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Piano nazionale per gli investimenti complementari al PNRR
Ministero dell'Università e della Ricerca

FIT4MEDROB

D4.4.2

REPORT ON MULTI-LEVEL GOVERNANCE OF ROBOTS, BEFORE AND AFTER SET-UP OF THE EU RECOVERY PLAN (NRRP)#2

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Editors: David Natali, Andrea Terlizzi, Gianluca Piccolino, Alessandro Gazzetti, Elena Vivaldi, Andrea Chiappetta

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HISTORY OF CHANGES

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1.0	30/11/2023	First version
1.1	20/09/2024	Executive summary modified following reviewers' suggestions.

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1 EXECUTIVE SUMMARY

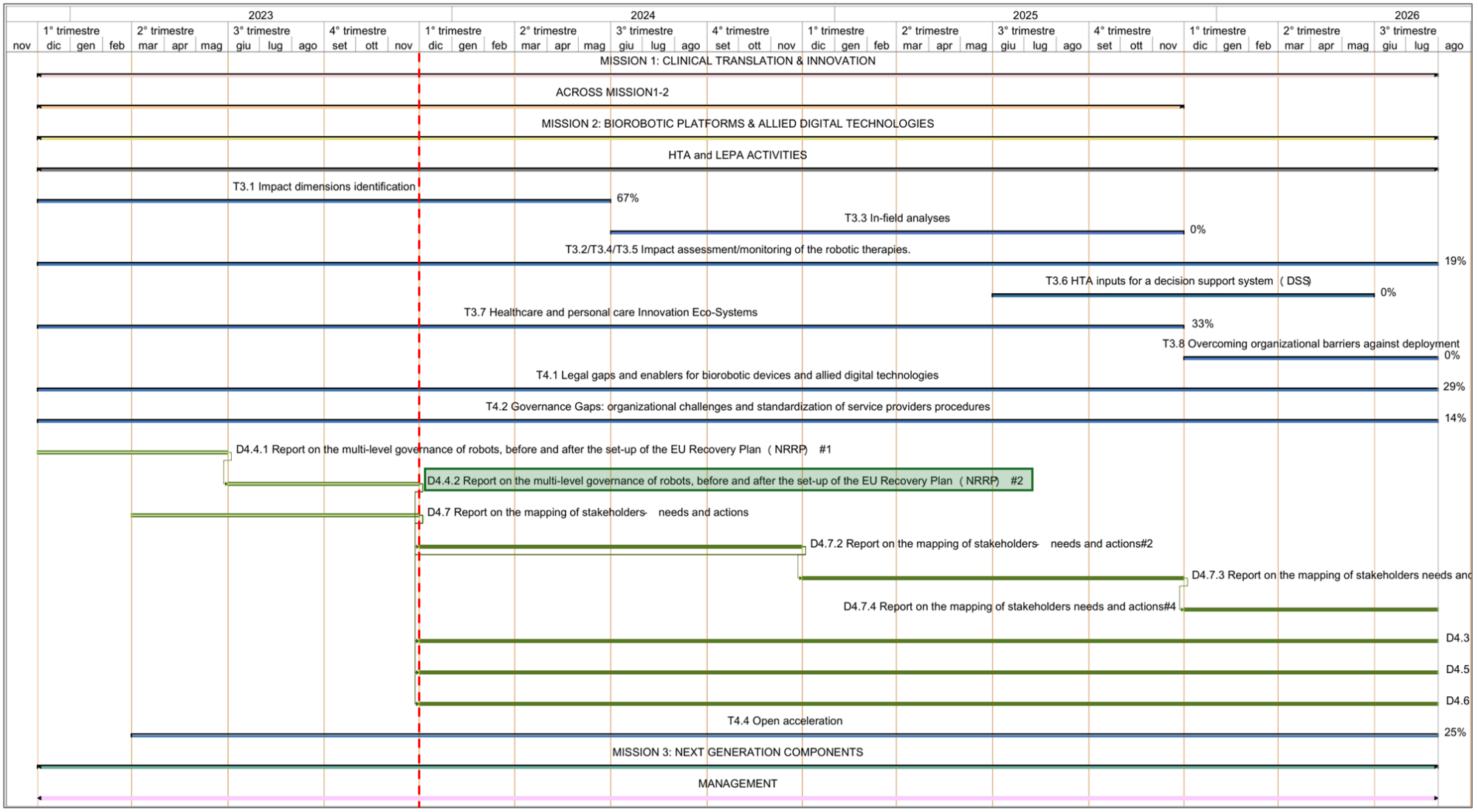
The present report provides the updated map of governing tasks and functions in the field of Artificial Intelligence (AI) and Robotics after the launch of the Next Generation EU (NGEU) programme. The aim is to contribute to the definition of the responsibilities across levels of government, and the identification of actors and institutions, and their priorities and instruments to support an effective strategy for the spread of new technologies, with particular reference to the fields of healthcare and personal care. This deliverable is focused on the more recent EU strategies that were set up in the aftermath of the Covid-19 pandemic crisis. The reference is to additional financial resources for investments in the area; and new rules for the coordination of AI and robotics across levels of governance.

The report looks at the multi-level governance of AI and Robotics with the description of the main strategies set up at the global, European, national and regional level. This first deliverable provides the broad picture with the focus on some institutions particularly active in the field. We refer to: OECD and WHO at the global level; European Union (with a focus on both regulation and financial programmes). As far as the National and Regional levels, the present report sums up the Italian National Strategic Programme on AI and the potential investments and reforms included in the National Recovery and Resilience Plan (NRRP) of 2021 (part of the NGEU programme). The present report provides the analysis of the programmes for AI and Robotics while next deliverables will give the more in-depth study of the missions and investments in the fields of healthcare and personal care (already at the core of D4.1.1).

The different levels of the complex governance in the field provide evidence of shadows (persistent weakness and loose coordination) and lights (new ambitious programmes and initiatives, including new budgetary lines at EU level). The report confirms Multi-level Governance (MLG) in the field is a work in progress, while important achievements concern the definition of common understandings of AI and Robotics and their consequences. More ambitious investments have been set at the European level. Different initiatives have been launched in line with the definition of ambitious strategies for the post-pandemic recovery. While the post-pandemic EU strategy lack a coherent approach, new resources are at disposal of national and sub-national policymakers. These resources represent the potential for further investments in the area. The in-depth analysis of three key missions of the Italian National Recovery and Resilience Plan, in the context of the NGEU programme launched by the EU, provides further evidence of the potential for progresses in both investments and governance approaches to AI and robotics in these fields.

In line with Chart below, the present deliverable is totally consistent with the timetable. The report contributes to Action 4 and its lines of enquiry. The research carried out for the deliverable will then contribute to further deliverables: D4.3 Report on key recommendations for the effective governance of robots, and D4.6 Policy recommendations for the governance of robot care, both due by Month 44.

The report shows that **while the multi-level governance of AI and Robotics remains in a formative stage, the growing alignment between financial investments and coordination mechanisms — especially at the European level — is laying the foundations for more effective and structured policy action in key sectors like healthcare.**


2023
2024
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MISSION 1: CLINICAL TRANSLATION & INNOVATION
ACROSS MISSION1-2
MISSION 2: BIOROBOTIC PLATFORMS & ALLIED DIGITAL TECHNOLOGIES
HTA and LEPA ACTIVITIES
T3.1 Impact dimensions identification
67%
T3.3 In-field analyses
0%
T3.2/T3.4/T3.5 Impact assessment/monitoring of the robotic therapies.
19%
T3.6 HTA inputs for a decision support system (DSS)
0%
T3.7 Healthcare and personal care Innovation Eco-Systems
33%
T3.8 Overcoming organizational barriers against deployment
0%
T4.1 Legal gaps and enablers for biorobotic devices and allied digital technologies
29%
T4.2 Governance Gaps: organizational challenges and standardization of service providers procedures
14%
D4.4.1 Report on the multi-level governance of robots, before and after the set-up of the EU Recovery Plan (NRRP) #1
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D4.7 Report on the mapping of stakeholders- needs and actions
D4.7.2 Report on the mapping of stakeholders- needs and actions#2
D4.7.3 Report on the mapping of stakeholders needs and
D4.7.4 Report on the mapping of stakeholders needs and actions#4
D4.3
D4.5
D4.6
T4.4 Open acceleration
25%
MISSION 3: NEXT GENERATION COMPONENTS
MANAGEMENT

2 INTRODUCTION: A MULTI-LEVEL GOVERNANCE PERSPECTIVE OF AI AND ROBOTICS

The present report provides the updated map of governing tasks and functions in the field of Artificial Intelligence (AI) and Robotics. The aim is to contribute to the definition of the responsibilities across levels of government, and the identification of actors and institutions, and their priorities and instruments to support an effective strategy for the spread of new technologies, with particular reference to the fields of healthcare and personal care. The report thus contribute to the key goals of Mission 1, Activity 4 that aims at contributing to the definition of the responsibilities across levels of government, and the identification of actors and institutions their priorities and instruments to support an effective strategy for the spread of new technologies.

While D4.4.1 was aimed at mapping governance instruments at international, European, national and subnational levels, the present deliverable looks into more detail at the most recent programmes set up at the European Union (EU) level in the aftermath of the pandemic crisis. The present report represents an up-date of the deliverable D4.4.1, with a new section on the EU strategy for AI and robotics. The new section is added to shed light on the Italian recovery and resilience plan and the investments set up to address the technological challenges in healthcare and social care fields: 12 pages of text are added to the previous delivery for a more in-depth reconstruction of the governance of AI and robotics after the pandemic crisis.

The report looks at the multi-level governance of AI and Robotics with the description of the main strategies set up at the global, European, national and regional level. In line with governance studies, the next pages focus on key programmes and initiatives that, at least potentially, involve different policy instruments – regulation, coordination, distribution of resources – that support the development of new approaches to health and personal care. The report provides a first preliminary map of the governance in the field, while it outlines the key characteristics of the same governance architecture (in terms of strength and weakness). That way it contributes to the accumulation of first information on the governance challenges that will be analysed in further reports and deliverables.

The report is structured as follows. After the introduction, Section 3 focuses on key concepts: AI, Robotics and governance. As for the latter, the reference is to the multi-level governance approach with the definition of the actors, institutions and instruments that are set at different levels. The same section sheds light on AI and robotics with the clarification of terms and concepts. Through the review of the more recent contributions in the literature, we aim at identifying the main problems, risks and opportunities that come from the interaction of different forms of governance with different policy problems.

Section 4 starts the analysis of multi-level governance of AI and Robotics with particular emphasis on the last couple of decades. We start with a focus on the global dimension. Some international organizations (IOs) have increasingly addressed issues related to the field, setting standards and guidelines while also providing room for the systematic exchange of information and comparable data across the globe. While the long list of international organisations in the field is added to the text (Annex 1), this first deliverable focuses more on some of the same IO s. We focus on the main interventions of the Organisation for the economic cooperation and development (OECD) and the World Health Organisation (WHO). Other IOs are at the core of other FIT4MEDROB deliverables (see D4.1.1).

Section 5 then looks at the European level with a focus on the European Council and the increased role of the European Union (EU). The latter has developed different programmes and initiatives that have recently gained momentum in the context of the so-called digital transition and the pandemic crisis. As well as in the previous section, while there is reference to different institutions and programmes (in line with Annex 1), the focus is more on some recent initiatives on the broad field of AI.

Sections 6 and 7 focus on the governance of AI and Robotics in Italy at both national and regional levels. The focus is on regulation, administrative strategies and financing programmes. The Italian National Recovery and Resilience Plan (NRRP) and new budgetary lines for supporting the digital transitions are analysed with reference to Missions 4, 5 and 6 of the same Plan. Section 8 concludes.

The different levels of the complex governance in the field provide evidence of shadows and lights with the persistent weakness of the governing instruments. The report confirms Multi-level Governance (MLG) in the field is a work in progress with evidence of lose coordination, while important achievements concern the definition of

common understandings of AI and Robotics and their consequences. More ambitious investments have been set at the European level. Different initiatives have been launched in the line with the definition of ambitious strategies for the post-pandemic recovery.

While the first policy interventions date back to the 1980s, the area of AI and Robotics proves to be still an emerging multi-level governance. While new financial resources have been mobilized especially at EU, national and regional level, and there is evidence of increased coherence between different texts, the coordination and synergies between the different levels is still limited. All this is consistent with the first insights from FIT4MEDROB: irrespective of the increased importance and evidence of possible advantages of robotics in addressing healthcare and personal care, legal and procedural barriers prevent them from being included in the national and regional healthcare policies and regulations or adopted by rehabilitation hospitals.

3 Concept clarification: AI, Robotics and their Governance

The concept of Artificial Intelligence[1] (AI) has been addressed in policy analysis from the late 20th Century. AI refers to computer programs and machines that can perform predefined tasks at high speeds and accuracy with advanced processing power (Izenman, 2008). Originally based on neural networks, AI was further developed through big data analytics and Machine-learning algorithms that replicate human decision making (Taehiagh, 2021). The broad concept of AI includes different applications – such as: cognitive computing, machine-learning (algorithms that can teach themselves tasks), augmented intelligence (cooperation between human and machine) and robotics' (EESC 2017 quoted in Ulikane et al, 2021) – in different domains and for different purposes. Among them, the use of assistive and surgical robots in healthcare and personal care that have been introduced to address problems of budgetary costs, labour market shortages, low productivity and ageing (World Economic Forum, 2018). Table 1 below provides a summary of terms used in the field.

