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D8.2 ODIN Policy, Legal and Ethics Framework

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Key data

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Abstract

This deliverable represents the Policy, Legal and Ethics framework of the ODIN project. After an analysis of the current social and digital context, in which the project operates, the deliverable surveys the policy ecosystem, which is relevant for the consortium. An introduction to the ODIN ethics framework and legal context is also offered. The deliverable also describes the role of the ODIN Policy, Ethics, Legal and Gender Board and includes its terms of reference.

Statement of originality

This deliverable contains original unpublished work except where clearly indicated otherwise. Acknowledgement of previously published material and of the work of others has been made through appropriate citation, quotation, or both.

Table of contents

List of tables

List of figures

1 Introduction

Aging, multiple chronic conditions, workforce shortages, and the rise of preventable diseases caused by tobacco, alcohol, and obesity are only some of the challenges the European health and care systems are facing right now. Current healthcare structures are no longer adequate to withstand health threats of a global dimension, and the outbreak of the COVID-19 pandemic showcased that without fundamental rethinking and restructuring, the system is doomed to fail. Significant reforms in the sector are essential also from a financial point of view, as GDP expenditure on health is expected to grow significantly and put significant pressure on European financial models. Shifting the care model from hospital-based to community-based is going to help citizens remain in good health instead of directly turning them into patients. Essential for solving problems the healthcare is already facing, or will be very soon, the implementation of information, computer, or communication technology, also referred to as e-Health. Key for achieving a transition to a person-centred healthcare model are digital technologies and digitalisation. For example, wearables and Mobile Health (mHealth) apps are already popular digital solutions, which help users to actively engage in health promotion and monitoring. These tools are beneficial for disseminating knowledge in an easily accessible and understandable form, allowing citizens to better monitor and even self-manage chronic conditions. Furthermore, new technologies allow for wider use of genomic and other information such as molecular profiling, diagnostic image, environmental and lifestyle data, which lets medical doctors and scientists acquire a superior grasp of different diseases and find ways to predict, prevent, diagnose, and treat them more efficiently. Once a person becomes a patient, technology makes prescription of a personalised medicine possible. However, to seize the full measure of opportunities these innovations and the digital single market grant us, we should know where and how exactly to implement them. To achieve this, apart from the joint engagement of many different actors and financial investments, we need high quality data and appropriate regulatory frameworks within the EU. Though obtaining high quality data is a problematic issue, as it is managed differently by each Member State and therefore often not available to neither medical authorities and researchers, nor to even patients themselves. Some of the digital tools do enable citizens to provide feedback and data about their health to their doctors but this practise is still conducted on a smaller scale, and only by itself it is insufficient. In order to really achieve a swift deployment of innovative digital health solutions, there is a great need for EU-wide exchange of experience and best practise, as well as citizens' data and follow-up results of the impact of certain implementations. Further, data substantially depends on the utilized technology, which is a lot of times interoperable across Member States. A rather social issue on the implementation of digital technologies to health is citizens' concerns about the integrity of their data, especially in terms of its electronic transfer due to potential privacy breaches, and other cybersecurity risks. The GDPR should have provided trust, as it puts data owners in control of their personal data, including their health data. Even so, the problem of fragmented and incomprehensive data records, and the lack of standardised electronic health records remains, which leaves great need for adoption of a safe and secure European electronic health record exchange format. If there are appropriate safeguards in place, people will feel more confident to share their data for research. It is against this background and in this context that the ODIN project will develop its activities.

1.1 The ODIN Project

The ODIN project will focus on identified hospitals' critical challenges which will be faced by combining robotics, Internet of Things (IoT) and artificial intelligence (AI) to empower workers, medical locations, logistics and interaction with the territory.

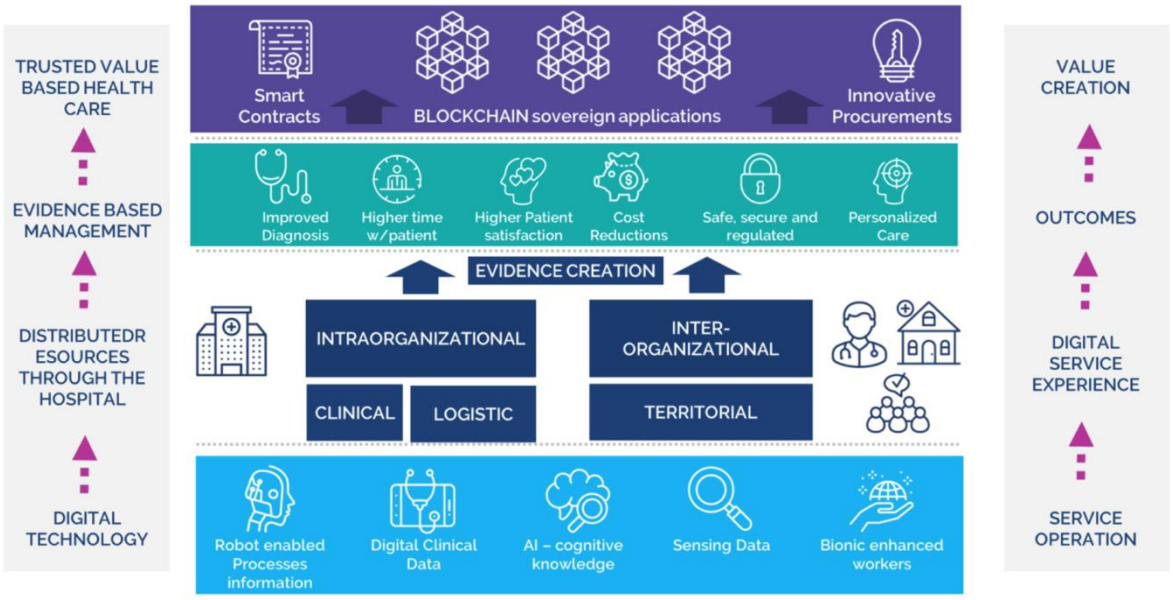

Figure 1: Visualisation of the ODIN Project

As shown in the figure above, numerous ethical issues emerge from the ODIN project, in relation to the AI and robotics fields, techniques, approaches and methods; their physical technological products and procedures that are designed for practical applications; and the uses and applications of these products and procedures. The international debate has focused on a broad range of ethical issues, which include potential harms to autonomy, dignity, and privacy, moral responsibility, and overall wellbeing, but also justice, equality, explainability, transparency, safety, accountability, liability, privacy, and data protection. This reflects the international academic debate, that is now including potential broad-scoped solutions to ethical issues, including through laws, standards, and regulation, as well as through ethics by design and implementation of moral reasoning systems in robots and AI systems.

To reflect on these concerns, the dedicated Work Package (WP) 8 of the project, will overview the project throughout its entire lifetime, encompassing three tasks: T8.1 on "Legal Aspects on Data Processing", T8.2 on "Certification and Standardization", and T8.3 on "Data Ethics". Both T8.1 and T8.3 have already started at M1, as they play crucial role for the overall execution of the project. Below, a figure visualizes the WP distribution in the project and the interconnection between the work packages. As it can be seen, WP8 actuates as an ethical and legal umbrella on the other actions.

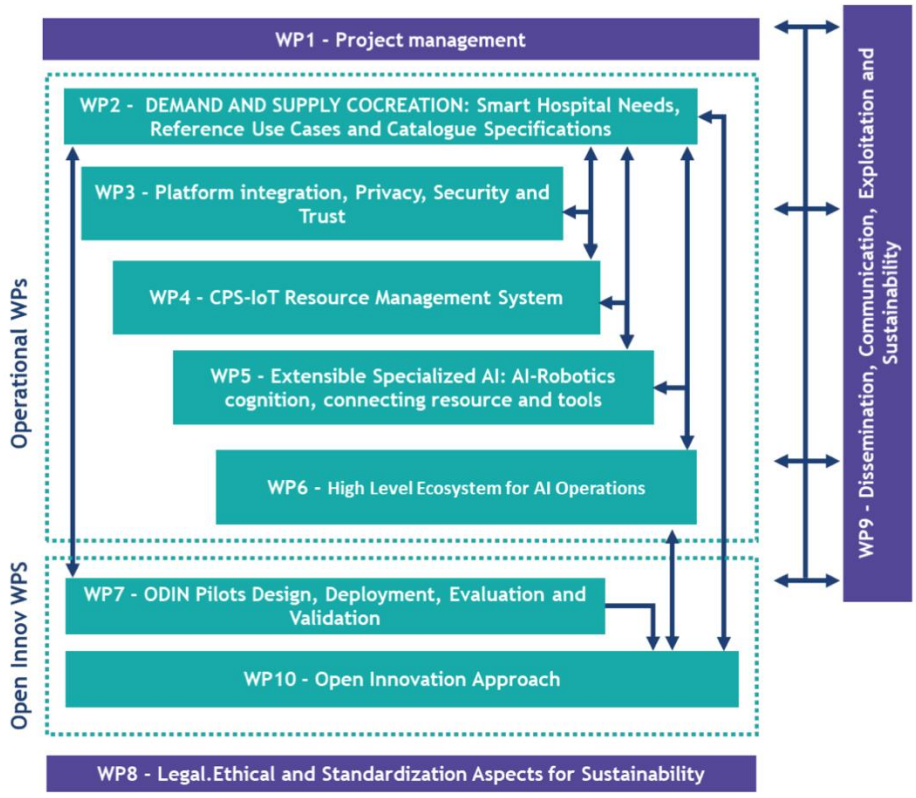

Figure 2: Work Packages Structure

1.2 About this Deliverable

The current deliverable aims at mapping regulatory, privacy and ethical initiatives, relevant for the ODIN project, taking into consideration its mission, strategical approach, deployment of emerging technologies, and exploitation and sustainability goals. It is directly related to Task 8.1, which is dedicated on establishing the ODIN Policy, Legal and Ethics Framework (PLEF). To successfully achieve this, it is important to address partners' concerns from legal, ethical and privacy perspective, in order to fully align ODIN with current and upcoming EU Regulations and initiatives and be able to swiftly adapt to the changing regulatory environment. This current deliverable document covers global and European initiatives in e-health, such as WHO's Strategy on Digital Health for the time period 2020-2025, current actions and challenges around the deployment of robots in the health domain, and the European Health Data Space, but also accounts for the impact of crisis such as Covid-19. The collected findings flow and consolidate into 6 ethics principles, which constitute the ODIN ethics framework, and by which the project's consortium and its pilots will abide. Moreover, the current deliverable has initiated the creation of a dedicated Policy, Legal, Ethical and Gender Board, described in section 4.3. Finally, the deliverable introduces instruments on data protection and their requirements. The figure below provides a clear overview of the methodology.

