SHAPES

Smart and **H**ealthy **A**geing
through **P**eople **E**ngaging in supportive **S**ystems

D8.14 – Final SHAPES Ethical Framework Final Version

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Table of Acronyms and Abbreviations

Table 3 Acronyms and Abbreviations

Acronym	Full Term
AI	Artificial intelligence
CERT	Computer Emergency Response Team
CFR	Charter of Fundamental Rights
CJEU	Court of Justice of the European Union
CPS	Cyber-physical system
CRPD	United Nations Convention on the Rights of Persons with Disabilities
CSIRT	Computer Security Incidence Response Team
CSR	Corporate Social Responsibility
DPIA	Data Protection Impact Assessment
ECHO	European network of Cybersecurity centres and competence Hub for innovation and Operations

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EIP-AHA	European Innovation Partnership for Active and Healthy Ageing
EPSU	European Public Service Union
EU4Health	Programme for the Union's action in the field of health, 2021–2027
GDPR	General Data Protection Regulation
H&C	Health and Care
HLGE	High-Level Expert Group on Artificial Intelligence
HMI	Human-machine interaction
IA	Innovation Action
IaaS	Infrastructure as a service
ICT	Information and communication technology
IOC	Indicator of compromise
IoT	Internet of things
ISMS	Information security management system
IT	Information technology
LTC	Long-term care
NIS	Network and information systems
OES	Operators of essential services
OSE	European Social Observatory
PaaS	Platform as a service
RDSP	Relevant digital service providers
RWD	Real-world data
SA	Situational awareness
SaaS	Software as a service
SDG	Sustainable development goals
SIEMs	Security information and event managers
SLBMC	Service logic business model canvas
SME	Small and medium size enterprises
SPC-WG-AGE	Social Protection Committee Working Group on Ageing
TEU	Treaty on European Union

Keywords

Ethical requirements, fundamental rights, values and norms, ethical guidelines, privacy and data protection, cybersecurity

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Executive Summary

This deliverable, Final SHAPES Ethical Framework (D8.14), outlines the ethical framework for the SHAPES solution. From these features, the ethical requirements for the SHAPES technology and user support processes, as well as governance, business, and ecosystem models, are derived.

From an ethics viewpoint, SHAPES is a diverse initiative. Ethical requirements and their implementation are essential for the sustainability of SHAPES. Ethical requirements stem from both EU fundamental rights and different ethical norms and approaches, as well as from various ethical guidelines for business and technology. In addition, the General Data Protection Regulation (GDPR) is used as a foundation when addressing data protection and cybersecurity requirements (Figure 1).

The purpose of the ethical requirements is to ensure that the SHAPES initiative becomes an ethically responsible endeavour and a positive innovation for its various end-users and service providers, as well as for society as a whole. Alongside user requirements, ethical requirements are particularly important when developing and employing solutions linked to fundamental rights and when the target group is older persons.

Figure 1 SHAPES ethics "word cloud"

After the introduction and presentation of SHAPES in section 4, pertinent norms and values are discussed in the context of SHAPES, the purpose of which is to provide an overview of the value base for the development and use of SHAPES. In section 5, various guidelines and approaches relevant to SHAPES governance, businesses and technology are discussed. In section 6, privacy and data protection regulation are presented. In section 7, the focus is on data security and cybersecurity. Section 8 investigates potential challenges and options for SHAPES as identified in both academic discussions and literature. Based on this desktop study, covered in sections 4–8, the ethical requirements for the SHAPES solution are defined in section 9. The SHAPES Code of Conduct in section 10 summarizes the key aspects of this framework. Section 11 presents the conclusions.

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1 Introduction

1.1 Rationale and purpose

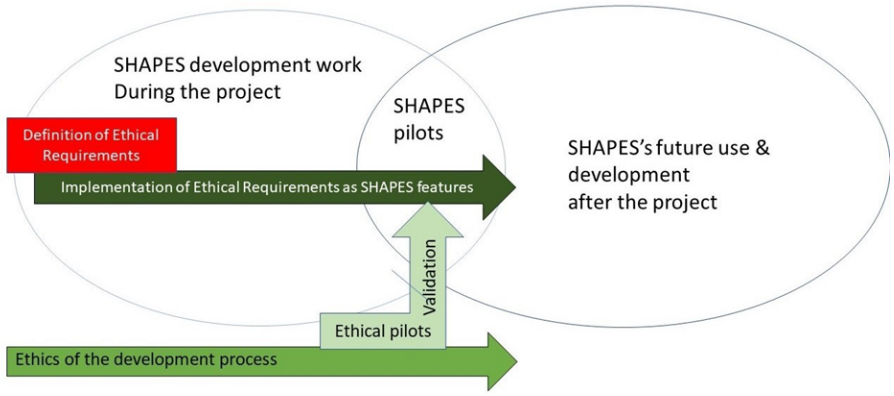

Figure 2 Ethical dimensions of the SHAPES Project

The focus of this deliverable, Final SHAPES Ethical Framework (D8.14), is the definition of the ethical requirements of the SHAPES solution (Figure 2). Here the term 'SHAPES solution' generally refers to the SHAPES Digital Solutions, SHAPES Marketplace, SHAPES Integrated Care Platform and the SHAPES Ecosystem. In the analyses within the various subsections and in the context of the ethical requirements (section 8), the term is more precisely defined according to the SHAPES component being addressed.

The aims of this deliverable are 1) to provide a better understanding of the ethical aspects relevant to the SHAPES solution and 2) to define the ethical requirements that the SHAPES technology, user support processes, business model, governance and ecosystem should adhere to. This deliverable is part of the normative guidelines and requirements that WP8 will provide for the SHAPES project and solution (Table 4). Please note that the legal frameworks and the data management plan are discussed in separate deliverables SHAPES Data Management Plan (D8.13)[1] and Regulatory Frameworks for Pan-European Smart and Healthy Ageing (D8.3).

The purpose of the Ethical Framework and the ethical requirements herein is to ensure that SHAPES becomes a positive innovation for its various end-users and service providers, as well as for society.

This final version of the SHAPES Ethical Framework is based on the initial SHAPES Ethical Framework (D8.4) submitted in M7 in April 2020. Initial ethical requirements defined in deliverable D8.4 are now specified in more detail and organised according

[1] An updated version of The Data Management Plan (as RFC) is ready by the end of June 2021. And the release based on partners' comments is ready by the end of year 2021.

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to key support processes and use cases. New subsections related to the Convention of the Rights of Persons with Disabilities (3.3.3 and 3.3.4), EU policies (4.4), lifelong learning, (7.3) SHAPES terminology (7.5), and SHAPES & Covid-19 (7.6) have been provided. In addition, the SHAPES Code of Conduct has been developed to communicate the basic values, principles, and ethical guidelines for the SHAPES Integrated Care Platform.

Table 4 WP8 deliverables providing guidelines and requirements

Deliverable		Focus and Content
Baseline for Project Ethics D8.2	M6	Provides guidelines and templates for research integrity and for the ethics management of the SHAPES project.
SHAPES Ethical Framework D8.4	M7 and M18	Provides ethical requirements for the SHAPES solution (technology and services, user processes and training, business/governance, and ecosystem models). Serves as guidance for developing SHAPES such that it complies with common ethical standards, regulations, and policies to ensure that the SHAPES solution will be ethically acceptable. Legal frameworks for Smart and Healthy Ageing and for Privacy and Data Protection will be investigated in more detail later in separate deliverables D8.3, D8.11 and D8.12. Data Management is investigated in separate deliverable D8.13.
SHAPES Data Management Plan 8.13	M6	Provides Data Management Plan for: 1) SHAPES solution (data processed on the SHAPES platform) 2) SHAPES R&D process (research data collected and processed during the SHAPES project). An updated version of The Data Management Plan (as RFC) is ready by the end of June 2021. And the release based on partners' comments is ready by the end of year 2021.
Regulatory Frameworks for Pan-European Smart and Healthy Ageing D8.3	M42	Analyses the extent to which current legal frameworks facilitate the creation of pan-European systems for healthy ageing. Spin off –document D8.3.1 - The SHAPES Integrated Platform, the SHAPES DIGITAL Solutions in the EU Legal Context has been provided in April 2021.
SHAPES Privacy and Data Protection Legislation and Impact Assessment D8.11 and D8.12	M24 and M48	Elaborates on privacy and data protection regulation (based on the initial requirements defined in D8.4) and provides Privacy and Data Protection Impact Assessments of the SHAPES solutions to be piloted.
Privacy and Ethical Risk Assessments D8.8 and D8.9	M12 and M24	Analyses risks and mitigation strategies and actions related to the ethical and privacy risks of the SHAPES solution (technology and services, user processes and training, business/governance, and ecosystem models).

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1.2 Methodology and key inputs and outputs

The methodology related to the definition of ethical requirements is not yet well established in literature – at least if compared to the methodologies for defining user requirements. In addition, both the term 'ethics' or 'ethical' and the concept of 'requirement' are vague. Often, no distinction is made between the requirements of research ethics and the ethical requirements of the solution being developed (see, e.g., HORIZON2020 Ethical Self-assessment, 2019; RRI handbook, 2019).

The approach to defining ethical requirements in this deliverable is based on the ethics work developed during several Horizon 2020 projects, including INACHUS, WeLive, RANGER, MARISA, and ANDROMEDA (see, e.g., Sarlio-Siintola & Tammilehto, 2019). Ethical requirements are defined on the basis of relevant principles, values, and norms of the domain and on various documents providing normative guidelines, recommendation, and requirements, as well as conceptual approaches. See the Table 5.

Table 5 Effects, source materials and method of analysis in SHAPES

Section	Effect on SHAPES	Source materials	Method
4. Values and norms	How can SHAPES protect and promote the rights, capabilities, and wellbeing of persons?	Fundamental rights, conventions, ethical theories	Content analysis
5. Ethics guidelines in business and technology	How can SHAPES promote sustainable development and digital transformation of human-centred services?	Ethical guidelines and agendas Scientific articles and publications	Content analysis Literature review
6. Privacy Data Protection	What are the privacy and data protection requirements for the SHAPES technology and organisational arrangements?	GDPR	Legal analysis
7. Cybersecurity and resilience	What are the ethical aspects of cybersecurity and resilience for the SHAPES technology and its organisational arrangements?	Articles and other literature	Literature review
8. Challenges identified	What kind of key challenges have been identified in digital solutions for older people?	Articles and other literature	Literature review
9. Ethical requirements	What are specific normative requirements for the SHAPES integrated care platform?	Contents of sections 3–8	Content analysis Workshops and Brainstorming sessions
10. Code of Conduct	What are the key principles, values, and norms of the SHAPES ethical framework?	Contents of sections 3-8	Content analysis

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The implementation of ethical requirements affects technical solutions and services, as well as the organisational arrangements of SHAPES as part of the SHAPES Integrated Care Platform, Digital Solutions, Marketplace, and Ecosystem. Ethical requirements therefore provide input to both the software engineering process (WP3, WP4, WP5) and to the design of the SHAPES governance, business and ecosystem and support processes (WP3, WP6 (pilots), WP7, WP9).

1.3 Structure

After the introduction and presentation of the SHAPES solution in section 4, pertinent norms and values are discussed in the context of the SHAPES solution, the purpose of which, is to provide an overview of the value base for the development and use of SHAPES. In section 5, various guidelines and approaches relevant to SHAPES businesses and technology are discussed. In section 6, privacy and data protection regulation is presented. Section 7 focuses on data security and cybersecurity. Section 8 investigates potential challenges and options for SHAPES as identified both in academic discussions and literature. Based on this desktop study, covered in sections 4–8, the ethical requirements for the SHAPES solution in section 9 are defined. The SHAPES Code of Conduct in section 10 summarises the key aspects of this framework. Section 11 presents the conclusions.

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2 The SHAPES solution in a nutshell

SHAPES Innovation Action (IA) is a pan-European endeavour seeking to build, pilot and deploy a large-scale, EU-standardised open platform. The integration of a broad range of technological, organisational, clinical, educational, and societal solutions seeks to facilitate long-term healthy and active ageing and the maintenance of a high-quality standard of life.

- SHAPES Integrated Care Platform is an open, EU-standardised platform based on four factors: home, behaviour, market, and governance (Figure 3). Big data analytics and artificial intelligence (AI) analyse information pertaining to health, environment and lifestyle and individual needs, and create user profiles and deliver personalised solutions. Adherence to EU data protection rules ensures user privacy, safety, security, trust, and acceptance.
- SHAPES Digital Solutions include assistive robots, eHealth sensors and wearables, Internet of Things (IoT)-enabled devices and mobile applications (apps).
- SHAPES Ecosystem is a network of relevant users and key stakeholders working together to scale-up the platform and digital solutions. The SHAPES ecology – a network comprised of networks – enables the creation of a reference architecture and standardised platform, platform testing and validation via large-scale piloting, the preparation of SHAPES's deployment and standardisation across Europe.
- SHAPES Marketplace seeks to connect demand-and-supply across H&C delivery and to facilitate the co-creation of affordable, effective, and trustworthy solutions. A dynamic catalogue of solutions and services allows the transparent expansion of the market offer, prevents vendor lock, and enhances the competitiveness of the EU H&C industry.
- SHAPES Recommendations provide guidelines, a roadmap, and an action plan, including a set of priorities dedicated to standardisation and to supporting key EU stakeholders to foster the large-scale deployment and adoption of digital solutions and new integrated-care services in Europe. This will be based on evidence-based results from SHAPES, i.e., the recognised added-value of the SHAPES platform to support AHA; extend independent, empowered and socially connected living; and improve the long-term sustainability of H&C delivery systems in Europe. (SHAPES, 2019).

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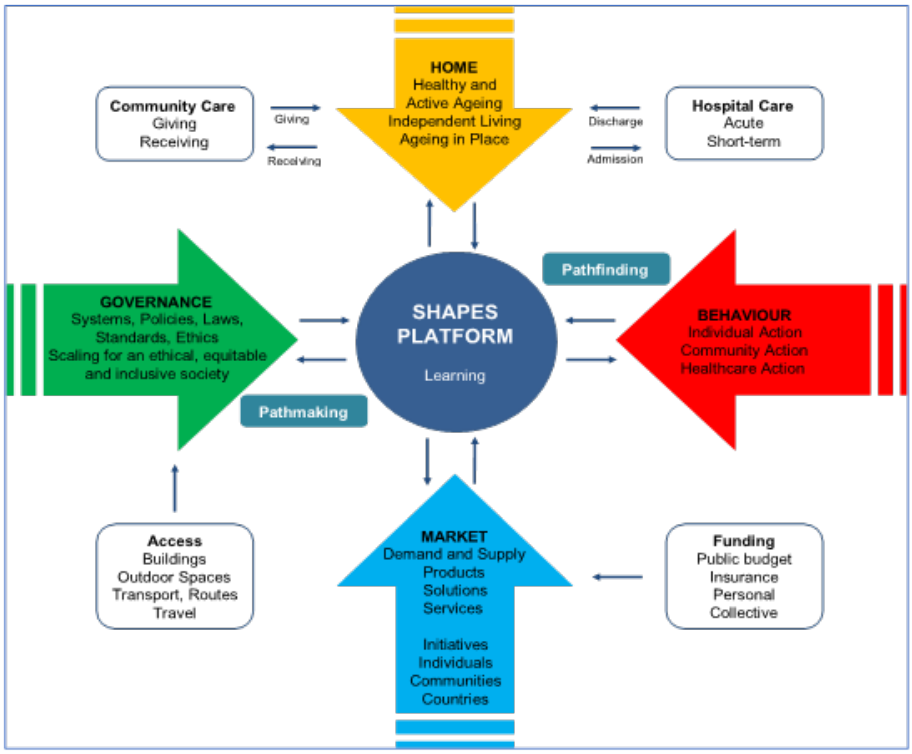

Figure 3 The SHAPES Integrated Care Platform (Adapted from SHAPES, 2019, p. 85)

The SHAPES Platform is designed to promote inclusive, smart, and healthy ageing. SHAPES emphasises that the home is much more than a house-space; it entails a sense of belonging, a place, and a purpose in the community. Care-giving in the community is a crucial element of this support; along with older individuals feeling empowered to make decisions about how and from whom they receive care. The Platform is continually learning from the needs and preferences expressed in the active behaviour of different users. The Platform facilitates the cross-over of individual, community and clinical action-taking; integrating interaction. This high level of integration is key to Platform user's sense of coherence. SHAPES's interactions necessarily constitute a market for products, services, and opportunities. This market must be managed to allow equitable access for all, utilizing a range of funding mechanisms. SHAPES embraces market shaping to ensure fairness in access and competition in innovation, locally, nationally, across Europe and globally. The Platform is secure and reliable; allowing users the degree of anonymity they choose, while also providing them with the benefits of a population level evidence-based resource. SHAPES promotes ethical, equitable and inclusive values, which will be achieved through good platform governance. It promotes and scales-up good practices through directly engaging with local and national authorities, ensuring that the broader systems and policy context is contributing to and learning from the Platform, priming itself for innovation and evolution. The Platform facilitates the navigation of complex referral processes, clinical services, community supports, welfare entitlements and citizens' rights. It also facilitates path-making through, for instance, community engagement, contributing to local events, mapping age-friendly routes. (SHAPES 2019).

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3 Norms and values in the context of SHAPES

In this section, we introduce some central frameworks and theories within social ethics that are relevant to and helpful in the planning and building of SHAPES from the perspective of older persons and other end-users. These are: The Charter of Fundamental Rights of the European Union, the Convention on the Rights of Persons with Disabilities, biomedical ethics, the ethics of care, and the capabilities approach.

3.1 EU Fundamental Rights

3.1.1 Introductory remarks

As provided for in Article 2 of the Treaty on the European Union (TEU), the EU is "founded on the values of respect for human dignity, freedom, democracy, equality, the rule of law and respect for human rights, including the rights of persons belonging to minorities." Article 2 also highlights that these values "are common to the Member States in a society in which pluralism, non-discrimination, tolerance, justice, solidarity and equality between women and men prevail." (TEU, 2012 p. 17). Further, the EU "places the individual at the heart of its activities by establishing the citizenship of the Union and by creating an area of freedom, security and justice" (EU CFR, 2016 p. 395).

Article 3(1) of TEU states that the EU's aim is "to promote peace, its values and the wellbeing of its peoples". In addition, Article 3 lists a number of objectives that the EU must pursue. One of those goals is the establishment of the internal market, which was the original tenet of the European Economic Community (EEC), and which remains at the core of the EU. Within the internal market, goods, services, capital, and people can travel freely. All EU citizens have the right to study, work or retire in a Member State other than their home state. (TEU, 2012 p. 12).

Article 6 of TEU provides for the protection of fundamental rights in the EU context. According to Article 6(1), the EU recognises the rights, freedoms and principles set out in the Charter of Fundamental Rights (EU CFR). Article 6(2) mandates the EU's accession to the European Convention for the Protection of Human Rights and Fundamental Freedoms (European Convention on Human Rights – ECHR). Article 6(3) affirms that fundamental rights, as guaranteed by the ECHR and as they result from the constitutional traditions common to the Member States, "shall constitute general principles of the Union's law". (TEU, 2012 p. 19).

The EU CFR was solemnly proclaimed on 7 December 2000 by the European Parliament, the Council, and the Commission. Until 2009, it remained a non-binding document. Following the entry into force of the Treaty of Lisbon in 2009, the EU CFR has acquired the same legal status as the Treaties by virtue of Article 6(1) TEU. The

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legal aspects related to the applicability of the Charter will be expanded upon in the Regulatory Frameworks for Pan-European Smart and Healthy Ageing (D8.3).

3.1.2 The EU Charter of Fundamental Rights

The Charter aims to "strengthen the protection of fundamental rights in the light of changes in society, social progress and scientific and technological developments" (CFR, 2016 p. 395). It comprises seven titles and 54 Articles. The six substantive titles of the EU CFR are as follows: Dignity (Articles 1–5); Freedoms (Articles 6–19); Equality (Articles 20–26); Solidarity (Articles 27–38); Citizens' Rights (Articles 39–46); and Justice (Articles 47–50). The EU CFR thus encompasses civil and political rights, as well as economic, social, and cultural rights. It also incorporates 'new' rights, such as the right to data protection and the rights of the elderly. (CFR, 2016).

When it comes to the meaning of the rights included in the EU CFR, Article 52(3) EU CFR provides that "[i]nsofar as this Charter contains rights which correspond to rights guaranteed by [the ECHR], the meaning and scope of those rights shall be the same as those laid down by the said Convention. This provision shall not prevent Union law providing more extensive protection". Moreover, Article 52(1) CFR requires any limitation on the exercise of the rights and freedoms recognised by the Charter to be provided for by law and to respect the essence of those rights and freedoms. Hence, subject to the principle of proportionality, restrictions can only be imposed where they are necessary and genuinely meet objectives of general interest recognised by the EU, or if they are needed to protect the rights and freedoms of others. (CFR, 2016 p. 406).

All fundamental rights protected and promoted by the EU CFR apply to older persons. In the Table 6, we highlight how EU CFR Articles are relevant in the context of SHAPES. It is essential that all activities within SHAPES promotes as many rights as possible and that SHAPES activities do not in any way undermine them.

Table 6 EU Fundamental Rights in the context of SHAPES

Chapter/ article	Analysis in more detail	Implications for the SHAPES solution
CHAPTER 1 Dignity	**Dignity is a starting point for SHAPES. These articles play a central role in SHAPES.**	
1. Human dignity	Smart and healthy ageing aims to promote human dignity by promoting a good quality of life. Human dignity can also be seen explicitly: for example, in the (everyday) language used around older persons. Depersonalisation has to be avoided. In research and development activities and in governance, special attention must be paid to human dignity. The Explanations to	SHAPES Platform and Digital Solutions (for example, robots and virtual nurses). Research and co-creation with end-users as part of SHAPES Platform and SHAPES Marketplace.

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	the Charter (pp. 17–35) state: "It results that none of the rights laid down in this Charter may be used to harm the dignity of another person, and that the dignity of the human person is part of the substance of the rights laid down in this Charter. It must therefore be respected, even where a right is restricted."	Participation in the SHAPES governance. Language to be used.
2. Right to life	SHAPES promotes the right to life by aiming to improve the health of older persons, thus enabling a better and longer life.	SHAPES Platform and Digital Solutions.
3. Right to the integrity of the person	As everyone has the right to respect for one's physical and mental integrity, in SHAPES special attention must be paid to the free and informed consent related to research activities and service provision, and to their impact on living conditions. For research activities, the procedures are clear, but it might be more difficult sometimes to define this in the context of co-creation and governance work.	SHAPES Platform and Digital Solutions and consents (for example hosting a company robot, a webcam or assistant such as Alexa). Research and co-creation with end-users as part of the SHAPES Platform and SHAPES Marketplace. Participation in the SHAPES governance.
4. Prohibition of torture and inhuman or degrading treatment or punishment	The adoption of the SHAPES vision and Integrated Care Platform can also help reduce inhuman and degrading treatment and punishment, since the new SHAPES human, organisational, technological and ethical approaches reinforce human dignity, the right to life and the right to integrity, as well as the right to feel safe and secure.	SHAPES Ecosystem and Platform.
5. Prohibition of slavery and forced labour	Though not directly relevant to SHAPES activities, this may be relevant in the context of professional caregiving. Human trafficking is a growing problem, and victims may be forced to work as caregivers. If signs of trafficking or forced labour are indirectly detected, it needs to be reported according to the participant country's procedures.	SHAPES Ecosystem and Platform.
CHAPTER 2 Freedoms	**Freedoms play a central role in SHAPES.**	
6. Right to liberty and security	Everyone has the right to feel safe and secure within SHAPES activities, and this must be promoted. *A feeling of security* may be threatened when SHAPES researchers and developers meet with older people if special attention is not paid to establishing a safe space.	SHAPES Platform and Digital Solutions. Research and co-creation with end-users as part of the SHAPES Platform and SHAPES Marketplace.

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7. Respect for private and family life	Special attention must be paid to home visits and to the impact on the living conditions. Private and family life should not be affected by participation in SHAPES. The respect of private and family life should be reinforced by SHAPES efforts to ensure a longer stay at one's own home.	SHAPES Platform and Digital Solutions (e.g. hosting a company robot, a webcam, or an assistant such as Alexa). Research and co-creation with end-users as part of the SHAPES Platform and SHAPES Marketplace.
8. Protection of personal data	This is analysed in more detail in section 5.	SHAPES technology and SHAPES organisational arrangements.
10. Freedom of thought, conscience, and religion	SHAPES activities are not likely to threaten this right. By contrast, this right will be promoted by SHAPES, as older persons' own thoughts are valued and appreciated as part of co-creation.	Research and co-creation with end-users as part of the SHAPES Platform and SHAPES Marketplace.
11. Freedom of expression and information	SHAPES activities are not likely to threaten this right. By contrast, this right will be promoted as older persons' own thoughts are valued and appreciated as part of co-creation and governance.	SHAPES Platform and Digital Solutions (for example, information collected by assistants or robots are at no point in time to be used against the individuals). Research and Co-creation with end-users as part of the SHAPES Platform and SHAPES Marketplace. Participation in the SHAPES governance.
12. Freedom of assembly and of association	SHAPES activities aim to increase the capabilities of older persons, and SHAPES will indirectly increase opportunities to turn these rights into action.	SHAPES Care Platform and Digital Solutions. Participation in the SHAPES governance.
13. Freedom of the arts and sciences	SHAPES activities are not likely to threaten this right and vice versa: indirectly, SHAPES aims to increase opportunities to take part in art and science activities.	SHAPES Platform and Digital Solutions.
14. Right to education	SHAPES favours lifelong learning as a right but also the benefits of learning for the ageing population (or anyone).	SHAPES Platform and Digital Solutions. Research and co-creation with end-users as part of the SHAPES Platform and SHAPES Marketplace.
15. Freedom to choose an occupation and the right to engage in work	This right is relevant with regards to professional caregivers of older people.	SHAPES Ecosystem.

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16. Freedom to conduct a business	SHAPES open innovation platform offers business possibilities for various types of organizations providing services for older persons.	SHAPES Ecosystem and Marketplace.
17. Right to property	SHAPES does not threaten this right. SHAPES will endeavour to ensure that material collected (conversations etc.) is lawful and does not threaten the right to property	Research and co-creation with end-users as part of the SHAPES Platform and Marketplace.
CHAPTER 3 Equality	**This chapter is important for SHAPES.**	
21. Non-dis-crimination	Age and disability are mentioned as grounds upon which discrimination is prohibited. SHAPES aims to prevent non-discrimination, for example, regarding the language used about the ageing population/older persons and persons with disabilities, and by improving their abilities to participate in everyday life. "Positive discrimination" plays a role in SHAPES in how the services/platform are tailored to the needs of older persons.	Language to be used. SHAPES Platform and Digital Solutions. Research and co-creation with end-users as part of the SHAPES Platform and SHAPES Marketplace. Design for all –approach in the development.
22. Cultural, religious, and linguistic diversity	SHAPES activities aim to promote all of these, but these also demand special understanding from each SHAPES researcher/developer.	SHAPES Digital Services and user interfaces. Research and co-creation with end-users as part of the SHAPES Platform and SHAPES Marketplace.
23. Equality between men and women	SHAPES activities aim to promote gender equality and the awareness that gender is not just a binary woman–man categorisation. At the same time, SHAPES acknowledges that the care sector is female dominated.	SHAPES Ecosystem. SHAPES Platform and Digital Solutions. Research and co-creation with end-users as part of the SHAPES Platform and SHAPES Marketplace.
25. The rights of the elderly	This provision draws on Article 23 of the revised European Social Charter and Articles 24 and 25 of the Community Charter of the Fundamental Social Rights of Workers. It aims to promote equal participation in society of older persons. The Charter uses the term 'elderly', but within SHAPES it has been decided to use 'older persons' instead.	SHAPES Ecosystem. SHAPES Platform and Digital Solutions. Research and co-creation with older persons as part of the SHAPES Platform and SHAPES Marketplace. Participation in the SHAPES governance.

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26. Integration of persons with disabilities	Older persons may have increased prevalence of chronic diseases and physical and cognitive impairments, which in interaction with various barriers may result in disabilities.	SHAPES Digital Solutions and user interfaces (tailored services, supported decision-making). Research and co-creation with persons with disabilities as part of the SHAPES Platform and SHAPES Marketplace. Participation in the SHAPES governance.
CHAPTER 4: Solidarity	**This chapter is important for employees and older persons.**	
31. Fair and just working conditions	Caregivers are also end-users of SHAPES. There is a growing need for more staff in the care sector. Often, the care sector is not very well paid. During the COVID-19 pandemic, care workers have been obliged to work. SHAPES enables caregiving with social distance. See also subsection 7.5.	SHAPES Digital Solutions for caregivers. Caregiver participation in the SHAPES governance.
34. Social security and social assistance	SHAPES and its various digital solutions promote this right.	SHAPES Platform and Digital Solutions. SHAPES Marketplace and Ecosystem.
35. Healthcare	SHAPES and its various digital solutions promote this right.	SHAPES Platform and Digital Solutions. SHAPES Marketplace and Ecosystem.
37. Environ-mental protection	Environmental protection is virtually inalienable in all we do in the modern world, and so it is in SHAPES. SHAPES promotes environmental protection by enabling digital solutions for health promotion that are aware of environment impact and that adopt sound environmental practices.	SHAPES Digital Solutions.
38. Consumer protection	These are to be considered as part of the SHAPES business aspect.	SHAPES Marketplace. End-users' participation in the SHAPES governance.
CHAPTER 5 Citizen rights	**This chapter and some of its rights are indirectly relevant to the SHAPES context.**	
41. Right to good administration	SHAPES participants have the right to expect proper administration of this EU-funded project (and also when the realisation begins).	SHAPES Ecosystem.