Table 1 Key terms in AI and Robotics

Terms	Definitions
Artificial intelligence	Computer programmes and machines able to mimic human intelligence or even surpass it to perform a given task such as prediction or reasoning.
Machine Learning	ML is a subfield of AI and concerns the methods that learn to perform given tasks, such as prediction or classification, based on existing data.
Big Data	The term big data is used in instances in which the data samples are too large to be adequately analysed with traditional AI methods. New methods consist of e.g. deep neural networks.
Neural Networks	NNs, technically known as artificial NNs, are circuits composed of a set number of interconnected neurons organised hierarchically in layers and which are capable of learning to perform highly complex tasks from data.
Deep learning	DL refers to NNs with more than three layers; in this case, the availability of big data is needed to estimate the optimal values of the parameters for this larger, more complex type of deep neural network
Healthcare AI	This is a type of AI which is focused on specific applications in medicine or healthcare.
Robotics	movable machines that perform tasks either automatically or with a degree of autonomy
Healthcare Robotics	From exoskeletons to surgery robots and therapeutic robots, healthcare robots help patients such as wheelchair users walk again, perform surgeries autonomously, or support children under autism spectrum disease in learning emotions

Source, own elaboration from World Economic Forum (2018); EU Parliament (2021).

[1] The concept of AI was coined already in the 1950s, while major progresses have taken place more recently due to considerable increase in computational power and availability of data (Ulnicane et al, 2021).

The spread of AI and Robotics (that is movable machines that perform tasks either automatically or with a degree of autonomy2) was thus consistent with the definition of evident advantages and potential progress in economic and social terms.

Health and personal care represent a typical example (Dickinson et al, 2021). The so-called 'care crisis' consists of alarming demographic trends: a greater proportion of the population demands for more care services for chronic and complex health conditions. This is paralleled by the 'workforce crisis': labour shortcomings (e.g. shrinking labour force) together with lack of competences, skills obsolescence, dangerous working conditions and risks of ineffective care (if not abuses) (Broadbent et al, 2016). All this happens in the context of budgetary strains for health and LTC policies and the progressive devaluation of care activities and care workers (e.g. low salaries). AI and Robotics may represent an effective solution to at least some of these problems.

At the same time, risks and possible unintended consequences are also envisaged. Complex interaction of human beings and machines, the difficulty of the latter to manage unexpected scenarios, ethical issues and possible negative social consequences represent some of the possible 'side effects' of the diffusion of AI in contemporary societies.

In such a complex context, policy analysts started to address questions about the governance of such technological advancements. In the words of Tahehiag, (2021: 138) it is evident the 'need to reassess the efficacy of traditional governance approaches such as the use of regulations, taxes, and subsidies, which may be insufficient due to the lack of information and constant changes'. National governments as well as supranational (and subnational) institutions and non-governmental organisations need instruments to strike the balance between opportunity-enhancement and risks-prevention strategies while cultivating legitimate solutions as well accountability, transparency and efficacy.

Many have outlined the limit of traditional command and control mechanisms: 'regulations often fail to frame technological developments accurately' while norms are fragmented into binding rules, non-binding guidelines, self-regulatory codes of conduct just to name a few (Ducharck et al, 2023). It is in this context of mounting criticisms of the role of governments in contemporary societies that the concept of governance (applied to technology) has emerged. For governance we mean 'the structures and practices involved in coordinating social relations that are marked by complex, reciprocal interdependence' (Jessop, 1998).

Definitions of governance of technology and socio-technical systems often build on the idea of a shift from government to governance (e.g. Pierre & Peters, 2000) characterised by participation of a wider range of interacting and interdependent actors, such as civil society organisations, as well as complementing traditional hierarchies with coordination. In this study, governance is related to different analytical dimensions of interest:

- The merging of domestic and international politics: Beyond the clear separation between national and international, nation states are not the sole actors in the policymaking process. International organization act in the domestic decision making, while domestic actors act at the supra-national level (e.g. through Transgovernmental networks).
- Increased role of non-state actors: Beyond state-to-state relations, international relations as a complex conglomerate system where NGOs represent interests; engage in information exchange; negotiate, provide advice.
- New modes of governance and enforcement, beyond 'command and control'. Non-binding rules, codes of conduct, and best practices are consistent with more transparency and participation, while there is evidence of the rise of private governance (private actors play a key role).

In what follows, we propose the term Multi-level Governance to capture the main traits of the governance of technological innovation. Multi-level governance (MLG) has been one of the key concepts used to describe such a changing policymaking (Stephenson 2013). Table 2 summarises the first list of levels and Organisations in the area of AI and Robotics that are analysed in the next sections (see Annex 1 for a larger set of Institutions and Actors involved in the MLG of the field).

[2] See Ducharck et al, 2023, p. 1.

Table 2. Multi-Level Governance of AI and Robotics: A preliminary Map

Level	**Organisations/Actors**
Global	OECD; WHO
European	EU, Council of Europe
National	Italian Government
Sub-national	Italian Regions

Source, own elaboration.

In line with Niemann and Schmitter (2009), we define Multi-level Governance as '(...) an arrangement for making (...) decisions that engages a multiplicity of politically independent but otherwise interdependent actors (...) at different levels of territorial aggregation in more-or-less continuous negotiation/deliberation/implementation, and that does not assign exclusive policy competence or assert a stable hierarchy of political authority to any of these levels'.

The MLG approach has been consistent with the assumption that new plurilateral governing modes lead to the reduced relevance of governments, in that they are nested in a complex set of actors and levels (Pagoulatos and Tsoukalis 2014). National governments cannot dominate these networks even if they are a constituent part of them. This is especially the case of 'day to day' decision-making, where a plethora of actors (lobbies, technical committees, independent agencies) interact with each other and at different levels of jurisdiction. MLG gives particular attention to the increased role of supranational institutions as well as subnational actors who enjoy some freedom vis à vis the state (Piattoni 2010). What is more, the MLG perspective looks at the reciprocal interference between actors and levels of governance through open-ended and non-hierarchical modes of interaction (Littoz-Monnet 2010; Natali, 2015).

4 The Global Level of AI and Robotics Governance

As stressed above, AI is key to solving global challenges and some of the world's most pressing problems such as climate change, sustainable economic activity and access to quality health services for all. AI brings many opportunities but also risks and challenges for governments, public administrations, and citizens. As such, AI developments have gained increased attention at the level of international organizations (IOs) which, together with national and supranational organizations, are working to provide a framework for common (ethical and democratic) standards for AI governance.

In this regard, the OECD Global Parliamentary group on AI—established in 2020 as the first international network of parliamentarians—is working in partnership with the European Parliaments' Panel for the Future of Science and Technology (STOA) to foster international cooperation on AI-related issues, share expertise and best practices on AI policies, and promote legislative changes. The working basis for the group is constituted by the OECD principles on AI adopted in 2019[3]. These principles revolve around the promotion of human-centric AI policies whose development must comply with human rights and democratic values. These principles are:

1. Inclusive growth, sustainable development and well-being.
2. Human-centered values and fairness.
3. Transparency and explainability.
4. Robustness, security and safety.
5. Accountability.

From these value-based principles, a series of policy recommendations for policymakers follow. These are:

1. Investing in AI research and development.
2. Fostering a digital ecosystem for AI.

[3] OECD Council Recommendation on Artificial Intelligence adopted on 22/05/2019. Available here. The Recommendation is the first intergovernmental standard on AI.

3. Shaping an enabling policy environment for AI.
4. Building human capacity and preparing for labor market transformation.
5. International co-operation for trustworthy AI.

Helping governments in implementing these principles is the key priority of the OECD Working Party on Artificial Intelligence Governance (AIGO), established within the OECD's Committee on Digital Economy Policy (CDEP)[4]. Members of AIGO are nominated by OECD member governments and are primarily national officials responsible for AI policies in their countries. Within AIGO, the OECD.AI Network of Experts works as an informal group of experts from governments, businesses and civil society who provide policy advice on AI-related matters. The Network also serve as a venue for sharing information with other international organizations and features representatives from important international organizations such as the Council of Europe, the Inter-American Development Bank, the United Nations, and the World Bank, as well as from international initiatives such as the Global Partnership on AI.

4.1 AI, Robotics and Healthcare

IOs have also emphasized the role of AI in different policies, including health care[5]. AI systems applied to health care may help activities such as outbreaks' prevention, health systems' optimization (e.g. resource allocation, workflow management), health research (e.g. drugs and treatment discovery, vaccine development), provision of personalized healthcare (e.g. self-monitoring tools, applications and trackers), nursing and elderly care, disease diagnosis (e.g. radiology), and precision medicine (OECD, 2019, 2022; WHO, 2021). AI applications in health care may be physical (e.g. a robotic system) or virtual (e.g. machine or deep learning). Narrowing down the focus from AI to health-related robotics, the OECD underscores the importance of public support for research and development (R&D) in this field. In fact, "robots are the most significant interface between AI and the physical world" (OECD, 2021: 14) and may have many roles in health care. For example, remote-controlled robotic surgery can improve the safety of interventions and makes surgery possible in anatomic locations not otherwise reachable (OECD, 2020). Also, in the context of the COVID-19 pandemic, robots have been used to disinfect remotely to reduce the exposure of health workers to the virus and to assist doctors with medical image screening for COVID-19 diagnosis (OECD, 2021, 2023). However, it has been highlighted that the deployment of such applications has been limited due to poor health data governance and privacy concerns.

The health policy area is therefore extremely relevant to AI, above all because the health sector is a knowledge-intensive sector which depends on data and analytics to improve therapies and practices. However, AI systems deployed in this policy domain also pose crucial challenges (OECD, 2019, 2020). International organizations such as the OECD and the WHO have been active in the debate over the benefits and risks of AI and health-related robotics. As highlighted by the WHO, AI holds great promise for improving healthcare and medicine worldwide, but only if ethics and human rights are put at the heart of its design (WHO, 2021). Table 3 presents governance opportunities and challenges of AI applications in the health sector.

Table 3. AI applications in health: Opportunities and challenges for governance

Opportunities	**Challenges**
Improving patient care Secondary use of health data can improve the quality and effectiveness of patient care, in both clinical and homecare settings. Rapid processing of complex datasets such as a patient's health records, physiological reactions and genomic data (*precision medicine*).	*Data privacy* AI challenges personal data protection principles of collection limitation, use limitation and purpose specification. To train AI systems, machine learning algorithms require a vast quantity of data. This creates an incentive to maximize data collection. In health care, a

[4] Other OECD expert groups include the Expert Group on AI Risk & Accountability, the Expert Group on AI Foresight, the Expert Group on AI Incidents, and the Expert Group on Compute & Climate.

[5] Deliverable D4.1.1 provides the analysis of the role of the United Nations (UN) through the United Nations Convention on the Rights of Persons with Disabilities (UNCRPD) (see Vivaldi et al 2023).

Real-time feedback from prevention to diagnosis, treatment and monitoring (*mobile health*). AI can facilitate the shift from hospital to home-based care.	substantial part of such data derives from individuals, and is of a particularly sensitive nature.
Managing health systems Health data can inform decisions regarding programmes' planning and funding. AI can be used to assist personnel in complex logistical tasks, such as optimization of the medical supply chain.	*Interoperability* Healthcare systems still tend to capture data in silos and analyze them separately. Standards and interoperability are key challenges that must be addressed.
Understanding and managing population and public health Data can be used to identify unanticipated side effects and contraindications of new drugs. AI might be used to predict illness or major health events before they occur. AI technologies may allow for early identification of outbreaks and surveillance of disease spreading.	*Fairness and ethics* Algorithms tend to reflect and repeat the biases implicit in their training data, such as racial biases and stereotyped associations. AI technology may not meet the standards of scientific validity and accuracy that are currently applied to medical technologies. The quality and availability of data may not be adequate for use of AI. Concerns linked to the digital divide.
Facilitating health research Health data can support clinical research and accelerate discovery of new therapies. AI could change drug discovery from a labour-intensive to a capital- and data-intensive process with the use of robotics.	*Cybersecurity* Increased frequency of High-profile ransomware and malware attacks (e.g. software supply chain attacks) The emergence of health data as a high-value target for cyber criminals Increased technical complexity to implement and maintain tight security controls

Source: Authors' elaboration based on Council of Europe (2021), Council of Europe - Committee on Social Affairs Health and Sustainable Development (2020), OECD (2019; 2020), WHO (2021).

To limit the risks and maximize the benefits linked to the use of AI in the health sector, the WHO provides six principles for AI governance in health care. These are the following (WHO, 2021):

1. *Protecting human autonomy*: Humans should remain in control of medical decisions and privacy and confidentiality should be protected.
2. *Promoting human well-being and safety and the public interest*. AI systems employed in health care-related activities should satisfy standards for safety.
3. *Ensuring transparency, explainability and intelligibility*. Sufficient information must be published and easily accessible before the design or deployment of AI systems. Debate on how the AI technology is designed and how it should (not) be used must be facilitated.

4. *Fostering responsibility and accountability*. AI technologies bust be used under appropriate conditions and by appropriately trained people.
5. *Ensuring inclusiveness and equity*. AI for health-related activities should be designed to encourage equity in use and access, irrespective of age, sex, gender, income, race, ethnicity, sexual orientation, ability or other characteristics protected under human rights codes.
6. *Promoting AI that is responsive and sustainable*. Designers, developers and users should continuously assess AI applications during actual use. AI systems should be designed to minimize their environmental impact. Governments and companies should provide training for health-care workers to adapt to the use of AI systems.

5 The European Level of AI and Robotics Governance

As stressed above, in Europe different organisations have proved active in the field of AI[6]. The Council of Europe[7], and in particular the Committee on Artificial Intelligence (CAI), has a central role to ensure that human rights and the rule of law are not undermined by AI systems (Council of Europe - Commissioner for Human Rights, 2019). The CAI is instructed to "establish an international negotiation process and conduct work to elaborate an appropriate legal framework on the development, design, and application of artificial intelligence[8]".

