



# SHAPES

Smart and Healthy Ageing  
through People Engaging in supporting Systems

## D8.4 – SHAPES Ethical Framework

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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
EIP-AHA	European Innovation Partnership for Active and Healthy Ageing
EPSU	European Social Observatory
GDPR	General Data Protection Regulation
H&C	Health and Care
HMI	Human-machine interaction
IaaS	Infrastructure as a service
ICT	Information and communication technology
IOC	Indicator of compromise
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
SPC-WG-AGE	Social Protection Committee Working Group on Ageing
TFEU	Treaty on the Functioning of the European Union

## Keywords

Ethical Requirements, Fundamental rights, Values and norms, Ethical guidelines, Privacy and data protection, Cybersecurity

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# 1 Introduction

The aims of this deliverable, “SHAPES Ethical Framework” (D8.4), are 1) to aid SHAPES developers in better understanding the ethical aspects relevant to the SHAPES Integrated Care Platform and 2) to lay out the ethical requirements that SHAPES (including technology and user processes, as well as its 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 (see the table 4).

The focus of this version of “SHAPES Ethical Framework” is on ethical issues most relevant to the SHAPES Integrated Care Platform in general and in particular from the viewpoint of strategic choices and architecture. Some of the ethical requirements presented herein are currently still at a fairly general level, but others are specified in more detail. For example, privacy, data protection and security requirements have been defined as precisely as possible. Based on the requirements, various technical notes are to be produced as part of WP8, if necessary, to support the implementation of the requirements as features of the SHAPES Technical Platform and the SHAPES Market Place and Ecosystem.

The updated and final version of this deliverable is to be provided in M18. The final version shall also include a code of conduct that has not yet been possible to define in this early phase of the project.

*Table 4 WP8 deliverables providing guidelines and requirements*

Deliverable	Timetable	Focus and Content
<b>Baseline for Project Ethics D8.2</b>	M6	Provides guidelines and templates for research integrity and for the ethics management of the SHAPES project.
<b>SHAPES Ethical Framework D8.4</b>	M7 and M18	Provides ethical requirements for the SHAPES Integrated Care Platform (technology and services, user processes and training, business/governance and ecosystem models). It serves as guidelines from developing the SHAPES such that it complies with common ethical standards, regulations and policies to ensure that 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 on in separate deliverables D8.3, D8.11 and D8.12.
<b>SHAPES Data Management Plan 8.13</b>	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).
<b>Regulatory Frameworks for Pan-European Smart and Healthy Ageing D8.3</b>	M42	Analyses the extent to which current legal frameworks facilitate the creation of pan-European systems for healthy ageing.
<b>SHAPES Privacy and Data Protection Legislation and Impact Assessment D8.11 and D8.12</b>	M24 and M48	Elaborates the 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.
<b>Privacy and Ethical Risk Assessments D8.8 and D8.9</b>	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.)

After the introduction and presentation of the SHAPES solution and SHAPES terminology in section 4, pertinent norms and values are discussed in the context of the SHAPES solution. The purpose 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. In section 7, the focus is 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. Section 10 presents the conclusions.

Table 5 describes the significance of the above ethical topics for the SHAPES Integrated Care Platform, as well as the methods and source materials used.

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

Chapter	Effect on SHAPES	Source materials	Method of analysis
<b>4. Values and norms</b>	How SHAPES can protect and promote rights, capabilities and well-being of persons?	Fundamental rights, international conventions, ethical theories	Content analysis
<b>5. Ethics guidelines in business and technology</b>	How SHAPES can promote sustainable development and digital transformation of human-centred services?	Ethical guidelines and agendas Scientific articles and publications	Content analysis Literature review
<b>6. Privacy Data Protection</b>	What are the privacy and data protection requirements for the SHAPES technology and	General Data Protection Regulation GDPR	Legal analysis

	organisational arrangements?		
<b>7. Cybersecurity and resilience</b>	What are the ethical aspects of cybersecurity and resilience for SHAPES technology and organisational arrangements?	Articles and other literature	Literature review
<b>8. Challenges identified</b>	What kind of key challenges have generally been identified in digital solutions for older people?	Articles and other literature	Literature review

## 2 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 2019).

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



Figure 2 The SHAPES Integrated Care Platform (Adopted SHAPES 2019, 85)

SHAPES Platform is designed to be for all older individuals, promoting 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 the Platform user's sense of coherence; of being at home with it and ageing in place. SHAPES' 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 pathfinding through the complexities of 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).



## 3 Norms and values in the context of the SHAPES Integrated Care Platform

In this chapter, we introduce some central frameworks and theories within social ethics that are relevant and helpful in the planning and building of the SHAPES Integrated Care Platform 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. These frameworks and theories are essential inputs to SHAPES alongside end-users' requirements, and they affect both the technology and various organisational arrangements as part of SHAPES Integrated Care Platform.

### *3.1 EU Fundamental Rights and SHAPES Integrated Care Platform*

#### *3.1.1 Introductory Remarks*

In this chapter, an analysis will be provided of the EU Fundamental Rights in relation to SHAPES. An overview will be provided on how SHAPES promotes the Fundamental Rights and, on the other hand, how the SHAPES project may undermine those rights (particularly those relevant in the context of SHAPES).

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 TEU 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”. 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” (Preamble of the Charter of the Fundamental Rights of the European Union).

Article 3(1) TEU provides that the EU’s aim is “to promote peace, its values and the wellbeing of its peoples”. In addition, Article 3 TEU 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 remains at the core of the EU project. Within the internal market, goods, services, capitals 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.

Article 6 TEU provides for the protection of fundamental rights in the EU context. According to Article 6(1) TEU, 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) TEU 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”.

### 3.1.2 The EU CFR

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. Despite being part of EU constitutional law, the Charter does not expand the existing EU competences, which are laid down in the Treaties. Hence, on the one hand, the power of the EU to protect and promote fundamental rights is limited to the areas in which the EU has competence to act. On the other hand, the EU CFR is applicable to Member States only when “they are implementing Union law” (Article 51[1] CFR). The legal aspects related to the applicability of the Charter will be expanded upon in D8.3.

As stated in its Preamble, the Charter aims to “strengthen the protection of fundamental rights in the light of changes in society, social progress and scientific and technological developments”. 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 last title deals with the interpretation and application of the Charter.

The EU CFR 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.

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.

All fundamental rights protected and promoted by the EU CFR apply to older persons. In the following table 6, we highlight how EU CFR Articles are relevant in the context of SHAPES.

It is essential that all activities within SHAPES project will promote as many rights as possible and that SHAPES activities will not in any way undermine any of them.

Table 6 EU Fundamental Rights in the context of SHAPES

Chapter/ article	Analysis in more detail	Implications to SHAPES (to be defined more in detail)
<b>CHAPTER 1 Dignity</b>	<b>Dignity is a starting point for SHAPES. These articles play a central role in SHAPES.</b>	
<b>1. Human dignity</b>	Human dignity is the starting point for SHAPES. Smart and healthy ageing aims to promote human dignity by promoting a good quality of life. Human dignity can also be seen explicitly: e.g., in the (everyday) language used around older persons. In research and development activities, special attention needs to be paid to human dignity. The Explanations to the Charter (Explanations relating to the Charter of Fundamental Rights OJ C 303, 14.12.2007, p. 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.”	SHAPES Integrated Care Platform and Digital Solutions (e.g. robots).  Research and co-creation with end-users as part of SHAPES Integrated Care Platform and SHAPES Market Place.  Language to be used in the SHAPES Integrated Care Platform.
<b>2. Right to life</b>	SHAPES promotes the right to life by aiming to improve the health of older persons and thus enabling a better and longer life.	SHAPES Integrated Care Platform.
<b>3. Right to the integrity of the person</b>	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 to their impact on living conditions. <sup>1</sup> This dictates that researchers must first receive approval from local ethics committees who will review the consent documents and information leaflets and that the researchers informing the participants are well aware of the ethical and legal requirements to be complied with. They are also aware of research and development ethics, in relation to the pilots and co-creation workshops. In relation to those activist risk could arise if procedures are not managed correctly. In SHAPES research will not be carried out without prior approval from local ethics	SHAPES Digital Solutions and consents (e.g. hosting a company robot, a webcam or assistant such as Alexa)  Research and co-creation with end-users as part of SHAPES Integrated Care Platform and SHAPES Market Place.

<sup>1</sup> In case C-377/98 *Netherlands v European Parliament and Council* ECLI:EU:C:2001:523, the Court of Justice confirmed that a fundamental right to human integrity is part of Union law and encompasses, in the context of medicine and biology, the free and informed consent of the donor and recipient (see para 70, 78 and 80 of the judgement and Explanations relating to the Charter of Fundamental Rights OJ C 303, 14.12.2007, p. 17–35).

		committees. For research activities, the procedures are clear, but it might be more difficult sometimes to define this in the context of co-creation and developmental work.	
4. Prohibition of torture and inhuman or degrading treatment or punishment <sup>2</sup>		-	
5. Prohibition of slavery and forced labour		Not directly relevant to the SHAPES activities, but this may be relevant in the context of professional caregiving. Trafficking is a growing problem, and victims of human trafficking might 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.
<b>CHAPTER 2</b>	<b>2</b>	<b>Freedoms play a central role in SHAPES.</b>	
6. Right to liberty and security		Everyone has a right to feel safe and secure within SHAPES activities, and this must be promoted. <i>A feeling of security</i> might be threatened when SHAPES researchers/developers are meeting with older people for research or developmental purposes if special attention is not paid to building and creating a safe space.	SHAPES Integrated Care Platform and Digital Solutions.  Research and co-creation with end-users as part of SHAPES Integrated Care Platform and SHAPES Market Place.
7. Respect for private and family life		Special attention needs to be paid to visits at homes and to the impact on the living conditions of e.g., "hosting" of a company robot, a webcam or an assistant such as Alexa. Private and family life should not be affected by participation in SHAPES. The respect of private and family life should be reinforced by the efforts of SHAPES to ensure a longer stay within one's own home.	SHAPES Digital Services (e.g. hosting a company robot, a webcam or an assistant such as Alexa).  Research and co-creation with end-users as part of SHAPES Integrated Care Platform and SHAPES Market Place.
8. Protection and personal data		This has been analysed in more detail in a subsection 5.	SHAPES Integrated Care Platform, including both SHAPES Technological Platform and organisational arrangements as part of SHAPES governance models. See section 4 on privacy and data protection.
9. Right to marry and to found a family			
10. Freedom of thought,		SHAPES activities are not likely to threaten this right. By contrast, this right will be promoted by SHAPES as older	Research and co-creation with end-users as part of SHAPES

<sup>2</sup> This article has the same wording as Article 3 ECHR. Hence, as noted in the Explanations relating to the Charter (Explanations relating to the Charter of Fundamental Rights OJ C 303, 14.12.2007, p. 17–35), by virtue of Article 52(3) CFR, it has the same meaning and the same scope as the ECHR provision.

conscience and religion	persons' own thoughts are valued and appreciated as part of cocreation.	Integrated Care Platform and SHAPES Market Place.
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 cocreation.	SHAPES Digital Solutions (e.g. 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 Research and co-creation with end-users as part of SHAPES Integrated Care Platform and SHAPES Market Place.
12. Freedom of assembly and of association	SHAPES activities aim to increase the capabilities of older persons, and SHAPES will indirectly increase the possibility to take these rights into actions.	SHAPES Digital Solutions.
13. Freedom of the arts and sciences	SHAPES activities are not likely to threaten this right and vice versa: indirectly, SHAPES aims to improve the possibility to take part in art and science activities.	SHAPES Digital Solutions.
14. Right to education	As SHAPES is in favour of lifelong learning as a right, but also the benefits of learning for the ageing population (or anyone), SHAPES shall promote this aspect.	SHAPES Digital Solutions.  Research and co-creation with end-users as part of SHAPES Integrated Care Platform and SHAPES Market Place.
15. Freedom to choose an occupation and the right to engage in work	This right is relevant with regard to professional caregivers of older people.	SHAPES ecosystem.
16. Freedom to conduct a business	This right is relevant with regards to private service providers. <sup>3</sup>	SHAPES Market Place
17. Right to property	SHAPES is not threatening this right. But what if the evidence collected (conversations etc.) is unlawful and hence threatens other rights such as this?	Research and co-creation with end-users as part of SHAPES Integrated Care Platform
18. Right to asylum	Not directly relevant within SHAPES context, but if a need for this is recognised, at least relevant information needs to be provided to the person in need.	
19. Protection in the event of removal, expulsion or extradition	-	
<b>CHAPTER 3</b> <b>Equality</b>	<b>This chapter is important for SHAPES.</b>	
20. Equality before the law		
21. Non-discrimination	Age and disability are mentioned as grounds upon which discrimination is prohibited. SHAPES aims to prevent non-	Language to be used.

<sup>3</sup> The Court of Justice has recognised the freedom to exercise an economic or commercial activity and freedom of contract. This right is to be exercised with respect for Union law and national legislation. It may be subject to the limitations provided for in Article 52(1) of the Charter (Explanations relating to the Charter of Fundamental Rights OJ C 303, 14.12.2007, p. 17–35)



	discrimination, e.g., by the language used about the ageing population/older persons and persons with disabilities, and by improving their capabilities to participate in everyday life. “Positive discrimination” plays a role in SHAPES in the way that the services/platform are tailored to the needs of older persons.	SHAPES Digital Services (tailored to older persons, Design for All –approach to avoid discrimination).
<b>22. Cultural, religious and linguistic diversity</b>	SHAPES activities aims to promote all 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 SHAPES Integrated Care Platform and SHAPES Market Place.
<b>23. Equality between men and women</b>	SHAPES activities aim to promote gender equality and the awareness that gender is not just binary woman-man. At the same time, SHAPES acknowledges the care sector is female dominated.	SHAPES Digital Solutions.  SHAPES Ecosystem.
<b>24. The rights of the child</b>	-	
<b>25. The rights of the elderly</b>	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 Digital Solutions.  Research and co-creation with older persons as part of SHAPES Integrated Care Platform and SHAPES Market Place.  SHAPES Ecosystem.
<b>26. Integration of persons with disabilities<sup>4</sup></b>	Older persons may have increased possibilities of chronic diseases and physical and cognitive impairments, which in interaction with various barriers may result in disabilities. Older persons are a diverse group and include e.g. older persons with disabilities.	SHAPES Digital Solutions and user interfaces (tailored services, supported decision making etc.)  Research and co-creation with persons with disabilities as part of SHAPES Integrated Care Platform and SHAPES Market Place.
<b>CHAPTER 4: Solidarity</b>	<b>This chapter is important for the employees that work with older persons on the SHAPES platform but not so much to older persons themselves.</b>	
<b>27. Workers’ right to information and consultation within the undertaking</b>	-	

<sup>4</sup> Article 26 CFR, on the integration of persons with disabilities, establishes that the EU “recognizes and respects the right of persons with disabilities to benefit from measures designed to ensure their independence, social and occupational integration and participation in the life of the community”. It is reflective of the social model, focusing on inclusion and participation in society and the need to ensure the independence of persons with disabilities (Ferri, 2020). Article 26 CFR has been classified as a principle rather than a right. This means that it is intended to guide the EU institutions when they legislate, but that it does not oblige them to act.

28. Right of collective bargaining and action	-	
29. Right of access to placement service	-	
30. Protection in the event of unjustified dismissal	-	
31. Fair and just working conditions	People working with older persons. 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, but this is not specifically a SHAPES issue.	SHAPES Digital Solutions for caregivers.
32. Prohibition of child labour and protection of young people at work	-	
33. Family and professional life	SHAPES aims to promote this right.	
34. Social security and social assistance	SHAPES aims to promote this right.	SHAPES Integrated Care Platform and Digital Solutions.  SHAPES Market Place and Ecosystem
35. Healthcare	Important. SHAPES aims to promote this in many ways.	SHAPES Integrated Care Platform SHAPES Ecosystem
36. Access to services of general economic interest	-	
37. Environmental protection	Environmental protection is inalienable in everything in the world we live in nowadays, and so it is in SHAPES. SHAPES promotes environmental protection by enabling digital solutions for health promotion.	SHAPES Digital Solutions.
38. Consumer protection	These are to be taken into account as part of SHAPES business	SHAPES Market Place
CHAPTER 5 Citizen rights	<b>This chapter is not directly relevant to the SHAPES context.</b>	
39. Right to vote and to stand as a candidate at elections to the European Parliament	-	
40. Right to vote and to stand as a candidate at municipal elections	-	
41. Right to good administration	SHAPES participants have the right to expect good administration from the EU-funded project (and also when the exploitation begins.)	SHAPES Ecosystem.

42. Right of access to documents	The right to access documents concerning oneself is important. What is meant 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 Technological Platform and Digital Solutions.  Privacy and data protection, see chapter 4 of this deliverable.
43. Ombudsman	-	
44. Right to petition	-	
45. Freedom of movement and of residence	This is relevant both to the context of older persons and the people working with them. SHAPES aims to ease movement since the platform is digital, and it doesn't matter where the user is located.	SHAPES Digital Solutions.
46. Diplomatic and consular protection	-	
CHAPTER 6 Justice	<b>This chapter is not especially relevant in the SHAPES context.</b>	
47. Right to an effective remedy and to a fair trial	-	
48. Presumption of innocence and right of defence	-	
49. Principles of legality and proportionality of criminal offences and penalties	-	
50. Right not to be tried or punished twice in criminal proceedings for the same criminal offence	-	

## 3.2 Biomedical ethics and Ethics of Care as the guiding principle

In this chapter, the concepts of biomedical ethics and care ethics and their guiding principles will be briefly considered.