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42. Right of access to documents	The right to access documents concerning oneself is important. What is referred to with the article is the documents of European Parliament, Council and Commission. In that sense, it is not especially relevant to SHAPES. But the information gathered about any individual on the SHAPES platform is important.	SHAPES Platform and Digital Solutions. Participation in the SHAPES governance. Privacy and data protection (see section 5 of this deliverable).
45. Freedom of movement and of residence	This is relevant both in the context of older persons and the people working with them. Because the platform is digital and user location is not important, SHAPES aims to ease movement.	SHAPES Ecosystem. SHAPES Platform and Digital Solutions.

3.2 Biomedical ethics and Ethics of Care

3.2.1 Background

Deontology, consequentialism, and virtue ethics are the three main theories concerning normative ethics. They provide moral rules that have implications for human actions, institutions, and ways of life. In addition to these well-known theories, other approaches deserve attention, especially in the context of SHAPES and social and healthcare service provision. In this sub-section, we briefly cover biomedical ethics and the ethics of care and their implications for SHAPES.

3.2.2 Biomedical ethics

Biomedical ethics is an interdisciplinary, contemporary approach to ethics based on four main principles included in some form in most classical ethics theories. Those principles are justice, beneficence, non-maleficence, and autonomy. (Beauchamp & Childress, 2001). The biomedical ethics approach serves as a paradigm that assists healthcare professionals and public policymakers to identify and respond to moral dilemmas in biomedical and healthcare work and research (Beauchamp & Childress, 2013; Kass, 2001). The framework encompasses several different types of moral norms. These include moral ideals, virtues, rules, and principles. Different rules, virtues and rights are considered important in the framework, but according to Beauchamp and Childress, the principles provide the most comprehensive and general norms. Principles are considered general norms, and they leave considerable leeway for judgement in a number of cases. Unlike clear-cut judgements and rules, principles do not function as 'precise action guides' that would inform us in every single circumstance on how to act. The four-principle cluster is not a general moral theory: it is only a framework for identifying and reflecting on moral problems. The principles are rather abstract. The approach has often been called the *four-principle approach* and *principlism* (Beauchamp & Childress, 2001). There is also critical discussion about principlism (see for example Saxén, 2017).

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In high-tech development and related research such as SHAPES, biomedical ethics help bridge gaps between public healthcare, private healthcare, social services, and engineering. The focus is on ethical and morally sound renewal of services provided to assist healthy ageing and to foster dignity and independence. The principles are further described in the context of SHAPES in Table 7.

Table 7 Biomedical principles within the SHAPES context

Principle according to Beauchamp and Childress 2001	Points relevant to SHAPES
Respect for autonomy - A norm of respecting the decision-making capacities of autonomous persons. In this context, it means especially decisions about informed consent and refusal. - Autonomy: from the Greek *autos* ('self') and nomos ('rule'). - Personal autonomy as a minimum is self-rule that is free from limitations such as inadequate understanding that would prevent meaningful choices and is free from controlling interference. - Two conditions are especially relevant to autonomy: agency, meaning capacity for intentional action, and liberty, meaning independence from any controlling interference. - In decision-making, the concept of competence has close ties to the concept of autonomy. - The components of informed consent are: Threshold elements: competence, voluntariness. Informational elements are disclosure, recommendation and understanding. Consent elements are decision and authorisation.	Involvement of older people in decision-making regarding their everyday lives Research participation and informed consents The choice of the digital services to be used by the older person The use of the digital services (utilising artificial intelligence)
Non-maleficence - A norm of avoiding the causation of harm. - The maxim *Primum non nocere*: 'Above all, do no harm.' - Many theories recognise non-maleficence. - Some theories combine non-maleficence and beneficence into one principle. - People should be protected against harm; it is synergistic with the conclusion that there is also a positive obligation to provide benefits such as healthcare.	Societal Impact Assessment (SIA) and risk assessment regarding the use of various digital services Compliance with legal frameworks (e.g. Medical Device Regulation and General Data Protection Regulation)
Beneficence - A group of norms for providing benefits and balancing benefits against risk and cost. - Contributes to persons' welfare. - There are two categories of beneficence: positive beneficence and utility. Positive beneficence requires that agents provide benefits. Utility means agents are required to balance drawbacks and benefits to produce the best result overall. - It includes all kind of actions that aim to benefit others. - It refers to actions done for others. - The principle of benevolence refers to a moral obligation that one needs to act for the benefit of the others.	In all SHAPES actions, doing good for others should be the prime aim Long term behaviour change inspired by SHAPES

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Justice - A group of norms for fair distribution of benefits, risks, and costs. - Fairness, deservedness, and entitlement have often been used to explicate justice. - Aristotle: "Equals must be treated equally, and un-equals must be treated unequally." This does not often provoke debate, but what is understood as justice is more complex. - Theories such as utilitarian, libertarian, communitarian, and egalitarian offer tools for theoretical thinking about justice. None of them are necessary or sufficient within health policy and allocation decisions.	Rights of culturally diverse older people and users and developers of SHAPES Accessibility and affordability of SHAPES Caregivers may also face situations involving a question about justice

3.2.3 Ethics of Care

Ethics of care (or care ethics) is a feminist approach that emphasises the importance of responsibility, concern and relationship over consequences or rules. Carol Gilligan (1982) is seen as a key person to have developed this concept. Gilligan claimed that there are two different type of moralities: the ethic of justice and the ethic of care. Gilligan explains that "the ethic of care is centred on maintaining relationships through responding to needs of others and avoiding hurt". (Juujärvi et al., 2019 p. 187; Gilligan, 1982). Care ethics sees moral problems arising from ruptures or tensions in relationships. Within care reasoning, moral problems are solved by considering the unique characteristics of situations and persons, more than applying a hierarchy of rights or rules; the latter would be more typical of a justice ethics approach. "[C]are reasoning represents a particularistic mode of moral thinking that is based on the full description of the case at hand" (Juujärvi et al., 2019 p. 187; Blum et al., 1988; Vreeke, 1991) and is not so much looking for a solution that could be universally applied.

It has been said that in the nursing field, Gilligan's theory has been greeted with enthusiasm, because it has "theoretically captured the essence of caring embedded in patient-nurse relationships and explained the ethical difficulties nurses encountered in medically dominated healthcare contexts" (Juujärvi et al., 2019 p. 187; Woods, 2011). It has been seen as a promising approach for strengthening the voices of nurses in ethical discussions, which traditionally have been dominated by justice-based theories (Juujärvi et al., 2019; Juujärvi, 2011; Gilligan, 1982).

A relevant question to ask is: What would be the strongest ethical approach to highlight the key roles of clients, customers, and older persons in the SHAPES context? In Table 8, we identify perspectives of care ethics in the SHAPES context.

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Table 8 Main perspectives of care ethics in the SHAPES context

Perspectives	In the SHAPES context especially
Empathy	Showing empathy might require fresh approaches when acting on digital platforms: a smile, touch and eye contact might not work as in traditional face to face encounters – this applies to caregivers, researchers, and older persons.
Relationships	Building and maintaining relationships might mean learning new methods and approaches when operating on digital platforms. Building and maintaining relationships also means understanding the psychology, sociology, and spirituality of human beings.
Uniqueness of the case	In hectic working life, it might not always be easy to provide care, as each case is unique and not just one of a dozen similar-looking ones. On the other hand, technology and the utilization of big data and artificial intelligence can, at best, also enable a person to be considered as an individual with his or her individual needs.

3.3 Persons with disabilities

3.3.1 Introductory remarks

The UN Convention on the Rights of Persons with Disabilities (CRPD) is a key normative framework for SHAPES and it will also inform the legal analysis in the Regulatory Frameworks for Pan-European Smart and Healthy Ageing (D8.3). It is the leading instrument in international law that informs the SHAPES context. The General Assembly of the UN approved the CRPD in 2006. The CRDP entered into force in May 2008. It has been ratified by a large number of countries globally. Moreover, and significantly for the purpose of this project, the EU, alongside all its Member States, concluded ratification in 2010. (Council of the European Union, 2010).

The CRPD supports a paradigm shift in human rights law, since it embraces what has been termed the "social-contextual model of disability" (Broderick, 2015). The latter model is considered a more refined elaboration of the "pure" social model (Broderick & Ferri, 2019), and recognises that "disability results from the interaction between persons with impairments and attitudinal and environmental barriers that hinder their full and effective participation in society on an equal basis with others". (see also CRPD, 2006 p. 3).

The Convention is underpinned by general principles listed in Article 3 and specified in subsequent articles:

- Respect for inherent dignity, individual autonomy (including the freedom to make one's own choices) and independence of persons
- Non-discrimination
- Full and effective participation and inclusion in society

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- Respect for difference and acceptance of persons with disabilities as part of human diversity and humanity
- Equality of opportunity
- Accessibility
- Equality between all genders
- Respect for the evolving capacities of children with disabilities and respect for the right of children with disabilities to preserve their identities. (CRPD, 2006 p.4)

All the principles listed in Article 3 are relevant to the SHAPES project.

3.3.2 Respect for inherent dignity, individual autonomy, and independence of persons

The SHAPES context acknowledges that older people (including older people with disabilities) ought to retain their right to make decisions and live independently and their right to be provided with adequate support to exercise their legal capacity. The SHAPES Integrated Care Platform and Ecosystem context also acknowledges that recent developments in international human rights law have radically challenged the functioning of adult guardianship as well as the principle of 'best interests'.

The SHAPES Integrated Care Platform and Ecosystem, in line with the CRPD, makes a strong pivot on independence and autonomy of people with disabilities, including older people with disabilities. These principles of dignity, autonomy and independence lie at the heart of Article 12 CRPD. This provision enshrines the right to equal recognition before the law, often termed "the right to legal capacity" (CRPD/C/GC/1, 2014 p. 2; Fridström Montoya 2015).

The CRPD Committee distinguishes legal capacity and mental capacity. The former is "the ability to hold rights and duties (legal standing) and to exercise those rights and duties (legal agency)". The latter "refers to the decision-making skills of a person, which naturally vary from one person to another and may be different for a given person depending on many factors, including environmental and social factors". (CRPD/C/GC/1, p. 3).

As established in Article 12(3) CRPD, States parties to the CRPD "must refrain from denying persons with disabilities their legal capacity and must, rather, provide persons with disabilities access to the support necessary to enable them to make decisions that have legal effect" (CRPD/C/GC/1, 2014 p. 4). According to the CRPD Committee, the support in the exercise of legal capacity must respect the will and preferences of a person with a disability, and it should never amount to substitute decision-making. When, in spite of significant efforts, it is not possible to determine the will and preferences of an individual, "the 'best interpretation of will and preferences' must replace the 'best interests' determinations" (CRPD/C/GC/1, 2014 p. 5). Along the lines

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traced in its General Comment, the Committee, in its Concluding Observations on State Parties Reports on the implementation of the CRPD, has often highlighted that the human-rights-based approach to disability requires States Parties to embrace supported decision-making processes and abandon the model of substitute decision-making.

For the purpose of the SHAPES Integrated Care Platform, it is important to highlight that persons with disabilities must be supported, but only when support is needed or requested, in the exercise of their legal capacity in order to enable them to make decisions that have legal effect. Supported decision-making comprises a variety of support options that encompass both informal and formal support arrangements of varying types and intensity. For example, people with disabilities may choose one or more trusted support persons to assist them in exercising their legal capacity for certain types of decisions or may call on other forms of support, such as peer support, advocacy (including self-advocacy support), support from representative organisations (organisations of persons with disabilities) or assistance with communication. The estimation is that this requires considerable development from national systems in the developing of the supported ways for the autonomy (Arstein Kerslake, 2017). When identifying the most appropriate support, careful attention must be paid to the situation of the individual (Quinn, 2009).

Article 12(4) CRPD requires States Parties to ensure that all measures relating to the exercise of legal capacity provide for appropriate and effective safeguards to prevent abuse.

Most recently, in 2019, the UN Special Rapporteur of the Rights of Persons with Disabilities in her report on older persons with disabilities (UN, 2019) stated that:

“Having high support needs cannot justify the denial of autonomy and legal capacity. Loss of autonomy is not a natural process, but a social process that results from the failure of society to respect and support the will and preferences of all people. Older persons with disabilities have the right to maintain their legal capacity and to have access to supported decision-making, and their agency needs to be recognized and facilitated. Furthermore, all health and social care services should be based on the free and informed consent of the individual concerned, and all laws that allow involuntary treatment or placement in residential care upon the authorization of third parties, such as family members, or on the basis of an actual or perceived mental health condition or other impairment, should be repealed.” (UN, 2019 p. 12).

In summary, in the SHAPES project, the person’s right to make a decision on matters that are of concern to him/her has to be valued and upheld. The essential issues to be considered in the SHAPES context are (1) whether the person needs support in order to make a decision related to the provision of services; and (2) if their decision is legally valid under national law.

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With regard to the first issue, various types of support can be offered, including accessibility and reasonable accommodation measures (for example, using plain-language and easy-read materials, information in visual form, more time to discuss choices). If needed, the interpreters (e.g. supporter/caregiver/interpreters/guide) can be involved to assist the person, help them understand and/or remember and express his/her own choices. The involvement of a trustee or a caregiver can be helpful in identifying definitive situations for adaptation and in obtaining necessary information. Trustees, caregivers, interpreters and guide interpreters could make sure that information is provided in a way that is understandable to a person with a disability and could provide the researchers with relevant information about the will and preferences of the individual (Arstein Kerslake 2017).

With regard to the second issue, it will be necessary to ascertain whether the research participant is supported by a trustee or a caregiver or if a guardianship is in place. If a research participant is not deemed legally capable under national law, it is important to verify what requirements need to be respected in order to ensure that the consent to participate in the project is valid under the respective national law.

3.3.3 Accessibility

The SHAPES Integrated Care Platform and Digital Solutions will be informed by the principle of accessibility (and will follow accessibility requirements as detailed in EU law – see further Regulatory Frameworks for Pan-European Smart and Healthy Ageing (D 8.3). The UN Convention on the Rights of Persons with Disabilities recognizes access to information and communications technologies, including the Web, as a basic human right. The Convention on the Rights of People with Disabilities (CRPD) is a comprehensive human rights document that includes a direct reference to the rights of all people to have equal access to communications technology (CRPD, 2006; W3C, 2018).

Accessibility and its general features are important for the SHAPES project, considering that the SHAPES target group is older individuals. According to Ali et al. (2017) accessibility is a general term used to describe the degree to which a product, device, service, or environment is available to everyone possible. The digital solutions should be designed to work for all people, whatever their hardware, software, language, location, or ability and, it is accessible to people with a diverse range of hearing, movement, sight, and cognitive ability. Accessibility can be viewed as the “ability to access” and benefit from some system or entity. It supports social inclusion for people with disabilities as well as others, such as older people as in SHAPES scope, people in rural areas, and people in low-income countries.

Accessibility primarily focuses on people with disabilities and their right of access to digital services or digital platforms, often through use of assistive technology. Assistive technology enables and promotes inclusion and participation, especially of persons

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with disability, aging populations, and people with non-communicable diseases. The primary purpose of assistive products is to maintain or improve an individual's functioning and independence, thereby promoting their well-being. This is important to understand when designing digital solutions in SHAPES. Assistive technology for digital service use, enable people to live healthy, productive, independent, and dignified lives, and to participate in education, the labour market and civic life (WHO 2021).

Alongside being mentioned as one of the general principles in Article 3 CRPD, accessibility is spelled out in Article 9 CRPD as well as in other substantive provisions of the Convention. The CRPD also includes specific concepts and measures that are related to accessibility, such as the concept of 'universal design', which is included in Article 4 as a general and cross-cutting obligation. The CRPD also places emphasis on assistive devices, which are essential to guaranteeing accessibility in particular situations and for certain people.

Web accessibility means that websites, tools, and technologies are designed and developed so that people are able to perceive, understand, navigate, interact with and contribute to the Web. Web accessibility addresses all disabilities that affect access to the Web, including auditory, cognitive, neurological, physical, speech and visual. SHAPES Digital Solutions designers and developers amongst others, should consider Universal Design standards in the design process. Universal Design encompasses removing obstacles for people with disabilities for providing 'barrier-free' design. Some of the Universal Design principles are related to accessibility in the digital environment. Universal Design can be defined as the design of products and creation of environments that can be experienced by people of all ages and abilities. Principles of Universal Design are:

- Equitable use
- Flexibility in use
- Simple and intuitive use
- Perceptible information
- Tolerance for error
- Low physical effort
- Size and space for approach and use
  (IAAP, 2020).

In the CRPD, accessibility encompasses physical accessibility, economic accessibility (i.e., affordability) and accessibility of information. Lawson (2012 p. 20) clarifies that 'for CRPD purposes, accessibility covers more than technical design specifications for products, information and signage or the built environment. It also covers communication and forms of live assistance'. Accessibility is not only about technical standards, web architecture and design. It is a matter of political will and of moral obligation, enshrined in the CRPD.

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Cognitive accessibility is one part of the accessibility framework. The digital service developers can avoid creating barriers by considering accessibility requirements and thus optimize the user experience. Cognitive accessibility means flexible content, for example, users should have enough time to read and use content, easily navigate and find content, text and language should be readable and understandable, web pages should operate in a predictable way and users should be able to correct and avoid mistakes. (Seeman et al. 2016).

According to The World Health Organization (2020), dementia and cognitive impairment lead the list of chronic diseases contributing to disability and dependence among older people worldwide. Considering cognitive accessibility elements within SHAPES, provides simpler, more consistent, clearer, multi-modal, error-tolerant and attention focusing usage for SHAPES users. Cognitive accessibility benefits all users, but especially users who have cognitive and learning disabilities. Castilla et.al (2020) have stated that consequently, with the ageing of the population, the number of cognitively impaired individuals will also rise. Research has shown that the majority of seniors especially non-ICT seniors feel anxious and unsure as to how to use digital services and anticipate that the Internet is difficult to use and to understand. (Castilla et.al, 2020).

Article 9(1) CRPD requires the adoption of all measures that are necessary to ensure accessibility on a progressive basis. According to Article 9(1), these measures ‘shall include the identification and elimination of obstacles and barriers to accessibility’. Article 9(2) CRPD provides a wide range of detailed obligations. Article 9(2)(a) requires States Parties to develop accessibility standards. In fulfilling that obligation, States Parties can delegate the writing of technical standards to non-state authorities. Article 9(2)(b) and 9(2)(d) CRPD requires that States Parties ensure that private entities provide for accessible buildings, services, and facilities. In its General Comment No. 2, the CRPD Committee confirms that, ‘if goods, products and services are open or provided to the public, they must be accessible to all, regardless of whether they are owned and/or provided by a public authority or a private enterprise’. In a similar vein, the CRPD Committee’s General Comment No. 5, on living independently and being included in the community, states that ‘community services open to the public such as libraries, swimming pools, public parks/spaces, shops, post offices and cinemas must be accessible and responsive to the requirements of persons with disabilities.

Directive (EU) 2016/2102, in force since 22 December 2016, will provide people with disabilities with better access to the websites and mobile apps of public services. The rules laid down in the Directive reflect the Commission's ongoing work to build a social and inclusive European “Union of equality”, where all Europeans can take a full and active part in the digital economy and society. The Directive obliges websites and apps of public sector bodies, with a limited number of exceptions (for example,

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broadcasters, live streaming), to meet specific technical accessibility standards. It requires:

- an accessibility statement for each website and mobile app;
- a feedback mechanism so users can flag accessibility problems or request information published in a non-accessible content;
- regular monitoring of public sector websites and apps by Member States and reporting on the results.

The Directive complements the European Accessibility Act (EAA, 2019/882) which covers a wide range of products and services also in the private sector. Member States shall adopt and publish, by 28 June 2022, the laws, regulations, and administrative provisions necessary to comply with this Directive. They shall apply those measures from 28 June 2025. This legislation supports people with disabilities in other areas including electronic communications, audio-visual media services, eBooks, eCommerce, and ICT products. (European Commission 2020).

The European Union has set up the "Accessibility Requirements for Public Procurement of ICT Products and Services in Europe". The web and digital content requirements need to follow defined success criteria from the W3CWeb Content Accessibility Guidelines. Web Content Accessibility Guidelines (WCAG) 2.1 defines how to make Web content and digital services more accessible to people with disabilities. WCAG 2.1 is developed through the W3C process in cooperation with individuals and organizations around the world, with a goal of providing a shared standard for Web content accessibility that meets the needs of individuals, organizations, and governments internationally. (W3C, 2018).

In conclusion, the *SHAPES Digital Solutions, Ecosystem, Ecology, Marketplace* must assure easy access to information, accessible platforms and digital solutions for SHAPES users considering assistive technology, cognitive accessibility. SHAPES partners and projects should pay attention to clear, understandable, and accessible communication and instructions for SHAPES users.

3.3.4 Non-Discrimination and Equality

The SHAPES Integrated Care Platform and Ecosystem must be informed by the principle of non-discrimination and equality, which is a general principle of EU law and is enshrined in the EU Charter of Fundamental Rights, and is also guaranteed with reference to disability rights by the CRPD.

Non-discrimination is also the cornerstone of the CRPD and cuts across both civil and political rights, such as the rights to liberty and to legal capacity, and economic, social, and cultural rights, such as the right to education. Article 2 CRPD provides a broad definition of discrimination based on disability, highlighting that such discrimination

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includes the denial of a reasonable accommodation. The duty to reasonably accommodate is also defined in Article 2 CRPD as "necessary and appropriate modification and adjustments", "where needed in a particular case, to ensure that persons with disabilities experience the enjoyment or exercise on an equal basis with others of all human rights and fundamental freedoms. (CRPD, 2006 p.4).

Article 5 CRPD lays down the principle of equality. The CRPD Committee (CRPD/C/GC/6, 2018) has stated that the model of equality purported by the Convention is that of inclusive equality which embraces four dimensions as laid out in the Figure 4.

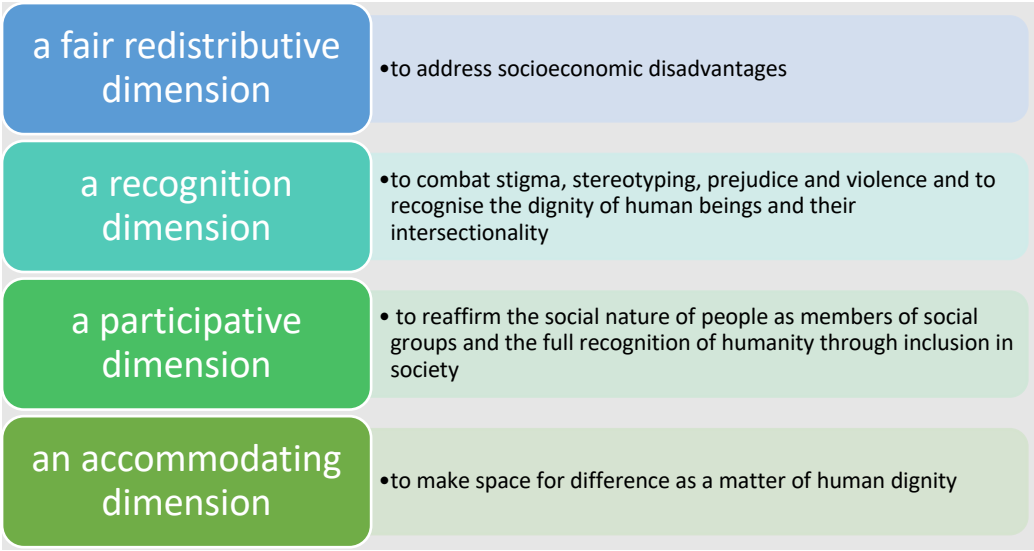

Figure 4 Four dimensions of inclusive equality (Text adapted from CRPD/C/GC/6, 2018 p. 3)

3.4 Capabilities approach, social justice, and wellbeing

3.4.1 Background

The notions of smart, healthy, active independent ageing are embedded in the arguments of the SHAPES project and solutions. However, the idea of 'healthy and successful ageing' has been critiqued by several scholars for several reasons: it homogenises, oppresses and neglects the physical realities of ageing individuals (see Stephans et al., 2015; Rowe & Kahn, 1997; Pfaller & Schweda, 2019). The preference for activity neglects many relevant and accessible dimensions of human life (for example, intellectual and spiritual experiences), as well as activities outside the domain of economy (for example, arts and crafts, political participation). In addition, active ageing is often equated with productive ageing and economic success. (Pfaller & Schweda, 2019).

The capability approach was originally developed by the economist Amartya Sen and the philosopher Martha Nussbaum. It criticises welfare economics, which focus on economic measures, utility, and material resources. According to the capability

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approach, the aim of development should be conceptualised as people's capabilities to function: what people are actually able to do and be and what their opportunities are to live a life they value. (Robeys 2005).

3.4.2 Nussbaum's capabilities approach

Nussbaum's capabilities approach is based on the principle of human dignity and of a life worthy of it, including the idea of a person's active striving and agency. Persons are both capable and needy and differ in their values. However, certain capabilities and restrictions are common for human beings. Based on these features, Nussbaum has defined a list of Central Human Capabilities (see Table 9). According to Nussbaum, these capabilities (which also cover aspects dealt with by both first- and second-generation human rights) are presented as the source of political principles for a liberal, pluralistic society. (Nussbaum, 1992, 2007 & 2011). Each capability on the list has intrinsic value but also, from the perspectives of other capabilities, instrumental value. However, capabilities of affiliation and practical reason have an architectonic role (Nussbaum, 2007 & 2011).

Table 9 The Central Human Capabilities (Adapted from Nussbaum, 2011 p. 7–9)

Central Human Capabilities	
1. Life	Being able to live to the end of a human life of normal length; not dying prematurely, or before one's life is so reduced as to not be worth living.
2. Bodily health	Being able to have good health, including reproductive health; to be adequately nourished; to have adequate shelter.
3. Bodily integrity	Being able to move freely from place to place; to be safe from violent assault, including sexual assault and domestic violence; having opportunities for sexual satisfaction and for choice in matters of reproduction.
4. Senses, imagination and thought	Being able to use the senses, to imagine, think, and reason—and to do these things in a "truly human" way, a way informed and cultivated by an adequate education including, but by no means limited to, literacy and basic mathematical and scientific training. Being able to use imagination and thought in connection with experiencing and producing works and events of one's own choice, religious, literary, musical, and so forth. Being able to use one's mind in ways protected by guarantees of freedom of expression with respect to both political and artistic speech and freedom of religious exercise. Being able to have pleasurable experiences and to avoid non-beneficial pain.
5. Emotions	Being able to have attachments to things and people outside ourselves; to love those who love and care for us, to grieve at their absence; in general, to love, to grieve, to experience longing, gratitude and justified anger. Not having one's emotional development blighted by fear and anxiety (Supporting this capability means supporting forms of human association that can be shown to be crucial in their development).
6. Practical reason	Being able to form a conception of the good and to engage in critical reflection about the planning of one's life (this entails protection for the liberty of conscience and religious observance).
7. Affiliation	Being able to live with and towards others, to recognise and show concern for other humans, to engage in various forms of social interaction; to be able to

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	imagine the situation of another (protecting this capability means protecting institutions that constitute and nourish such forms of affiliation, and also protecting the freedom of assembly and political speech). Having the social bases of self-respect and non-humiliation; being able to be treated as a dignified being whose worth is equal to that of others. This entails provisions of non-discrimination on the basis of race, sex, sexual orientation, ethnicity, caste, religion, national origin, and species.
8. Other species	Being able to live with concern for and in relation to animals, plants, and the world of nature.
9. Play	Being able to laugh, play and enjoy recreational activities.
10. Control over one's environment	Political: being able to participate effectively in political choices that govern one's life; having the right of political participation, protections of free speech and association. Material: being able to hold property (both land and movable goods) and having property rights on an equal basis with others; having the right to seek employment on an equal basis with others; having the freedom from unwarranted search and seizure. In work, being able to work as a human, exercising practical reason and entering into meaningful relationships of mutual recognition with other workers.

The distinction between capabilities and functioning and the freedom of choice is essential. Social justice concerns only the promotion of capabilities – the choice of actual functioning is left to citizens. For example, the promotion of health capabilities honours a person's own choices, whereas the promotion of health more generally does not. In addition, healthy functioning is in itself a way of being active, not just a passive state of satisfaction. (Nussbaum, 2011). Special attention should be paid to the capabilities of those with disabilities. It is the task of society's basic structure to secure a threshold level for central human capabilities, but other organisations also have a role in implementation. (Nussbaum, 2007 & 2011).

Nussbaum states that the list of Central Human Capabilities can be more definitively specified in accordance with local circumstances, leaving room for a reasonable pluralism. Nussbaum also claims that preferences alone cannot reflect the wellbeing of citizens. But by listening to people's conceptions about their desires and being, people can be aided in developing more informed desires. Nussbaum has also argued that the hunger for commodities (goods) can make people competitive, domineering, and arrogant towards other good things in life. (Nussbaum, 2011).

It is also important to note that the good of others is part of a person's own good: According to Nussbaum, a person cannot imagine a life without shared goals and shared lives with others. Further, caregiving must be provided in such a way that the capability of self-respect of the care receiver is not injured. Caregivers in turn should not be deprived of other capabilities. (Nussbaum, 2007 & 2011).

Central Human Capabilities are internal capabilities combined with external material, social, political, and familiar conditions for the exercise of function. Internal capabilities are fluid and dynamic states of the person. Basic capabilities are the innate faculties that make development and training of internal capabilities possible. By pointing out

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that capabilities are combined capabilities, Nussbaum emphasises the importance of circumstances in training internal capabilities and in using those capabilities once trained. (Nussbaum, 2007 & 2011).

The Capabilities approach and Nussbaum's Central Human Capabilities can be good starting points for formulating a holistic conception of self-development and dimensions relevant to having a good life and maintaining dignity as one ages (Pfaller & Schweda, 2019).