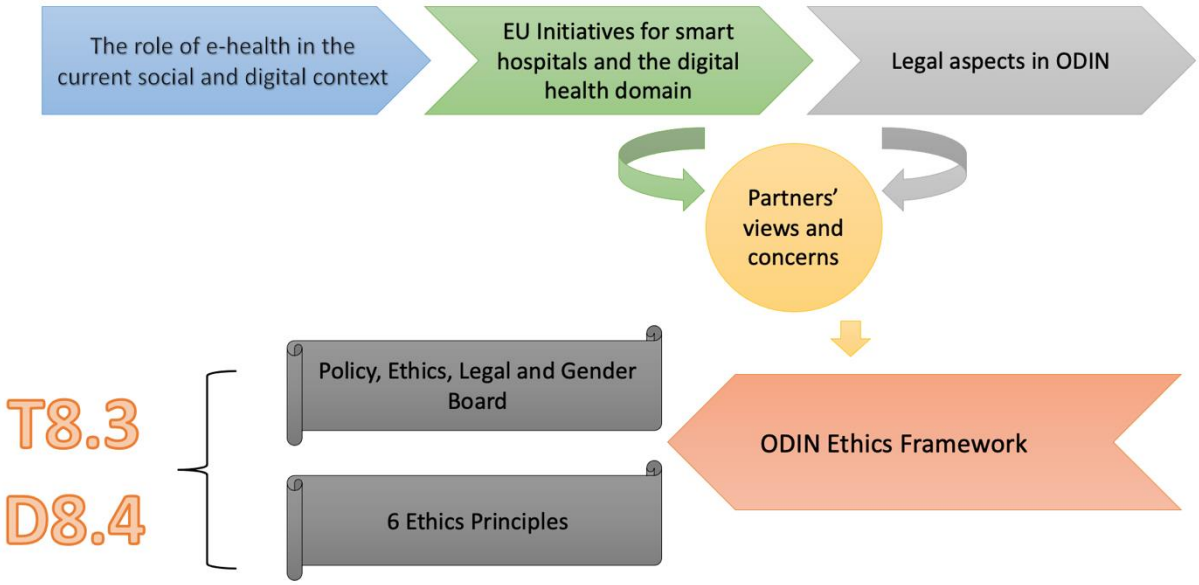

Figure 3: Methodology Overview

There will be only one version of this deliverable. However, the identified guiding principles serve as base for future deliverables, such as the Data Management Plan (D1.2) by M10, the Data Ethics in public procurement hospitals (D8.4) by M14, which will be continuously updated throughout the project, and will support and facilitate the work of T8.3 on Data Ethics. A timeline indicating the milestones, to which D8.2 is relevant to, is provided below.

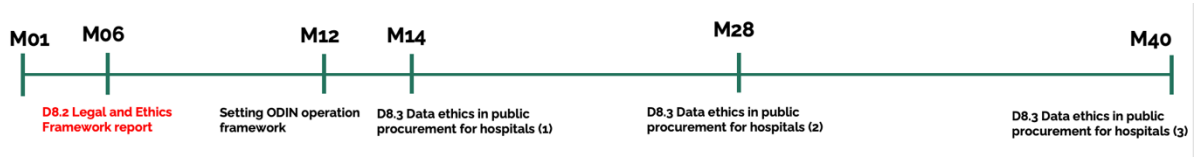

Figure 4: Timeline of relevant deliverables

1.3 Deliverable context

Table 1 puts the current deliverable D8.2 into the context of the whole project, outlining its relation to the project's overall goals, methodology, and expected result exploitation.

Table 1: Deliverable context

PROJECT ITEM	RELATIONSHIP
Objectives	This deliverable sets and describes the ODIN Policy, Legal and Ethics Framework and constitutes a reference point for the implementation of the action by pilots and partners.
Exploitable results	There is no specific contribution to any exploitable results. Instead, this document is the basis defining the policy, legal and ethical ecosystems that partners are called to consider.
Workplan	D8.2 is attributed to the tasks of WP8, Legal, Ethical and Standardization aspects for Sustainability. The tasks involved in the preparation of this deliverable are the following: T8.1 Legal aspects of data processing T8.3 Data Ethics
Milestones	D8.2 is a key deliverable of the PREPARATION phase of the project.
Deliverables	D8.2 defines the policy, legal and ethical ecosystem of the project. It is also connected to other deliverables of the WP such as D8.1; D8.3; D8.4; D8.5; D8.6 and establishes interconnections to ethical, security and personal data protection requirements detailed by the European Commission in WP 11, D11.1, D11.2 and D11.3. The provided outcomes will be further leveraged on in D1.2.
Risks	As a facilitator of the collaborative work within the project, D8.2 reduces project risks generally and sets key values to be considered by the partners. Thus, partners not considering important Ethic, Legal and Equality aspects described here is a significant risk. To avoid this, the project, and its Policy, Legal, Ethics and Gender Board should revisit this deliverable (and associated deliverables on similar topics) and ensure it is considered for future work of all partners.

2 The role of e-health in the current social and digital context

The data-driven and evidence-based hospital will be built in synergy with on-going global and European initiatives which will be important for ODIN to be synchronized with. This section frames the context and explains the centrality of robotics in the context of ODIN.

2.1 Global and European initiatives on e-health

Many countries in the world are developing policy strategies to advance the deployment of e-health solutions. This trend was also recently underlined by the World Health Organization (WHO) that in April 2019 released a draft Global Strategy on Digital Health (2020-2024) with the vision to "improve health for everyone, everywhere by accelerating the adoption of appropriate digital health". The Strategy was adopted in 2021 for the period 2020-2025. According to the Strategy: "Digital transformation of health care can be disruptive; however, technologies such as the Internet of things, virtual care, remote monitoring, artificial intelligence, big data analytics, blockchain, smart wearables, platforms, tools enabling data exchange and storage and tools enabling remote data capture and the exchange of data and sharing of relevant information across the health ecosystem creating a continuum of care have proven potential to enhance health outcomes by improving medical diagnosis, data-based treatment decisions, digital therapeutics, clinical trials, self-management of care and person-centred care as well as creating more evidence-based knowledge, skills and competence for professionals to support health care"[1].

The WHO has identified four guiding principles with the aim to orient the global strategy towards the appropriate and sustainable adoption of digital health technologies in the context of the national health sector and health strategies. The identified principles are the following:

- Acknowledge that institutionalization of digital health in the national health system requires a decision and commitment by countries;
- Recognize that successful digital health initiatives require an integrated strategy;
- Promote the appropriate use of digital technologies for health;
- Recognize the urgent need to address the major impediments faced by least-developed countries implementing digital health technologies.

These principles will guide the different actors towards the achievement of the strategic objectives identified by the strategy. For each objective the strategy has identified policy options and actions and specific outputs. The objectives highlighted in the strategy are:

- Promote global collaboration and advance the transfer of knowledge on digital health;
- Advance the implementation of national digital health strategies;
- Strengthen governance for digital health at global, regional and national levels;
- Advocate people-centred health systems that are enabled by digital health;

[1] WHO, *Global Strategy on digital health 2020-2025*, 2021, p.8.

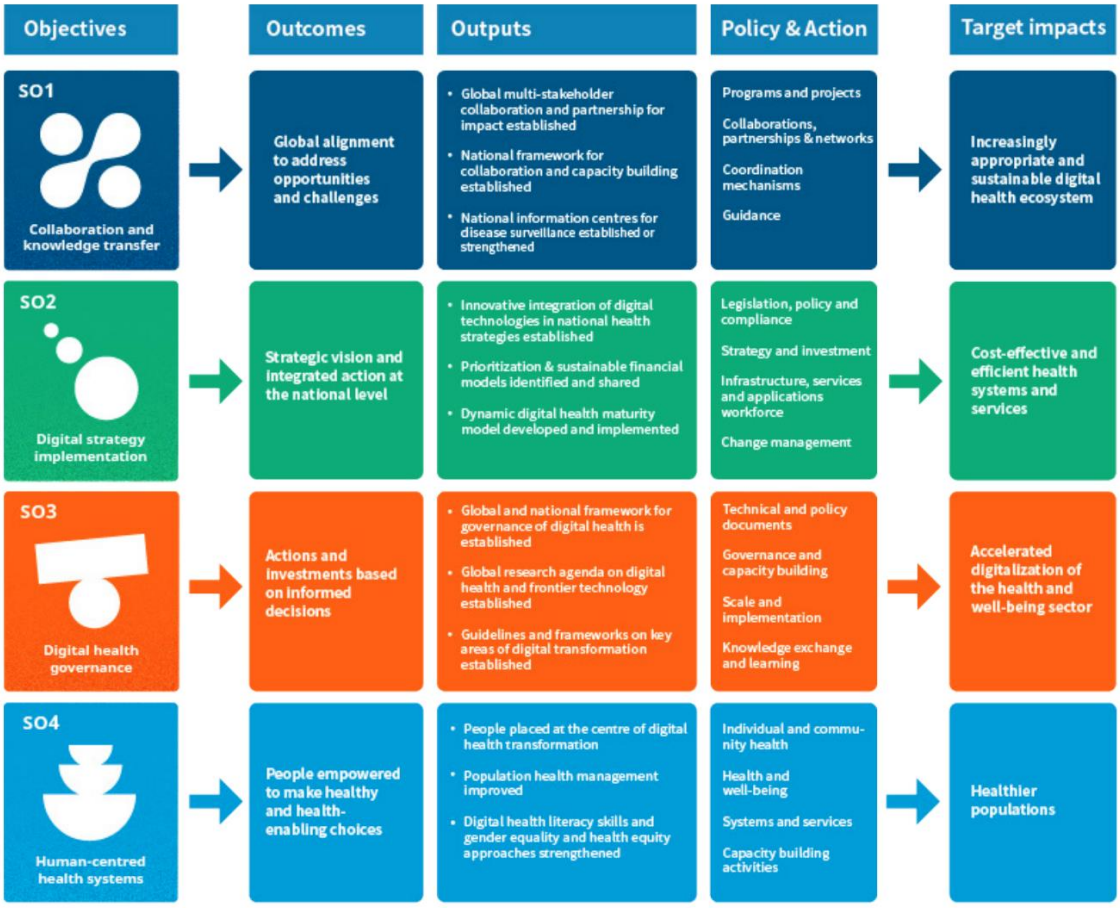

Figure 5: Summary of the implementation of the WHO action plan[2]

As we will see, the European Union (and the Member States) are responding to the challenges posed by the deployment of digital health technologies, and this is also reflected in the new European policy context that ODIN will need to take into consideration, and which is analysed in section 3 of this document.

[2] WHO, *Ibid*., p. 32.

2.2 Robotics in e-health

Robots have been in use in the healthcare sector for some time, operating essentially behind the scenes. Indeed, the introduction of robotics in healthcare is not new, as the first example of a Computer-Assisted Surgery (CAS) medical platform, integrating patient-specific images, was presented in 1988 by Yik San Kwoh et al[3]. In such a milestone, an industrial Unimate Puma 200 anthropomorphic robotic arm (Unimation Inc., U.S.A. – company founded in 1962 by Joseph F. Engelberger and George Devol[4]), properly interfaced with a CT scanner and with a surgical probe mounted at its end effector for CT-guided brain tumour biopsy, successfully performed faster and with more accuracy if compared to a manually-performed procedure.

Robots in the healthcare field are today transforming how medical practices are performed, streamlining supply delivery and disinfection, and freeing up time for practitioners to engage with patients. In particular, over the last years, AI-enabled data science and analytics have transformed healthcare robotics, expanding their physical capabilities and the range of possible applications. Robots are used not only in the operating room (*e.g.*, daVinci surgical robot, Intuitive Surgical Inc., U.S.A. or Medtronic's Hugo), but also in clinical settings to support health workers and enhance a more longitudinal patient care. For instance, during COVID-19 pandemic, robots were deployed in clinics and hospitals to help reducing the exposure to pathogens and it became more evident the operational efficiencies, risk reductions and potentialities in general provided by e-health robotics.

