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

FIT4MEDROB

D4.8.1

REPORT ON THE ETHICAL AND LEGAL COMPLIANCE OF HEALTHCARE AND PERSONAL CARE ROBOTS #1

Piano Nazionale Complementare (PNC) – Decreto Direttoriale n. 931 del 6 giugno 2022 – Avviso per la concessione di finanziamenti destinati ad iniziative di ricerca per tecnologie e percorsi innovativi in ambito sanitario e assistenziale

Project identifier: PNC0000007

Start date: 01/12/2022

Duration: 44 months

Website: www.fit4medrob.it

Editor(s): Francesca Gennari (SSSA), Arianna Rossi (SSSA) Federica Casarosa (SSSA)
PIs: Giovanni Comandé (SSSA).

Due date of deliverable: 30/11/2023
Actual submission date: 20/09/2024
Version: 4.1

DISSEMINATION LEVEL OF DELIVERABLE		
PU	Public, fully open, e.g. web	**X**
CO	Confidential, restricted under conditions set out in Partners Agreement	

HISTORY OF CHANGES

VERSION	SUBMISSION DATE	CHANGES
1	04/09/2023	First version
2	30/10/2023	Full version for finalization
3	30/10/2023	Full version sent to external referees
4	21/11/2023	Final version
4.1	20/09/2024	Executive summary modified following reviewers' suggestions

TABLE OF CONTENTS

1 EXECUTIVE SUMMARY

This is the first version of a deliverable mapping the relevant legal rules for biorobotics and clinical research having in mind that the audience is not made of legal experts within the Initiative. Hence it offers a schematic outlook helping to raise awareness and expertise for the non-legal experts in the Initiative. The further version of the deliverable (D4.8.2) will finalize and expand the mapping proceeding also to assesses the awareness of the Initiative about the legal gaps (existing and perceived) and the enablers stemming from the analysed sets of legal rules (Month 24). Moreover, the two last forthcoming versions of the deliverable (D4.8.3 at Month 36, and D4.8.4 at Month44) will also involve external stakeholders in order to create more precise guidance on future recommendations and policy advice. The present deliverable is fully in line with the foreseen plan, and will be completed by month 44, as illustrated in the chart below.

The report and its future updates contribute to Action 4 and its lines of enquiry. In particular, in the context of Task 4.1 on Legal Gaps and enablers for biorobotic devices and allied biotechnologies. The present deliverable will feed in: D4.8.2., D4.8.3 (Task 4.1) and D4.9.1 about the Web-Platform for open acceleration at Month 24 and its iteration D4.9.2 at Month 44 which is part of Task 4.4 Open Acceleration.

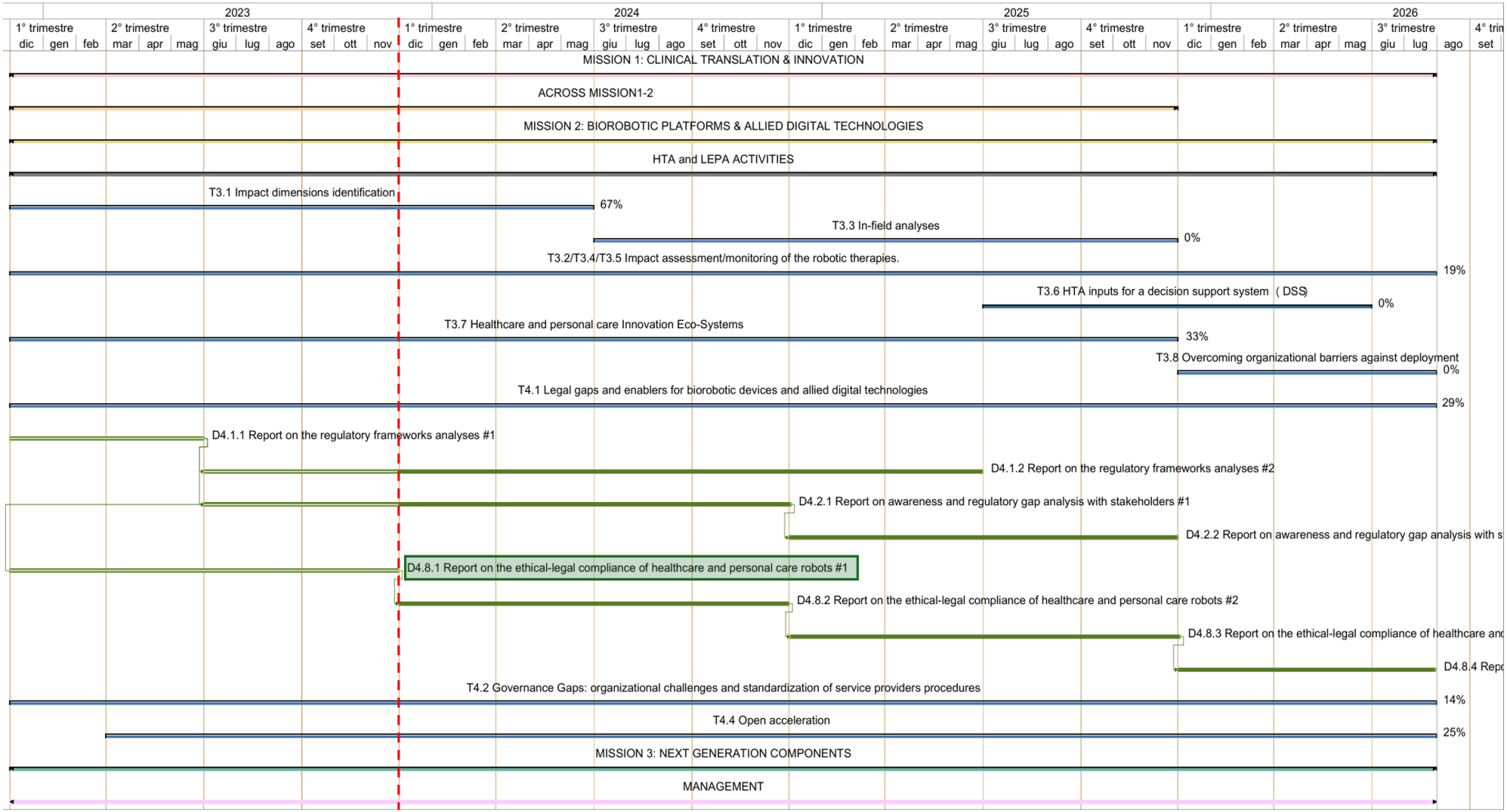
This deliverable's structure is two-fold. The methodology section (2) explains that the first part aims to map down the main legal and ethical requirements that the Fit4MedRob partners need to consider while developing a new generation of healthcare and personal care robots. The main difference with D4.1.1. is both in the means and in the substance of this deliverable. Mapping down legal and ethical compliance requirements this time was a process mainly addressed to non-lawyers (3). That is why a more concise and synthetic way of displaying information rationale was employed in selecting the most important points to raise in the short and medium run, as far as compliance is concerned. More precise and further research will be done in the further iterations of the deliverable. The reference audience being mainly non-lawyers explains the use of tables which are grouped in theme sections: the safety of products (3.1) (with medical functions or not), AI regulation and ethics (3.2), Liability issues (3.3), and Data Laws (3.4). For each of the legal acts commented there is a focus on the more pressing current legal and ethical compliance problems and open issues for researchers and innovators explained in the clearer way possible.

The methodology also explains the rationale of the second part of the deliverable and coincides with section 4. Activity 4 needed an instrument to check whether their mapping was correct and what were the most pressing ethical and legal compliance issues in researchers' everyday lives. This explains the origin and the development of the survey on ethical and legal compliance (4.1), its questions and their purpose (4.2) and its replies (4.3). After the survey results, Activity 4 decided to start drafting already a draft of the services that will be developed through the next deliverable, D4.9.1 (4.4) which will lay the foundation for the creation of a web-based platform for open acceleration which will then become part of the instruments developed by the future centre of excellence IURAT, created thanks to Fit4MedRob funds. Section 5 is a short part concerning the main findings of the two central sections (sections 3 and 4) of this deliverable.

It is important to highlight this deliverable's relevance for the Fit4MedRob project. Methodologically, the choice of having as reference audience doctors, engineers, and technical experts, which constitute the utter majority of the Fit4MedRob consortium, influenced the language use, correct but clearer, to make the readers understand what the relevant legal and ethical compliance rules are when designing a new generation of personal or healthcare robots and help them put those legal and ethical obligations in practice. The extent of the subjects covered is considerable and will be completed with additions and updates in November 2024 (M24). This is done to give the Fit4MedRob consortium partners a 365° view of the aspects they need to cover to design innovative personal or healthcare robots and other allied technologies - such as AI systems- while at the same time being compliant with the ever-increasing set of legal and ethical obligations. Moreover, the survey that was circulated aimed at focussing and making more granular choices in terms of the needs that the Fit4MedRob consortium partners have to better address their concerns with the upcoming update of this deliverable (D4.8.2) and with the upcoming web-based platform for open acceleration (D4.9.1).

The deliverable highlights that achieving legal and ethical compliance for next-generation healthcare and personal care robots requires **not only awareness of current regulations but also continuous training on emerging AI and data laws**. Building compliance by design will be key to fostering innovation that is both effective and future-proof.

The completion rate of this task/activity is **fully in line with the foreseen plan**, as described in the following chart.


2023
2024
2025
2026
1° trimestre
2° trimestre
3° trimestre
4° trimestre
dic gen feb mar apr mag giu lug ago set ott nov
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%
D4.1.1 Report on the regulatory frameworks analyses #1
D4.1.2 Report on the regulatory frameworks analyses #2
D4.2.1 Report on awareness and regulatory gap analysis with stakeholders #1
D4.2.2 Report on awareness and regulatory gap analysis with s
D4.8.1 Report on the ethical-legal compliance of healthcare and personal care robots #1
D4.8.2 Report on the ethical-legal compliance of healthcare and personal care robots #2
D4.8.3 Report on the ethical-legal compliance of healthcare and
D4.8.4 Repo
T4.2 Governance Gaps: organizational challenges and standardization of service providers procedures
14%
T4.4 Open acceleration
25%
MISSION 3: NEXT GENERATION COMPONENTS
MANAGEMENT

2 METHODOLOGY

2.1 THEORETICAL AND PRACTICAL NEEDS

This deliverable is at a crossroads between a concise synthesis concerning the state of regulatory policy and the internal needs of the Fit4Medrob consortium. This deliverable can be divided into two parts. The first one concerns a sum up of the legal framework that applies to personal care and healthcare robots (2.1.1). The second part is an analysis of a voluntary and anonymous survey conducted among the members of the Fit4MedRob consortium to gather their legal blocks and needs concerning the same EU and Italian legal acts and proposals concerning personal and social care robots (2.1.2).

2.1.1 Mapping and Commenting the Reference Legal and Ethical Framework

From a methodological point of view, it was not an easy task to map down the legal and ethical requirements concerning personal care and healthcare robots. In fact, since 2017 with the European Parliament resolution on the civil liability of robots[1], these objects have not been regulated directly, but through the general safety of products regulations and the medical devices regulation. Among the different kinds of laws, it was possible to identify three macro-areas: data laws, safety laws, and liability laws. The first one could be called the 'data laws', which include the GDPR, but also the recently implemented Data Governance Act. In addition, one has also to consider as part of the data laws the new proposals on data access such as the Data Act (DA), and the European Health Data Space (EHDS). Then there are the 'safety laws' with their most important subset which are the Medical Devices(MDR) and Clinical trials(CTR) disciplines. Moreover, it is also likely that the AI Act proposal might be approved soon, and the healthcare and personal care robot manufacturers need to understand whether they employ a high-risk AI system that needs to comply with a complex set of obligations. Further, to design and deploy a new series of products it is also essential to think about which kinds of liability regimes might come into play. Among these, we must take into account the Product Liability Directive (PLD) and its proposed update (PLDU), the two directives on certain aspects of the sales of goods (SG) and the directive on the supply of digital content and digital services (DCDS) and, the proposed artificial intelligence civil liability proposal (AILP).

As far as the ethical framework, ethics has always been more difficult to frame and write down but, certainly, some articles of the GDPR or of the AI HLEG guidelines on trustworthy AI do have an ethical significance for innovators.

To differentiate the contents of this deliverable from the ones of D4.1.1 concerning the mapping of the legal blocks concerning new-frontier medical devices research, this part of the deliverable will be mostly made of tables in order to summarise the contents for operators and people who are not lawyers. The main function is the one to highlight what possibilities are offered by proposed and enacted legal acts and what the problems could be for personal care and healthcare robots.

In this iteration of the document, we will exclude cybersecurity issues, intellectual property ones, and also issues connected to insurance as there would not be sufficient time to devote to each of these subjects in detail.

2.1.2 Building a survey for the Fit4MedRob Consortium needs

The second part of the deliverable is of capital importance to understand what the needs of the members of the consortium are. Activity 4 decided to draft a survey to reply to some simple but essential questions that are preliminary to the drafting of the future deliverable D4.9.1. which is a web-based platform for open acceleration. Despite deliverable D4.9.1 being due only next year, Activity 4 found that doing this kind of survey also highlighted the gaps and requirements concerning legal and ethical compliance which are part of this deliverable as well. The survey in the context of this present deliverable D4.8.1. is comparable to the 'other side of the moon': it is a

[1] European Parliament resolution of 16 February 2017 with recommendations to the Commission on Civil Law Rules on Robotics (2015/2103(INL)) OJ C 252, 18.7.2018, p. 239–257.

trustworthy picture of how ethical and legal compliance is dealt by non-legal professionals on a day-to-day basis. That is why it is important not only to explain how it was drafted and circulated but also to take an ideal step back and comment on the services that could be provided to the Fit4MedRob consortium in order to design a thorough legal and ethical compliance strategy.