The European Union is also involved in the multi-level governance of AI and Robotics. Her role is based on different programmes and aims at an encompassing approach to both opportunities and challenges. While the global level is marked by the focus on key principles and the definition of broad strategies to address both challenges and opportunities of AI and Robotics, the European level is characterized by the proliferation of different policy instruments (Brady, 2022).

In what follows, we first refer to the EU governance on AI to then focus on technological innovation in healthcare and personal care. We look in particular at what has happened in the last decade, with reference to the broad strategy for AI. Then we focus on the attempts for a coherent EU regulatory framework and then, to financing programmes before and after the pandemic crisis.

5.1 The EU Overall Strategy

Following the conclusions of the European Council of 19 October 2017 that called the European Commission (EC) to put forward a common approach to AI by early 2018 (EUCO 14/17) and the ***Declaration of cooperation on Artificial Intelligence (AI)*** signed by 25 European countries the 10th of April 2018, the EC published a communication, entitled ***"Artificial Intelligence for Europe"*** (COM(2018) 237 final). The Commission claims that a coordinated approach is needed to "make the most of the opportunities offered by AI and to address the new challenges that it brings" and sets out a European initiative on AI.

The Commission expresses its willingness to enhance the EU's technological and industrial capacity, prepare for socio-economic changes resulting from AI and provide an ethical and legal framework. The Communication envisages an increase of the investments in AI by 70% in the period 2018-2020, namely through the Horizon 2020 programme, reaching an average of €500 million per year. The EC further aims to attract private investments and enhance public investments, through Public-Private Partnerships, the European Fund for Strategic Investments, the cooperation with the European Investment Bank Group and the European Investment Fund. Finally, the EC proposes to increase the funds even more the investments in AI under the Multiannual Financial Framework 2021-2027.

In June 2018 the EC launched the AI Alliance, a community of citizens, civil society, business and consumer organisations, trade unions, academia, public authorities and experts, aiming at promoting an open policy dialogue

[6] The present report complements other FIT4MEDROB deliverables: notably, D4.1.1 that focuses on the EU Disability Strategy 2010-2020 that was drawn up in 2010.

[7] The Council of Europe is a human rights organization that It includes 46 member states, 27 of which are members of the European Union. All Council of Europe member states have signed up to the European Convention on Human Rights, a treaty designed to protect human rights, democracy and the rule of law. It consists of a committee of representatives of governments and of a consultative assembly.

[8] CAI's Terms of Reference, p. 1. Available here.

on Artificial Intelligence; moreover a High-Level Expert Group on AI was created, with the aim of working on the drafting of AI ethics guidelines.

At the end of 2018, the EC published the Coordinated Plan on Artificial Intelligence, [COM(2018) 795 final], whose goals were to: "to maximise the impact of investments at EU and national levels, encourage synergies and cooperation across the EU, including on ethics, foster the exchange of best practices and collectively define the way forward." It encourages MSs to implement by mid-2019 and share with the other countries "national AI strategies or programmes" or include "AI dimensions" in pre-existing strategies and programmes.

The Commission commits itself to working on the developing of a common *strategic research and innovation agenda* for AI and on assessing the suitability of the existing legislation "to allow for the new opportunities and tackle the challenges raised by AI".

Finally, the EC claims its willingness to promote at international level the ethics guidelines that were about to be developed by the High-Level Expert Group.

In April 2019 the Commission issued a new communication, *Building Trust in Human-Centric Artificial Intelligence* [COM(2019) 168], that, relying on the belief that *trustworthiness of AI* is of the utmost importance to promote an human-centric approach to AI, illustrates the ethical guidelines set up by the High-Level Expert Group.

Three components are deemed necessary to achieve trust: compliance with the law, fulfilment of ethical principles, robustness. Hence derive seven (non-binding) requirements for AI applications: *Human agency and oversight*; *Technical robustness and safety*; *Privacy and data governance*; *Transparency*; *Diversity, non-discrimination and fairness*; *Societal and environmental well-being*; *Accountability*. The EC endorses these requirements, launch a consultation plan with the relevant stakeholders to evaluate an assessment list for practical use by companies that came with the requirements, and reaffirms its intent to promote the Union's approach to AI globally.

In February 2020, when the COVID-19 pandemic was about to outbreak in Europe, the EC issued the *White Paper On Artificial Intelligence - A European approach to excellence and trust* [COM(2020) 65 final] aiming at illustrating the key elements of the policy framework necessary to achieve, in the AI field, an *ecosystem of excellence* and an *ecosystem of trust.*

Regarding the so-called *ecosystem of excellence*, the EC is determined to revise the Coordination Plan after consultations with Member States and other stakeholders, set up a new public private partnership in AI, data and robotics and promote the adoption of AI by the public sector (with particular attention to healthcare and transport). In the field of health and personal care, the EU has identified certain fields of application of new technologies: medical image quantification, automated analysis of genetic data, disease prediction, medical robotics, telemedicine and virtual doctors (European Parliament, 2022).

5.2 ATTEMPTS FOR A EU REGULATORY FRAMEWORK

With reference to the *ecosystem of trust,* the EC states that a "clear European regulatory framework would build trust among consumers and businesses in AI and therefore speed up the uptake of the technology". The EC identifies in the protection of fundamental rights, safety, and liability-related issues the main risks related to the use of AI that should be addressed by the regulation and claims the necessity to define wisely the scope of the aforementioned framework. Finally, regarding governance, the EC calls for a *framework for cooperation of national competent authorities,* with the aim of equipping Europe with the necessary capacity for testing and certifying AI-enabled products and services. The Commission further tries to identify possible tasks for a European governance structure, such as exchanging information and best practice, advising on standardisation and certification activities and facilitating the implementation of the legal framework. The Commission further adds that close links should be established with other EU (or national) competent authorities to coordinate and complement existing expertise.

In April 2021 the Commission put forward a comprehensive package, made up of the Communication *Fostering a European approach to Artificial Intelligence* [COM(2021) 205 final]*,* an updated *Coordinated Plan on AI* and the *Proposal for a regulation laying down harmonised rules on AI* (AI ACT). The Communication illustrates the reasons behind the decision of the EC to focus on this theme, namely "to promote the development of AI and address the potential high risks it poses to safety and fundamental rights equally" and summarises the content of the two other documents.

The review of the *Coordinated Plan on AI*, following the original version issued in 2018, provides four key sets of suggestions on how to *accelerate*, *act* and *align* to harness the potential of AI technologies and to ease the European approach to AI:

- Set enabling conditions for AI development and uptake in the EU.
- Make the EU the place where excellence thrives from the lab to the market.
- Ensure that AI works for people and is a force for good in society.
- Build strategic leadership in high-impact sectors.

A paragraph dedicated to the actions necessary to enable the contribution that AI technologies might give to healthcare is featured in the fourth set of suggestions. Further than advocating for the enactment of the proposal of Regulation on the European Health Data Space (EHDS) that the Commission advanced in May 2022 [COM(2022) 197 final], the Commission calls Member States to take a set of actions. In particular, the Commission encourages to undertake actions to improve "quality and semantic interoperability of health data", essential for development and use of AI; support initiatives to improve the knowledge and acceptance of digital technologies among healthcare professionals to facilitate the uptake of artificial intelligence-based systems in healthcare; support investment in secondary uses of health data, including artificial intelligence, for instance through the Recovery & Resilience Facility (RRF) funds; adopt measures to facilitate the integration of innovative AI-enabled systems (such as machine learning, autonomous systems, conversational agents, big data, robotics) in health and care facilities such as hospitals and care homes, particularly where the digitisation of health systems is outlined in national recovery and resiliency plans; work with national, regional and international standardisation bodies to define and set common standards to update current standards for AI for health.

Furthermore, in this Coordinated Plan, the Commission arranged a Strategy for Robotics in the world of AI, committing itself to "implement actions to ensure that Europe remains a global powerhouse in robotics"; work with Member States to identify possible gaps, priorities and policy metrics, define common standards and promote robotics in education. Finally, the Commission calls Member States to develop national investment plans for robotics.

Regarding the third part of the Commission's package, the proposal of Regulation, it distinguishes between uses of AI that create (i) unacceptable risk, (ii) high risk, and (iii) low or minimal risk. By means of this differentiation, the EC claims to be promoting a *future-proof* and *innovation-friendly* approach.

Those AI systems whose use is deemed unacceptable because contrary to the values of the Union, are banned (for instance, social scoring for general purposes implemented by public authorities).

High risk AI systems are allowed on the European market under the meeting of mandatory requirements and an ex-ante conformity evaluation. A first list of AI systems classified as high-risk, whose assessment has been based not only on the function but also on the aim and on the modalities of its use, is provided in the Annex III.

Furthermore, the EC proposal contains transparency requirements that apply to those AI systems that interact with humans, detect emotions, determine associations with social categories based on biometric data, or generate and manipulate content such as deep fakes.

Regarding governance, the proposal contains provisions affecting both the European and the national level. Regarding the European level, the establishment of a European Artificial Intelligence Board is envisaged, made up of a representative of the MSs and of the Commission. The tasks of the Board would be those of "facilitat[ing] a smooth, effective and harmonised implementation of this regulation by contributing to the effective cooperation of the national supervisory authorities and the Commission and providing advice and expertise to the Commission". Furthermore, it will also be in charge of the collection and sharing of best practices among the MSs. Moreover, the EC acknowledges the European Data Protection Supervisor as the competent authority for the oversight of the Union institutions, agencies and bodies when acting within the scope of this regulation.

At national level, instead, the EC proposal requires the MSs to designate at least one national competent authority and a national supervisory authority.

With respect to the monitoring, the EC proposes to create a Europe-wide database for high-risk AI systems with primarily impacting fundamental rights which would be managed by the Commission itself; at national level, the proposal does not provide for the automatic creation of additional bodies or authorities.

This Proposal has not been approved yet. A first partial compromise text of this proposal has been published by the Slovenian Presidency of the Council in November 2021; a second compromise text has been reached by the French Presidency in July 2022. Negotiations between MSs were mainly focused on the scope of the Regulation (namely on the exclusion of national security issues), on the risk-based classification of AI systems, that has been revised by both compromise texts, and on the governance field, with a strengthened Board.

A final compromise by the Council has been reached between November and December 2022. Among the most relevant revisions of the Commission Proposal might be flagged: the introduction of *life and health insurance* among the high-risk AI systems, an horizontal layer on top of the risk-based approach to take into account the relevance of the AI system's output on a person's action and, finally, the requirement for the EC to designate one or more Union testing facilities and to create a "central pool of independent experts to support the enforcement activities". The text is now subject to trilogue negotiations between the Council of the EU, the European Commission and the European Parliament.

Following the European Parliament own-initiative resolution of 20 October 2020 [2020/2014(INL)] calling for a civil liability regime for AI, in November 2022 the EC issued a proposal for a Directive regarding the liability of AI systems [COM(2022) 496 final]. This proposal aims at encouraging the deployment of trustworthy AI in order to fully take advantage of its benefits for the internal market. The EC wants to enhance trust on AI systems by ensuring that victims of damage caused by AI have the same protections as victims of damage caused by products in general. Furthermore, the Directive aims at reducing legal uncertainty about the potential liability of companies developing or using AI, and at preventing fragmentation that might arise from uncoordinated AI-related adaptations of national civil liability rules.

In addition, it is worth mentioning the proposal for a directive on liability for defective products repealing Directive 85/374/EEC. The proposed revision of the PLD aims at ensuring – among other objective - the high level of protection of consumers' health and property in the context of the green and digital transitions [COM(2022) COM(495 final].

5.3 EU FINANCING PROGRAMMES

As for the European financing programmes regarding AI, and specifically robotics, in the field of healthcare, we provide an overview of the programmes enforced in the seven-year-term 2021-2027 (corresponding to the current European multiannual financial framework term).

The first Programme we refer to is HorizonEurope that, following the path left behind by Horizon2020 in the previous Multiannual Financial Framework, enhances investing in AI and robotics. Horizon2020, established with the Regulation 1291/2013, was equipped with about €77 billion and aimed at "contribut[ing] to building a society and an economy based on knowledge and innovation across the Union by leveraging additional research, development and innovation funding and by contributing to attaining research and development targets". More specifically, Horizon2020 goal was declined into three objectives: strengthening the EU's technological and scientific position; strengthening industrial leadership in innovation, including major investments in key technologies, better access to capital and support for SMEs; addressing major concerns shared by all Europeans, such as climate change, sustainable transport, affordable renewable energy, food security and coping with an ageing population. Although no mention of AI was made in the Horizon2020 Regulation, there were two funding lines concerned with the topic of this paper. Indeed, €7,4 billion were geared towards Health, demographic change and well-being and, among the activities deemed proper to be financed, featured the dissemination of innovative technologies and approaches, under which Robotics and AI fall. Furthermore, amongst the activities to be financed by the €7,7 billion devoted to Information and Communication Technologies, the Regulation envisaged Advanced interfaces and robots: robotics and smart spaces, under which could have been carried out investments in the field of healthcare. Finally a Public Private Partnership between the EC and the European Robotics Community was launched in December 2013 under the Horizon2020 programme. SPARC, this was the name of the PPP, benefited €700 million from the EC and 2.1 bn from the European robotics industry, and aimed at facilitating the growth and empowerment of the robotics industry and value chain, from research through to production.