### 3.2.1 Biomedical ethics

Biomedical ethics can be described as an interdisciplinary, contemporary ethical approach based on four main principles. Those principles are included in most classical ethical theories in some form (Beauchamp and Childress 2001, 12). The principles are **justice, beneficence, non-maleficence and autonomy**. The biomedical ethics approach serves a paradigm that assists healthcare professionals and public policymakers to identify and respond to moral dilemmas in biomedical and healthcare 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 space for judgement in a number of cases. Principles do not function as “precise action guides” that would inform us in every single circumstance on how to act the same way as detailed judgements and rules would guide. The four-principles cluster is not a general moral theory: it is only a **framework** to identify and reflect on moral problems. The principles are rather abstract. The approach has often been called the *four-principle approach* and *principlism* (Beauchamp and Childress 2001, 12, 15, 23). There is also critical discussion about principlism (see, e.g., Saxén 2017).

The biomedical ethics approach encourages SHAPES participants to apply ethically solid decision-making. The principles are further described in Table 7 below.

Table 7 Biomedical principles within the SHAPES context

Principle According to Beauchamp and Childress 2001	Points especially relevant to the SHAPES context
<p>Respect for autonomy</p> <ul style="list-style-type: none"> <li>- A norm of respecting the decision-making capacities of autonomous persons. In this context, it means especially decisions about informed consent and refusal.</li> <li>- Autonomy derives from the Greek <i>autos</i> (“self”) and <i>nomos</i> (“rule”).</li> <li>- Personal autonomy as a minimum is self-rule that is free from limitations like inadequate understanding that would prevent meaningful choices and free from controlling interference.</li> <li>- Two conditions are especially relevant to autonomy: agency, meaning capacity for intentional action; and liberty, meaning independence from any controlling interference.</li> <li>- In decision-making, the concept of competence has close ties to the concept of autonomy.</li> <li>- The components of informed consent are: <b>Threshold elements:</b> competence, voluntariness. <b>Information elements:</b> disclosure, recommendation, understanding. <b>Consent elements:</b> decision, authorisation.</li> </ul>	<p>Respect for autonomy within the SHAPES context needs to be appreciated during all the actions at all times, but it is especially crucial within research activities and consent forms related to those activities.</p> <p>Acknowledging participants of actions of research/developmental work.</p>
<p>Non-maleficence</p> <ul style="list-style-type: none"> <li>- A norm of avoiding the causation of harm.</li> <li>- Associated with the maxim <i>Primum non nocere</i>: “Above all, do no harm.”</li> <li>- Many theories recognise non-maleficence.</li> <li>- Some theories combine non-maleficence and beneficence into one principle.</li> <li>- People should be protected against harm; it is synergistic with the conclusion that there is also a positive obligation to provide benefits like healthcare.</li> </ul>	<p>Sometimes it might be difficult to foresee the possible consequences of our actions that may do harm to other people. These should not be very likely in the SHAPES activities, but attention to these should also be paid at all times.</p>

<p>Beneficence</p> <ul style="list-style-type: none"> <li>- A group of norms for providing benefits and balancing benefits against risk and cost.</li> <li>- Contributes to persons' welfare.</li> <li>- There are two chapters of beneficence: positive beneficence and utility. Positive benefits require that agents provide benefits. Utility means agents are required to balance drawbacks and benefits to produce the best result overall.</li> <li>- It includes all kind of actions that intend to benefit others.</li> <li>- It refers to actions done for others.</li> <li>- Principle of benevolence refers to a moral obligation that one needs to act for the benefit of the others.</li> </ul>	<p>In all SHAPES actions, doing good for others should be the prime aim.</p> <p>SHAPES is publicly funded; the outcomes and results of the project will benefit many, including people not directly involved with SHAPES activities.</p>
<p>Justice</p> <ul style="list-style-type: none"> <li>- A group of norms for distributing benefits, risks, and costs fairly.</li> <li>- Fairness, deservedness and entitlement have often been used to explicate justice.</li> <li>- Aristotle: "Equals must be treated equally, and unequals must be treated unequally." This does not often provoke debate, but what is understood as justice is more complex.</li> <li>- Theories like 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.</li> </ul>	<p>SHAPES workers may encounter situations in which there is a question about justice. Thus, an analysis about the justice issues need to be undertaken.</p>

### 3.2.2 Ethics of Care

Ethics of care has been applied in the care sector. Ethics of care can be said to have several roots, but Carol Gilligan (1982) is seen as a key person to have developed it. 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, see also 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; see also Blum 1988 et al. and 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, as 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; see also Woods 2011). It has been seen as a promising approach to strengthen the voices of nurses in ethical discussions, which traditionally has been dominated by justice-based theories (Juujärvi et al. 2019, Juujärvi 2011; see also Gilligan 1982).

A relevant question to ask would be: what would be the strongest ethical approach to highlight the key roles of clients, customers and older persons in the SHAPES context?

*Table 8 Main characteristics of care ethics*

Perspectives	In the SHAPES context, especially
<b>Empathy</b>	Showing empathy might need new forms when acting on digital platforms: e.g., a smile, touch and eye contact might not work as in traditional face to face encounters – this applies to caregivers, researchers and older persons.
<b>Relationships</b>	Building and maintaining relationships might mean learning new methods and forms when acting on digital platforms.  Building and maintaining relationships also means understanding of, e.g., psychology, sociology and spirituality of human beings.
<b>Uniqueness of the case</b>	In hectic working life, it might not always be easy to provide care, as the case is unique and not just one of a dozen similar-looking ones.

### *3.3 UN Convention on the Rights of Persons with Disabilities and Supported Decision-making*

The SHAPES ecosystem 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 ecosystem context also acknowledges that recent developments in international human rights law have radically challenged the institute of adult guardianship as well as the principle of “best interests”.

In that connection, the UN Convention on the Rights of Persons with Disabilities (CRPD) is the leading instrument in international law that informs the SHAPES ecosystem context. The General Assembly of the UN approved the CRPD in 2006. The CRDP entered into force on 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<sup>5</sup> it in 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 and 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” (Article 1(2) CRPD). To date, the CRPD Committee, i.e., the treaty body entrusted with the interpretation and monitoring of the CRPD, has not had yet the opportunity to extensively discuss the content and meaning of Article 1(2) CRPD. It did, however, briefly elaborate on the concept of disability in *S.C. v. Brazil* (CRPD 2013), an individual communication that was ultimately declared inadmissible, as well as on two other communications against Tanzania (*X v. Tanzania* and *Y v. Tanzania*). The Committee emphasised that “persons with disabilities include, but are not limited to, those who have long-term physical, mental, intellectual or sensory impairments which, in interaction with various barriers, may hinder their full and effective participation in society” (emphasis added).

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
- Respect for difference and acceptance of persons with disabilities as part of human diversity and humanity
- Equality of opportunity
- Accessibility
- Equality between men and women
- Respect for the evolving capacities of children with disabilities and respect for the right of children with disabilities to preserve their identities

On the whole, the CRPD makes a strong pivot on independence and autonomy of people with disabilities. These principles 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”.

The CRPD Committee provided an interpretation of Article 12 CRPD in its General Comment N. 1 (CRPD/C/GC/1, General Comment No.1, 2014). The CRPD Committee

<sup>5</sup> The term “conclusion” is used in the TFEU. See, e.g., Article 216 TFEU, “Agreements concluded by the Union are binding upon the institutions of the Union and on its Member States”.



highlighted that “legal capacity is a universal attribute inherent in all persons by virtue of their humanity and must be upheld for persons with disabilities on an equal basis with others” (CRPD/C/GC/1, para. 8; Fridström Montoya 2015, 188). 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)” (CRPD/C/GC/1, para. 13). 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, para. 13).

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, para 16). 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, para 21). Along the lines 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 ecosystem, it is important to highlight that persons with disabilities must be supported, but *only* when support is needed, 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) or assistance with communication. Support provided to individuals with disabilities might encompass the provision of reasonable accommodation (or measures relating to accessibility) (Arstein Kerslake 2017, 70). When identifying the most appropriate support, careful attention must be paid to the situation of the individual (Quinn 2009, 105–106).

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, the UN Special Rapporteur of the Rights of Persons with Disabilities in her report on older persons with disabilities (Aguilar 2019, para 31) stated that:

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“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.”

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 enhanced. 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.

With regard to the first issue, members of the SHAPES consortium have to estimate what support is most suitable for the person. Researchers can resort to various types of support, including accessibility measures and reasonable accommodation measures (e.g., using plain-language materials, information in visual form, more time to discuss choices). If needed, the researcher can involve the supporter/caregiver 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 concrete situations for adaptation and in obtaining necessary information. Trustees or caregivers 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, 71).

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.

### *3.4 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 solution. However, the idea of healthy and “successful ageing” has been critiqued by several scholars for several reasons: it homogenizes, oppresses and neglects the physical realities of ageing individuals (see



e.g., Stephans et al 2015; Rowe and Kahn 1997; Pfaller and Schweda 2019). The preference for activity neglects many relevant and accessible dimensions of human life (e.g., intellectual or spiritual experiences), as well as activities outside the domain of economy (e.g., arts and craft, political participation). In addition, active ageing is often equated with productive ageing and economic success. (Pfaller and Schweda 2019, 48-49).

The capability approach has originally been developed by the economist Amartya Sen and the philosopher Martha Nussbaum. It criticizes welfare economics, which focus on economic measures, utility and material resources. According to the capability 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. (see, e.g., 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 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 the table 9). According to Nussbaum, these capabilities (also covering the terrain 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 and 2011). Each capability on the list has intrinsic value but also instrumental value from the perspectives of other capabilities. However, capabilities of affiliation and practical reason have an architectonic role. (Nussbaum 2007 and 2011).

*Table 9 The Central Human Capabilities (Adopted Nussbaum 2011, 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 be not 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 secure against 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 toward others, to recognize and show concern for other humans, to engage in various forms of social interaction; to be able to 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, to play, to 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 itself a way of being active, not just a passive state of satisfaction (Nussbaum 2011). Special concern should be paid to the capabilities of those who are disadvantaged. It is the task of society's basic structure to secure a threshold level for the central human capabilities, but other organisations also have a role in implementation. (Nussbaum 2007 and 2011).

Nussbaum states that the list of Central Human Capabilities can be more concretely specified in accordance with local circumstances, leaving room for a reasonable



pluralism. Nussbaum also claims that preferences cannot alone reflect the wellbeing of citizens. But by listening to people's conceptions about their desires and being, people can be helped to develop 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 ends 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 and 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 that capabilities are combined capabilities, Nussbaum emphasizes the importance of circumstances in training internal capabilities and in using those capabilities once trained. (Nussbaum 2007).

The Capabilities approach and Nussbaum's Central Human Capabilities can be a good starting point for formulating a holistic conception of self-development and dimensions relevant to having a good life and dignity when getting older. (Pfaller and 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 innovation projects, since these projects gradually renew the institutional structures and the division of labour in the development work and in 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 have. (Sarlio-Siintola 2011).

The main objective of an innovation project is to promote and protect central human capabilities, more precisely the development, maintenance and use of person's internal capabilities (see Table 10 below). A single solution (like SHAPES) may not promote all of them, but neither should it not lead to 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. The 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 are weaker and disadvantaged 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 (Adopted Sarlio-Siintola 2012, 8).

Capability	Examples of user needs		Viewpoints of division of labour
<b>Bodily health</b>	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 weekly.  Is not able to cook healthy food without help.
<b>Bodily Integrity</b>	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 safely and freely outside and into the fresh air;  being able to undertake activities outside the home (e.g., shopping, visiting the library).	Being able to move around alone if one's physical condition is ok.  Needing physical help in everyday activities, as well as in handling money.
<b>Practical reason</b>	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.	Is interested in controlling one's own health on a daily basis.  Have a strong feeling of autonomy.  Is motivated to plan her/his own future.
<b>Affiliation</b>	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.	Needs incentives in maintaining her/his own networks.  Needs 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 taken to the development work early in the strategic planning phase and also have the option to participant in the steering of the project. (Sarlio-Siintola 2011).

The representatives of the public sector are to be involved in the planning and steering of the project, since 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 possibilities 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 or in home-like environments. It is essential both to 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.

Several capabilities, such as “Practical Reason”, Affiliation”, “Emotions” and “Senses, Imagination and Thought” are related both to the variety of SHAPES services (i.e., do SHAPES provide means for this capability to function), but also to the methods and ways how SHAPES is developed with the older individuals in providing a means to achieve these capabilities both 1) during the project and 2) after it, as part of the SHAPES ecosystem.

This capability, “Control over Own Environment”, is mainly related to the R&D work with the older persons during the project and after it, as part of the SHAPES ecosystem. This option of participating in the SHAPES development during the project and after it 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 like SHAPES are summarised.

*Table 11 Capabilities approach –based project framework (Adopted Sarlio-Siintola 2011, 17)*

Capability approach based argument	Practical guidelines and tools for development	Possible outcomes (if applicable)		
		Elderly	Business	Public
<b>Objectives and target groups</b>  <b>The primary objective of development is the promotion of wellbeing capabilities. Expected outcomes of the innovation projects concern services and technology, as well as social and political renewals that promote the development, maintenance and use of users’ internal</b>	Search 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.  Make an analysis of 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 elderly	Equal possibilities to wellbeing, no unjust innovations	Sustainable business, new customer segments	Equality and justice within a system of diminishing resources (see also Hellsten 1995)

<p><b>capabilities.</b></p> <p><b>It is a public sector responsibility to secure the threshold level of capabilities for its citizens.</b></p> <p><b>Attention is paid especially to the capabilities of the weaker and disadvantaged.</b></p> <p><b>A single innovation may not promote all the central capabilities, but it can't compromise them either.</b></p>	<p>persons outside the target group on whose life the innovation may have an impact.</p> <p>Involve the public sector in project planning and steering.</p>			
<p><b>User participation</b></p> <p><b>Development is based on the idea of dignified citizens' active agency and on the capabilities of practical reason and affiliation.</b></p> <p><b>Participation in the project, at its best, offers users the possibility to actualise various central human capabilities during the development.</b></p>	<p>Set wellbeing objectives for user participation. Respect the users and their privacy.</p> <p>In addition to the development work, take users to the strategic planning of the project and to the steering of it. Pay attention to the internal capabilities and external conditions of the users when choosing working models and methods.</p> <p>Choose working models that offer users various possibilities to discuss with professionals and with other users the values and wellbeing (practical reason and affiliation), and how the innovation could promote them.</p> <p>Choose working models that promote central human capabilities other than practical reason and affiliation during the project.</p>	<p>Active agency.</p> <p>Wellbeing during the project.</p> <p>Better innovation, more wellbeing.</p>	<p>Better possibility for value creation and CSR.</p>	<p>Active citizenship and social inclusion.</p> <p>Wellbeing .</p>
<p><b>Design of the service</b></p> <p><b>Persons are perceived as both capable and needy in their activities and have potential for both care receiving and caregiving.</b></p> <p><b>Capabilities of</b></p>	<p>Maintain focus at the beginning of the design phase in capabilities and in their material and social circumstances, not only commodities.</p> <p>In the design of the division of labour, avoid the risk of underestimating or overestimating users' own</p>	<p>More wellbeing with less money.</p> <p>Variety of choice increases.</p>	<p>Scalability of the technology and services.</p>	<p>Freedom of choice.</p> <p>Economic progress through productivity and smart</p>

<p><b>practical reason and affiliation organise and suffuse users' choices and activities.</b></p> <p><b>Preferences alone cannot inform the wellbeing of citizens.</b></p> <p><b>Freedom of choice to function or not and how to function is to be secured and promoted through the innovation and its functionalities.</b></p>	<p>capacities with the help of central capabilities and material, social and political circumstances.</p> <p>Develop solutions that offer users various ways to act according 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.</p> <p>In the detailed design of the service and technology, pay attention to various capabilities to function that the commodities could and should enable.</p>	<p>No useless or harmful commodities.</p>	<p>growth.</p> <p>More wellbeing with less resources.</p>
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## 4 Guidelines and approaches for businesses and technology

In this chapter, we introduce some central ethical guidelines and approaches applied in business and technology development. They place demands, in particular, on SHAPES business and governance models and on the SHAPES Technological Platform. These guidelines and approaches are: the UN sustainable development goals and Corporate Social Responsibility, the Customer-centric approach and Service design, Artificial intelligence and ethics, and the Blueprint for Digital Transformation of Health and Caring for the Ageing Society.

### *4.1 Sustainable development and Corporate Social Responsibility*

#### 4.1.1 The EU approach

Companies have significant impacts on the lives of citizens in the EU and around the world 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 that companies understand their positive and negative impacts on society and the environment. (EU 2019).

The EU and its Member States have been promoting Corporate Social Responsibility (CSR), Responsible Business Governance 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. (EU 2019).

Corporate Social Responsibility (CSR) is defined in the CSR Strategy as the “responsibility of enterprises for their impacts on society”. To fully meet their social responsibility, 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 maximizing 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 (RBC) is an alternative term for CSR, introduced by the OECD. (EU 2019, 4).

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) The role of business enterprises as specialized organs of society performing



specialized 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” (EU 2019; UN 2011). These Guiding Principles should be implemented in a non-discriminatory manner, with particular attention paid to 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 (EU 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 business.

*Table 12 Topics of social responsibility and sustainability vs. SHAPES*

Topic	Relevance to SHAPES
<b>Acting to respect and protect human rights, providing adequate access to remedies for victims of business-related abuses</b>	SHAPES should promote human rights (> see the chapter on EU Fundamental Rights).  SHAPES should not violate any rights.
<b>Encouraging companies to carry out appropriate due diligence, including with respect to human rights protection, along their supply chains.</b>	N/A (the recommendation mainly applies to large manufacturing) companies).
<b>Increasing transparency and promoting sustainable finance</b>	N/A (the recommendation mainly applies to large manufacturing companies).
<b>Encouraging socially and environmentally-friendly business practices, including through public procurement.</b>	Consider possibility to support Socially Responsible Public Procurement.
<b>Promoting the implementation of CSR/RBC, including UNGPs on Business and Human Rights outside the EU.</b>	This may be relevant if SHAPES has an export item in the future.
<b>Sectoral and horizontal initiatives</b>	Consider the use of ISO 26000 standard in the design of SHAPES businesses.