3 LEGAL AND ETHICAL COMPLIANCE IN THEORY

3.1 SAFETY LEGISLATION

As an over-arching rule of law, the more specific law applies to the issue at hand. In the case of safety, if the object has a medical function according to its manufacturer, it will be the Medical Device Regulation or Clinical Trial Regulation that will be applicable (3.2.2). Instead, if the object, even if technologically advanced such as a personal care robot, is not marketed as a medical device, then, the general rules concerning the safety of products will apply (3.2.1).

3.1.1 General Safety laws

General safety legislation corresponds to the heterogeneous group of enacted or proposed legal acts that sets up all the requirements and surveillance mechanisms that will apply to products that are not medical devices, even if they will interact with healthcare robots (which could be considered as medical devices, see infra 3.2.1.) both as accessories or part of a connected system of robots with medical devices functions. Moreover, the need to follow up closely this legislation is that the Fit4MedRob consortium also hosts partners which are commercial entities and that might decide to market a personal care robot as an object with no medical functions. Hence, they will be obliged, depending on the characteristics of their personal care robot or device to apply two or more of the following regulations. As far as the machinery legislation, they are applicable if the parts that compose the device are part of the list enclosed in the annexes of the Machinery Directive (MD) or the recently approved Machinery regulation (MR). Nevertheless, there is one point in common among all these different legislative acts: the product conformity to specific EU (harmonized) or, where they are not present, to national standards is a (rebuttable) presumption of conformity of that product or part of the product.

Table 1 General legislation

Name of the Initiative	Legal Compliance and obstacles	Ethical principles
Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (Text with EEA relevance) OJ L 218, 13.8.2008, p. 30–47 (**CE Marking Regulation**)	It creates a market surveillance system, including conformity obligations as follows. Most notably that happens through the • set-up of **conformity assessment bodies**; a **market surveillance system** and a system for rapid information • set-up of a **Community Rapid Information System** **Obstacles** The CE marking regulation might need an **update** sometime soon as it was drafted and enacted when technology such as the mainstream use of IoT, robotics or AI were in their first days.	Highest level of safety possible. The CE marking conveys an idea of trustworthiness both for the professional subjects that use the object for work but also for the consumer

Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (Text with EEA relevance) OJ L 11, 15.1.2002, p. 4–17 General Safety of Products Directive (**GSPD**)	A product's compliance with EU or national safety requirements is a presumption (rebuttable) of its safety. The requirements concern not only producers but distributors and National states as well. It sets up an EU fast recall system which is called RAPEX. **Obstacle**: The GSPD will be shortly substituted by the General Safety of Products Regulation (**GPSR**, see infra in this table)	Same as above
Regulation (EU) 2023/988 of the European Parliament and of the Council of 10 May 2023 on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council and Directive (EU) 2020/1828 of the European Parliament and the Council, and repealing Directive 2001/95/EC of the European Parliament and of the Council and Council Directive 87/357/EEC (Text with EEA relevance) PE/79/2022/REV/1 OJ L 135, 23.5.2023, p. 1–51General Safety of Products Regulation (**GSPR**)	The **GPSR** is an update of the previous directive **GPSD**. It makes it explicit that a presumption of conformity if the products comply with **harmonized** and/or **national standards** as well as **voluntary certification schemes**. It sets out horizontal requirements (meaning general ones unless there are other more specific that apply to the case) on the safety of products for a series of **economic operators** and not just manufacturers. This list also includes **online platforms** and fulfilment service providers. These last ones are not only traditional consumer objects but also **interconnected ones** (Article 2.2 GPSR), such as IoT and, in principle personal care robots. **Obstacle:** This system partly builds up on the previous general safety one but there are also new **traceability requirements** (Article 18) that will add up to the system of recall such as the Safety Gate Rapid Alert System (for the Member States to share information about product safety) and the Safety Business Gateway (for online market places to provide consumer with information) but also of market surveillance. It might be complex to connect all these requirements that involve not only manufacturers but a much longer list of economic operators. All these rules will become applicable by **2024.**	Same as above
Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast) (Text with EEA relevance) OJ L 157, 9.6.2006, p. 24–86 Machinery directive (**MD**)	It applies to products that might be part of a personal care robot and that are comprised in the list of **Article 1 MD** (e.g., interchangeable equipment and safety components, chains…). It is a more specific regulation that in the case of personal care robots might be considered apart from the more general **GSPD**. It sets a system of market surveillance and obligations	Highest level of safety possible. The CE marking conveys an idea of trustworthiness both for the professional subjects that use the object for work purposes but also the consumer. Specifically for this case, it is applied to machinery components or their groupings with inherently higher risk for human health and physical integrity.

	before putting the machinery into the market or into service. **Obstacle**: the MD does not consider new technologies as well as the GSPD. That is why a new Machinery Regulation (MR) has been approved	
Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery and repealing Directive 2006/42/EC of the European Parliament and of the Council and Council Directive 73/361/EEC (Text with EEA relevance) PE/6/2023/REV/1 OJ L 165, 29.6.2023, p. 1–102 Machinery regulation (**MR**)	The Machinery Regulation will be applicable from **2024.** It builds on the previously existent MD and relies on the **same presumption concerning conformity** underpinning the previous regulations and directives. However, the MR modifies the list of parts and machinery to which the MR can potentially be applicable. Moreover, the MR comprehends a series of annexes that provide more details concerning conformity procedures which depend on the level of risk and type of object. It can be of particular interest that software has been included in the MR and specifically in annex II concerning the indicative list of safety components.	Same as above

3.1.2 Medical Safety laws

This is a group of special legal acts that still are connected to the area of safety of objects from an administrative point of view. They are relevant as there is not a more specific regulation concerning healthcare robots but the medical devices one. It is also important to highlight the importance of the Clinical Trials Regulation (CTR) of the projects. Activity 4 believed it was relevant also to better outline how the Italian implementation of both the MDR and the CTR given its importance for Activity 1 and 2 of the Fit4MedRob project.

Table 2 Medical Safety Legislation

Name of the Initiative	Legal Compliance and Obstacles	Ethical principles
Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance) OJ L 117, 5.5.2017, Medical Devices Regulation (**MDR**)	MDR sets all the compliance duties a manufacturer must follow to commercialize medical devices in the single EU market. In particular, it is useful to highlight as follows. As in the previous directive, the medical devices are divided into **classes of risk (I, IIa, IIb, III)**. The higher the risk for human health, the more thorough must be the procedure audit/certification for the medical device. In general, the different classification rules are spread between Article 51 MDR and Annex VIII. After having found the appropriate class for the medical device, the manufacturer must choose one certification/conformity procedure following the rules of Article 52 MDR and Annexes from IX to XI.	The main ethical principle is to ensure **the highest level of protection of health possible**. *This is not an absolute threshold, as it has to take into account also of the level of technology and the state of medical science*.

	The objective is to obtain the **CE marking for the medical device** to be put into the market or put into service. In order to trace with more precision medical devices in the EU market (which will be used also to know whether there are ongoing clinical investigations on a medical device), the MDR sets the rule on how to create and how to make operative a EU database for medical devices (**EUDAMED**, Articles 33 and ff. MDR). Moreover, every medical device will be traceable thanks to the inclusion of in a system called **UDI** (Unique Device Identification system), whose functioning is described at Article 27 and in part C of annex VI. **Obstacles** According to the MDR, **software** can also be considered as a medical device according to Article 2(1) MDR. The criteria on how to differentiate software from software as a medical device have been collected at the EU level by the Medical Devices Control Group (MDCG)[2]. However, in practical terms it might be difficult to understand whether a software could be considered a medical device. The **product and value chain** of medical devices has become more complex than it used to be. There are not only manufacturers as subjects which do have requirements and obligations but also authorised representatives, importers, and distributors who also do have requirements (Articles 10, 11, 12,13, 14 MDR). More interestingly the list of manufacturers requirements can be found at Article 10 MDR but must be complemented with the post-market surveillance duties which can be found at Article 83 MDR. Concerning manufacturers duties and requirements, particularly interesting is the mention at Article 10(16) MDR of the necessity to have financial means to face product liability claims. In some specific cases, manufacturers obligations	

[2] More on the strategies on how to categorise software as a medical device can be found here: Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR https://ec.europa.eu/docsroom/documents/37581 accessed 27 October 2023.

	must be carried out by importers or distributors (16 MDR) Moreover, **Notified Bodies** (NB) (Article 35 and ff MDR) are audit/certification bodies selected by the Member State and recognised by the EU Commission as trustworthy enough to certify whether a device can be certified as medical device. Because a NB was involved in a health scandal under the previous regime, the NB have more requirements to respect which concern the acquisition of the status of NB but also their obligations. For instance,they are considered responsible if they use subsidiaries or hire contractors to carry out their duties which was not the case in the past (Article 37.2 MDR) The MDR deadline for national implementation is **26 May 2024** therefore it is extremely important that medical devices producers comply with these rules.	
National Implementation of the MDR D.lgs 137/2022 and decrees 12 April 2023. GU 13 June 2023 n.136 Concerning respectively: *A) Administrative procedures of national relevance for the submission of communications relating to clinical investigations for devices bearing the CE marking used in the context of their intended use referred to in Article 16(3) of Decree No 137 of 2022.* *B) Administrative procedures of national relevance for the submission of the application for clinical investigation for medical devices not bearing the CE marking referred to in Article 16, paragraph 2 of Legislative Decree No. 137 of 2022. (G.U. General Series, no. 136 of 13/06/2023)*	*A) Devices bearing the CE marking*. This implementing decree's contents concern: 1) how to **handle the official communication** for products bearing the CE marking, at least until the EUDAMED database (see MDR supra) is fully operative. In any case, all manufacturer's communications are officially addressed at the **Italian Health Ministry**. 2) the fact that it is the **manufacturer's duty** to send **complete and compliant documents** and files documentation sent must be compliant with the MDR requirements. 3) further, that **preliminary** to the manufacturer's official relevant documents communication to the Health Ministry, the manufacturer submitting the file **must obtain the approval by an Ethical Committee** either at a **local** level from a CET (Comitato Etico Territoriale) or at a **national**, from a CEN (Comitato Etico Nazionale) 4) that manufacturer must give **notice** of the trial(s)'s start **within 30 days to the competent authority**	Same as above

	B) Devices not bearing the CE marking. This implementing decree's content concerns 1) how to **handle the official communication** for products not bearing the CE marking, at least until the EUDAMED database (see MDR supra) is fully operative. In any case, all manufacturer's communications are officially addressed at the **Italian Health Ministry**. 2) the **clarification** about the **sponso**r being the legal entities/subjects habilitated to **officially communicate information** to the Italian Health Ministry is the sponsor 3) that the **request** for the start of clinical trials must be done **only after obtaining a favourable opinion from either a local Ethical Committee (CET) or national (CEN)**. 4) that the **sponsor** communicates the **beginning of the trial promptly** to the competent authority (Health Ministry). **Obstacles :** The manufacturer's and sponsor's difficulties in this phase is that the implementing acts are ready but they need to be tried in practice and there is always a margin of uncertainty.	
Clinical Trials regulation (and its implementation in Italy): Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC Text with EEA relevance OJ L 158, 27.5.2014 (**CTR**)	The CTR should have both a **digitalisation** and **harmonisation** effect on the clinical trials' discipline. Its founding principles are the following ones: 1) that each clinical trial needs to **pass both a scientific and an ethical review** 2) that the said **ethical review** must be carried out by a **national ethics committee.** The review by the ethics committee may encompass aspects addressed: → in Part I of the assessment report for the authorisation of a clinical trial as referred to in **Article 6 CTR** and → in Part II of the assessment report as referred to in **Article 7 CTR** as appropriate for each Member State concerned. 3) that the **procedure will be standardised through a common EU portal** where all the documents must be submitted (CTIS) and the	Same as above

	authorisation procedure is led by one Member State (generally the one of the person submitting the documentation in CTIS). **Obstacles** This regulation was needed but the problem is the **implementation time**. It was firstly adopted in 2014 and it is not fully applicable after 10 years. This is understandable given the level of harmonization required. Nevertheless, 10 years it is also the time in which there could have been a consolidation of this regulation at the EU level and research could have progressed more rapidly.	
National implementation of Clinical Trials Regulation into the Italian discipline: 26, 27, 30 January 2023 decrees	The Italian framework concerning the implementation of the CTR hugely relies on the re-organization and rationalization of the discipline of the Ethical Committees. Here follows a synthesis of the main points of the three decrees. ***Decree Jan 26, 2023*:** describes the way in which to select the Ethical Committees per region **(there will be only 40 ethical committees).** ***Decree Jan 27, 2023***: The first part of this second decree concerns its field of application (substantial amendments of clinical trials proposals) and postponement of the application of the CTR **until 31 January 2025**. However, one can already start using the new EU portal, Clinical Trial Information System (CTIS) for the presentation of Clinical Trials (CT) proposal; The second part of the decree concerns the implementation of the clinical trials evaluation proposals into 2 parts. The first part concerns (see Article 6 CTR). 1. the clinical trial type (e.g. low-intervention clinical trial); 2. what the therapeutic and the public health benefits of the proposed CT are. 3. what the subject could risk; 4.marketing and labelling requirements compliance and 5. the presented material's fitness for the CT	

	The second part instead concerns (Article 7 CTR): 1) informed consent compliance requirements (chapter V CTR) 2) rewards and compensation requirements for CT participants which need to be compliant with the requirements set out in Chapter V (CTR)and investigators. 3) subjects' recruitment with the compliance requirements set out in Chapter V (CTR) 4) compliance with Directive 95/46/EC; 5) compliance with Article 49 CTR (Suitability of individuals involved in conducting the clinical trial) 6) compliance with article 50 CTR (Suitability of clinical trial sites) 7) compliance with article 76 CTR (Damage compensation) 8) compliance with the applicable rules for the collection, storage and future use of biological samples of the subject. ***Decree Jan 30, 2023***: definition of the Local Ethical Committees (Comitati Etici Territoriali) and National Ethical Committees (Comitati Etici Nazionali); respective subject and territorial competences; composition criteria; independence of the members requirement; methods of financing (national system of fees). **Obstacles** As already observed in the part concerning obstacles and the EU CTR, even these last implementing decrees create some uncertainty, as it is typical in all the transitional periods as it still needs to be fully applied.	