Focusing now on the Horizon Europe programme, it was established by Regulation 2021/695 with a total budget of €95.5 billion over the MFF 2021-2027, and the aim of "deliver[ing] scientific, technological, economic and societal impact from the Union's investments in R&I so as to strengthen the scientific and technological bases of the Union and foster the competitiveness of the Union in all Member States including in its industry, to deliver on the Union

strategic priorities and to contribute to the realisation of Union objectives and policies, to tackle global challenges, including the SDGs by following the principles of the 2030 Agenda and the Paris Agreement, and to strengthen the ERA". Regarding the topic of this research paper, two financing lines of the programme are related. Among the areas of intervention eligible for being financed by the €13 billion devoted to the cluster 'Digital, Industry and Space' features, indeed, artificial intelligence and robots. In the cluster Health, to which about €6.9 billion are allocated tools, technologies and digital solutions for health and care, including personalised medicine appears among the financeable areas.

Several projects concerning AI and robotics, with Italian institutions among the beneficiaries, have been already approved. To give some examples, Scuola Superiore Sant'Anna (€778,750) and Istituto Italiano di Tecnologia (€629,500) will receive funds from the Small AI-powered robots for a new future, researching on AI-powered small-sized robots that could find application in fields like medical interventions and water treatment. Università di Siena is the coordinator of Human-robot interface for upper-limb disabilities, from which it will receive around 1 million euros, while two other Italian institutions, Fondazione Santa Lucia (€799,100) and Istituto Italiano di Tecnologia (€617,500) will receive other relevant fundings. Finally, several Italian public institutions (Istituto Italiano di Tecnologia; Consorzio Interuniversitario Nazionale per l'Infomatica; Universities of Cagliari, Genoa, Milan, Modena and Reggio Emilia and Polytechnic University of Turin) and two firms (Leonardo and Pluribus One) will receive around €1,5 million euro in the framework of the European Lighthouse on Secure and Safe AI project. Other European funds have been potentially available for AI and robotics in recent years. For such investments, a discourse similar to that just seen for NextGenerationEU can be made. While they are not solely directed to AI and robotics, but more generally to improve the country's innovation, they could be an opportunity for some projects related to these fields.

Another programme worth a mention is InvestEU. It consists of a EU budget guarantee of €26.2 billion aimed at mobilising private and public investment in member states on four policy windows: research, innovation and digitalisation; SMEs; social investment and skills; sustainable infrastructures. The plan lists on its website 34 operations covering Italy, among which three are exclusively directed to the country. In this regard, we can highlight the funds for a project managed by Cassa Depositi e Prestiti supporting Mid-cap companies' capacities on industrial research and experimental development related to the green innovations, health and breakthrough technologies.

Finally, in continuity with SPARC, a partnership between the EC and the newly born European AI, Data and Robotics Association (ADRA) was signed. The Partnership, falling under the cluster Digital, Industry and Space, envisages an EC investment of 1.3 bn and an equal contribution from the partners.

Unlike Horizon Europe, EU4Health is a brand-new programme focused on healthcare and its innovation. It was established in March 2021 by the Regulation 2021/522 as a response to the COVID-19 pandemic. With a €5.3 billion budget available during the 2021-27 term, the general aim of this Programme is to develop stronger, more resilient and more accessible health systems. More specifically, the Programme provides four general objectives representing the programme's ambitions (*Improve and foster health, Protect people, Access to medicinal products, medical devices and crisis-relevant products, Strengthen health systems*) and ten specific objectives representing intervention areas. Among the specific pertaining to the latter general objective, it is featured the specific objective that relates to the subject of this research work: *Reinforcing health data, digital tools and services, digital transformation of healthcare.*

In particular, according to the Annex of the Regulation 2021/522, that specifies, for each objective, the actions that are deemed to be compliant with, the following measures can be financed under the objective above:

- (c) Supporting the digital transformation of healthcare and health systems, including through benchmarking and capacity building, for the uptake of innovative tools and technologies such as artificial intelligence, and supporting the digital upskilling of healthcare professionals.
- (d) Supporting the optimal use of telemedicine and telehealth, including through satellite communication for remote areas, fostering digitally driven organisational innovation in healthcare facilities and promoting digital tools to support citizen empowerment and patient-centred care.
- (i)Actions to support e-health, such as the transition to telemedicine and at-home administration of medication.

No specific provisions on the amount of the budget that is reserved to the field of AI and robotics is contained in the Regulation.

A third European financing Programme that is relevant for the subject of this research paper is the *Digital Europe Programme (DIGITAL)*. This program, established in April 2021 by the Regulation 2021/694, is budgeted at €7.6 billion euros. The global objective of the initiative is the development of the EU's strategic digital capacities and the promotion of the widespread use of digital technologies. Getting down to the details, the Regulation envisages five specific objectives: *High Performance Computing* (€2.1 bn); *Artificial Intelligence* (€2.1 bn); *Cybersecurity and Trust* (€1.6 bn); *Advanced Digital Skills* (€0.6 bn); *Deployment and Best Use of Digital Capacities and Interoperability* (€1.1 bln). Measures related to AI and Robotics in the field of healthcare fall under both the second and the last specific objective. In particular, healthcare is comprised in the first operational objective of the specific objective Artificial Intelligence, while the Annex, with specific reference to the objective Deployment and Best Use of Digital Capacities and Interoperability acknowledges the development of digital tools person-centred care (with specific reference to AI) among the actions to be included. The Programme recipients are companies, organisations and public administrations from EU Member States and other countries associated to the Digital Europe Programme.

Regarding European Cohesion policy, no reference to robotics and AI is made in their 2021-2027 Regulations. Despite this, since the Regulation of the European Regional Development Fund (2021/1058) envisages the promotion of "the transition from institutional to family-based and community-based care" among its goals (art. 3, c. 1), investments in Robotics and AI in the field of healthcare seems to be eligible for the ERDF funding. Robotics and AI, indeed, play a central role in the shifting of the care setting towards an always more individual-based approach.

One last programme to be assessed is the NextGeneration-EU (NGEU), the €750 billion programme that, complementing the Multiannual Financial Framework 2021-2027, constituted the European Union response to the COVID-19 pandemic. Focusing on the Recovery & Resilience Facility (RRF), its main instrument that distributed €672.5 billion (€360 bn in loans and €312.5 bn in grants) among Member States, no specific reference to AI and robotics in healthcare is present in its regulation [241/2021].

However, investments in this area were aligned with three out of the six pillars of the RRF: *digital transformation; health, and economic, social and institutional resilience; smart, sustainable and inclusive growth, including economic cohesion, jobs, productivity, competitiveness, research, development and innovation, and a well-functioning internal market with strong SMEs*. Member States could thus envisage measures pertaining to AI and robotics in the field of healthcare in their National Recovery & Resilience Plan (NRRP), see the Italian case below (section 7).

Finally, in June 2023 the European Commission put forward a proposal (COM(2023) 335 final) for an innovative programme, called Strategic Technologies for Europe Platform (STEP), aimed at "support[ing] critical and emerging strategic technologies". Not envisaging the creation of any new instrument or fund, it involves instead a combination of leverages on existing programmes, through their reprioritisation and targeted top-ups - amounting to 10 billions of euro. The EC believes that this mix of interventions could result in investments amounting to around 160 billions of euro, devoted to three strategic fields: 1) deep and digital technologies; 2) clean technologies; 3) biotechnologies. With respect to the topic of this report, robotics as well as artificial intelligence are both listed among the areas eligible for investments under the first heading. Although no direct reference to the application of robots and AI in the field of healthcare is made, medical technologies are envisaged under the third heading, and related investment can therefore fall also under this. At the moment in which this report is being written, the proposal is waiting to be discussed by the co-legislators. The report made by the two appointed committees of the European Parliament is due to be put to the vote of the plenary in the second half of October 2023.

To conclude this overview of the programmes and relative funds, it's proper to report an observation found in the *Study on eHealth, Interoperability of Health Data and Artificial Intelligence for Health and Care in the European Union*, published by the Directorate-General for Communications Networks, Content and Technology of the European Commission in 2021. Indeed, the Study sheds light on the fact that there is not a precise measure of the amount of investments committed to AI in the healthcare sector, as "funding programmes are either focusing on Applications of AI without specifying a particular sector or on Applications of ICT in healthcare".

6 The National Level of AI and Robotics Governance

6.1 The National AI Strategy

In September 2018, the Ministry of Economic Development launched a call for applications[9] for the selection of members of an expert group for drafting a National Strategy on Artificial Intelligence. The overall aim was to deepen the knowledge of AI systems to boost public and private investments in the AI policy area. The initiative is inserted within the broader EU strategy leaning on the EU Commission strategy for "Digitizing European Industry"[10] and the "Renewed EU Industrial Policy Strategy"[11]. Moreover, EU member states were encouraged to develop national strategies on AI already with the Communication on "Artificial intelligence in Europe" [12] of April 2018 aimed at favoring the digital transformation and ensuring adequate funding and resources for the development of AI systems.

In July 2020, the Ministry published the final document with proposals for the "Italian Strategy for Artificial Intelligence". The strategy is structured in three parts. The first part is dedicated to the analysis of the global, European and national AI markets. The second part describes the basic elements of the strategy, while the third part delves into the proposed governance of AI and proposes some recommendations for implementation and monitoring.

While identifying the core components of the Italian AI ecosystem (Figure 1 below), the document highlights that the deployment of AI services in Italy is still limited.

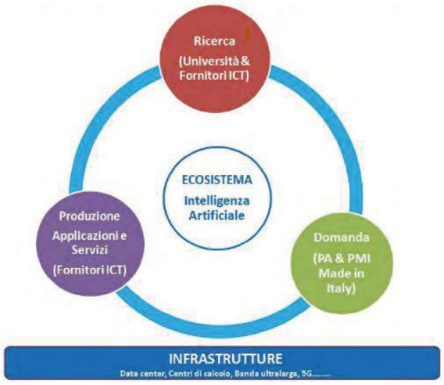


Figure 1. The Italian AI Ecosystem
Source: Ministero dello Sviluppo Economico (2020)

The strategy outlines a holistic approach to AI governance (whole-of-government) that ensures a constant dialogue between the scientific input from the research ecosystem, the support for innovation through regulatory policy, and the constant monitoring of the impact of national policies on sustainable development goals. The document ends with 89 recommendations. In terms of governance, it proposes the creation of an inter-ministerial control room (*cabina di regia*), the strengthening of innovation policy instruments, and an increased efforts in building up public-private partnerships (Ministero dello Sviluppo Economico, 2020).

In July 2021, the Ministry of University and Research, the Ministry of Economic Development and the Minister for Technological Innovation and Digital Transition established a Working Group tasked with supporting the ministries in their activities to update the national strategy on AI, and - in particular - to make it consistent with the National Recovery and Resilience Plan (NRRP) and recent developments at the European Union (EU) level.

In November 2021, the "Strategic Programme on Artificial Intelligence 2022-2024" (Italian Government, 2021a) is adopted. In line with the European Strategy[13], the Strategy outlines twenty-four policies to be implemented over

[9] Call for applications for the selection of members of a group of experts for the drafting of a national strategy on artificial intelligence, 13 September 2018, available here.
[10] COM(2016) 180 final, available here.
[11] COM(2017) 479 final, available here.
[12] COM(2018) 237 final, available here.
[13] See the "Coordinated Plan on Artificial Intelligence 2021 Review", available here.

the next three years to strengthen AI policies in Italy through the creation and enhancement of AI skills and research and development programs. The Strategy includes policies to promote courses and careers in STEM subjects and to strengthen digital and AI skills. Also, it encompasses policies needed to strengthen the structure of the Italian research ecosystem in AI, fostering collaborations between academia and research, industry, public bodies and civil society. The aim is to create new research chairs in AI, promote projects to incentivize the return of professionals Italy, and fund platforms for sharing data and software at the national level. The strategic document also refers to policies to expand the application of AI in public administration (PA). The latter are aimed at the creation of data infrastructures to securely exploit the potential of big data generated by the PA, the simplification and personalization of public service provision, and the use of periodic calls for proposals to identify and support startups offering AI-based solutions that can solve public sector problems.

Figure 2 represents the strategy's guiding principles, the key objectives, and the core areas of policy intervention, while Figure 3 below illustrates the key policies envisioned by the Strategy.

