelines for SHAPES architecture and application implementations are provided in a form of Q&A



in D4.1. The deliverable summarises numerous discussions among WP4, WP5, WP6 and WP8 in order to align the understanding of how data is managed in the SHAPES Platform between technology providers from WP5, architecture developers in WP4, end users from WP6 and data management plan DMP WP8 (confer D4.1 SHAPES TP Requirements and Architecture, version 1.3, p. 54-58). The current plan in WP8 is that updated SHAPES Data Management Plan D8.13 includes summaries of SHAPES architecture and application (pilot) implementation strategies and implementation guidelines.



## 8 Main ethical challenges, risks and viewpoints emerged

This chapter summarises the main ethics topics and challenges discussed with partners and EAB during the reporting period. Most of the issues discussed have emerged during the DPIA's work, but other issues have also been raised regarding, for example, SHAPES business.

### 8.1 Topics discussed with partners during the reporting period

#### 8.1.1 Implementation of the SHAPES General ethical requirements

Situation: SHAPES Ethical Requirements in D8.14 were categorised as General ethical requirements, Ethical requirements for the technology, Ethical requirements for the user processes and support and Ethical requirements for the business/governance model. In the D3.9 those requirements were further analysed and categorised, and finally, in D4.1, translated into technical system specifications. General ethical requirements were left out of this process. As stated in D3.9 (p. 84), *“it is essential that the SHAPES Platform and its implementation, including the integration of digital solutions, take general ethical requirements as formulated by WP 8 into consideration”*. However, WP5 and the SHAPES Digital Solutions have adopted the approach that they follow only the D4.1 requirements. This means that the D5.3 does not provide information regarding General ethical requirements for digital solutions.

Next steps: In the Table 15 are listed those general ethical requirements which should be mapped against digital solutions. While writing this document, there is currently a discussion about how this work could best be done together in the WP5 and WP8 ethical risk work.

Table 15 SHAPES General ethical requirements relevant for each digital solution

Nro	General ethical requirement
GE 1	Maximise the level of fundamental rights of older persons and of care givers that SHAPES and its digital services can promote. Ensure they do not violate any fundamental rights of older persons and/or other stakeholders (e.g., non-discrimination, dignity, integrity and privacy when having robots, web-cameras at home) (Fundamental Rights Impact Assessment FRIA).
GE3	Be aware of the four biomedical principles and perspectives of care ethics. Apply and promote those within SHAPES (justice, beneficence, non-maleficence autonomy, empathy, relationships, uniqueness).
GE5	Maximise the level of human capabilities of older persons and caregivers that SHAPES and its digital services can promote. Ensure that SHAPES is not detrimental to any human capabilities of older people and/or other stakeholders. Pay attention especially to those who are more vulnerable of with disabilities.
GE58	Apply Design for All, and Universal Design –approaches in SHAPES development
GE47	Be aware of the importance and challenges with the terminology regarding older persons, also in your own language as well as the diversity of older persons as a group. Use non-stigmatising language.



### 8.1.2 SHAPES Data Model and processing of personal data

**Situation:** During the reporting period, a number of discussions were around the questions related to the processing of personal data provided by several digital solutions. How can we ensure, that this combination of personal data from various digital solutions is compliant with GDPR and minimises the risks related to privacy and data protection?

**Answer:** The SHAPES Platform will provide a federated data model approach. Each Digital Solution retains the access control of their own platform and data. Hence, the symbloTe platform functions as a mediator between Digital Solutions for IoT -type of medical data, while FHIR Interoperability component offers similar translations for exchanging Medical Information among interconnected systems. Those mechanisms define a mapping between different Data Models used on Digital Solutions aiming to exchange their data. Matching parameters between Data Models used by each entity participating in the exchange of information thus enables them to understand the data that is being transmitted between them. The important aspect of the SHAPES interoperability mechanisms is that NO actual personal data is transmitted to the core of the SHAPES Platform. Only metadata, needed to align diverse data models, is being provided, after that both entities are able to exchange their data and information bilaterally. This way, issues of data privacy are reduced to a minimum, as there is no personal identifiable data sent to interoperability mediation components in the SHAPES core. See also chapter “Data Management”.