3.2 AI REGULATION AND ETHICS

Artificial Intelligence is a technology which is bound to influence other ones such as robotics and the IoT. The algorithms that power it have become increasingly more complex and efficient in just a few years. Given the possibilities offered by large language models (LLMs) but also Natural Language Processing (NLP) AI systems, it might be tempting for new personal and healthcare robot creators to integrate those into the device's functioning. Since 2018, the AI has been the technology that has received more public and media attention and in a matter of a few months the text of the AI act (now still a proposal) should be voted into law and become effective. One of the main

problems is that AI applications such as the LLMs were not considered in the first drafts of the AI proposal (which was presented almost two years ago) and this creates some doubts as if the AI act will be still an applicable legislation in practice when it will become effective. That is why the ALTAI checklist for ethical AI might still be a useful tool for assessing new kinds of AI for which the AI act might be difficult to apply.

Table 3 AI Regulation

Name of the Initiative	Legal Compliance and Obstacles	Ethical compliance
ALTAI checklist for a trustworthy AI [3]		This document is a **checklist** of **ethical/legal principles** that should always be followed and applied since the early stages of AI systems development, especially the ones that might not be formally considered as high-risk by the combination of Article 6 and annexes II and III of the AI act but that could have impactful effects on society The principles that AI providers should follow from the design phase for their algorithms are the following ones: • **human agency and oversight** • **technical robustness and safety** • **privacy** and **data governance** • **transparency** • **diversity, non-discrimination and fairness** • **environmental and societal well-being** and • **accountability**
AI act proposal (general regulation for Artificial Intelligence, COM/2021/206 final), AI act	AI Act will be the **most general** regulation on AI, including: **AI systems** definition as **software** (primarily) and connection with annex I; Division in **high-risk** and **low-risk AI** systems. The definition of **high-risk system** is the result of the application of **Article 6**, which concerns AI used as a safety component or as a part of a safety component, and Annexes II and III which explain the specific harmonization regulations and directives which will be considered a framework for the use of AI high-risk systems.	The AI act will make it mandatory for high-risk AI systems operators and developers to draft a **fundamental rights impact assessmen**t. It is in itself an ethical compliance document. It is not yet clear how it will be done but for sure there is a reference to Article 35 GDPR concerning the **Data Protection Impact Assessment (DPIA**). In the case of the AI act, possibly, the document will need to detail the functioning of the AI system used, the risks on fundamental rights that are taken but also the precautions and risk minimization techniques that will be adopted. As well as the DPIA the

[3] ALTAI, Assessment List Trustworthy Artificial Intelligence. ALTAI Self-Assessment https://digital-strategy.ec.europa.eu/en/library/assessment-list-trustworthy-artificial-intelligence-altai-self-assessment. Accessed 25 October 2023.

	Compliance requirements for high-risk AI systems, including obligations to **train the data fairly** in a **non-biased way** are **quite extensive** and concern AI high risk systems before and after they are put into service. **Obstacles** **Some forms of AI are forbidden**, such as the ones that overtly or subconsciously discriminate against a person or certain groups (article 5 Ai Act). Concerning **high-risk AI systems**, they will need to follow complex **requirements** not only about their **design** and **training** but will need to undergo a process of **certification** with **specialized notified bodies**. Moreover, **an EU database of high-risk AI systems** should be implemented. Concerning Fit4MedRob partners which create personal and healthcare robots, they will need to combine the AI act to the MDR and the MR compliance. In fact The Machinery regulation is connected to the AI Act as well the MDR and the In Vitro Fertilization rules because of they appear in Annex II list. Therefore, we can expect that AI systems for medical devices and machines will need to follow the AI act discipline which concerns high-risk AI systems and will include several obligations about transparency and training of these algorithms and it will be necessary as well to draft a fundamental rights AI impact assessment.	fundamental rights impact assessment will be a living document that must be updated every time that it will be needed.

3.3 LIABILITY LAWS

Liability rules are essential to design better and safer personal and healthcare robots. Moreover, the characteristics of liability sets might greatly influence the final price of the final product/device. In fact, if the manufacturer needs to invest more in R&D to have a compliant object, this cost will be likely to be absorbed in the final cost of the product. There will be the brief description of the new proposed EU product liability rules, the AI civil liability proposal and the directives concerning goods with digital elements (SG and DC) to conclude with a sum up of the Italian private law responsibility rules.

Table 4 Liability laws

Name of the Initiative	Legal Compliance and Obstacles	Ethical Compliance
Product liability directive proposal (COM/2022/495 final) (**PLDU**)	The current product liability fundamental rules of the Product Liability Directive (PLD) (which in Italian can be found in Codice Del Consumo) are not different from	The ethical (and social) paradigm to check the defectiveness of the product is the **safety that the public at large** can expect of the object (which could or could not be a medical device) whereas in the

	substantially from the ones of the PLDU. Both in the PLD as well as in the PLDU, the consumer must prove **the damage**, **the defectiveness** of the product and **the causal link** between the two of them. However, some of the **old terms** are being **applied more extensively**. One example is the definition of **product** which now comprehends **data** and **software** as well as the word damage, which can also be about data used both for personal and work purposes. Moreover, there is an increasing similarity in the subjects which might be considered liable. Article 7 details a long list of economic operators, by using the same terms of the MDR. The consumer must contact the *manufacturer as the first subject to be liable*. If they are not in the EU or are unknown, the consumer will need to follow the list of the subjects that could be considered liable at the place of the manufacturer and that can be found in Article 7 PLDU. This proposal will be important as it considers software and data used by **connected products** as traditional medical devices as well. It is relevant both for personal robots (because they will be consumer objects according to EU law) but also for medical devices. The MDR is currently directly linked to the actual product liability directive, and it is possible that even the new regime will be connected to it also in the foreseeable future but not for all healthcare and personal care robots (see infra Obstacles). Moreover, the specific mention of **surrogation** in the position who has been damaged by other subjects makes it clear that to insurance contracts will become of even greater importance in goods with digital elements issues. **Obstacles**: The problematic thing might be that medical devices such as **healthcare robots** might **integrate high-risk AI systems** in situ or in the cloud. This will result in the need to apply the AI act compliance rules but also the AI civil liability proposal rules (infra). This might create confusion in how to apply different set of rules for robots that might be similar but are certified differently. The same thing might	current regime it is the safety that a person can legitimately expect. This might be a more pro-consumers' choice than the actual regime. One must also not forget that the manufacturer can also have exemptions of liability. One that might be interesting in relation to ethics is the so-called **'risk-development' exception**. If the manufacturer proves that they followed the best state of the art at the moment of putting the product into the market they cannot be held liable for damages caused by the same product. However, one must remember that the consumer now has can count on of 15 years for a damage to become apparent (this number was the result of past case-law concerning side-effects with medical products litigation in the past) and three years instead of two to act upon it. Moreover, legal rules that are actually a source of ethical compliance duties are the ones contained in Article 8 and 9 PLDU. The first article states that claimant can ask judges to get access to the functioning of the product to prove one or more of the elements they need to provide evidence for (provided that they justify this request). If the defendant refuses to give access then they are presumed liable. This responds to a principle of fairness towards the consumer who might not have access to the technical knowledge to prove their point. The same ethical foundation underpins Article 9 PLD sets some ground rules for rebuttable presumptions concerning the defective and/or the causal link elements that the consumer must provide evidence for. Even in case Article 9 PLDU applies the manufacturer can always rebut the presumptions concerning defectiveness.

	happen when **a personal care or healthcare robot** has parts that fall within the MD/MR system. Moreover, it is not clear how the MDR will still be connected to the PLD. The MDR recalls explicitly that it is connected to the currently applicable product liability directive thanks to Article 10.16 MDR. This article states that **the manufacturer must have enough funds** (including insurance) to cover **product liability claims.** There is no reference of the MDR in the new text of the proposal. That makes it clear that the PLDU might be applied to medical devices only when they are not connected devices.	
AI civil liability directive proposal (COM/2022/496 final) (**AILP**)	There are **two new rules** (especially Articles 3 and 4) that are set to harmonize tort liability rules ***whenever an AI system contributes or directly causes technological damage***. **Obstacles**: This proposal is closely **connected to the AI act** and is also complementary to the PLDU as stated in Article 1(3)(a) AILP. It might be difficult to understand in practice when to apply the AILP. Especially when robots are also medical devices, there can be other connected objects (even personal care robots) that are not medical devices and hence might need to apply the PLDU rules (see supra). It will need to be clarified if, in this last case, the choice of liability rules follows the specific function of the object or its function (as an auxiliary to the medical device or as part of a system of mixed medical and non-medical devices). Further, this directive is going to heavily influence the **civil procedural rules** of the Member States. Specifically, Article 3-disclosure of evidence and rebuttable presumption of noncompliance- and Article 4 of the proposal – rebuttable presumption of a causal link in the case of fault-provide principles according to which the MS civil procedural laws will need to conform.	The ethical-legal compliance rule is that the *injured person must be able to prove difficult technical and scientific elements that are relevant for the functioning of AI high-risk systems by using legal presumptions*. This principle is counter-balanced by the fact that ***the causal link presumption is not an absolute one***, hence the defendant always has a chance to rebut the presumption
Directive (EU) 2019/770 of the European Parliament and of the Council of 20 May 2019 on certain aspects concerning contracts for the	These directives regulate contractual liability aspects of liability. They both are interesting as they are complementary in character, and they do consider both	Contractual liability in this case does not start from the assumption that the contracting parties are equal but that the one buying the good or service is **more vulnerable** as a

supply of digital content and digital services (Text with EEA relevance.) PE/26/2019/REV/1 *OJ L 136, 22.5.2019, p. 1–27* **(DCDS)** Directive (EU) 2019/771 of the European Parliament and of the Council of 20 May 2019 on certain aspects concerning contracts for the sale of goods, amending Regulation (EU) 2017/2394 and Directive 2009/22/EC, and repealing Directive 1999/44/EC (Text with EEA relevance.) PE/27/2019/REV/1 OJ L 136, 22.5.2019, p. 28–50 771(**SG**)	the notions of **good with digital elements** (Article 2.5.a SG, Article 2.3 DCDS). *They are applied both to personal and healthcare robots whenever there is a conformity issue about the interconnected good or the digital service acquired and downloaded and supplied to the good*. Services and goods are judged according to **conformity criteria** which can be **objective** (mainly connected to technical features that were promised to the consumer) but also **subjective** conformity criteria which are mainly connected on the expectations that the seller or trader made the consumer have about the connected object or digital service/content. The seller or trader are always presumed liable (**rebuttable presumption**) for the non-conformity of the good/service. The remedies for both these directives are almost the same and are the 'traditional ones' of EU consumer law. They are almost the same for the two directives: **repair**, **substitution**, **price reduction**, and or **termination of the contract**. As far as the DCDS, there are some more specifications concerning the duty of the trader to ensure, in the event of a termination of a contract (Article 16 DCDS), the respect of some obligations. The trader needs to reimburse the sums paid in carrying out the contract and they will comply with the GDPR obligations including Article 20 GDPR on the portability of data. Finally, the trader must not use content other than personal data that was provided or created by the consumer unless such content *'(a) has no utility outside the context of the digital content or digital service supplied by the trader;* *(b)only relates to the consumer's activity when using the digital content or digital service supplied by the trader;* *(c) has been aggregated with other data by the trader and cannot be disaggregated or only with disproportionate efforts; or* *(d)has been generated jointly by the consumer and others, and other consumers are able to continue to make use of the content'* Article 16(3) DCDS.	consumer as they do not have any leverage on the trader or seller. Hence, these rules might appear more favourable to the weakest of the two parties

General liability issues under Italian law (civil Code)	There are two main kinds of liability in Italian private law: contractual and extracontractual (tort liability). The former (almost) always implies the need of a contract among parties (e.g. a contract of sale). The latter kind of liability does not need a contract to be valid (e.g. a pedestrian is run over by a car). In liability parlance, there are shared concepts among extracontractual and contractual liability but with different declinations. Some examples are • disrespect of a legal obligation •causality link, •fault/ presumption of fault The general rules for both contractual and extra-contractual liability can be found in the **Italian Civil Code** and **special laws** such as the Consumer code and Private Insurances codes. **Obstacle:** Both the SG and DCDS are implemented in Italian law. The implementation of the PLDU and especially the AILP will also **significantly impact** the concept of causality link and the concept of defectiveness in Italian private law together with civil procedural law.	The ethical principle underpinning these rules is that liability must restore *the status quo ante*, meaning that **it must limit itself to compensate for the value or to restore the state of how things were before the damage**.