3.4.3 Capabilities approach vs. the SHAPES project and solution

Nussbaum's claim about the political purpose of capabilities is relevant in the context of wellbeing-oriented innovation projects because these projects gradually renew institutional structures and the division of labour in the development work and service production. Although Nussbaum's approach is not a comprehensive account of value, it can be used as a holistic approach to wellbeing and to the promotion of it, and to frame other consequences that innovation may pose. (Sarlio-Siintola, 2011).

The main objective of an innovation is to promote and protect central human capabilities, more precisely the development, maintenance and use of person's internal capabilities (see Table 10). A single solution (such as SHAPES) may not promote all of them, but neither should it lead to the detriment of capabilities. The starting point for the design should be the promotion of capabilities, followed by a concern with material resources and the other circumstances needed. Target groups are to be defined from the viewpoint of older persons' internal capabilities and external circumstances. Attention is to be paid especially to those who have disabilities from the viewpoint of their internal capabilities and/or social and material conditions. Both the capabilities and needs of the (family) caregiver and the care receiver are to be considered. (Sarlio-Siintola, 2011).

Table 10 Examples of capabilities vs. needs (Adapted from Sarlio-Siintola, 2012 p. 8)

Capability		Examples of user needs	Division of labour
Bodily health	Being able to have good health; to be adequately nourished; to have adequate shelter.	Being able to maintain one's own health. Being able to eat healthy and tasty food.	Needing professional help in maintaining her/his physical condition. Not being able to cook healthy food without help.
Bodily integrity	Being able to move freely from place to place; to be secure against violent assault, including sexual assault and domestic violence.	Being able to go outside safely and freely and take in fresh air. Being able to undertake activities outside the home	Being able to move around on one's own if physical condition allows. Needing physical help in

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		(e.g., shopping, visiting the library).	everyday activities, as well as in handling money.
Practical reason	Being able to form a conception of the good and to engage in critical reflection about the planning of one's life.	Being able to understand one's own status of wellbeing and health. Being able to cope with everyday activities at home. Being able to plan one's future.	Being interested in controlling one's own health on a daily basis. Having a strong feeling of autonomy. Being motivated to plan her/his own future.
Affiliation	Being able to live with and towards others; to recognise and show concern for other human beings; to engage in various forms of social interaction; to be able to imagine the situation of another. Having the social bases of self-respect and non-humiliation; being able to be treated as a dignified being whose worth is equal to that of others.	Being able to maintain personal networks. Being able to meet new people. Being able to help other people and to be helped.	Needing incentives in maintaining her/his own networks. Needing encouragement in maintaining one's own self-respect.

The idea of a citizen's active agency in change and in her/his own life and the capabilities of practical reason and affiliation are at the centre. End-users are to be involved in the development work early in the strategic planning phase and also have the option to participate in the steering of the project (and later on the SHAPES governance and ecosystem). (Sarlio-Siintola, 2011).

The representatives of the public sector are to be involved in the planning and steering of the project (and later on the ecosystem), because it is the responsibility of the public sector to ensure that the institutions of society make its citizens capable of functioning. Working methods should offer end-users opportunities to discuss critically the values and wellbeing of their lives and how innovations could promote them. (Sarlio-Siintola, 2011).

The SHAPES Integrated Care Platform focuses on wellbeing at home and in home-like environments. It is essential to both perceive the wide scope of capabilities for a good life, including 'life', 'bodily health', 'bodily integrity', 'other species' and 'play', as well as to make sure that the circumstances and the solution itself make it possible for older persons to achieve these capabilities.

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Several capabilities, such as 'practical reason', 'affiliation', 'emotions' and 'senses, imagination and thought', are related to both the variety of SHAPES services (i.e., does SHAPES provide a means for this capability to function), and also to the methods in which SHAPES is developed in close relation with older individuals in providing a means to achieve these capabilities both 1) during the project and 2) afterwards, as part of the SHAPES governance.

The capability 'control over one's environment' is mainly related to the R&D work with the older persons during the project and after it, as part of SHAPES governance. This option to participate in SHAPES development during the project and after can therefore be perceived as some kind of 'service', which has both instrumental and intrinsic value. In Table 11, the main implications of the capabilities approach to solutions such as SHAPES are summarised.

Table 11 Capabilities-approach-based project framework (Adapted from Sarlio-Siintola, 2011 p. 17)

Capability-approach-based argument	Practical guidelines and tools for development	Possible outcomes
Objectives and target groups The primary objective of development is the promotion of capabilities. Expected outcomes of the innovation projects concern services and technology, as well as social and political renewals that promote the development, maintenance, and employment of users' internal capabilities. It is the public sector's responsibility to secure the threshold level of capabilities for its citizens. Attention is paid especially to the capabilities of persons with disabilities. A single innovation may not promote all central capabilities, but it cannot compromise them either.	Study socially and economically justifiable target groups and define the wellbeing objectives and expected outcomes with the help of the central human capabilities and their material and social circumstances and by paying attention to the issue of care. Analyse the innovation's outcomes and other potential impacts from the viewpoint of the development, maintenance and use of central capabilities and their material, social and political circumstances. Include in this analysis other older persons outside the target group on whose life the innovation may have an impact. Involve the public sector in project planning and steering.	**Older persons** Equal possibilities to wellbeing, no unjust innovations **Business** Sustainable business, new customer segments **Public** Equality and justice within a system of diminishing resources (see also Hellsten 1995)
User participation Development is based on the idea of dignified citizens' active agency and on the capabilities of practical reason and affiliation. Participation in the project, at its best, offers users the possibility to actualise various central human capabilities during the development.	Set wellbeing objectives for user participation. Respect the users and their privacy. In addition to the development work, involve users in both the strategic planning and the steering of the project. Pay attention to the internal capabilities and external conditions of the users when choosing working models and methods.	**Older persons** Active agency Wellbeing during the project Better innovation, more wellbeing **Business** Increased opportunities for value creation and

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	Choose working models that offer users various opportunities to discuss with professionals and other users the values and wellbeing (practical reason and affiliation) and how the innovation could promote them. Choose working models that promote central human capabilities other than practical reason and affiliation during the project.	Corporate Social Responsibility (CSR) **Public** Active citizenship and social inclusion Wellbeing
Design of the service Persons are perceived as both capable and needing in their activities and have potential for both care receiving and caregiving. The capabilities of practical reason and affiliation organise and suffuse users' choices and activities. Preferences alone cannot inform the wellbeing of citizens. Freedom of choice to function or not and how to function are to be secured and promoted through the innovation and its functionalities.	Maintain focus at the beginning of the design phase on capabilities and in their material and social circumstances, not only commodities. In the division of labour, avoid the risk of underestimating or overestimating users' own capacities with the help of central capabilities and material, social and political circumstances. Develop solutions that offer users various ways to act according to their own choices and practical reasoning. Be open to non-market solutions that may not presuppose commodities or at least do not restrict opportunities for them. In the detailed design of the service and technology, pay attention to various capabilities to function that the commodities could and should enable.	**Older persons** Increased wellbeing with less money Increased variety of choices No useless or harmful commodities **Business** Scalability of the technology and services **Public** Freedom of choice Economic progress through productivity and smart growth More wellbeing with fewer resources

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4 Guidelines, approaches, and policies

In this section, we introduce some central ethical approaches applied in business and technology development, as well as some relevant guidelines and EU policies that should aid in the framing of SHAPES. We will focus on sustainable development and corporate social responsibility, paying attention to UN soft law and EU action. We will also discuss the customer-centric approach and service design artificial intelligence and ethics. Furthermore, a section will be devoted to other relevant EU policies, which will be also used as a frame for the legal analysis conducted in deliverable Regulatory Frameworks for Pan-European Smart and Healthy Ageing (D8.3).

4.1 Sustainable development and corporate social responsibility

4.1.1 The EU approach

Companies pose significant impact on the lives of people in terms of the products and services they offer and the jobs and opportunities they create, as well as how they affect working conditions, human rights, health, the environment, innovation, education and training. EU citizens expect companies to understand their positive and negative impacts on society and the environment. (COM, 2019 p. 5).

The EU and its Member States have been promoting corporate social responsibility (CSR), responsible business conduct (RBC), and business and human rights globally. The 2015 adoption of the Sustainable Development Goals (SDG) and the Paris Agreement on climate action marked a fundamental shift in the EU's approach. (COM, 2019).

Corporate social responsibility is defined in the European CSR Strategy as the "responsibility of enterprises for their impacts on society". To fully meet the goals of their social responsibility policy, companies "should have in place a process to integrate social, environmental, ethical, human rights and consumer concerns into their business operations and core strategy in close collaboration with their stakeholders, with the aim of maximising the creation of shared value for their owners/shareholders and civil society at large and identifying, preventing and mitigating possible adverse impacts". Responsible business conduct is an alternative term for CSR, introduced by the OECD. The OECD has defined RBC as "a) making a positive contribution to economic, environmental, and social progress with a view to achieving sustainable development and b) avoiding and addressing adverse impacts related to an enterprise's direct and indirect operations, products or services". (COM, 2019, p. 3; COM, 2011).

The UN Guiding Principles on Business and Human Rights (UNGPs) were endorsed by the UN Human Rights Council in 2011 and provide that "(a) States' existing obligations to respect, protect and fulfil human rights and fundamental freedoms; (b)

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The role of business enterprises as specialised organs of society performing specialised functions, required to comply with all applicable laws and to respect human rights; (c) The need for rights and obligations to be matched to appropriate and effective remedies when breached". (COM, 2019; UN, 2011 p. 3). These Guiding Principles should be implemented in a non-discriminatory manner, noting in particular the rights and needs of individuals who may be at heightened risk of becoming vulnerable or marginalised. Business enterprises should express their commitment to meet this responsibility through a statement of policy, and to assess businesses' impact on human rights, they should seek to understand the concerns of potentially affected stakeholders. (UN, 2011).

The EU Commissions' progress report (COM, 2019) on the issue focuses on the topics described in the left column of the Table 12. Identified in the right column are those topics relevant in the context of SHAPES sustainable business operations.

Table 12 Topics of social responsibility and sustainability vs. SHAPES

Topic	Relevance to SHAPES
Acting to respect and protect human rights, providing adequate access to remedies for victims of business-related abuses.	SHAPES should promote human rights (see the section on EU Fundamental Rights). SHAPES should not violate any rights, such as privacy and data protection or non-discrimination.
Encouraging companies to carry out appropriate due diligence, including with respect to human rights protection, along their supply chains.	N/A (the recommendation mainly applies to large manufacturing companies).
Increasing transparency and promoting sustainable finance	N/A (the recommendation mainly applies to large manufacturing companies).
Encouraging socially and environmentally friendly business practices, including ones conducted through public procurement.	SHAPES should pay attention to the inclusion of older persons with disabilities. The rights and wellbeing of care providers is also an essential part of SHAPES activities. SHAPES should encourage its service providers to act responsibly, as well as to support socially responsible public procurement.
Promoting the implementation of CSR/RBC, including UNGPs on business and human rights outside the EU.	SHAPES aims to make an impact worldwide. The project has already acquired non-EU partners, such as Norway, and we are open to engaging non-EU suppliers and customers in the SHAPES Marketplace. Further, we have just completed the first open call challenge and were able to pique the interest of non-EU participants.
Sectoral and horizontal initiatives.	Consider the use of ISO 26000 standard in the design of SHAPES businesses.

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4.1.2 The evolution of corporate social responsibility

In business literature, perspectives on corporate social responsibility (CSR) have gradually shifted from the risk-based approach of avoiding harm to the concept of looking at business opportunities from the viewpoint of societal challenges such as ageing societies and climate change. It is essential to see CSR as linked to the company's strategy and core business.

According to Porter and Kramer (2011), "The purpose of the corporation must be redefined as creating shared value, not just profit per se. This will drive the next wave of innovation and productivity growth in the global economy" (Porter & Kramer, 2011 p. 2). However, as Beschorner and Hajduk (2017) argue, in this approach, social needs are seen as a mere means to an end: to make a profit. Such behaviour is about good rational agency, but it has nothing to do with genuinely responsible ethical behaviour. Through lobbying and campaign donations or by engaging in public discourse, companies are also political actors. (Beschorner & Hajduk, 2017).

Mäkinen and Kourula (2008) examine Political CSR through the concept of the moral division of labour. The moral division of labour refers to the ways in which work is divided in society between key political and socio-economic institutions, practices, and various actors. This way of dividing the moral division of labour also affects how free and equal members of society are. Indeed, for the efficient allocation of moral resources, the moral division of labour is a political issue and not a purely technical problem. (Mäkinen & Kourula, 2008). Political CSR is essential from the viewpoint of the SHAPES Ecosystem. From the viewpoint of citizens' rights of wellbeing and social services, it is essential that public actors retain their political responsibility and capacity to act in the era of digital services and platform economy, while at the same time creating better business opportunities for companies.

4.1.3 ISO 26000 Social Responsibility

The ISO 26000 Social Responsibility standard was launched in 2010. Representative from governments, NGOs, industry, consumer groups and labour organisations around the world were involved in its development. The standard clarifies what social responsibility is, helps businesses and organisations translate principles into effective action and shares best practices related to social responsibility. It is aimed at all types of organisations, regardless of activity, size, or location. (ISO, 2010).

The seven key underlying principles of social responsibility are:

- Accountability
- Transparency
- Ethical behaviour
- Respect for stakeholder interests

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- Respect for the rule of law
- Respect for international norms of behaviour
- Respect for human rights
  (ISO, 2010).

ISO 26000 addresses seven core subjects (see Figure 5) that are relevant to virtually every organisation. Each of these core subjects includes several issues of social responsibility with related actions and expectations. (ISO, 2010). Organisations that take action according to the recommendations offered in ISO 26000 will necessarily contribute to the Sustainable Development Goals (ISO, 2016). (For further reading on sustainable development goals, see the next sub-section). In the SHAPES context, ISO 26000 is a tool to consider when designing the SHAPES governance model.

Figure 5 ISO 26000 core subjects (Adapted from ISO, 2010)

4.1.4 UN Sustainable Development Goals

The United Nation's Sustainable Development Goals came into effect at the beginning of 2016. They apply to both poor and rich countries, i.e., they are universal. There is a total of 17 goals (see Figure 6), with 169 sub-objectives. The aim is to turn global development into a career track in which people's wellbeing, human rights, economic prosperity, and social stability are safeguarded in an environmentally sustainable way. The implementation of these goals is the role of public, private, and third-sector actors, as well as citizens. (UN, 2020).

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Figure 6 UN Sustainable Development Goals (Adapted from UN, 2015)

Table 13 presents essential goals in the context of SHAPES, both for individual SHAPES Digital Solutions and SHAPES business governance and operations.

Table 13 Sustainable Development Goals and SHAPES

Goal	SHAPES perspective
1. End poverty	This regards pricing of the SHAPES services. Pricing alone does not end poverty. The SHAPES Platform includes educational resources to help fight poverty (concerning the fulfilment of basic needs such as health and social care) and technological solutions to support health and care delivery.
2. End hunger	SHAPES could also provide services to support good nutrition. SHAPES digital solutions may also support volunteerism and solidarity initiatives that work to end hunger.
3. Good health and wellbeing	This is one of the key objectives of the SHAPES project. SHAPES is building an ecosystem of actors and resources to ensure that wellbeing and a superior quality of life are accessible to older individuals.
4. Good education	To improve the health and care literacy of older individuals, augmenting their self-management capabilities and empowering them to take part in health and care decision-making is a key objective of SHAPES.
5. Gender equality	The needs of all gender groups are to be considered in the SHAPES Integrated Care Platform. Not only will SHAPES digital solutions take their needs into consideration, but the SHAPES project will also strive to involve end-users of all gender groups in the co-creation process, namely the piloting activities.
8. Decent work and economic growth	Better vocational wellbeing for service providers and attractiveness of the work is an essential part of SHAPES. SHAPES digital

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	solutions aim to reduce the workload of care professionals and improve the efficiency of care service delivery. The starting point for the long-term sustainability of the SHAPES Ecosystem is responsible business practices within SHAPES companies.
9. Industry, innovation, and infrastructure	One of SHAPES's objectives is to develop business and innovation opportunities for industry, particularly SMEs, in the health and care technology sector and data analytics domain. These opportunities should reinforce and modernise existing infrastructures that benefit from SHAPES's governance models and sustainability schemes.
10. Reduced inequality	SHAPES will level the playing field for all groups within the older citizens group.
11. Sustainable cities and communities	SHAPES Ecosystem and SHAPES Marketplace should support this approach.
12. Sustainable consumption and production	The SHAPES Integrated Care Platform supports the diffusion of environmentally sound technologies and promotes the reduction of non-efficient health and social care resource utilisation.
17. Participation for the goals	SHAPES explores the benefits of digital solutions and technology to support improved quality of life and good health and wellbeing. This goal is facilitated by the development of sound partnerships with the relevant end-users to support all design, development and validation phases of the SHAPES project as part of the SHAPES co-creation methodology.

4.2 Customer centric approach and service design

4.2.1 Customer understanding and customer-centric thinking

Theoretical concepts of business have changed with the world and economic development. There has been a shift from a traditional production-centric approach to a service- and customer-centric mind set. We are currently living in a service society utilising the digital service economy. Most of this market changes and increased dynamism is the result of technological evolution. However, the real challenge for companies and organisations does not stem from technological developments but from how customer behaviour has changed along with development. (Heinonen & Strandvik, 2018).

The success of an organisation is based on an understanding of the role the service provider plays in the customer's life and customer ecosystem, how the customer's needs can be identified and how they are met. The service provider must therefore understand the life and ecosystem of the customers and the resulting holistic customer logic that the customers apply to achieve their goals. (Heinonen et al., 2013; Heinonen & Strandvik, 2018).

It has been found that a holistic understanding of the customer requires in-depth internalisation of customer logic and customer operations. Customer logic is always individual, original, cognitive, and emotional. It manifests itself not only in customer

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action but also in reactions, preferences, and behaviour. Customer logic influences how customers make the decision to use the service and how they commit to using it. (Heinonen & Strandvik, 2015)

The customer-centric way of thinking also places the customer in the role of an active actor (Mickelsson, 2013). Customer operations refer to both visible and invisible actions and experiences that integrate as a whole into the customer's own operations (Heinonen & Strandvik, 2015). However, it must be taken into account that the customer's activities also manifest themselves other than as a visible and perceptible interaction with the service provider. Interaction is thus only one part of the customer's operations (Mickelsson, 2013). Thus, it is essential for the service provider to understand all the customer's functions and experiences, including the more difficult-to-identify so-called invisible actions related to the use of the service (Heinonen & Strandvik, 2018).

By understanding the customer's operations, one can contribute to both service planning and communication. The service can be designed to support the activities in which the customer wants to participate. Communication can also be harmonised to match the customer's operations (Mickelsson, 2013). In customer-centric business logic, value is created through the customer's operations (Heinonen et al., 2013). With digitalisation, the customer's own activities in creating value have become more important. Despite the fact that the service provider provides the service, the customer, supported by technology, controls the service process through his or her own operations. In this case, the customer is responsible for creating and producing value his- or herself (Mickelsson, 2017). The service provider acts as an enabler of value production, but it cannot itself generate value for the customer. The value the customer receives from the service becomes clear to the customer through experience. Customer-centric business logic combines value with what a person experiences, determines, and relates to emotions.

Value is always formed for the customer in their own operating environment, the customer ecosystem. The customer ecosystem covers not only the service provider but also other customers and actors, as well as the physical and virtual structures associated with the service. (Heinonen & Strandvik, 2015). Customer ecosystems are thus not only social systems but also include economic and commercial features (Heinonen & Strandvik, 2018). From the perspective of ecosystem thinking, it is worth paying attention to the fact that service ecosystems are only part of the customer's ecosystem. The service provider must therefore understand the service provider's position and influence in customer ecosystems. (Heinonen & Strandvik, 2015).

The Open Innovation 2.0 (OI2) paradigm addresses multi stakeholder co-creation and citizen involvement in innovation ecosystems. It underlines the harnessing of creativity of many instead of a selected few, and foregrounds fostered collaboration in innovation ecosystems "enabled by and fuelled by" (Curley & Salmelin, 2018) digital technologies and geared towards shared value creation. Citizens can have a crucial role as users

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of public services in identifying problems, ideating solutions, and adopting innovations (Curley & Salmelin, 2018).

In Citizen Science, a closely related concept to Open Innovation 2.0, the potential provided by digitalization and online collaboration platforms is utilised for organized collective action in citizen engagement (EC Directorate General Connect, 2020a) in scientific knowledge production and increasingly in initiatives of sustainability and social innovation (EC Directorate General Connect, 2020b). User panels, both online and in real-life, is an approach well-suited for the systematic and sustained involvement of stakeholders with diverse interests in different phases of co-creation (Schuurman et al., 2012).

4.2.2 Service Logic Business Model Canvas

Incorporating a customer-centric perspective into a company's business model requires a new way of thinking, as traditional business model concepts do not take into account a customer-centric perspective. However, the business model cannot be based on a customer-centric approach alone but must also consider the business perspective. Ojasalo & Ojasalo (2018) have developed a thinking model and tool, Service Logic Business Model Canvas (SLBMC), see Figure 7, based on the customer and service logic perspective, to support the development of organisations' business models (Ojasalo & Ojasalo, 2018).

The Service Logic Business Model Canvas follows the same structure as the original Business Model Canvas (Osterwalder & Pigneur, 2005), but in each of the nine areas, the customer's perspective is systematically taken into account, in addition to the organisation's own perspective. The usability of the model is supported by the fact that the use of the canvas ensures the internalisation of the customer perspective. By using the canvas, organisations can make sure they put the customer at the centre of all design and analyse their business from the perspective of customer operations, practices, and experiences. The canvas is a concrete, easy-to-apply and practical tool, and its users do not have to master the theories of different business logics themselves. (Ojasalo & Ojasalo, 2018).

The goal of the Service Logic Business Model Canvas is to provide the service providers with an in-depth understanding of the customer, taking into account, among other things, the customer's potential emotional, social, ethical, environmental, and symbolic aspects. The model thus has strong links to customer-centric business logic. It is recommended that the utilisation of the canvas begin with a perception of the customer's world. Based on the customer's in-depth knowledge, customer profiles and activities can be designed to help develop a business model. (Ojasalo & Ojasalo, 2018).

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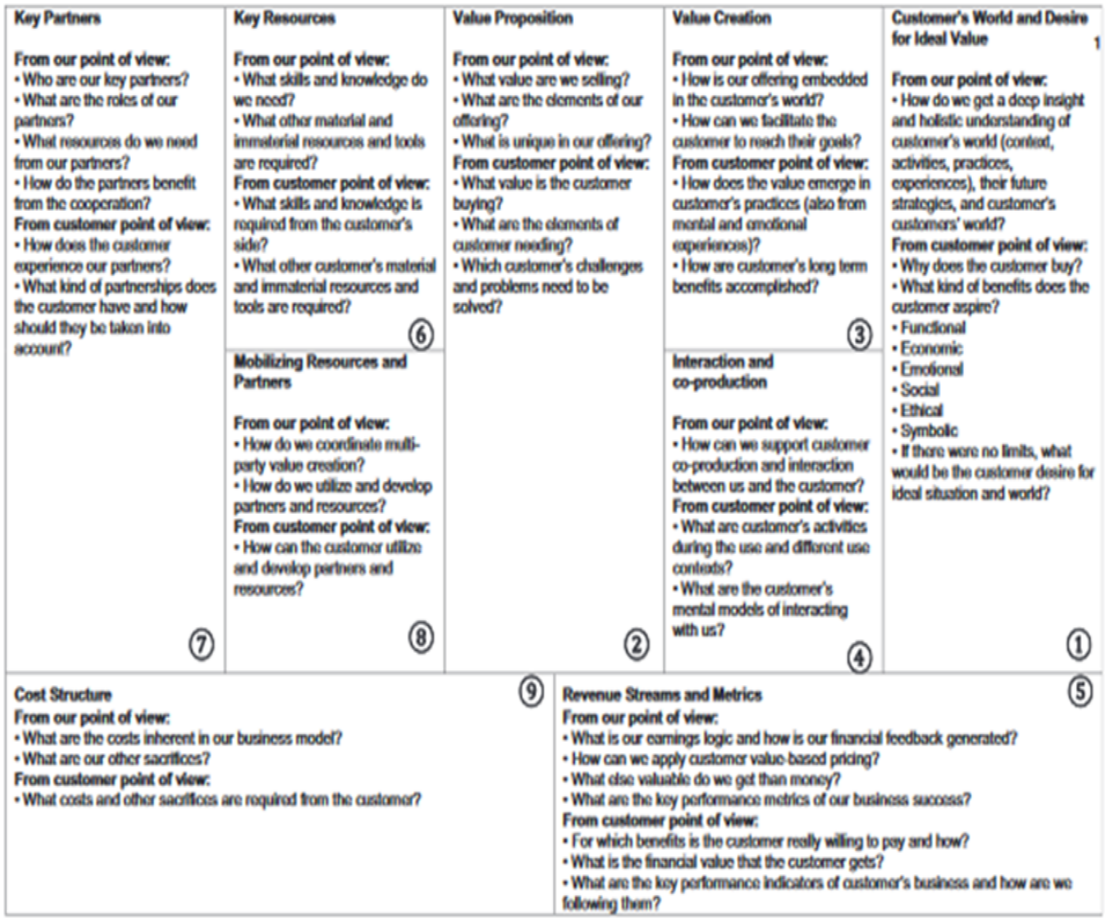

Figure 7 Customer logic Business Canvas Adapted from Ojasalo-Ojasalo, 2018)

4.2.3 Customer logic and SHAPES ethics

Customer-centric business logic provides a good frame of reference for service development in conjunction with customers (Heinonen & Strandvik 2018). Heinonen & Strandvik (2018) emphasise that with increased dynamics, different ways of thinking and perspectives are more important than ever before. In a dynamic operating environment, the decisive factor is which service provider the customer chooses and which he/she undertakes to use. Service providers need to understand customers holistically, weighing the factors that guide and limit each customer's operations. It is noteworthy that the customer's individual, subjective logic may differ from the service provider's logic, and that value is generated when using the service (Heinonen & Strandvik, 2018). By solving business challenges in a customer-centric manner, it is possible to ensure not only that the customer receives products and services that meet their needs and values but also to contribute to the sustainability and profitability of the organisation's business.

Increased transparency has also contributed to empowering both citizens and customers. Customer logic expresses what is important to the customer both now and

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in the future. Thus, the market for new ideas and innovations depends on the dynamics of customer logic. (Heinonen & Strandvik, 2018).

The starting point for developing and producing services must be a) understanding the customer and his/her life and world, and b) understanding the dynamics of the service ecosystem from the customer's perspective. Service design provides a process and methods for this: in the customer understanding phase, data is collected extensively (qualitative with an ethnographic approach, supplemented by quantitative data) and based on its analysis, representations of customer life and the world, as well as ecosystem actors and dynamics, are formed: for example, personalities, empathy maps, stakeholder maps and ecosystem maps. (Stickdorn et al., 2018).

In the development and production of services, the customer's active, even partner-like role in both service development (Yu & Sangiorgi, 2018a) and service provision and value creation must be considered (Yu & Sangiorgi, 2018b), as well as interaction with the customer, which occurs in numerous ways. The active role of the customer may extend to learning about development methods in service design collaborations (Yu & Sangiorgi, 2018a). Enabling mutual learning is pinpointed as one of the core commitments of participatory design (Robertson & Simonsen, 2013), an approach that shares the basic structure and obligations with service design (Holmlid, 2009).

Service design provides a multiplicity of methods for customer interaction and engagement: the service path can be used to visualise the customer's progress and points of contact in the service system, and the service blueprint can also be used to visualise activities and actors who are invisible to the customer. The customer's wider operating environment and the customer's ecosystems, as well as their dynamics – which must be taken into account in the development and production of services – can also be modelled using Service Design Methods (ecosystem mapping). (Stickdorn et al., 2018).

Open innovation draws attention to the evolving role of the users. It recognizes them both in the sense of customers and business clients, as sources of innovation. It acknowledges their creative competence that may extend to an ability to innovate products and services, and take advantage of innovations by others, even without the involvement of other businesses (von Hippel, 2006). The development known as 'democratizing innovation' that highlights the need to distribute resources for design and innovation widely (von Hippel, 2006) has substantial ethical implications. It serves to promote users' autonomy, participation, and influence on the socio-technical development of the society.

In addition to customer needs, economic (business) factors must be considered in the development and production of services in order to create a profitable and sustainable business. Service design provides a method and a tool for this: SLBMC can be used to examine different aspects of a service, including economic factors and their coordination with other factors. Economic factors need to be considered also from the

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point of view of the customer, the older person, considering the customer's willingness and ability to pay for the service and the available local subventions and benefits.

Participatory design highlights some basic ethical principles that can guide developers' reflective considerations of "how do we 'act well'" (Robertson & Wagner, 2013) in situations in which new technologies are introduced in our everyday life and work practice. Specifically, participatory design underlines the active participation and emancipatory efforts in processes of design. It considers as one of its cornerstones the idea that individuals who are affected by the introduction and implementation of technologies should have the right to influence their design and the ways in which they are put into use. Furthermore, participatory designers strive to enable the inclusion and equal expression of multiple voices in design, to ensure the self-representation of the users themselves in actions concerning them, both in the current and in the future, and to appreciate the design-in-use as a substantial part in the design's completion. (Robertson & Wagner, 2013).

4.3 Artificial intelligence and ethics

4.3.1 Background

Artificial intelligence (AI) refers to systems that display intelligent behaviour by analysing their environment and taking actions – with some degree of autonomy – to achieve specific goals. AI-based systems can be purely software-based, acting in the virtual world (for example voice assistants, image analysis software, search engines, speech and face recognition systems) or AI can be embedded in hardware devices (for example advanced robots, autonomous cars, drones or Internet of Things applications). (COM, 2018).