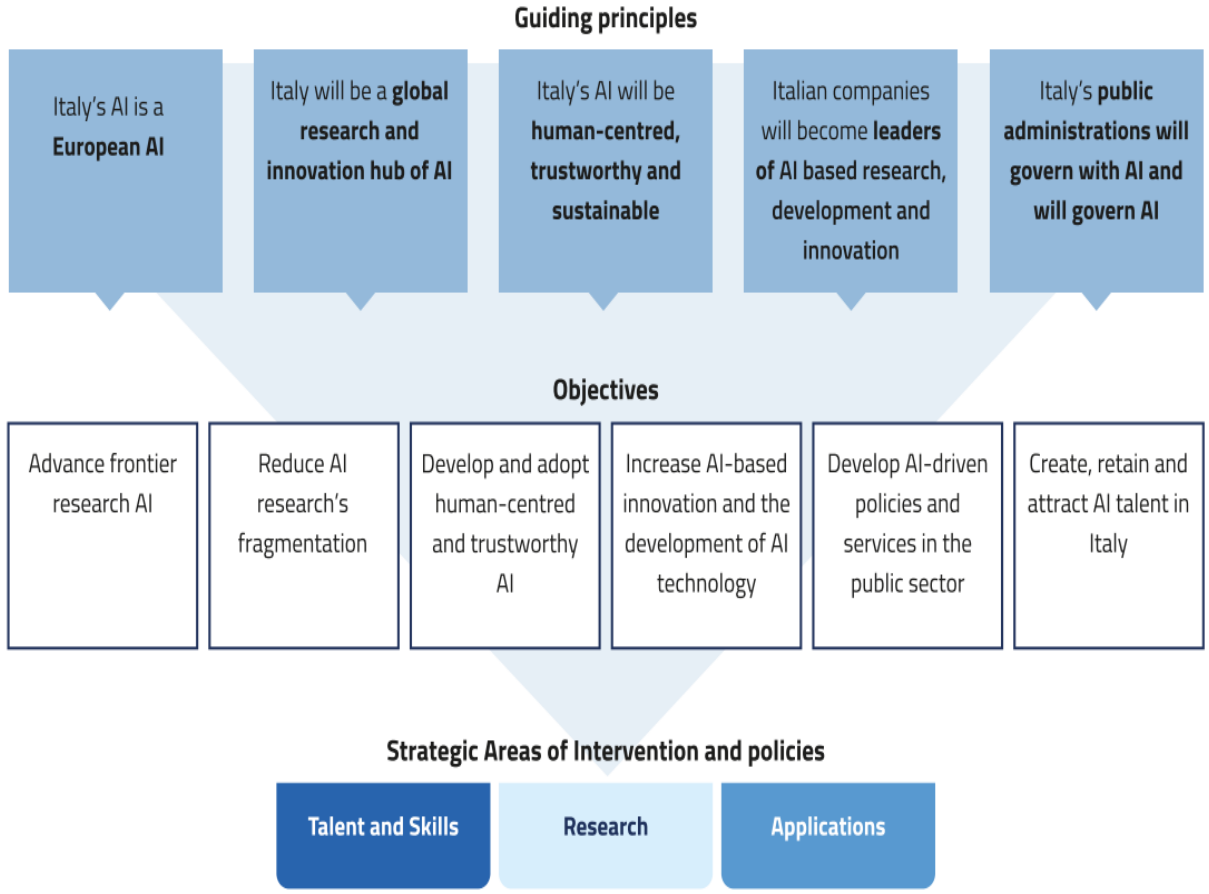


Figure 2. Principles, objectives, and areas of intervention of the Strategic Programme on Artificial Intelligence 2022-2024

Source: Italian Government (2021a: 20)

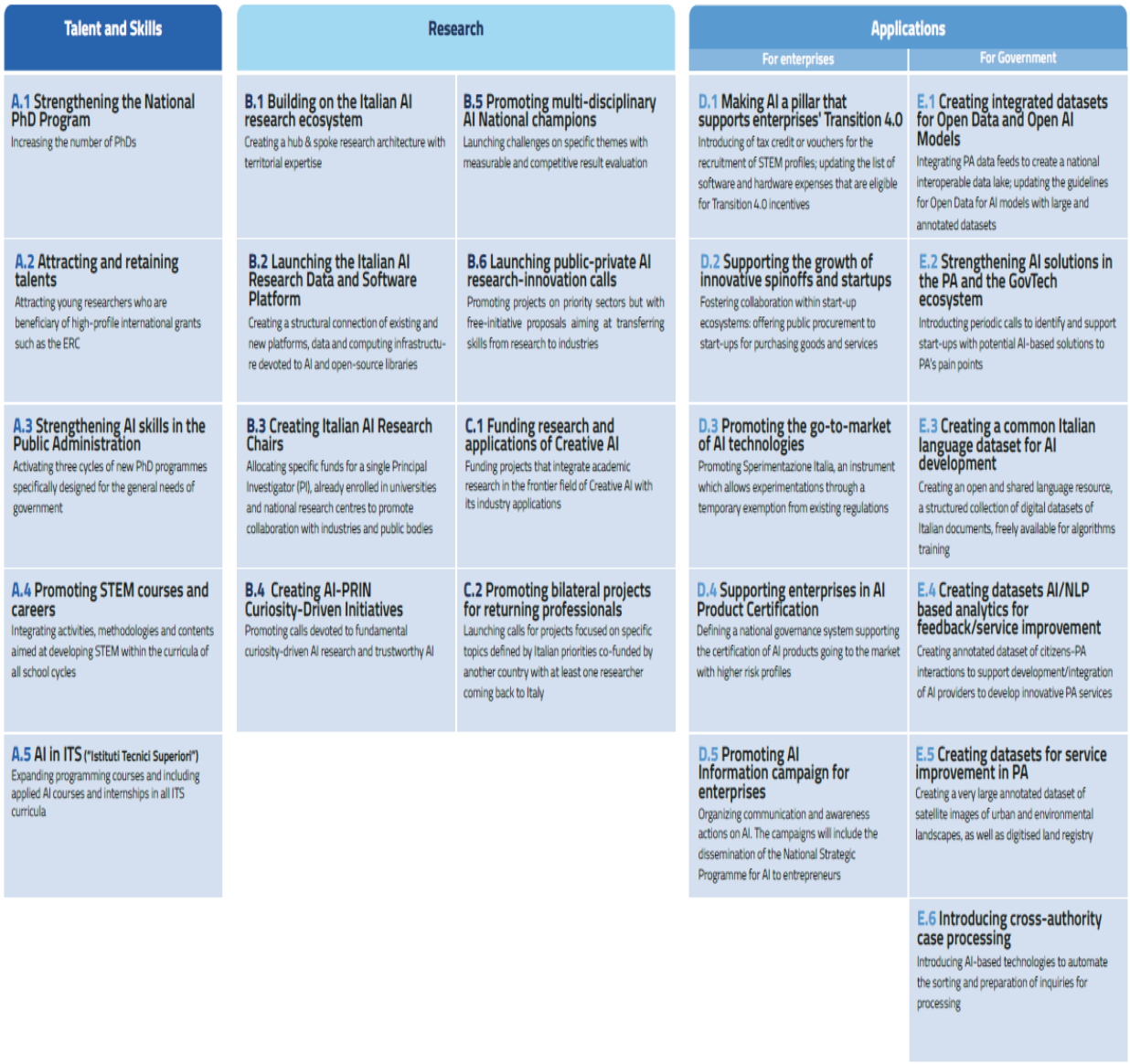


Figure 3. Key AI policies envisioned by the Strategic Programme on Artificial Intelligence 2022-2024 Source: Italian Government (2021a: 3).

Health care is amongst the priority policy sectors. The Strategy recognizes that, in the health care policy field, AI applications would boost product and process innovation by exchanging and aggregating information that is currently scattered in a multitude of underused databases. AI applications may help meet the needs arising from an ageing population and the population at risk of severe diseases (e.g., degenerative, oncological, and viral diseases), an may increase social inclusion of disadvantaged groups.

In terms of governance, the standing working group on AI within the Inter-ministerial Committee for the Digital Transition has been created with the aim to direct, monitor and evaluate the implementation of the strategy, as well as to coordinate all policy actions. This implies the possibility of involving other institutional players, research and academic circles and representatives from civil society and the private sector. Amongst the possible sources of investment, the document mentions the Italian NRRP.

7 AI and Robotics in the National Recovery and Resilience Plan

The National Recovery and Resilience Plan (NRRP) for Italy is a key policy instrument for the country to recover from the economic effects of the Covid-19 pandemic. Italy is the country with the largest share of funds coming from NextGeneration EU program, with a NRRP amounting to 191.5 billion euros of investments to be spent – with different timetables – within 2026. These funds are targeted to a variety of policy objectives, with a particular emphasis on the ecological and the digital transitions (Figure 4).

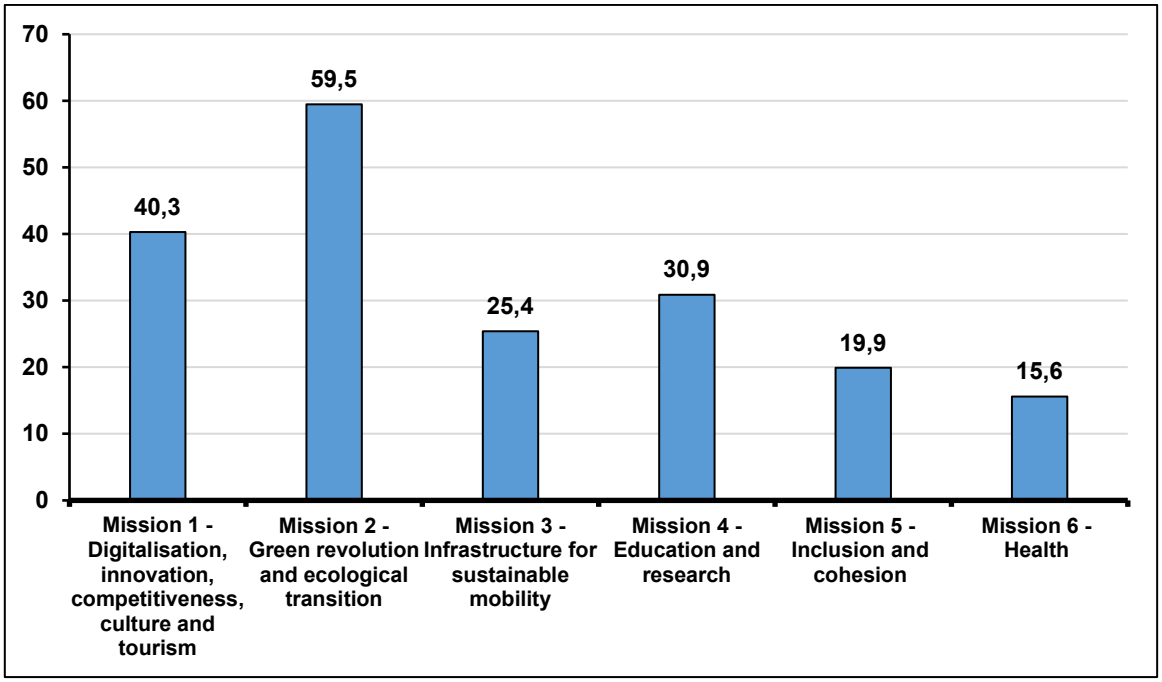


Figure 4. Missions of Italy's National Recovery and Resilience Plan (billion euros)
Source, Italian Government (2021b)

However, as some observers have complained[14], it lacks a coherent and organic strategy for AI and robotics. Moreover, the direct references in the plan to such instruments are rather scarce. IA is cited among the key instruments for the reform of Public Administration[15] and for the prevention of environmental risks through land monitoring[16]. Home automation plays a role, and in particular for investments targeted to elderly people the who are not self-sufficient or with chronic pathologies[17]. Despite the absence of a comprehensive strategy in the NRRP, the plan outlines several interventions that – while not directly targeted to AI and robotics – may represent an opportunity for scholars, researchers, and economic players in these fields.

[14] Bicchi, A., & Siciliano, B. (2021). Robotics for InterAction Technology: Italy's key role in the next revolution. *Nature Italy*, available at: https://www.nature.com/articles/d43978-021-00124-4 e Siciliano, B. (2021). *Il Pnrr trascura robotica e intelligenza artificiale*, la Repubblica, available at: https://www.repubblica.it/tecnologia/blog/robots/2021/10/10/news/il_pnrr_trascura_robotica_e_intelligenza_artificiale-321677263/.

[15] Italian Government, National Recovery and Resilience Plan, available at: https://www.governo.it/sites/governo.it/files/PNRR.pdf, p. 50, 68, 74 and 68.

[16] Ivi, p. 150.

[17] Ivi, pp. 214 and 228.

In the following we provide an in-depth analysis of three different missions of the Italian Plan: Mission 4 (Education and Research) and Mission 5 (Inclusion and Cohesion) in section 7.1 below; and Mission 6 (Health) in section 7.2 below.

7.1 NRRP - MISSIONS 4 AND 5

As anticipated in the section on the Italian strategy, the Strategic Programme on Artificial Intelligence of the Italian government indicates the NRRP as a major source of investments in the filed (Figure 5 below).

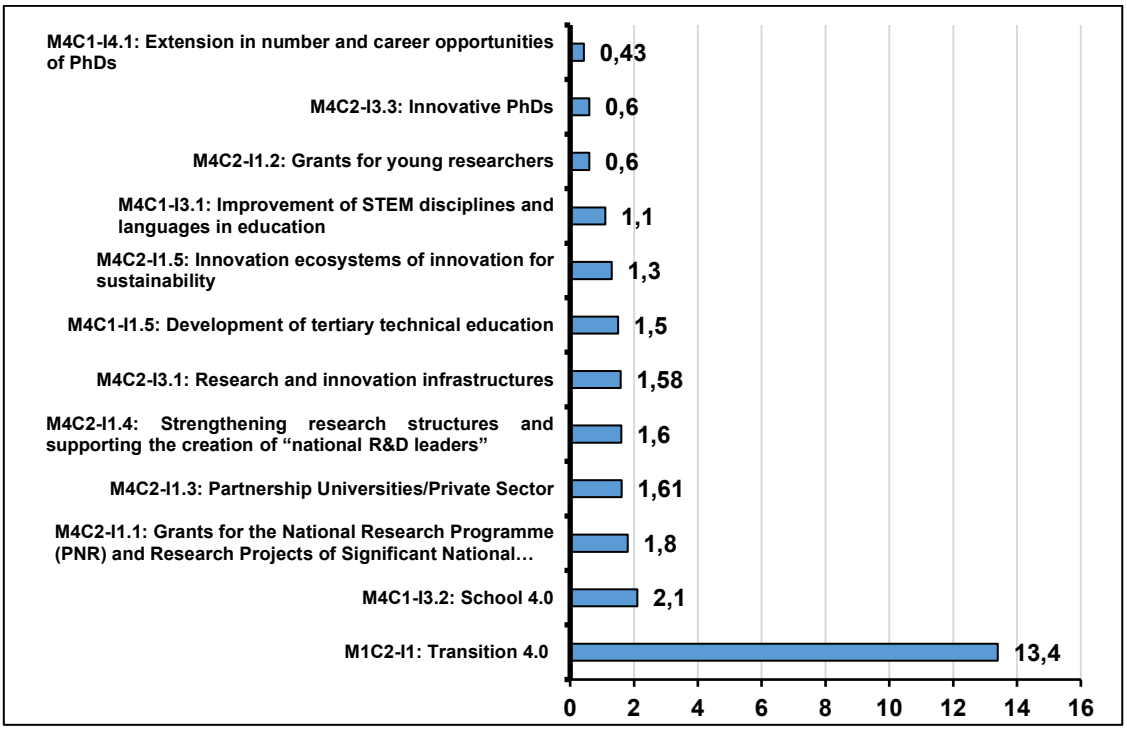


Figure 5. AI Investments in the Italian RRP (billion euros per Mission)
Source, Italian Government (2021b)

Most of the investments are part of the fourth mission, that dedicated to education and research. More in detail, about 1 billion euros is directed to funding innovative PhD programmes, through two Investments (M4C2-I3.3 and M4C1-I4.1)[18]. 600 million euros in grants are instead directed toward young researchers[19], while 1,8 billion will strengthen the National Research Programme and Research Projects of Significant National Interest.