### 4.1.2 The evolution of Corporate Social Responsibility

In business literature, the perspective of Corporate Social Responsibility (CSR) has gradually shifted from the risk-based approach of avoiding harm to the concept of

looking at business opportunities from societal challenges, such as ageing societies or climate change. It is essential to see CSR as linked to the company's strategy and core business (see, e.g., FIBS 2019). According to Porter and Kramer (2011), "the purpose of the corporation must be redefined as creating shared value (CSV), not just profit per se. This will drive the next wave of innovation and productivity growth in the global economy" (Porter and Kramer 2011, 4). However, as Beschorner and Hajduk (2017) argue, in this approach, social needs are seen as a mere means to an end, to make profit. Such businesses' 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 and Hajduk 2017).

The aspect of Political Corporate Social Responsibility is essential (see also Mäkinen and Kourula 2008) from the viewpoint of the SHAPES ecosystem of services. From the viewpoint of citizens' rights for wellbeing and social services, it is essential that public actors keep 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 UN Sustainable Development Goals

The United Nation's Sustainable Development Goals came into effect at the beginning of 2016. They apply both to poor and rich countries; i.e., they are universal. There are a total of 17 Sustainable Development Goals (see picture 3), with a total of 169 sub-objectives. The aim is to turn global development into a career 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).



Figure 3 UN Sustainable Development Goals (Adopted [www.un.org/sustainabledevelopment/](http://www.un.org/sustainabledevelopment/))



In the table 13 are the identified essential goals in the context of SHAPES.

Table 13 Sustainable Development Goals and SHAPES

Goal	SHAPES perspective
1 End poverty	Pricing of the SHAPES services.
2 End hunger	SHAPES could also provide services to support nutrition.
3 Good health and wellbeing	To support this goal is the main idea of SHAPES.
4 Good education	The possibility to learn with the help of digital services could also be a SHAPES service.
5 Gender equality	The need of all gender groups is to be taken into account in SHAPES Integrated Care Platform. Therefore also participants for the pilots are needed from all gender groups.
8 Decent work and Economic growth	Better vocational wellbeing for service providers and attractiveness of the work is essential part of SHAPES.  Responsible business for SHAPES companies is the starting point for sustainability of the SHAPES Ecosystem.
9 Industry, innovation and infrastructure	Develop opportunities for SMEs in the technology sector and stimulation of innovation, data analytics and enhanced primary care IT infrastructure capability as part of the SHAPES
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 Market Place should support this approach.
12 Sustainable consumption and production	SHAPES Digital Solutions enables reduced environmental impact plus reduced healthcare resource utilisation.
17 Participation for the goals	Enhanced use of technology by full engagement in design and development as part of SHAPES co-creation.

## 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 mindset. We are currently living in a service society utilising the digital service economy. Most of this market change 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, Strandvik, Voima 2013, 115; 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 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, 477–478)

The customer-centric way of thinking also places the customer in the role of an active actor (Mickelsson 2013, 540). 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, 477). 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, 540). 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, 5).

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, 546). In customer-centric business logic, value is created through the customer's operations (Heinonen, Strandvik, Voima 2013, 104). 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, 24–25). 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, 480). Customer ecosystems are thus not only social systems but also include economic and commercial features (Heinonen & Strandvik 2018, 4). 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, 480).

#### 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, 82) have developed a thinking model and tool, Service Logic Business Model Canvas, based on the customer and service logic perspective, to support the development of organisations' business models (Ojasalo & Ojasalo 2018, 82).

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, 89).

The goal of the Service Logic Business Model Canvas is to provide the customer 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, 83–85).

<b>Key Partners</b> <b>From our point of view:</b> <ul style="list-style-type: none"> <li>• Who are our key partners?</li> <li>• What are the roles of our partners?</li> <li>• What resources do we need from our partners?</li> <li>• How do the partners benefit from the cooperation?</li> </ul> <b>From customer point of view:</b> <ul style="list-style-type: none"> <li>• How does the customer experience our partners?</li> <li>• What kind of partnerships does the customer have and how should they be taken into account?</li> </ul> <div>7</div>	<b>Key Resources</b> <b>From our point of view:</b> <ul style="list-style-type: none"> <li>• What skills and knowledge do we need?</li> <li>• What other material and immaterial resources and tools are required?</li> </ul> <b>From customer point of view:</b> <ul style="list-style-type: none"> <li>• What skills and knowledge is required from the customer's side?</li> <li>• What other customer's material and immaterial resources and tools are required?</li> </ul> <div>6</div> <b>Mobilizing Resources and Partners</b> <b>From our point of view:</b> <ul style="list-style-type: none"> <li>• How do we coordinate multi-party value creation?</li> <li>• How do we utilize and develop partners and resources?</li> </ul> <b>From customer point of view:</b> <ul style="list-style-type: none"> <li>• How can the customer utilize and develop partners and resources?</li> </ul> <div>8</div>	<b>Value Proposition</b> <b>From our point of view:</b> <ul style="list-style-type: none"> <li>• What value are we selling?</li> <li>• What are the elements of our offering?</li> <li>• What is unique in our offering?</li> </ul> <b>From customer point of view:</b> <ul style="list-style-type: none"> <li>• What value is the customer buying?</li> <li>• What are the elements of customer needing?</li> <li>• Which customer's challenges and problems need to be solved?</li> </ul> <div>2</div>	<b>Value Creation</b> <b>From our point of view:</b> <ul style="list-style-type: none"> <li>• How is our offering embedded in the customer's world?</li> <li>• How can we facilitate the customer to reach their goals?</li> </ul> <b>From customer point of view:</b> <ul style="list-style-type: none"> <li>• How does the value emerge in customer's practices (also from mental and emotional experiences)?</li> <li>• How are customer's long term benefits accomplished?</li> </ul> <div>3</div> <b>Interaction and co-production</b> <b>From our point of view:</b> <ul style="list-style-type: none"> <li>• How can we support customer co-production and interaction between us and the customer?</li> </ul> <b>From customer point of view:</b> <ul style="list-style-type: none"> <li>• What are customer's activities during the use and different use contexts?</li> <li>• What are the customer's mental models of interacting with us?</li> </ul> <div>4</div>	<b>Customer's World and Desire for Ideal Value</b> <b>From our point of view:</b> <ul style="list-style-type: none"> <li>• How do we get a deep insight and holistic understanding of customer's world (context, activities, practices, experiences), their future strategies, and customer's customers' world?</li> </ul> <b>From customer point of view:</b> <ul style="list-style-type: none"> <li>• Why does the customer buy?</li> <li>• What kind of benefits does the customer aspire?</li> <li>• Functional</li> <li>• Economic</li> <li>• Emotional</li> <li>• Social</li> <li>• Ethical</li> <li>• Symbolic</li> <li>• If there were no limits, what would be the customer desire for ideal situation and world?</li> </ul> <div>1</div>
<b>Cost Structure</b> <b>From our point of view:</b> <ul style="list-style-type: none"> <li>• What are the costs inherent in our business model?</li> <li>• What are our other sacrifices?</li> </ul> <b>From customer point of view:</b> <ul style="list-style-type: none"> <li>• What costs and other sacrifices are required from the customer?</li> </ul> <div>9</div>	<b>Revenue Streams and Metrics</b> <b>From our point of view:</b> <ul style="list-style-type: none"> <li>• What is our earnings logic and how is our financial feedback generated?</li> <li>• How can we apply customer value-based pricing?</li> <li>• What else valuable do we get than money?</li> <li>• What are the key performance metrics of our business success?</li> </ul> <b>From customer point of view:</b> <ul style="list-style-type: none"> <li>• For which benefits is the customer really willing to pay and how?</li> <li>• What is the financial value that the customer gets?</li> <li>• What are the key performance indicators of customer's business and how are we following them?</li> </ul> <div>5</div>			

Figure 4 Customer logic Business Canvas (adopted Ojasalo-Ojasalo 2018, 83-85).

### 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, 4). Heinonen & Strandvik (2018, 10) 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, 10). 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 citizens and customers. Customer logic expresses what is important to the customer both now and in the future. Thus, the market for new ideas and innovations depends on the dynamics of customer logic (Heinonen & Strandvik 2018, 10).

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 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: e.g., personalities, empathy maps, stakeholder maps and ecosystem maps (e.g., Stickdorn, Adam, Hormess, & Schneider, 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 providing and value creation must be considered (Yu & Sangiorgi, 2018b), as well as interaction with the customer, which occurs in numerous ways. Service design provides methods for this: 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) (e.g., Stickdorn, Adam, Hormess, & Schneider, 2018).

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



## 4.3 Artificial intelligence and ethics

### 4.3.1 Background

In February 2020, 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 the risks with 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 chapter 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).

The High-Level Expert Group on Artificial Intelligence 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 met throughout the system’s entire life cycle:

- 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, 7)

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)The guidelines can be summarised from SHAPES’s viewpoint as follows (the texts in the subsections 5.3.2 – 5.3.4 are taken from the Ethical guidelines for Trustworthy AI document)

### 4.3.2 Ethical principles and values

Develop, deploy and use AI systems that adheres to the ethical principles of respect for human autonomy, prevention of harm, fairness and explicability. Particular attention is to be paid to situations involving vulnerable groups, like persons with disabilities or disadvantaged or are at risk of exclusion, and to situations characterised by asymmetries 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, 9-13).

### 4.3.3 Seven requirements for AI systems

Ensure that the development, deployment and use of AI systems meets 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. Consider technical and non-technical methods to ensure the implementation of requirements. Foster research and innovation to help assess AI systems; disseminate results and systematically train experts in AI ethics. Communicate information to stakeholders about the AI system's capabilities and limitations. Be transparent for the users about the fact that they are dealing with an AI system. Facilitate the traceability and auditability of AI systems, including involvement of stakeholders. Foster training. Be aware that there might be tensions between different principles and requirements - and therefore continuously identify, evaluate, document and communicate these trade-offs and their solutions. (AI Ethics 2019, 14 - 23).

### 4.3.4 Trustworthy AI assessment list

*Table 14 Trustworthy AI assessment list (Adopted AI Ethics 2019, 28-33)*

Trustworthy Artificial Intelligence assessment list
<p><b>1. Human Agency and Oversight</b></p> <p><b>Fundamental Rights:</b></p> <p><b>Did you carry out a fundamental rights impact assessment where there could be a negative impact on fundamental rights? Did you identify and document potential trade-offs made between the different principles and rights?</b></p> <p><b>Does the AI system interact with decisions by human (end) users (e.g. recommended actions or decisions to take, presenting of options)?</b></p> <ul style="list-style-type: none"> <li>• <b>Could the AI system affect human autonomy by interfering with the (end) user's decision-making process in an unintended way?</b></li> <li>• <b>Did you consider whether the AI system should communicate to (end) users that a decision, content, advice or outcome is the result of an algorithmic decision?</b></li> <li>• <b>In case of a chat bot or other conversational system, are the human end users made aware that they are interacting with a non-human agent?</b></li> </ul>



### Human Agency:

Is the AI system implemented in work and labour process? If so, did you consider the task allocation between the AI system and humans for meaningful interactions and appropriate human oversight and control?

- Does the AI system enhance or augment human capabilities?
- Did you take safeguards to prevent overconfidence in or overreliance on the AI system for work processes?

### Human Oversight:

Did you consider the appropriate level of human control for the particular AI system and use case?

- Can you describe the level of human control or involvement?
- Who is the 'human in control' and what are the moments or tools for human intervention?
- Did you put in place mechanisms and measures to ensure human control or oversight?
- Did you take any measures to enable audit and to remedy issues related to governing AI autonomy?

Is there is a self-learning or autonomous AI system or use case? If so, did you put in place more specific mechanisms of control and oversight?

- Which detection and response mechanisms did you establish to assess whether something could go wrong?
- Did you ensure a stop button or procedure to safely abort an operation where needed? Does this procedure abort the process entirely, in part, or delegate control to a human?

## 2. Technical Robustness and Safety

### Resilience to Attack and Security:

Did you assess potential forms of attacks to which the AI system could be vulnerable?

- Did you consider different types and natures of vulnerabilities, such as data pollution, physical infrastructure, cyber-attacks?

Did you put measures or systems in place to ensure the integrity and resilience of the AI system against potential attacks?

Did you verify how your system behaves in unexpected situations and environments?

Did you consider to what degree your system could be dual-use? If so, did you take suitable preventative measures against this case (including for instance not publishing the research or deploying the system)?

### The Fall-back Plan and General Safety:

Did you ensure that your system has a sufficient fall-back plan if it encounters adversarial attacks or other unexpected situations (for example technical switching procedures or asking for a human operator before proceeding)?

Did you consider the level of risk raised by the AI system in this specific use case?

- Did you put any process in place to measure and assess risks and safety?
- Did you provide the necessary information in case of a risk for human physical integrity?
- Did you consider an insurance policy to deal with potential damage from the AI system?
- Did you identify potential safety risks of (other) foreseeable uses of the technology, including accidental or malicious misuse? Is there a plan to mitigate or manage these risks?

Did you assess whether there is a probable chance that the AI system may cause damage or harm to users or third parties? Did you assess the likelihood, potential damage, impacted audience and severity?

- Did you consider the liability and consumer protection rules, and take them into account?
- Did you consider the potential impact or safety risk to the environment or to animals?
- Did your risk analysis include whether security or network problems such as cybersecurity hazards could pose safety risks or damage due to unintentional behaviour of the AI system?

Did you estimate the likely impact of a failure of your AI system when it provides wrong results, becomes unavailable, or provides societally unacceptable results (for example discrimination)?

- Did you define thresholds, and did you put governance procedures in place to trigger alternative/fall-back plans?
- Did you define and test fall-back plans?

#### Accuracy

Did you assess what level and definition of accuracy would be required in the context of the AI system and use case?

- Did you assess how accuracy is measured and assured?
- Did you put in place measures to ensure that the data used is comprehensive and up to date?
- Did you put in place measures in place to assess whether there is a need for additional data, for example to improve accuracy or to eliminate bias?

Did you verify what harm would be caused if the AI system makes inaccurate predictions?

Did you put in place ways to measure whether your system is making an unacceptable amount of inaccurate predictions?

Did you put in place a series of steps to increase the system's accuracy?

#### Reliability and Reproducibility:

Did you put in place a strategy to monitor and test if the AI system is meeting the goals, purposes and intended applications?

- Did you test whether specific contexts or particular conditions need to be taken into account to ensure reproducibility?
- Did you put in place verification methods to measure and ensure different aspects of the system's reliability and reproducibility?
- Did you put in place processes to describe when an AI system fails in certain types of settings?
- Did you clearly document and operationalise these processes for the testing and verification of the reliability of AI systems?
- Did you establish mechanisms of communication to assure (end) users of the system's reliability?

### 3. Privacy and Data Governance

#### Respect for Privacy and Data Protection:

Depending on the use case, did you establish a mechanism allowing others to flag issues related to privacy or data protection in the AI system's processes of data collection (for training and operation) and data processing?

Did you assess the type and scope of data in your data sets (for example whether they contain personal data)?

Did you consider ways to develop the AI system or train the model without or with minimal use of potentially sensitive or personal data?

Did you build in mechanisms for notice and control over personal data depending on the use case (such as valid consent and possibility to revoke, when applicable)?

Did you take measures to enhance privacy, such as via encryption, anonymization and aggregation?

Where a Data Privacy Officer (DPO) exists, did you involve this person at an early stage in the process?

#### Quality and Integrity of Data:

Did you align your system with relevant standards (for example ISO, IEEE) or widely adopted protocols for daily data management and governance?

Did you establish oversight mechanisms for data collection, storage, processing and use?

Did you assess the extent to which you are in control of the quality of the external data sources used?

Did you put in place processes to ensure the quality and integrity of your data? Did you consider other processes? How are you verifying that your data sets have not been compromised or hacked?

#### Access to Data:

**What protocols, processes and procedures did you follow to manage and ensure proper data governance?**

- Did you assess who can access users' data, and under what circumstances?
- Did you ensure that these persons are qualified and required to access the data, and that they have the necessary competences to understand the details of data protection policy?
- Did you ensure an oversight mechanism to log when, where, how, by whom and for what purpose data was accessed?

## 4. Transparency

**Traceability:**

**Did you establish measures that can ensure traceability? This could entail documenting the following methods:**

**Methods used for designing and developing the algorithmic system:**

- Rule-based AI systems: the method of programming or how the model was built;
- Learning-based AI systems; the method of training the algorithm, including which input data was gathered and selected, and how this occurred.

**Methods used to test and validate the algorithmic system:**

- Rule-based AI systems; the scenarios or cases used in order to test and validate;
- Learning-based model: information about the data used to test and validate.

**Outcomes of the algorithmic system:**

- The outcomes of or decisions taken by the algorithm, as well as potential other decisions that would result from different cases (for example, for other subgroups of users).

**Explainability:**

**Did you assess:**

- To what extent the decisions and hence the outcome made by the AI system can be understood?
- To what degree the system's decision influences the organisation's decision-making processes?
- Why this particular system was deployed in this specific area?
- What the system's business model is (for example, how does it create value for the organisation)?

**Did you ensure an explanation as to why the system took a certain choice resulting in a certain outcome that all users can understand?**

**Did you design the AI system with interpretability in mind from the start?**

- Did you research and try to use the simplest and most interpretable model possible for the application in question?
- Did you assess whether you can analyse your training and testing data? Can you change and update this over time?
- Did you assess whether you can examine interpretability after the model's training and development, or whether you have access to the internal workflow of the model?

**Communication:**

**Did you communicate to (end-)users – through a disclaimer or any other means – that they are interacting with an AI system and not with another human? Did you label your AI system as such?**

**Did you establish mechanisms to inform (end-)users on the reasons and criteria behind the AI system's outcomes?**

- Did you communicate this clearly and intelligibly to the intended audience?
- Did you establish processes that consider users' feedback and use this to adapt the system?
- Did you communicate around potential or perceived risks, such as bias?
- Depending on the use case, did you consider communication and transparency towards other audiences, third parties or the general public?