The use of anonymisation/pseudonymisation techniques were further discussed and clarified in the WP6 telco on 24<sup>th</sup> June 2021. The materials and recordings of the meeting can be found in the WP6 Teams folder.

### 8.1.3 The use of external services/devices in SHAPES service provision

**Question:** Among the SHAPES digital solutions there is a need to use external services and devices in the SHAPES service provision. This includes so far

- 1) The use of Google Transfer and Google Analytics. These services have their servers located in the EU. In practice, there are no relevant EU alternatives for such services.
- 2) The use of Fitbit device (owned by Google), which in their privacy policy declares that personal data collected via the device will also transfer to US. There are several devices like Fitbit on the market provided by EU-based companies.





Answer: The pilot sites have been instructed to list those entities within transfers to third countries in their DPIAs. Mostly, the major companies claim they abide by the GDPR (and, therefore, would not transfer data outside the EU/EEC in their own interest), but in practice, many infringements have been seen. In his doctoral thesis, Wiatrowski (2021, 157) argues that even enormous fines have not stopped Google from acting how it pleases. Therefore, it is best to take that aspect into consideration and openly declare the services used (SHAPES D8.11, 2021).

WP8 cannot recommend using Fitbit in SHAPES. Fitbit has not stated how they would provide supplementary measures for mitigating the stated possibility of US authorities accessing personal data. There are derogations, such as explicit consent, for situations where the GDPR's level of protection cannot be provided by supplementary measures listed in Article 49. However, the Article has an exceptional nature and must be interpreted restrictively and mainly relates to processing activities that are occasional and non-repetitive. During the SHAPES project, the transfers and processing activities would undeniably be repetitive, and the situation would become even more difficult after the research project in the anticipated commercial version of SHAPES. We are also must consider potentially vulnerable natural persons, and in those cases the more complicated the matter, the harder it is to make certain the data subjects are actually adequately informed of the processing they are consenting to. Buying a device and a service as a consumer is one thing and providing a service or asking people to use services in a research project is another. It would be generally more favourable to use EU devices and services in EU funded projects if there are suitable solutions available on the market.

#### 8.1.4 Legal basis for research data processing in SHAPES

Question: SHAPES is collecting a lot of personal data to conduct research. The purpose of this study is to provide critical information on the well-being and needs of older adults, and/or effectiveness of SHAPES (e.g., harmonised psychosocial & sociodemographic data will inform on both older adults' wellbeing and evaluate SHAPES). The aim of this research is not just to promote the uptake of technology and businesses. It can also be thought of as serving the public interest. Therefore the question of legal basis of processing personal data is relevant – could it also be public interest?

Answer: The conclusion is that the legal basis for the processing of personal data in the SHAPES project is consent (Article 6(1)(a) and Article 9(2)(a) GDPR). The main reason for this is that in a pan-European project, it is a solution that fits all the Use Cases. It can be seen appropriate when the data is collected directly from the data subjects. The consents will be requested in a written template, and alongside, the data subject will be provided with an information sheet in accordance with Articles 12 and 13 GDPR. (SHAPES D8.11, 2021).



### 8.1.5 Processing of harmonised data

Situation: Collection and processing of harmonised data has opened up several discussions related to GDPR issues, including the processors and controllers of that data, and the possibility to use the SHAPES Data Lake in the collection of the data (see Figure 14 and Figure 15).