Robotics in e-health will continue to evolve alongside advancements in machine learning, data analytics, computer vision, and other technologies. So far, a possible classification of robotics could consider: 1) *surgical-assistance robots*, such as for minimally-invasive abdominal and orthopaedic procedures, 2) *wearable/implantable robots*, such as therapeutic exoskeleton robots and prosthetic robotic arms and legs, 3) *service robots* to support healthcare workers by handling routine logistical tasks, such as set up patient rooms and restock medical supply cabinets, 4) *social robots*, interact directly with humans in long-term care environments to provide social interaction and patient monitoring, and 5) *mobile robots* for heavy and repetitive tasks, such as disinfecting rooms, helping transport patients, or moving heavy machinery.
In terms of regulations and ethics, a series of regulatory issues shall be addressed "by design" (*i.e.*, since their development) in order to be able to achieve all the organizational and technical requirements "by default"[5] that are functional to put the given e-health robot in the market[6]. These processes are identified as "compliance activities" with an applicable framework that generally includes technical norms to achieve an acceptable level of safety (mainly recognised by ISO standards), as well as a complex system of binding obligations, whose violation determines consequences in terms of administrative and/or criminal and/or civil sanctions (*e.g.*, pecuniary ones)[7]. In this regard, in the EU, both the Proposal for the so-called Artificial Intelligence Act (COM/2021/206 final) and the one on Machinery Products (COM/2021/202 final) adopt the same

[3] Y.S. Kwoh, J. Hou, E.A. Jonckheere, and S. Hayati, *A Robot with Improved Absolute Positioning Accuracy for CT Guided Stereotactic Brain Surgery*, IEEE Trans. Biomed. Eng., vol. 35, no. 2, pp. 153-160, 1988.
[4] "*Unimate - The First Industrial Robot.*" [Online]. Available: https://www.robotics.org/joseph-engelberger/unimate.cfm. [Accessed: 20-Nov-2020]
[5] EDPS, *Preliminary Opinion on\Privacy by Design and Privacy by Default*, 5/2018," 2018 and also EDPS, *EDPB, Guidelines 4/2019 on Article 25 Data Protection by Design and by Default*, Version 2.0, 20.10.2020
[6] H. R., *Intercultural User Interface Design*. Springer International Publishing, 2019.
[7] D. Amram, *Building up the 'Accountable Ulysses' model. The impact of GDPR and national implementations, ethics, and health-data research: Comparative remarks*, Comput. Law Secur. Rev., vol. 37, p. 105413, Jul. 2020.

risk-based approach aiming at firstly identifying possible attempts to the involved fundamental rights (dignity, health, private life, work life, data protection and privacy, etc.), providing then a series of obligations to address critical effects. In particular, at this stage, the level of trustworthiness could be assessed through the developed soft-law guidelines and provisions, such as in the case of the "*Report on the safety and liability implications of Artificial Intelligence, the Internet of Things and Robotics*", accompanying the "*White Paper on Artificial Intelligence: a European approach to excellence and trust*"[8]. Then, a conformity assessment is required to obtain the proper CE marking.

All these grounds of assessment shape the so-called "accountable approach" (*i.e.*, the legal principle standing for "responsible one", "appropriately trusted"), to which the ODIN Consortium is fully committed to boost a human-centric approach towards technologies and avoid any consequences in terms of liability in case of unforeseen implications of the system. At the same time, the accountable approach allows to address the research and innovation purposes of the project towards the ODIN solutions among users/stakeholders.
The main expected benefit of robotics in the healthcare sector is to enable high-quality patient care, efficient processes and operations in clinical settings, and a safe environment for both patients and health workers[9]. In conclusion, the disruptive impact of robots and technologies would improve the efficiency of a healthcare service, strengthening the accuracy and automation of clinical tasks, under the condition that continuous impact assessments under the applicable regulatory frameworks, technical standards, and ethical issues are addressed by design (during their development) and tailored to the given circumstances by default[10].

[8] EU Commission, White Paper On Artificial Intelligence - A European approach to excellence and trust, 19.2.2020," 2020.
[9] G.-Z. Yang et al.,Medical robotics—Regulatory, ethical, and legal considerations for increasing levels of autonomy, Sci. Robot., vol. 2, no. 4, Mar. 2017.
[10] D. S. Sebastian Lohsse, Reiner Schulze, Liability for Artificial Intelligence and the Internet of Things. NomosHart, 2019.

3 ODIN policy context and current European initiatives

This section discusses the most relevant policy initiatives that ODIN is called to consider in the deployment of its activities. The ODIN strategic vision and approach should aim to address all of them.

3.1 The EU programme for health

EU4Health is the fourth EU eHealth programme, it will run from 2021 to 2027. It will be particularly important for ODIN to coordinate its initiatives with ongoing activities in the context of EU4Health. The programme is focused on improving and fostering health in the EU by:

- protecting people from serious cross-border health threats;
- improving the availability, accessibility and affordability of medicines, medical devices and other crisis relevant products in the EU;
- strengthening the national health systems.

Several actions will be focused on the digital transformation of healthcare delivery by:

- strengthening health data, the uptake of digital tools and services and the digital transformation of the healthcare systems, including by supporting the creation of a European Health Data Space;
- promoting the implementation of best-practices and promoting data sharing;
- enhancing access to quality, patient-centered, outcome-based healthcare and related care services;
- support integrated work among Member States and in particular their health systems.

All these aspects will be considered in the context of the ODIN deployment and in the adaptation to the policy ecosystem also for reasons of long-terms sustainability with the aim to maximize the impact of the project and the benefits for the partners and the society at large. The deployment of e-health solutions will be key in addressing the challenges of an ageing population and health inequalities. In this context ODIN will need to liaise also with the newly established European Health and Digital Executive Agency which will play a key role in the context of the European e-health deployment.

3.2 COVID-19 impact on e-health policies

Covid-19 has significantly shifted public health policies worldwide. Although different States have deployed different solutions and provided different answers, one commonality is the growing role of digital health solutions. Member States of the European Union have undertaken a coordinated action to facilitate the deployment of treatments and vaccines and accelerated the transition to the deployment of digital health solutions. The Covid-19 pandemic, among other things, has

highlighted the importance of having timely access to health data for research and policy making purposes and therefore the European Council has recognised this urgency to make progress towards the European Health Data Space (see section 3.3).

An important role in the context of the Covid-19 has also been played by the deployment of the EU digital COVID certificate regulation which entered into application on July 1st 2021. Through this regulation EU citizens and residents are able to have their digital COVID certificates issued and verified across the EU. In the context of the deployment of the certificate, national authorities have shown important synergies which could be replicated in other e-health related efforts. For instance, Member States have agreed on a common design that can be used for the electronic and paper version of the certificate in order to facilitate its recognition. The development of the certificate has also been an important exercise for privacy by design in the field of e-health: in fact, the certificate contains only key information such as name, date of birth, date of issuance, information on vaccine/test/recovery and a unique identifier. The data remains on the certificate and when the certificate is verified in another Member State it is not stored.

3.3 The European Health Data Space

The creation of a new European Health Data Space is one of the priorities for the European Union in the years 2019-2025. The creation of such a data space aims at facilitating the exchange of different types of health data (electronic health records, genomics data, data from patients' registries). The data space will therefore support health delivery (primary use of data) but also scientific research and the development of health policies (secondary use of data). The European Health Data Space will be built around three main principles:

- a strong system of data governance and rules for data exchange;
- data quality;
- strong infrastructure and interoperability.

The creation of such data space is key to the announcement made by the Commission with the Communication on the European Strategy for Data which aims to address issues such as the collection, access, storage, use and re-use of data. The achievement of the objectives of the Data Strategy requires a regulatory framework that serves individual interests and rights especially considering the processing of sensitive personal health data. Therefore, the Commission also adopted the Data Governance Act proposal (2020) with conditions regarding access to data, and provisions to foster trust in voluntary data sharing. The upcoming regulatory framework will tackle barriers that are specific to the exchange of health data and the use of digital services. Among them the impact assessment produced by the Commission has highlighted:

- insufficient health data exchange negatively impacts on the provision of healthcare services (primary use of data);
- need to provide a framework to exercise access and control over their own health data for the patients;
- address the fragmentation of digital standards and limited digital interoperability between healthcare systems;

- access to, and exchange of, health data for scientific research and innovation, policy-making and regulatory activities which remains very limited in Europe (secondary use of health data).

Many analyses have underlined how the current fragmentation is not helpful in the logic of European single market. In fact, the free movement of people, products and services can be ensured when people can take their health data with them and when health data can move and be accessed cross-border considering data protection rules and the need for security. The current fragmentation can be faced with an initiative at the EU level.

Digital Health Europe has developed a set of more than 30 recommendations on the emerging European Health Data Space[11]. The recommendations, which are worth taking seriously into account as they cover a variety of topics. Among them:

- Adapt the legal framework for trustworthy data collection, access and uses;
- Accelerate interoperability across Europe and globally;
- Support large scale implementation pilots and health data infrastructures;
- Support large scale implementation through specific focus projects and coordination and support actions;
- Establish a European Digital Health Hub;
- Scale up research and innovation to advance Europe's digital capacity for clinical research.

To address the European Data Strategy, published in February 2020[12], several initiatives have been created. Among them the International Data Spaces Association (IDSA)[13] is one of the most important at the moment. The IDSA, a non-profit organization, aims at promoting the International Data Spaces Reference Architecture Model (IDS-RAM)[14] to establish an international standard. ODIN platform aims at contributing to a single market for healthcare data (e. g. IDSA) that will ensure Europe's global competitiveness and data sovereignty.

[11] Digital Health Europe, *Digital Health Europe's Recommendations on the European Health Data Space*, July 2021, available at: https://digitalhealtheurope.eu/wp-content/uploads/DHE_recommendations_on_EHDS_July_2021.pdf.
[12] European Data Strategy, https://ec.europa.eu/info/sites/default/files/communication-european-strategy-data-19feb2020_en.pdf
[13] International Data Space Association, https://internationaldataspaces.org/
[14] IDS Reference Architecture Model, https://internationaldataspaces.org/wp-content/uploads/IDS-Reference-Architecture-Model-3.0-2019.pdf.

4 ODIN Ethics framework

This section outlines the core of the ODIN Ethical approach also describing the institutions (Policy, Ethics, Legal and Gender Board) that will play a key role in the deployment of the ethics framework. ODIN will therefore take into account the complex ethical framework applicable to the e-health domain, based also on the experience of previous and on-going research projects such as GATEKEEPER which have mapped and developed ethical frameworks applicable to the field. The principles identified in this deliverable are based on those experiences and adapted to ODIN. They will be further developed in the context of the project with the feedback received from the different partners.