**Did you clarify the purpose of the AI system and who or what may benefit from the product/service?**

- Did you specify usage scenarios for the product and clearly communicate these to ensure that it is understandable and appropriate for the intended audience?
  - Depending on the use case, did you think about human psychology and potential limitations, such as risk of confusion, confirmation bias or cognitive fatigue?
- Did you clearly communicate characteristics, limitations and potential shortcomings of the AI system?
- In case of the system's development: to whoever is deploying it into a product or service?
  - In case of the system's deployment: to the (end-)user or consumer?

## 5. Diversity, Non-Discrimination and Fairness

### Unfair Bias Avoidance:

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 assess and acknowledge the possible limitations stemming from the composition of the used data sets?
- Did you consider diversity and representativeness of users in the data? Did you test for specific populations or problematic use cases?
- Did you research and use available technical tools to improve your understanding of the data, model and performance?
- Did you put in place processes to test and monitor for potential biases during the development, deployment and use phase of the system?

Depending on the use case, did you ensure a mechanism that allows others to flag 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 consider others, potentially indirectly affected by the AI system, in addition to the (end)users?

Did you assess whether there is any possible decision variability that can occur under the same conditions?

- If so, did you consider what the possible causes of this could be?
- In case of variability, did you establish a measurement or assessment mechanism of the potential impact of such variability on fundamental rights?

Did you ensure an adequate working definition of 'fairness' that you apply in designing AI systems?

- Is your definition commonly used? Did you consider other definitions before choosing this one?
- Did you ensure a quantitative analysis or metrics to measure and test the applied definition of fairness?
- Did you establish mechanisms to ensure fairness in your AI systems? Did you consider other potential mechanisms?

### Accessibility and Universal Design:

Did you ensure that the AI system accommodates a wide range of individual preferences and abilities?

- Did you assess whether the AI system usable by those with special needs or disabilities or those at risk of exclusion? How was this designed into the system and how is it verified?
- Did you ensure that information about the AI system is accessible also to users of assistive technologies?
- Did you involve or consult this community during the development phase of the AI system?

Did you take the impact of your AI system on the potential user audience into account?

- Did you assess whether the team involved in building the AI system is representative of your target user audience? Is it representative of the wider population, considering also of other groups who might tangentially be impacted?

- Did you assess whether there could be persons or groups who might be disproportionately affected by negative implications?
- Did you get feedback from other teams or groups that represent different backgrounds and experiences?

#### Stakeholder Participation:

Did you consider a mechanism to include the participation of different stakeholders in the AI system's development and use?

Did you pave the way for the introduction of the AI system in your organisation by informing and involving impacted workers and their representatives in advance?

## 6. Societal and Environmental Wellbeing

#### A Sustainable and Environmentally Friendly AI:

Did you establish mechanisms to measure the environmental impact of the AI system's development, deployment and use (for example the type of energy used by the data centres)?

Did you ensure measures to reduce the environmental impact of your AI system's life cycle?

#### Social Impacts:

In case the AI system interacts directly with humans:

- Did you assess whether the AI system encourages humans to develop attachment and empathy towards the system?
- Did you ensure that the AI system clearly signals that its social interaction is simulated and that it has no capacities of 'understanding' and 'feeling'?

Did you ensure that the social impacts of the AI system are well understood? For example, did you assess whether there is a risk of job loss or de-skilling of the workforce? What steps have been taken to counteract such risks?

#### Society and Democracy:

Did you assess the broader societal impact of the AI system's use beyond the individual (end) user, such as potentially indirectly affected stakeholders?

## 7. Accountability

#### Auditability:

Did you establish mechanisms that facilitate the system's auditability, such as ensuring traceability and logging of the AI system's processes and outcomes?

Did you ensure, in applications affecting fundamental rights (including safety-critical applications) that the AI system can be audited independently?

#### Minimising and Reporting Negative Impact:

Did you carry out a risk or impact assessment of the AI system, which takes into account different stakeholders that are (in)directly affected?

Did you provide training and education to help developing accountability practices?

- Which workers or branches of the team are involved? Does it go beyond the development phase?
- Do these trainings also teach the potential legal framework applicable to the AI system?
- Did you consider establishing an 'ethical AI review board' or a similar mechanism to discuss overall accountability and ethics practices, including potentially unclear grey areas?

Did you foresee any kind of external guidance or put in place auditing processes to oversee ethics and accountability, in addition to internal initiatives?

Did you establish processes for third parties (e.g., suppliers, consumers, distributors/vendors) or workers to report potential vulnerabilities, risks or biases in the AI system?

#### Documenting Trade-Offs:

**Did you establish a mechanism to identify relevant interests and values implicated by the AI system and potential trade-offs between them?**  
**How do you decide on such trade-offs? Did you ensure that the trade-off decision was documented?**

**Ability to Redress:**

**Did you establish an adequate set of mechanisms that allows for redress in case of the occurrence of any harm or adverse impact?**

**Did you put mechanisms in place both to provide information to (end) users/third parties about opportunities for redress?**

#### 4.3.5 Limitations of AI ethics

During recent years, many initiatives have been taken to define values and principles and the ethical development and deployment of artificial intelligence. They have offered great value in raising the awareness among the public, developers and institutions. However, many initiatives have been characterised as mere “virtue signalling” intended to delay regulation and focus on abstract problems and technical solutions. This means that the ethics of artificial intelligence has have produced high-level principles and value statements but have provided few specific recommendations and failed to address fundamental tensions embedded in key concepts such as fairness and privacy. (Mittelstadt 2019, 2)

Mittelstadt (2019, 2-3) 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 “have converged on a set of principles that closely resemble the four classic principles of medical ethics”.

Mittelstadt (2019, 2-8) 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 don’t synergise. Furthermore, in medicine there are formal professions that mean certain duties towards patients.
2. Professional history and norms. AI development and ethics don’t have the long professional history and well-defined norms of “good” behaviour as medicine does (e.g., 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 (e.g., 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.


Based on the four characteristics mentioned above, Mittelstadt (2019, 9-10) gives 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 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 strongly involve the organizations organisations that they represent, as well as the whole ecosystem.

#### *4.4 Blueprint on Digital Transformation of H&C for the Ageing Society*

The European Blueprint on Digital Transformation of Health and Care for the Ageing Society (originally presented by EIP on AHA) reflects a policy vision shared by different stakeholders, ranging from European policy makers, to civil society, to professional organisations and to industry on how innovation can transform health and care provision in an ageing society. The latest version of the Blueprint, in 2019, includes the development of user scenarios, the development of building blocks and the identification of key ICT solutions and digital health technologies identified to meet the needs of the Blueprint personas. The figure 5 shows how various ICT solutions cover a wide range of unmet needs; it includes personas and needs of both younger and older persons. Older retired persons under 80 years are marked in light red and persons over 80 with red arrows. (WE4AHA 2019).





<div>Persona</div> <div>Unmet need</div>	Generally well				Chronic conditions and/or social needs				Complex needs			
	Rose	Leila	Randolph	Teresa	Millie	Nikos	Eleni	Maria	Ben	Antoni o	Procolo	Jacqueline
ICT support to health & wellbeing, health & social care delivery / EHRs, management of health data / health information exchange												
Telehealth / Telecare / Home care / Tele-monitoring												
Education, including gamification or serious games; health and digital health literacy, empowerment												
Smart homes and age-friendly environments (e.g., home sensors, Internet of Things (IoT), Ambient Assisted Living (AAL), Independent Living (IL) solutions)												
Social or peer support / social networks, messaging												
Other: Assistive technology/wearable robotics (exoskeleton)												

Figure 5 Suggested ICT solution categories (adopted WE4AHA 2019, 7)

Examples of solutions under each ICT category are listed in the table 15. The table is continuously being updated based on feedback from Blueprint partners and external stakeholders.

Table 15 ICT categories and examples of solutions (Adopted WE4AHA 2019, 8)

ICT solution category	Examples of ICT solutions
ICT support to health & wellbeing	<ul style="list-style-type: none"> <li>Interoperable Electronic Health Records, Patient Portals</li> <li>Electronic consultations and appointments</li> <li>Secure and reliable search portals for health information</li> <li>Booking solutions for care support</li> <li>Health data management solutions</li> <li>Personal health folder apps</li> <li>24/7 eHealth call centre</li> <li>ICT for integrated care supporting</li> </ul>
Telehealth	<ul style="list-style-type: none"> <li>Teleconsultations with child and mental health services</li> <li>Monitoring of health parameters</li> <li>Internet of (medical) things</li> <li>Telecare personal alarms (panic button service, medication reminders, access to assistance during emergencies)</li> <li>Vibrating carer alerts linked to movement sensors in house</li> <li>Electronic diary with visual and auditory reminders</li> </ul>

	<ul style="list-style-type: none"> <li>Physical training solutions</li> <li>Self-monitoring of frailty</li> <li>Tele-assistance subscription service – supervising daily activity trends of elderly people, notifications of potential risk situations</li> <li>Wearables</li> </ul>
Education, including gamification or serious games	<ul style="list-style-type: none"> <li>Web platform for digital and health literacy</li> <li>Massive Open Online Courses</li> <li>Information on relevant support infrastructures in the region</li> <li>Healthier lifestyle management (games for physical exercise, computerized anger management, management of chronic conditions)</li> <li>Healthy cooking and eating</li> <li>Tutorials (for ex. dancing, fashion, lifestyle, music and other hobbies)</li> <li>Educational tools (memory exercises, reading , speech and languages)</li> <li>Online libraries (e.g. for reading newspapers)</li> <li>Virtual reality (e.g. virtual museum visits)</li> </ul>
Smart homes and age-friendly environment	<ul style="list-style-type: none"> <li>Home or property sensors</li> <li>Internet of (non-medical) Things</li> <li>Regulated heating systems</li> <li>Food shopping support</li> <li>Home health/wellbeing monitoring</li> <li>Support for daily routines</li> <li>Wearables</li> </ul>
Social or peer support	<ul style="list-style-type: none"> <li>Networking apps (e.g. sports or cooking clubs, social events, healthy lifestyle groups)</li> <li>Discussion fora (e.g. to exchange similar experiences)</li> <li>Easy phone / video connections</li> <li>Platforms to put care givers and patients in touch</li> <li>Online services, e.g. shopping, banking meal delivery, travel</li> </ul>
Other	<ul style="list-style-type: none"> <li>Assistive technology/wearable robotics-exoskeletons</li> </ul>

In April 2018, the European Commission published a Communication 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 16 are those ICT solution categories, grouped according to those Commission priorities.

Table 16 ICT solution categories and COM priorities (Adopted WE4AHA 2019, 9-10)

Table of ICT solution categories according to COM priorities
<p><b>Priority 1: Citizen's secure access to and sharing of health data across borders</b></p> <ul style="list-style-type: none"> <li>➤ 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</li> <li>➤ Interoperable EHRs deployed at national and/or regional levels enabling citizens' secure access to and sharing of health data; General Data Protection Regulation (GDPR) compliant, secure health data exchange</li> <li>➤ Citizen-enabled sharing of health data across borders: patient summary and/or ePrescription, discharge letter, medical images, lab results</li> <li>➤ Citizen-controlled data governance, health data cooperatives, health data donation</li> </ul>
<p><b>Priority 2: Better data to promote research, disease prevention and personalized health and care</b></p> <ul style="list-style-type: none"> <li>➤ Digital infrastructure for personalized medicine, -omics databanks, biomedical infrastructures</li> <li>➤ Good practice in digital genomics, including whole genome sequencing</li> <li>➤ Use of real-word data (RWD), data quality assessment and improvement</li> <li>➤ Health data analytics ( Artificial Intelligences, algorithm development and calibration, machine learning, risk stratification tools, etc)</li> <li>➤ Big data analysis, particularly for preventive medicine and treatment</li> <li>➤ Interoperability of disease registries including for rare diseases, data aggregation and sharing across borders, including at EU level</li> <li>➤ Digital tools for public health, epidemiology, pharmacovigilance, clinical research, including reuse of EHRs for clinical research</li> </ul>
<p><b>Priority 3: Digital tools for citizen empowerment and for person-centred care</b></p> <p>Citizen/patient-focused solutions:</p> <ul style="list-style-type: none"> <li>➤ Digital tools to support health education (health literacy), digital health literacy</li> <li>➤ mHealth systems, wearables devices for monitoring and prevention, alerts, reminders</li> <li>➤ Digital tools to support patient feedback and reporting of outcomes and experiences</li> <li>➤ Digital tools to support proactive prevention, self-management, homecare, tele monitoring</li> <li>➤ Tele-mentoring/coaching, virtual consultations, virtual coach, personal assistant</li> <li>➤ ICT supporting adherence to medication and care plans</li> <li>➤ Robotics (e.g. companion robots)</li> <li>➤ Tools and services supporting independent living, ambient assisted living technologies, telecare</li> </ul> <p>Care practitioners' solutions:</p> <ul style="list-style-type: none"> <li>➤ Advanced digital tools for support Integrated Care, including integration of health and social care services</li> <li>➤ Interoperable digital solutions to support person-centred and integrated care</li> </ul>

- Regional and national EHPR systems and ePrescription 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

The Blueprint includes building blocks supporting digital transformation. Each Blueprint scenario depicts topics important for advancing better person-centred health and care delivery. The Blueprint building blocks provide **guidance on how to tackle a particular challenge** using lessons learnt from the practice, as well as expert knowledge and advice. Since spring 2019, work on three draft building blocks has been under way:

- Ensuring interoperability
- Exploring social care and carers' perspectives
- Implementing integrated care

The blueprint and its coming updates provide tools and checklists that can be used widely in the context of SHAPES.

## 5 SHAPES privacy and data protection

In this chapter, we describe the key elements of the General Data Protection Regulation 2019/679 (GDPR 2016) that need to be implemented in SHAPES. This chapter provides the foundation for the project's privacy and data protection work by explaining what GDPR means in the scope of SHAPES and by providing requirements that must be considered when creating the SHAPES technological platform and SHAPES solutions. How to implement these requirements varies, based on solutions to be created and those that will be planned as part of the development work.

Both privacy and data protection are instrumental in preserving and promoting fundamental values and rights and are also important for SHAPES. Privacy is a fundamental right (see Universal Declaration of Human Rights, article 12, the European Convention of Human Rights, article 8 and the European Charter of Fundamental Rights article 7), and the notion of data protection originates from the right to privacy. Data protection aims to protect information related to an identified or identifiable person. While reading chapter 5, “personal data” should be understood broadly, considering that information that is already anonymized or pseudonymized can be de-anonymized when combined with other data.

### 5.1 *Processing Personal Data*

#### 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, 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 types must be processed even more carefully than others. This is often referred to as a 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, 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. At the beginning of the project, a working assumption is that the processing will be based on the informed, explicit consent of data subjects.

### 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 article 4) In practice, this means that GDPR regulations must be followed in all activities involving Personal data processing.

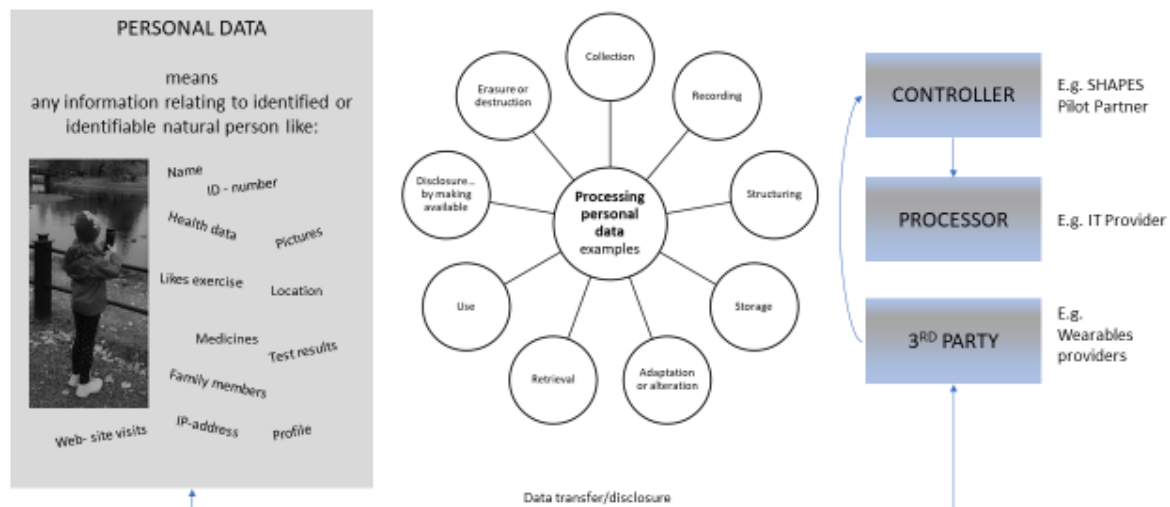
For example, natural persons, companies and public authorities can be responsible for processing Personal data. Because the processing can also be undertaken by different actors who don't have the same ability to influence how the data will be used, the GDPR separates the actors into “controllers” and “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 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 they have 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.





# Processing Personal Data



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

Figure 6 Processing Personal data

In Figure 6 “Processing of Personal data”, 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 picture 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 picture describe the roles that, e.g., 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 picture need to be analysed and documented.

## Categories of Personal data

Categories of personal data describes 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. The Table 17 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.





## Categories of Data subjects

Table 17 Categories of Personal data in SHAPES

Categories of Personal data in SHAPES	
Category	Example of data
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 following list 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 chapter describes those principles and how those will be followed in SHAPES.

### 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.

“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.

### Purpose limitation and data minimisation

“Purpose limitation” means it is important to know for what purpose a 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 not essential nor and justifiable in use.

### 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.

### 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.

### 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 chapter 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 into 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
- 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 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 done 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. Consent can also be part of the agreement.

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 in D8.4.

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.