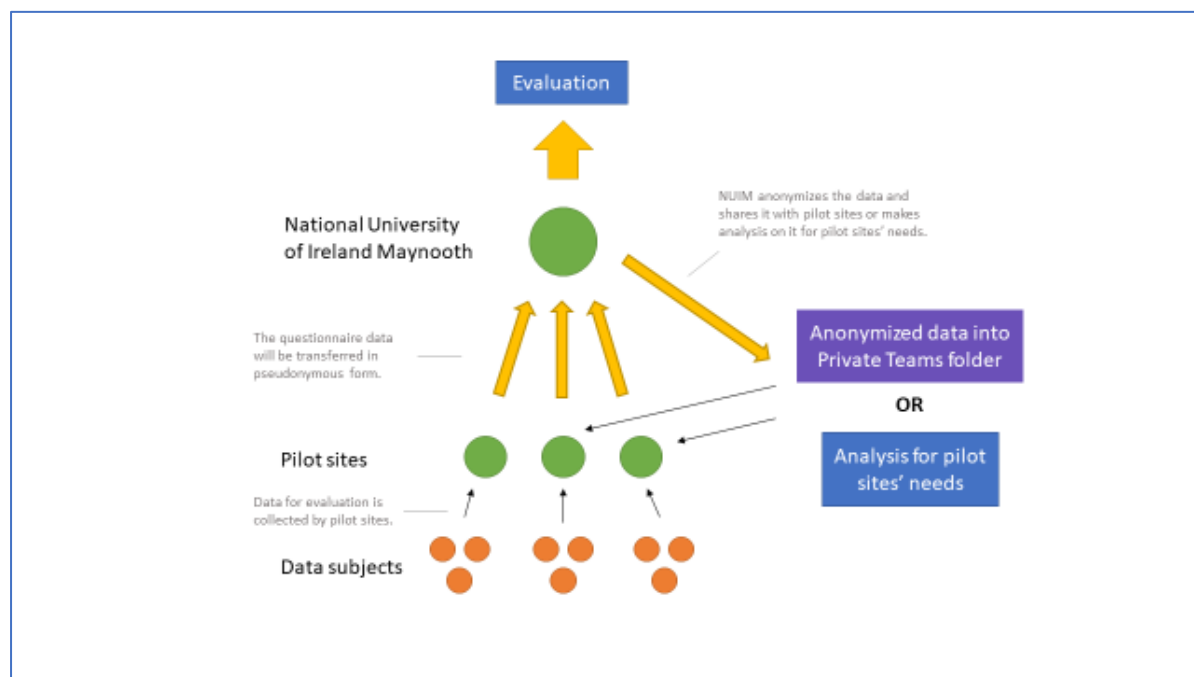


Figure 14 Alternative (a) for the processing harmonized data

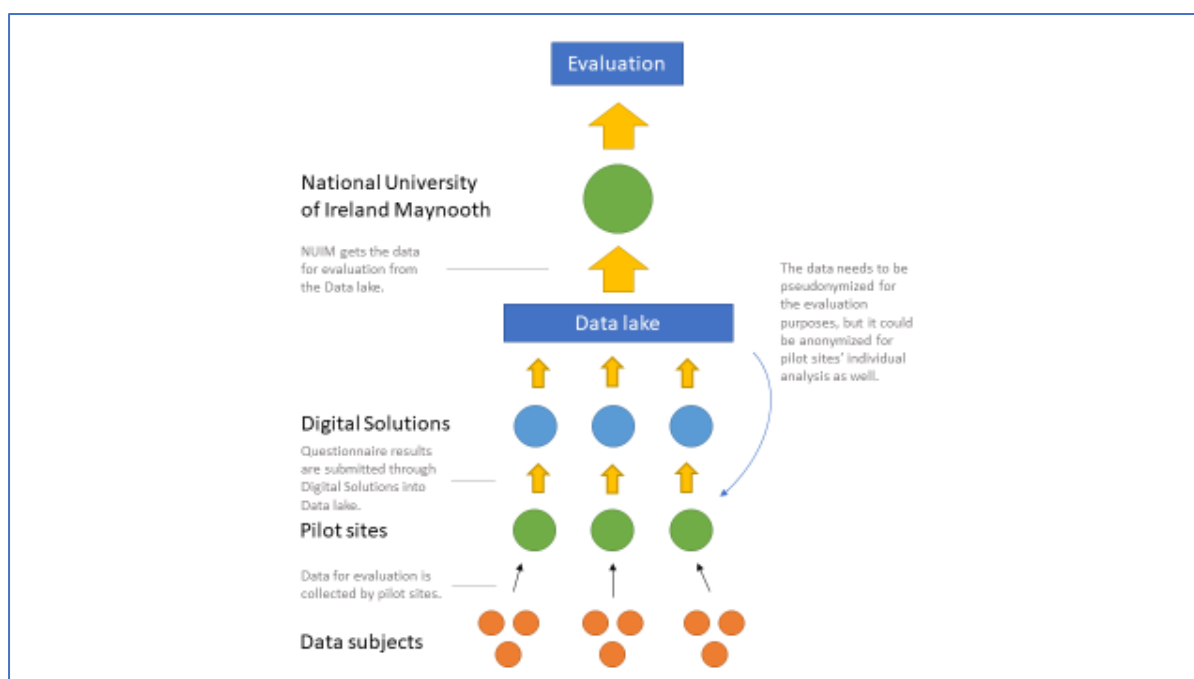


Figure 15 Alternative (b) for the processing of harmonized data



Answer: In the cross-alignment meeting on 23<sup>rd</sup> September 2021, it was decided not to use the SHAPES Data Lake in the collection of the harmonized data. However as it has been discussed that there is potential value a range of stakeholders in transferring psychosocial data to the platform in some way, and demonstrating related capabilities, this possibility remains under consideration, but likely only for later pilots.

While this deliverable is being written, a separate agreement template for sharing personal data acquired by harmonisation questionnaires between the pilot sites and Maynooth University is in preparation. This data is used mainly for analysing the outcomes of the whole project, but also for analysis performed by the pilot sites for writing scientific articles based on it. These activities will happen as part of the SHAPES project, and the data subject will be informed about them. It has been seen as appropriate to have an agreement in place for controller-to-controller situations in order to demonstrate compliance with GDPR, as is stated in Articles 5(2) and 24(1) (SHAPES D8.11, 2021).

It may be possible to apply joint controllership in processing of the harmonised data (discussions about this matter are ongoing).

#### 8.1.6 Secondary use of personal data in research

Several SHAPES work-package researchers have asked about the possibilities for the secondary use of personal data (including WP2, WP6).

Answer: Legislation concerning the secondary use of health-related data is fragmented within the EU. Generally, if further research is not specified accurately enough, such processing may be classified as ‘further processing’, and as such may be prohibited; because data may not generally be subjected to further processing in a manner that is incompatible with the purpose stated at the time of collection (Articles 5(1)(b) and 6(4) GDPR). Anonymisation could be an answer to these issues, but Member States’ authorities interpret it differently. Some of them believe that health-related data cannot remain useful while anonymised, and this makes open sharing difficult at this point. Upcoming supranational legislation is seen as one possible solution (SHAPES D8.11, 2021).