In February 2020, the European Commission released A White Paper on Artificial Intelligence – a European approach to excellence and trust. The purpose of the paper is to discuss policy options for how to achieve two goals: to promote the uptake of AI and to address risks inherent to certain uses of AI. The paper proposes that trust and excellence are key elements of future data regulation policy in Europe. (European Commission 2020). In regards to creating an ecosystem of trust, the white paper refers to the Ethics Guidelines, and in particular the seven key requirements for AI that were identified (see sub-section 4.3.3).

The European Commission identifies two categories of risks in AI:

- risks for fundamental rights (including data protection, due to the large amounts of data being processed, and non-discrimination, due to bias within the AI)
- risks for safety and the effective functioning of the liability regime (European Commission, 2020).

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The High-Level Expert Group on Artificial Intelligence (HLGE) provided the AI Ethics Guidelines to the Commission in March 2019. The AI Ethics Guidelines forms part of a vision embracing a human-centric approach to AI, which will enable Europe to become a globally leading innovator in ethical, secure and cutting-edge AI. It strives to facilitate and enable **"**Trustworthy AI made in Europe" that will enhance the wellbeing of European citizens. (AI ETHICS, 2019).

Trustworthy AI has three components that should be employed throughout the system's entire lifecycle:

- It should be lawful, complying with all applicable laws and regulations
- It should be ethical, ensuring adherence to ethical principles and values
- It should be robust, both from technical and societal perspective, since even with good intentions, AI systems can cause unintentional harm (AI ETHICS, 2019 p. 5).

The framework does not explicitly deal with the first component (lawful AI). Instead, it offers guidance for fostering and securing ethical and robust AI. Guidelines seek to go beyond a list of ethical principles by providing guidance on how such principles can be operationalised in sociotechnical systems. (AI ETHICS, 2019 p. 2). From a SHAPES viewpoint, the guidelines can be summarised as follows:

4.3.2 Ethical principles and values

The HLGE summarises the ethical principles and values as follows;

- Develop, deploy, and use AI systems that adhere to the ethical principles of respect for human autonomy, prevention of harm, fairness, and explicability.
- Particular attention is to be paid to individuals who might be in vulnerable situations, disadvantaged or at risk of exclusion, such as persons with disabilities, and to situations characterised by asymmetry of power or information.
- Remember that AI systems also pose certain risks and may have a negative impact.
- Adopt adequate measures to mitigate risks
  (AI ETHICS, 2019, p. 13-14).

4.3.3 Seven requirements for AI systems

The Assessment List for Trustworthy Artificial Intelligence (AI ETHICS 2019; ALTAI 2020) is grounded in the protection of people's fundamental rights, which is the term used in the European Union to refer to human rights enshrined in the EU Treaties, the Charter of Fundamental Rights (the Charter) and international human rights law (Table 15).

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The list strives to ensure that the development, deployment and use of AI systems meet requirements for trustworthy AI: (1) human agency and oversight (2) technical robustness and safety (3) privacy and data governance (4) transparency (5) diversity, non-discrimination and fairness (6) environmental and societal wellbeing and (7) accountability. The technical and non-technical methods to ensure the implementation of requirements is described in Table 14. (AI Ethics, 2019 p. 2-3).

Table 14 Technical and non-technical methods to realise trustworthy AI (Adapted from AI Ethics, 2019 p. 22-25)

Technical methods	Non-technical methods
Architectures for trustworthy AI	Regulation
Ethics and rules of law by design	Code of conduct
Explanation methods	Standardisation
Testing and validating	Stakeholder participation and social dialogue
Quality of service indicators	Diversity and inclusive design teams
	Certification
	Accountability via governance frameworks

Table 15 Trustworthy AI assessment list (Adapted from ALTAI, 2020)

Trustworthy artificial intelligence assessment list
Fundamental Rights Fundamental rights encompass rights such as human dignity and non-discrimination, as well as rights in relation to data protection and privacy, to name just a few examples. Prior to self-assessing an AI system with this list, a fundamental rights impact assessment (FRIA) should be performed.

1. Human Agency and Oversight
Human Agency and Autonomy
• Is the AI system designed to interact, guide or take decisions by human end-users that affect humans or society?
  ○ Could the AI system generate confusion for some or all end-users or subjects on whether a decision, content, advice or outcome is the result of an algorithmic decision?
  ○ Are end-users or other subjects adequately made aware that a decision, content, advice or outcome is the result of an algorithmic decision?
• Could the AI system generate confusion for some or all end-users or subjects on whether they are interacting with a human or AI system?
  ○ Are end-users or subjects informed that they are interacting with an AI system?
• Could the AI system affect human autonomy by generating over-reliance by end-users?
  ○ Did you put in place procedures to avoid that end-users over-rely on the AI system?
• Could the AI system affect human autonomy by interfering with the end-user's decision-making process in any other unintended and undesirable way?
  ○ Did you put in place any procedure to avoid that the AI system inadvertently affects human autonomy?
• Does the AI system simulate social interaction with or between end-users or subjects?

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- Does the AI system risk creating human attachment, stimulating addictive behaviour, or manipulating user behaviour? Depending on which risks are possible or likely, please answer the questions below:
    - Did you take measures to deal with possible negative consequences for end-users or subjects in case they develop a disproportionate attachment to the AI System?
    - Did you take measures to minimise the risk of addiction?

Human oversight

- Please determine whether the AI system (choose as many as appropriate):
    - Is a self-learning or autonomous system;
    - Is overseen by a *Human*-in-the-Loop;
    - Is overseen by a *Human*-on-the-Loop;
    - Is overseen by a *Human*-in-Command.
- Have the humans (human-in-the-loop, human-on-the-loop, human-in-command) been given specific training on how to exercise oversight?
- Did you establish any detection and response mechanisms for undesirable adverse effects of the AI system for the end-user or subject?
- Did you ensure a 'stop button' or procedure to safely abort an operation when needed?
- Did you take any specific oversight and control measures to reflect the self-learning or autonomous nature of the AI system?

2. Technical Robustness and Safety

Resilience to Attack and Security

- Could the AI system have adversarial, critical, or damaging effects (e.g. to human or societal safety) in case of risks or threats such as design or technical faults, defects, outages, attacks, misuse, inappropriate or malicious use?
- Is the AI system certified for cybersecurity (e.g. the certification scheme created by the Cybersecurity Act in Europe) or is it compliant with specific security standards?
- How exposed is the AI system to cyber-attacks?
    - Did you assess potential forms of attacks to which the AI system could be vulnerable?
    - Did you consider different types of vulnerabilities and potential entry points for attacks such as:
        - Data poisoning (i.e. manipulation of training data);
        - Model evasion (i.e. classifying the data according to the attacker's will);
        - Model inversion (i.e. infer the model parameters)
- Did you put measures in place to ensure the integrity, robustness, and overall security of the AI system against potential attacks over its lifecycle?
- Did you red-team/pentest the system?
- Did you inform end-users of the duration of security coverage and updates?
    - What length is the expected timeframe within which you provide security updates for the AI system?

General Safety

- Did you define risks, risk metrics and risk levels of the AI system in each specific use case?
    - Did you put in place a process to continuously measure and assess risks?
    - Did you inform end-users and subjects of existing or potential risks?
- Did you identify the possible threats to the AI system (design faults, technical faults, environmental threats) and the possible consequences?
    - Did you assess the risk of possible malicious use, misuse, or inappropriate use of the AI system?
    - Did you define safety criticality levels (e.g. related to human integrity) of the possible consequences of faults or misuse of the AI system?

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- Did you assess the dependency of a critical AI system's decisions on its stable and reliable behaviour?
    - Did you align the reliability/testing requirements to the appropriate levels of stability and reliability?
- Did you plan fault tolerance via, e.g. a duplicated system or another parallel system (AI-based or 'conventional')?
- Did you develop a mechanism to evaluate when the AI system has been changed to merit a new review of its technical robustness and safety?

Accuracy

- Could a low level of accuracy of the AI system result in critical, adversarial, or damaging consequences?
- Did you put in place measures to ensure that the data (including training data) used to develop the AI system is up-to-date, of high quality, complete and representative of the environment the system will be deployed in?
- Did you put in place a series of steps to monitor, and document the AI system's accuracy?
- Did you consider whether the AI system's operation can invalidate the data or assumptions it was trained on, and how this might lead to adversarial effects?
- Did you put processes in place to ensure that the level of accuracy of the AI system to be expected by end-users and/or subjects is properly communicated?

Reliability, Fall-back plans, and Reproducibility

- Could the AI system cause critical, adversarial, or damaging consequences (e.g. pertaining to human safety) in case of low reliability and/or reproducibility?
    - Did you put in place a well-defined process to monitor if the AI system is meeting the intended goals?
    - Did you test whether specific contexts or conditions need to be taken into account to ensure reproducibility?
- Did you put in place verification and validation methods and documentation (e.g. logging) to evaluate and ensure different aspects of the AI system's reliability and reproducibility?
    - Did you clearly document and operationalise processes for the testing and verification of the reliability and reproducibility of the AI system?
- Did you define tested failsafe fallback plans to address AI system errors of whatever origin and put governance procedures in place to trigger them?
- Did you put in place a proper procedure for handling the cases where the AI system yields results with a low confidence score?
- Is your AI system using (online) continual learning?
    - Did you consider potential negative consequences from the AI system learning novel or unusual methods to score well on its objective function?

3. Privacy and Data Governance

Privacy

- Did you consider the impact of the AI system on the right to privacy, the right to physical, mental and/or moral integrity and the right to data protection?
- Depending on the use case, did you establish mechanisms that allow flagging issues related to privacy concerning the AI system?

Data Governance

- Is your AI system being trained, or was it developed, by using or processing personal data (including special categories of personal data)?
- Did you put in place any of the following measures some of which are mandatory under GDPR, or a non-European equivalent?
    - Data Protection Impact Assessment (DPIA);

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- Designate a Data Protection Officer (DPO) and include them at an early state in the development, procurement or use phase of the AI system;
- Oversight mechanisms for data processing (including limiting access to qualified personnel, mechanisms for logging data access and making modifications);
- Measures to achieve privacy-by-design and default (e.g. encryption, pseudonymisation, aggregation, anonymisation);
- Data minimisation, in particular personal data (including special categories of data);

  - Did you implement the right to withdraw consent, the right to object and the right to be forgotten into the development of the AI system?
  - Did you consider the privacy and data protection implications of data collected, generated, or processed over the course of the AI system's life cycle?
- Did you consider the privacy and data protection implications of the AI system's non-personal training-data or other processed non-personal data?
- Did you align the AI system with relevant standards (e.g. ISO, IEEE) or widely adopted protocols for (daily) data management and governance?

4. Transparency

Traceability

- Did you put in place measures that address the traceability of the AI system during its entire lifecycle?
  - Did you put in place measures to continuously assess the quality of the input data to the AI system?
  - Can you trace back which data was used by the AI system to make a certain decision(s) or recommendation(s)?
  - Can you trace back which AI model or rules led to the decision(s) or recommendation(s) of the AI system?
  - Did you put in place measures to continuously assess the quality of the output(s) of the AI system?
  - Did you put adequate logging practices in place to record the decision(s) or recommendation(s) of the AI system?

Explainability

- Did you explain the decision(s) of the AI system to the users?
- Do you continuously survey the users if they understand the decision(s) of the AI system?

Communication

- In cases of interactive AI systems (e.g., chatbots, robo-lawyers), do you communicate to users that they are interacting with an AI system instead of a human?
- Did you establish mechanisms to inform users about the purpose, criteria and limitations of the decision(s) generated by the AI system?
  - Did you communicate the benefits of the AI system to users?
  - Did you communicate the technical limitations and potential risks of the AI system to users, such as its level of accuracy and/ or error rates?
  - Did you provide appropriate training material and disclaimers to users on how to adequately use the AI system?

5. Diversity, Non-Discrimination and Fairness

Avoidance of Unfair Bias

- Did you establish a strategy or a set of procedures to avoid creating or reinforcing unfair bias in the AI system, both regarding the use of input data as well as for the algorithm design?
- Did you consider diversity and representativeness of end-users and/or subjects in the data?
  - Did you test for specific target groups or problematic use cases?

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- Did you research and use publicly available technical tools that are state-of- the-art, to improve your understanding of the data, model, and performance?
- Did you assess and put in place processes to test and monitor for potential biases during the entire lifecycle of the AI system (e.g. biases due to possible limitations stemming from the composition of the used data sets (lack of diversity, non-representativeness)?
- Where relevant, did you consider diversity and representativeness of end-users and or subjects in the data?

- Did you put in place educational and awareness initiatives to help AI designers and AI developers be more aware of the possible bias they can inject in designing and developing the AI system?
- Did you ensure a mechanism that allows for the flagging of issues related to bias, discrimination, or poor performance of the AI system?
  - Did you establish clear steps and ways of communicating on how and to whom such issues can be raised?
  - Did you identify the subjects that could potentially be (in) directly affected by the AI system, in addition to the (end-) users and/or subjects?
- Is your definition of fairness commonly used and implemented in any phase of the process of setting up the AI system?
  - Did you consider other definitions of fairness before choosing this one?
  - Did you consult with the impacted communities about the correct definition of fairness, i.e. representatives of elderly persons or persons with disabilities?
  - Did you ensure a quantitative analysis or metrics to measure and test the applied definition of fairness?

Accessibility and Universal Design

- Did you ensure that the AI system corresponds to the variety of preferences and abilities in society?
- Did you assess whether the AI system's user interface is usable by those with disabilities or those at risk of exclusion?
  - Did you ensure that information about, and the AI system's user interface of, the AI system is accessible and usable also to users of assistive technologies (such as screen readers)?
  - Did you involve or consult with end-users or subjects in need for assistive technology during the planning and development phase of the AI system?
- Did you ensure that Universal Design principles are taken into account during every step of the planning and development process, if applicable?
- Did you take the impact of the AI system on the potential end-users and/or subjects into account?
  - Did you assess whether the team involved in building the AI system engaged with the possible target end-users and/or subjects?
  - Did you assess whether there could be groups who might be disproportionately affected by the outcomes of the AI system?
  - Did you assess the risk of the possible unfairness of the system onto the end-user's or subject's communities?

Stakeholder participation

- Did you consider a mechanism to include the participation of the widest range of possible stakeholders in the AI system's design and development?

6. Societal and Environmental Wellbeing
Environmental well-being

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- Are there potential negative impacts of the AI system on the environment?
    - Which potential impact(s) do you identify?
- Where possible, did you establish mechanisms to evaluate the environmental impact of the AI system's development, deployment and/or use (for example, the amount of energy used and carbon emissions)?
    - Did you define measures to reduce the environmental impact of the AI system throughout its lifecycle?

Impact on work and skills

- Does the AI system impact human work and work arrangements?
- Did you pave the way for the introduction of the AI system in your organisation by informing and consulting with impacted workers and their representatives (trade unions, (European) work councils) in advance?
- Did you adopt measures to ensure that the impacts of the AI system on human work are well understood?
    - Did you ensure that workers understand how the AI system operates, which capabilities it has and which it does not have?
- Could the AI system create the risk of de-skilling of the workforce?
    - Did you take measures to counteract de-skilling risks?
- Does the system promote or require new (digital) skills?
    - Did you provide training opportunities and materials for re- and up-skilling?

Impact on Society at large or democracy

- Could the AI system have a negative impact on society at large or democracy?
    - Did you assess the societal impact of the AI system's use beyond the (end-)user and subject, such as potentially indirectly affected stakeholders or society at large?
    - Did you take action to minimize potential societal harm of the AI system?
    - Did you take measures that ensure that the AI system does not negatively impact democracy?

7. Accountability

Auditability

- Did you establish mechanisms that facilitate the AI system's auditability (e.g. traceability of the development process, the sourcing of training data and the logging of the AI system's processes, outcomes, positive and negative impact)?
- Did you ensure that the AI system can be audited by independent third parties?

Risk management

- Did you foresee any kind of external guidance or third-party auditing processes to oversee ethical concerns and accountability measures?
    - Does the involvement of these third parties go beyond the development phase?
- Did you organise risk training and, if so, does this also inform about the potential legal framework applicable to the AI system?
- Did you consider establishing an AI ethics review board or a similar mechanism to discuss the overall accountability and ethics practices, including potential unclear grey areas?
- Did you establish a process to discuss and continuously monitor and assess the AI system's adherence to this Assessment List for Trustworthy AI (ALTAI)?
    - Does this process include identification and documentation of conflicts between the 6 aforementioned requirements or between different ethical principles and explanation of the 'trade-off' decisions made?
    - Did you provide appropriate training to those involved in such a process and does this also cover the legal framework applicable to the AI system?

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- Did you establish a process for third parties (e.g. suppliers, end-users, subjects, distributors/vendors or workers) to report potential vulnerabilities, risks or biases in the AI system?
  - Does this process foster revision of the risk management process?
- For applications that can adversely affect individuals, have redress by design mechanisms been put in place?

4.3.4 Limitations of AI ethics

During recent years, many initiatives have been taken to define values, principles and the ethical development and deployment of artificial intelligence. This ethics of artificial intelligence have produced high-level principles, value statements and few specific recommendations, but failed to address fundamental tensions embedded in key concepts such as fairness and privacy. (Mittelstadt, 2019).

Mittelstadt (2019) assesses the strategies and recommendations proposed by current artificial intelligence initiatives. He refers to recent comparisons made between AI ethics initiatives and medical ethics. It seems that AI ethics have converged on a set of principles that closely resemble the four classic principles of medical ethics. Mittelstand finds four characteristics of AI intelligence development that suggest a principle-based approach may have had a restricting impact on design and governance. Compared to medicine, artificial intelligence development lacks:

1. Common aims and fiduciary duties. Medicine has a common aim of promoting patient health and the wellbeing of the patient. AI development lacks this kind of goal: AI is based on public needs, but mostly developed by the private sector. This may lead to a situation where the aims of developers and users do not synergise. Furthermore, in medicine there are formal professions that dictate certain obligations towards patients.
2. Professional history and norms. AI development and ethics do not have the long professional history and well-defined norms of "'good"' behaviour as medicine does (for example, the Hippocratic Oath). Whereas medicine has a quite narrow aim (the wellbeing patient), AI can be deployed basically in any context involving human expertise.
3. Proven methods to translate principles into practice. Medicine has proven methods of translating principles into practical requirements (for example, professional boards, ethics review committees, codes of conduct). AI does not have such methods.
4. Robust legal and professional accountability mechanisms. The field of medicine is highly governed by legal and professional frameworks. AI development only has few methods to exclude risks like data protection law to govern privacy violations, but no accountability mechanisms comparable to medicine. (Mittelstadt, 2019).

Based on the four characteristics mentioned above, Mittelstadt (2019) provides the following recommendations regarding the further development of artificial ethics: (1) To clearly define sustainable pathways to impact, (2) to support bottom-up AI Ethics

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in the private sector, (3) to license developers of high-risk AI, (4) to shift from professional ethics to organisational ethics and, finally, (5) to pursue ethics as a process, not technological solutionism.

Following Mittelstadt's views, one conclusion is that ethical challenges in SHAPES AI must not only be the responsibility of individual researchers and developers, but also of those organisations that they represent, as well as the whole SHAPES Integrated Care Platform and the governance of SHAPES.

The prevention of harm is emphasized in the literature and in critics regarding the HLGE work. According to Brugage et al (2018) the dual-use nature of IA research and engineering in in artificial intelligence should be taken seriously. According Vesnic-Alujevic et al. (2020) impacts of AI are complex. Analysis of policy papers produced by European institutions, European national governments and other organisations reveals that both individual and authorities are aligned in calling for more responsibility, accountability, transparency, safety, and trust. (Vesnic-Alujevic et al., 2020). Furthermore, Veale (2020) criticises the HLGE work regarding the framing, representation and expertise, and the lack of acknowledgement of key issues of power and infrastructure underpinning modern information economies.

The above critics demonstrates that in SHAPES, the Societal Impact Assessment is an essential part of the SHAPES Governance not only during but also after the SHAPES project.

4.4 EU policies relevant to the SHAPES

The EU can adopt health legislation under the Treaty on the Functioning of the European Union: Article 168 (protection of public health), Article 114 (approximation of laws) and Article 153 (social policy). In addition, The Council of the EU can address recommendations on public health to EU countries. While the Member States are responsible for the functioning of their health systems, there are specific areas where the EU can legislate, and others where the Commission can support Member States' efforts. There is already a comprehensive regulatory framework for medical products and technologies (medicinal products, medical devices, and substances of human origin), as well as on tobacco legislation, patients' rights in cross-border healthcare and serious cross-border health threats. (COM, 2020a).

4.4.1 EU4Health

EU4Health is the fourth and largest of the EU Health Programmes since their inception in 2003, with a dedicated budget of €9.4 (TBC) billion (2021–2027) allocated to it under the agreement by the European Parliament and Council on the next multiannual financial framework. New EU4Health Programme for 2021-2027 was officially established March 2021 (EU, 2021).

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EU4Health aims to:

- Make health systems more resilient to deal with cross-border health threats like COVID-19 and improve crisis management capacity
- Make the European Health Union a reality by investing in cancer care, better pandemic preparedness, availability of medicines and innovation
- Boost digital health and disease prevention
- Ensure prevention, preparedness, surveillance, and response to cross-border health threats
- Build emergency reserves of medicines, medical devices, and other health supplies. (COM, 2020a).

The EU4Health Programme should support Member States in the transition to better preparedness and the reinforcement of their health systems and support them in achieving the health-related United Nations Sustainable Development Goals (SDGs).Beyond the required level of preparedness and response, there are a number of further challenges (below) in the areas of health security and health systems impeding their overall functioning, and rendering an adequate crisis response overall more demanding, in particular (COM, 2020a).

Future challenges in health security and health systems:

- Inequalities in health status among population groups, countries and regions, and access to affordable, preventive, and curative health care of good quality
- Burden from non-communicable diseases, including cancer, mental health, rare diseases, and risks from health determinants
- Uneven distribution of health care systems capacity, including health care workers
- Obstacles to the wide uptake and best use of digital innovations as well their scaling up
- Growing health burden from environmental degradation and pollution, in particular air, water, and soil quality, and also from demographic changes. (COM, 2020a, p.2).

As many of the new and innovative suggestions are closely related to the functioning of health systems, the Commission should work closely with the Member States to make sure that the support provided by the EU4Health Programme is based on national needs. (COM, 2020a).

The Programme should be dynamic and flexible to adapt to emerging new challenges, and to serve the EU and the Member States in their evolving needs and priorities. It needs to address inequalities by benchmarking, providing support and closing identified gaps between countries, regions, population groups and citizens. It should help reduce gaps in life expectancy and access to care and services. It should provide tools for enhanced solidarity in preparedness and crisis response, as well as in finding

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common ground to improve prevention and in addressing non-communicable diseases, and in particular cancer, and for better coordinating between different policies, tools, and financial instruments. Finally, it should contribute to tackling the negative impact of climate change and environmental degradation on human health. (COM, 2020a).

The EU4Health Programme should contribute to the Charter of Fundamental Rights of the European Union as it aims to improve access to preventive health care and the right to benefit from medical treatment under the conditions established by national laws and practices. The new Programme is also aligned with the Charter's objective that a high level of human health protection is to be ensured in the definition and implementation of all the Union's policies and activities. (COM, 2020a).

4.4.2 EU Funding for health

Funding for health under the next Multiannual Financial Framework (MFF) includes several instruments. Working across programmes and having shared objectives between policies will be key considerations to channel health funds across policies and support the achievement of their objectives more effectively than before (COM, 2020a).

Following EU agencies have a role to play in Europe's defence against serious cross border health threats and pandemics, both on the prevention and on the crisis management front:

- the European Centre for Disease Prevention and Control
- the European Medicines Agency
- the European Food Safety Authority,
- the European Chemicals Agency
- the European Safety and Health at Work Agency (COM, 2020a).

In Table 16 roles of these agencies in EU Health funding are explained

Table 16 Principles for Health Union (Adapted from COM, 2020a)

• **Health funding instruments (COM, 2020a)**
• **rescEU - EU emergency response** Through the enhanced Union Civil Protection Mechanism (UCPM/rescEU) capacities, the EU and the Member States should be better prepared for and able to react quickly and flexibly in a future crisis. The upgraded UCPM and in particular its emergency rescEU capacities will also endow the Union with enhanced preparedness and a proficient logistic infrastructure that can cater for different types of emergency, including those with a medical emergency component. Where the UCPM will focus on the direct crisis response capacities which should have to be immediately ready and available in case of an emergency, the EU4Health Programme should include structural, large-scale reserves, including a reserve of ready medical staff and experts, and the underlying resilience of the health care systems and necessary structures. Those resources are crucial for a coordinated crisis response at Union level

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- **European Fund for Regional Development** (ERDF) should support the health care systems capacity in the regions in terms of infrastructures, modernisation of the public and private healthcare sectors, and (inter)regional cooperation networks. The ERDF also provides investments in research and innovation, uptake of advanced technologies and innovative solutions, and in digitalisation, including in health. Further, it supports capacity building, technical assistance, and cross-border cooperation.
- **European Social Fund Plus** (ESF+) should create synergies and complementarities with the EU4Health Programme by supporting, among other, skills development for health staff and improved access to health care for people in socio-economic vulnerable situations, and long-term care.
- **The Recovery and Resilience Facility** should provide financial support to reforms and investments that will have a lasting impact on the growth potential and resilience of the economy of the Member States and will address challenges identified in the European Semester.
- **Horizon Europe** will finance research and innovation in health: health throughout the life; environmental and social health determinants; non-communicable and rare diseases; infectious diseases; tools, technologies and digital solutions for health and care and healthcare systems are the areas of intervention in the Commission's proposal for a 'Health' cluster. The EU4Health Programme should help to ensure best use of research results and facilitate the uptake, scale-up and deployment of health innovation in healthcare systems and clinical practice.
- **Digital Europe Programme** (DEP) will support the deployment of digital infrastructure underpinning the wide use of digital technologies in areas of public interest. The programme will support, amongst other elements, tools and data infrastructures supporting data spaces in different sectors. Building on that infrastructure and pilot implementations in different sectors supported by the DEP Programme, the EU4Health Programme will focus on delivering data sharing and citizen platform applications covering areas such as secure and effective management of personal health data across borders; better data for research, disease prevention and personalised health and care; and use of digital tools for citizen empowerment and for person-centred care, in compliance with data protection rules.
- **The Connecting Europe Facility Programme 2 Digital** (CEF Digital) will fund highly resilient Gigabit networks to connect socio-economic drivers, including hospitals and medical centres, in areas where no such networks exist or are planned to be deployed in the near future; this will enable critical applications such as tele-operated surgery as well as the sharing of medical data. It will also bring connectivity to households to enable remote patient monitoring in a secure manner and in compliance with data protection legislation.

4.4.3 European Health Union

In her 2020 State of the Union address, the President of the Commission called on Europe to draw lessons from the current COVID-19 crisis and build a European Health Union. In its Communication (COM, 2020b) the Commission proposes first building blocks for a European Health Union. It implements the obligation to ensure high level of human health protection as defined in the Charter of Fundamental Rights of the European Union. (COM, 2020b). Principles for Health Union see Table 17.

These first proposals are envisaged within the current Treaty provisions, particularly in respect of Article 168 (5) of the TFEU. By upgrading the EU framework for cross-border health threats, these first building blocks of the European Health Union should

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bring greater overall impact while there still should fully respect for the Member States' competence in the area of health.

European health Union Communication is accompanied by three legislative proposals

- An upgrading of Decision 1082/2013/EU on serious cross-border health threats
- A strengthening of the mandate of the European Centre for Disease Prevention Control (ECDC),
- An extension of the mandate of the European Medicines Agency (EMA) 10. It links to the proposal for enhancing the Union Civil Protection Mechanism 11, proposed by the Commission in June 2020 12. (COM, 2020b).

Idea is that together, these proposals will put in place a framework to enable EU Member States to respond to future health crises as a Union. Where the legislative proposals entail the processing of personal data, this should happen in full compliance with the applicable EU data protection rules. The principles and specific safeguards laid down by the EU data protection framework allow for an effective and comprehensive protection of personal data, including data concerning health (COM, 2020b).

Table 17 Principles for Health Union (Adapted from COM, 2020)

• **Stated principles how all health policies should be based on a series of principles:**
• Priority to measures that deliver wellbeing and longer and healthier lives for all Europeans;
• Precaution, proportionality, and dignity, while also respecting fundamental rights, including equality on any grounds, including sex, race, colour, ethnic or social origin, genetic features, language, religion or belief, political or any other opinion, membership of a national minority, property, birth, disability, age or sexual orientation of gender, ethnicity, or sexuality;
• Respect for regional and national differences, both in the design and prioritisation of policies, taking account of differing contexts, and in their implementation, taking account of the principle of subsidiarity;
• Solidarity within and among Member States and with the rest of the world, with measures to safeguard their ability to deliver safe and effective health services. No one is safe until all are safe

4.4.4 Commission Green Paper on ageing

The purpose of the Commission's Green Paper on ageing (COM, 2021) was to launch a policy debate on ageing and to discuss options on how to anticipate and respond to the challenges and opportunities it brings and taking into account the UN 2030 Agenda for Sustainable Development and UN Decade for Healthy Ageing. Competences for dealing with the effects of ageing are largely in the hands of Member States and the EU is placed better to identify key issues and trends, and to support action on ageing

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at national, regional, and local level. The idea of the Green Paper is that it should help Member States and regions develop their own, tailor-made policy responses to ageing. According to the paper the number of people who receive publicly funded long-term care is expected to increase from 19.5m in 2016 to 23.6m in 2030 and 30.5m in 2050 in the EU. (COM, 2021).