3.4 DATA LAWS

Data Laws is an unofficial term that Activity 4 used to regroup the enacted and proposed legal acts that concern data protection, data sharing and data access rules. To sum up, data in all its forms. In order for the Fit4MedRob partners to build a new generation of medical devices and allied technologies, they need to know, in a concise and a succinct way what the main legal and compliance requirements they need to abide by. These laws are fundamental for the design and deployment of a new generation of robotic devices as they will mostly rely on data both in situ (within the device) and remotely (in the cloud). Only two of the following documents are enacted[4] and just one of these, the GDPR, almost fully implemented. The Table 5 proposal acts that are listed below will take more time to become effective as they both need to be voted into law and implemented at a national level. In fact, they concern the construction of new infrastructures and regulated data-based economic activities[5]. That is why it is important since now to follow the evolution of these proposals and use their rationales as ethical compliance to integrate in the design and in the deployment of future robotic devices. The table sums up the most important elements that the Fit4MedRob consortium needs to focus on for its activities. The list will become more structured and become definitive in the following iterations of this deliverable.

[4] The GDPR and the DGA, see Table 1 for the complete legislative reference.

[5] We are referring to the Data Act and the European Health Data Space, see Table 5 for the complete legislative reference.

Table 5 Data Laws

Name of the Initiative	Legal compliance and obstacles	Ethical compliance
Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance) OJ L 119, 4.5.2016 (**GDPR**)	It sets the of principle data protection of personal data but also of its safe and as free as possible sharing. **Obstacles**: Article 9 GDPR implementations in the national states can be implemented and – especially for **scientific research** and **statistics purposes** – could constitute a gap for data sharing. For example, in Italy, the consent of the data subject is required also in cases where the GDPR seems to promote another legal basis for data processing, like in the case of use and reuse of health-related data for scientific purpose. Difficulty in the attribution of the different roles of **data controller**, **data processor** and **third party** with connected objects such as personal care robots in connected environments (e.g. hospitals or the home) as in the Fit4MedRob project. This has practical consequences in terms of **liability** and **accountability** allocation	The GDPR is important as it sets for the first time some ethical principles to enhance the data protection and privacy as fundamental rights: • Accountability; • Lawfulness; • Fairness; • Transparency; • Data minimisation; • Accuracy; • Storage limitation; • Integrity and confidentiality • Privacy-by-design and by-default
Italian Code of Privacy D. lgs 193/2003 updated with D.lgs. 101/2018 Italian Data Protection Authority provisions implementing and /or clarifying some aspects of the GDPR	Code: at articles **100**, **110** and **110bis** the Italian Privacy Code sets the main rules to process personal data for **medical biomedical** and **epidemiological** research and further data-sharing for these activities. According to article 100 public entities such as **universities** can communicate and share data concerning study ad research activities even to private parties and through electronic means. Articles 110 and 110bis are about the **medical**, **biomedical** and **epidemiologic research** and the **reuse** of data for **scientific research** or for **statistical purposes**. In Article 110, data processing can be carried out when there the application of Article 9 (2) j GDPR conditions(which means that it needs to be carried out for reasons of public interest) are applicable and a Data Protection Impact Assessment (DPIA) has been carried out. Further, consent is not necessary when it implies a disproportionate effort or might the result of the whole research. Article 110 bis instead explains that the national Data Protection Authorities	Same as above

	can authorise the reuse for scientific or statistical research when: I) it is not possible to inform the interested data subject or II) the delay risks to bring prejudice to the outcome of the research. It adopts its decision within 45 days. The further treatment of personal data by third parties can be authorised by the national authority through general provisions. **Data protection authority provision on 5.6.2019**[6] concerns specific categories of data. One of the joint documents deals with data that are used scientific research (Autorizzazione generale 9/2016). Basically, it explains the interaction between Articles 5 and 89 of the GDPR. It is possible to use derogations for scientific research when collecting data subjects' consent for the processing of their health data if the following conditions are met: 1) **ethical reasons** concerning the data subjects' ignorance about their health condition 2) **unsolvable organization problems** which could affect the final results (for instance they are either dead or not reachable) 3) **serious health concerns** (and in that case the research should have a specific result the objective to make the data subjects' health better). In any case, the data controller must to put in place the **technical and organizational measures** apt to safeguard the data subjects' right to data protection according to the principle of minimization. **Deontological rules on processing for scientific research**[7] One of the most important rules of this document is to be compliant with Helsinki Declaration on patient's safety. The data subject must express their intention to be informed about possible health-related issues that they might not have been aware about. Moreover,	

[6] Provvedimento recante le prescrizioni relative al trattamento di categorie particolari di dati, ai sensi dell'art. 21, comma 1 del d.lgs. 10 agosto 2018, n. 101 [9124510] https://www.garanteprivacy.it/web/guest/home/docweb/-/docweb-display/docweb/9124510 Accessed 25th October 2023.

[7] Regole deontologiche per trattamenti a fini statistici o di ricerca scientifica pubblicate ai sensi dell'art. 20, comma 4, del d.lgs. 10 agosto 2018, n. 101 - 19 dicembre 2018 [9069637]https://www.garanteprivacy.it/home/docweb/-/docweb-display/docweb/9069637 Accessed 25th October 2023.

	this document mandates the respect of these deontological rules by universities and research institutes carrying out medical research. **Rules on the use of consent to re-use data concerning health Opinion of 30 June 2022, n. 9791886**[8] The Italian Data Protection Authority (DPA, aka Garante per la Protezione dei Dati Personali) explained that for medical research it is possible to use consent to process data. However, the initial consent clause must not be ultra-general, but it is required that consent must be obtained and must be specific for each kind of processing that will be carried out starting from the health data that the patient had provided the controller originally. **Obstacles:** Following up on the previous point, it can be difficult to create an information policy that is sufficiently granular and specific that can cover all the further research and re-use activities	
Regulation (EU) 2022/868 of the European Parliament and of the Council of 30 May 2022 on European data governance and amending Regulation (EU) 2018/1724 (Data Governance Act) (Text with EEA relevance) PE/85/2021/REV/1 OJ L 152, 3.6.2022, p. 1–44 (**DGA**)	The DGA sets up quite a complex system of data intermediaries based on the principle that private parties can access certain categories of data of the national public sector bodies which are generally protected 1) by **commercial confidentiality**, 2) **statistical confidentiality**, 3) **protection of intellectual property of third parties** (Article 3 DGA). **Obstacles**: The DGA is creating a complex system of data intermediaries in the 27 EU member states which will give each their own implementation. SMEs and start-ups might not be aware of **how to take advantage of the data that the public administration can let them access according to the DGA**. Moreover, the role of data intermediaries, which can share data for altruistic and non-altruistic purposes (depending on their mission), are still brand-new entities which have never existed in this form. It could constitute a great opportunity, but it still is difficult to visualise how these data intermediaries will work in practice	Data re-use: "*the use by natural or legal persons of data held by public sector bodies, for commercial or non-commercial purposes other than the initial purpose within the public task for which the data were produced, except for the exchange of data between public sector bodies purely in pursuit of their public tasks*"; Article 2(2) DGA Data altruism: the ethical and legal principle that allows a person to share their data related to health for research and business implementing research on the basis of consent. Article 2(16) DGA

[8]Parere ai sensi del ai sensi dell'art. 110 del Codice e dell'art. 36 del Regolamento - 30 giugno 2022 [9791886] https://www.garanteprivacy.it/web/guest/home/docweb/-/docweb-display/docweb/9791886 Accessed 25th October 2023.

Data Act (rules on access and re-use of personal and non-personal data from IoT, COM/2022/68 final), (**DA**)	The DA is set to be the most general regulation for all kinds of IoT devices in the EU which could also apply both to personal care and healthcare robots. It deals with several issues: • **data access rules** which concern **new business subjects**: a) a **user** (which could be a consumer or a professional) who asks to have access to the IoT device's data to the b) **data holder**, the manufacturer of an IoT product and a 3) **data recipient** which is a subject authorised by the user to receive the data asked from the data holder. Upon reception of the data, the user or the data recipient could develop a product or a service which will not compete with the original one(s) but it will be destined to secondary markets. •**data-holder requirements** about how to make data available and **dispute settlement provisions**; • the **unfair contractual terms** in data access contracts (if a clause is unfair according to Article 13 DA then it is null and void); • data availability for public **sector bodies and union institutions**, agencies or bodies based on exceptional need (e.g. pandemic); •**switching rules** between data processing services; •the **safeguards** for **non- personal data sharing in international context**; •**interoperability** rules. In theory it will be applicable for all IoT object (see the definition of product in Article 2 DA) also for e-health purposes. **Obstacles**: the DA has been criticised for its generality (which also extends to medical IoT hence to healthcare robots). Therefore, it will be applicable in theory both **to personal care** and also to **healthcare robots.**	The ethical-legal principle is that **access must be guaranteed by the subjects that are bound by the DA rules (data controllers)** and have to **provide data possibly for free**, if not by using the **F/RAND method** (Fair, Reasonable and Non-Discriminatory) to calculate access fees. Moreover, the users and data recipients of the accessed data must create a *product or a service that is not in competition with the original product/service* and must respect the **trade secrets** they might come across while accessing the relevant data. The enforceability of this aspect will probably be taken care of through non-disclosure agreements
European Health Data Space (EHDS, secondary use of health Data for research, COM/2022/197 final), (**EDHS**)	EHDS proposal will give rise to a new EU harmonised framework which will eventually: • help EU citizens have **control over their own health data** independently from the EU country they are in through the **European Health Records (EHR)** • **boost the use of health data** for better healthcare delivery, better	The secondary use of genetic, biometric and data related to health is encouraged both for research and business purposes (**wellness apps are included in the EDHS**) much more explicitly in the GDPR. This is represented by the model on **data access permit** in the Annexes of the proposal. Given the sensitivity of these kinds of data, access is streamlined through the evaluation

	research, innovation, and policy making • incentivise a secure exchange, use and reuse of health data in centralized infrastructures (the data access bodies) authorised by MS and the EU. **Obstacles**: The EDHS proposal sets the groundwork for the creation of a new system to share health record data and to take advantage of the secondary use of health data. However, to operate efficiently, it requires quite some work in terms of **standardization** and **interoperability** among the systems of the different EU Member States (MS), and the proposal in itself does not give much practical guidance on this aspect. Moreover, the national DPAs will need to revise or *partially change their strict interpretation of data re-use for research*.	of data access bodies to balance the ease of accessing health data by a larger platform of public and private subjects.

4 Legal and Ethical compliance in Action

This second part of the deliverable will give a more precise overview concerning the development of the Survey from its design (4.1), its questions (4.2), the replies given (4.3) and a first attempt to create ad hoc services for the Fit4MedRob consortium (4.4).

4.1 The Survey Design

As already outlined in Section 2 (Methodology), Activity 4 decided that it was important to look for the input of the Fit4MedRob partners to check whether the mapping of the compliance requirements was exact but also to pave the way forward to deliverable D4.9.1. concerning the web-based platform for open acceleration and the services that the future (I)URAT centre of excellence will need to provide.

It was decided that an anonymous survey was the best way to let the different members of the Fit4MedRob consortium be free to express their ideas. However, both in the survey and in the e-mail introducing the survey, Activity 4 made it clear that it did not want survey participants to disclose important or sensitive information concerning their organisation.

That is why it was created a Microsoft forms survey which is accessible at this link

https://forms.office.com/e/038YSBxPNj.

The survey was circulated on Monday 9 October 2023 through the Fit4MedRob mailing list with a reminder on 13 October 2023 through the same channels. In the first email, the deadline to fill in the survey was 16th October 2023. In the reminder email, a new deadline was set for 20th October 2023. The text of both the emails can be found in Annex 1 (6.1.1, 6.1.2).

Activity 4 received in total 59 answers.

The text of questions is added as an Annex 2 (6.2) at the end of this deliverable. The complete series of visualisations starting from the replies to the survey is included in Annex 3 of this deliverable (6.3.).

4.2 The Survey Questions

There is a total of 19 questions divided into three main parts.

The first three questions aimed at identifying the educational background and the role within the Fit4MedRob consortium. The fourth question inquired what the participant's strategy was to answer an ethical question. They were all multiple-choice questions all of which were mandatory to reply but that allowed to select more options.

Questions from 5, 7, 9, 11, 13 and 15 instead aim at understanding what services the Fit4MedRob practitioners need. The questions were divided in themes: regulation of medical devices, intellectual property, data management, ethical compliance of research and product development, contract drafting and cybersecurity. These questions were structured as likert charts. For each of the issues connected to the main theme, the survey participant needed to express their opinion. The alternatives from which to choose from were the following:

1) Slightly important
2) Somewhat important
3) Highly important
4) Not Applicable

Questions 6, 8, 10, 12 and 14 instead are open questions that asked what services they considered important if they had not found a match in the previous question, for each of the themes previously mentioned (e.g. regulation of medical devices et cetera).

Questions 17 to 19 objective was to make the analysis more granular and let the Fit4MedRob participant express themselves and to understand

1) which activities would best serve the survey participant organization in terms of legal-ethical support
2) the most appropriate form to respond to the training needs (if present)
3) if, in the survey participants' opinion, their organization needs specific training in one or more of the topics presented earlier.

4.3 THE SURVEY REPLIES. A SYNTHESIS.

The survey's questions and complete answers are available in Annexes I, II and III but it can be useful to give a synthesis here and to comment on some of the open questions replies.