## 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 18). 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 18 Data subject's rights (GDPR)

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 3 <sup>rd</sup> parties – create a functionality to easily get information about the 3 <sup>rd</sup> 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 / 3 <sup>rd</sup> 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

Data subjects will be informed about these rights on SHAPES webpages and on the descriptions of the processing of Personal data as part of the services. The proper implementation of the services will be analysed as part of DPIA. In the SHAPES ecosystem, it is important to pay attention to processes implemented to ensure the data subject can easily access their rights; SHAPES must consider creating a “one point of contact” type of process to ensure that data subjects can easily use his/her 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 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 possibility 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, and 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 ecosystem to ensure that potential risks are properly estimated. 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 manager 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 Data protection by design and by default*

Data protection 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 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*

### Security of personal data

GDPR requires that both controller and processor implement appropriate technical and organisational measures to ensure a level of security appropriate to the risk.<sup>6</sup> 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.

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, at minimum, the same security principles that SHAPES has in place. With this approach, it is ensured that the SHAPES ecosystem is secure and that individuals can trust that their data is safe.

### Notification of a personal data breach to the supervisory authorities

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<sup>6</sup> GDPR article 32 Where is this citation in the page, I can't see it? NR Again brackets are used above. Please be consistent



SHAPES shall create a process 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 breach. The process is to be in place before the SHAPES pilots are launched. The initial process description will be undertaken by the Data Protection Manager, and the process will be finalised with the processors to ensure proper implementation. The process description will contain all required elements, such as documentation and communication obligations.

### 5.10 Accountability

According to the GDPR article 5 and article 30), the controller shall be responsible for, and able to demonstrate compliance with, personal data processing principles. Many actions related to these requirements have already been described in this chapter, but the following tools and methods will also be implemented to ensure accountability obligations are met. The guiding principle is that SHAPES shall plan all processing activities related to personal data and activities will be properly documented.

#### Personal data processing descriptions

- This is a template that will be used for describing how personal data is processed in SHAPES
- SHAPES shall use a tool provided by the CNIL, *Commission Nationale de l'Informatique et des Libertés*, and will be modified to fit to needs of SHAPES, but the intention is to describe all processing activities in the same place
- The aim is to find a digital solution that can be used for describing the processing activities, but before that is in place, the tool described above will be used

#### Data flows/data mapping

- SHAPES shall create a tool that makes it easier to follow data flows, and this information will be used, for example, for executing data subject rights and for ensuring data accuracy
- Until this tool is in use, the source of the data and the parties to whom data will be transferred or disclosed will be covered by the Personal data processing descriptions

#### DPIA

- DPIA will be undertaken using a template or tool selected for this purpose, and the content will be modified to fit the scope of SHAPES
- All DPIAs will be stored, and the potential risks identified as part of the analysis will be managed

#### Information about the processing of Personal data

SHAPES will have a webpage with a privacy information section. The content will be provided at the beginning of the project, and it will be kept up to date. In addition to personal data processing descriptions, the controllers are responsible for creating a description of the usage of personal data in any specific service. SHAPES will provide a template for this to ensure that the information given will be easily understandable and provided in clear language. The purpose of this is to ensure that data subjects understand how their data will be used in any services.

## 6 Cybersecurity and resilience requirement

Cybersecurity is an important ethical dimension of the features of future H&C solutions. This chapter studies the cybersecurity and resilience requirements for the SHAPES solution with regards to ethical and legislative points of view. The first section is an orientation to cyberspace and cybersecurity management. The second section focuses on relevant requirements from the NIS Directive related to the SHAPES solution. The third section connects the chapter to the (technical) cybersecurity research carried out so far in the SHAPES and ECHO projects. The next section presents the rationale behind SHAPES cybersecurity and resilience requirements. The last section provides the main cybersecurity and resilience requirements for the SHAPES platform from an ethical point of view.

### 6.1 Orientation

The growing complexity of the digital ecosystem in combination with increasing global risks involves various ethical issues associated with cybersecurity. Christen, Gordijn and Loi (2020, p. 1) express the dilemma: “Overemphasising cybersecurity may violate fundamental values such as equality, fairness, freedom or privacy. However, neglecting cybersecurity could undermine citizens’ trust and confidence in the digital infrastructure, in policy makers and in state authorities.” They continue (p. 2), “cybersecurity is still an under-developed topic in technology ethics. Although there are numerous papers discussing issues such as ‘big data’ and privacy, cybersecurity is—if at all—only discussed as a tool to protect (or undermine) privacy.” For example, if a medical implants producer protects the data transfer between implant and receiver server by means of suitable cryptology, this significantly increases the energy consumption of the implant and frequently requires more surgeries for battery exchange (Christen; Gordijn; & Loi, 2020).

Weber and Kleine (2020) have investigated the ethical issues of cybersecurity in H&C applying the approach of principlism based on Beauchamp and Childress’ (2009) four principles of biomedical ethics (respect for autonomy, nonmaleficence, beneficence and justice). According to Christen, Loi and Kleine (2018), the important aims of the employment of ICT in H&C are efficiency and quality of services, privacy of information and confidentiality of communication, usability of services and safety. Weber and Klein (2002) map the ethical principles to technical aims as shown in the Figure 7.

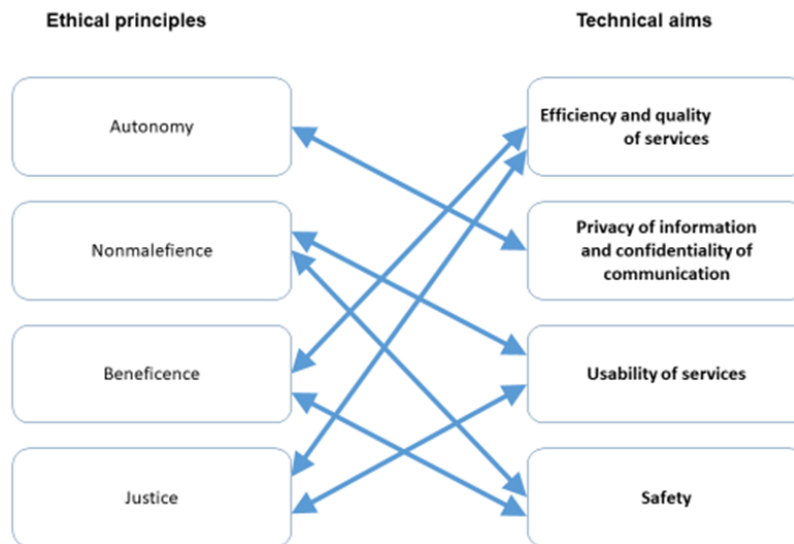


Figure 7 Technical aims mapping to ethical principles (Adopted Weber & Kleine, 2020)

The aim of cybersecurity is to make cyberspace safe from damage or threat. The figure 8 shows three perspectives of cyberspace: (1) a data or information perspective that comes from the information theory space; (2) a technology perspective that includes the hardware, silicon and wires, as well as software, operating systems and network protocols; and (3) a human perspective that acknowledges that the human is as responsible for the dynamics of the system as the data and the technology are (Edgar & Manz, 2017).

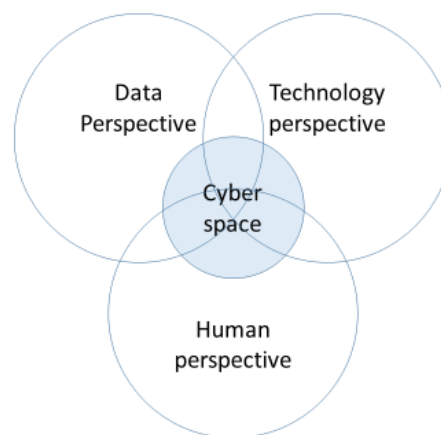


Figure 8 Cyberspace at the overlap of data, technology and humans (Adopted (Edgar & Manz, 2017)

The terms “information security” and “cybersecurity” are often used synonymously. Indeed, while many cybersecurity incidents are related to data breaches, it is important to understand that cybersecurity is a wider phenomenon. To understand the scope of cybersecurity and its impact on society, we first introduce the main concepts based on

The European Union Agency for Cybersecurity (*ENISA*) report on definitions of cybersecurity<sup>7</sup> and the NIST Glossary of Key Information Security Terms:<sup>8</sup>

The term “**security**” addresses intent, such as being protected from personal and organisational data-related dangers and threats; the term “security” can be used to refer to protection against undesirable data-related threats.

The term “**cyberspace**” refers to the set of links and relationships between objects accessible through a generalised telecommunications network and to the set of objects themselves, where they present interfaces allowing their remote control, remote access to data or their participation in control actions within that cyberspace.

The term “**cybersecurity**” refers to security of cyberspace, and it means the ability to protect or defend the use of cyberspace from cyber-attacks.

The term “**information security**” refers to the protection of information and information systems from unauthorised access, use, disclosure, disruption, modification or destruction in order to provide confidentiality, integrity and availability.

The term “**resilience**” means the ability to recover from or easily adjust to misfortune or change. In systems that provide critical services, resilience is characterised by four abilities: to plan/prepare, absorb, recover from and adapt to known and unknown threats.

The term “**cyber threat**” refers to the possibility of a malicious attempt to damage or disrupt a computer network or system, including an attempt to access files and infiltrate or steal data.

Finally, the term “**vulnerability**” means any type of weakness in a computer system itself, in a set of procedures, or in anything that leaves information security exposed to a threat.

From a societal point of view, it is important to recognise the differences, because cybersecurity addresses assets other than information that need to be protected. These assets can include a person him- or herself, household appliances, medical devices and the interests of a society as a whole, such as critical infrastructure. As presented in the figure 9, cybersecurity includes anyone or anything that can be reached via cyberspace.

<sup>7</sup> ENISA (2016). Definition of Cybersecurity –Gaps and overlaps in standardisation. Retrieved from <https://www.enisa.europa.eu/publications/definition-of-cybersecurity>

<sup>8</sup> NIST (National Institute of Standard and Technology) (2013). Glossary of Key Information Security Terms. Retrieved from <http://nvlpubs.nist.gov/nistpubs/ir/2013/NIST.IR.7298r2.pdf>



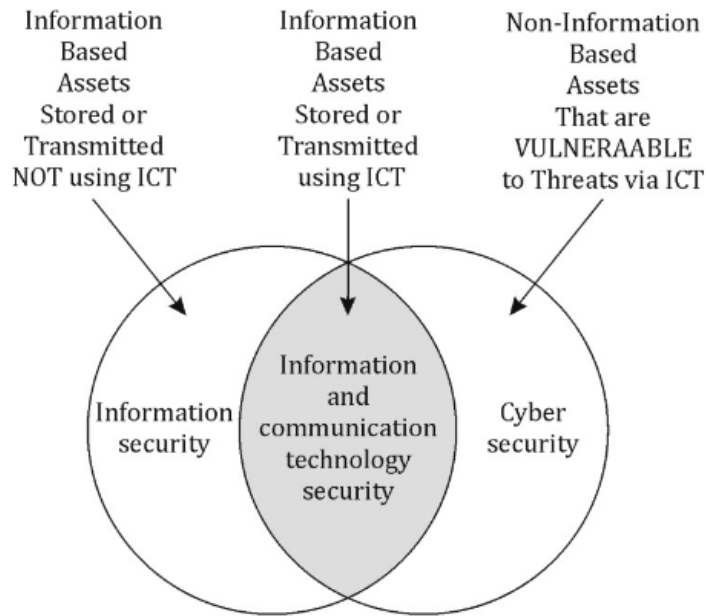


Figure 9 Information security and cybersecurity

From an organisation's point of view, cybersecurity management starts with a risk-management procedure, as shown in the figure 10. If cybersecurity risks are not managed, organisations will face disasters over time. Risk management research focuses on how to measure and quantify a state of cybersecurity, including quantifying the value of cybersecurity to an operation, how much of a threat the operation is exposed to and scoring how mitigations and security controls affect the overall operational risk (Edgar & Manz, 2017). All organisations are becoming more and more dependent on unpredictable cybersecurity risks. Ubiquitous and constant computing means that organisations do not know when they are using dependable devices or services, and they face a chain reaction of unpredictable risks.

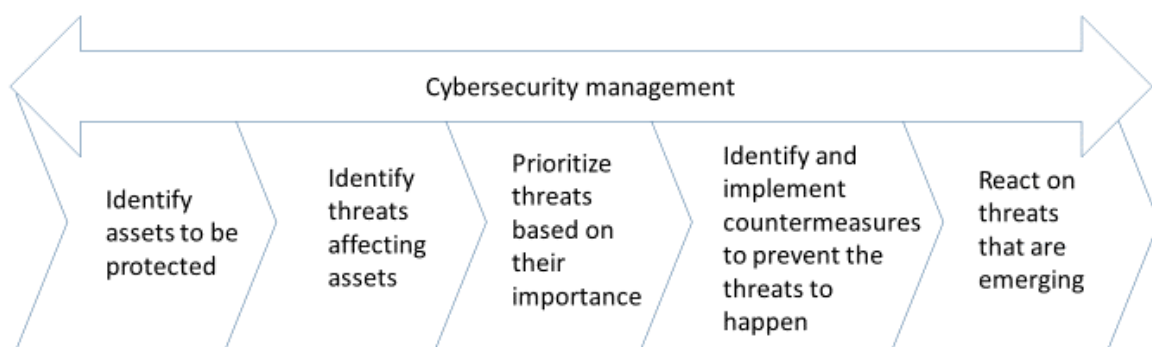


Figure 10 Cybersecurity management as a risk-management procedure

## 6.2 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. It 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.

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, 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 popular in recent years: more and more, companies are being hacked, resulting in the theft of data. The consequences 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 for the following opportunities of improvement:

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

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

### 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. 'OES' 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 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, n.d.)<sup>9</sup>

### Applications within digital services

*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.

<sup>9</sup> <https://www.securehospitals.eu/nis-directive/>

## 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 legislations 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.

### *6.3 Cybersecurity research in the ECHO and SHAPES projects*

The SHAPES project develops and pilots a platform for H&C services, and that platform must be cyber-secure. ECHO (the European network of Cybersecurity centres and competence Hub for innovation and Operations) is one of the four pilot projects under the H2020 program with the objective of connecting and sharing knowledge across multiple domains to develop a common cybersecurity strategy for Europe. The ECHO Multi-Sector Assessment Framework provides a structured method for multi-dimensional analysis of security disciplines (e.g., cryptography, network security, application security, IoT/cloud security, etc.); sector specific use cases (e.g., analysis of sector specific needs and challenges); transversal cybersecurity needs analysis (e.g., common cyber-security needs such as policies, regulations, and skills frameworks) and inter-sector technology and dependency analysis (e.g., identification of common technology roadmaps solving inter-sector technology challenges). One of the sectors analysed in the ECHO Project is H&C.

Therefore, both of these projects share a common issue, and together they are organising a webinar in May 2020 that focuses on dissemination of early research findings related to H&C sector cybersecurity. The tables 19 and 20 list the relevant publications and deliverables published or submitted so far and present the issues of the H&C-related analyses in the ECHO deliverables.

*Table 19 ECHO deliverables dealing with the H&C sector*

Publication/deliverable	Version	Date
ECHO D2.1 SECTOR SCENARIOS AND USE CASE ANALYSIS	1.0	31/10/2019
ECHO D2.2 ECHO MULTI-SECTOR ASSESSMENT FRAMEWORK	1.0.15	31/10/2019
ECHO D2.4 INTER-SECTOR TECHNOLOGY CHALLENGES AND OPPORTUNITIES	1.0	31/10/2019
ECHO D2.5 MULTI-SECTOR REQUIREMENTS DEFINITION AND DEMONSTRATION CASES	1.0	31/01/2020
Jyri Rajamäki. "SHAPES Cyber Secure HealthCare Platform in Digital Environments." WSEAS Transactions on Communications,		04/03/2020

ISSN/E-ISSN: 1109-2742/2224-2864, Volume 19, 2020, Art. #3,  
pp. 18–25. <https://doi.org/10.37394/23204.2020.19.3>

Table 20 The ECHO project's H&C sector cybersecurity-related published analyses

Aim of analysis	Deliverable	Section
Known cyber-attacks in the H&C domain	D2.1	4.1.1
Cybersecurity threat trends in the H&C domain	D2.1	4.1.2
Scope and context of an H&C scenario	D2.1	4.1.3
Description of a healthcare scenario <ul style="list-style-type: none"> <li>• Storyline HC01 "Social engineering attacks on hospital staff"</li> <li>• Storyline HC02 "Tampering with medical devices"</li> <li>• Storyline HC03 "Theft or loss of hospital equipment or data"</li> <li>• Storyline HC04 "Malware attacks on hospital information systems"</li> </ul>	D2.1	4.1.4
Study of inter-sector cybersecurity dependencies; Telecommunication and H&C sectors	D2.1	5.2
Modelling and analysis of the use cases of the H&C scenario	D2.1	6.3
Analysis of existing cybersecurity framework adoption in the H&C domain <ul style="list-style-type: none"> <li>• NIST Cybersecurity Framework</li> <li>• HITRUST Common Security Framework</li> <li>• CIS Critical Security Controls</li> <li>• ISO 27000</li> <li>• COBIT</li> <li>• ECHO healthcare scenarios: weaknesses and potential mitigation actions</li> <li>• Conclusions</li> </ul>	D2.2	3.2
Inter-sector and transversal aspects: H&C	D2.2	3.6.3
Analysis of selected scenarios and use-cases per sector – technological context; analysis of selected sectors: H&C	D2.4	3.1.1
Identified common technological opportunities/countermeasures to be targeted: H&C	D2.4	3.3.1
Sector-specific issues and solutions – technological context: H&C	D2.4	3.4.1
Inter-sector cybersecurity challenges, opportunities and dependencies; cybersecurity challenges and opportunities in the H&C sector	D2.5	3.3.1
Analysis of inter-sector cybersecurity dependencies; Dependencies between healthcare, telecommunication, navigation and big data	D2.5	Table 6
Multi-sector analysis; healthcare sector analysis	D2.5	4.2.2.3

## 6.4 Rationale behind SHAPES cybersecurity and resilience requirements

The overall goal of cybersecurity is that all systems and infrastructures are resilient. Situational awareness (SA) is the main prerequisite towards cybersecurity. Without SA, it is impossible to systematically prevent, identify and protect the system from cyber incidents and if a cyber-attack happens, to recover from the attack. The SHAPES platform is a cyber-physical system (CPS) that has human, technological and data-based domains.