An important investment is foreseen toward the improvement of the STEM disciplines and multilingualism in schools with 1.1 billion, which - albeit with effects on AI and robotics quite indirect - should strengthen the skills of Italian students on scientific subjects[20]. Similarly, another intervention in the high school sector aims at increasing the potentialities and the attractiveness of technical high schools (15 billion euros)[21]. Eventually, 2.1 billion euros will be used for the digital transition of schools.

Several relevant investments have the goal to stimulate the partnership between the private sector and the universities on R&D projects. The first one (M4C2-I 1.5) concerns the creation of 12 "territorial champions" of

[18] Ivi, pp. 199 and 191-192.
[19] Ivi, pp. 195-196.
[20] Ivi, pp. 189-190.
[21] Ivi, p. 185.

ecosystems for innovation, with a focus on sustainability[22]. The second (M4C2-I.13) will fund up to 15 partnerships between universities/research centres and firms[23]. In the third investment (M4C2-I3.1), 1.58 billion euros are directed toward the research infrastructure, namely thirty interventions on already existing infrastructures or to be created[24]. Eventually, 1.6 billion will be directed toward the funding of national champions of R&D (M4C2-I.1.4)[25].

One relevant investment is instead part of the first mission, that is dedicated to the Digital transition. The investment *Transizione 4.0* is one of the most ambitious of the whole NRRP, with a total 13.4 billion euros for several intervention directed on improve the digital transition of private firms[26].

While not directly addressed on the Strategic Programme on Artificial Intelligence, also the fifth mission contains certain interventions that involve, or may involve, AI and robotics.

Regarding Mission 5, two are the investments that are specifically relevant for the topics of this report: Supporting vulnerable people and preventing institutionalization (M5C2I1.1) and Autonomy patterns for people with disabilities (M5C2I1.2). They are both part of the second component of Missione 5, Social infrastructures, families, communities and third sector, whose general aim is to contrast social exclusion, reaching out to vulnerable population groups.

The first investment, with an allocation of 500 mln of euro, is designed to prevent institutionalization and it is articulated in four lines of action 1) Actions aimed to support parenting skills and to prevent vulnerability of families and children; 2) Actions for an autonomous life and the deinstitutionalisation for elderly people; 3) Reinforcing home social services to guarantee early supported discharge and prevent hospitalisation; 4) Strengthening social services and preventing burnout among social workers.

Domotics, indeed, is expressly quoted in the provisions related to the second line of action, which, gathering more than 300 mln of euro, is considered the core of the investment. It is called to play a central role in the conversion of retirement homes for the elderly into groups of autonomous apartments or, alternatively, in the establishment of networks of separated apartments to enable elderly people to maintain an independent life in their houses. This investment in technology, however, will have to be complemented by efficient social services to successfully meet the goal.

The second relevant investment, Autonomy patterns for people with disabilities, is likewise equipped with a 500 mln of euro allocation. The aim of the project is to improve the autonomy of people with disabilities through the enhancement of community and home-based social and health services. Three are the lines of activities envisaged: definition and launch of customised projects to support people with disabilities; renovation and adaptation of home spaces, with new technology solutions and remote assistance; development of digital competences to allow people with disabilities to tele-work.

Domotics is specifically cited in the actions to be carried out under the second line, to which about 30% of the total investment is planned to be allocated and that should contribute to the adaptation of home spaces according to the personal specific needs of the targets of this investment. Finally, a number of interventions that are contained in the sixth and last Mission of the Italian NRRP should be addressed as they envisage, or might allow, investments in AI and robotics (exspecially bio-robotics).

7.2 NRRP - MISSION 6

In line with the policy macro-area and fundamental pillar of NGEU "Health, Economic, Social and Institutional Resilience", the Italian NRRP encompasses numerous health-related reforms and investments in Mission 6 for a total amount of 15,63 billion euros (European Parliament, 2023[27]).

The Mission aims to strengthen the National Health Service (NHS) by tackling territorial, gender and intergenerational inequalities in access to healthcare and to the Basic Levels of Care and realizing the personalization

[22] Ivi, pp. 196-197.
[23] Ivi, p. 196.
[24] Ibidem
[25] Ivi, pp. 196-197.
[26] Ivi, p. 103-104.
[27] European Parliament, Briefing on Health-related measures in the National Recovery and Resilience Plans, 2023.

of care through the integration of sanitary, sociosanitary and social services also in favor of vulnerable people (Italian NRRP, 2021[28]).

The latter objectives of the Mission are also interconnected with the foundational ones of Mission 5 on Inclusion and Cohesion (Italian NPRR, 2021[29]): particularly, its Component 2 "Social Infrastructures, Families, Community and Third Sector" introduces significant measures to develop new and personalized strategies of care for people with disability and Long-Term Care (LTC) for non-self-sufficient elderly (Biondi Dal Monte, 2021[30]).

Despite the acknowledged lack of a coherent and organic strategy for AI and robotics in the NRRP, the structure of Mission 6 is built on two Components which are potentially crucial for the full spread of such technologies in the sector of healthcare and for the development of their governance both at the national and regional levels (Cingolani et al., 2023[31]).

Mission 6	Reforms	Investments
Component 1	• Proximity Care, Structures and telemedicine for territorial assistance and the national network for health, environment and climate	• Houses of Community • Home Care and Telemedicine • Secondary Care and Infrastructures
Component 2	• Reorganization of IRCSS	• Modernization of technologies and digital tools for hospital • Towards a safe and sustainable hospital • Strengthening of technological infrastructure and tools for control and assessment of data

On the one side, the Component 1 "Proximity Care, Structures and Telemedicine for Healthcare" opens the pathway to the reform of Primary Health Care (PHC) with the aim to enhance prevention and proximity healthcare among the regional territories, promote home care and, in line with the transversal theme of green transition, ultimately embrace the One Health approach (Balduzzi, 2022[32]).

On the other, by taking steps forward the process of technological and digital transformation, the Component 2 "Innovation, Research and Digitalization of the National Health Service" comprehends a variety of measures to strengthen the health information systems and digital tools, human resources and health infrastructures as well as overcome the fragmentation of the implementation of the Electronic Medical Record (EMD) across the regional health services (Cuttaia, 2023[33]).Among the interventions of Component M6C1, Home as the first place of care and telemedicine (M6C1I2) is the core one, with an allocation of 4 mld of euro out of the 7 mld euro dedicated to the Component. In order to reach the general aim of enhancing the number of people treated in home care, this investment envisages the design of a shared model for home care provision (Homecare as first point of assistance,

[28] Italian National Recovery and Resilience Plan, 2021, p. 237.
[29] *Ibid*.., p. 222.
[30] F. Biondi Dal Monte., *Per un sistema integrato di interventi e servizi sociali. Sfide e prospettive nel quadro del PNRR e dopo vent'anni dalla approvazione della legge 329/2000*, in *Le Regioni*, 2021, pp. 779-806.
[31] M. Cingolani, R. Scendoni, P. Fedeli. F. Cembrani, A*rtificial Intelligence and digital medicine for integration of home care services: Opportunities and limits*, in *Frontiers of Public Health*, 2023, pp. 1-7.
[32] R. Balduzzi, *Gli standard (e il modello) dell'assistenza territoriale: prime considerazioni*, in *Corti supreme e salute*, 2, 2022, pp. 461-473.
[33] F. G. Cuttaia, *Il recupero della centralità del diritto alla salute. Prospettive di riforma del Servizio sanitario nazionale*, 2022, pp. 125-135.

M6C1I2.1). As specified in ItaliaDomani, this should be able to get the most from new technologies, among whose domotics is expressly quoted.

In order to manage the supply of healthcare services, especially in the light of improvements in homecare that we have just dealt with, an efficient coordination is necessary. With this purpose, 280 mln of euro are devoted to the Implementation of a new organizational model: Territorial Coordination Centres (M6C1I2.2). The intervention provides the creation of 602 Territorial Coordination Centres (TCC) - one every 100.000 inhabitants - that should coordinate territorial, social and hospital health services. Furthermore, they will "be equipped with technological means to ensure the remote control of the devices provided to the patients, will support the exchange of information between the health professionals involved in the care, will constitute a reference point for caregivers, both for training in self-care and for its implementation, and will act as a reference point in the event of further care needs of the patients". Adoption of "advanced ICT tools'' and "development of an artificial intelligence model aims at streamlining the communication systems between the various parties involved" are further envisaged to enable the simplification of the existing information flows. In particular, 50 mln of euros has been specifically devoted to piloting the implementation of AI and machine learning tools in healthcare among a sample of 1 million of Italian citizens. AI and advanced ICT tools, finally, are central for the third sub-investment, Telemedicine to better support patients with chronic diseases (M6C1I2.3), to which the Italian NRRP allocates 1 bln of euro.

Interventions in AI and robotics might be envisaged also in the second component of Missione 6, Innovation, research and digitalisation of national healthcare service (M6C2), that aims at supporting the transformation and renewal of the Italian National Health Service and that is, to this end, equipped with 8.63 bln of euro. In particular, Investments M6C2I1.1 Digital update of hospitals' technological equipment and M6C2I1.3 Strengthening of the technological infrastructure and of the tools for data collection, data processing, data analysis and simulation might both involve fundings for AI and robotics.

7.3 The Ministry of Health Decree no. 77 of 2022 (DM 77): Models and Standards for the Development of Territorial Assistance within the National Health Service

An emerging space for their application discloses in field of telemedicine (Brozetti et al., 2022[34]). Precisely, the Ministry of Health Decree no. 77 of 2022 (DM 77) has recently regulated the new organization of territorial integrated healthcare and has introduced telemedicine as a wide and open set of promising tools and modalities to delivery integrated care services (Ferioli, 2023[35]). In addition, the Guidelines for the digital model for the implementation of home care, below detailly examined, introduce assistive domotics and home automation as new tools, not included in the Basic Levels of Care, which can effectively support the process of personalization of care (Guidelines by the Ministry of Health, 2022, par. 2.1.5).

Similarly, despite the absence of direct and specific references, a potential space for application of AI and robotics can be traced in the ongoing reforms of Disability (Act no. 227 of 2021) and of Long-Term Care (Act no. 33 of 2023) both framed in the patchwork of Mission 5 and currently undergoing a process of implementation.

By fulfilling the milestone of Component 1 of Mission 6, the Decree no. 77 redefines the organizational structure of territorial assistance within the National Health Service in response to the structural shortfalls forcefully emerged during the pandemic[36]. Despite the ongoing proposals of amendments, Regions are expected to ultimate the implementation of this complex regulatory framework in the regional health services by 2026 (Cicchetti et al., 2022)[37].

[34] F. E. Brozetti, G. M. Cannella, A. Randazzo, *Telemedicina, teleassistenza e intelligenza artificiale in un sistema sociosanitario di prossimità: nuovi paradigmi etico-giuridici*, in *L'integrazione sociosanitaria e il diritto delle Regioni*, a cura di C. Buzzacchi e altri, 2022, pp. 258-276.

[35] E. A. Ferioli, *Il diritto alla salute alla prova della Digital Health*, in *Politiche Sociali*, fascicolo 2, 2023, pp. 207-226.

[36] A. Pioggia, *La sanità italiana di fronte alla pandemia. Un banco di prova che offre una lezione per il futuro*, in *Diritto pubblico*, fascicolo 2, 2020, pp. 385-403

[37] A. Cicchetti, F. Morandi (a cura di), *PNNR Missione Salute: una missione possibile?*, 2022, pp. 1-6.

The introduction of the Decree is expression of the renewed interest of the State in exercising its constitutional prerogatives in sector of territorial assistance: indeed, after an attempt to reform and heterogeneous territorial experiences of innovation evolved in the last two decades, this regulation is moved by the necessity to overcome this historical weakness of the NHS and halt the stabilization of its unequal development among the regional health services (Bottari, 2022)[38].

By highlighting the foundational principles of universality of access, globality of care and equality of treatment, the inspiring objective of the Decree is the implementation of a model of territorial service delivery homogeneously along the national territory and to strengthen the inclusive, equity-driven and integrated nature of the National Health Service (Balduzzi, 2021)[39].