As far as the background, the majority of respondents were bioengineers (26 replies) and doctors (20)

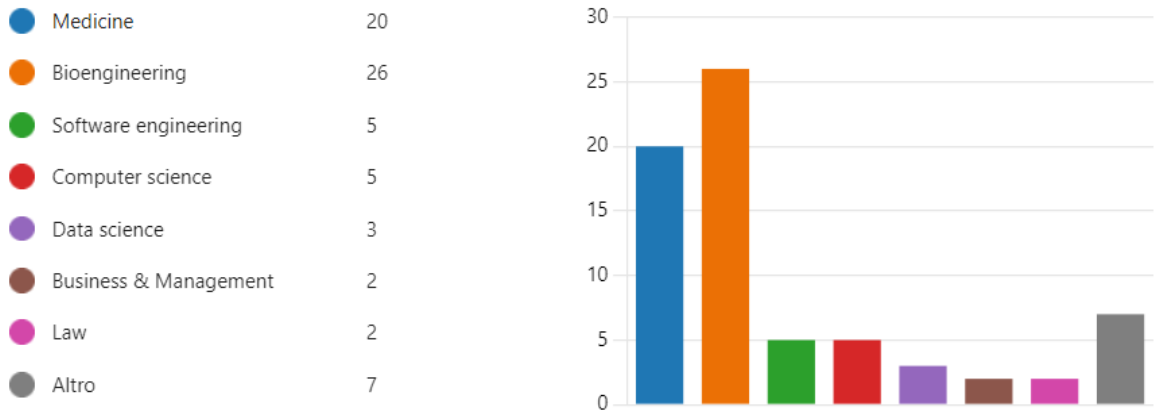


Figure 1: Replies Question 1

Then, as far as the working place, it appears that 42% of the survey participants works for an academic institution. However, one must remember that in this case the replies were mandatory but there was freedom to choose multiple options. Therefore, it might not be surprising that some or all the people who chose 'academic institution' also selected 'public institution' and/or 'healthcare facility'.

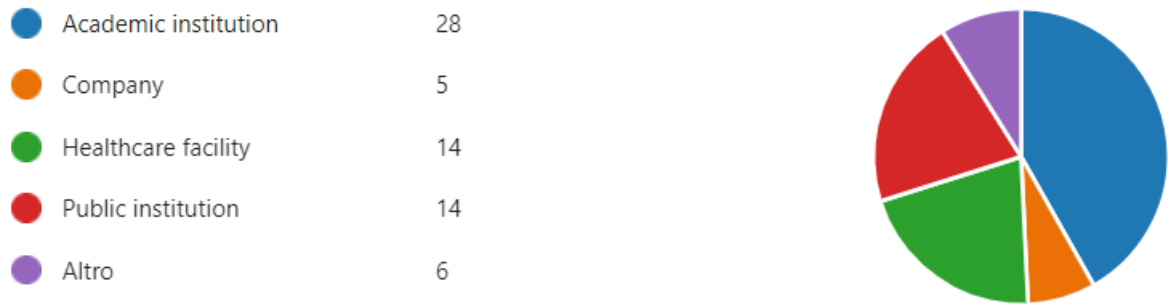


Figure 2: Replies Question 2

As far as the role within Fit4MedRob, 31 respondents chose theoretical and clinical research; this group is followed by people who have selected the option 'clinical practice' (21) and then data analysis (20) and data collection (19). It is also interesting to point out that there are also several people dealing with product development (13). The least represented categories concern ethical compliance (3), legal compliance (2) and administration (1).

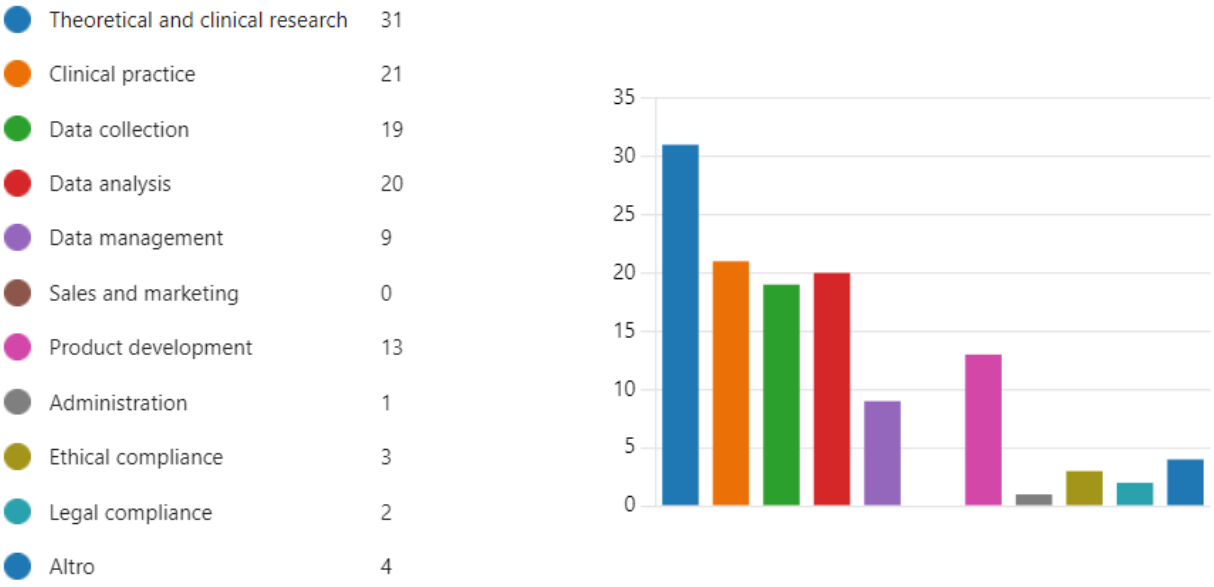


Figure 3: Replies Question 3

It was also interesting to observe the trends concerning how to solve a legal or ethical question. 42 people responded that they would ask a legal-ethical expert(s) within their organisation, or the organisations' Data Protection office (30). A non-negligible group of respondents also selected the option 'you browse the internet (e.g. specialised forums)' (21 people). It is true that also in this case the reply was mandatory but there was the possibility to select more options. Hence it is possible that more strategies (e.g. Internet browsing and asking the DPO) might have been selected together.

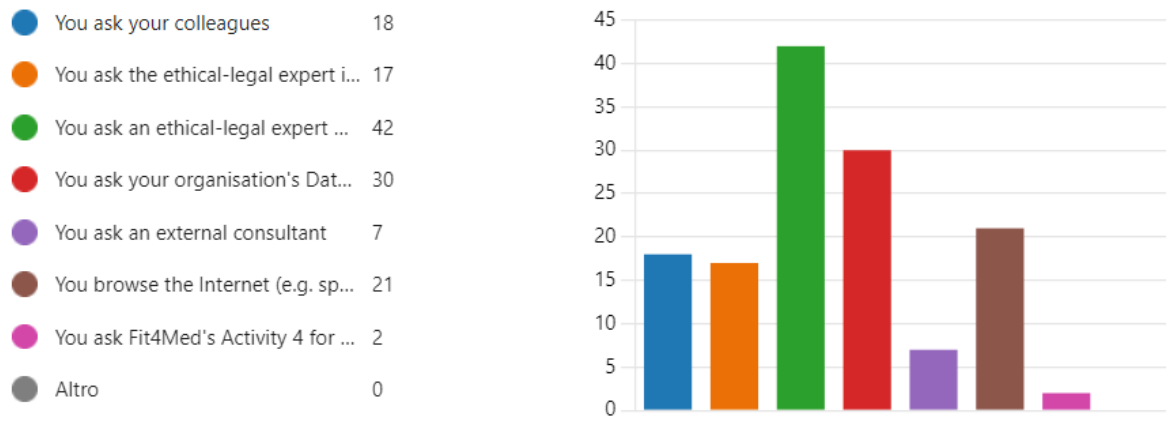


Figure 4: Replies Question 4

The results of the group of questions which were structured as likert diagrams gave interesting results.

The first theme was medical devices regulation and the areas that were considered highly important were

1) Pre-trial research and clinical evaluation (72,9% of the respondents)
2) Device classification (45,8% of the respondents)
3) Product conformity and quality management (each 44,1% of the respondents)

Post market surveillance duties instead was not considered highly important (only 18,6% of respondents considered that as highly important) and yet, as showed in subsection 3.2.2. post market surveillance is one of the new features for the application of the MDR and it will be important to prepare for that set of requirements as well.

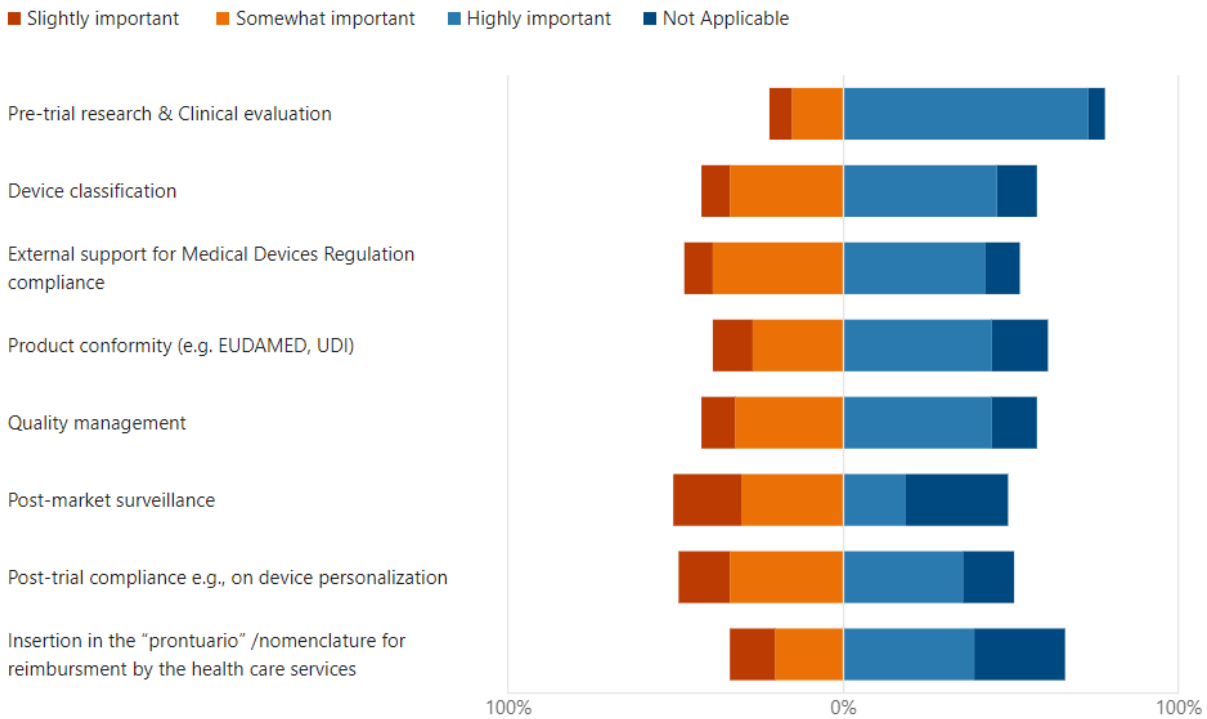


Figure 5: Replies to Question 5

Nobody replied to question 6, which intended to understand whether if none of the options fitted with the survey participant's situation to specify the services which could be considered as highly important.

As far as intellectual property, the item that was considered most as highly important was licences (61%), followed closely by Non-Disclosure Agreements (NDAs) and patents and standards (57,6%).

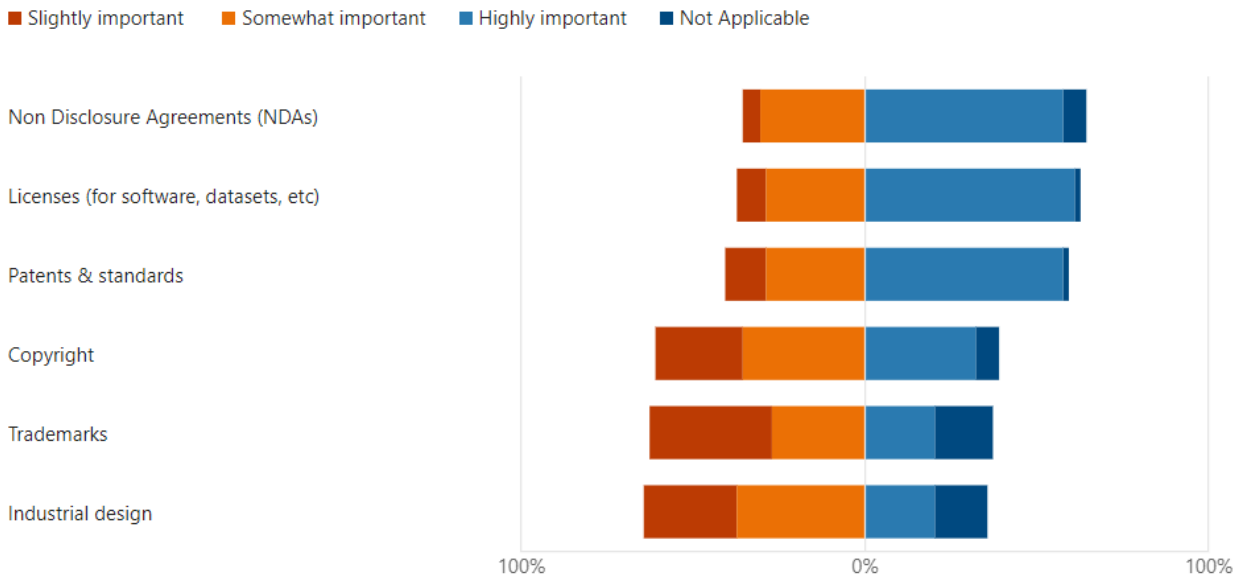


Figure 6: Replies to Question 7

Question 8 was the same of question 6 but applied to intellectual property. Unlike question 6, in this case there was just one answer. The only respondent asked to care more for and "Data protection agreement and IPR management."