The Network-Centric Warfare (NCW) doctrine (Alberts, 2002) identifies four domains that create shared situational awareness and inform decentralised decision-making:

1. Physical: Physical resources and the capabilities and design of those resources
2. Information: Information and information development about the physical domain
3. Cognitive: Use of the information and physical domains to make decisions
4. Social nexus: Organisation structure and communication for making cognitive decisions

One can think of a CPS as consisting of two sub-systems: the proper resilient operational system and the (*cognitive*) situational awareness system that both have human (*social*), technological (*physical*) and data-based (*information*) domains. The resilient cyber-physical eHealth system in the centre of the figure 11 shows this concept. *Security management*, *security technologies* and *security information* connect these sub-systems. However, security information is mostly created or transferred from the operational system to the SA system via security technologies.

*Security management* covers the human and organisational aspects of cybersecurity. Its focus areas include: security policy development and implementation, risk management and information security investment, incentives and trade-offs. An information security management system (ISMS) focuses on the continuous management and operation of a system by documented and systematic establishment of the procedures and processes to achieve confidentiality, integrity and availability of the organisation's information assets that do the preserving. Security management also integrates the social layer's operational and cognitive aspects; all technical and organisational components should learn from prior events and incidents.

*Security technologies* include all technical means towards cybersecurity, such as secure system architectures, protocols and implementation, as well as tools and platforms for secure system development and deployment. Technologies that create or transfer *security information* from the operational system to the SA system include sensors that collect the first level of data. Commonly, host- and network-based tools

generate logs that are used for SA. Firewalls, system event logs, antivirus software, packet captures, net flow collectors and intrusion detection systems are examples of common cyberspace sensors. Level-two technologies generate information from the data to determine a current situation. Generally, level-two technologies require the bringing together of data and performing some level of analytics. The simplest form is signature-based tools such as antivirus and intrusion detection systems. These systems have encapsulated previous knowledge of detected attacks into signatures that detect and alert when they are detected in operational systems. More advanced systems such as security information and event managers (SIEMs) provide infrastructure to bring together datasets from multiple sensors for performing correlations. Also, vulnerability analysis to determine how many unpatched vulnerabilities exist in a system is also a form of level-two technology. The third and final level is hard to achieve and, as such, there are few examples of effective tools. Things such as cyber-threat intelligence, which provide information on active threat actor methods, techniques and targets, provide some level of predictive information to enable taking pre-emptive security measures. Artificial intelligence for cybersecurity develops with the speed and offers new possibilities for better SA.

*Situational awareness* involves being aware of what is happening to understand how information, events and one's own actions affect the goals and objectives, both now and in the near future. The most important enablers of SA are observations, analysis, visualisation and governmental cyber-policy. The most significant challenges of an organisation's SA deal with to the observation of the vulnerabilities and operational deviation of the complex technical system wholeness. The cognitive SA system for supporting decision-making needs several input and output interfaces (Kokkonen, 2016):

- Sensor information interfaces. The system implements interfaces for input of cybersecurity sensor information.
- Interfaces for status information. The system implements interfaces for inputting the status information of all the known cyber entities. Information of systems, devices and sensors with their status and configuration information, but also the spare parts of physical devices are relevant information for a cybersecurity SA system. Also, information about the status of saved data and the status of information flows should be reported. Some of that information can be automatically generated using data interfaces and some should be user generated by using HMI.
- Interfaces for analysis information. The system implements interfaces for information based on analysis. That kind of information includes analysed impact assessment information, Indicator of Compromise (IOC) information and early-warning information from open-source intelligence using, e.g., social media or CERT bulletins. Further, required policies and objectives should be input to the system.



- Interfaces for information exchange. The system implements interfaces for cybersecurity information exchange with trusted companions.
- HMI. The system implements HMI for effective visualisation of the current status of the cyber domain under control and for input of information that cannot be entered automatically. HMI is also used for controlling the data fusion process. HMI should implement different visualisations for different levels of users: e.g., technical user who requires detailed technical information, whereas a decision-maker needs totally different visualisation. HMI also implements filters for data allowed for different users.

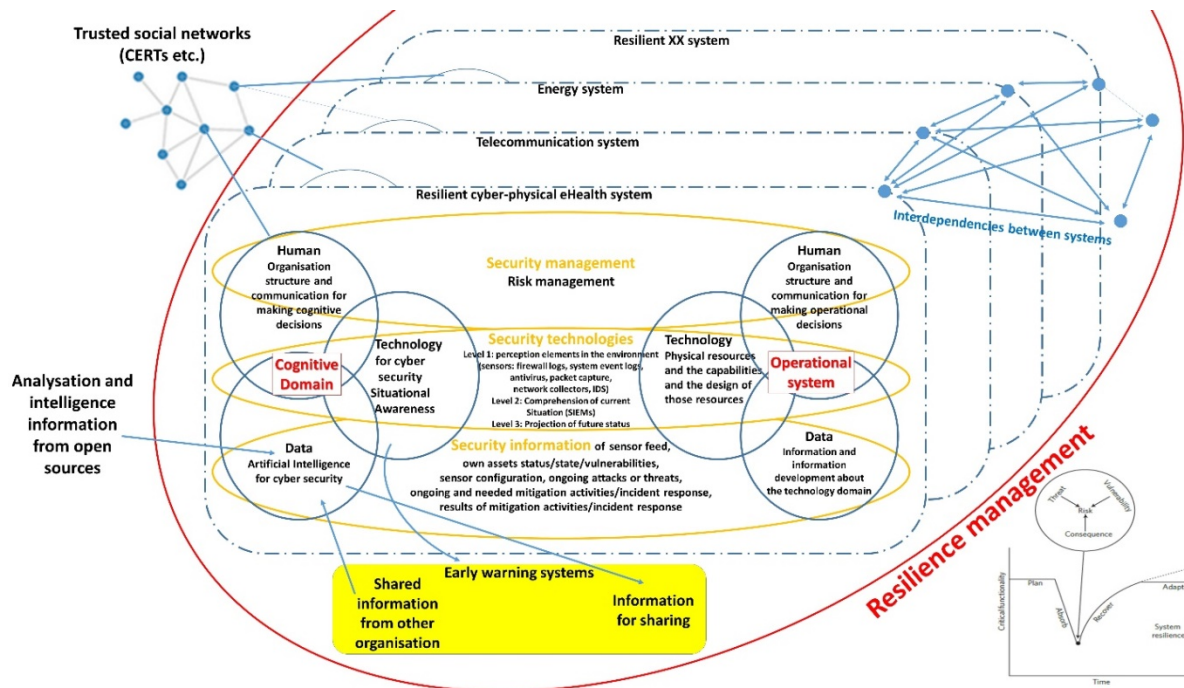


Figure 11 Conceptual resilience governance framework for eHealth CPSs

Increasingly interconnected social, technical and economic networks create large, complex systems, and risk assessment of many individual components becomes cost and time prohibitive or even impossible (Linkov, et al., 2014). No one can control the wholeness, and our outlook should move to co-ordination and co-operation. The uncertainties associated with the vulnerabilities of these systems challenge our ability to understand and manage them. Risk assessment and risk management are no longer sufficient to focus on increasing risks in the modern cyber-physical world, which has unforeseeable and non-calculable stress situations. To address these challenges, risk assessment should be used whenever possible to help prepare for and prevent consequences of foreseeable events, but resilience must be built into systems to help them quickly recover and adapt when adverse events do occur (Linkov, et al., 2014).

The National Academy of Sciences identifies four event management cycles that a system needs to maintain to be resilient (National Academy of Sciences, 2012):

1. Plan/Prepare: Lay the foundation to keep services available and assets functioning during a disruptive event (malfunction or attack)
2. Absorb: Maintain most critical asset function and service availability while repelling or isolating the disruption
3. Recover: Restore all asset function and service availability to their pre-event functionality
4. Adapt: Using knowledge from the event, alter protocol, configuration of the system, personnel training or other aspects to become more resilient

Linkov et al. (2013) combined the event management cycles and NCW domains to create resilience metrics for cyber systems.

## 6.5 SHAPES cybersecurity and resilience requirements and future design goals

The figure 11 presents the conceptual resilience governance framework for a resilient cyber-physical H&C system. From that framework, the following cybersecurity and resilience requirement can be derived for the SHAPES platform:

- 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 for these systems)
  - Educate/train employees about resilience and the organisation's resilience plan

From a citizens' point of view, eHealth is wholeness in which sectors 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 change even vital information. The mental picture of cybersecurity should turn from "threat, crime, attack" to "trust". Creating confidence in a safe digital future is truly needed in the integration of 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 "bad touch", 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 knowledge-base of security and risk management by developing frameworks and models enabling network-wide resilience management that strives for maintaining and improving critical functionalities. (Rajamäki and Pirinen 2017).

## 7 Ethical challenges and opportunities for SHAPES

The purpose of this chapter 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 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 ageing people are explored. As Houssein (2017) and Taipale & Hänninen (2018) state, at the same time the digitisation of all spheres of society and an increase in lifespans in Western societies is being experienced. In order to ensure inclusion and prevent exclusion of ageing people in a digitalised society, an understanding has to be gained of how the demographic phenomenon of an increased lifespan with the digitalisation of society can be successfully reconciled (Houssein, 2017). In addition, it is important to consider how to ensure that digital innovations benefit society, especially older adults (Houssein, 2017). The increased longevity opens up 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 in the marketplace 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 adults, i.e., the misconception that older adults 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, old people are diverse with regards to their physiological, psychological, social and functional traits. The diversity materialises in how older adults adopt and use digital technologies (Taipale & Hänninen, 2018). In addition, what needs to be

acknowledged among older adults 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 adults, 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 (e.g., education, income, health and age) and social-context factors (e.g., 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 adults. The key finding of the study highlights that to mitigate the shortcomings of eHealth systems for older adults, it is important to address the challenges that relate to cultural appropriateness, e.g., the culture of various ethnic groups, including possible language barriers (Fang et al., 2018).

### 7.1.3 Exclusion and inclusion

#### **Exclusion**

According to Seifert et al. (2018), various reasons can be detected for older adults’ 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 adults many times lack 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, 70+ adults 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 have to make a greater effort to learn to use new technologies and often have to overcome barriers arising from having fewer cognitive, physical, financial and social resources (Seifert et al., 2018).

#### **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 adults need help and constant assistance. The social networks of older adults have a strong effect on encouragement to adopt and use technological devices (Friemel, 2016; Olsson & Viscovi, 2018; Schreurs & Quan-Haase, 2017). In Friemel’s (2016) study, the most attractive way of learning to use the internet was to 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 elderly 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 adult come to terms with domestic technological devices and services (Olsson & Viscovi, 2018). As Olsson & Viscovi (2018) argue, older adults 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 adults from digital society (Olsson & Viscovi, 2018; Schreurs & Quan-Haase, 2017).

Since there is an ever-increasing number of older people living alone in Western societies, in order to prohibit exclusion from society there has to 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 as a way to work more easily and to enhance health and public services may be overly optimistic from the point of view of older adults. Despite the good intention to make various services and information more available via digitalisation, it might actually make them less available for older adults if they do not get help and assistance in using ICT. Decisions by policymakers emphasise that online services have to 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 for the informal networks of older adults in the usage of technology and technology-mediated information (Godfrey & Johnson, 2009). These "digital circles of support" can consist of tech-savvy older adults 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 adults. They state that the factors contributing to the usage and non-usage are in line with older adults' personal circumstances and biography (Spann & Steward, 2018). The finding of the study is congruent with other similar studies (Friemel, 2016; Hargittai & Dobransky, 2017; Taipale & Hänninen, 2018; Siren & Knudsen, 2017). In the study concluded by Spann & Steward (2018), the older adults' 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 adults 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 adults 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 adults to weigh the pros and cons of mHealth usage. In addition, the study highlighted that older adults 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 has to 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 adults, mHealth devices and technology need to be designed in a manner that they allow the *Personalisation* of the functions. *Personalisation* also supports older adults' autonomy and independence and has a positive effect on their *Self-Efficacy* (C) and *Sense of Self* (D). The study also found that older adults' 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 adults in the usage of mHealth. If mHealth was experienced as 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 adults, whereas they did not experience confidentiality to be an issue. The study participants trusted their healthcare professionals to keep their data safe or did not think it held any particular 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 adults feel they cannot afford mHealth devices and services, they will not use it, regardless of the acknowledged personal needs and benefits. Therefore, it is important to pay attention to the costs of mHealth for older adults.

### 7.1.5 Conclusion

As Spann & Steward (2018) state, mHealth devices and services are complex interventions. Their integration into older adults' lives requires that developers, providers and policymakers ensure that older adults 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 adults (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, Steinhubl & Topol, 2019).

In a study (Kim & Choi, 2019) exploring older adults' willingness to share their personal and health information when using healthcare technologies and service, the authors conclude that older adults 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 adults 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 adults requires the understanding of what it is to be a "digitally engaged and self-monitoring older adult".

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

## 7.2 *The moral division of labour in digital service provision*

In this section, the service platforms and platform economy made possible by digitalisation are investigated from the perspective of older citizens and their new roles. 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”.

### 7.2.1 About the idea of a platform economy

New types of ecosystems made possible by technology and digitalisation have typically been considered in the literature from an economic and business perspective. We are talking about a platform economy (Kenneth and 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 and Zysman 2015; Ailisto & al 2016).

In practice, the platform economy and digital ecosystems are changing patterns of work and value creation in society (Kenneth and Zysman 2015). 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). The SHAPES solution, which utilises the logic and digitalisation of the platform economy, opens up new types of roles for end-users. 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 central idea of the platform economy is demand driven. 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 ecosystem, it is therefore essential to ensure conditions for 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?

### 7.2.3 An active citizen who uses and produces services

Service thinking has become even more important in healthcare and its development (Laitinen & 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 metre 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.

But how does the SHAPES ecosystem ensure that older persons have opportunities 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, e.g., Vargo and Lush; 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 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 exploitation phase after the project. But in practice, how do we ensure that the end-users have real power? 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 Summary

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 – 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 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 “good circle” to support the wellbeing of active older people.

## 7.3 Welfare technology and attracting elderly care professions

In the integrative literature review of nursing and caring literature, Korhonen et al. (2015) conclude that technology as a concept has three implications. First, technology is devices and products, including ICT and advanced, simple and assistive technology. Second, technology refers to a process consisting of methods for helping people. Third, technology as a service indicates the production of care by technology. From the perspective of caring science, this outlines technology as products and devices used in care, whereas technology as a process refers to all methods helping people in caring relationships and promoting good in health, sickness and suffering. Technology as a process is essentially interactive. Nurses act as interpreters between patients and technology. Finally, technology as a service means producing care by using technology and its applications in the act of caring. When the act of caring comes true in the ethical way, human dignity and human rights, as well as the human good of the patient, are realised and potential harms are prevented.

A few years ago, the European Social Observatory (EPSU) asked the European Social Observatory (OSE) to carry out an exploratory study on the impact of digitalisation on the content and quality of jobs in two sectors covered by EPSU: the home-care sector and public employment service sector. (Peña-Casas, Ghailani and Coster 2018).



The EPSU research findings demonstrate that digitalisation indeed has concrete effects on many aspects of employment and its quality, as well as direct outcomes for workers, particularly on their physical and mental health. If digitalisation had a positive effect on the rationalisation and improvement of a work since its introduction, it also had adverse effects for the workers whose views have not been sufficiently considered during its design and implementation. The impacts of digitalisation vary according to sector and occupation, in terms of the tasks performed and skills applied. Measuring the impact of digitalisation at the level of occupations and tasks blurs the differences between countries, as the content of the work itself is largely similar across borders. It is important to ensure that digitalisation is a positive pathway of evolution for the work and job quality of workers, in particular by setting the necessary safeguards to protect workers (Peña-Casas, Ghailani and Coster 2018).

### 7.3.1 Attracting elderly homecare professions

Long-term care will face three major related and simultaneous challenges: (a) a *huge increase in need*. Over the next five decades, the number of Europeans over 80 requiring long-term care (LTC) is expected to triple; (b) a threat to the *supply of long-term carers* from the decline in the number of people of working age and from social changes making it less likely for families to provide, in the future, the same level of informal care they do today; and (c) the pressure that rapid growth in demand, and the expectations of the “baby boom” generation, will place on ensuring *care quality* (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. 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 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 minority of workers and that those with no previous paid work experience are primarily attracted to roles within the residential elder care sector. Although workers usually come into aged care with substantial employment histories and experience, pathways into the sector differed strongly for nurses and care workers. The three key drivers that increase attraction to the aged-care sector are a direct interest in aged-care work, the availability of work and the convenience and flexibility of work. Such work was seen as being rewarding and offering opportunities to fulfil an interest in working with older people.

In European research literature, only professional nursing autonomy is a known aspect related to attractiveness of homecare nursing. A Dutch study reports aspects that



registered nurses, currently working in homecare, find attractive about their work. Three themes were identified: spider in the web, autonomy and diversity. Registered nurses find it attractive that they can truly make a difference for their clients as the leading professional. Registered nurses experience freedom and independency in their work through autonomy. Diversity in their work prevents boring routines and makes their work challenging (De Groot 2016).

Many workers expressed concerns that aged-care work was seen in a poor light, both within the general community and other health and care sectors. Aged care was widely perceived to be a low-status job that offers poor pay. Moreover, recent media exposure of poor practices within the aged-care sector has added to these negative perceptions. In addition, aged-care work was often viewed as lacking clinical and technical expertise and providing limited career pathways; this was considered to hamper the attractiveness of the sector to nurses and nursing graduates. Because of these factors, other health and care sectors were perceived to offer more attractive employment than aged care (Isherwood et al. 2018).