The European Pillar of Social Rights sets out a number of principles that relate directly or indirectly to areas impacted by ageing, such as old age income and pensions, long-term care, health care, inclusion of people with disabilities, social protection, work-life balance and education, training and life-long learning. Von der Leyen Commission has emphasised demography change on the EU policy agenda. In June 2020, it presented a report (COM, 2020c) setting out the key facts of demographic change and its likely impacts.

Green paper on ageing was the first outcome of this Demographic change report. As a result of demographic change, there will be more older patients suffering from chronic and, in many cases, multiple diseases. Almost half of persons 65 years or older are perceived as having a disability or long-standing activity limitation. In addition, the effects of climate change, natural disasters and environmental degradation and pollution tend to disproportionately increase pressure on older people's health. This will increase the need for healthcare and other care or support services. (COM, 2021).

The Paper mentions the large-scale introduction of social and technological innovation, such as e-health, mobile health, telecare, integrated care, or independent living, could substantially improve the efficiency of health and long-term care systems. Remote monitoring healthcare models, in particular those that include patients and family members in the care team, have shown clear benefits for patients with chronic disease according to paper. Also, in the paper, integration of care through close cooperation and information-sharing between professionals, patients and their carers (including informal carers) has the potential to contain the rising costs of health and social care and at the same time help older people to remain independent for longer and increase their well-being. (COM, 2021).

4.4.5 The Digital Single market strategy

On relevant EU policies, on the one hand, SHAPES aims to contribute to the fulfilment of the objectives down in those policies. On the other hand, it will be itself framed by those policies, which are interlinked and connected to the priority identified by the Commission in its mandate in 2019 of shaping a 'digital future' for the EU. Those policies will be discussed as part of deliverable Regulatory Frameworks for Pan-European Smart and Healthy Ageing (D8.3) in conjunction with relevant EU legislative acts.

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While the EU Treaties do not contain any specific legal basis on digital technology or ICT, EU policies and legislation is adopted within the framework of internal market policies, but also making use of sectoral competences in certain area such as competition, trans-European networks, research and technological development education, vocational training, youth and sport.

The Digital Single Market Strategy was launched in 2015 under the Juncker Commission. That Strategy was linked and intertwined for the advancement of certain legislative proposals in several areas including e-commerce, data protection, IP rights and cybersecurity. Further to the 2014-2019 Digital Single Market Strategy, on February 19, 2020, the Commission guided by Ursula Von Der Leyen released a paper on how it intends to shape the EU digital future in the next five years. In that context, the Commission also published the already mentioned White Paper on Artificial Intelligence (see sub-section AI ethics), and the European Strategy for Data. (COM 2020d).

This new EU's digital strategy needs to be read in conjunction with the EU work towards sustainability and the green deal. Furthermore, after the pandemic, digitisation has proven key in the move towards the European Health Union that the Commission aims to advancing. In the Council conclusions (EU 2020) on the EU's digital policy the digital transformation, including training and upskilling, is linked to the promotion of a digital market and digital value chains. Furthermore, the Council made a strong pivot on eHealth and on the need to use digital technology to address the impact of COVID-19. (Council of the European Union, 2020). See Figure 8.

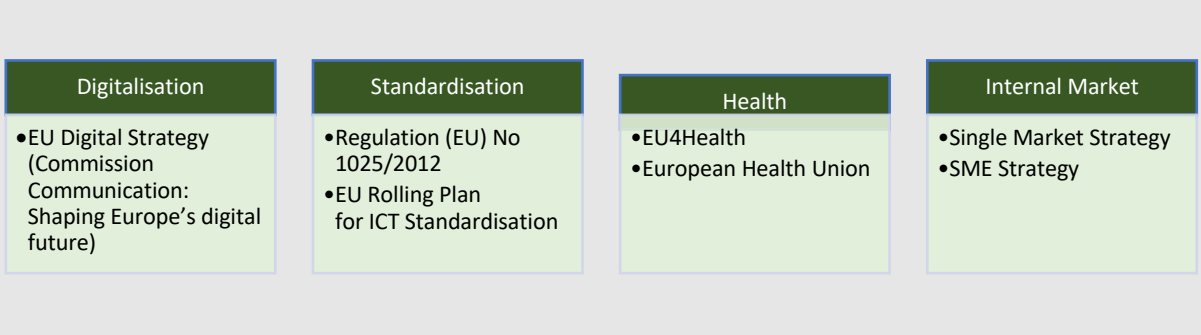

Figure 8 EU policies affecting on digital health development (Adopted from Council of the European Union, 2020)

In April 2018, the European Commission published a Communication paper on Enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society. It is crucial to accelerate the meaningful use of digital solutions in public health and healthcare in Europe. The Commission set action in three areas: 1) citizens' secure access to and sharing of health data across borders; 2) better data to advance research, disease prevention and personalised health and care and 3) digital tools for citizen empowerment and person-centred care (COM, 2018). In Table 18 are those ICT solution categories, grouped according to those Commission priorities (WE4AHA 2019).

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Table 18 ICT solution categories and COM priorities (Adapted from WE4AHA, 2019 p. 9-10)

Table of ICT solution categories according to COM priorities
Priority 1: Citizen's secure access to and sharing of health data across borders ➢ Citizen's secure access to their health data – e.g. via a secure online porta, citizen access to an Electronic Health Record (EHR), a Personal Health Record (PHR) including tele monitoring data and shared with health professionals ➢ Interoperable EHRs deployed at national and/or regional levels enabling citizens' secure access to and sharing of health data; GDPR compliant, secure health data exchange ➢ Citizen-enabled sharing of health data across borders: patient summary and/or ePrescription, discharge letter, medical images, lab results ➢ Citizen-controlled data governance, health data cooperatives, health data donation
Priority 2: Better data to promote research, disease prevention and personalized healthcare ➢ Digital infrastructure for personalized medicine, -genomics databanks, biomedical infrastructures ➢ Good practice in digital genomics, including whole genome sequencing ➢ Use of real-word data, data quality assessment and improvement ➢ Health data analytics (AIs, algorithm development and calibration, machine learning, risk stratification tools, etc.) ➢ Big data analysis, particularly for preventive medicine and treatment ➢ Interoperability of disease registries including for rare diseases, data aggregation and sharing across borders, including at EU level ➢ Digital tools for public health, epidemiology, pharmacovigilance, clinical research, including reuse of EHRs for clinical research
Priority 3: Digital tools for citizen empowerment and for person-centred care Citizen/patient-focused solutions: ➢ Digital tools to support health education (health literacy), digital health literacy ➢ mHealth systems, wearables devices for monitoring and prevention, alerts, reminders ➢ Digital tools to support patient feedback and reporting of outcomes and experiences ➢ Digital tools to support proactive prevention, self-management, homecare, tele monitoring ➢ Tele-mentoring/coaching, virtual consultations, virtual coach, personal assistant ➢ ICT supporting adherence to medication and care plans ➢ Robotics (e.g. companion robots) ➢ Tools and services supporting independent living, ambient assisted living technologies, telecare Care practitioners' solutions: ➢ Advanced digital tools for support Integrated Care, including integration of health and social care services ➢ Interoperable digital solutions to support person-centred and integrated care ➢ Regional and national EHPR systems and ePresciption solutions enabling person-centred care ➢ Regional, national, and local electronic Integrated Care Record (eICR) systems, integration of EHR and social care records ➢ Digital share care plan (e.g. support to multi-disciplinary teams) ➢ Decision support for multi-morbidity and polypharmacy management ➢ ICT support for management of frailty ➢ ICT support for falls prevention ➢ eLearning to support workforce development for person-centred integrated care

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5 SHAPES privacy and data protection

This section describes how privacy and data protection will be taken into consideration in SHAPES. This section focuses on the GDPR implementation and data governance is introduced in SHAPES Data Management Plan (D8.13). Information about the European Strategy for data can be found in D8.3.1. These deliverables together will form the bases for SHAPES data management. The main focus in this section is on SHAPES project, but the same principles will apply also in future SHAPES services. Principles described in this section shall be implemented to SHAPES processes and different digital solutions. The practical implementation of privacy and data protection principles will be assessed as part of the DPIAs that will be done for pilots and also for SHAPES platform. SHAPES ethical requirements will complement this section by giving more detailed descriptions for practical implementation. The aim is to tell what needs to be done and all SHAPES partners who processes personal data can then decide how the implementation will be done.

5.1 Processing Personal Data

5.1.1 Personal data

'Personal data' means any information relating to an identified or identifiable natural person ('data subject'); an identifiable natural person is one who can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person (GDPR, 2016, article 4). 'Any information' means both objective and subjective information about an individual, and it is not limited to any particular format: video, audio, numerical, graphical, and photographic data can be personal data. 'Identifiable' means that any individual who can be distinguished from others is identifiable. Identifiers are used to identify one specific individual.

Although all Personal data is protected under the GDPR, certain data types must be processed even more carefully than others. This is often referred to as sensitive data, and according to GDPR, they are called 'special categories of personal data'. This data consists of Personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, as well as the processing of genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person's sex life or sexual orientation. (GDPR, 2016, article 4). Special categories of Personal data can only be used in cases listed in GDPR art. 9. In practice, this means that when SHAPES is planning data processing, the right to process sensitive data must be ensured. This will be done as part of the data-processing descriptions. Since the beginning of the

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project, a working assumption is that the processing will be based on the informed, explicit consent of data subjects.

5.1.2 Processing

According to the GDPR, the processing of personal data means “any operation or set of operations which is performed on personal data or on sets of personal data, whether or not by automated means, such as collection, recording, organisation, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure or destruction” (GDPR, 2016, article 4). In practice, this means that GDPR regulations must be followed in all activities involving Personal data processing.

For example, natural persons, companies, and public authorities can be responsible for processing Personal data. Because the processing can also be undertaken by different actors who don’t have the same ability to influence how the data will be used, the GDPR separates the actors into ‘controllers’ and ‘processors’. ‘Controller’ means ‘the natural or legal person, public authority, agency or other body which, alone or jointly with others, determines the purposes and means of the processing of personal data; where the purposes and means of such processing are determined by Union or Member State law, the controller or the specific criteria for its nomination may be provided for by Union or Member State law”. ‘Processor’ means “a natural or legal person, public authority, agency or other body which processes personal data on behalf of the controller”. (GDPR, 2016, article 4). It is not always easy to determine who is a controller, who is a processor or who are the joint controllers, which means they share responsibilities. The European Data Protection Supervisor has noticed this challenge and has created a flowchart for EUIs (European Data Protection Supervisor, 2020) Although the instructions are aimed at EU institutions, they can be used a reference when identifying these roles in SHAPES.

SHAPES processes personal data for different purposes: a) for research b) for running the pilots and c) for running the SHAPES project. The controller is a partner who is responsible for these processing activities. For pilots, this is always the partner who provides the pilot solution.

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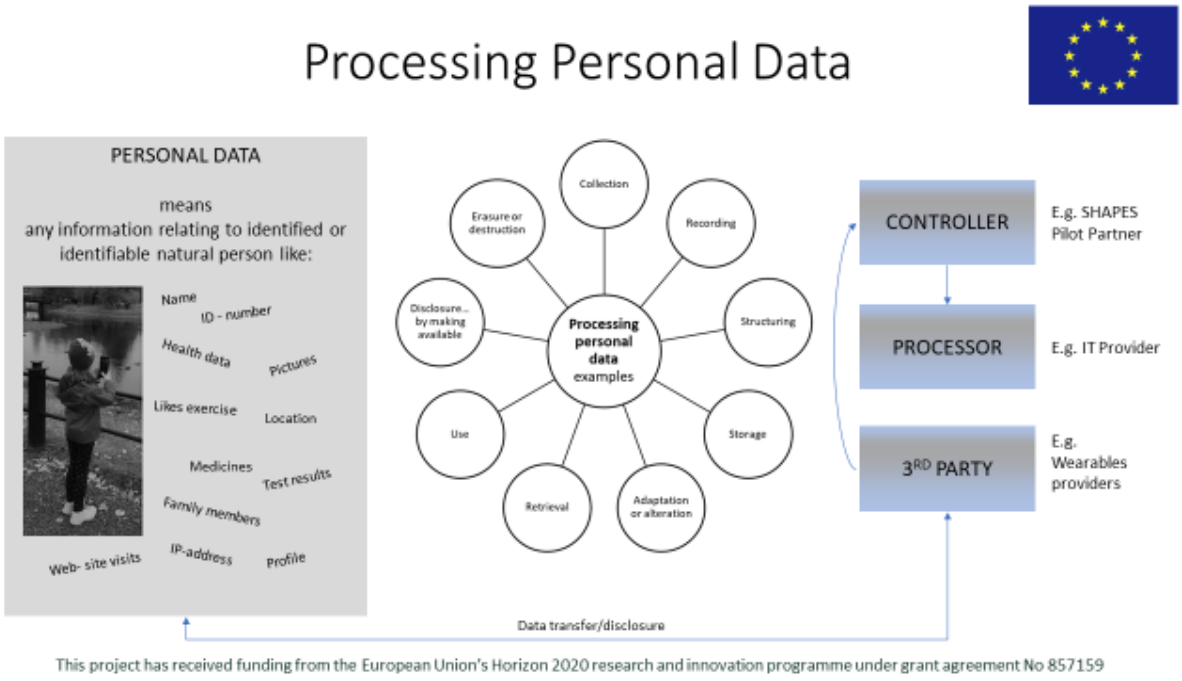

Figure 9 Processing Personal data

Figure 9 describes the different elements that link to the usage of Personal data. Personal data is defined widely in the GDPR, with the aim to get all such data under the scope of legislation that can be linked to an individual person. Identifying personal data is a key task when data usage is being planned in SHAPES. The diagram in the middle of the figure illustrates the different ways the data can be used. It is important to note that the list is not comprehensive; those are examples of the most commonly used processing methods. The boxes on the right side of the figure describe the roles that, for example a company can have when processing personal data. The arrows give an example of how the personal data can be transferred or disclosed from one party to another. 'Transferring' means that the data can only be used according to the given instructions from the controller, and 'disclosure' means the data will be given to a third party who will, after the disclosure, work as a controller for such data. When personal data is processed as part of SHAPES, all aspects described in the figure need to be analysed and documented.

5.1.3 Categories of Personal data

Categories of personal data describe the types of data relating to an individual's life. In SHAPES, this information will be used when describing the processing of Personal data as part of the services. Categorisation can also be used in Data Lifecycle Management Plans, DPIAs and when SHAPES creates the Personal Data Processing Descriptions. Table 19 describes the personal data categories to be used in SHAPES. Categories can be modified, but the intention is that the categories themselves stay as stable as possible, though the data itself can vary based on the use case, service, or processing activities.

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5.1.4 Categories of Data subjects

Table 19 Categories of Personal data in SHAPES

Categories of Personal data in SHAPES	
Category	**Example of date**
Basic information	Name, address, personal ID, contact details, age, gender, education
Social data	Family, social network, communication (chat)
Habits	Exercise, smoking, alcohol use
Preferences	Marketing consent/prohibitions, points of interest, hobbies, purchasing habits
Medical and health data	Evaluations, medical information, diagnoses, mental or psychological state
Financial data	Bank accounts, credit cards, transactions
Tracking data	Contact, device, location
Technical verification data	IP addresses, usernames, identification
Agreements	Service agreements, research consent forms
Analytics	User profiles, marketing groups

Categories of Data subjects describes the different individual groups whose Personal data is processed. This classification helps, for example, when describing whose data is being processed. Again, the aim is to make communication easier, and it helps to describe the data processing activities in a uniform manner. The list in Table 19 is only an example, and these categories need to be identified separately for each processing activity. In SHAPES, these categories will be used when filling in Personal Data Processing Descriptions. If SHAPES needs to develop a data-processing agreement for data that may be transferred outside the EU/EEA, these categories also need to be described there.

Categories of Data subjects can be for consortium members, patients, customers, service end-users, potential customers, website end-users, suppliers, research participants and employees.

5.2 Data protection principles

Principles relating to processing of personal data are described in GDPR (article 5). This section describes those principles and how those will be followed in SHAPES.

5.2.1 Lawfulness, fairness, and transparency

SHAPES will process Personal Data only according to the rules set in GDPR (article 6), 'Lawfulness of Processing'. In this document, those are described in section 5.3.2. In addition, SHAPES partners must ensure they are not violating any other laws and are following relevant domestic regulation. Because SHAPES will be piloted in several EU countries, local differences may need to be considered.

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'Fairness' in SHAPES means that data subject's data is processed in a way that individuals could reasonably expect and that it can be explained as to why the data is processed differently. Also, when developing services, SHAPES will consider how the processing may affect individuals. If any adverse impacts are detected, SHAPES will first try to find an option that does not cause harm to individuals. If there is no alternative solution, the potential adverse impact will be justified and explained. In practice, this analysis will be done as part of DPIA.

To help data subjects understand how their data will be processed, SHAPES will clearly, openly, and honestly explain how their personal data will be processed. Because SHAPES solutions are targeted at older individuals, a special focus will be paid to the language and formatting of the information. SHAPES will use services – and legal design methods to ensure the information will be provided as clearly as possible. In practice, SHAPES shares information about the processing of personal data on its webpage and as part of service descriptions. Information will also be provided when personal data is collected on the first occasion and when SHAPES requests a consent for processing from the data subject.

5.2.2 Purpose limitation and data minimisation

'Purpose limitation' means it is important to know for what purpose personal data will be processed, and the purpose must be clearly defined prior to data collection. This also means that the usage of Personal data needs to be well planned. The purpose needs to be documented and shared with the individuals whose personal data will be processed. Describing the purpose of the processing consists of telling why the data will be needed and what we (as a processors) will do with it.

Personal data can be used for a new purpose if a) it is compatible with the purpose for which it was originally collected, b) a data subject consents to reuse of the data for this new purpose or c) there is an obligation set out in other legislation. The GDPR does not prevent further processing for archiving purposes in the public interest, scientific or historical research purposes or statistical purposes.

Describing the purpose for processing Personal data is a fundamental requirement in terms of building trust with individuals. People need to know how their data is being used. When they receive this information, they are able decide whether to consent to the purpose or not; usually, they are more willing to consent.

Data minimisation means that only data that is adequate, relevant, and limited to what is necessary, in relation to the purposes for which they are originally processed, can be used. SHAPES shall not process any Personal data that is neither essential nor and justifiable in use.

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5.2.3 Storage minimisation

When Personal data is no longer needed for the purpose it was originally collected, it shall be erased or anonymised. SHAPES will describe how long personal data will be stored and how the time period will be justified. The retention period depends on the purpose, and legal obligations may require the storage of certain personal data. SHAPES will aim to create standardised retention periods when possible. Retention periods will be decided on either as part of Data Lifecycle Management Planning or when creating Personal data descriptions.

5.2.4 Accuracy

Personal data needs to be accurate and, when necessary, kept up to date. SHAPES must ensure that the data is not incorrect or misleading. In cases where such data is found to be incorrect, it must be corrected or erased as soon as possible. In SHAPES, the accuracy, and potential challenges for keeping the data accurate shall be analysed as part of DPIA. When developing new services, part of the development process is to ensure that there are appropriate technical and organisational processes in place to ensure data accuracy. The source of the data will also be recorded so that it is possible to estimate the accuracy of the data. Removing inaccurate Personal data is also a right of the data subject.

5.2.5 Integrity and confidentiality

SHAPES shall ensure that it has appropriate security measures in place to protect Personal data. Data protection is part of SHAPES cybersecurity activities, and these will be described in the section that deals with how cybersecurity will be ensured. In addition, integrity and confidentiality are taken into consideration in DPIA.

5.3 Legal basis for processing

Personal data can be processed only if and to the extent that at least one of the following applies:

a) the data subject has given consent to the processing of his or her personal data for one or more specific purposes
b) processing is necessary for the performance of a contract to which the data subject is party or in order to take steps at the request of the data subject prior to entering a contract
c) processing is necessary for compliance with a legal obligation to which the controller is subject
d) processing is necessary in order to protect the vital interests of the data subject or of another natural person

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e) processing is necessary for the performance of a task carried out in the public interest or in the exercise of official authority vested in the controller
f) processing is necessary for the purposes of the legitimate interests pursued by the controller or by a third party, except where such interests are overridden by the interests or fundamental rights and freedoms of the data subject which require protection of personal data, in particular where the data subject is a child. (GDPR, 2016, article 6).

Point f of the first subparagraph shall not apply to processing carried out by public authorities in the performance of their duties. In SHAPES's context, lawful processing will most likely be based on the consent given by the data subject**;** processing is necessary for the performance of the contract with the data subject, or processing is necessary for the purposes of the legitimate interest of the controller. In rare cases, the lawful basis could be based on point d, described above. As part of the data planning activities, the legal basis for processing will be defined. In a situation in which the processing is based on the legitimate interest of the controller, a balancing test shall be done to ensure the interests or fundamental rights and freedoms of the data subject are not overridden. The balancing test will be documented as part of SHAPES's Data processing descriptions.

5.4 Conditions for consent

Where processing is based on consent, consent needs to be obtained in a written format so that it can be demonstrated. SHAPES will document all consent forms used for obtaining consent from a data subject, and those will be linked to the signed consents. For documentation purposes as well, the time and place where the consent was given will be recorded. Consent can be requested separately, for example, by using a Word or similar program's template, or it can be requested as part of the service.

In all cases, consent shall be presented in a manner clearly distinguishable from other matters and in an intelligible and easily accessible form, using clear and plain language. SHAPES will use a service and legal design approach to ensure these requirements are fulfilled. During the project, SHAPES will create templates for the different types of consent needed. In addition to the consent requirements set by the GDPR, other legal obligations, such as the UN Convention on the Rights of Persons with Disabilities (CRDP), must be considered. The requirements of the CRDP are also described earlier in this deliverable.

Requesting consent in a legally correct manner requires co-operation with several SHAPES partners. The work has begun, but a more detailed description will be included in the updated version of this deliverable. At this point, it is important that SHAPES creates technical capabilities to properly record the consents and potential revokes.

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5.5 Rights of the Data Subjects

SHAPES shall develop processes to ensure that the rights of the data subjects are fulfilled. To achieve proper implementation, SHAPES has identified the following actions to be considered when developing a SHAPES Ecosystem (Table 20). The left side describes the organisational requirements to be planned when the service or other processing activity is undertaken. The right side describes the technical requirements to be implemented when the SHAPES platform is developed.

Table 20 Data subject's rights (Adopted from GDPR, 2016)

Data subject rights	
General requirements	**Technical requirements**
Right of access – define what data will be included	Right of access – build up a self-service portal where data subject can get access to his/her data
Right to rectification – define the process to correct information	Right to rectification – ensure that the data can be corrected in all places (including storage)
Right to be forgotten – define what data can be erased	Right to be forgotten – build up capabilities for deleting personal data
Right to restriction – define the right level for restriction	Right to restriction - Build up a capability for restricting data processing
Information to 3rd parties – inform about data rectification / erasure to parties to whom data is disclosed	Information to 3rd parties – create a functionality to easily get information about the 3rd parties to whom data has been disclosed (data mapping)
Right to data portability – define what data will be given to data subject	Right to data portability – create a capability to transmit data to data subject / 3rd party in a structured, commonly used and machine-readable format
Right to object: 1) define a process for manual processing instead of automated decision making + ensure information to data subject. 2) ensure that the balancing test has been done when using profiling	Right to object: 1) ensure that the information about automated decision making can be given to user (data subject) before the process starts 2) create a capability to prevent data subject's data to be part of profiling in case data subject has objected profiling

SHAPES Pilots will describe the usage of the personal data in both the Consent Form and Information Sheet that will be provided to the data subjects before the pilot starts. Information will be based on the data processing descriptions and Pilots own data plans. A special focus will be on format that the information will be given; it needs to be easily understandable and give a data subject a realistic view on how his/her data will be used in the Pilot. Information will also be given on data subject rights.

5.6 Automated individual decision-making, including profiling

According to the GDPR (article 22), the data subject shall have the right not to be subject to a decision based solely on automated processing, including profiling, which

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produces legal effects concerning him or her or similarly affects him or her. Automated decision-making is allowed if the processing is necessary for entering into, or for the performance of, a contract between the data subject and data controller. This can also be authorized by Union or Member State law, or the data subject can accept it by providing explicit consent. If automated decision-making is based on an agreement or a data subject's consent, the data subject must have the option to take the decision to a manual process where a human will analyse the decision and where the data subject has the opportunity to express his or her point of view and contest the decision.

It is important to note that automated decision-making cannot be based on special categories of personal data. There are a few exceptions to this rule, but this should be a guiding principle in SHAPES, and if there is a need for using automated decision-making based on sensitive information, the Data Protection Manager and ethical manager are to be consulted before such processing can start.

If it is recognised as part of the Data Processing Description activities that some SHAPES solutions might use automated decision-making, the manual process will be developed as part of the solutions. The data subject is also to be informed about usage of the automated decision-making. These requirements will be implemented as part of the development work.

5.7 Data Protection Impact Assessment (DPIA)

DPIA is to be done in situations where any type of processing uses new technologies, or when processing is likely to result in a high risk to the rights and freedoms of natural persons. DPIA shall also consider the nature, scope, context, and purposes of the processing. The purpose of DPIA is to assess the impact of processing activities on the protection of Personal data.

In SHAPES, DPIA will be done for each of the pilots and for the whole SHAPES Integrated Care Platform to ensure that potential risks are properly estimated. After SHAPES project the need for new DPIA needs to be identified as part of the governance model. The template for executing DPIAs will be prepared by WP8. The completion of DPIA is the responsibility of the pilots with the support of the Data Protection Manager; the pilot lead will decide with the pilot's data protection officers who should attend DPIA workshops. DPIA is to be completed before processing activities can start.

5.8 Privacy by design and by default

Privacy by design is a guiding principle when discussing SHAPES data protection. In practice, this means that data protection is part of development and research activities. SHAPES has a risk-based approach, which means the processing of personal data will always be carefully planned and the potential harms caused to the data subjects

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will be analysed at the planning phase in order to find other solutions or ways to minimise potential risk. SHAPES will also build in strong privacy defaults and user-friendly options and controls. SHAPES aims to create solutions where data subjects can decide how his/her data is used.

SHAPES will apply data minimisation and purpose limitation principles to ensure personal data is only used to the extent necessary to achieve a specific purpose. Using personal data will be planned, and SHAPES will use anonymised data whenever possible. SHAPES creates solutions that support a 'privacy-first' approach. To give an example, SHAPES will not use cookies or similar technologies for any other reason than to ensure the proper functioning of the services. For other purposes, the data subject will be provided with an opt-in option where she/he can provide consent for other processing reasons described in the consent form. SHAPES provides data subjects sufficient controls and options to exercise their rights.

5.9 Security of personal data and personal data breaches

5.9.1 Security of personal data

GDPR (article 32) requires that both controller and processor implement appropriate technical and organisational measures to ensure a level of security appropriate to the risk. SHAPES shall ensure that a proper level of security is achieved by taking cybersecurity aspects into consideration at the very beginning of the project. Cybersecurity in SHAPES is described in its own section, and the appropriate level of security will be analysed as part of DPIA and as part of SHAPES architecture and digital solutions planning.

To support the security activities – for example, setting up identity and access management – SHAPES controllers are to define who can access the personal data processed in their service or other area of responsibility. Only persons who need to access personal data can get such information, and it is the responsibility of the controller to ensure this rule is followed. This applies to the potential processors the controller might use.

SHAPES shall ensure that if the parties use processors, they are obligated to follow, as a minimum, the same security principles that SHAPES has in place. With this approach, it is ensured that SHAPES is secure and that individuals can trust that their data is safe.

5.9.2 Notification of a personal data breach to the supervisory authorities

SHAPES controllers are obligated to have a process in place for notification of a personal data breach to supervisory authorities. A process will be developed so that the notification can be issued no later than 72 hours after becoming aware of the

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breach. The process is to be in place before the SHAPES pilots are launched. In case a personal data breach, the controller contacts SHAPES Data Protection Manager, SHAPES Ethics Manager and SHAPES Project Manager and the needed corrective actions will be planned together.

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6 Cybersecurity and resilience requirement

Cybersecurity is an important ethical dimension of the features of future H&C solutions (Christen, Gordijn & Loi 2020). This section explains the cybersecurity and resilience requirements for the SHAPES solution with regards to ethical and legislative points of view. The first section focuses on relevant requirements from the NIS Directive related to the SHAPES solution. The second section creates a conceptual model for analysing ethical aspects of cybersecurity in healthcare. The third section presents the rationale behind SHAPES cybersecurity and resilience requirements and provides the main cybersecurity and resilience requirements for the SHAPES platform from an ethical point of view.

6.1 Security on Network and Information Systems (NIS) Directive

Directive (EU) 2016/1148 of the European Parliament and of the Council of 6 July 2016, concerning measures for a high common level of security of network and information systems across the Union (NIS Directive), is a piece of EU-wide legislation on cybersecurity providing some minimum standards. The new Commission proposal (COM 2020) aims to address the deficiencies of the previous NIS Directive, to adapt it to the current needs and make it future-proof. NIS Directive applies to Member States and two other groups of organisations: operators of essential services (OES) and Relevant Digital Service Providers (RDSPs). OES include critical industries such as energy, transport, healthcare, and financing. RDSPs offer one or more of following services: 1) an online marketplace; 2) an online search engine or 3) a cloud computing service. However, the new proposal eliminates the distinction between OES and RDSP, and entities would be classified based on their importance, and divided respectively in essential and important categories with the consequence of being subjected to different supervisory regimes. (COM 2020).

Critical infrastructures are not secure from cybersecurity threats, and citizens cannot be sure of the security of the systems they use daily. The overall risk (operational, economic, and reputational) can be high (medium likelihood and high impacts), and possible risk indicators are:

- Lack of information necessary to assess the security of network and information systems, including documented security policies
- Lack of evidence of the effective implementation of security policies

The objective of the NIS Directive is to drive different companies to use IT security solutions and establish practices to protect IT networks and data – both their own and those of third parties. The European Commission therefore wants to stem the phenomenon of cybercrime that has become prevalent in recent years: more and more, companies are being hacked, resulting in the theft of data. The consequences

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of a successful attack are often heavy, both in terms of economic and reputational losses.