Question 9 instead tried to understand which services were more suitable to participants in the field of data management. 62,7% of respondents considered the data management plan and compliance services highly important. Data sharing agreements are the second choice (59,3%) and standardized policies and processes are the third choice (55,9%) more than secondary use of data (50,8%). It will be important to focus on the fact that the DGA and the future DA and EDHS are instruments that can help innovators extract value from the data they have gathered from their devices to build innovative products and services maybe on secondary markets. It is also interesting to notice that the data management services that could be used to evaluate the possible market entrance of a product are considered not applicable to this scenario by at least 25,4% of the respondents.

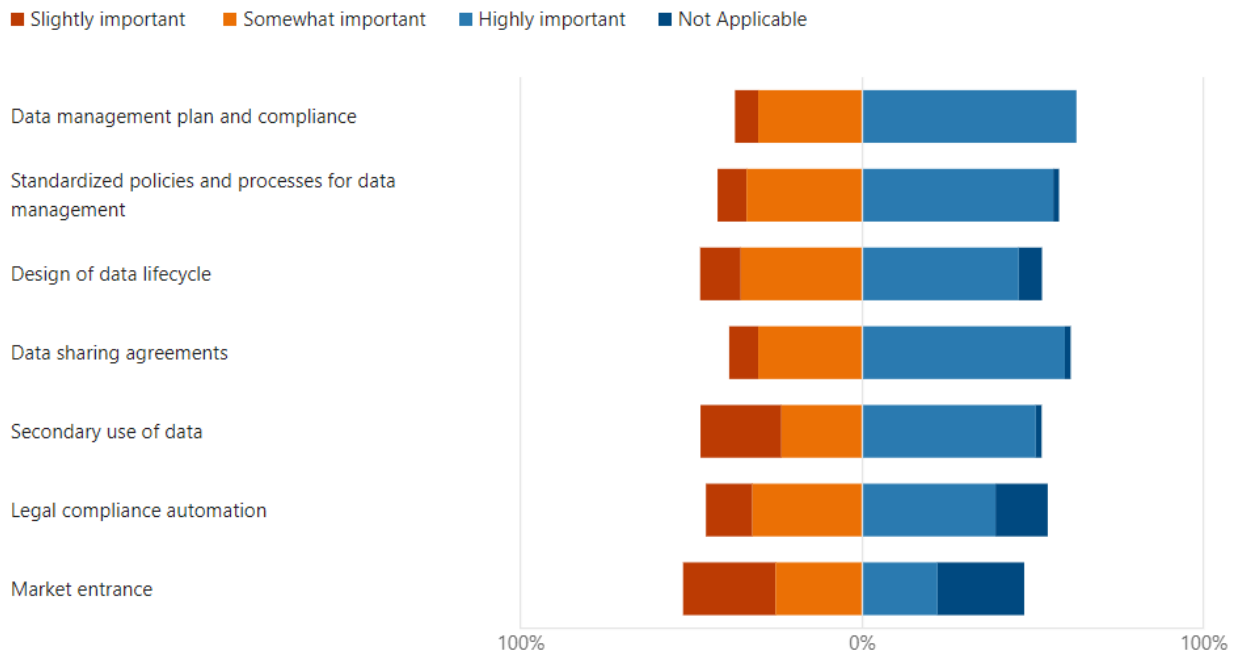


Figure 7: Reply to Question 9

Also question 10 as well as number 6 did not have any reply.

Question 11 instead inquired on which services were more useful in the field of ethical compliance of research and product development. In this case, it was very clear what was considered highly important. In the first place, there are the services to have a correct application to submit for the ethical committee's authorization (86,4%); this item was closely followed by the issue of obtaining consent, especially from vulnerable groups (76,3%) and ethical risk assessment (74,6%) as a third choice. It is interesting to notice that the item about services concerning 'open science was considered 'somewhat important' with the highest percentage (39%), followed by the option concerning trustworthy AI self-evaluation (33.9%). It might be important to make the Fit4MedRob consortium partners that, especially in the near future, the trustworthy AI self-evaluation is going to become highly important in the near future because of the AI act enactment and its connection with liability rules as well as with the MDR and the MR.

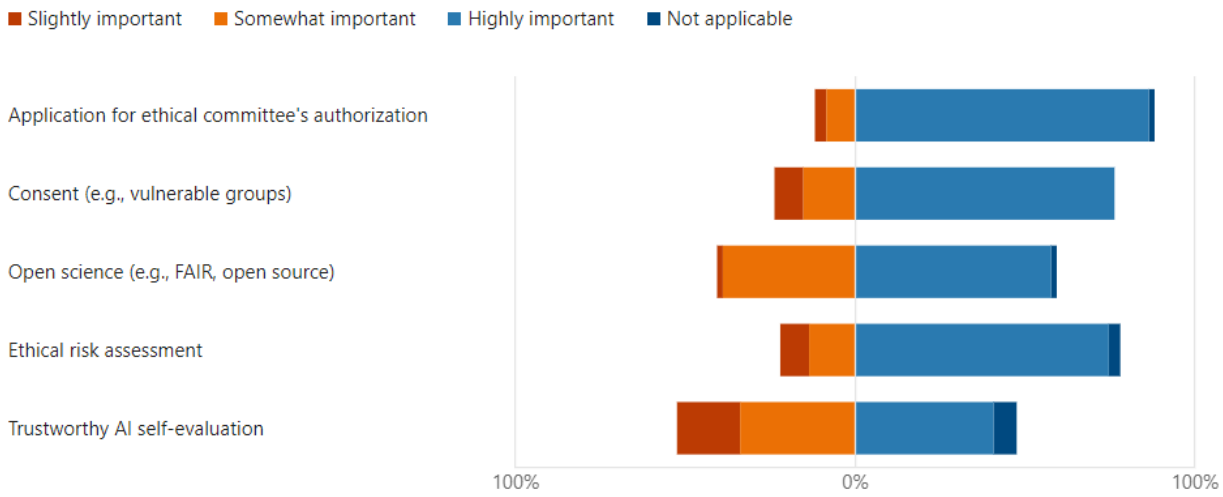


Figure 8: Replies to Question 11

Question 12 like question 6 got no answers.

Question 13 concerned contract drafting. In this case the services concerning insurance or financial coverage things were considered highly important by most of the respondents (55,9%). What is interesting is that consultancy agreements were considered 'somewhat important' with the highest percentage (50,8%).

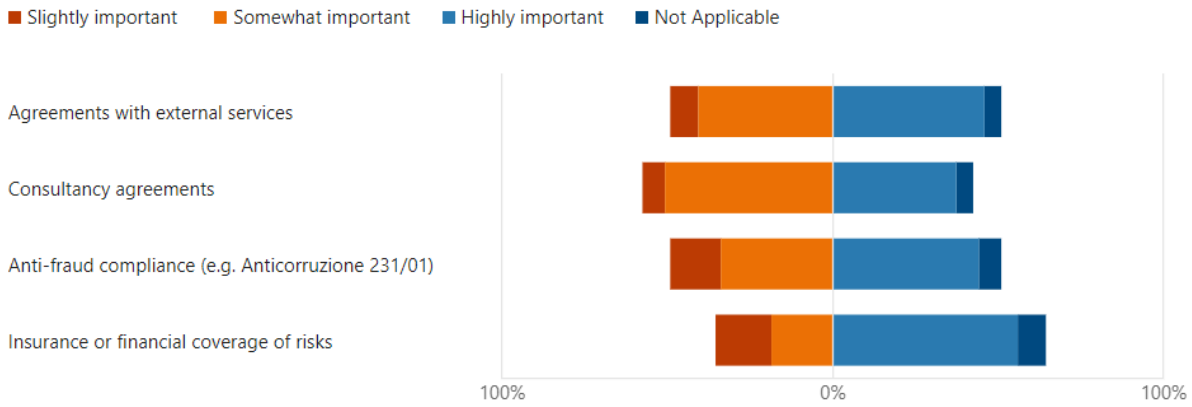


Figure 9: Replies to Question 13

Question 14 inquired which contract-drafting-related services were considered important and, as question 8, got only one reply. This last reply specified that they did not know what their organization's views were on the topic.

Question 15 concluded the series with likert charts by asking preferences concerning the theme of cybersecurity. The distribution of the 'highly important' evaluation is quite homogeneous and high for most of the options presented:

1) Cyber-risk analysis (57,6%)
2) Data breach crisis management (55,9%)
3) (Cyber) security policy (54, 2%)
4) Conformity with cybersecurity certifications (52,5%)

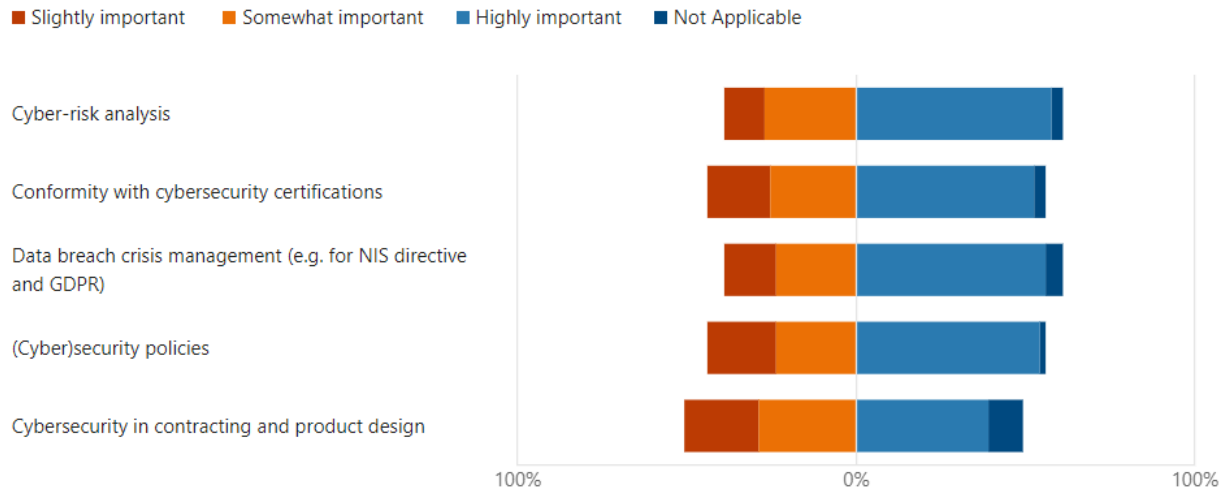


Figure 10: Replies to Question 15

Question 16 which inquired if there were other services concerning cybersecurity that might have been left out was without reply too.

Question 17 was an open question asking what service would best serve the participant's organization to provide legal-ethical support. 40% of the respondents replied that a dedicated role in their company should fit their organization's need best.

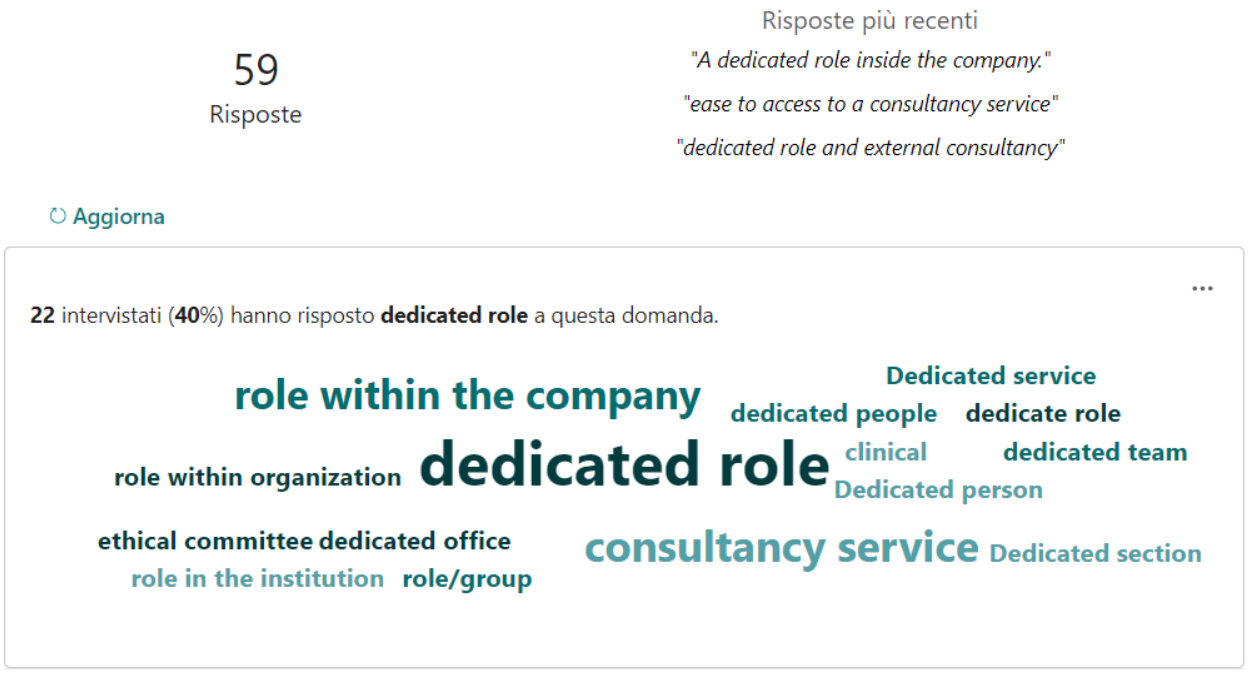


Figure 11: Replies to Question 17

Question 18 on the preferred options for the participants' training needs the replies were also interesting. The most popular options were seminars (40 respondents) and hands-on workshops (36 respondents). Both these choices could be carried out online or in person.