Some pilots will request the consents for making their own analysis for some years after the project. This will be done on the basis of Recital 33 GDPR, which allows the data subjects to consent for certain areas of scientific research, if the specific purposes cannot be identified when consenting. Specific safeguards will be applied in such scenarios in accordance with the European Data Protection Boards Guidelines 05/2020 on Consent, such as de-identifying those datasets and keeping the data only in the initial controller's possession. The pilots have also been instructed to inform the data subjects, when possible, of their research plans and stages of research as they clarify.



In the arrangement described above it is emphasized that the data protection principles still need to be applied to the data even when it has been anonymised in such a way that the controller is unable to re-identify the data subjects with the information at its possession. The main reason is the strict interpretation adopted by the European Data Protection Board's predecessor Article 29 Data Protection Working Party in its Opinion 05/2014 on Anonymisation Techniques. According to the Opinion, because the data controller needs to take new techniques into consideration, one can never be sure whether anonymous data might become personal data again.

### 8.1.7 Open sharing of data

Open access is the default setting for research data generated in Horizon 2020 projects. Still, according to the Commission, the approach can be described as "as open as possible, as closed as necessary", because it is acknowledged that not all data can be open. One of the reasons for opting out - partially or entirely - is that participation is incompatible with rules on protecting personal data.

As it is known, the objective of sharing research data openly is being impeded by the difficulties of anonymizing personal data reliably, so that it would become non-personal data in the sense of Recital 26 GDPR. This is problematic, because there is currently in preparation new Union level regulation on secondary use of health data (European Health Data Space), but many of the SHAPES pilots are already on the brink of beginning. In other words, there needs to be specified purposes and means of the data processing operations already at this point, but the regulatory situation remains somewhat unclear.