4.1 Introduction

In the context of its deployment ODIN will need to consider overlapping normative environments. On one hand, it should operate in the context of an ethical framework which aims at safeguarding and promoting a set of values that will contribute to generate and maintain trust among end-users and the different stakeholders. ODIN should also guarantee compliance with applicable legal norms. To guarantee the constant analysis of its framework and the normative environment, ODIN will establish a Policy, Ethics, Legal and Gender Board that will coordinate the work in this area. The board has approved its terms of reference in its first meeting and will adopt a yearly plan that will be communicated to the management team. This will sustain the action of the project in the deployment of its ethical framework.
This board will complement the continuous support to the ODIN partners with any ethical issue that may appear during the implementation of the different components, as well as those that may appear during the exploitation phases to both the project partners and the partners that join through the Open Innovation approach.

4.2 ODIN Policy, Ethics, Legal and Gender Board

The Policy, Ethics, Legal and Gender Board is formed by legal experts from industry and demand users of the consortium (one per local pilot), as well as by policy makers and gender equality officers from the demand cities in the consortium. The work will be carried out in the context and resources of WP8. In the context of its first meeting held on July 28th, 2021, approved its terms of reference that will govern its working procedures.

Table 2: Composition of the Policy, Ethics, Legal and Gender Board

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In order to facilitate the work of this board the following terms of reference have been approved:

4.3 Terms of reference for the ODIN Policy, Ethics, Legal and Gender board

This board is coordinated by and linked with the work of the **Ethical and Trusted Data Manager (ETDM) (UDGA) position currently held by MA. M.Sc. Adrian Quesada Rodriguez and Ms. Stea Miteva**, will be jointly responsible (with the support of the Policy, Ethics, Legal and Gender Board) for dealing with the following issues: a) Legal aspects: the legal issues associated to the deployment of ODIN tools and actions (e.g. IPR, data protection and access, privacy issues, ethical aspects, etc.), b) Policy issues: how new policies could help innovative smart living technologies get users acceptance and market uptake, Gender issues: the ETDM will be responsible to supervise the implementation of the gender equality policy of the project; and c) ethical, security and data management concerns in data management.

Purpose

1. To ensure proper ethical, legal and gender management in the context of the ODIN project;

2. To provide and encourage the use of resources that promote discussion and resolution of ethical and legal situations that are encountered in the context of the activities of the project;

3. To provide a forum to facilitate information flow and debate on gender equality initiatives within the project and in other research projects of relevance for the researchers of the partners organizations;

4. To contribute to policies and decisions to ensure they reflect ethical principles;

5. To support ethics case consultation and ethics review;

6. To support ethics education

Responsibilities

1. To participate and provide input into policy, procedures and governance processes;

2. To partner with the pilots involved in the project and contribute to their resolution of ethical and legal issues;

3. To provide regular awareness activities that would inform all stakeholders of ethics recommendations, activities and changes within the project;

Accountability

The Board is accountable to the management team and to all the researchers involved in the activities of the project;

Membership

The membership of the board has been defined in par. 4.2. Members of the project can be invited as guests to the sessions of the board.

Procedures

Confidentiality: All matters discussed by the Board will remain private and confidential. Recommendations generated by the board will be shared with the appropriate stakeholders.

Frequency: A minimum of 6 meetings will be held per year. Additional meetings may be held at the call of the chair.

Quorum: A simple majority.

Reporting: Minutes of the meetings will be created and uploaded in the Alfresco repository.

Recommendations: Will be forwarded to the relevant stakeholders and to the management team.

Sub-Committees: If needed, the Board may create ad hoc sub-committees as required.

Terms of Reference: The Terms of Reference will be reviewed annually.

Workplan: A work plan will be prepared and reviewed annually.

4.4 ODIN ethical strategy

The ODIN project combines partners from different countries who adhere to different ethical principles and procedures and have distinct ways of dealing with ethical dilemmas. Therefore, rather than proposing a detailed "top-down" approach, in accordance with international documents and charters, we will follow an inductive approach which will also allow a constant adaptation of our framework. In this way it will be possible to identify affinities and differences between countries and an attempt will be made to achieve a uniformity not perceived as an imposition for anyone but negotiated by everyone. Common ground principles will be however detailed and considered. The ethical framework and strategy deployed by the ODIN project will also consider previous and on-going research experiences. Several partners of the consortium are involved in the GATEKEEPER project and in its work concerning legal and ethical compliance. The principles identified in the context of the GATEKEEPER project[15] can constitute a valuable resource also for the ODIN consortium. Below the main principles applicable to the ODIN project and which will inform its ethical strategy are reproduced.
The deployment of ODIN solutions will need to consider the principles highlighted by the WHO in its recent Global Strategy on digital health according to which: "The appropriate use of digital health takes the following dimensions into consideration: health promotion and disease prevention, patient safety, ethics, interoperability, intellectual property, data security (confidentiality, integrity, and availability), privacy, cost-effectiveness, patient engagement, and affordability. It should be people-centered, trust-based, evidence-based, effective, efficient, sustainable, inclusive, equitable and contextualized"[16]

Table 3: ODIN ethical strategy

Principles	Application
Respect for confidentiality and privacy Legal compliance should be guaranteed, but also a moral and ethical commitment to respect confidentiality and privacy. A key aspect is here represented by the **principle of informed consent.**	• The ODIN project (all project partners) must treat participant information with confidentiality; • Participants may exercise control over personal information by consenting to, or withholding consent for, the collection, use and/or disclosure, modification, loss or theft;

[15] Gatekeeper, Deliverable 1.5.
[16] WHO, *Global Strategy on digital health 2020-2025*, 2021, p.16.

	• Implement the Privacy by design principle and provide with transparency all the relevant information; • Adherence to national and international regulations on privacy and data protection.
Beneficence Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by making efforts to secure their well-being. A key aspect is here represented by **person-centered care** (or tailor made/customised).	• Explain the limitations of the ODIN pilots, particularly in terms of probable personal and/or health benefits during and after the pilot; • Inform of possible clinical incidental findings prior of informed consent form and how these will be handled; • Follow standard clinical practices for consulting relevant specialist and for informing patients of clinical incidental findings and take appropriate actions; • Maximise probable benefits and minimise possible harms; • Continuously assess probable risk and benefits. The probable benefits must be deemed higher than the probable harm; • Put the health and welfare of participants at the highest priority
Justice It included the process of selecting participants in a justifiable manner. A key aspect is represented here by the issues of **inclusion and non-stigmatisation.**	• The selection of participants must be fair and equal i.e. inclusion/exclusion in the trial must not be denied a person without good reason, but must be based on reason directly related to the objectives of the pilot; • Pilots should strive to address the differences between participants, by calibrating recruitment effort with the aim of mitigating socio/economic barriers to participation especially in the field of digital literacy. • A particular attention should be devoted to the gender dimension.
Respect for Persons It includes respect for autonomy and dignity. Respect for persons demands that subjects enter into the research voluntarily and with adequate information. A key aspect is here represented by the issues concerning **autonomy and dignity**.	• Inform and seek advice if there are concerns related to the integrity and quality of the project and pilots. • Pilots should try to support older citizens/patients to be active participants in the intervention processes and not passive recipients

	• Treat patients and all the participants as autonomous agents and respect their right to determine their own best interest. • Actions conducted in the pilot should always consider the respect of the dignity of the participants and of all the people involved • Enable participants to make reasoned informed choices and decisions • The collection of informed consent must follow four steps: -*Accessibility*: The information must be formulated in a non-technical, plain language. The achievement of the accessibility level of the information must be verified, i.e. the definition of the key information is co-designed with participants and/or its efficacy been tested with end users; -*Information*: detailed information of the pilot, including potential benefits, intended use of the collected data, risks and limitations, must be provided; -*Comprehension*: The information must be given both verbally and written in clear language, in a precise and calm manner and in the proper context. Participants should be invited to ask any questions they may have; -*Voluntariness*: The informed consent form must stress that participation is voluntary and that participants are free to withdraw at any time at their own discretion and at no cost (without reprehension)
Transparency Open and transparent information shall be guaranteed to researchers and participants. Particular attention should be devoted to the data ethics dimension in the context of public procurement (see section 4.4).	• The ODIN project must be as transparent as possible in explaining its goals; • Information shall be explained to help citizens/users to navigate themselves through the available sources • The ODIN project should also strive to empower participants as only ensuring access to information is not enough. Skills to have access to the information

	and how to use technologies should be part of the empowerment process; ● The use of AI and machine learning should be made as transparent as possible by enabling end-users to access relevant information; ● Access to public documents of the project shall be guaranteed.
Sustainability and Impact The solutions proposed by the project are sustainable in the medium and long term. In particular there must be good reasons to believe that the deployment of an e-health solution will provide sufficient net-value back to citizens or society. There must be good reasons to believe that the proposed solution will be an effective tool in dealing with the health problem at stake.	● The ODIN project must strive to find sustainable solutions both for the hospitals and for the patients; ● The ODIN project must aim to minimize the impact of the suggested solutions on the environment and on the use of energy ● The ODIN project should pursue the social acceptability of its solutions also by analysing the potential negative impact in the specific deployment context ● The ODIN project should ensure the safety/security of its solutions in terms of functional safety in relation to the technologies but also as a condition of being able to live at home or outside his/her personal life.

Taking into consideration the specific aims of the ODIN consortium, through the work of the ODIN Policy, Legal, Ethics and Gender board the project will deploy a strategy in connection with all the WPs to ensure consistency and coherence in the ODIN project. Besides the principles identified in the GATEKEEPER project and fully adopted by ODIN we can also identify through the role of the Board a "Trust Matrix" that can serve as a guidance for the ODIN deployment in the context of AI. As highlighted in our DoA, we will build on the following principles:

- Fairness: ODIN will build strategies to address bias mitigation to detect and minimize them from datasets and correct them from current models, addressing the bias problem in three areas: 1) Enabling changes in data from training are transparent; 2) Use of agnostic models and 3) Success metrics definition to judge the performance of our model in training;

- Value alignment: ODIN will specify preferences, so teaching AI desired behaviours and implementing them in real pilot settings;

- Robustness: ODIN will create by design security measures for defending solutions from malicious attack focusing on formal robustness certification methods, tools for quantifying

the vulnerability of the systems, and specific control tools for avoiding malicious data samples;

- Self-explanatory: ODIN will build into the trustworthy approach the necessary interaction mechanisms to successfully perform their different purposes and objectives, accessing to the information in a meaningful way according to the needs of each user role and learning from the previous experiences of the user.

ODIN and its partners will also adapt to the guidelines for GDPR compliant IoT deployment which have been identified by previous Large Scale Pilots projects[17]. The identified principles are:

1. Perform a preliminary data protection impact assessment;
2. Minimize personal data collection;
3. Minimize personal data transfer;
4. Minimize data storage and retention time;
5. Maximize the use of anonymization and pseudonymization techniques;
6. Ensure that data processing is lawful;
7. Clarify who are the data controllers and data processors;
8. Designate a Data Protection Officer;
9. Ensure that the Data Protection Officer can be easily contacted through the website;
10. Formalize your data protection policy;
11. Organize regular communication and training activities on data protection;
12. Write a data management plan;
13. Secure your IoT network;
14. Each IoT mote should be protected by a unique and distinct password;
15. Define and implement a clear access right policy;
16. Adopt and enforce a strict policy and procedure for updating the firmware;
17. Establish procedures to comply with the data subjects' rights;
18. Exchange and collaborate with other DPOs;
19. Use external certification of compliance with data protection regulation;
20. Identify any cross-border data transfer;
21. Clearly inform and communicate the purpose of data collection;
22. Take advantage of online commitment tools.