Figure 12: Replies to Question 18

The last question was an open-ended question as well. It was asked whether respondents thought that their organization needed training on one or more of the topics previously mentioned. The word cloud visualization tool showed that 13% of the survey participants wrote clinical trials as a response but also cybersecurity, data, patents and ethical issues were considered important (9% each).

Figure 13: Replies to Question 19

4.4 From the Survey to the Services. A draft of plan for the future of Fit4MedRob consortium

This last table is an experiment on which the Fit4MedRob partners can give feedback. Section 3 revealed the main legal and ethical compliance requirements for whoever wants to build healthcare or personal care robots. Section 4 explains the origin of the survey both as a means to understand how much Fit4MedRob partners were aware about the said legal and compliance requirements, and as a means to check what Activity 4 might have been postponing in terms of legal and ethical mapping and analysis. The survey also offered an opportunity to already start the work concerning deliverable D4.9.1. concerning the creation of an Open Web Acceleration platform, which in itself will become a structured system within the (I)URAT centre of excellence. The survey replies gave Activity 4 ideas already in terms of the services that could be needed in the medium and long term to Fit4MedRob partners and that are succinctly explained in table 6 below.

Table 6 Future services for Fit4MedRob

Area of expertise	Service(s) suggested	Brief description
Safety legislation: Medical Safety laws	Pre-trial research & Clinical evaluation Device classification External MDR responsible person Product confromity (e.g. EUDAMED UDI certification) Approval from Notified body:help with documents and compliance Quality management system establishment Post-market surveillance Post-trial e.g., on service personalization	The MDR is the legislation that has prompted quite a lot of interest in the survey that is why it is treated as the first one. The services that could be developed by the Open Web Platform Acceleration in the following years and iterations is the possibility to streamline and make it apparent the services listed (in forms of checklist and other forms of easy-to-do compliance forms). Moreover, give the future centre of excellence URAT could help provide tailored care for the specific needs of researchers and provide MDR continuous compliance services as requested by Article 15 MDR
AI Regulation and Ethics will translate into Research and product development ethical compliance	Preparing and manage application to the ethics committees Legal design of consent experience for specific groups (e.g., vulnerable populations, etc) or settings (e.g., internet research) Codes of conduct Open science training Ethics assessment Risk assessment Fundamental rights impact assessment Product\service reimbursement from Health care systems	This part of ethical regulation is partly connected also with the discipline of the clinical trials, both for medical devices and for medicines in general. Ethical committee procedures prompted quite a lot of reactions in the comments also because the discipline has been deeply reformed recently and is in a transitional application phase. However, given the more and more widespread use of AI systems it is important to integrate the traditional ethics requirements with the ones which are more tailored with the AI development
Liability laws which will translate mainly into contract drafting at the moment.	External services agreements Consultancy agreements Anti-fraud d. lgs 231/01 compliance ICT contracting	There can be support in the drafting of these kinds of contracts Concerning other kinds of liability such as product and extra-contractual one with reference to new technologies (AILP and PLDU) things are more complex as far as coordination with other thematic law areas is concerned. Product liability issues, despite their importance, need more time for implementation as they need also to be put into relation with insurance issues and harmonized with the upcoming discipline on the Levels of Essential

		Assistance which are not yet fully clear and drafted at this moment in time.
Data laws. In this case we need to divide the services provided in *Data management* (concerning both personal and non-personal data)	Data management plan and compliance Information policies Data Protection Impact Assessments for personal data treatments (if needed) Standardized policies and processes for data management (whole cycle) Data sharing agreements Secondary uses design Legal compliance automation	It is necessary to plan the resources and set out the policies that are needed for the management of research data within a research group/project / consortium / etc. And to draft, update and routinely revise the data management.
And *Data Flow design* (which also includes management for the whole data life cycle	Oversee whether behaviours and decisions are in line with the established data management policies (DA, DGA, GDPR, EDHA) and plan courses of actions to correct deviations and to find solutions to obstacles. Support with data sharing and data processing agreements for private businesses. Support providers of secure processing environments for health data. Analysis of existing or developing information systems and consultancy or co-development service (with help from software engineers).	The Data Flow design is not as focussed on compliance as data management as it is also directed on how to improve a product or service and will help researchers figure in advance what obstacles (legal or ethical) their research might encounter and develop strategies to solve them.
Intellectual property	NDAs Licenses Patents & standards Copyright Trademarks Industrial design	It is true that in Section 3 there was not time to map down the several relevant IP EU and Italian legislative acts. However, from the survey, it was apparent that all these issues connected to legal compliance do have considerable weight for the everyday work of the Fit4MedRob consortium. That is why support with the previous cell themes could be also the start for a more intelligent IP mapping and the starting point to create more tailored IP services.
Cybersecurity	Risk analysis Compliance with existing certification	The Cybersecurity Act, the Cyber-resilience Act and the NIS II directive requirements and their application

	Data breach crisis management (e.g. for NIS directive and GDPR) Security policies Cybersecurity relevance in contracting and in product design	will be dealt with in depth in the next iteration of this deliverable

5 PRELIMINARY CONCLUSIONS

The deliverable's two-fold structure allowed to reach some interesting preliminary conclusions. Section 2 in particular made it possible to focus on the current legal and ethical compliance problems and open issues for researchers and innovators for each of the legal acts commented. What appears is that although the Medical Safety laws are approved, they need to be implemented. Moreover, although they are not so old, Medical Safety Laws do not consider all the issues concerning the EU digital policy and, most notably, the AI Act proposal and the Data laws, meaning all the regulations concerning data ranging from the GDPR to the DA, from the EDHS to the DGA. Moreover, new regulations which concern the general safety of products have just been voted into law such as the GSPR and the MR. It will be necessary to understand how their compliance will adapt to the requirements of the data laws and the AI Act. Further, two new proposals have appeared as far as civil and product liability (AILP and the PLDU) which will need to interact with the contractual liability directives (SG and DCDS). The first two proposals need to be voted into law, but they are likely to influence the civil procedural laws of the EU member states as well.

The second part of the deliverable coincides with section 3 which explains the origin and the development of the survey on ethical and legal compliance (3.1), its questions and their purpose (3.2) and the replies received (3.3). After the survey results, Activity 4 decided to sketch a draft of the services that will be developed through the next deliverable, D4.9.1 which will lay the foundation for the creation of an Open Web Platform Acceleration which will then become part of the instruments developed by the future center of excellence IURAT, created thanks to Fit4MedRob funds.

The conclusions can be summed up as follows: the survey showed some preferred areas of interest concerning legal and ethical compliance themes that were mostly also mapped down in the first part of the deliverable, especially issues related to compliance with the MDR and CTR issues. Other topics, such as the issues concerning the secondary use of data to extract value from it were not felt as important as they are not yet recurring issues in the everyday work of the Fit4MedRob partners. However, these overlooked topics are essential for the development of new healthcare and personal care robots. Knowing more about how to harvest value from data in compliance with new and future data regulations will enable researchers and innovators to really change the paradigms of contemporary robotics and allied technologies as they will be compliant by design. Consequently, the survey outlined a need to train and inform the Fit4MedRob partners on the upcoming changes that will especially invest the area called Data Laws and the one concerning AI. There is also the willingness of Fit4MedRob partners to have seminars and hands-on workshops on the themes they need to be acquainted with, both the most pressing and the least pressing. Data Laws and AI regulation as thematic areas will be extremely important as they will interact with one another and one of the tasks of the next iterations of this deliverable and of the D4.9 ones will be to highlight a precise order on how to carry out different kinds of compliance for the same device and make it understandable for Fit4MedRob partners who do not have a law background.

The results of this first survey are promising as they showed that Fit4MedRob partners care about creating a new generation of personal and healthcare robots that are legally and ethically compliant. However, Fit4MedRob partners who are not lawyers might focus only on a few legal elements they know and do not keep updated with other relevant innovations in the field. That is why Activity 4's work is precious also in terms of continuous education through workshops and seminars and, in general, as a reference for the legal and ethical compliance of the whole consortium. Through the future dissemination within the consortium of these results, there are chances to make other activities and missions' research legally and ethically compliant. This would also be one of the expected targets of the Fit4MedRob mission, which is to build the next generation of medical robots and allied technologies.

6 ANNEXES

6.1 ANNEX 1: CONTENT OF THE EMAILS SENT

As anticipated in section 4, there were two emails being sent. The first one was sent on the 9th October 2023 and the second one as a reminder on 13th October 2023. Their texts will be displayed in the following subsections.

6.1.1 9th October e-mail addressed to the Fit4MedRob consortium

survey anonima per D4.8.1 dell' Activity 4

Francesca Gennari <Francesca.Gennari@santannapisa.it>
Mon 09/10/2023 10:57

To:fit4medrob-mission1@googlegroups.com <fit4medrob-mission1@googlegroups.com>;fit4medrob-mission2@googlegroups.com <fit4medrob-mission2@googlegroups.com>;fit4medrob-mission3@googlegroups.com <fit4medrob-mission3@googlegroups.com>

Gentili membri del consorzio Fit4MedRob,

Il team dell'Activity 4 avrebbe bisogno di una decina di minuti del vostro tempo per aiutarci a comprendere le **questioni etico-legali** che incontrate nelle vostre attività, ad esempio sull'uso dei dati, la conformità dei prodotti, la gestione della proprietà intellettuale, eccetera.

Abbiamo preparato un questionario le cui risposte sono **anonime proprio perché ci serve avere la vostra valutazione oggettiva e libera da qualsiasi vincolo (si prega di non condividere però informazioni riservate)**. Le vostre **risposte** e i **vostri suggerimenti** ci sono necessari per elaborare dei servizi, degli strumenti e delle eventuali attività di **training** che vi forniscano il supporto necessario.

https://forms.office.com/e/038YSBxPNj

Sarebbe importante che persone con ruoli diversi all'interno di ogni organizzazione rispondessero: quindi **invitiamo tutti a partecipare anche più persone per ciascuna organizzazione e con ruoli diversi**! Presenteremo i risultati in modo aggregato nel Deliverable "D4.8.1 Report on ethical and legal compliance of healthcare and personal healthcare robots #1 "

Vi chiediamo di compilare il questionario entro il prossimo **16 ottobre 2023**

Resto a disposizione per eventuali dubbi o chiarimenti

Francesca Gennari

per conto del coordinatore Prof Giovanni Comandé (LIDER Lab, Scuola Superiore Sant'Anna)

6.1.2 13th October e-mail addressed to the Fit4MedRob consortium

survey anonima per D4.8.1 dell' Activity 4 - Reminder

fit4medrob-activity3-4@googlegroups.com <fit4medrob-activity3-4@googlegroups.com>
on behalf of
Francesca Gennari <Francesca.Gennari@santannapisa.it>
Fri 13/10/2023 15:56

To:fit4medrob-activity1-2@googlegroups.com <fit4medrob-activity1-2@googlegroups.com>;fit4medrob-activity5@googlegroups.com <fit4medrob-activity5@googlegroups.com>;fit4medrob-activity3-4@googlegroups.com <fit4medrob-activity3-4@googlegroups.com>;fit4medrob-activity6@googlegroups.com <fit4medrob-activity6@googlegroups.com>;fit4medrob-activity7@googlegroups.com <fit4medrob-activity7@googlegroups.com>; fit4medrob-activity8-9@googlegroups.com <fit4medrob-activity8-9@googlegroups.com>;fit4medrob-activity10@googlegroups.com <fit4medrob-activity10@googlegroups.com>
Cc:fit4medrob-mission1@googlegroups.com <fit4medrob-mission1@googlegroups.com>;fit4medrob-mission2@googlegroups.com <fit4medrob-mission2@googlegroups.com>;fit4medrob-mission3@googlegroups.com <fit4medrob-mission3@googlegroups.com>;fit4medrob-sc@googlegroups.com <fit4medrob-sc@googlegroups.com>

Gentili membri del consorzio Fit4MedRob,

Il team dell'Activity 4 avrebbe bisogno di una decina di minuti del vostro tempo per aiutarci a comprendere le **questioni etico-legali** che incontrate nelle vostre attività, ad esempio sull'uso dei dati, la conformità dei prodotti, la gestione della proprietà intellettuale, eccetera.

Abbiamo preparato un questionario le cui risposte sono **anonime proprio perché ci serve avere la vostra valutazione oggettiva e libera da qualsiasi vincolo (si prega di non condividere però informazioni riservate)**. Le vostre **risposte** e i **vostri suggerimenti** ci sono necessari per elaborare dei servizi, degli strumenti e delle eventuali attività di **training** che vi forniscano il supporto necessario.

https://forms.office.com/e/038YSBxPNj

Sarebbe importante che persone con ruoli diversi all'interno di ogni organizzazione rispondessero: quindi **invitiamo tutti a partecipare anche più persone per ciascuna organizzazione e con ruoli diversi**! Presenteremo i risultati in modo aggregato nel Deliverable "D4.8.1 Report on ethical and legal compliance of healthcare and personal healthcare robots #1 "

Vi chiediamo di compilare il questionario entro il prossimo **20 ottobre 2023**

Resto a disposizione per eventuali dubbi o chiarimenti

Francesca Gennari

per conto del coordinatore Prof Giovanni Comandé (LIDER Lab, Scuola Superiore Sant'Anna)

6.2 Annex 2: The Survey Questions

Here follows the complete list of questions that the participants needed to answer. Please apologise for the jpeg format of the following pages. The transformation from the original pdf to a word document risked making the template for this deliverable not usable. Hence this shortcut was preferred.

Fit4MedRob
Survey on ethical and legal compliance

Responsabile Prof. Giovanni Comandé
Grant. n. PNC0000007

* Obbligatoria

Objectives of the survey

We would like to better understand your needs and plan our legal-ethical activities accordingly, such as the provision of services, tools and trainings.
Please answer the following questions carefully. Your answers will be anonymous: do not share any confidential information.