The choice of workplace had not been a conscious decision for a majority of workers in aged care but instead, the availability of employment opportunities was of foremost importance. However, some workers had directly sought employment with a specific aged-care provider. This was due primarily to the organisation having a good reputation, positive values and favourable working conditions. Location and, for new hires and care workers, a previous positive experience of the organisation (through work placements or employment in a non-care role) also led to decisions to choose a particular workplace. Personal circumstances, working conditions and aspects of aged-care work itself were the three main factors identified in the worker surveys as contributing to decisions to transition to a new employer (Isherwood et al. 2018).

If attraction to the aged-care sector workforce is to be improved, evidence from the qualitative interviews suggests that a multifaceted approach is needed. A campaign approach – to promote the benefits of working in the sector – would both allow the promotion of the positive aspects of aged-care work and address negative perceptions held by the community. In particular, the rewards that a career in aged care can bring, the availability of work within an expanding sector and the ability to obtain a good work-life balance should be promoted. In addition, the situating of aged care within the broader health and social care industry could appeal to those looking to develop transferable skills and experience within health and care work. In order to adequately grow in size and to be able to better service the increasingly diverse needs of older people, however, the aged-care sector will also need to attract greater numbers of non-traditional pools of labour, such as men and younger people (Isherwood et al. 2018).

Special attention will be required, therefore, to ensure the relevance of attraction strategies targeting these cohorts, both industry-wide and at organisation or local levels. For instance, strategies to attract more male workers would need to challenge

perceptions that aged care work is “women’s work” and emphasise activities and roles that may appeal to men. A greater emphasis on aged care within training courses, as well as the promotion of aged care as a distinct specialism requiring complex clinical and technical skills, could also improve worker attraction. As some of these perceptions centred upon working conditions and career pathways, it is important that consideration is given to how working conditions can be improved and opportunities for career advancement provided in order to allow potential workers to feel that they are coming into a sector that values and develops its workforce (Isherwood et al. 2018).

### 7.3.2 The impact of welfare technologies on work

Generally, welfare technologies are in early stages of development. The impact of technological development has been widely researched, and the focus of many researchers has been to produce evidence to support nurses in providing ethical, safe, effective and holistic care (Caligian and Dykes 2011; Nagel et al. 2013). However, less attention has been given to the impact of digitalisation on many aspects of people’s economic and social lives and the changes in the nature and content of work.

The problems or challenges in healthcare that should be solved to provide ethical care have been found to consist of several items. First, better communication pathways, training and technical support systems, and workable protocols should be created. Second, new skills and management should be taught and put into operation (Smith 2008; Alexander and Stagger 2009).

According to the European Economic Area Consultative Committee (EACC) (2017) digitalisation entails both opportunities and risks for the labour market, but its effect on employment is not yet fully understood. 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. Digitalisation also creates a demand for specialised workers with strong interpersonal and cognitive skills, and generic soft-skills such as creativity, communication, teamwork and perseverance are becoming more important.

Bergey et al. (2019) found that health information technology implementation generated significant reconfigurations of work practices at the expense of nurse-patient interaction. Following such changes, nursing leadership described re-prioritising patient care and interaction – perceived to them as essential to the patient experience and unit functioning – through realignments in staffing that prioritised more versatile staff and task delegation of less visible care practices previously completed by nurses to unit clerks. Despite maintaining an integral role as “gatekeeper” and the “face on the floor”, unit clerks experienced significant reconfigurations of their work and some concomitant uncertainty about their role. The authors of the study therefore suggest that both the people who care and the people who are cared for are

considered “users” and the process should ensure that digitalisation is not detrimental to users.

Cijan et al. (2019) suggested that digitalisation improves job satisfaction, blurs 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 whether it is necessary to update the legal framework of work in order to maintain worker protection, including rules regarding working hours, social protection and health and safety issues.

Larsson et al. (2012) concludes that proactive workplace interventions need to focus on potentially modifiable factors such as self-efficacy, safety climate, physical job demands and musculoskeletal wellbeing. Cirillo et al. (2019) showed negative employment dynamics among professions combining a high level of digitalisation and routineness.

When managers are aware of nurses’ attitudes towards IT, managers can offer tailored support in changing situations and the implementation of new applications. Managers of nurses should implement new IT applications to foster a positive atmosphere and improve job satisfaction and thus ensure future willingness to work in this changing work environment (Koivunen et al. 2013).

The EACC (2017) has emphasised the importance of skills development to provide workers with the right skills and specific competences to unlock the full potential of digital technologies.

More opportunities are needed to train and upskill staff and expand their capabilities, both to overcome the digital divide (notably for older workers) but also to develop the new competences linked to the changing nature of jobs. The impact of digitalisation on job quality in homecare service evinces a lack of available professional development activities. A great effort is needed to address this issue. At the company level, there is a need to support change by embracing new technologies and developing communication. There is a need for training on the use of new digital tools and programs in order to increase the know-how of workers (Peña-Casas, Ghailani and Coster 2018).

Also in EPSU research, workers in both health and social sectors emphasised digitalisation to increase differences between colleagues at the workplace, including a generational gap in mastering the necessary digital skills. The education and training system should provide broader skill-sets, including competencies that are growing in importance because of new technology. Specific digital skills should be embedded in a wider strategy, alongside the development of transversal skills (soft skills and communication skills) (Peña-Casas, Ghailani and Coster 2018).

Simply increasing quantities of functional training may not render a technology any more workable in practice. Instead, the implementation should be further facilitated through greater involvement of all stakeholders in discussions and decision-making in order to deepen understandings about the range of potential benefits and challenges from the use of monitoring technologies. Staff training might need to move beyond functional instruction to include deeper exploration of anticipated benefits and the underlying rationale for using technologies (Hall et al. 2017).

Technology should primarily be a tool for the profession, and understanding the professions' reasoning about technology use in healthcare at home must be the basis for implementing it (Wälivaara et al. 2011). Among care workers, change readiness seems to be quite contagious, and organisations should strive towards a shared psychological state of welcoming changes that are collectively determined to be beneficial (Turja et al. 2019).

Niemeijer et al (2014) investigated how nurses and support staff in residential care facilities are actually using surveillance technology for people with dementia or intellectual disabilities in order to explore the possible benefits and drawbacks of this technology in practice. They found that participants tended to incorporate surveillance technology into existing care routines and to do so with some reluctance and reservation. They also tended to favour certain technologies, for example, making intensive use of certain devices while demonstrating ambivalence about others. The participants also often appeared unwilling to take risks with technology. Care facilities wishing to implement surveillance technology should encourage ongoing dialogue on how staff members view and understand the concepts of patient autonomy and risk. A clear and well-formulated vision for the use of technology seems imperative to successful implementation.

Digitalisation should not just consider a management and production tool. Digitalisation is also about protection for the individual and workers. Social dialogue structures should be consulted and included from the beginning of the process to its end (Peña-Casas, Ghailani and Coster 2018).

Personal interaction with elderly 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 is not yet seen as an integral part of the care profession. Further, the need for education in this field is often overlooked. A comprehensive introduction to technology used in care services or nursing homes should be offered to employees on a regular basis. Competence in using assistive technology and transmitting this knowledge and know-how to other users should be promoted through training (Mort M., et al. 2014 & Oudshoorn, 2011).

A trusting relationship is a prerequisite for good homebased nursing care (Wälivaara and Axelsson, 2013), and it has to be safeguarded during the development of different distance-spanning technologies (Milligan et al., Szczepura, 2011; Wälivaara and



Axelsson, 2013). It's important to work consciously to build and protect a trusting relationship when implementing technology in homebased healthcare in order to provide good care (Meleis, 2011). Wälivaara et al. (2009) show that when the person trusts the distant working nurses, they also feel confident with the use of technology in healthcare at home.

When new technology is used in elder care ja articulation work, the nurses assume the role of an interpreter between technology and patient. In those situations, the nurses' perceptions regarding impacts of the technology influence the actual usage of technology (Piscotty et al 2015). When new technology is implemented in elderly care, professional skill and reflection, including articulation of work tasks, has to 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 and Grosen, 2019). The dimensions of patient-centred technology are usability and acceptability (Wolpin and Stewart, 2011). The necessity 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. (2019) identify key forces in Finnish care workers' readiness for robotization. Potential change agents are distinguished from others 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.

In previous studies, carers have posited that communication technology could lead to dehumanised care (Sävenstedt et al. 2006) and that technology is used too often to replace human interaction in elderly care (Rytkönen, 2018). Technical devices have been experienced to be difficult to handle, expensive, complicated to maintain etc., and visions of future technology have been thought more likely to create frustration in care professionals than confidence. Negative experiences with assistive devices also prevailed over positive memories in care professionals (Mort et al., 2014; Oudshoorn, 2011). Therefore, it is important to follow the changes of attitudes on technology during interventions.

The impacts and outcomes highlighted in the EPSU report point to a clear need to promote decent working conditions and, largely, sustainable quality employment. It is crucial to improve and/or develop regulations as safeguards against potential negative outcomes of digitalisation: across all levels of governance and social dialogue. Both public authorities and social stakeholders should carry out detailed studies of the impact of digitalisation at local, regional and national levels and across sectors and occupations to better understand the impact of digitalisation on work dimensions and prepare for changes in occupations. These studies should be part of an integrated approach under the auspices of multistage holder alliances, including social partners. This integrated approach should ensure that digitalisation is not detrimental to users. It seems necessary to keep services focused on users: to strike the right balance



between digital tools and personalised services to users and to ensure that quality is guaranteed (Peña-Casas, Ghailani and Coster 2018).

To more fully understand a new technology's introduction and utilisation, it is critical to explore not only the outcomes related to implementation but also how the technology interrelates with the 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 if and how factors such as workflow, staffing, roles and responsibilities evolve and are negotiated over time. Ethnographic research would be well-suited to an in-depth analysis of the processes and related implications of technology implementation as they unfold (Berg, 2001, Mort M, et al. 2014 and Oudshoorn, 2011).

Social and organisational factors have a significant impact on technology implementation and use (Randell and Dowding, 2010) with organisations characterised by collaboration, teamwork and supportive leadership more likely to report successful technology implementation and use. Important opportunities to increase efficiency, improve quality and safety, pursue organisational priorities and optimise the function of the multidisciplinary team may be missed if the introduction of technology is not accompanied by a thoughtful approach to its effect on team-based care. As well as these questions about the place of technology in care practice, financial issues are important for the perceived competition of technology versus staff.

## 7.4 Movement of caregivers across Europe

Free movement of people in the EU is the cornerstone of Union citizenship, which was originally established by the Treaty of Maastricht. The free movement of workers is one of the fundamental freedoms on which the EU internal market is based. It is provided for in Article 45 TFEU, which entails the abolition of any discrimination on the grounds of nationality in employment, remuneration and other conditions of work and employment across the EU. An EU worker has the right to move freely across the EU for the purpose of employment and to stay in a Member State (different from his/her home State) even when the employment contract has ended under certain conditions.

Currently, the key pieces of EU legislation on free movement are:

- Directive 2004/38/EC of the European Parliament and of the Council of 29 April 2004 on the right of citizens of the Union and their family members to move and reside freely within the territory of the Member States amending Regulation (EEC) No 1612/68 and repealing Directives 64/221/EEC, 68/360/EEC, 72/194/EEC, 73/148/EEC, 75/34/EEC, 75/35/EEC, 90/364/EEC, 90/365/EEC and 93/96/EEC
- Regulation (EU) No 492/2011 of the European Parliament and of the Council of 5 April 2011 on freedom of movement for workers within the Union

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These pieces of legislation complement those regulations related to social security coordination.

In 2019, the European Labour Authority (ELA) was set up (Regulation (EU) 2019/1149 of the European Parliament and of the Council of 20 June 2019 establishing a European Labour Authority, amending Regulations (EC) No 883/2004, (EU) No 492/2011, and (EU) 2016/589 and repealing Decision (EU) 2016/344). The Authority has been given mandate to assist Member States and the Commission in the application and enforcement of EU law related to labour mobility across the Union and the coordination of social security systems within the Union.

The free movement of workers is extremely relevant with regard to formal/professional caregivers. Data shows (<https://www.oecd.org/health/health-systems/help-wanted-9789264097759-en.htm>) that in several countries in Western Europe, the majority of workers involved in the provision of care assistance to older people are EU migrants (i.e., citizens of other Member States) or Third countries citizens. (see [https://www.europarl.europa.eu/doceo/document/E-9-2020-001761\\_EN.html](https://www.europarl.europa.eu/doceo/document/E-9-2020-001761_EN.html)).

Free movement of informal caregivers (family members of EU citizens moving to another Member State Directive 2004/38, the Citizens' Rights) is also relevant. In that vein, research will also look at rights related to informal caregivers under EU law. In that connection, it will also discuss rights that are not necessarily linked to the exercise of free movement, and it will discuss relevant pieces of legislation, such as the EU Work-life Balance Directive, which introduces carers leave (i.e., workers providing personal care to a relative will be entitled to five days of leave per year).

The research on this topic during the SHAPES project will focus on the legal framework (CJEU case law and relevant free movement provisions). The points that will be included:

- a) Free movement of formal caregivers (free movement of workers and related case law)
- b) Free movement of informal caregivers – which might entail family members of EU citizens moving to another Member State (Directive 2004/38, the Citizens' Rights)
- c) Issues not linked to free movement: EU Work-life Balance Directive that introduces a carers' leave (i.e., workers providing personal care to a relative will be entitled to five days of leave per year)

## 8 Initial Ethical requirements for the SHAPES Integrated Care Platform

In this chapter, we elaborate on the ethical requirements for the SHAPES Integrated Care Platform. These ethical requirements are derived from the contents of the previous chapters. In addition, feedback collected from partners and during the first dialogue workshop on 12 May 2020 have been considered in the ethical requirements and their more detailed formulation.

### 8.1 Ethical requirements

Ethical requirements, unlike end-user requirements, are primarily defined on the basis of literature and various documentary analysis. The implementation of ethical requirements has an impact not only on technical solutions and services, but also on organizational arrangements of SHAPES. Ethical requirements are particularly important alongside user requirements when developing solutions that are linked to fundamental rights and where the target group is older persons.

The purpose of these ethical requirements is to help ensure that SHAPES becomes a positive innovation for end-users, service providers and society. Traditional research integrity issues during the SHAPES project are excluded in this section and discussed in “the Baseline for Project Ethics” (D8.2.)

The ethical requirements are categorised as General Ethical Requirements (GE), Ethical Requirements for the technology (TE), Ethical Requirements for user processes and support 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 optional (see the table below).

The ethical requirements in this deliverable “SHAPES Ethical Framework” due in M7 are initial ethical requirements that will be specified in more detail in technical notes. The final version of the ethical requirements is to be published in M18 in the final version of this deliverable “SHAPES Ethical Framework”. In this version an emphasis has been put on those requirements that must be in place at the beginning (the first 1.5 years of the project), including requirements related to data protection.

*Table 21 Categories related to ethical requirements*

Importance	Clarification
<b>Mandatory</b>	Has to be implemented/is based on law.
<b>Essential</b>	Is relevant from the viewpoint of ethical sustainability and quality of SHAPES.
<b>Optional</b>	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
<b>General requirement</b>	Reflects the values, guidelines, regulations and ethical challenges of the SHAPES Integrated Care Platform discussed in D8.4. May affect technology, user processes and/or governance/business models. Will be specified more in detail during the SHAPES project and its design phase.
<b>Technical requirement</b>	Features of the SHAPES Technological Platform.
<b>User processes</b>	Support service/function(s) related to implementation and use of the SHAPES services by end-users.
<b>Governance/business/ecosystem model</b>	Governance and management requirements related to SHAPES Market Place and SHAPES Ecosystem.