4.5 Data ethics in public procurement

ODIN will build novel service models on the top of the technological platform to facilitate sustainability of the model and scale-up investments. The Innovative Procurement Journey proposed by ODIN will support healthcare service providers and regional governments to boost innovation, improve better care, productivity, and stakeholder engagement. The increase in data generation has expanded the possibilities of data analytics and therefore organizations are called to consider different aspects of the role of data such as: biases in data generation and extraction; quality of data inputs used to train artificial intelligence models, misuse, and abuse of data. The

17 S. Ziegler and others, *Personal Data Protection for Internet of Things Deployment: Lessons learned from the European Large-Scale Pilots of Internet of Things*, February 2020, pp. 30-31.

OECD has already published a report on *the Good practice principles for data ethics in the public sector*[18]. These principles are particularly relevant also in the hospital's sector. They are:

- Manage data with integrity;
- Be aware of and observe relevant government-wide arrangements for trustworthy data access, sharing and use;
- Incorporate data ethical considerations into governmental organisational and public sector decision-making processes;
- Monitor and retain control over data inputs, in particular those used to inform the development and training of AI systems, and adopt a risk-based approach to the automation of decisions;
- Be specific about the purpose of data use, especially in the case of personal data;
- Define boundaries for data collection, access, sharing and use;
- Be clear, inclusive and open;
- Publish open data and source code;
- Broaden individuals' and collectives' control over their data;
- Be accountable and proactive in managing risks.

4.6 ODIN Open Innovation approach

Open innovation is characterised by a multi-layered, open search and solution process between multiple players across project boundaries. According to European Commission, open innovation is focused on opening up the innovation process to all active players so that knowledge can circulate more freely and be transformed into products and services that create new markets, fostering a stronger culture of innovation.

This opening up of the innovation process creates a great deal of new innovation potential. We understand open innovation as the systematic and methods-based exploitation of this potential. By collaborating with external players, organisations have improved access to detail about information on needs and an expansion in the sources of solution information. In this way, the knowledge and creativity of external players that was previously unavailable is integrated into the process. This represents a departure from the traditional idea of the innovation process as being located largely within the project, which can be described as a closed innovation model.

Exploiting the potential of translating big data into actionable insights is hampered by not taking into account the valorisation aspect when developing data analytics enabled predictive models. Researchers are used to working towards publishing their findings in a paper but often forget to adopt an early valorisation strategy, or only do so in a late phase. Moreover, they are unfamiliar with the kind of evidence that is needed for digital health implementation. Hence, promising actionable insights that took years of intensive research often ground before yielding value for patients without adding to the sustainability of the healthcare system. This apparent mismatch between research output and market needs is often referred to as the innovation 'valley of death'.

Digital health researchers and developers aiming at valorisation of their results frequently are frustrated by getting lost in the complex system of fragmented regulatory requirements as there

[18] OECD, *Good Practice Principles for Data Ethics in the Public Sector*, 2021, available at: https://www.oecd.org/gov/digital-government/good-practice-principles-for-data-ethics-in-the-public-sector.pdf

is no comprehensive integrated regulatory framework for digital health. Guidelines and regulations are often scattered around different departments and stakeholders within hospitals. For example, IT-departments provide computing power clusters, medical technology departments control medical devices, ethics departments guard moral boundaries and technology transfer offices guide intellectual property discussions. This multi-faceted digital health domain therefore highly demands for interconnected interdisciplinary scrutiny.

Moreover, digital health poses a challenge for the interpretation of emerging regulations such as the recent medical device regulation and Artificial Intelligence Act. Unclarity with regards to the boundaries of emerging regulations pose a fear of crossing them unknowingly and punishment with reputation damage for developers as a result. Within this perceived regulatory void, digital health researchers and developers, healthcare professionals and hospitals struggle to realize their ambitions to develop and implement applications to endorse the healthcare capabilities of patients, support the work of healthcare professionals and in the end pave the way for a more sustainable healthcare system.

To facilitate effective collaborative development of digital health that adds value to clinical care, there is thus a critical need for a step-by-step valorisation methodology that integrates current and emerging regulatory boundaries. As a product owner for the Dutch Ministry of Health, the UMC Utrecht developed an innovation funnel to facilitate the development of valuable digital health. The tool supports the innovation process in five domains (value, usability, ethics, technology, responsibility) through eight different innovation phases.

Each phase leaves room for iterative development, yet there is a specific goal and accompanying resources are to be allocated. Each gate between phases comes with a checklist to help to ask the right questions at the right time in the development process. The innovation funnel assumes multidisciplinary development and implementation, with a focus on valorisation.

Each team consists of a developer and an end user (healthcare professional and/or patient). Transparency with demonstrations of intermediate models and products helps to create support and retrieve feedback within the project. Moving through the funnel and pausing at the gates helps the developer to comply with (inter)national rules and regulations as well as user expectations, thus bridging the innovation valley of death.

ODIN will be creating an open innovation approach by enlarging the consortium through the current established networks and participants from the open call including the ethics framework. In this context, the ODIN ecosystem will engage partners mainly from the healthcare and ICT domains (AI, robotics, IoT). The supply-side is formed by partners and associated partners, which compose and offer their services. In this sense, new technologies and applications from start-ups and SMEs attracted and connected through the Digital Innovation Hubs, academia and research, public bodies, SMEs, start-ups, industry, ICT innovators, and investors are incorporated and accelerated in the ODIN Ecosystem to demonstrate benefits from their AI-enabled applications (including apps over robots and IoT systems).

The ODIN Open Innovation approach will also stimulate use of the Innovation funnel to support structured and value-driven multidisciplinary development of digital health solutions in the pilots.

4.7 The gender dimension in ODIN

As the consortium has already underlined, the gender dimension is an integral part of the ODIN innovation action. The ODIN consortium, which involves members with relevant expertise in gender in R&I, shares the gendered innovations vision to stimulate inclusive-responsible science and technology, and is fully committed to improve the relevance of equal opportunities between women, men and racial minorities in innovation activities to be undertaken by adopting a critical perspective to the gender and inclusiveness in all phases of the project implementation.

The gender dimension will be one of the key focus areas of the activities of the ODIN Policy, Ethics, Legal and Gender Board which will outline its effort in the yearly activities plan. The Board will liaise also with WP9 in order to ensure that in the context of ODIN dissemination activities the gender dimension will be fully considered and also that in its communication, and through its communication (especially through its websites) ODIN fully considers the gender and diversity aspect.

5 Legal & ethical aspects in ODIN

Laws and regulations will need to be considered by the Consortium since the initial phases of the project. This section highlights the normative ecosystem in which the project is called to operate.

5.1 Introduction

Both at project level and at pilots' level, ODIN considers various normative sources to ensure necessary legal compliance and respect for fundamental data protection principles. The following section introduces most important instruments in the field of data protection on international and European level, and lists all relevant legal sources which address ethical, social and data protection-related issues of the project. It is to be underlined that the personal data related to health are considered as the information concerning the past, present and future, physical and mental health of an individual. In particular, data related to people's health are those referring to their percentage of disability and their genetic information.

European legislation on data protection, characterizes in a different way the treatment and transfer of health data, with respect to the treatment and transfer of other types of personal data (eg name, surname, etc.) and qualifies as data specially protected or sensitive data. The General Data Protection Regulation (GDPR) determines the possibility of the treatment of health data, without the prior consent of the interested party (patient) provided that said treatment is carried out by a health professional subject to the duty of professional secrecy or by personnel also subject to an equivalent obligation of secrecy, when is necessary in any of the following cases:

- Medical prevention or diagnosis,
- Provision of health care or medical treatments,
- Health services management,
- To safeguard the vital interest of the patient or another person if he or she is physically or legally incapacitated to grant her consent.

Therefore, the data provided by the patients who come to the health centre are collected and processed to manage their health control and health care received.

In this sense, in the treatment of personal data collected in the clinical history of patients, in cases not collected by the aforementioned cases, the express and written consent of the patients must be obtained. Therefore, when they are carried out for research or teaching purposes, the express and written consent of the patients participating in the clinical, biomedical research study or clinical trial that is going to be carried out will be required, or otherwise, a dissociation mechanism in said data to safeguard its anonymity.

5.2 International and European instruments in the field of data protection and security

The right to data protection is a fundamental human right. Article 8(1) of the Charter of Fundamental Rights of the European Union, and Article 16(1) of the Treaty on the Functioning of the European Union (TFEU) provide that "everyone has the right to the protection of personal data concerning him or her".[19] Personal data is defined as any information relating to an identified or identifiable natural person, such as name, address, birthday, footage, video, telephone number, email address, but also IP address and other communications content related to or provided by an end-user. Data protection aims at ensuring lawful and justified processing of data, as well as empowering data subjects to exercise their freedoms and control the way information about them is collected and used. Legal instruments concerning the right to data protection are available both under the Council of Europe and the European Union legal framework.

The chronologically first legal instrument under the Council of Europe, from which the right to data protection can be derived, is Article 8 of the European Convention of Human Rights (ECHR). Although article 8(1) provides that "everyone has the right to respect for his private and family life, his home and his correspondence" and does not explicitly mention the right to data protection as such, it is considered that this right is of fundamental importance for a person to enjoy their right to respect for private life. This interpretation has been confirmed by the European Court of Human Rights on its ruling concerning the collection of personal medical data by a State agency without the consent of the data subject.[20] Article 8 ECHR constitutes a right in a form of informational self-determination, allowing individuals to rely on their right to privacy in regards to personal data.

Historically, the adoption of the Resolutions (73) 22[21] and (74) 29[22] in 1973 and 1974 is considered to be one of the first steps taken towards the protection of personal data in automated data banks in the private as well as in the public sector. Already in the late 1960s, as the technological progress in electronic data processing made possible for both governmental bodies and private enterprises to collect and record great amounts of personal data in computer data banks, data subjects raised concerns about their data being inaccurate or disclosed for unauthorised purposes.[23] Even though some countries[24] had taken legislative measures to deal with the emerging problem, it became apparent that a comprehensive personal data protection could be achieved by means of binding international norms.[25]

The first legally binding instrument in the field of data protection is the Convention for the Protection of Individuals with regard to Automatic Processing of Personal Data (Convention

[19] Article 8(1), Charter of Fundamental Rights of the European Union (2000/C 364/01); Article 16(1)
[20] L.H. v. Latvia (no. 52019/07), 29 April 2014.
[21] Resolution (73) 22 on the Protection of the Privacy of Individuals Vis-a-Vis Electronic Data Banks in the Private Sector (adopted by the Committee of Ministers on 26 September 1973).
[22] Resolution (74) 29 on the Protection of the Privacy of Individuals Vis-a-Vis Electronic Data Banks in the Public Sector (adopted by the Committee of Ministers on 20 September 1974).
[23] Evans, A. C. "European Data Protection Law." The American Journal of Comparative Law, vol. 29, no. 4, 1981, pp. 571–582 (571).
[24] For example, a 1973 Data Protection Act passed by Sweden; German "Bundesdatenschutzgesetz" of 1 January 1978; French "Loi 78-17" of 8 January 1978 and others by Denmark, Norway, Austria, and Luxembourg.
[25] https://www.coe.int/en/web/data-protection/convention108/background.