In Recital 162 GDPR it is stated that "the result of processing for statistical purposes is not personal data, but aggregate data, and that this result or the personal data are not used in support of measures or decisions regarding any particular natural person". Also, the opinion of the EU Article 29 working party (WP29, 05/2014) on Anonymisation Techniques makes a slight but meaningful distinction between anonymous data in general and anonymous aggregated data. The requirements for aggregated data to be considered are strict as well: the data are to be considered personal data if the raw data at event-level exist, but "if the data controller would delete the raw data, and only provide aggregate statistics to third parties on a high level, that would qualify as anonymous data". Thereby, the consents are requested from the data subjects also for creating aggregated data sets and storing it indefinitely for scientific purposes after making sure the original raw data has been deleted.

At the time being, it seems that only the sharing of high-level aggregated data can be considered. If there will be seen new regulation or further instructions from EU level authorities concerning anonymization techniques, the plans can be changed accordingly.



### 8.1.8 Data processing agreements, including UK

During the reporting period, a debate was also opened on whether separate data processing agreements are needed or whether SHAPES GA covers this aspect.

Answer: As is required in Article 28(3) GDPR, all the processing operations in SHAPES will be governed by a contract. For situations where a partner resides in the UK's jurisdiction, there is a slightly amended version in place, which also contains referrals to the UK Data Protection Act 2018 in relevant parts. The idea is that the data protection level provided in the GDPR is not decreased, but it merely takes the national rules into account for parties in the UK; thereby, in this case, providing additional protection, because the GDPR as itself is not applied in the UK anymore (SHAPES D8.11, 2011).

### 8.1.9 Legal frameworks for the SHAPES (technical platform)

The legal analysis concerns EU level hard and soft law and is extremely wide and complex. It is difficult to cover all relevant aspects extensively. The deadline for the document is M42. Before that - and as soon as possible - however, information is needed on the regulation of the SHAPES technical platform.

Solution: A D8.3 spin-off document D8.3.1 on the regulations relevant for SHAPES technical platform was provided in spring 2021. In addition, WP6 provided a separate document regarding the use of non-CE marked medical devices during the pilots.

In SHAPES pilots we are using medical device of class II-a and II-b within SHAPES. Depending on the call of the medical device either the Notified Bodies or the competent authorities of the different countries are responsible for the approval process. In principle (according to the Medical Device Regulation) it is possible to not complete the full approval process for a clinical trial for class II-a and II-b medical devices, but this is different in every country. While it seems to be possible in the Czech Republic and in Germany, it doesn't seem to be possible in the UK and Ireland. This means that we have to decide for each use case (and involved pilot sites) separately which approval is needed and if this is feasible in the remaining time (Grigoleit, 2021).

Recommendations: Review every potential medical device in use case, including software. Confirm if the medical devices are CE marked. Confirm if any partners want to use information collected during the pilot to inform future certification or commercialisation of these medical devices. Identify the Sponsor and have a conversation about indemnity arrangements. Identify the competent authority and confirm what applications are required (Grigoleit, 2021).



### 8.1.10 Trust of actors and review of real-world ransomware cases

Pseudonymisation and anonymisation are both highly recommended by the GDPR regulation, such techniques reduce risk and assist “data processors” in fulfilling their data compliance regulations. However, one current discussion in WP8 is addressed to the proofing of trust-security aspects and confidence of shared structures and risk management, e.g., “that only the pilot sites have the real names of the participants”, “the Digital Solutions only have an alias (or ID-number as a coded identifier) related with the participant (thus, data is pseudo-anonymized)”. In WP8, there are such questions as the following: how can “ID-number as a code” and “pseudo-anonymised data” be proofed as fully secured for SHAPES, e.g., trust of actors and review of real-world ransomware cases in where the risk is related to the actors itself? These are aspects to be investigated as part of the SHAPES Ethics Work in T8.4.

### 8.1.11 FAIR principles and the SHAPES Data Management Plan

Updating the Data Management Plan (DMP, D8.13), including the FAIR principles (see review comment), is a larger entity than it was originally thought. The key is to decide to what extent the DMP descriptions will be implemented during the SHAPES project - and to what extent the current update work regarding FAIR will only be included as part of the governance model to be created in WP3/T3.4.

SHAPES technical view for FAIR data is understood as a technical ecosystem that enables FAIR data and services development in a coordinated, interoperable and cross-disciplinary way.