Preventing the risk with mitigation actions, it is possible to commit to the following opportunities for improvement regarding technical and organizational requirements:

Technical requirements:

- Understanding one's own resources and having a tool for identifying unknown devices
- A vulnerability management program
- Advanced systems for threat detection, including detection, identification, and reporting capabilities
- Effective mechanisms for reporting incidents, including systems to record and report incidents within 72 hours of detection to CSIRTs
- Effective incident management
- Response and recovery plans. (Rajamäki, 2020 p. 5).

Organisational requirements:

- An organisational approach to risk management
- Adequate management policies and processes to govern the approach to security of networks and information systems
- Understanding and management of security risks throughout the production chain
- Adequate staff training and awareness in the field of security of networks and information systems
- A CSIRTs network established and composed of representatives of the Member States' CSIRTs and CERT-EU
- Designation of each Member State to have one or more competent national authority on the security of network and information systems, covering at least the sectors of OES and DSP
- A cooperation group established in line with article 11
- When determining the significance of a disruptive effect, as referred to in point (c) of Article 5(2), Member States shall consider at least the cross-sectoral factors stated in Article 16
- Article 14 security requirements and incident notification for OES
- Article 16 security requirements and incident notification for DSP. (Rajamäki, 2020 p.5)

6.1.1 Applications in the healthcare sector

The NIS Directive imposes different obligations on operators of essential services, and healthcare entities will almost always fall under the definition of operator of essential services (Art. 4, 4, Art. 5, 2 and Annex II Directive (EU) 2016/1148) and thus need to comply with its provisions. Operators of essential services will need to prevent and minimise the impact of disruptions affecting the security of their systems and take technical and organisational measures to reduce the risk posed to the security of their

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network and information systems. They also need to notify the competent authority of every incident that has a significant disruptive effect on the service. (SecureHospitals, 2021).

Online marketplaces are digital services that allow individuals or traders to carry out sales or service contracts with traders, either on their own websites or by means of providing services to traders' websites. Online retailers that sell directly to individuals on their own behalf are not covered. *Cloud services* are digital services that enable access to a scalable and elastic pool of shareable computing resources. This can include common cloud models like 'platform as a service' (PaaS) and 'infrastructure as a service' (IaaS). If you provide 'software as a service' (SaaS), you are also covered to the extent that your service is scalable and elastic. The EU Commission has also published an implementing act, Regulation 2018/151. It is specifically concerned with digital service providers, including their security requirements and incident reporting thresholds. (Rajamäki, 2020 p. 6).

6.1.2 NIS Directive and SHAPES

As discussed above, the NIS Directive applies to SHAPES: the SHAPES platform can be considered to be RDSP, and SHAPES service providers can be considered to be OES. Because the NIS Directive is a minimum directive, the legislation of member states can be stricter than the minimum requirements provided by the NIS Directive. The legislation of the Member State in question with which the directive has been brought into effect has to be checked before carrying out the SHAPES pilots. Then one must act in accordance with this national legislation.

6.2 Ethical aspects of cybersecurity in H&C

6.2.1 Core values in cybersecurity

According to van de Poel (2020), four important value clusters exist that should be considered when deciding on cybersecurity measures. The first one 'security' is a combination of more specific values, such as individual security, national resilience, and information security. These values protect humans and other valuable entities from all kinds of harm and respond to morally problematic situations in which harm occurs, ranging from data breaches and loss of data integrity to cybercrime and cyberwarfare. (van de Poel, 2020).

The second value cluster 'privacy' contains such values as privacy, moral autonomy, human dignity, identity, personhood, liberty, anonymity, and confidentiality. According to van de Poel (2020), these values correspond to the following norms: "we should treat others with dignity, we should respect people's moral autonomy, we should not store or share personal data without people's informed consent, and we should not use people (or data about them) as a means to an end." Moral problems with these

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values include the secret collection of large amounts of personal data for cybersecurity purposes or the unauthorised transfer of personal data to a third party (van de Poel, 2020 p. 49).

The third cluster 'fairness' consists of values such as justice, fairness, equality, accessibility, freedom from bias, non-discrimination, democracy and the protection of civil liberties. These values highlight the fact that cybersecurity threats, or measures to avoid them, do not affect everyone equally being sometimes morally unfair. Another moral problem is that cybersecurity threats, or measures to increase cybersecurity, may undermine democracy, civil rights, and liberties. Moral reasons that correspond to these values are that people should be treated fairly and equally, and democratic and civil rights should be upheld. (van de Poel, 2020).

The fourth cluster 'accountability' includes values such as transparency, openness and explainability. If governments take cybersecurity measures that harm citizens and require the weighing of a range of conflicting substantive values such as security, privacy, and fairness, then accountability, as a more procedural value, is particularly relevant (van de Poel, 2020).

In addition to the four value clusters, some domain-specific ethical principles and values are different from domain to domain, and technical aims can be different even from application to application. They are connected to a range of instrumental or technical values related to the proper functioning of applications such as efficiency, ease of use, understandability, data availability, reliability, compatibility, and connectivity. However, technical values are morally relevant as they are instrumental for achieving moral values. (van de Poel, 2020).

6.2.2 Desiderata of ICT in H&C and the instrumental role of cybersecurity

Four main functions of ICT systems in healthcare are: improving the quality and efficiency of services, protecting confidentiality, enhancing usability, and protecting patients' safety. Weber and Kleine (2020, 143-145) summarizes these functions as follows:

1. "One of the main purposes of ICT systems in health care is the administration of information to increase the efficiency of the healthcare system and to reduce its costs. Improvements in healthcare in qualitative terms refer, for instance, to new services that provide treatment or processes with better health-related outcomes. Big Data, the collection and sharing of as much health-related data as possible might be used to establish new insights regarding diseases and possible treatments."
2. "Using ICT to process patient data creates a moral challenge in terms of quality on the one hand and privacy and confidentiality on the other hand — yet both are important aims in healthcare. In particular, privacy is often seen as a prerequisite of patients' autonomy and therefore privacy maps to the principle of autonomy.

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Privacy and confidentiality are also foundations of trust among patients on the one hand and healthcare professionals on the other."

3. Roman, et al. (2017) define usability as the degree of effectiveness, efficiency, and satisfaction with which users of a system can realize their intended task. Concerning health, users include patients, medical staff and/or administrators, which have different degrees of ICT competences, depending on personal attitudes and socio-demographic variables (Weber & Kleine 2020).
4. "Safety can be defined as the reduction of health-threatening risks. Safety, quality, efficiency and usability are interrelated, but they do not always align, because safety measures might reduce the efficiency and usability of services and therefore quality."

The instrumental role of cybersecurity in healthcare is to protect against three types of threats based on the target of the attack: threats against information, information systems and medical devices (Loi, et al., 2019).

6.2.3 Conceptual model for systematic analysis of the ethics of cybersecurity in healthcare

Figure 10 proposes a new conceptual model for a systematic relation analysis of ethical matters related to cybersecurity in digital healthcare and well-being. The systematic mapping of the relations between the four different ethical aspects generates 84 value pairs[2].

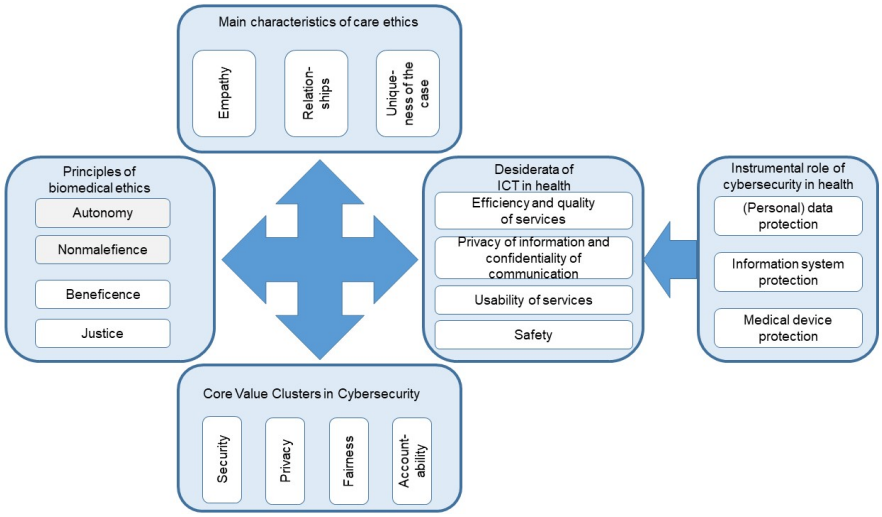

Figure 10 Conceptual model for analysing ethical aspects of cybersecurity in healthcare (Adapted from Rajamäki, 2021)

2 Biomedical ethics [n=4] and care ethics [n=3] generates 12 value pairs, biomedical ethics and technical aims [n=4] generates 16 value pairs, biomedical ethics and core value clusters in cybersecurity [n=4] generates 16 value pairs, care ethics and technical aims generates 12 value pairs, care ethics and core value clusters in cybersecurity generates 12 value pairs, and technical aims generates and core value clusters in cybersecurity generates 16 value pairs.

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Ethics is crucial in healthcare and new eHealth services make ethical questions even more pressing and raises new ones, such as ethics of cybersecurity in healthcare (Weber & Kleine 2020). Loi et al. (2019) have investigated the relation between ICT desiderata and the four principles of medical ethics and mapped trade-offs between the goals of cybersecurity into conflicts between the four principles of medical ethics. A similar analysis is needed from the relations between (1) biomedical ethics and ethics of care, (2) biomedical ethics and core values in cybersecurity, (3) ethics of care and technical aims, (4) ethics of care and core values in cybersecurity, and (5) technical aims and core values in cybersecurity.

6.3 SHAPES cybersecurity and resilience requirements

According to a thesis carried out in Laurea (Kaukonen 2021) that compares the importance of different value clusters in H&C presented in previous section, 'safety' and 'security' are the most important ones. For that reason, SHAPES cybersecurity and resilience requirements are based on these value clusters.

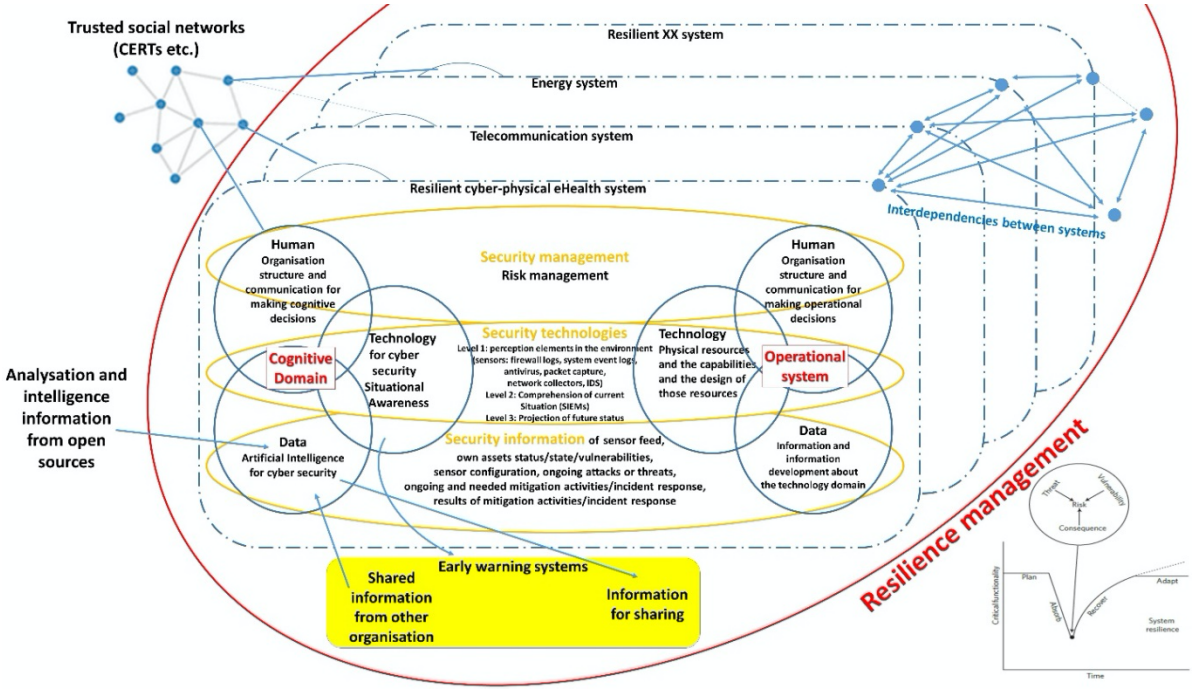

Figure 11 Conceptual resilience governance framework for eHealth CPSs (Adapted from Rajamäki, 2020)

The rationale behind the SHAPES cybersecurity and resilience requirements has been presented in DIGILIENCE 2020 Conference (Rajamäki, 2020). Figure 11 presents the conceptual resilience governance framework for a resilient cyber-physical H&C system. From that framework, the following cybersecurity and resilience requirements can be derived for the SHAPES platform:

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- Design and implement a Security Management Plan
  - Carry out cyber risk management
  - Identify and coordinate with external entities that may influence or be influenced by internal cyber-attacks (establish point of contact)
  - Educate/train employees about cybersecurity and the organisation's security management plan
  - Delegate all assets and services to specific employees
  - Prepare/establish security communications
  - Establish a cyber-aware culture
- Employ all appropriate security technologies
  - Implement controls/sensors for critical assets
  - Implement controls/sensors for critical services
  - Assess network structure and interconnection to system components and the environment
  - Redundancy of critical physical infrastructure
  - Redundancy of data physically or logically separated from the network
- Ensure the adequacy and quality of security information (suitability for AI)
  - Categorise assets and services based on sensitivity
  - Document certifications, qualifications, and pedigree of critical hardware and/or software providers
  - Prepare plans for storage and containment of classified or sensitive information
  - Identify internal system dependencies
- Make sure that situational awareness is always up to date (cognitive domain)
  - Anticipate and plan for system states and events
  - Understand performance trade-offs of organisational goals
  - Scenario-based cyber war-gaming
  - Utilise applicable plans for system state when available
  - Utilise artificial intelligence or prepare to utilise it for responding to threats with greater confidence and speed
- Design and implement a Resilience Management Plan that covers all four event management cycles (plan/prepare, absorb, recovery, adapt) and interdependencies with other systems
  - Consider how all previous requirements can be utilised throughout the four event management cycles
  - Identify external system dependencies (i.e., telecommunication, electricity, built environment) and plan the coordination framework with these systems (you have no control over these systems)
  - Educate/train employees about resilience and the organisation's resilience plan

From a citizens' point of view, eHealth is wholeness in which the protection goals of information security (availability/confidentiality/integrity) hold true. Present procedures emphasise confidentiality at the expense of integrity and availability, and regulations/instructions are used as an excuse not to exchange even vital information. The mental picture of cybersecurity should move from 'threat, crime, and attack' to 'trust'. Creating confidence in a safe digital future is truly needed in the integration of

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digital and physical worlds, leading to a digital revolution. Digitalisation and new, better services require cooperation. Safety-and-security thinking has been based on the supposition that we are safe and we are able to prevent evil effects, and the focus of actions has been the control of our own systems, improvement of protection and staying inside that protection. However, nobody is able to control large, complex, integrated cyber-physical systems, but on the other hand, co-ordination and co-operation are needed. In the H&C sector, this means that the focus is moved from the control and securing of health information towards utilising of eHealth to promote health. We have an urgent need to complement the existing knowledgebase of security and risk management by developing frameworks and models enabling network-wide resilience management that strives to maintain and improve critical functionalities. (Rajamäki & Pirinen, 2017).

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7 Ethical challenges and opportunities for SHAPES

The purpose of this section is to discuss various challenges and opportunities raised in the literature regarding digital service development and transformation in society. These topics include digital inclusion and exclusion, the moral division of labour in digital service provision, and welfare technology and the attractiveness of care professions. These issues provide essential insights for the design of both SHAPES Digital Solutions, SHAPES Integrated Care Platform and the SHAPES Ecosystem.

7.1 Digital inclusion and a sense of security

7.1.1 Introduction

In this section, the phenomenon of how digitalisation changes societies and especially what kind of effect it has on older persons are explored. As Houssein (2017) and Taipale & Hänninen (2018) state, the digitisation of all spheres of society and an increase in lifespans in Western societies is being experienced at the same time. To ensure inclusion and prevent exclusion of older persons in a digitalised society, an understanding must be gained of how the demographic phenomenon of an increased lifespan can be successfully reconciled with the digitalisation of society (Houssein, 2017).

In addition, it is important to consider how to ensure that digital innovations benefit society, especially older persons (Houssein, 2017). The increased longevity opens a new horizon for investigating the role of new technologies in human lives, since when people live longer, they have more years to experience frequent waves of innovation in technologies (Taipale & Hänninen, 2018). In addition, people's longer lives are, at the individual level, influenced by and integrated with digital technologies to a varying extent (Taipale & Hänninen, 2018): all sorts of traditional and new digital solutions – such as senior phones, alarm pendants and smart home and telecare systems – are available to facilitate successful ageing and autonomous living, whether in institutional care, home-like environments or at home (Hänninen & Taipale, 2018).

7.1.2 The heterogeneity of older adults

According to Houssein (2017), there are two misconceptions regarding the connection between technology and older persons, i.e., the misconception that older persons are reluctant to use digital technologies due to a lack of interest and that the main role of such technologies should be social and medical assistance with connection to dependency and loss of autonomy in old age. However, as Taipale & Hänninen (2018) point out, older persons are diverse with regards to their physiological, psychological, social, and functional traits. The diversity materialises in how older persons adopt and use digital technologies (Taipale & Hänninen, 2018). In addition, what needs to be

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acknowledged among older persons is both the differences between and within generations and cohorts in readiness and capability to use digital devices. The digital divide compounds both generational and life-cycle components among older persons, and, therefore, people 65 and over are not one homogeneous group with identical online behaviour (Hargittai & Dobransky, 2017). As Friemel (2016) argues, based on his representative survey (N=1105) conducted in Switzerland in 2009, the digital divide is closing for middle-aged adults (55–64 years) but not in the same manner among seniors over 65. The study points out that there is a 'grey divide' that leads to partial exclusion of older seniors (70+). So, one can say there is a digital divide within the cohorts of seniors. The digital divide is a result of both individual factors (for example education, income, health, and age) and social-context factors (for example marital status and social networks) (Friemel 2016; Siren & Knudsen 2017). As Fang et al. (2018) argue, it is important to acknowledge the cultural and linguistic factors that influence technology appropriation of older persons. The key finding of the study highlights that to mitigate the shortcomings of eHealth systems for older persons, it is important to address the challenges that relate to cultural appropriateness, for example, the culture of various ethnic groups, including possible language barriers. (Fang et al., 2018).

7.1.3 Digital exclusion and inclusion of older persons

7.1.3.1 Exclusion

According to Seifert et al. (2018), various reasons can be detected for older persons' social exclusion from our digitalised society. First, there is a widespread conception that new technologies contribute to a stimulating environment for successful ageing. However, since older persons in many cases lack the experience, skills, and social support, they face numerous barriers to the effective use of these technologies, leading them to regard this environment as exclusionary rather than stimulating. For example, older adults (70 years and over) have not grown up with digital technologies and, therefore, are not familiar with their use, especially if they have not used new technologies as part of their careers. From a developmental perspective, people become more vulnerable as they grow older. They therefore must make a greater effort to learn to use new technologies and often must overcome barriers arising from having fewer cognitive, physical, financial, and social resources. (Seifert et al., 2018).

7.1.3.2 Inclusion

As many studies (Friemel, 2016; Olsson & Viscovi, 2018; Schreurs & Quan-Haase, 2017) highlight regarding the adoption and usage of digital technologies and devices, older persons need help and constant assistance. The social networks of older persons have a strong effect on encouragement to adopt and use technological devices (Friemel, 2016; Olsson & Viscovi, 2018; Schreurs & Quan-Haase, 2017). In Freimel's (2016) study, the most attractive way of learning to use the internet was to

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learn it from friends and family. The study also highlights that social networks not only provided direct support but also acted as motivators to adopt other kinds of support. Olsson's & Viscovi's (2018) study concluded with Swedish older adults (data from survey n=1264 and 18 semi-structured qualitative interviews) showed that although older Swedes have been online for more than a decade, the need for continuous assistance from so-called 'warm experts' seem to persist even among experienced users. The concept of 'warm experts' refers to a nonprofessional person, usually a family member, who helps the older person come to terms with domestic technological devices and services (Olsson & Viscovi, 2018). As Olsson & Viscovi (2018) argue, older persons have experienced domestication of ICT, i.e., the new ICT has become part of everyday life, often materialising in the household. In addition, the abovementioned researchers argue that contemporary and highly developed technologies are even more difficult to use and handle. As a consequence of the development and emergence of new-wave technologies, the warm experts, i.e., family members, play an important role in the adoption of ICT devices and in preventing the exclusion of older persons from digital society. (Olsson & Viscovi, 2018; Schreurs & Quan-Haase, 2017).

Since there is an ever-increasing number of older persons living alone in Western societies, to prohibit exclusion from society there must be established means and services to provide help and assistance in the adoption and usage of technological devices. These kinds of actions both prevent exclusion and increase inclusion in digital society. As Olsson & Viscovi (2018) point out, governments' plans to widely implement technologies to work more easily and to enhance health and public services may be overly optimistic from the point of view of older persons. Despite the good intention to make various services and information more available via digitalisation, it might make them less available for older persons if they do not get assistance in using ICT.

Decisions by policymakers emphasise that online services must be organised and delivered in an accessible manner, and assistance and help must be provided by the service organisations (Olsson & Viscovi, 2018). One initiative of this kind is the adoption and use of so-called 'technology literate mediators' who provide support, e.g., online by advising and advocating the informal networks of older persons in the usage of technology and technology-mediated information (Godfrey & Johnson, 2009). These 'digital circles of support' can consist of tech-savvy older persons and thus promotes their engagement as active citizens and prevent exclusion from society (Godfrey & Johnson, 2009).

7.1.4 Barriers and facilitators of older adults' usage of mHealth

In their study, Spann & Steward (2018) mapped out factors that both inhibit and facilitate the usage of mHealth among older persons. They state that the factors contributing to the usage and non-usage are in line with older persons' personal circumstances and biography (Spann & Steward, 2018). The finding of the study is

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congruent with other similar studies (Friemel, 2016; Hargittai & Dobransky, 2017; Taipale & Hänninen, 2018; Siren & Knudsen, 2017). In the study concluded by Spann & Steward (2018), older persons' acceptance or non-acceptance of mHealth are categorised into six core themes: Perception of Usefulness (A), User Requirements (B), Self-Efficacy (C), Sense of Self (D), Privacy and Confidentiality (E) and Cost (F). The study found out that Perception of Usefulness (A), i.e., perceived or experienced need and usefulness and benefit of a device or service, significantly influenced uptake and engagement with technology. If the older persons felt that they did not need mHealth, they were less likely to use it. In addition, whether mHealth was seen as useful depended on participants' need for assistance and of their perception that mHealth would suitably address that need. Since the Perception of Usefulness is a major factor influencing mHealth acceptance and usage, it is important to acknowledge that the user must see the personal gain or benefit of using mHealth. (Spann & Steward, 2018).

Another central theme in the study (Spann & Steward, 2018) was User Requirements (B). Within this theme were three subthemes: Functional Requirements (what devices can be used for), Technical Requirements (how devices operate) and Personalisation (whether a device is adaptable to suit functional and aesthetic preferences). The older persons in the study appreciated devices that allowed them to manage their disease. They also valued technology that helped them remember to take their medication, identify, and alter behaviour perceived as unhealthy and motivate them to become more active. However, having to rely on the devices and associated services can be experienced as a loss of independence, and that can cause older persons to weigh the pros and cons of mHealth usage. In addition, the study highlighted that older persons prefer technology that is easy to use and does not require lot of time using it and learning to use it. To conclude, for mHealth to be truly useful it must be reliable, unobtrusive and integrable into people's lives. (Spann & Steward, 2018).

This study (Spann & Steward 2018) states that because of the diversity and heterogeneity of the group of older persons, mHealth devices and technology need to be designed in a manner that they allow the Personalisation of the functions. Personalisation also supports older persons' autonomy and independence and has a positive effect on their Self-Efficacy (C) and Sense of Self (D). The study also found that older persons' faith and confidence in their own ability to operate successfully had a great impact on their self-efficacy and the adoption of mHealth. In addition, being able to maintain their identity and sense of self is important to older persons in the usage of mHealth. If mHealth was experienced as a threat to one's self-concept, i.e., in a way that it made him/her feel older, frailer or vulnerable, or that mHealth was experienced as a monitoring and controlling entity, it did not enhance the adoption and usage of mHealth.

In the study, the theme Privacy and Confidentiality (E) showed that privacy appears to be a concern for older persons, whereas they did not experience confidentiality to be

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an issue. The study participants trusted their healthcare professionals to keep their data safe or did not think it held any value. However, monitoring and video-recording functions were experienced as surveillance and invasive and it affected the participants' sense of self.

The final factor that had a direct impact on the usage or non-usage of mHealth was the cost of the device and service. The study (Spann & Steward, 2018) highlights that central to the usage of mHealth is the Cost (F). If older persons feel they cannot afford mHealth devices and services, they will not use them, regardless of the acknowledged personal needs and benefits. Therefore, it is important to pay attention to the costs of mHealth for older persons.

7.1.5 Conclusion

As Spann & Steward (2018) state, mHealth devices and services are complex interventions. Their integration into older persons' lives requires that developers, providers, and policymakers ensure that older persons are included in decisions about technology use and in the developmental processes of the technology. In addition, if these technologies are seen as a panacea for societal and budgetary problems and are poorly integrated into systems of health and social care, they can contribute to even greater isolation and create more harm than good for older persons (Evangelista, Steinhubl & Topol, 2019; Spann & Steward, 2018). To avoid this hazard, designers must acknowledge and understand the diversity and complexity of ageing and incorporate such understanding into the design of health technology devices, including the realistic assessment of their usability (Evangelista et al., 2019).

In a study (Kim & Choi 2019) exploring older persons' willingness to share their personal and health information when using healthcare technologies and service, the authors conclude that older persons lack confidence and trust in sharing personal information. They are suspicious of how the collected data is processed and how privacy is maintained (Kim & Choi, 2019). Therefore, it is of utmost importance that these factors are considered when designing and developing healthcare technologies so that older persons feel trustworthy (Kim & Choi, 2019). As Kuhlmann (2006) argues, trust remains an important characteristic of healthcare and social care practices and that, due to digitalisation, the strategies for building trust are changing. In the era of digitalisation, trust is built on flows of information and disembodied work practices since trust in bodily practices and perceptions is disrupted (Kuhlmann, 2006). To provide trustworthy healthcare technologies to older persons requires the understanding of what it is to be a "digitally engaged and self-monitoring older person".

By acknowledging the factors described in this subsection, a sense of security for older persons in adopting and using digital devices and services can be enhanced and thus help promote inclusion and prevent the exclusion of older persons in digitalised society.

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7.2 The moral division of labour in digital service provision

7.2.1 Introduction

In this section, the service platforms and platform economy made possible by digitalisation are investigated from the perspective of older people and their new emerging roles.[3]

New types of ecosystems made possible by technology and digitalisation have typically been considered in the literature from an economic and business perspective (Kenneth & Zysman, 2015; Accenture Technology, 2015). Web-based service platforms enable new forms of collaboration between users, peers and service providers that generate value for all parties – and also beyond the market (Benkler, 2007). The result of all this is claimed to be a more efficient use of the resources of the entire ecosystem (Kenneth & Zysman, 2015; Ailisto et al., 2016). In practice, the platform economy, and digital ecosystems with new applications of big data, new algorithms and cloud computing are changing patterns of work and value creation in society (Kenneth & Zysman, 2015, Kenneth & Zysman, 2019).

The active role of consumers as developers, producers and users of products and services is the basic premise of the platform economy (see, for example, Raunio et al., 2016). People begin to evolve from customers of healthcare services into empowered co-creators of value within the ecosystem (Hermes et al., 2020). The moral division of labour between service providers and end-users is thus changing, perhaps radically.

7.2.2 An active citizen making choices

The platform economy is based on customer-driven logic. With freedom of choice, citizens have the opportunity to choose services that are right for them from among public, private, and third-sector service providers. In making these choices, citizens are also believed to steer the market in a better direction.

From the point of view of the SHAPES Integrated Care Platform and SHAPES Ecosystem, it is therefore essential to ensure conditions for an older person to make responsible choices. For example, what rules of the game and incentives allow the market to offer better options in practice? And what kind of information and support services are needed to support older persons' choices, and how is this information production organised reliably? It is also important to create workable solutions for situations where the person does not have the desire or ability to make choices. Older persons with disabilities comprise a diversified user group. How can SHAPES contribute to supporting the 'freedom of choice' of these citizens?

[3] The original and now abbreviated text, adapted to the SHAPES context, can be found in the pamphlet "Citizen at the centre - perspectives on social reform in Finland".

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7.2.3 An active citizen who uses and produces services

Service thinking has become even more important in healthcare and its development (Laitinen et al., 2013; see also Philips). As part of this development, the responsibility of end-users for processes that were previously the responsibility of service providers has increased (Tuorila, 2012). When buying a blood pressure monitor, for example, to monitor health, the monitor alone is not enough; it requires person's own active activity, which is where value is created.

With the advent of internet platforms, the production of services and content is also changing. Geographical and temporal constraints are being removed. The content produced on platforms can be utilised and reproduced more widely. In addition to service production, platforms can also be used to organise the ownership and exchange of various tools, according to the logic of the sharing economy (see, for example, Ailisto, 2016). Peer support activities or the exchange of goods open up new opportunities with internet platforms.