108+)[26]. Signed in 1981, entered into force in 1985, and modernised in 2018, the Convention introduces key principles of fair and lawful data collection and automatic processing to the personal data of everyone in the territory of the Contracting Parties. Member Countries could, however, apply the same rules to non-automatic data processing as well. The principles demand that personal data is collected and automatically processed in a fair and lawful way, stored for specific legitimate purposes only, and not kept longer than necessary. In regards to the quality of data, adequacy, relevance and proportionality is demanded. Concerning special categories of data, such as health data, art. 6 of the Convention states that they can only be automatically processed if adequate safeguards are defined by national law.[27] The enshrined safeguards need to prevent risks for data subjects on the grounds of their sensitive data, such as discrimination.[28] At the same time another organisation, the Organisation for Economic Cooperation and Development (OECD), has enriched the international legal framework with a soft law[29] by issuing guidelines on data protection in transborder flows.[30] These two instruments, the Convention 108+ and OECD's Guidelines, defined a new international framework for data protection, exceeding the traditional right to privacy. The Council of Europe's Committee of Ministers has further enhanced Convention 108+ by adopting additional non-legally binding recommendations, which have been reflected in the Directive 95/46/EC[31], predecessor of the General Data Protection Regulation (GDPR). The Directive aimed at developing a general legal framework for the processing of personal data by leveraging on the rules introduced by Convention 108+. With the directive, the general framework on data protection was not complete; instead it was further supplemented by sectoral directives with more specific rules, such as Directive 97/66/EC[32] for the telecommunications sector, later replaced by the E-privacy Directive[33] for the electronic communications sector. Similarly, in 1999, in the area of soft law, the Council of Europe adopted a Recommendation on the Guidelines for the protection of privacy information highways[34], which affirm the already established principles by the European legal instruments[35], such as the user's duty to use digital signature and encryption techniques, the internet service provider's duty to use certified privacy enhancing technologies in order to ensure data confidentiality and integrity in addition to the logical and physical security of the network. Especially regarding medical data, it has been established that previous informed and explicit consent of the data subjects is required in order to communicate medical data for marketing purposes. Therefore, information about the privacy settings implemented by the service providers is mandatory as well.

[26] Convention for the protection of individuals with regard to automatic processing of personal data (ETS No. 108,28.01.1981).
[27] Article 6(1) of the Modernised Convention for the Protection of Individuals with Regard to the Processing of Personal Data (Adopted by the Committee of Ministers, 18 May 2018).
[28] Article 6(2) of the Modernised Convention for the Protection of Individuals with Regard to the Processing of Personal Data (Adopted by the Committee of Ministers, 18 May 2018).
[29] The term "soft law" denotes agreements, principles and declarations that are not legally binding.
[30] Recommendation of the Council Concerning Guidelines Governing the Protection of Privacy and Transborder Flows of Personal Data of 23 September 1980.
[31] Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data.
[32] Directive 97/66/EC of the European Parliament and of the Council of 15 December 1997 concerning the processing of personal data and the protection of privacy in the telecommunications sector.
[33] Directive 2002/58/EC of the European Parliament and of the Council of 12 July 2002 concerning the processing of personal data and the protection of privacy in the electronic communications sector (Directive on privacy and electronic communications).
[34] Recommendation No.. R(99) 5 of the Committee of Ministers to Member States for the Protection of Privacy on the Internet, adopted by the Committee of Ministers on 23 February 1999.
[35] In particular Convention 108, Recommendation No. R (90) 19 on the protection of personal data used for payment and other related operations

The Charter of Fundamental Rights[36] (the Charter) is the primary legal instrument which shapes the European Union legal framework in the field of data protection. Unlike ECHR, it explicitly separates the right to data protection from the right to privacy, providing a dedicated legal basis for the former. With the entry into force of the Lisbon Treaty in 2009, the Charter has been given the same legal status as the constitutional treaties of the European Union. Article 8(1) of the Charter grants everyone the right to protection of personal data concerning him or her. Moreover, article 8(2) sets out requirements of the lawful personal data processing: it must be fair, serving specified purposes and based either on the explicit consent of the concerned person, or on a legitimate basis laid down by law. The provision also provides everyone with the right of access to their collected personal data and allows them to have it rectified. Finally, an independent authority controls the compliance with the rules.

5.3 The General Data Protection Regulation

The General Data Protection Regulation[37] (GDPR) came into force across the European Union on May 25th, 2018, aiming at creating a uniform set of rules to provide enhanced protection for citizens' data, promote innovation in the European Single Market and respond to the emerging challenges of the digital age. Similarly, to the Data Protection Directive, the GDPR enshrines fundamental rights for the data subject and imposes significant obligations to data controllers and data processors. GDPR confirms the principles for information privacy set by the Directive, such as lawfulness, fairness, transparency, purpose limitation, data minimisation, accuracy, storage limitation, integrity, confidentiality, and accountability.[38] However, the GDPR broadens those principle and introduces new features such as: easier access to personal data, the right to data portability, the right "to be forgotten" the right to know when the data has been hacked, the principle of clear and affirmative consent to the processing of personal data, the principles of "data protection by design" and "data protection by default", and stronger enforcement of the rules through improved administrative and judicial remedies in case of violation. Example for the latter is the new approach to supervisory data protection authorities (DPAs) that oversee the compliance with the GDPR in their respective jurisdictions and cooperate to achieve consistent application of the regulation across the EU. Furthermore, to avoid "forum shopping"[39] in case of cross-border data processing, a "one-shop-stop" approach is considered, where the lead authority from the jurisdiction of the establishment's headquarter considers the positions of the other concerned authorities, conducting joint investigations where needed.[40]

Another tool introduced by the GDPR is the Data Protection Impact Assessment (DPIA). Article 35(1) GDPR requires data controllers carry out an assessment of the impact of the envisaged processing operations on the protection of personal data, when they are likely to impose high risk to the rights and freedoms of national persons. This is particularly relevant when a new data

[36] Charter of Fundamental Rights of the European Union, created in 2000 and ratified in 2009.
[37] Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data and repealing Directive 95/46/EC (General Data Protection Regulation).
[38] Article 5 GDPR.
[39] "Forum shopping" refers to the practice of choosing the court or jurisdiction with the most favourable rules or laws for the position being advocated.
[40] Bennett, Colin J. "The European General Data Protection Regulation: An instrument for the globalization of privacy standards?" Inf. Polity 23 (2018): 239-246 (242).

processing technology is utilized, but also for actions involving evaluation or scoring, automated decision making, sensitive data, data processed on a large scale and data concerning vulnerable data subjects. [41] Finally, public authorities and any other organisation whose core activities consist of processing operations which require regular and systematic monitoring of data subjects on a large scale, or data processing on a large scale of special categories, need to appoint a Data Protection Officer (DPO).[42] These instruments are designed to promote organisational accountability.

Territorially, the GDPR is applicable to EU based establishments, regardless of the where the data processing takes place, as long as it is "in the context of its activities".[43] The Regulation applies as well when EU's resident's data is being processed for activities related to offering of goods and services and monitoring of their behaviour.[44] The term monitoring includes online tracking and profile-creating of individuals, including analysing and predicting their preferences. The GDPR categorises data according to their nature, so data on racial or ethnic origin, political opinions, religious or philosophical beliefs, as well as generic and biometric data are considered "special categories of personal data", meaning their processing is only permissible under defined conditions.[45] Furthermore, the use of pseudonymisation is encouraged, so that personal data can no longer be attributed to a specific data subject without the use of additional information.[46]

Another directive, passed at the same time as the GDPR is the Data Protection Law Enforcement Directive (LED).[47] Regarded as either parallel or *lex specialis*[48] to the GDPR, LED aims at ensuring that Member States protect the fundamental rights and freedoms of natural persons and in particular their right to the protection of personal data, and ensure that the exchange of personal data by competent authorities within the Union is neither restricted nor prohibited for reasons connected with the protection of natural persons with regard to the processing of personal data.[49] LED's material scope extends to activities by competent authorities for prevention, investigation and prosecution of criminal offences.[50] Unlike the GDPR, LED is an EU Directive which means that it has to be implemented by national legislations of the Member States.

The table below lists relevant normative sources which ODIN considers throughout its various phases. Arising ethical issues will be handled according to the principles of the following legal instruments:

- Helsinki Declaration of 1964 (revised version 2004);
- European Convention of Human Rights;

[41] Guidelines on Data Protection Impact Assessment (DPIA) and determining whether processing is "likely to result in a high risk" for the purposes of Regulation 2016/679 (WP 248 rev.01), adopted on 4 April 2017; Recitals 71, 75, 89, 91 and Article 35(1) and 35(3) GDPR.
[42] Article 37 (1) GDPR.
[43] Article 3(1) GDPR.
[44] Article 3(2)(a), (b) GDPR.
[45] Article 9(1) GDPR.
[46] Article 4(5) GDPR.
[47] Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA.
[48] A law governing specific subject matter that overrides a law governing only general matters (*lex generalis*).
[49] Article 1(2)(a)(b) LED.
[50] Article 1(1) LED.

- Rules if the Convention of the Council of Europe for the Protection of Individuals (automatic processing of personal data);
- EU General Data Protection Regulation (GDPR);
- Charter of Fundamental Rights of the European Union.

5.4 The Medical Device Regulation

The Medical Device Regulation (MDR) got into effect on May 26th, 2021, after a year of delay because of the covid-19 pandemic (the new regulation on In Vitro Diagnostic Medical Devices (IVDR) will get into effect in 2022). MDR's predecessor MDD was revised to improve quality assurance of Medical Devices on the European Market.

Medical Devices are defined as any instrument, apparatus, appliance, software, implant, reagent, material, or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- Diagnosis, prevention, monitoring, prediction, prognosis, treatment, or alleviation of disease;
- Diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability;
- Investigation, replacement, or modification of the anatomy or of a physiological or pathological process or state;
- Providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations.

and which does not achieve its principal intended action by pharmacological, immunological, or metabolic means, in or on the human body, but which may be assisted in its function by such means. Devices for the control or support of conception and products specifically intended for the cleaning, disinfection or sterilization of devices are also seen as medical devices[51].
MDR aims to secure high quality development, (clinical) evaluation and post-market surveillance of medical devices through safety and performance requirements. For specific requirements, manufacturers are referred to (harmonized) standards. Manufacturers have to show they comply with MDR and the accompanying standards for risk management, quality management and medical device (software) development. Low-risk devices can be self-certified, yet notified bodies are appointed to assess documentation and grant access to the European market by handing out CE certificates for any medical device above risk classification I.

One of the amendments in the MDR when compared to the MDD is the more prominent place of software, more specifically medical device software. In Annex VIII, Rule 11 states that software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is at least classified as class IIa[52]. This means that manufacturers of (web) applications, machines or decision rules that fall under the MDR have to be certified by notified bodies before they can be implemented in clinical practice (with the exception of healthcare institutions that develop medical devices for in-house use and do not place it on the European market).