- 1) DIGITAL OBJECTS such as data, code and other technological artifacts represented in standard formats;
- 2) using of Persistent Identifiers (PIDs) of DIGITAL OBJECTS;
- 3) DIGITAL OBJECTS related metadata and contextual documentation;
- 4) applied STANDARDS, CODES and DESIGN PATTERNS using of open and documented formats.

## 8.2 Challenges discussed with EAB members during the reporting period

Based on the discussions with the EAB members during the reporting period, the following issues related to contents of the D8.14 are especially important/critical:

**Digital Inclusion** has several angles: social inclusion, skills (e.g., digital literacy) and e-accessibility. All these perspectives are essential, see also the Directive 2019/882 on the accessibility requirements for products and services.





In addition to lifelong learning, the viewpoint regarding **the lack of social support of older persons** is essential in the SHAPES context. It is also important to remember that older persons may not be interested in using and buying new technology.

**Ethics of automatisisation of care**, including responsibilities and liabilities is a challenge, which has been lately discussed in academia and which is very relevant in the SHAPES context.

**The use of terminology** is essential. In SHAPES we can have an impact on how people talk about older persons in the future.

**Business Ethics and Ethics of service providers** is a multifaceted issue.

- How SHAPES Digital Service providers operate and take into account ethical requirements and the Code of Conduct
- The use of external service providers as part of the current SHAPES Digital Solutions, such as Google analytics and Google translator & ethics

Business ethics is a complex matter and may not be straightforward enough to put into practice in a holistic way (**without sub-optimisation**).

- How do we make sure that businesses and their solutions/data processing are transparent, and how can we figure out the impacts of businesses?
- It is essential to investigate during the project where this all new technology is really needed from the viewpoint of older persons.
- The tension between ethics and businesses is present in the SHAPES project. The purpose of SHAPES is not to promote technology and digital services, but to investigate their pros and cons in a critical way, including ethical viewpoints. In SHAPES, there might be outcomes which are negative from the viewpoint of certain digital service.





## 9 Summary and conclusions

Ethics work has proceeded according to the original plans, although including small delays in ethics risk work. No significant new ethical challenges have emerged during the reporting period. Ethical issues have focused in particular on the implementation of ethical requirements and on various ethical and data protection issues for pilots.

The ethics work package WP8 has produced several deliverables during the reporting period and has organised and participated in various meetings where ethical issues have been addressed. In addition to this, several smaller meetings or email discussions have been held, especially with the pilots.

Ethics -related work, based on WP8 inputs, has been intensive inside various work packages. Ethics requirements and guidelines have been taken into account in SHAPES deliverables and in the technical and organisational solutions created.

In the appendix 1, there is a summary of ethics topics and challenges discussed during the first two years of the project.



# 10References

## *10.1 SHAPES Deliverables*

SHAPES Grand Agreement (2019).

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

SHAPES D3.9. (2021). Final User Requirements for the SHAPES Platform

SHAPES D4.1. (2021). SHAPES TP and Architecture

SHAPES D5.3. (2021). SHAPES Digital Solutions

## *10.2 Other SHAPES documents*

SHAPES Review report. (2020). General Project Review Consolidated Report

Grigoleit, S. (2021). SHAPES Summary of the meeting, emails, further literature research about non-CE marked medical devices within SHAPES

Ethical Self-Assessments of each WP

Ethical Self-Assessments of each pilot



## 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)
<b>Fundamental rights (3.1)</b>	<b>This deliverable reports the progress regarding the definition and implementation of ethical requirements in section 5.</b>
<b>Biomedical ethics and ethics of care (3.2)</b>	
<b>CRPD and supported decision-making (3.3)</b>	
<b>Capabilities approach (3.4)</b>	
<b>Sustainable development and CSR (4.1)</b>	
<b>Customer logic approach (4.2)</b>	
<b>Artificial intelligence (4.3)</b>	
<b>Digital transformation (4.4)</b>	
<b>Privacy and data protection (5)</b>	
<b>Cyber security and resilience (6)</b>	
<b>Digital inclusion (7.1)</b>	
<b>The moral division of labour (7.2)</b>	
<b>Care givers and welfare technology (7.3)</b>	
<b>Movement of caregivers across Europe (7.4)</b>	

**Comments:** \_\_\_\_\_