The use of digital services also encourages to gain more information about health and wellbeing (Hermes et al., 2020).

But how does the SHAPES Integrated Care Platform ensure that older persons have opportunities and capabilities for self-care and the use of technology? Persons with reduced physical, mental, and social abilities may not be willing or able to take on increasing responsibilities. And can the end-user choose the traditional service model if he or she feels that his or her own resources are limited? Or is it the case that pricing effectively 'forces' self-care?

7.2.4 An active citizen who develops services

The idea of the consumer as a person who also participates in the development of commodities has long been presented in innovation policy and business literature (see, for example, Vargo & Lush, 2004; von Hippel, 2008). The underlying assumption is that by participating in development work, consumers will be able to steer the development activities of service providers in the right direction and develop better commodities.

The role of users in development activities can vary greatly. The perspective can be of mere testing and collecting customer feedback. Alternatively, the starting point for all development work can be familiarisation with the user's everyday life and its challenges, which in turn guide further co-development with users and experts. The former can be described as participation, while the latter can be described as influencing or empowering. The purpose of participation is to provide citizens with the opportunity to participate in the process of planning, decision-making or implementation of social policies. Empowerment, on the other hand, leads more

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directly to 'influencing', i.e., the strengthened ability of civil society actors to act effectively as improvers of their own living conditions and advocates of their interests (Anttiroiko et al., 2010).

SHAPES Integrated Care Platform is a place also for the co-creation during the SHAPES project, and in the realisation phase after the project. But in practice, how do we ensure that the end-users have real power in service development – and in the governance of the SHAPES? Is there a risk that participating citizens will only have the tools to ensure the success of services that are already 'locked in' in the market? And how does one ensure that end-users are not held accountable for development choices that are the responsibility of policymakers or experts?

7.2.5 Conclusions

Internet-based operating models and ecosystems enabled by technology and digitalisation are about changing societal institutional structures and operating models, not just the economy and business opportunities.

Particularly in the context of welfare services, the ethical and political challenges of who and what ultimately guide development – and based on which values – are therefore noteworthy. It is also important to understand the role of the active citizen in the ecosystem and on social platforms. To function in such a platform-based ecosystem, significant reforms to the current practices and roles of the individual citizen are required.

In practice, the rights and obligations of end-users – and the underlying value base – need to be redefined in one form or another. The aim should therefore be to create a new kind of "virtuous circle" to support the wellbeing of active older people.

7.3 Life-long learning of older persons

7.3.1 Introduction

In the European Union, policy -making lifelong learning has been encouraged as one of the active ageing practices that contributes to facing the economic, employment and social implications of ageing society (Ryky et al., 2020; COM, 2005b). According to the World Health Organisation (2002), active ageing is "the process of optimising opportunities for health, participation and security in order to enhance the quality of life as people age". Lifelong learning is an essential part of it. By European Commission's (COM, 2001) definition, it is "all learning activity undertaken throughout life, with the aim of improving knowledge, skills, and competences within a personal, civic, social and/or employment-related perspective".

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7.3.2 Formal, Non-formal and Informal Learning

Lifelong learning expands the concept of education from mere schooling to activities that stem from integration of learning and living throughout one's life (UN, 2016). Hence, in addition to formal education, lifelong learning encompasses non-formal and informal learning. The importance of the two latter aspects are emphasized as people retire although the first is not excluded either.

Formal learning takes place in a structured setting with specified learning curriculum and objectives in traditional education institutions such as elementary, vocational, and higher education. It typically leads to a degree or certification. Non-formal refers to any structured educational activities inside or outside of the formal education institutions that do not lead to degrees or certifications. Informal learning can occur everywhere. It happens by doing things rather than by studying them and is often unintentional. One could also say that we learn by living (Ala-Mutka et al., 2008a; Lawson 2007; Pantzar, 2020).

7.3.3 Relevance of Lifelong Learning in the Information Society

The relevance of lifelong learning is heightened in the information society. As the use of new technologies becomes increasingly essential to managing everyday lives, people's agency and wellbeing, digital competence emerges in the very core of people's skill sets. It provides skills for learning and living. In addition to abilities to use technology, digital competence is skills and knowledge to use it safely and ethically. This includes considering privacy and security issues, as well as ethical and legal matters whilst taking an overall critical attitude towards using and creating content. (Ala-Mutka et al., 2008b).

Hence learning about technology and how to use it in order to manage everyday tasks are key subject matters for lifelong learning, but technology can also be a beneficial tool to support realizing lifelong learning. It brings formal and non-formal ways of learning closer together and opens a wealth of on-line learning resources from materials to learning avenues creating possibilities for more obtainable learning that can be social yet is not bound by time nor place (UN, 2016).

7.3.4 Normative Basis in European Union

Lifelong learning should be perceived as a human right since the right to fundamental education is stated in international human right treaties (including The Convention against Discrimination in Education of 1960 and The International Covenant on Economic, Social and Cultural Rights of 1966). The right to education is not limited by age or gender and therefore gives normative bases to lifelong learning as well. (UN, 2016).

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Although the history of lifelong learning stems nearly a century back and UNESCO has led the focus to shift from education to learning in the 1970s (UN, 2016), the EU started emphasizing lifelong since the Lisbon Council of the year 2000 (Ryky et al., 2020; COM, 2005b). In 2001, strategies for lifelong learning were published in the European Commission Communication Making a European Area of Lifelong Learning a Reality (COM, 2001). The importance of lifelong learning was further enforced and its close tie to digitalization established in the EU initiative 'i2010 - A European information society for growth and employment' as well as in the linked flagship initiative 'Ageing Well in the Information Society' that presented technology as a means for wellbeing and independent living among others (COM, 2005a). In 2006 the Ministerial Declaration 'ICT for an Inclusive Society' drew attention to the needs of older people and highlighted its relevance in contexts like active participation, autonomy, self-expression, safety, and quality of life (COM, 2006).

By the end of 2020s, the European Commission will further underpinned its stance on learning being important throughout one's life whether it is- formal, non-formal or informal as well as specified key competences for lifelong learning highlighting the relevance of learning in holistically good and active life (COM, 2015 & 2018).

7.3.5 Conclusion and Implications

Lifelong learning is a human right and therefore is an obligation for society. It is also regarded as a necessity as we face the current challenges as well as an opportunity to enhanced wellbeing and economic growth.

Lifelong learning as a human right creates an obligation for society in general to support it. Service providers that wish to tap into the market of technology solutions for the older persons are similarly obliged. Especially in the era of information society, considering digital competences of all ages is crucial. If society relies increasingly on technology in ensuring wellbeing to its older citizens, ability to utilize that technology becomes a question of equity. Lacking the capacity to use the solutions could increase the risk of social exclusion and detrimental to wellbeing. Private actors collaborating with public sector in producing health and wellbeing services should be equally concerned.

In addition to the human rights aspect, the EU has revised active aging and lifelong learning connected to it as social and economic necessity to overcome challenges of demographic change. They are also seen as a possibility to maintain growth and competitiveness as well as attract investment and innovation in the area. (Ala-Mutka et al., 2008.) The market for technology solutions for older people is a growing market that has business potential both in the consumer and in the public services end. Technology that supports lifelong learning is essentially wellbeing technology that enhances skills, social capital, agency, and good life in general (Ala-Mutka et al. 2008;

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WHO, 2002). This broadens the concept of wellbeing technology to also include solutions that facilitate learning of all ages.

Implications of lifelong learning as an ethical requirement has two-fold implications for SHAPES service providers:

1. Ensuring user's capabilities to adopt digital services on the SHAPES platform enforces social inclusion as well as safe and ethical use of the services. Hence, the services should be designed to support users in learning of digital skills.
2. Learning throughout one's life provides quality and wellbeing in living. As a platform that enhances older people's holistic wellbeing and support their agency and autonomy later in the life, SHAPES should include digital services that enable lifelong learning.

7.4 Welfare technology and attracting elderly care professions

7.4.1 Introduction

In the review of Korhonen et al. (2015), the authors remind us that technology as a concept has three implications. First, technology as devices and products; second, technology as a process, referring to all the methods helping people in caring relationships and promoting good in health, sickness, and suffering; third, technology as a service, that means using technology and its applications when taking care of people. In this service nurses work as interpreters between technology and patients that use it. (Korhonen et al., 2015).The EPSU research (Peña-Casas et al., 2018) reminds us that digitalisation has concrete effects on employment and job quality of workers, as well as on workers' health. Although digitalisation have positive effects on the rationalisation and improvement of work, it also may have adverse effects if worker's views are not sufficiently considered.

7.4.2 Attracting elderly homecare professions

According to the Social Protection Committee and European Commission Services (2014) long-term care have three challenges in the future. First, a huge increase in need of long-term care; second, decline of long-term carers and the level of informal care; and third, pressure on ensuring quality of care in these circumstances. (Social Protection Committee and European Commission Services, 2014).

The Social Protection Committee Working Group on Ageing have suggested priorities for action by Member States to meet the challenges mentioned above. These include actions to improve the efficiency of long-term care services by ensuring better care coordination, raising the productivity of services, improving recruitment and retention in the long-term care workforce, improving support for family care and making it easier

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for them to reconcile family and care responsibilities. (Social Protection Committee and European Commission Services, 2014).

An Australian study (Isherwood et al., 2018) indicates that aged care is one of the first jobs for a small number of workers and that those with no previous work experience are primarily attracted to roles within the residential elder care work. A direct interest in aged-care work, the availability of work and the convenience and flexibility of work were found to be the main reasons for the attraction of the elder care work. (Isherwood et al., 2018).

In Europe, professional nursing autonomy is a known aspect related to attractiveness of homecare nursing (De Groot, 2017). The Dutch study reported three themes that registered nurses, currently working in homecare, found attractive. These were 'spider in the web', autonomy, and diversity. For the registered nurses studied, it was important that they can truly make a difference for their clients as leading professionals. Also, autonomy was important in order to experience freedom and independency. Diversity in the work was seen to prevent boring routines and to make the work challenging. (De Groot 2016).

7.4.3 The impact of welfare technologies on work

Generally, welfare technologies are in the early stages of development. The impact of technological development has been researched. Often this research has focused on care giving. (Caligtan and Dykes, 2011; Nagel et al., 2013.) However, the impact of digitalisation on work is less studied. According to the European Economic Area Consultative Committee (2017) digitalisation has been predicted to transform the organisation of work and employment relationships, cause atypical career patterns, and increase the need to upgrade medium-skilled worker skills.

A trusting relationship is a key for homebased nursing care (Wälivaara and Axelsson, 2013), and researchers remind us, that it must be safeguarded during the development of different technologies and when implementing technology (Milligan et al., 2011; Szczepura, 2011; Wälivaara and Axelsson, 2013; Meleis, 2011). A Finnish study shows, that when the persons trusts the distant working nurse, they also feel confident with the use of technology they use at home (Wälivaara et al., 2009).

In some previous studies, carers in elderly care have posited that communication technology can lead to dehumanised care (Sävenstedt et al., 2006), and that technology is used too often to replace human interaction (Rytkönen, 2018). Also, in some studies technical devices have been experienced to be difficult to handle, expensive and complicated to maintain. Visions of future technology have also been thought more likely to create frustration in care professionals than confidence. In some cases, negative experiences with assistive devices have been more prevalent than positive ones. (Mort et al., 2014; Oudshoorn, 2011; Saborowski and Kollak 2015).

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Therefore, it is important to follow the changes of caregiver's attitudes on technology during interventions.

Technology should primarily be a tool for the profession and understanding the carers reasoning about technology use must be the bases for implementing it (Wälivaara et al., 2011; Rantanen et al., 2017). Personal interaction with older people has been considered the backbone of care. Care professionals are trained to care for and work with people, not with technical devices; therefore, the use of technology may not necessary be seen as an integral part of care profession. Therefore, introduction to technology and education on how to use it should be regular in interventions. Competence in using assistive technology and transmitting this expertise to other users and patients should be promoted through training. (Mort et al., 2014; Oudshoorn, 2011).

Turja et al. (2020) argues that among care workers change readiness is contagious, and organisations should strive towards a shared psychological state of welcoming upcoming changes (Turja et al., 2020). It is crucial to incorporate workers into the technological change early on and individual differences in new technology acceptance should be considered because the organization of work changes as well. Co-design with employees should include assessments of the technology's usability as well as personal and shared values. Cooperation negotiations with staff should be started already at the beginning of the implementation. (Turja, 2019).

Bergey et al. (2019) show that health information technology implementation generates significant changes of work practices at the expense of nurse-patient interaction. These changes cause re-prioritising patient care and interaction, and delegation of less visible care practices from nurses to clerks. This causes significant reconfigurations of clerks work and uncertainty about their role. (Bergey et al., 2019).

Cijan et al. (2019) suggested that digitalisation improves job satisfaction, changes work-life balance and promotes worker autonomy across industries and disciplines. The European Economic Area Consultative Committee (2017) highlights the need to examine to what extent workers' private lives require additional protection in a time of ubiquitous digital mobile communications. They also stressed the need to assess and update the legal framework of work, including rules about working hours, social protection and health and safety issues. Larsson et al. (2012) concludes that proactive workplace interventions need to focus on factors such as self-efficacy, safety climate, physical job demands and musculoskeletal wellbeing.

The European Economic Area Consultative Committee (EEACC) has emphasised the importance of skills development to unlock the full potential of digital technologies. Digitalisation has also shown to increase differences between colleagues at the workplace in mastering the digital skills, especially between different generations. Competences and transversal skills are growing in importance because of new technology. (Peña-Casas et al. 2018). Digitalisation also creates a demand for

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specialised workers with strong interpersonal and cognitive skills, and generic soft skills such as creativity, communication, teamwork, and perseverance are becoming more important. (European Economic Area Consultative Committee, 2017).

Niemeijer et al. (2014) found out that although staff in residential care incorporated surveillance technology into existing care routines, they did so with some reluctance and reservation. This caused drawbacks for the technology use in practice. Staff also tended to favour certain technologies and appeared unwilling to take risks with some other. The researchers concluded that a clear and vision for the use of technology is necessity for successful technology implementation. (Niemeijer et al., 2014).

7.4.4 Conclusions and implications

When managers are aware of nurses' attitudes towards technology, they can better offer tailored support for the nurses in the implementation of new applications. While implementing new technological applications the managers should also remember to foster positive atmosphere and to improve job satisfaction. This ensures nurses willingness to continue working in spite the changes the technology brings along. (Koivunen et al., 2013).

When new technology is used in elder care, the nurses act as an interpreter between technology and patient. In those situations, it is not surprising, that the nurses' own perceptions regarding the technology influence also patient's usage of technology. (Piscotty et al., 2015) Also professional skill and reflection, including articulation of work tasks, must be considered. There is risk of non-use of the technology if the planning of time and work is not adjusted to allow for sufficient continuity and time for experimentation with the technology in day-to-day care practices. (Hansen & Grosen, 2019) In patient-centred technology usability and acceptability are the key aspects (Wolpin & Stewart, 2011). The importance of technology is understood when it corresponds to its purpose, is easy to use, is flexible and operates without problems (Rytkönen, 2018).

Turja et al. (2020) identified key forces in Finnish care workers' readiness for robotization. Potential change agents were characterized by their high interest in technology, high-robot-use, self-efficacy, perception that co-workers approve robots and optimism that robots will not take people's jobs. Randell & Dowling (2010) reported that organisations characterised by collaboration, teamwork and supportive leadership report more likely successful technology implementation and use. The introduction of technology also has consequences on team-based work e.g., increase in efficiency and optimisation of team function. (Randell & Dowding, 2010).

Digitalisation is surely a management and production tool, but it also affects workers. Therefore, social dialogue structures should be consulted and included from the beginning of the process to its end. (Peña-Casas et al., 2018) When new technologies are introduced, it is important not only concentrate on the outcomes related to

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implementation but also the effects of the technology on daily work activities and occupational roles of the people whose jobs are affected by it (Motulsky et al., 2011). Longitudinal analysis is necessary to better understand how workflow, staffing, roles, and responsibilities will change due to technology introduction. (Berg, 2001; Mort et al., 2014; Oudshoorn, 2011).

In SHAPES services we should remember to protect the trusting relationship between the older persons and health care service providers, and to consider the values, attitudes, and visions of the caregivers. The health care professionals need to experience technology usable and acceptable to use it. Although functional training is important for the implementation, also involvement of all stakeholders in discussions and decision-making should be considered, to gain the potential benefits the use of technology will have on elderly care. As Hall et al., (2017) pointed out, staff training needs to move beyond functional instruction to include deeper exploration of possible benefits and the underlying rationale for using technologies. Bergey et al. (2019) made also a sound point in that both the people who care and the people who are cared should be considered users and the process should ensure that digitalisation is not detrimental to users (Bergey et al., 2019).

7.5 Older persons – challenges with the terminology

Age can be considered from several point of views. From the statistical viewpoint, people are often considered old when they are retired: in many societies this equals age 65 and older. From the capabilities point of view, people are old from 75 years on. Biological and physiological dimensions are based on the condition. Psychological, social, and subjective age are different dimensions to the same phenomenon. Chronological age is based on the running of time. Subjective and cultural age are based on one's own feelings and expectations of the society (Verneri, 2019).

Terms often used about this group of people in English are older persons, ageing individuals, old people, aged, senior, late adulthood, elderly. Also pensioned or retired have been used when referring to these individuals or groups – but the latter terms may no longer be appropriate, since older persons may still be involved in working life. It seems that the terminology about ageing individuals is widely debated. There are different points of views, established practices and discussion about the terminology. Perhaps none of the terms can be considered as neutral.

Language conveys meaning which can feed judgements and assumptions that may lead to the development of discrimination and stereotypes (Grendon et al., 2016). Those might be difficult to identify since the language of ageism is rooted in implicit attitudes and explicit actions. It can be quite complex. In order to recognize language-based age discrimination, and to rectify it, continued examination of the language used is needed (Grendon et al., 2016). Special attention needs to be paid to the terminology and understand that by the choices we make with the terminology we also support the

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creation of images about a particular group of people. The discussion about the concepts and the problem with ageism is not new but, indeed, has been going on for a long time (see for example Nuessel, 1982).

Ageing individuals are not a homogenous group, and vice versa very versatile. Some individuals might want to identify themselves as old people, some ageing individuals, some elderly and some something else. None of the terms are neutral and people may also use the concepts with different attitude too. Ageing individuals is actually now no longer an appropriate term either, since that does not literally mean everyone who is living – getting older is the only way to live longer.

Older persons are part of a unique minority, like women or members of racial minorities. Ageing is a minority that cuts across all social divisions since we all join that minority as we get older (Morgan & David, 2002). It might be impossible to find a concept that all researchers, not to mention the ageing population themselves, would agree or identify themselves as to which they belong.

It is important to notice that the language used also is subject to ongoing changes. What used to be ok, illustrative, accepted or close to neutral term may no longer be appropriate. The meanings and connotations that the words carry within may change within times, cultures, and contexts.

One challenge is the use of ageist terminology to discuss and describe people in their late adulthood. This has been a particular challenge in research studies that have been attempting to measure attitudes towards that group of people (Polizzi & Millikin, 2002). Some consider elderly as an ageist concept; then again according to Oxford Advanced Learner's Dictionary (2000), "elderly is used as a polite word for 'old'".

Senior is a concept that in the working environment refers to someone who has a higher position or rank than others (Oxford, 2000). In that context, it is not a negative term. At the same time, it needs to be pointed out that senior citizen is often used to avoid calling people old (Oxford 2000). Old refers to someone who has lived for a long time (Oxford 2000). It could be understood as opposite or a pair concept to young, that could be understood only as something referring to age only as a number.

The United Nations have launched the International Day of Older Persons. Older persons is the concept that is used. One point of the UN international days is to educate the public (United Nations). Based on the concept used by UN, one could assume that the term older people is widely accepted and still valid, yet the day was launched long time ago. (UN 1990).

It has also been argued that attitudes towards a general term 'people in their 70-85 years of age' would be more positive than to 'old people' (Polizzi & Millikin, 2002). In Polizzi's and Milikin's (2002) study, the description of that particular group called as

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'old' was the group viewed least positively; and the group referred as the '70-85 years of age' was viewed most positively.

United Nations Principles for Older Persons uses the term old. At the international level, the United Nations Principles for Older Persons encourages States inter alia to support the independence of older people, to respect their dignity and to provide them with adequate care. (UN, 1991).

In the EU constitutional framework, the rights provided for in Charter of Fundamental rights (EU CFR) apply to everyone including older persons. Moreover, Article 25 specifically addresses the rights of the elderly. It provides that "[t]he Union recognizes and respects the rights of the elderly to lead a life of dignity and independence and to participate in social and cultural life". Moreover, Article 34 on social security and social assistance establishes that "[t]he Union recognizes and respects the entitlement to social security benefits and social services providing protection in cases such as […] old age […]". (CFR, 2016).

The European Pillar of Social Rights (EPSR or Pillar), which is a soft law document, can also provide an impetus to further protect and promote the rights of older people and to integrate an older persons-perspective in EU legislation. The EPSR was released in 2017 at the Gothenburg Social Summit, as part of an ambitious EU 'Social Agenda' and was intended to foster the social dimension of the EU and to emphasize the EU commitment towards social rights. The EPSR contains 20 principles, which are structured around three core themes: equal opportunities and access to the labour market, fair working conditions, and social protection and inclusion. Principle 15 is particularly relevant in that it focuses on old age income and pensions, and affirms inter alia that both workers and self-employed people have the right to a pension commensurate to their contributions, and, importantly for this framework that "[e]veryone in old age has the right to resources that ensure living in dignity". (EPSR 2017a p. 5; EPSR 2017b).

The best way to tackle the terminology challenge is to choose to select a concept and define how it is understood within that framework or context. Ageing is a concept that is used in the name of the SHAPES-project: Smart and Healthy Ageing through People Engaging in Supportive Systems. Ageing is not a neutral term either, but since it is used in the name of the project, this is not considered as ageist. In the SHAPES dictionary, the term older persons has been decided as the correct terminology. By that SHAPES means something 'as neutral as possible'. Whatever is chosen to be used, SHAPES admits, that for some, it may not be the correct or right word to describe their identity or to get the big picture of the phenomenon that SHAPES is working with. Whatever term SHAPES chooses to use SHAPES is doing 'ageing politics' as well and strengthening the awareness that the concepts are not to be taken for granted. Perhaps during the SHAPES-project a totally new concept arises. Also, it is relevant that each participant will think over what is the concept/s that they will use in their native language when discussing about older persons and also be aware of the

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cultural differences there might be. The concepts SHAPES chooses to use also build the reality, so by the discourse SHAPES uses, the project also affects on the understanding of the older persons.

7.6 SHAPES ethics and COVID-19

The COVID-19 pandemic has highlighted the transformative power of digital technologies. Digital tools help keep caregivers and care receivers safe while providing continued care. The increasing reliance on digital solutions to support social distancing, the need to further involve citizens in their own care delivery, and the needs of care professionals and caregivers are all issues that the COVID-19 crisis has brought to the fore. More importantly, the pandemic has brought into the social sphere the discussion of public safety and health versus privacy and individual freedoms, further highlighting the role of digital solutions that provide services in an ethically responsible and sustainable way.

During a pandemic, digital tools can be used to 1) monitor the spread and impact of viruses (such as COVID-19) 2) research and develop diagnostics, treatments, and vaccines and 3) ensure that Europeans stay connected to friends and families and remain safe online. Digital solutions also ensure the continuity and availability of services. Trusted security systems protect privacy and identity online – increased online activity can attract malicious players and increase the risk of cyberattacks. Artificial intelligence and high-performance computing are used in advanced data analytics to detect the patterns behind coronavirus spread. And, in healthcare, artificial intelligence plays an integral role in robots and other tools used to sustain social activity when direct human interaction must be kept to a minimum due to public health concerns. (COM, 2021).

The Table 21 describes the SHAPES Integrated Care Platform and Digital Solutions from the perspective of European fundamental rights. Further, the right-hand column looks at the realisation of rights when considering the COVID-19 situation specifically.

Table 21 SHAPES from the perspective of European fundamental rights

Fundamental rights	Clarification	Relevance in the COVID-19 situation
The rights of the elderly (25)	SHAPES respects the rights of the elderly to lead a life of dignity and independence and to participate in social and cultural activities. ➢ SHAPES digital solutions. ➢ Co-creation of digital solutions. ➢ Participation in SHAPES governance.	The elderly have been the most vulnerable group throughout the COVID-19 pandemic. The importance of SHAPES as a solution specifically for older people is therefore high.

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Right to life (2) Right to education (14) Social security and social assistance (34) Healthcare (35) Freedom of assembly of associations (12) Freedom of arts and sciences (13) Freedom of expression and information (11) Respect for family life (7)	SHAPES digital solutions support holistic wellbeing and coping during home confinement and quarantine. Co-creation of digital solutions. Participation in SHAPES governance.	SHAPES Digital Solutions support holistic wellbeing and participation while observing social distancing. SHAPES also includes solutions that support the COVID-19 response.
Human dignity (1) Non-discrimination (21) Cultural, religious, and linguistic diversity (22) Gender equality (23)	SHAPES Digital solutions and services observe human rights and freedoms through specific features, such as the use of user interfaces for robots and virtual nurses. Co-creation of digital solutions. Participation in SHAPES governance. ➢ Design-for-all approach. ➢ Avoidance of depersonalisation. ➢ The language to be used. ➢ The methods to be used in collaboration.	Protecting and promoting these rights is even more important when computer-mediated communication is in place and when the use and adoption of digital services increases.
Right to liberty and security (6) Protection of personal data (8)	Cybersecurity features of the SHAPES Platform. GDPR features of the SHAPES Platform.	The importance of data protection and security is growing as services are delivered digitally and/or from a distance and trusted and non-trusted IT environments are connected.
Freedom to conduct a business (16)	The SHAPES open innovation platform and ecosystem offers business possibilities for various types of organisations and supports the development of local economies.	The need for digital services and businesses has increased during the COVID-19 crisis. SHAPES provides a platform to support the flourishing of business.
Fair and just working conditions (31)	SHAPES Platform, Digital solutions and Ecosystem. Caregivers are also SHAPES end-users and key resources whose vocational wellbeing is important.	SHAPES Digital Solutions enable social distancing during a pandemic, and the use of mHealth and eHealth technologies safeguards caregivers and frontline care professionals at points of care.

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Freedom of movement and of residence (45)	SHAPES Platform and Digital Solutions allow the use of services regardless of location, thereby preventing unnecessary travel.	There is no need to travel in order to use SHAPES services. mHealth and eHealth technologies supporting remote care services help reduce the need for travel while maintaining the quality of care.

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8 Ethical requirements for the SHAPES solution

In this section, we elaborate on the ethical requirements for the SHAPES Integrated Care Platform. These ethical requirements are derived from the contents of the previous section. In addition, feedback collected from partners and during the dialogue workshop in May 2020 and September 2020, during the initial ethical requirements – implementation meetings in June-September 2020, and during various thematic meetings have been considered in the ethical requirements and their more detailed formulation. Moreover, brainstorming sessions with LAUREA master students on SHAPES Societal Impact Assessment have provided input for the definition of the ethical requirements.

8.1 Ethical requirements

The definition and methodology related to ethical requirements is not yet well established in literature. In addition, both the concept 'ethics' or 'ethical' and the concept 'requirement' are vague. Ethical requirements here are defined on the basis of norms and principles relevant for the domain, and on various documents providing both normative guidelines, recommendation, and requirements, as well as conceptual approaches.

The implementation of ethical requirements has an impact not only on technical solutions and services, but also on organizational arrangements of SHAPES. Ethical requirements therefore provide input both to the software engineering process (WP3, WP4, WP5), but also to the design of SHAPES governance, business and ecosystem and support processes linked to them (WP3, WP6 (pilots), WP7, WP9)

The purpose of these ethical requirements is to help ensure that SHAPES becomes and stays a positive innovation for end-users, service providers and society.

In the development phase the ethical requirements are particularly important alongside user requirements when developing and taking in to use solutions that are linked to fundamental rights and where the target group is older persons. On the other hand and when adding new digital services to the existing SHAPES platform after the project (or during the open calls), the ethical requirements offer a relatively quick way to check whether the new digital service and its organizational arrangements fulfils (at least the mandatory) the ethical requirements.

The ethical requirements are organized as General Ethical Requirements for the development (GE), Ethical Requirements for the technology (TE), Ethical Requirements for support processes and services (PE) and Ethical Requirements for governance, business, and ecosystem modelling (ME). The importance levels of the ethical requirements are classified as mandatory, essential, and desirable. In addition, categorization is performed according to the responsibilities during the project (column

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'responsibility during the project') and after the project (responsibility 'after the project'). In addition, the processes in which each requirement is related to, are identified in the column "processes". See Table 22 providing information about the categories, and Tables 23-26 providing the actual ethical requirements.

Please note, that since SHAPES architecture or Governance are not yet specified in detail, the categories regarding the responsibilities and processes after the project are only hypothetical. This concerns especially requirements related to privacy and data protection, AI ethics and Cybersecurity which (may) cross boundaries of single digital solutions. The further specification of the requirements will be done as part of the WP3 and WP7 work. The progress regarding the implementation of the ethical requirements will be reported in annual Ethics Progress Reports. For verification, validation, and assessment of the ethical requirements, see SHAPES Project Ethics (D8.2).

The complete list of ethical requirements as a living Excel document is available in the SHAPES TEAMS folder WP8. These requirements may be updated during the SHAPES project, among other things, as part of privacy and ethics risk management work in T8.4.