[51] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32017R0745&from=EN Article 2
[52] https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:32017R0745&from=EN Annex VIII Chapter III on Active Devices

To further specify the classification of medical device software under the MDR, the Medical Device Coordination Group issued the Guidance on Qualification and Classification of Software in 2019 [53]. In this document, software is defined as a set of instructions that processes input data and creates output data. Examples are given as to what software classifies as medical device software, and explicit exclusions from the MDR include software for storage, archiving, communication or a 'simple search' and/or software that does not act for the benefit of individual patients. Some software systems, such as hospital information systems, may contain modules, where some modules may classify as a medical device and others do not. These modules then may be subject to MDR and need a CE-mark before they can be put onto the market.

Software that will be developed within the scope of the ODIN program may be medical device software. The decision whether or not a specific software application is a medical device will be up to the manufacturer, yet of course there is the opportunity to discuss this in the consortium. Development of medical device software in the ODIN consortium will follow the harmonized standard NEN-and-IEC 62304 for the development of medical device software. Moreover, as deemed necessary by the MDR, developers will use this standard together with a quality management system, for example ISO-13485 or ISO-15189. Other norms that may be of use include ISO 14971 (risk management) and ISO 82304 (health software).

Before medical device software can be placed on the market, CE-marking is needed. Yet, different stages of innovation and development may require different norms and standards to be followed and resources to be adjudicated to optimize value creation. Moreover, MDR interacts with GDPR, the AI act, and other laws and regulations and design principles. To enable business-driven and value-focused development, we will use the innovation funnel developed by UMCU and the Dutch Ministry of Health as a guideline.

5.5 The EU proposals on the Data Governance Act and Artificial Intelligence

As the policy and legal context develops ODIN will need to also consider the finalization of two legislative proposals made by the European Commission that have the potential to affect the ODIN ecosystem and development. A first legislative proposal which needs to be taken into consideration is the Data Governance Act[54]. The Data Governance Act (DGA) is also a proposal of the European Commission that aims to create a framework to facilitate data sharing. If approved, this piece of legislation will enable the creation of "secure spaces" where different kinds of data, including health data, can be shared and re-used for commercial or altruistic purposes, including scientific research. The draft proposal of the Act also aims to introduce a "European data altruism consent form" for altruistic data re-use. "Data altruism" and "general interest" as the "consent by data subjects to process personal data pertaining to them, or permissions of other data holders to allow the use of their non-personal data without seeking a reward, for purposes of general interest, such as scientific research purposes or improving public services". E-health

[53] https://ec.europa.eu/docsroom/documents/37581

[54] European Commission, *Proposal for a Regulation of the European Parliament and the Council on European Data Governance (Data Governance Act)*, 25/11/2020, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020PC0767.

related research projects working in the context of WG5 have already submitted comments to the proposal highlighting a few points that need further refinement. Among them:

- A need to clarify the territorial scope of application of the proposed regulation and also the role and liability of the EU-based representatives;
- A request to extend the scope to non-public entities in health whose data is of great relevance and value (e.g., private not for profit hospitals or third sector organizations providing social care or integrated care);
- Greater clarity about the alignment of the national competent authorities undertaking the Data Governance Act oversight and enforcement with the bodies performing that role for the General Data Protection Regulation;
- The different projects welcome, as part of the implementation of data altruism, the introduction of data subject consent for areas of general interest including processing for scientific research purposes that cannot be precisely specified at the time of collecting the consent. However, greater clarity and guidance will be needed on how to remain compliant with the GDPR which requires consent to be specific. Clear and detailed guidance will be required for the public, data intermediaries, research users and regulators to ensure consistent pan-European interpretation and application, and to give confidence to all stakeholders;

On April 21st, 2021, the European Commission presented its proposal for a Regulation on Artificial intelligence[55] as part of the European approach to AI legislative package which includes: i) the aforementioned legal framework on AI; ii) an updated coordinated plan with Member States; iii) a new proposal for a Regulation on Machinery products. The proposed regulation joins other EU initiatives in the digital sector (such as the Data Governance Act, Digital Service Act and Digital Markets Act) which are currently being discussed and considered. The proposal of the Commission is based on a risk-based approach which looks at the specific uses of AI and their corresponding level of risk in order to determine the level of requirements they will be subject to. The proposal also includes several provisions aimed at ensuring that the framework remains futureproof for example through the possibility by the Commission of adapting the list of high-risk systems. The proposed regulation includes a number of provisions intended to promote the development and the uptake of AI systems in the European Union. In the context of the regulatory framework envisaged a European Artificial Intelligence Board will oversee and coordinate the enforcement of the regulation.

Importantly, the proposal envisages a two-year period for application following adoption and publication of the final regulation therefore the new requirements could apply as early as 2024. The new European Data Governance ecosystem aims at increasing trust in data sharing, strengthening the mechanisms to increase data availability and overcome technical obstacles to the re-use of data. The research project will also closely follow the developments on common European data spaces in the strategic domain of health. In May 2021 the European Commission

[55] European Commission, Proposal for a Regulation of the European Parliament and the Council laying down harmonized rules on artificial intelligence (Artificial Intelligence Act) and amending certain Union legislative acts, 21/4/2021, available at: https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52021PC0206

also published its Inception Impact Assessment of the forthcoming Data Act[56]. This legislative initiative will aim at facilitating data access, use and review the rules on legal protection of databases. The initiative therefore aims at ensuring fairness in the allocation of data value among actors of the data economy and has been already considered also by the European Parliament that through the adoption of a report of its Industry, Research and Energy Committee has called the Commission to submit legislation to foster data access and interoperability in the forthcoming Data Act.

A focus on data governance is also needed from a business perspective as also other countries such as China and the United States are building their data governance frameworks. The project will build on the EU experience maturated on the implementation of the GDPR and extend it to the new challenges of data sharing and secondary use of data for health research.

5.4 Ethical Principles

An initial mapping of data protection and ethical principles in the context of the ODIN project can be found below. ODIN will continue to work on an ethical assessment model which will take into consideration the different ethical dimensions involved in the project.

Table 4 Ethical principles and their application in ODIN

Principles	Application
Respect for confidentiality and privacy Legal compliance should be guaranteed, but also a moral and ethical commitment to respect confidentiality and privacy. A key aspect is here represented by **principle of informed consent**.	• The ODIN project (all project partners) must treat participant information with confidentiality; • Participants may exercise control over personal information by consenting to, or withholding consent for, the collection, use and/or disclosure, modification, loss or theft; • Implement the Privacy by design principle; • Adherence to national and international regulations on privacy and data protection
Beneficence Persons are treated in ethical manner not only by respecting their decisions and protecting them from harm, but also by	• Explain the limitations of the ODIN pilots, particularly in terms of probably personal and/or health benefits during and after the pilot;

[56] European Commission, Inception Impact Assessment-Data Act (including the review of Directive 96/9/EC on the legal protection of databases), available at: https://ec.europa.eu/info/law/better-regulation/have-your-say/initiatives/13045-Data-Act-&-amended-rules-on-the-legal-protection-of-databases_en.

making efforts to secure their well-being. A key aspect is here represented by the issues of **inclusion and non-stigmatisation**.	• Inform of possible clinical incidental findings prior of informed consent form and how these will be handled; • Follow standard clinical practices for consulting relevant specialist and for informing patients of clinical incidental findings and take appropriate actions; • Maximise probable benefits and minimise possible harms; • Continuously assess probable risk and benefits. The probable benefits must be deemed higher than the probable harm; • Put the health and welfare of participants at the highest priority
Justice It included the process of selecting participants in a justifiable manner. A key aspect is here represented by the issues of **inclusion and non-stigmatisation**.	• The selection of participants must be fair and equal i.e. inclusion/exclusion in the trial must not be denied a person without good reason but must be based on reason directly related to the objectives of the pilot
Respect for Persons It includes respect for autonomy and personal integrity. Respect for persons demands that subjects enter into the research voluntarily and with adequate information. A key aspect is here represented by the issues concerning **autonomy and dignity**.	• Inform and seek advice if there are concern related to the integrity and quality of the project and pilots • Treat patients as autonomous agents and respect their right to determine their own best interest. • Actions conducted in the pilot should always take into account the respect of the dignity of the participants and of all the people involved • Enable participants to make reasoned informed choices and decisions • The collection of informed consent must follow three steps: *-Information*: detailed information of the pilot, including potential benefits,

	risks and limitations, must be provided; -*Comprehension*: The information must be given both verbally and written in clear language, in a precise and calm manner and in the proper context. Participants should be invited to ask any questions they may have; -*Voluntariness*: The informed consent form must stress that participation is voluntary and that participants are free to withdraw at any time at their own discretion and at no cost (without reprehension)
Transparency Open and transparent information shall be guaranteed to researchers and patients.	• The ODIN project must be as transparent as possible in explaining its goals; • The use of AI and machine learning should be made as transparent as possible • Access to public documents of the project shall be guaranteed;
Sustainability The solutions proposed by the project are sustainable in the medium and long term.	• The ODIN project must strive to find sustainable solutions both for the hospitals and for the patients; • The ODIN project must aim to minimize the impact of the suggested solutions on the environment and on the use of energy

Table 5: Relevant ethical and social issues and legal sources

Ethical and Social Issues	Field	Law/ Directive
Human Dignity and Integrity of Users	Human Rights	• Universal Declaration of Human Rights (United Nations); • Convention for the Protection of Human Rights and Fundamental Freedoms (Council of Europe); • European Charter for Fundamental Rights (European Union)

		• Draft Recommendation of the Council of Europe on the Promotion of the Human Rights of Older People; • European Charter of the Rights of Older People in Need of long-term Care and Assistance.
Privacy	Data Protection Cyber Security	• Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation); • Directive (EU) 2016/680 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data by competent authorities for the purposes of the prevention, investigation, detection or prosecution of criminal offences or the execution of criminal penalties, and on the free movement of such data, and repealing Council Framework Decision 2008/977/JHA; • Directive 2006/24/EC of the European Parliament and of the Council of 15 March 2006 on the retention of data generated or processed in connection with the provision of publicly available electronic communication services or of public communications networks and amending Directive 2002/58/EC; • Directive 2002/58/EC of the European Parliament and of the Council concerning the processing of personal data and the protection of privacy in the electronic communications sector; • Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) 178/2002 and Regulation (EC) 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC; • Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices and

		repealing Directive 98/79/EC and Commission Decision 2010/227/EU; ● 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; ● Regulation (EU) 2019/881 of the European Parliament and of the Council of 17 April 2019 on ENISA (the European Union Agency for Cyber-security) and on information and communications technology cyber-security certification and repealing Regulation (EU) No 526/2013 (Cyber-security Act).
Bioethics and clinical trials	Medical Research	● World Medical Association Declaration of Helsinki-Ethical Principles for Medical Research involving human subjects; ● Opinion on the processing of health data by Article 29 Data Protection Working Party; ● Universal Declaration on Bioethics and Human Rights; ● Directive 2001/20/EC on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use; ● Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of biology and Medicine: Convention on Human Rights and Biomedicine (and Guide for Research Ethics Committee Members); ● Charter for the Rights of Older People in Clinical Trials; ● Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to Active Implantable Medical Devices as amended by Directive 2007/47/EC of 5 September 2007; ● Commission Regulation (EU) 207/2012 of 9 March 2012 on electronic instructions for use of medical devices; ● Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products of human use;