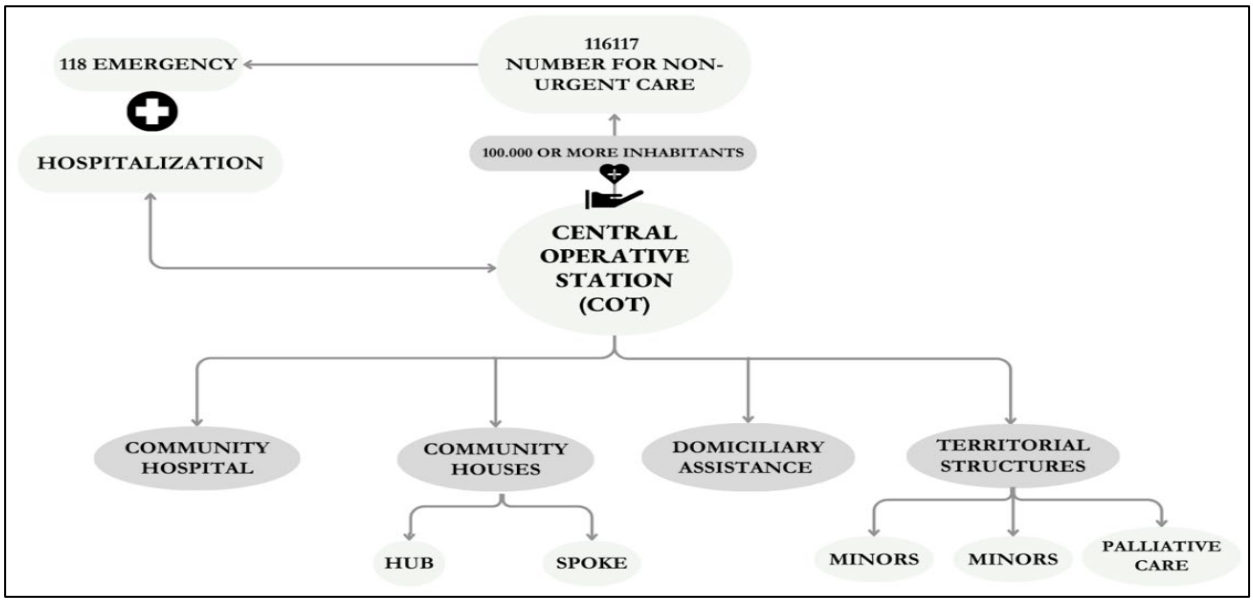


Figure 6. The new organizational structure of the Health District (AGENAS)

As stressed above, the Decree promotes the development of an innovative and complex set of norms, which comprehends the organization of territorial healthcare structures and the relative standard of services, numerous tools of coordination and promising methods of intervention for professional staff (Figure 6 above). In this regard, the major aim is to finally realize an effective integration between sanitary, sociosanitary and social services (Vivaldi, 2021[40]). On this line, the connection with the introduction of an additional regulatory framework of Basic level of Social Service (LEPS) and of Territorial Social Ambit (ATS) is particularly emphasized (Allegri et al., 2021)[41].

The central focus of the Decree is Primary Health Care (PHC) intended in accordance with the definition adopted by the Health Directorate of the European Commission (DG SANCO) in 2014: "the provision of universally accessible, integrated, person- centred, comprehensive health and community services, provided by a team of professionals accountable for addressing a large majority of personal health needs. These services are delivered in a sustained

[38] C. Bottari (a cura di), *L'assistenza territoriale: nuova centralità dei sistemi sanitari*, Maggioli, 2022, pp. i-iv.
[39] R. Balduzzi., *Il diritto alla salute durante e dopo la pandemia. Milestones per un confronto*, in *Rivista di BioDiritto*, n. 4, 2021, pp. 39-55.
[40] E. Vivaldi, *L'integrazione tra sociale e sanitario: una sfida sempre attuale*, in *Scritti in memoria di Paolo Carrozza*, a cura di P. Bianchi, E. A. Ferioli, G. Martinico, C. Napoli, Pisa University press, 2021, pp. 463-486.
[41] E. Allegri, T. Consoli, A. Decataldo, *I servizi sociali dall'emergenza alla pianificazione: le sfide per il welfare futuro*, in Autonomie locali e servizi sociali, fascicolo 3, 2022, pp. 409-424.

partnership with patients and informal care givers, in the context of family and community and play a central role in the overall coordination and continuity of people's care"[42].

Firstly, the Decree introduces several models of and approaches to assess, plan and manage health need of the population: the instruments of "Medicine of Initiative", "Stratification of Population" and "Project of Health" are particularly significant for the reorganization of proximity care (par. 3).

At the very core of the Decree lies the complex regulatory framework of territorial assistance which is composed of numerous and newly featured health structures.

Precisely, the regulation introduces the new organizational structures and standard of the Health District, intended as the territorial articulation of the Local Health Company (ASL) whose functions are vastly and differently regulated under Regional Laws, according to the structure of which the interaction and coordination of territorial structures for Primary Care and Secondary Care takes place (par. 4). According to the innovative design traced by the Decree, the Health District comprehends the Houses of Community, the Hospitals of Community, the Unity of Continuative Care, and the Operative Territorial Central Station (COT) as well as the new professional figure of the Family and Community Nurse (par. 6) (Pesaresi, 2022)[43].

The Decree further describes the role, functions and standards of the House of Community (par. 4). Generally defined as "a fundamental structure of the NHS", this structure owns numerous functions such as providing the universal and integrated access to services sanitary, sociosanitary and social services, delivering multidisciplinary and integrated Primary Care services and promoting of innovative forms of participation of the community and its human and financial resources also through the legal tools of co-planning and co-projecting. Drawing a line of comparison with the previous experimental diffusion of the Houses of Heath in several regional health services the introduction of such proximity-care structures is characterized by a higher and more effective integration between sanitary, sociosanitary and social services on the ground of the legacy of the previous territorial experiences (Barretta, 2009)[44]. Indeed, according to this regulatory framework, the integration is realized through the presence of a multidisciplinary professional staff, which includes social assistants, and the institution of the One Point of Access (PUA) which evaluates the needs of the population, facilitates the response to the care demand and further supports the administration and organization of the universal access to integrated services (Brambilla, Maciocco, 2022) [45].

Next to the latter proximity-care structure, this regulation also introduces the standards of the Hospital of Community which furnishes multiple service and continuative assistance for chronic diseases, for stabilization and rehabilitation of fragile patients with the aim to guarantee an appropriate level of coordination between acute hospitalization and domiciliary assistance or homecare (par. 11).

According to the organizational model defined by the Decree, the House of Community and Hospital of Community are further coordinated with the existing territorial centers for the health of minors, women and families (par. 13) and palliative care centers (par. 12) under the guidance of the Central Operative Station (COT) (par. 9).

Another important innovation of the Decree is the recognition of the home as "the main privileged setting of care" and in the promotion of appropriate domiciliary services (par. 10). Precisely, it introduces a detailed regulation of Integrated Domiciliary Assistance (ADI) and, after a relevant period of impoverishment and fragmentation of territorial experiences (Sandulli, 2021[46]), prospects its delivery in favor of 10% of over 65 years-old population by 2026.

Among the numerous innovations, it can be further noted that the key concept of integration also drives to the new role and functions of the Department of Prevention in the field of health, environment and climate and regulates

[42] European Commission, Report of the Expert Panel on Effective Ways of Investing in health (EXPH) on Definition of a Frame of Reference in relation to Primary Care with a special emphasis on Financing Systems and Referral Systems, 2014, p. 4.

[43] F. Pesaresi (a cura di), *Il DM 77/22 sull'assistenza sanitaria territoriale. La norma, gli approfondimenti, le valutazioni*, in *Welfare Ebook* n.77, 2022.

[44] A. D. Barretta (a cura di), *L'integrazione socio-sanitaria. Ricerca scientifica ed esperienze operative a confronto*, Bologna, Il Mulino, 2009.

[45] A. Brambilla, G. Maciocco, *Dalle Case della Salute alle Case di Comunità. La sfida del PNRR per la sanità territoriale*, Roma, Carocci, 2022.

[46] M. A. Sandulli (a cura di), *L'assistenza domiciliare integrata. Esperienze, problemi, prospettive*, Napoli, Editoriale Scientifica, 2021.

the institution of the National System of Prevention, Health and Climate (SNPS) according to the "Planetary Health" approach (par. 14) (Aperio Bella, 2022[47]).

Finally, the Decree detailly addresses the necessity to enhance the capacity of the NTH through to respond to the demand of care through the homogeneous application of the promising category of telemedicine in healthcare (Aperio Bella, 2020[48]). It introduces the regulatory frame of telemedicine, further detailed in the Guidelines on Telemedicine examined below, defines it as "*unity of technology and organization*" and describes it as an essential component to effectively realize of the new organizational model of territorial integrated assistance and as an innovative tool to strongly support the network of professional staff involved in the delivery of services (par. 15). Particularly, the importance of digital health and telemedicine is strongly recognized for the delivery of appropriate, personalized and coordinated care for chronic patients. On the same line, the digitalization of services and the interoperability of data are also promoted to achieve the full implementation of integrated local and regional informative systems (par. 16).

7.4 THE GUIDELINES FOR THE DIGITAL MODEL FOR THE IMPLEMENTATION OF HOME CARE

Telemedicine is a crucial issue that has received further attention through the Italian NRRP. The most immediately impacting effects of the digital transition on the National Health Service (and the relevant Public Administrations) come from the relationship between the daily life of the community and the need to guarantee - always and in any case - social and health care.

In this sense, the pandemic crisis and distancing obligations have further highlighted the need to make use of the latest technological advances to ensure the full protection of individual rights.

Therefore, the context of progressive digitisation of healthcare has called for the appropriate regulatory and administrative interventions likely to produce a general transformation of the therapeutic relationship.

It is precisely to this context that Telemedicine, conceived as the remote delivery of healthcare services, belongs.

An initial definition of the tool came from the WHO, which already in 1997 conceived of telemedicine as «the provision of health services in which distance is a critical factor, by all health professionals using information and communication technologies for the exchange of valid information for the diagnosis, treatment and prevention of diseases, injuries and accidents, for research and evaluation, and for the continuing education of health professionals, all in the interest of promoting and advancing the health of individuals and their communities».

Since then, the telemedicine tool has undergone continuous evolution.

In Italy, the approach to telemedicine has finally taken shape with the adoption by the Consiglio Superiore di Sanità, on 10 July 2012, of National Guidelines to integrate the organisational model of the National Health System and to ensure a consistent deployment of telemedicine services.

The Guidelines have the following objectives:

- Identify the priority areas of application of telemedicine;
- Analyse models, processes and ways of integrating telemedicine services into clinical practice;
- Define common taxonomies and classifications;
- Define aspects concerning legal and regulatory profiles and the economic sustainability of telemedicine services and performances.

The Guidelines were reinforced by the Agreement between the State, the Regions, and the Autonomous Provinces of Trento and Bolzano aimed at ensuring 'a coordinated, harmonious, and coherent development of telemedicine within the National Health Service'. As of 2018, all Regions have implemented the guidelines with their own resolutions. Given the differing application of the Guidelines among the individual Regions, the Ministry of Health

[47] F. Aperio Bella (a cura di), *One Health: la tutela della salute oltre i confini nazionali e disciplinari*, 2022.

[48] F. Aperio Bella, *L'accesso alle tecnologie innovative nel settore salute tra universalità e limiti organizzativi (con una postilla sull'emergenza sanitaria)*, in PA *Persona e Amministrazione*, n. 1, 2020, pp. 219-245.

felt the need to provide truly uniform indications throughout the country for the remote provision of healthcare services, with particular regard to specialist activities.

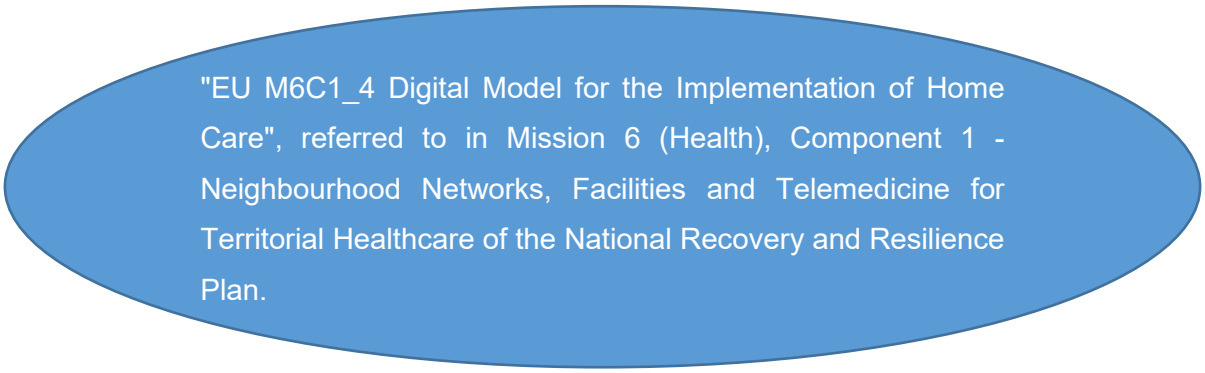
The working group that was set up then drafted two further documents:

- The **"National indications for the provision of telemedicine services"** adopted by Agreement in the State-Regions Conference on 17 December 2020;
- The **"Directions for the provision of telerehabilitation services and services by the health professions"** adopted by Agreement in the State-Regions Conference on 18 November 2021.

Having ascertained the effectiveness of the tool and the need to ensure its most profitable dissemination, on 24 May 2022 the Ministry of Health announced the adoption, by ministerial decree, of organisational guidelines concerning the 'Digital Model for the Implementation of Home Care', which prefigure a new organisational model for the implementation of the various telemedicine services in home care.

The Guidelines propose the identification of new procedures for taking care of patients at home and presuppose the need to ensure interaction between different specialists.