Table 22 Categories related to ethical requirements

Importance	Clarification
Mandatory	Has to be implemented/is based on law.
Essential	Is relevant from the viewpoint of ethical sustainability and quality of SHAPES.
Desirable	Enables SHAPES to be more valuable. Implementation is recommended during the SHAPES project if it can be done without significant financial and time input.
Type	**Clarification**
General requirement for development	Reflects the values, guidelines, regulations and ethical challenges of the SHAPES Integrated Care Platform. May affect technology, user processes and/or governance/business models.
Technical requirement	Features of the SHAPES Technological Platform.
Support processes for users	Support service/function(s) related to implementation and use of the SHAPES services by end-users.
Governance/ business/ ecosystem	Governance and management requirements related to SHAPES Market Place and SHAPES Governance.
Responsibilities	**Clarification**
During the project	Each WP related to the requirement is mentioned
After the project	Responsibilities are related to *Governance (to be defined more in detail in WP3) *Marketplace (to be defined more in detail in WP7) *Service provider
Processes	**Clarification**
User joins **User uses**	New end user joins SHAPES/selects new services End-user uses SHAPES services

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User leaves	End-user stops using SHAPES services
Service joins **Service leaves** **Service development** **Platform development**	New service provider joins SHAPES Service provider leaves SHAPES Services are developed (with end-users) The whole SHAPES integrated care platform & concept is developed
Governance	SHAPES it-governance, clinical governance, data governance etc. (to be defined as part of WP3)
Market Place	SHAPES marketplace (to be defined as part of WP7)

8.2 General Ethical Requirements for the development

Table 23 General ethical requirements

No.	Requirement	Importance	Responsibility during the project	Responsibility after the project	Processes	More in D8.14 sections
GE1 **GE2**	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 for example non-discrimination, dignity, integrity, and privacy when having robots, web-cameras at home) (Fundamental Rights Impact Assessment FRIA)	Essential	WP2 W3 WP6 WP7 WP9?	Marketplace Service provider Governance	Service joins Service development Platform development	Rights Disabilities AI Ethics Policy Privacy & DP Lifelong learning
GE3 GE4	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, and uniqueness).	Mandatory	WP2 WP3 WP6	Marketplace Service provider Governance	Service joins Service development Platform development	Bioethics AI ethics Cyber-security
GE5 **G6**	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 of with disabilities.	Essential	WP2 WP3 WP6	Marketplace Service provider	User joins Service joins Service development Platform development	Capabilities Lifelong learning Disabilities
GE 57	Investigate and collect user feedback related to services that may be considered intrusive (for example facial recognition), risky for autonomy or for depersonalisation or for sense of security (for example robots), or associated with a surveillance type of services without one's own control	Essential	WP6 WP8	Service provider		Rights Ethics of care Capabilities

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	(sensors at home). Find out how end-users experience the processing of their own personal data.					
GE 58	Apply Design for All, and Universal Design –approaches in SHAPES development	Essential	WP2 WP3 WP4 WP5/D5.1	Marketplace Service provider	Service development Platform development	Rights Persons with disabilities Digital inclusion Lifelong learning
GE 48 GE49 GE50	Digital inclusion, acknowledge -Heterogeneity of (older) persons that materialise in the diversity of how persons adopt and use digital devices -Barriers and facilitators of (older) persons' usage of digital devices (perception of usefulness, user requirements, self-efficacy, sense of self, privacy and confidentiality, cost). -Diversity and complexity of ageing and incorporate that gained understanding into the design process of health technology devices, including the realistic assessment or their usability.	Essential	WP2 WP3 WP5 (5.1)? WP6	Marketplace Service provider	Service development Platform development	Disabilities Digital inclusion Lifelong learning
GE7	Develop solutions that offer users different options to act according their own choice and practical reasoning. Be open to innovations that may not presuppose commercial commodities.	Essential	WP2(use cases) WP4 WP5 WP6 WP7	Marketplace Service provider	Service development Platform development	Capabilities Division of labour
GE 47	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.	Essential	All WPs and Deliverables	Marketplace Service provider	Service development Service joins Platform development	Rights Disabilities Terminology
GE 12 **GE13**	Be aware that the use of various digital solutions has an impact on the workload of caregivers but also their work displacement. Investigate the improvement and provide training.	Essential	WP3 WP6 WP8	Governance? Marketplace? Service provider	Service development Service joins Platform development	Rights Caregivers Sustainable development
GE 14	Figure our opportunities to apply current services or implement new solutions to fight COVID-19	Optional	WP5			Sustainable development Covid and SHAPES
GE 15	Consider and follow up policy papers	Essential	WP2, WP3, WP4, WP5, WP7, WP8, WP9			Policy
GE 16 **GE17-GE22**	Ensure SHAPES AI solutions: -Human agency and oversight -Technical robustness & safety	Mandatory	WP3? WP 4 (4.5)? WP5 (5.5, 5.7?) WP7	Governance? Marketplace? Service provider	Service joins Service development	Rights Capabilities Sustainable development

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	-Privacy and data governance -Transparency -Diversity, non-discrimination -Societal and environmental wellbeing -Accountability		WP8		Platform development	AI Ethics Lifelong learning
GE 24 GE25-GE30	Ensure Data subject rights: right of access, right to rectification, right to be forgotten, right to restriction, information to 3rd parties, right to data portability, right to object	Mandatory	WP4 WP5 WP6	Governance? Marketplace Service provider	Service joins Service development Platform development	Privacy & DP
GE 31 GE32-GE36 GE40 GE46	Conduct DPIA and ensure that the following data protection principles are embedded in the DPIA: lawfulness, fairness, transparency, purpose limitation, storage limitation, accuracy	Mandatory	WP5 WP6	Governance? Service provider	Service joins Service development Platform development	Privacy & DP Data processing description and DPIA (appendix)
GE 38	Automated decision-making: if processing contains automated decision-making, build a manual process to comply with art. 22 of GDPR.	Mandatory	WP6 WP5	Marketplace? Governance? Service provider	Service joins Service development	Privacy & DP
GE 39	Privacy by design and by default: ensure data protection is taken into account when start planning for new services or processes. Adopt a “privacy first” approach.	Mandatory	WP4 WP5 WP6	Marketplace? Governance? Service provider	Service joins Service development Platform development	Privacy & DP
GE 41	Personal data breach: ensure that data controllers and processors have a process for handling personal data breaches, including communication to the data subject and to the supervisory authority.	Mandatory	WP6	Governance Service provider	Service joins Service development Platform development	Privacy & DP
GE 42	Technical and organisational security measures: identify and document who needs to have access to personal data.	Mandatory	WP6	Governance? Marketplace? Service provider	Service joins Service development Platform development	Privacy & DP
GE 45	Ensure that privacy and data protection related legal documents are in place (for example NDAs and data processing agreements).	Mandatory	WP6 WP7	Marketplace Service provider	Service joins Service development Platform development	Privacy & DP
GE 51	Design and implement a Security Management Plan for SHAPES.	Essential	WP4 WP5	Governance Service provider		Cyber-security
GE 52	Employ all appropriate security technologies.	Essential	WP4 WP5	Governance Service provider		Cyber-security
GE 53	Ensure the adequacy and quality of security information (suitability for AI).	Essential	WP4 WP5	Governance Service provider		Cyber-security
GE 54	Make sure that situational awareness is always up to date (cognitive domain).	Essential	WP4 WP5	Governance Service provider		Cyber-security

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GE 55	Implement and update a Resilience Management Plan that covers all four event management cycles (plan/prepare, absorb, recovery, adapt) and interdependencies with other systems.	Essential	WP3 WP4	Governance Service provider		Cyber-security
GE 56	Ensure that penetration testing is undertaken for software solutions.	Essential	WP4 WP6?	Governance Service provider		AI Ethics Cyber-security
GE 57	Ensure that legal frameworks related to the SHAPES Integrated Care Platform are taken into account.	Mandatory	WP3, WP4, WP5, WP6	Governance Service provider		Legal framework (see appendix)

8.3 Ethical requirements for the SHAPES Technological Platform

Table 24 Ethical requirements for the SHAPES Technological Platform

No.	Requirement	Importance	Responsibility during the project	Responsibility after the project	Processes	More in D8.4 sections
ET1	Ensure equal and non-discriminatory access to technology and its support services by using well-designed user interfaces, instructions, and authentication.	Essential	WP2 WP3 WP4 WP5	Marketplace Service provider	Service development Platform development Service joins	Rights
ET2	Consider cultural diversity of users; for example, create avatars that represent different genders and cultures and let the user choose what to use. (TBD)	Essential	WP4	Marketplace Service provider	Service development Platform development Service joins User joins User uses	Rights Capabilities
ET3	Create functionalities for the end-user to switch off/on various sensors and services whenever she/he want to do it.	Mandatory	WP4	Marketplace Service provider	Service development Service joins User joins User uses	Rights
ET4	Data subject rights: right of access – provide a self-service portal where the data subject can get access to his/her data.	Desirable	WP4 WP5	Marketplace? Service provider	Platform development User joins User uses	Privacy & DP
ET5	Data subject rights: right to rectification – ensure that the data can be corrected in all places (incl. storage).	Mandatory	WP4 WP5	Marketplace? Service provider	Service development Platform development Service joins	Privacy & DP
ET6	Data subject rights: right to be forgotten – build capabilities for deleting personal data.	Mandatory	WP4 WP5	Marketplace? Service provider	Service development Platform development Service joins User leaves	Privacy & DP
ET7	Data subject rights: right to restriction – build a capability for restricting data processing.	Mandatory	WP4 WP5	Marketplace? Service provider	Service development Platform development Service joins	Privacy & DP

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ET8	Data subject rights: information provided to third parties – create a functionality to get information about the third parties to whom data has been disclosed as part of robust data mapping and flows.	Mandatory	WP4 WP5 WP6	Marketplace? Service provider	Service development Platform development Service joins	Privacy & DP
ET9	Data subject rights: right to data portability – create a capability to transmit data to the data subject/third party in a structured, commonly used and machine-readable format.	Mandatory	WP4 WP5	Marketplace? Service provider	Service development Platform development Service joins	Privacy & DP
ET10	Data subject rights: right to object: 1) ensure that the information about automated decision-making can be given to the user (the data subject) before the process starts; 2) create the capability to prevent the data subject's data to be part of profiling if a data subject has objected to profiling.	Mandatory	WP5	Marketplace? Service provider	Service development Service joins User uses	Privacy & DP
ET11	Data protection principles: storage minimisation – ensure that there are technical capabilities to erase or anonymise personal data after the relevant data retention period. Ensure that data will be removed from all systems. Define automated functions if this is possible.	Mandatory	WP4 WP5	Governance? Service provider	Service development Platform development Service joins	Privacy & DP
ET12	Data protection principles: accuracy – ensure that the source of the data is recorded.	Mandatory	WP4 WP5	Governance? Service provider	Service development Platform development Service joins	Privacy & DP
ET13	Legal basis: a) ensure that there are sufficient capabilities for asking consent as part of the service and that the consent is documented properly (obligatory); b) build up a repository where consents can be collected centrally (optional – to be defined if it brings value to SHAPES).	Mandatory	WP4 WP5	Governance? Service provider	Service development Platform development Service joins User joins	Privacy & DP
ET14	Create traceability capabilities for personal data; data mapping/data flows.	Mandatory	WP4 WP5	Governance? Service provider	Service development Platform development Service joins	Privacy & DP
ET15	Automated decision-making: Ensure that there's a capability to re-direct the decision to a manual process.	Mandatory	WP5	Governance? Service provider	Service development Service joins	Privacy & DP
ET16	Privacy by design and by default: implement needed privacy enhancing technologies.	Mandatory	WP4 WP5	Governance? Service provider	Service development Platform development Service joins	Privacy & DP

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ET18	Personal data breach: create capabilities to identify potential personal data breaches	Mandatory	WP4 WP5	Governance? Service provider	Service development / Platform development Service joins User uses	Privacy & DP
ET19	Technical and organisational security measures: ensure that users' access can be limited to certain categories of personal data and the need to restrict access to certain data is taken into consideration in SHAPES architecture.	Mandatory	WP	Governance Service provider	Service development Platform development Service joins	Privacy & DP
ET20	Keep logs for personal data (who has seen/modified personal data and when).	Mandatory	WP4 WP5	Service provider	Service development Platform development Service joins	Privacy & DP
ET21	Deploy the functionalities related to the trustworthy AI guidelines.	Mandatory	WP4 WP5	Governance Service provider	Service development Platform development Service joins	AI Ethics
ET22	Utilise the AI solutions also to provide self-diagnosis of the SHAPES's security and other issues.	Optional	WP4 WP5	Governance	Platform development	AI Ethics
ET23	Deploy the functionalities related to cybersecurity	Mandatory	WP4 WP5/D5.1	Governance Service provider	Platform development Service development	Cyber-security
ET24	Follow the WCAG 2.1. Standards and Universal Design principles in designing and implementing process. Perform formative, summative, and continuous evaluations. Test throughout the project lifecycle and any time new content is added or code is updated.	Mandatory	WP5 WP3	Service provider Governance Marketplace	Service development Platform development Service joins	Persons with disabilities
ET26	Ensure the platform usage by using assistive technology (screen magnifiers, text-to-speech, color combinations with high contrast etc.)	Essential	WP5/D5.2	Service provider Governance Marketplace?	Service development Platform development Service joins User uses	Persons with disabilities

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8.4 Ethical requirements for user support processes

Table 25 Ethical requirements for the user processes and support

No.	Requirement	Importance	Responsibility during the project	Responsibility after the project	Processes	More in D8.4 sections
PE1	Provide a process for the implementation of services for single end-users (older persons) + and for the assessment of the suitability of the services from time to time (including a process to assess the digital literacy of the end-user and adapt the services according to end-user needs and capabilities). The process should include more time to discuss choices or have an advocate regarding important appointments in order to make notes and help the person understand or remember choices.	Essential	WP3?	Marketplace Service provider	User joins User uses	Capabilities Customer logic Lifelong learning
PE2	Provide a detailed process to determine if the older person is able to decide on accessing the services and secondly if she/he is able to give informed consent and re-consent for the collection of the information. In that work take into consideration also local regulations.	Mandatory	WP3?	Marketplace Service provider	User joins User uses	Persons with disabilities Privacy & DP
PE3	Provide for the end-user (older persons) plain and understandable language materials, instructions, information in visual form (including information on each service and how it operates and what data it collects.) Video-based instructions	Mandatory	Each service provider & WP3?	Service provider Marketplace	User joins User uses	Persons with disabilities Lifelong learning
PE4 **PE5**	Provide training material on data protection and cybersecurity to end-users who need to understand data protection (older persons, caregivers, researchers).	Mandatory	WP8	Governance? Service provider	User joins User uses	Privacy & DP Cyber-security Lifelong learning
PE6	Provide a process for executing data subject rights in SHAPES.	Mandatory	WP6 WP8 other?	Marketplace? Governance Service provider	User uses User leaves	Privacy & DP
PE7	Be aware of skills and specific competences needed for the care givers using the SHAPES services and provide training materials.	Essential	WP3?	Governance Marketplace Service provider	User joins (caregiver)	Caseworkers
ME5	Deploy responsibilities /liability regarding the SHAPES and each of	Mandatory	WP3?	Governance? Marketplace?	User uses	Rights AI Ethics Legal

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	its various services (for example if something goes wrong, if the quality of data is poor, false positive & false negative situations). This includes processes related to the personal safety solution that require organisational arrangements.					framework (appendix)
ME6	Provide processes and guidelines regarding the incidental findings when using or analysing SHAPES data.	Mandatory	WP8	Governance	User uses (older person, caregiver,researcher)	See deliverable D8.2
PE8	Provide help contacts or communication aids for SHAPES users.	Essential	WP3? WP7?	Marketplace Service provider	User joins User uses User leaves	Persons with disabilities

8.5 Ethical requirements for the governance, business and ecosystem models

Table 26 Ethical requirements for the governance, business and ecosystem models

No.	Requirement	Importance	Responsibility during the project	Responsibility after the project	Processes	More in D8.4 sections
GE 10	Consider Corporate Social Responsibility, Sustainable Development Goals and ISO 2600 in order to optimise the value SHAPES can bring to society. Work towards both the economic, social and environmental sustainability of SHAPES.	Essential	WP3 WP7 WP9	Ecosystem Marketplace Governance		Sustainable development
GE 11	Consider that the public sector, as part of the SHAPES ecosystem, plays a role as a bearer of political responsibility for ensuring the wellbeing of older persons.	Essential	WP3 WP9	Governance Marketplace Service provider		Rights Capabilities Sustainable development
GE8 +GE9	Note that the participation of older persons in the development and governance of SHAPES can in itself be seen as a service that supports a person's human capabilities. Ensure that end-users have real power and impact in service development. Consider working methods and tools in the end-user collaboration so that they support a person's capabilities and ensure that essential information on end-users' needs is captured.	Essential	WP6	Marketplace Governance Service provider		Capabilities Disabilities Inclusion Customer logic Division of Labour Lifelong learning
ME1	Update the SHAPES Code of Conduct that outlines the value base and key principles of the SHAPES (to	Mandatory	WP8	Marketplace Governance		Code of Conduct

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	be utilised especially after the SHAPES project itself has ended and the realisation begins).				
ME2	Provide periodical audits and process to conduct SIA (Societal Impact) of the SHAPES Integrated Care Platform (and especially related to AI) on a regular basis, including the compliance with regulatory frameworks and recommendations.	Mandatory	WP3 WP7	Governance	Sustainable development AI ethics
ME4	Create a process to ensure that members of the SHAPES Integrated Care Platform (during the open calls and after the project) have the capabilities to comply with mandatory ethical requirements.	Mandatory	WP7	Marketplace Governance	Sections 3-7
ME3 GE10	Adopt customer logic in the building and expansion of the SHAPES Integrated Care Platform and its business governance. Pay attention to the fact that even the most vulnerable should be able to use SHAPES.	Essential	WP3 WP7 WP9	Governance Marketplace	Rights Capabilities Disabilities Customer logic Sustainable development
ME7	Establish AI governance and management for SHAPES.	Mandatory	WP3	Governance	AI Ethics
ME8 **ME9-ME11** **GE40** **GE46**	Establish privacy and data protection governance model for SHAPES - Roles and responsibilities - Data subject rights - DPIAs - Privacy information - Privacy policy	Mandatory	WP3 WP6	Governance	Privacy & DP
ME 14	Create and implement the cybersecurity and resilience management of the SHAPES Integrated Care Platform	Mandatory	WP3 WP4?	Governance	Cyber-security
ME 15	Provide accessibility statement for SHAPES	Essential	WP3	Marketplace? Governance?	Persons with disabilities
GE 23	Update and publish data protection and cybersecurity policies	Mandatory	WP8 WP10	Governance?	Privacy & DP Cyber-security

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9 SHAPES Code of Conduct

9.1 Introduction

This Code of Conduct is based on the contents and ethical requirements of this deliverable D8.14, and the existing codes of conduct of SHAPES partners (Table 27 and Table 28). The nature of the process of creating this code of conduct is to be truly dialogical to integrate and to commit all the SHAPES actors to the creation and implementation of the code.

The purpose of the code of conduct is to guide the work, not only during, but following the completion of the SHAPES project. The code of conduct will act as a guide to ensure that SHAPES becomes a positive innovation for its multitude of end-users, such as older individuals, caregivers, different stakeholders, decision makers, authorities, and service providers as well as society.

SHAPES services promote rights and capabilities of people. By the development of this Code we want to articulate our values concerning technological development, user processes, business model, governance, and ecosystem with the aim of achieving high quality life. Under this code of conduct there will be discussion of what kind of values we want to promote by our work.

We appreciate ethically sustainable management of the process and organizations, not just the solution to be created. Ethically sound leadership is built-in to the SHAPES processes, including pilots. We are committed to both national and EU level laws and ethical standards and to think about the social aspects of our actions, innovations, and solutions. Continuous development work is built-in in SHAPES, therefore research and development ethics and Responsible Research and Innovation (RRI) approach is also characteristic of SHAPES.

9.2 SHAPES

SHAPES – Smart and Healthy Ageing Through People Engaging in Supportive Systems

SHAPES Innovation Action is a pan-European endeavour seeking to build, pilot and deploy a large-scale, EU-standardised open platform. The integration of a broad range of technological, organisational, clinical, educational, and societal solutions seeks to facilitate long-term healthy and active ageing and the maintenance of a high-quality standard of life.

SHAPES Integrated Care Platform is an open, EU-standardised platform based on four factors: home, behaviour, market, and governance. SHAPES Digital Solutions

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include assistive robots, eHealth sensors and wearables, Internet of Things (IoT)-enabled devices, mobile applications (apps), big data analytics and utilizing AI.

SHAPES Marketplace seeks to connect demand -and-supply across health care delivery and to facilitate the co-creation of affordable, effective, and trustworthy solutions.

SHAPES Platform is designed to be suitable for all older individuals, promoting inclusive, smart, and healthy ageing. SHAPES Ecosystem is a network of relevant users and key stakeholders working together to scale-up the platform and digital solutions.

9.3 Values and guiding principles

Table 27 Values and guiding principles of SHAPES Code of Conduct

Dignity – Autonomy – Participation – Justice – Equality – Solidarity – Freedoms

EU Fundamental Rights: They entail 50 rights that are divided into the areas of dignity, freedoms, equality, solidarity, citizen rights and justice.

Biomedical ethics and Care Ethics: The classical principles are justice, beneficence, non-maleficence and autonomy. Perspectives to care ethics entail empathy, relationships, and uniqueness of the case.

Capabilities Approach, Social Justice and Wellbeing:10 central human capabilities are life, bodily health, bodily integrity, senses, imagination and thought, emotions, practical reason; affiliation; other species; play; control over one's environment.

Convention on the Rights of the Persons with Disabilities (UN CRPD): The SHAPES Ecosystem context acknowledges that older persons, including older persons with disabilities, ought to retain their right to make decisions and live independently and their right to be provided with adequate support to exercise their legal capacity. The underpinning principles are accessibility, respect for the dignity, autonomy and independence of persons, non-discrimination, participation and inclusion, respect for difference and acceptance of persons an equality of opportunity.

9.4 Code of Conduct

Table 28 Code of Conduct

		Q & A
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 opportunity to be empowered. Cultural diversity is valued. We understand participation and inclusivity of people in the development, actions and with the	Question: How SHAPES actors ensure the inclusion of older persons in SHAPES? Answer:

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	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 to SHAPES, end-users are themselves subjects of outcomes and impacts.	By gaining the widespread understanding of heterogeneity of the older persons and by understanding the variety in the ability to adapt and use digital services.
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 to promoting lawfulness, fairness and transparency. The aim of cybersecurity is to make cyberspace safe from damage or threat. Cyber security is a wider phenomenon than 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 into our cybersecurity management and taken seriously. The overall goal of cybersecurity is that all systems and infrastructures are resilient.	Question: Person who uses several digital solutions of SHAPES wants to be forgotten. How this data will be erased? Answer: SHAPES Platform includes a method to withdraw consent and all the personal data from the system. User will also receive confirmation when the data is removed.
3 Trustworthy Artificial Intelligence (AI)	Multiple legal and societal issues have revealed the potential of Artificial Intelligence technologies to produce undesirable impacts. For these reasons, we explore the ethical, social, and legal aspects of AI systems. Trustworthy AI has three components that need to be met throughout the system's lifecycle: it needs to be lawful, ethical, and robust. The possible risk of AI to fundamental rights is taken seriously in SHAPES. We protect fundamental rights and work for them not to be violated within SHAPES project. We adopt adequate measures to mitigate risks of AI. We apply the following values to AI ethics in all our actions: human autonomy, prevention of harm, fairness, and explicability.	Question: How SHAPES ensures autonomy of the end-user? Answer: End-user are informed when they are interacting with an AI system. And they are made aware when a decision, content, advice or outcome is the result of an algorithmic decision. Potential risks and negative consequences for end users are investigated systematically

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4 Communication and the use of terminology	In SHAPES we understand that the concepts and terms used to construct the world we live in and our understanding of the world around us. We do not use discriminatory, such as ageist or ableist, language. We are committed to an inclusive and empowering terminology. We suggest avoiding terms that might appear to be the use of discriminatory language and can show prejudicial attitudes and stereotypes. We pay attention to the way other people use challenging concepts and robustly bring into discussion the challenge of using those. We promote gender-neutral and bias-free language. We also pay great attention to terms used in languages other than English (which is the working language of SHAPES). When we communicate (verbal, written, visual), we think about diversity and inclusiveness and accessibility.	Question: What does this mean, give me an example? Answer: We do not describe people to be confined to a wheelchair, instead we say for example a wheelchair user - when that information is needed.
5 Sustainability, corporate social responsibility and customer logic	We are committed and expect our partners and stakeholders also to understand their positive and negative impacts on society and the environment. We understand our responsibility for our impacts on the environment, society, and individuals. To fully meet our social responsibility we have a process to integrate social, environmental, ethical, human rights and consumer concerns into our business operations and core strategy in close collaboration with our stakeholders, with the aim of maximizing the creation of shared value for the owners/shareholders and civil society at large and identifying, preventing and mitigating possible adverse impacts. We are committed to the 17 UN sustainable development goals and promote those in all SHAPES initiatives, process, and solution. In providing services and creating new solutions we are committed to understand customers holistically, weighing the factors that guide and limit customer's operations. We understand customer logic being individual, original, cognitive, and emotional. We promote transparency in empowering citizens and customers. We see customers and end-users as co-creators in the developmental work.	Question: How can end-users take part in the SHAPES decision making? Answer: Answer: End-users are invited to participate both to the development of the SHAPES services, as well as in the governance of SHAPES.
6 Positive Social Impact Assessment (SIA)	SIA process is built-in into the idea of creating SHAPES platform. We take into account the positive and possible negative impact of our actions. We have a proactive approach to this. SHAPES is committed to foster positive social impact, performing the identification of social	Question: How can I take into account the SIA of the digital ecosystem that is not ready yet?

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	risks and the management of social issues. We aim to identify, analyse, assess, manage and monitor the positive and possible negative social impacts of our project and later at the digital platform. The social impacts of SHAPES are both direct and indirect and we are also committed to tackle the impacts after the project, as the digital platform is in use. This applies to both individuals and organizations.	Answer: By doing your best at all times and by co-operation with wide range of colleagues and partners from different special areas.

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10 Conclusion

This deliverable, Final SHAPES Ethical Framework (D8.14) describes the ethical dimensions associated with features of the SHAPES solution. From these features the ethical requirements for the SHAPES technology and user support processes, as well as for governance, business, and ecosystem models, are derived. This deliverable is part of the normative guidelines and requirements that WP8 will provide for the SHAPES project and solution.

SHAPES is a diverse initiative from the ethics viewpoint. Ethical requirements and their implementation are essential for the sustainability of SHAPES. Ethical requirements arise both on the basis of EU fundamental rights and different ethical norms and approaches, as well as on the basis of various ethical guidelines for business and technology. In addition, the General Data Protection Regulation (GDPR) is used as a foundation when addressing data protection and cybersecurity requirements.

The purpose of the ethical requirements and the SHAPES Code of Conduct is to help ensure that the SHAPES initiative becomes an ethically responsible endeavour and a positive innovation for its various end-users and service providers, as well as for society as a whole. Alongside user requirements, ethical requirements are particularly important when developing and taking into use solutions linked to fundamental rights and when the target group is older persons.

A comprehensive ethical framework is vital to ensure that the SHAPES solution is truly sustainable. Applied ethics cannot be treated as a mere legitimising tool of ‘ethics approval’ but must be seen as a way of putting critiques to work. The SHAPES technology and architecture, SHAPER user support processes and decision-making, and the future governance- and business models of SHAPES are all linked with numerous legal, ethical, and societal questions. Four sets of challenges and opportunities in particular come into prominence:

1. Ethical issues related to EU Fundamental Rights, Bioethics and Ethics of Care, human capabilities and rights of persons with disabilities (section 3 and 7)
2. Ethical and legal issues relating to privacy and data protection and cyber security (section 5 and 6)
3. Approaches related to Sustainability and Customer logic (section 4)
4. EU guidelines and policies, and especially related to artificial intelligence and ethics (section 4)

Each of these challenges has implications for the SHAPES technology, but even more so for the SHAPES business, governance, and ecosystem models. SHAPES can, and should, be designed and used to actively promote the fulfilment of these rights and values. Ethics should thus be seen as a resource, not only as a source of risks.

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APPENDIX

Appendix 1: Ethical requirements check of each SHAPES deliverable

The focus of this compliance check is on the ethical requirements and SHAPES Code of Conduct defined in D8.14 and having impact on the SHAPES solution (technology and related digital services, user processes and support, governance-, business- and ecosystem models). In the left column there are ethical issues discussed in D8.14 (corresponding D8.14 subsection in parenthesis). For each deliverables, report on how these topics and corresponding ethical requirements have been taken into account. If the topic is not relevant for the deliverable, enter N / A in the right-hand column.

Deliverable: _____

Ethical issue (corresponding number of D8.14 subsection in parenthesis)	How we have taken this into account in this deliverable (if relevant)
Fundamental Rights (3.1)	**see 3.1**
Biomedical Ethics and Ethics of Care (3.2)	**see 3.2**
Persons with Disabilities (3.3)	**see 3.3**
Capabilities approach (3.4)	**see 3.4**
Sustainable Development and CSR (4.1)	**see 4.1**
Customer logic approach (4.2)	**see 4.2**
Artificial intelligence (4.3)	**see 4.3**
EU Policies (4.4)	**see 4.4**
Privacy and data protection (5)	**see 5**
Cyber security and resilience (6)	**see 6**
Digital inclusion (7.1)	**see 7.1**
The moral division of labor (7.2)	**see 7.2**
Life-long learning of older persons (7.3)	**see 7.3**
Care givers and welfare technology (7.4)	**see 7.4**
Older persons – challenges with terminology (7.5)	**see 7.5**
SHAPES Ethics and COVID-19 (7.6)	**see 7.6**

Comments: _____

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