		• Regulation (EU) 2021/522 of the European Parliament and of the Council of 24 March 2021 establishing a Programme for the Union's action in the field of health ('EU4Health Programme') for the period 2021-2027, and repealing Regulation (EU) No 282/2014.
Disability	Accessibility	• Disability Rights Commission: Guidelines for ethical research (2004); • UN Convention on the Rights of persons with disabilities; • Accessibility Act.
New Technologies	Liability and Safety	• Directive 85/374/EC on liability for defective products as amended by Directive 1999/34/EC; • Directive 2011/24/EU on the application of patients' rights in cross-border healthcare; • RoHS Directive 2002/95/EC of the European Parliament and of the Council of 27 January 2003 on the restriction of the use of certain hazardous substances in electrical and electronic equipment; • Directive 98/34/EC of the European Parliament and of the Council of 20 July 1998 amended by Directive 98/34/EC laying down a procedure for the provision of information in the field of technical standards and regulation and of rules on information society services.
Covid-19	Epidemic	• European Commission recommendation on a common Union toolbox for the use of technology and data to combat and exit from the COVID-19 crisis, in particular concerning mobile applications and the use of anonymised mobility data, 8/4/2020; • E-health network Mobile applications to support contact tracing in the EU's fight against COVID-19. Common EU Toolbox for Member States, 15/04/2020; • Communication from the Commission, Guidance on Apps supporting the fight against COVID 19 pandemic in relation to data protection, 16/4/2020;

- European Commission's Joint European Roadmap Towards Lifting COVID-19 Containment Measures;
- European Data Protection Board, Statement on the processing of personal data in the context of COVID-19 outbreak, 19/3/2020;
- European Data Protection Board, Guidelines 3/2020 on the processing of personal data concerning health for the purpose of scientific research in the context of the COVID-19 outbreak, 21/4/2020;
- European Data Protection Board, Guidelines 4/2020 on the use of location data and contact tracing tools in the context of the COVID19 outbreak.

6 Planned Compliance coordination activities in ODIN

6.1 Personal Data Protection and Ethical Compliance activities

During the project, the ODIN pilots (UCBM, UMCU, CUB, MUL, ARMIENS, & SERMAS) shall ensure the implementation of specific activities towards the protection of personal data of participants, which include (and are not limited to) signing a declaration of conformity to national regulations; appointment of DPOs; ensuring the relevance and limitation of purposes of the collected data; detailing of technical and organizational measures regarding security, anonymization and pseudonymization techniques to be implemented, informed consent procedures and measures to address potential for profiling; and declaring/preventing any further processing of personal data. Further information on this point (including declarations of conformity to national regulations, appointment of DPOs by Pilot partners, relevance, and limitation of purposes of the collected data; technical and organizational and security measures; anonymization and pseudonymization techniques; procedures and profiling; and dispositions regarding further processing of personal data) can be found in ODIN D11.2.

These activities will be carried out with the direct support of the ODIN Policy, Ethics, Legal and Gender board, for which the board may deem necessary to pursue bilateral/multilateral calls, workshops and/or other capacity building activities. Furthermore, the Board will seek to facilitate regular ethical and personal data protection impact/risk assessments as part of its regular compliance support activities in direct collaboration with T7.3. These actions may be coordinated alongside the designated Pilot DPOs.

6.2 Data management-related compliance

Details on the data protection approach of the consortium and of the different pilots are reported in detail in D.1.2. The data management plan is a living document which is updated on a regular basis, and this report will further detail technical and organizational measures to ensure compliance with relevant regulations. The ODIN Policy, Ethics, Legal and Gender board will contribute to the review of the document alongside with the direct inputs of the ODIN Partners.

6.3 Procedures / Criteria for Identification and Recruitment of Participants and Informed consent

The identification and recruitment of participants is a pivotal moment in any research project like ODIN. Considering the diverse legal frameworks that are applicable to each pilot, leading partners have developed specific procedures to ensure the validity of their recruitment activities and compliance with relevant informed consent procedures. This information will be showcased in D11.1.

6.4 Ethical Approval from local committees

The ODIN pilots will apply for approval for the trials to the relevant local ethical committee. Approval must be obtained prior to the start of the pilot. Relevant information on the processes followed by each Pilot will be provided in ODIN D.11.1.

6.5 Planned activities of the Policy, Legal and Gender Board and initial timeline

- Mapping and discussion of the evolving policy ecosystem – Lead: UDGA - (ongoing)
- Involvement of female researchers in ODIN research teams – Lead: UDGA - (early 2022)
- Mapping of available structured innovation approaches – Lead: UMCU – (early 2022)
- Ethics proposal to consider gender balance when including subjects for studies – Lead: CUB – (early 2022)
- Ethics Impact Assessment (to be undertaken jointly by all partners, template reported below) Lead: UDGA (early 2022, iterative updates)
- Regular review of Ethics Management Questionnaire & Data Management Questionnaires to be filled by all project partners (& particularly Pilot partners) for D11.1 / 11.2 update. (late 2021, iterative updates)
- Coordination with regulatory, privacy and ethical initiatives (see below) – Lead: UDGA with support of board members. (mid 2022 & throughout project)

Minutes of the Policy, Legal and Gender Board are regularly reported in ODIN D11.3.

6.6 Preliminary template of ethical impact assessment

The ODIN Policy, Legal and Gender Board will closely monitor the ethical and social implications of the ODIN Project. To start the evaluation, a preliminary assessment template can be found below, which will be shared with the diverse project partners and refined as necessary at regular intervals. The information in this questionnaire will be further assessed in consideration to the Ethics Management Questionnaire & Data Management Questionnaires to validate the evaluation outputs.

Table 6 Draft ethical impact assessment template for the ODIN platform

	Guiding question	Substantive/Conceptual question
Q1	Does this platform threaten the freedom of individual humans?	Does this platform alter an individual's freedom of movement? Does this platform interfere intentionally with the formation of expression or beliefs?
Q2	Does this platform threaten the natural equality of persons?	Are expected benefits divided between groups for reasons not associated with difference in use?

Q3	Does this platform restrict the exercise of a dignified human life?	Will this platform reduce the chance of life choices (e.g. nudges) of individuals in ways they are not fully aware of?
Q4	Does this platform seek to change the way in which individuals' reason?	Will this platform restrict access to information? Will this platform promote specific decision-making schemes the users will not be aware of?
Q5	Does this platform alter the exercise of human moral conscience?	Will this platform promote specific visions of a good life?
Q6	Is this platform explicitly designed to create or exacerbate inequalities between individuals or groups?	Are expected benefits divided between groups for reasons nor associated with differences in use?
Q7	Is this platform intended to create tiers of persons based on social, International, or political factors?	Does this limit the rights of any individuals or groups based upon race? Does this limit the rights of any individuals or groups based upon biological sex?
Q8	Does this platform restrict the enjoyment of basic human rights?	Does this limit the natural life of an individual? Is this designed to enhance or augment the natural life of an individual? Does this restrict an individual's opportunity to exercise liberties?

6.7 Coordination with relevant regulatory, privacy and ethical initiatives

The following initiatives have been deemed as relevant for the ODIN project. The planned table includes a list of potential interactions that will be encouraged and pursued during the project.

Table 7 Coordination with relevant regulatory, privacy and ethical initiatives

Name of Initiative	Leadership	Type of Interaction
Eu4Health (European Health Data Space)	EC	*Follow developments on common European data spaces; On 24 June 2021 the European Commission adopted the work programme 2021 (C(2021)4793 final) which sets out the priorities and actions for 2021, including resource allocation, for the*

		implementation of the EU4Health Programme. We closely follow the EU4Health information sessions to ensure alignment of the ODIN project with identified action points on European level.
Innovation funnel by UMC Utrecht and the Dutch Ministry of Health	University Medical Centre (UMC) Utrecht	Guidance to support structured and value-driven multidisciplinary development of digital health solutions in the pilots.
European Group on Ethics and the High-Level Group on Ethics in AI 38 (AI HLEG)	Nathalie Smuha - AI HLEG Coordinator	The Project closely monitors the work of the AI HLEG, particularly its guidelines on trustworthy AI, which have been taken into consideration when developing ODIN's ethical framework.
OECD Thematic Group on Data-driven Public Sector	Barbara-Chiara Ubaldi	The project follows and incorporates OECD's "*Good practice principles for data ethics in the robotics sector*" principles. We acknowledge the open offer on OECD's website to contact its Secretariat for questions on these or other activities of the Thematic Group.
DTIC-MdM Strategic Program: Data-Driven Knowledge Extraction	Universitat Pompeu Fabra Barcelona	The project has partaken in the initiatives of the Maria de Maeztu Gender & ICT program for broad gender strategy and has identified and incorporated best practises for its gender strategy and also for fine-tuning its principles for minimizing and preventing gender bias in data used to train systems.
AI Watch EU JRC	EC, JRC, DG Connect	AI Watch is an initiative of the European Commission (EC) jointly developed by the EC Joint Research Centre (JRC) and the Directorate General for Communications Networks, Content and Technology (DG CONNECT). We closely monitor

		their weekly publications on AI developments and challenges in the global landscape. This helps the project stay up to date with current actions around the implementation of the European Strategy for AI and to adjust its methodology accordingly and incorporate best practises.
International Data Space Association (IDSA)	Thorsten Hülsmann - CEO	Follow developments on common European data spaces; The hub is part of ODIN's ecosystem.
European Data Protection Board + National Data Protection Supervisory Authorities	Andrea Jelinek - Chair	Follow developments regarding the diverse topics of relevance for ODIN, particularly on the guidance and recommendations by national competent authorities.
Panel for the Future of Science and Technology (STOA) and its dedicated Centre for AI (C4AI)	Ewa Kopacz- EP Vice President responsible for STOA	Follow STOA's studies and analysis on principles and guidelines on ethical AI through participation in their workshops on emerging and relevant techno-scientific topics of political relevance.
European Group on Ethics in Science and New Technologies (EGE)	Christiane Woopen - Chair	Closely monitor EGE's opinions, which examine the intersections between science and technological advances and broad societal, ethical and fundamental rights issues, and identify their implications of emerging and future developments.

7 Conclusions

As we are learning day by day policy, ethical and legal dimensions of data and artificial intelligence are strongly interconnected. This is particularly true in the case of e-health. The decision to collect certain data and process them is not a neutral one and the fact that through the deployment of different tools we collect a huge amount of data brings many challenges. This is true not only from the standpoint of data protection, but also from the standpoint of power dynamics. Data are in fact at the core of the definition of what a human being is and this is particularly true in the case of e-health. As Ivana Bartoletti has highlighted: "Choosing data to train algorithms means making a choice about which individuals will form the data set, the consequences of which can be profound and pervasive"[57]. The policy, ethical and legal dimension in the context of the ODIN project are therefore to be understood as central in the implementation of the project and the aim of the consortium is to closely follow them up also thanks to the contribution of the ODIN Policy, Ethics, Legal and Gender Board.

[57] I. Bartoletti, *An Artificial Revolution. On Power, Politics and AI*, Indigo Press, London, 2020, p. 35.