The governmental initiative is closely linked to the Milestone 6:

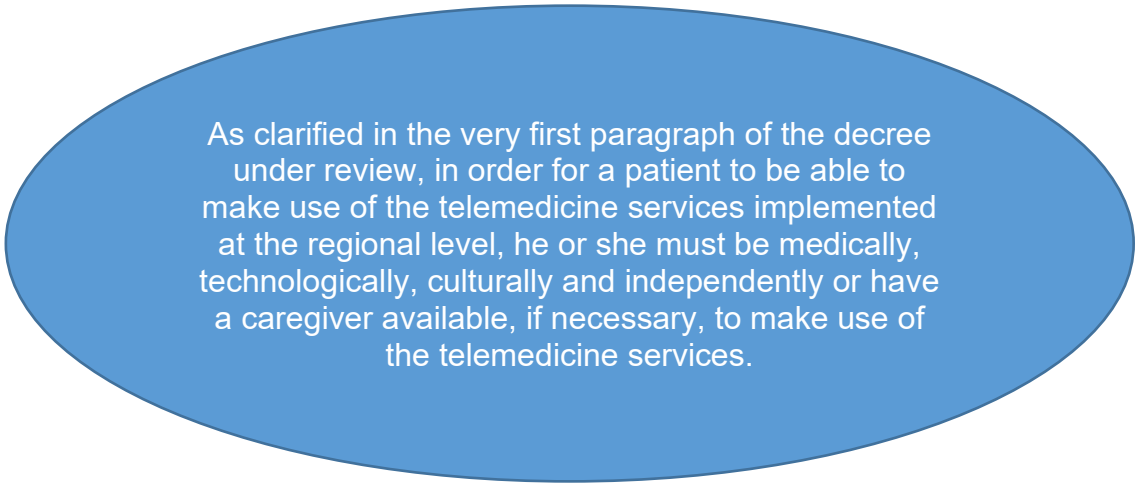


It is a milestone achieved in advance of the deadline for a model reform of the entire territorial assistance structure.

At the centre of the new framework is the health district, within which the Community House represents a place where citizens can find assistance around the clock, every day of the week. In the Community Homes, professionals working in an integrated and multidisciplinary manner are involved in the planning and delivery of social and health interventions.

The main novelties concern the general practitioners' offices (considered spokes of Community Homes) for which a network connection is envisaged, so as to guarantee openings of twelve hours and six days a week. The general practitioner (and/or the free-choice paediatrician) remains, however, the clinical head of the care relationship.

The telemedicine pathways thus prefigured can be activated from home care, or as a continuation of a hospitalisation (so-called protected discharge) and the related interventions (medical, care and rehabilitation) are coordinated by the Territorial Operations Centre (COT).



So, there are four parameters on which the eligibility of patients is based:

1. The clinic.
2. The technology available.
3. The culture.
4. The level of autonomy or the availability of caregiver support.

Clinical eligibility is at the sole discretion of the physician, who, on the basis of the patient's clinical and social conditions, assesses whether to propose telemedicine services to the patient.

For the first time, then, the decree takes care to identify the type of services that are to be included in the 'telemedicine' category.

The minimum services to be provided by the regional telemedicine infrastructure are the following:

- televisit;
- teleconsultation/teleconsultation;
- telemonitoring;
- telecare.

The prefigured system undoubtedly represents a turning point in the process of developing telemedicine throughout the country. The Guidelines seem to have clarified various aspects, not only of a technical nature, but the real challenge of efficiency remains the responsibility of the individual political decision-makers: it is on the concrete functioning, in each regional reality, of the supply and service centres that the actual application of telemedicine will depend.

In conclusion, the NRPP lacks a clear strategy on AI and robotics, despite the importance of these areas for the digital transition of the country. The plan does indeed contain several funding opportunities; however, these interventions are generally not directly dedicated to these areas, representing general funding opportunities in competition with other STEM disciplines, or their effects on these fields are often far in time (i.e. those involving schools).

7.5 THE NRRP AND THE REGIONS

As stressed above, since the COVID-19 outbreak, the need of improving the digital infrastructure of the Italian health system has been placed in the spotlight (Belvis et al., 2022). Technological innovation and the digital transformation constitute a primary and cross-cutting theme of the NRRP. The latter provides EUR 8.63 billion to boost digitalization policies, including interventions for modernizing and strengthening technological infrastructure for collection, processing, and data analysis, as well as for developing digital skills of health personnel. In particular, digital means related to domotics (home automation), telemedicine and remote monitoring are envisioned to support vulnerable people and the elderly and to strengthen territorial and “proximity health services” (*servizi di prossimità*).

In this respect, EUR 300 million is earmarked for the conversion of nursing homes for the elderly (*Residenze Sanitarie Assistenziali,* RSAs) into groups of independent flats to ensure autonomy and independence of the elderly. AI applications and robotics certainly may help in this regard.

Investments in digital technology appear particularly important in the Italian context given the slow pace of innovation in this policy area (Ricciardi and Tarricone, 2021). Barriers to the implementation of digital health services include lack of interoperability among different regional systems, limited resources, scarce know-how of health care professionals, heterogeneity in regional reimbursement schemes for telemedicine, as well as scarcity of governance tools (Belvis et al., 2022). Until 2019, expenditure in digital innovation have mostly focused on online services, digital treatments to remotely monitor adherence to therapy, and electronic medical records. With the COVID-19 outbreak, legislative changes inserted telehealth services into the list of reimbursable services (Belvis et al., 2022).

Within the governance structure of the NRPP, the Italian regions had to draft Territorial Plans identifying the objectives to be achieved, the resources to be used, the implementation methods, as well as the timing of interventions and the expected results. Whereas the digital transformation futures prominently in all plans, provisions regarding artificial intelligence and robotics are absent.

In 2022, the National Agency for Regional Health Services (*Agenzia Nazionale per i Servizi Sanitari Regionali*, AGENAS) has published notice of a procedure for the award of a contract for the design, implementation, commissioning and management of an AI Platform to support primary health care (as part of Mission 6, Component 1 of the NRRP). The Platform intends to be configured as an innovative infrastructure to enable services to support healthcare professionals ad use innovative territorial care services. In this respect, AI can act as a facilitating factor for the personalization of care, ensuring greater effectiveness and efficiency of the health care services[49].

AGENAS also undertakes Health Technology Assessment (HTA) activities. HTA is a multidisciplinary approach for analyzing the clinical, social, organizational, economic, ethical, and legal implications. It therefore assesses the actual or potential effects of technology. In light of the fast development of AI applications and robotics, AGENAS will therefore be a crucial actor in the governance of digital health services in the future. The Agency has in fact signed a partnership with the Agency for Digital Italy (AgID) – the technical agency of the Presidency of the Council of Ministers – and will be in charge of promoting and implementing data-driven health and socio-health services (Borghini et al., 2022).

[49] The call is available

8 Conclusions

The report has introduced the key concepts to describe and understand the complex multi-level governance of AI and Robotics. The analysis has shown AI and Robotics, especially in health care and personal care, are gaining momentum in the debate on the organization of public policy to address contemporary socio-economic challenges. Different programmes and initiatives are set at both global, European, national and regional levels. The increased complexity of the MLG is further sign of the salience of the issues at stake (especially in the aftermath of the pandemic crisis). Interventions are articulated and consist of different lines of action on: the identification of both challenges and opportunities related to the spread of AI and Robotics; the definition of common toolkits to analyse and assess AI strategies (e.g. common concepts, shared indicators, etc.). This is consistent with an encompassing approach for a broad comprehension of the spread of AI and Robotics and their main consequences. The definition of common frames and strategies is crucial for the future effective coordination between levels of governance.

When we move to the European level, the persistent focus on concepts, frames and objectives is paralleled by the attempt for common rules and the activation of networks of governmental and non-governmental organisations for deliberation. The EU launched a *Coordinated Plan on AI*, with the *Proposal for a regulation laying down harmonised rules on AI* , and the proposal of Regulation on the European Health Data Space (EHDS). The activation of budgetary lines to support the development of AI strategies at all levels is also evident. The launch of new programmes in the field of research and healthcare has been strengthened by the EU Recovery Plan with additional resources to address the consequences of the pandemic. This has represented a stimulus for the allocation of resources and the revision (still in progress) of programmes and investments.

The report has shown that the Italian NRRP represents a relevant progress in the definition of the governance of AI and robotics and in the provision of financial resources to support investments. When compared with the financial programmes of the past (e.g. Horizon 2020, etc.), the NRRP allows for an increase of financial capacities for the field. Three different missions, and Mission 6 on health in particular, have provided a new set of norms consistent with the increased emphasis on technological innovation for healthcare and social care. As shown above, new pieces of legislation has also aimed at revising the overall governance of AI and robotics and domotics. New health districts represent the milestone of the new governance of healthcare with a key role for new technologies to help increasing efficacy and efficiency of the system.

While the report has shed light on these progresses, the MLG in the field is still in progress with weak forms of coordination across the levels. In other words the MLG of AI and Robotics seem still an emergent phenomenon. Yet, new initiative especially at the European Union level, prove the governance is increasingly institutionalised with evident links between increased financial resources and new coordination processes.

LIST OF ABBREVIATIONS

ADRA	European AI, Data, and Robotics Association
AGENAS	Agenzia Nazionale per I Servizi Sanitari Regionali
AgID	Agency for Digital Italy
AI	Artificial Intelligence
DIGITAL	Digital Europe Programme
EC	European Commission
EHDS	European Health Data Space
ICT	Information and Communication Technology
IOs	International Organisations
ML	Machine Learning
MLG	Multi-level Governance
NGEU	Next Generation EU
NGOs	Non Governmental Organisations
NN	Neural Networks
NRRP	National Recovery and Resilience Plan
OECD	Organisation for the Economic Cooperation and Development
PPP	Public Private Partnership
RRF	Recovery and Resilience Facility
RSA	Residenze Sanitarie Assistenziali
R&D	Research and Development
SPARC	PPP between the EC and the European Robotics Community
STOA	European Parliaments' Panel for the Future of Science and Technology
WHO	World Health Organisation
CCB	Cascade Calls Board

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ANNEX 1

THE MULTILEVEL REGULATION OF THE USE OF ROBOTIC AND DIGITAL INSTRUMENTATION IN THE HEALTH AND CARE SECTORS.

The international dimension of the *digital health*: the strategic value of the technology.

The guidelines of the World Health Organization (WHO) of 2019: the principles for a successful introduction of digital instrumentation in the national healthcare systems.

sub A): Identifying key sectors of investment to safeguard people's health and to strengthen the essential services.

sub B): The Recommendations for maximizing the performance of digital technologies.

***The Global Strategy on Digital Health* (2020-2025) of the World Health Assembly**: the endpoint for a uniform regulation.

Sub A): The four strategic objectives and the priority actions for each Member State.

Sub B): The valorization of innovation in accordance with fundamental rights.

Artificial Intelligence technologies (AI) in international law: the need to adjust the use of automated technology.

Artificial intelligence from the perspective of the Council of Europe: the development of biology and medicine within the framework of the fundamental rights.

Sub A): **The Recommendation no.1160 of 1991 on the preparation of a convention on bioethics**: the first step towards codifying the existing regulation.

Sub B): **The Oviedo Convention of 1997 on Human Rights and Biomedicine**: the *mitigation* of bioethics to preserve human dignity.

Sub C): **The Strategic Action Plan on Human Rights and Technologies in of Biomedicine (2020-2025):** the guidelines for the better governance of biomedicine.

Sub D): **The 2022 report of the Steering Committee for Human Rights in the field of Biomedicine and Health (CDBIO):** the doctor-patient relationship (DPR) and the real implications of the artificial intelligence in the field of human rights.

Sub E): **The next European Convention on Artificial Intelligence:** the work of the Ad-hoc Committee on artificial intelligence (Cahai) to unify the regulatory framework.

The main activities of World Health Organization (WHO): the advantages of artificial intelligence tools put to the test of "balancing" with human autonomy.

Sub A): **International Ethical Guidelines for Biomedical Research involving human subjects of 1993**: the "advanced" protection of the right to health.

Sub B): **The six WHO Guidelines of 2021 (Ethics and Governance of Artificial Intelligence for Health):** transparency obligations and environmental sustainability constraints.

United Nations interventions: the impact of robotics technologies on the achievement of sustainable development goals.

Sub A): **The Convention on the Rights of the Child of 1989**: a basic approach to the scientific progress.

Sub B): **General Comments No. 25 of March 2, 2021, on the rights of the child in the digital environment**: guaranteeing minors' access to the digital environment.

Sub C): **The research *"Sustainable development goals via robotics and autonomous systems"* of June 21, 2022**: an horizon scan to identify the main opportunities and the biggest threats of applying technological innovation to the socio-sanitary sector.

The role of UNESCO: biomedical research between ethics and law.

Sub A): **The International Bioethics Committee (IBC):** the study of the impact of scientific and technical progress on the concrete protection of human rights.

Sub B): **The Draft Declaration on the Human Genome of 1996**: the search for common standards of well-being.

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Sub A): **Regulation (EU) of the European Parliament and of the Council of 5 April 2017 on medical devices:** standards and technical regulations in the field of medical devices.

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Sub E): **The proposal of the so-called *"AI Act"* Regulation:** a first attempt at codification.

Sub F): **The Digital Economy and Society Index (DESI) of 2021**: the latest monitoring of the progress of European countries in social and health digitization.

Sub G): **The European Health Data Space (EHDS):** the birth of a space for sharing health data at the European level.

European Parliament's interventions:

sub A): **The resolution of 16 February 2017 on the introduction of AI in health and care services**: balancing technology and human care.

sub B): **The resolution of 3 May 2022 on artificial intelligence in a digital age**: the need for a clear regulatory framework to accommodate technological advancements.

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The role of the International non-profit organization

The International Federation of Robotics:

Sub A): **International Standards on robotics**: standards (safety, performance criteria, modularity) prepared within the International Organization for Standardization (ISO).

Sub B): The **Report "World Robotics 2022"** on the service robotics industry structure.