## 8.2 General Ethical Requirements

Table 22 General ethical requirements

No.	Requirement	Importance	Responsibility	More information in D8.4 sections:
<b>GE1</b>	Maximise the level of fundamental rights of older persons and of care givers that SHAPES can promote (including balance between older persons' rights and care workers' rights).	Essential	WP2,WP3, WP6, WP7, WP9?	Rights 3.1 AI Ethics 4.3
<b>GE2</b>	Ensure that SHAPES does not violate any fundamental rights of older persons and/or other stakeholders (e.g., non-discrimination, dignity, integrity and privacy when having robots, web-cameras at home). (TBD)	Mandatory	WP2,WP3, WP7?, WP9?	Rights 3.1 AI Ethics 4.3 Privacy & DP 5
<b>GE3</b>	Be aware of the four biomedical principles. Apply and promote those within SHAPES (justice, beneficence, non-maleficence and autonomy when using SHAPES services).	Mandatory	WP2,WP3	Ethics of Care 3.2

<b>GE4</b>	Be aware of the perspectives of care ethics. Apply and promote those within SHAPES (empathy, relationships, uniqueness of the case).	Mandatory	WP2, WP3	Ethics of Care 3.2
<b>GE5</b>	Maximise the level of human capabilities of older persons and caregivers that SHAPES can promote.	Essential	WP2, WP3,	Capabilities 3.4
<b>GE6</b>	Ensure that SHAPES is not detrimental to any human capabilities of older people and/or other stakeholders.	Mandatory	WP2, WP3	Capabilities 3.4
<b>GE7</b>	Develop solutions that offer users different options to act according to their own choice and practical reasoning. Be open to innovations that may not presuppose commercial commodities.	Essential	WP7, WP6 WP4, WP5 WP2(use cases)	Capabilities 3.4 Division of Labour 7.2
<b>GE8</b>	Note that the participation of older persons in the development 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 as part of the SHAPES ecosystem.	Essential	WP2, WP3, WP4, WP5	Capabilities 3.4 Division of Labour 7.2
<b>GE9</b>	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. (incl. the use of suitable service design tools in order to acquire and communicate properly end-users needs.	Essential	WP2, WP3, WP6	Capabilities 3.4 Customer Logic 4.2
<b>GE10</b>	Consider sustainable development goals in order to optimise the value SHAPES can bring to society. Work towards both the economic, social and environmental sustainability of the SHAPES Integrated Care Platform.	Essential	WP3, WP7, WP9	Sustainable development 4.1
<b>GE11</b>	Consider that the public sector, as part of the SHAPES ecosystem, plays	Essential	WP3, WP9	Sustainable development 4.1 Rights 3.1

	a role as a bearer of political responsibility for ensuring the wellbeing of older persons.			Capabilities 3.4
<b>GE12</b>	Be aware that the use of various digital solutions has an impact on the workload of caregivers but also their work displacement.	Essential	WP3, WP8	Caregivers 7.3 Rights 3.1
<b>GE13</b>	Investigate improvements in the quality of work that the technology brings to homecare professions.	Essential	WP8, WP6	Caregivers 7.3
<b>GE14</b>	Figure out opportunities to apply current services or implement new solutions to fight Covid-19.	Optional	WP6, WP3	Sustainable development 4.1
<b>GE15</b>	Consider and follow up technologies, scenarios and building blocks elaborated in the document “Blueprint on Digital Transformation of Health and Care for the Ageing Society”.	Essential	WP8, WP2, WP3, WP7, WP8, WP9, WP4, WP5	Digital transformation 4.4
<b>GE16</b>	Ensure human agency and oversight in SHAPES AI solutions.	Mandatory	WP3?, WP 4 (4.5)?, WP5 (5.5, 5.7?), WP8	AI Ethics 4.3 Capabilities 3.4
<b>GE17</b>	Ensure technical robustness and safety of SHAPES AI solutions.	Mandatory	WP4, WP5	AI Ethics 4.3 Cybersecurity 6
<b>GE18</b>	Ensure privacy and data governance of SHAPES AI solutions.	Mandatory	WP4, WP5	AI Ethics 4.3 Privacy and DP 5
<b>GE19</b>	Ensure transparency of SHAPES AI solutions.	Mandatory	WP4, WP5	AI Ethics 4.3 Privacy and DP 5
<b>GE20</b>	Ensure the diversity, non-discrimination and fairness of SHAPES AI solutions.	Mandatory	WP3	AI Ethics 4.3 Rights 3.1
<b>GE21</b>	Ensure the societal and environmental wellbeing of SHAPES AI solutions.	Mandatory	WP3?	AI Ethics 4.3 Sustainable development 4.1
<b>GE22</b>	Ensure the accountability of SHAPES AI solutions.	Mandatory	WP4, WP5	AI Ethics 4.3 Privacy and DP 5
<b>GE23</b>	Develop data protection and cybersecurity policies to be published on the SHAPES website.	Mandatory	WP8, WP10	Privacy & DP 5
<b>GE24</b>	Data subject rights: right of access – define what data will be included.	Mandatory	All WPs that process personal data	Privacy & DP 5
<b>GE25</b>	Data subject rights: right to rectification – define the process to correct information.	Mandatory	All WPs that process personal data	Privacy & DP 5
<b>GE26</b>	Data subject rights: Right to be forgotten – define what data can be erased.	Mandatory	All WPs that process personal data	Privacy & DP 5

<b>GE27</b>	Data subject rights: right to restriction – define the right level for restriction.	Mandatory	All WPs that process personal data	Privacy & DP 5
<b>GE28</b>	Data subject rights: information to third parties – inform of data rectification/erasure to parties to whom data is disclosed.	Mandatory	All WPs that process personal data	Privacy & DP 5
<b>GE29</b>	Data subject rights: right to data portability – define what data will be given to the data subject.	Mandatory	All WPs that process personal data	Privacy & DP 5
<b>GE30</b>	Data subject rights: right to object: 1) define a process for manual processing instead of automated decision making + ensure information to the data subject; 2) ensure that the balancing test has been done when using profiling.	Mandatory	All WPs that process personal data	Privacy & DP 5
<b>GE31</b>	Data protection principles: lawfulness – identify and document a lawful basis for processing data.	Mandatory	All WPs that process personal data	Privacy & DP 5
<b>GE32</b>	Data protection principles: fairness – ensure that you use personal data so that it is fair from the data subject's point of view.	Mandatory	All WPs that process personal data	Privacy & DP 5
<b>GE33</b>	Data protection principles: transparency – ensure that data subjects are informed about the usage of their data.	Mandatory	All WPs that process personal data	Privacy & DP 5
<b>GE34</b>	Data protection principles: purpose limitation – 1) ensure that the data is used only for a specified purpose and inform data subjects why and for what purpose the data is used; 2) ensure that if the data is used for a new purpose, there is a right to do so.	Mandatory	All WPs that process personal data	Privacy & DP 5
<b>GE35</b>	Data protection principles: Storage minimisation – document how long data will be kept and justify it. Decide how the data will be processed when it is no longer required.	Mandatory	All WPs that process personal data	Privacy & DP 5
<b>GE36</b>	Data protection principles: accuracy – create a process to check data accuracy and record the source of the data.	Mandatory	All WPs that process personal data	Privacy & DP 5



<b>GE37</b>	Legal basis: define the legal basis for processing a) make a documented balancing test if needed (if processing is based on legitimate interest); b) if the legal basis is informed consent, ensure there is a proper documented process for asking consent. Note that there are also users who cannot give their own consent but whose consent is given by a legal representative.	Mandatory	All WPs that process personal data	Privacy & DP 5
<b>GE38</b>	Automated decision-making: if processing contains automated decision-making, build a manual process to comply with art. 22 of GDPR.	Mandatory	WP6, WP5/5.5	Privacy & DP 5
<b>GE39</b>	Data protection 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	All WPs that processes personal data	Privacy & DP 5
<b>GE40</b>	Risk management: conduct a DPIA for each pilot and for SHAPES Integrated Care Platform.	Mandatory	WP6, WP4	Privacy & DP 5
<b>GE41</b>	Personal data breach: ensure that SHAPES has a consistent process for handling personal data breaches, including communication to the data subject and to the supervisory authority.	Mandatory	WP8	Privacy & DP 5
<b>GE42</b>	Technical and organisational security measures: identify and document which roles need to have access to personal data.	Mandatory	All WPs that processes personal data	Privacy & DP 5
<b>GE43</b>	Create data protection-related templates: a) DPIA template b) personal data processing descriptions template c) personal data used in service xx d) template for balancing test.	Mandatory	WP8	Privacy & DP 5
<b>GE44</b>	Obligations of the controller: fill the template “Personal data used in service xx” for each service.	Mandatory	WP5, WP6	Privacy & DP 5
<b>GE45</b>	Ensure that privacy and data protection related	Mandatory	WP6, WP7, WP8	Privacy & DP 5

	responsibilities (e.g., NDAs, data processing agreements, data processing descriptions) are covered in service/technology agreements. The same applies to agreements with end-users.			
<b>GE46</b>	Investigate the ethical and legal aspects regarding the secondary use of personal data on the SHAPES for research purposes.	Mandatory	WP8 + EAB	Privacy & DP 5 Other
<b>GE47</b>	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	Other
<b>GE48</b>	Acknowledge the heterogeneity of older persons that materialise in the diversity of how older persons adopt and use digital devices (exclusion and inclusion).	Essential	WP2, WP3, WP5 (5.1)?, WP6	Digital Inclusion 7.1
<b>GE49</b>	Acknowledge the barriers and facilitators of older persons' usage of digital devices (perception of usefulness, user requirements, self-efficacy, sense of self, privacy and confidentiality, cost).	Essential	WP2, WP3, WP5 (5.1)?, WP6	Digital Inclusion 7.1
<b>GE50</b>	Acknowledge and understand the 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? WPx?	Digital Inclusion 7.1
<b>GE51</b>	Design and implement a Security Management Plan for SHAPES.	Essential	WP4, WP3?	Cybersecurity 6
<b>GE52</b>	Employ all appropriate security technologies.	Essential	WP4	Cybersecurity 6
<b>GE53</b>	Ensure the adequacy and quality of security information (suitability for AI).	Essential	WP4, WP5	Cybersecurity 6
<b>GE54</b>	Make sure that situational awareness is always up to date (cognitive domain).	Essential	WP4, WP5	Cybersecurity 6

<b>GE55</b>	Design and implement a Resilience Management Plan that covers all four event management cycles (plan/prepare, absorb, recovery, adapt) and interdependencies with other systems.	Essential	WP3, WP4	Cybersecurity 6
<b>GE56</b>	Ensure that penetration testing is undertaken for software solutions.	Essential	WP6?, WP4	Cybersecurity 6 AI Ethics 4.3
<b>GE57</b>	Investigate and collect user feedback related to services that may be considered intrusive (e.g., facial recognition), risky for autonomy or for depersonalisation or for sense of security (e.g., robots), or associated with a surveillance type of services without one's own control (sensors at home).	Essential	WP6, WP8	Rights 3.1 Ethics of Care 3.2 Capabilities 3.4
<b>GE58</b>	Apply Design for All – approach in SHAPES development	Essential	WP2, WP3, WP4, WP5	Persons with disabilities 3.3 Rights 3.1 Digital inclusion

### 8.3 Ethical requirements for the SHAPES Technological Platform

Table 23 Ethical requirements for the SHAPES Technological Platform

No.	Requirement	Importance	Responsibility	More information in D8.4 sections:
<b>ET1</b>	Ensure equal and non-discriminatory access to technology and its support services by using well-designed user interfaces and authentication.	Essential	WP2, WP3, WP4, WP5	Rights 3.1
<b>ET2</b>	Consider cultural diversity of users; e.g., create avatars that represent different genders and cultures and let the user choose what to use. (TBD)	Essential	WP4	Rights 3.1 Capabilities 3.4
<b>ET3</b>	Create functionalities for the end-user to switch off/on various sensors and services whenever they want to. (TBD)	Mandatory	WP4	Rights 3.1
<b>ET4</b>	Data subject rights: right of access – build a self-service portal where the data subject can get access to his/her data.	Essential	WP4	Privacy & DP 5
<b>ET5</b>	Data subject rights: right to rectification – ensure that the data can be corrected in all places (incl. storage).	Mandatory	WP4	Privacy & DP 5

<b>ET6</b>	Data subject rights: right to be forgotten – build capabilities for deleting personal data.	Mandatory	WP4	Privacy & DP 5
<b>ET7</b>	Data subject rights: right to restriction – build a capability for restricting data processing.	Mandatory	WP4	Privacy & DP 5
<b>ET8</b>	Data subject rights: information provided to third parties – create a functionality to easily get information about the third parties to whom data has been disclosed as part of robust data mapping and flows.	Mandatory	WP4	Privacy & DP 5
<b>ET9</b>	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	Privacy & DP 5
<b>ET10</b>	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	WP4	Privacy & DP 5
<b>ET11</b>	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	Privacy & DP 5
<b>ET12</b>	Data protection principles: accuracy – ensure that the source of the data is recorded.	Mandatory	WP4	Privacy & DP 5
<b>ET13</b>	Legal basis: a) ensure that there are sufficient technical 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). Note that there are also users who cannot give their own consent but it is given by a legal representative.	Mandatory	WP4, WP6?	Privacy & DP 5
<b>ET14</b>	Create traceability capabilities for personal data; data mapping/data flows.	Mandatory	WP4	Privacy & DP 5
<b>ET15</b>	Automated decision-making: Ensure that there's a capability	Mandatory	WP4, WP5, WP6?	Privacy & DP 5

	to re-direct the decision to a manual process.			
<b>ET16</b>	Data protection by design and by default: ensure that data-protection aspects are considered when designing and developing technological solutions by adding data-protection checkpoints to the development process.	Mandatory	WP4	Privacy & DP 5
<b>ET17</b>	Data protection by design and by default: add data protection section to “application portfolio” to describe if personal data is processed in the application and if yes, to add additional information such as sensitivity of the data, legal basis for processing data, retention period, link to data maps etc.; detailed information to be added will be defined with the WP8.	Mandatory	WP4	Privacy & DP 5
<b>ET18</b>	Personal data breach: create capabilities to identify potential personal data breaches and identification of personal data breaches.	Mandatory	WP4	Privacy & DP 5
<b>ET19</b>	Technical and organisational security measures: ensure that the IAM (identity and access management) can be used for limiting access to certain categories of personal data and the need to restrict access to certain data is taken into consideration in SHAPES architecture.	Mandatory	WP4	Privacy & DP 5
<b>ET20</b>	Create logs for personal data (e.g., who has seen/modified personal data and when).	Mandatory	WP4	Privacy & DP 5
<b>ET21</b>	Deploy the functionalities related to the trustworthy AI guidelines (TBD later).	Mandatory	WP4, WP5	AI Ethics 4.3
<b>ET22</b>	Utilise the AI solutions also to provide self-diagnosis of the SHAPES’s security and other issues.	Optional	WP4, WP5	AI Ethics 4.3
<b>ET23</b>	Deploy the functionalities related to cybersecurity (TBD later).	Mandatory	WP4, WP5	Cybersecurity 6

## 8.4 Ethical requirements for user processes and support

Table 24 Ethical requirements for the user processes and support

No.	Requirement	Importance	Responsibility	More information in D8.4 sections:
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<b>PE1</b>	Create 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?	Capabilities 3.4 Customer Logic 4.2
<b>PE2</b>	Create 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 for the collection of the information.	Mandatory	WP3?	Persons with disabilities 3.3
<b>PE3</b>	Provide for the end-user (older persons) plain language materials, information in visual form (including information on each service and how it operates and what data it collects.)	Mandatory	each service provider & WP3?	Persons with disabilities 3.3
<b>PE4</b>	Create training material on data protection to end-users who need to understand data protection (older persons, caregivers).	Mandatory	WP8	Privacy and DP 5
<b>PE5</b>	Provide training (materials) related to cybersecurity requirements (TBD).	Mandatory	WP8	Cybersecurity 6
<b>PE6</b>	Create a process for executing data subject rights in SHAPES (e.g., access to data).	Mandatory	WP8, WP6, other?	Privacy & DP 5
<b>PE7</b>	Define skills and specific competences needed for the care givers using the SHAPES services and provide training materials.	Essential	WP3?	C workers 7.3

## 8.5 Ethical requirements for the governance, business and ecosystem models

Table 25 Ethical requirements for the governance, business and ecosystem models



No.	Requirement	Importance	Responsibility	More information in D8.4 sections:
<b>ME1</b>	Create the SHAPES Code of Conduct that outlines the value base and key principles of the SHAPES (to be utilised especially after the SHAPES project itself has ended and the exploitation begins).	Mandatory	WP8	D8.4
<b>ME2</b>	Create a process to conduct SIA (Societal Impact) of the SHAPES Integrated Care Platform on a regular basis.	Mandatory	WP3	Sust. development 4.1
<b>ME3</b>	Adopt customer logic in the building and expansion of the SHAPES Integrated Care Platform. Pay attention to the fact that even the most vulnerable should be able to use SHAPES (>also money needed for home equipment). Understand the different cultures of health assistance and modify the SHAPES Integrated Care Platform accordingly.	Essential	WP3, WP7, WP9	Customer Logic 4.2 Sust.development 4.1 Rights 3.1 Capabilities 3.4
<b>ME4</b>	Create a process to ensure that members of the SHAPES ecosystem (during the open calls and after the project) have the capabilities to comply with mandatory ethical requirements.	Mandatory	WP7	D8.4
<b>ME5</b>	Define responsibilities regarding the SHAPES and each of its various services (e.g., if something goes wrong). This includes processes related to the personal safety solution that require organisational arrangements.	Mandatory	WP3?	AI Ethics 4.3 Rights 3.1
<b>ME6</b>	Create processes and guidelines regarding the incidental findings when using or analysing SHAPES data.	Mandatory	WP8	D8.2
<b>ME7</b>	Establish a management model for AI governance.	Mandatory	WP3	AI Ethics 4.3
<b>ME8</b>	Define roles and responsibilities of controllers and processors in SHAPES.	Mandatory	WP3	Privacy & DP 5
<b>ME9</b>	Define governance for handling requests of data subjects (rights).	Mandatory	WP3	Privacy & DP 5
<b>ME10</b>	Organise Data Protection and Privacy Impact	Mandatory	WP3	Privacy & DP 5

	Assessment (DPIA) of each SHAPES configuration.			
<b>ME11</b>	Create and update “The Privacy Information” section in SHAPES website.	Mandatory	WP10	Privacy & DP 5
<b>ME12</b>	Nominate a DPO (data protection officer) for each pilot (and after the project, for each SHAPES ecosystem). Pay attention; After the project, the individual SHAPES solutions are owned and governed by their respective providers that may not be SHAPES partners. This last part cannot be verified and therefore should not be a mandatory requirement. But it can be included in SHAPES Code Of Conduct.	Mandatory	WP6, WP8	Privacy & DP 5
<b>ME13</b>	Nominate a data owner for each WP (see DMP).	Mandatory	Every WP	Privacy & DP 5
<b>ME14</b>	Create and implement the cybersecurity and resilience management of the SHAPES Integrated Care Platform (TBD).	Mandatory	WP4?, WP3	Cybersecurity 6

## 9 Conclusion

In this deliverable, the ethical aspects of the SHAPES Integrated Care Platform have been discussed. On the basis of these contents and arguments, SHAPES ethical requirements have been defined. Altogether 101 requirements have been identified. The purpose of these ethical requirements is to ensure that SHAPES becomes a positive innovation for various end-users, service providers and society.

The ethical requirements defined in this first version of “SHAPES Ethical Framework” (D8.4) are intended to launch a more detailed discussion of the ethics of SHAPES with its developers during the first 1.5 years of the project. Based on those requirements, various technical notes are also to be produced as part of WP8, if necessary, to support the implementation of the requirements as features of the SHAPES Technical Platform and of the SHAPES Marketplace and Ecosystem. The updated and final version of this deliverable is to be provided in M18.

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