Who are you?

1. What is your educational background? You can choose more than one option. *

- [ ] Medicine
- [ ] Bioengineering
- [ ] Software engineering
- [ ] Computer science
- [ ] Data science
- [ ] Business & Management
- [ ] Law
- [ ] Altro

2. Where do you work? You can choose more than one option. *

- [ ] Academic institution
- [ ] Company
- [ ] Healthcare facility
- [ ] Public institution
- [ ] Altro

3. What is your role within the Fit4MedRob project ? You can choose more than one option. *

- [ ] Theoretical and clinical research
- [ ] Clinical practice
- [ ] Data collection
- [ ] Data analysis
- [ ] Data management
- [ ] Sales and marketing
- [ ] Product development
- [ ] Administration
- [ ] Ethical compliance
- [ ] Legal compliance
- [ ] Altro

5. Regulation of medical devices - Please rank the importance of the following services for your organization *

	Slightly important	Somewhat important	Highly important	Not Applicable
Pre-trial research & Clinical evaluation	○	○	○	○
Device classification	○	○	○	○
External support for Medical Devices Regulation compliance	○	○	○	○
Product conformity (e.g. EUDAMED, UDI)	○	○	○	○
Quality management	○	○	○	○
Post-market surveillance	○	○	○	○
Post-trial compliance e.g., on device personalization	○	○	○	○
Insertion in the "prontuario" /nomenclature for reimbursment by the health care services	○	○	○	○

6. If none of the previous options fits with your situation, specify the services you consider highly important.

7. Intellectual property - Please rank the importance of the following services for your organization *

	Slightly important	Somewhat important	Highly important	Not Applicable
Non Disclosure Agreements (NDAs)	○	○	○	○
Licenses (for software, datasets, etc)	○	○	○	○
Patents & standards	○	○	○	○
Copyright	○	○	○	○
Trademarks	○	○	○	○
Industrial design	○	○	○	○

8. If none of the previous options fits with your situation, specify the services you consider highly important.

9. Data management - Please rank the importance of the following services for your organization *

	Slightly important	Somewhat important	Highly important	Not Applicable
Data management plan and compliance	○	○	○	○
Standardized policies and processes for data management	○	○	○	○
Design of data lifecycle	○	○	○	○
Data sharing agreements	○	○	○	○
Secondary use of data	○	○	○	○
Legal compliance automation	○	○	○	○
Market entrance	○	○	○	○

10. If none of the previous options fits with your situation, specify the services you consider highly important.

11. Ethical compliance of research and product development - Please rank the importance of the following services for your organization *

	Slightly important	Somewhat important	Highly important	Not applicable
Application for ethical committee's authorization	○	○	○	○
Consent (e.g., vulnerable groups)	○	○	○	○
Open science (e.g., FAIR, open source)	○	○	○	○
Ethical risk assessment	○	○	○	○
Trustworthy AI self-evaluation	○	○	○	○

12. If none of the previous options fits with your situation, specify the services you consider highly important.

13. Contract drafting and other - Please rank the importance of the following services for your organization *

	Slightly important	Somewhat important	Highly important	Not Applicable
Agreements with external services	○	○	○	○
Consultancy agreements	○	○	○	○
Anti-fraud compliance (e.g. Anticorruzione 231/01)	○	○	○	○
Insurance or financial coverage of risks	○	○	○	○

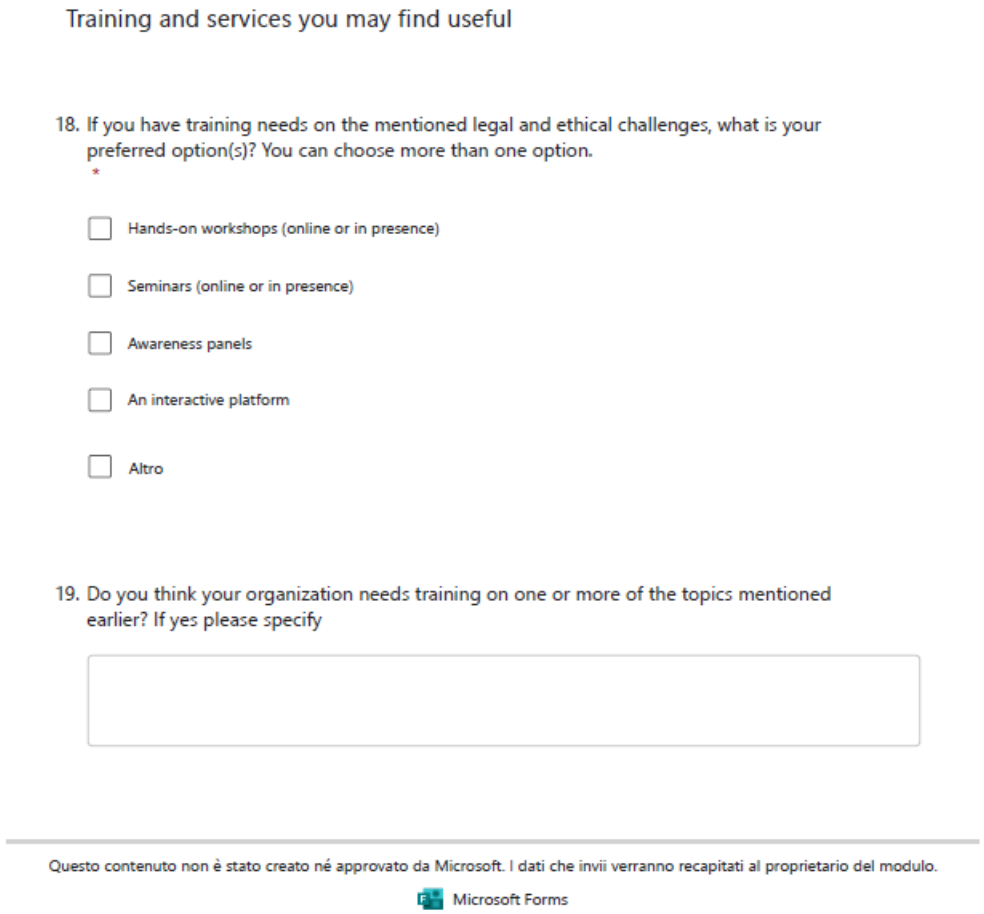
14. If none of the previous options fits with your situation, specify the services you consider highly important.

15. Cybersecurity - Please rank the importance of the following services for your organization *

	Slightly important	Somewhat important	Highly important	Not Applicable
Cyber-risk analysis	○	○	○	○
Conformity with cybersecurity certifications	○	○	○	○
Data breach crisis management (e.g. for NIS directive and GDPR)	○	○	○	○
(Cyber)security policies	○	○	○	○
Cybersecurity in contracting and product design	○	○	○	○

16. If none of the previous options fits with your situation, specify the services you consider highly important.

17. To provide legal-ethical support in your activities, what would best serve your organization (e.g., a dedicated role within the company, consultancy services, law firm...)? *



Training and services you may find useful

18. If you have training needs on the mentioned legal and ethical challenges, what is your preferred option(s)? You can choose more than one option.
*

- [ ] Hands-on workshops (online or in presence)
- [ ] Seminars (online or in presence)
- [ ] Awareness panels
- [ ] An interactive platform
- [ ] Altro

19. Do you think your organization needs training on one or more of the topics mentioned earlier? If yes please specify

Questo contenuto non è stato creato né approvato da Microsoft. I dati che invii verranno recapitati al proprietario del modulo.

Microsoft Forms

6.3 ANNEX 3: THE SURVEY REPLIES

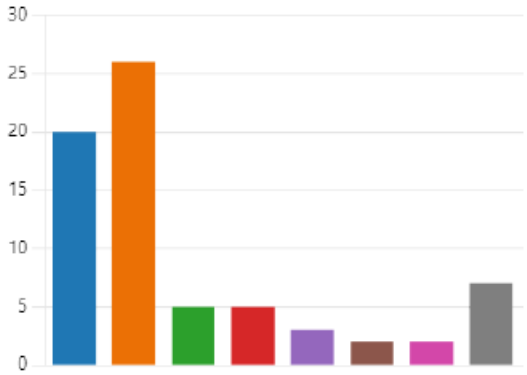
Here follows the complete list of visualizations taken from the survey replies. As well as in Annex II, transforming the original pdf document in a word one was creating problems with the deliverable template. Hence it was preferred to use the jpeg format.

Fit4MedRob Survey on ethical and legal compliance

59	09.27	Attivo
Risposte	Tempo medio per il completamento	Stato

1. What is your educational background? You can choose more than one option.

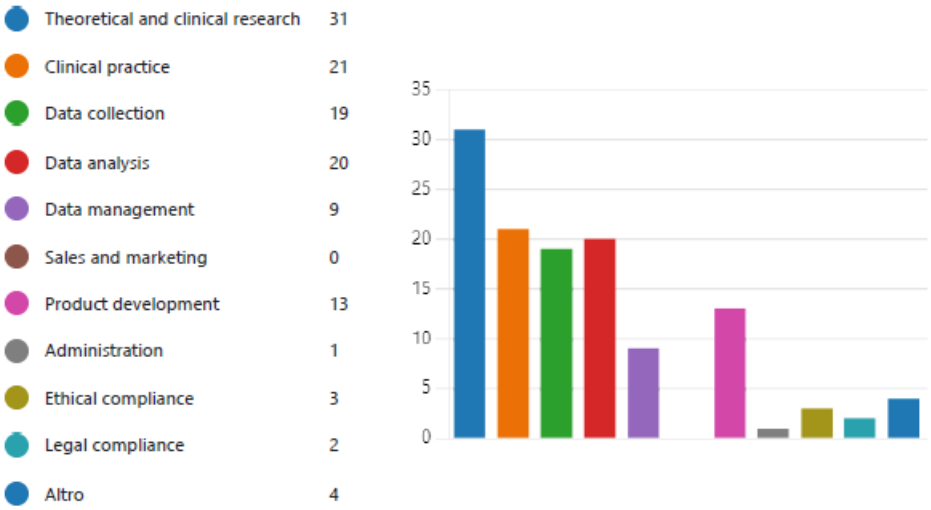
Medicine	20
Bioengineering	26
Software engineering	5
Computer science	5
Data science	3
Business & Management	2
Law	2
Altro	7



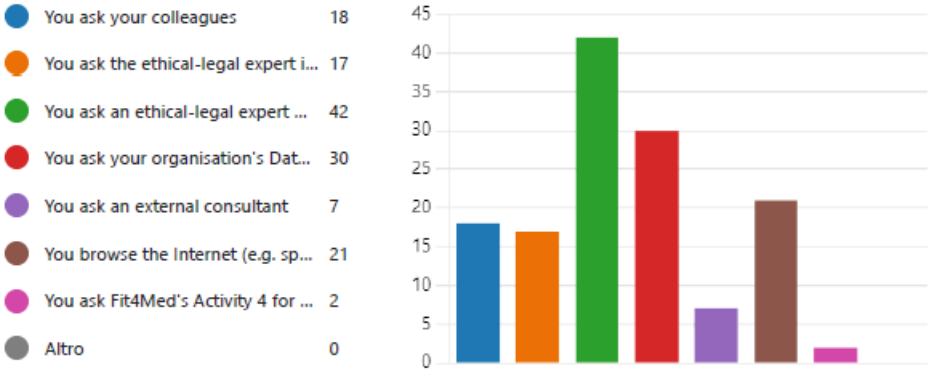
2. Where do you work? You can choose more than one option.

Academic institution	28
Company	5
Healthcare facility	14
Public institution	14
Altro	6

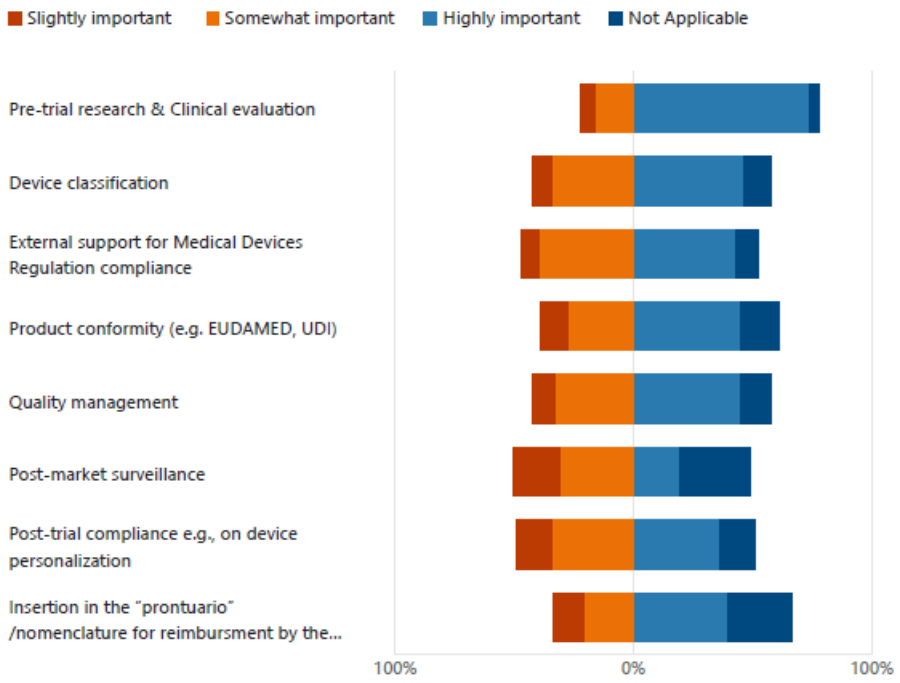
3. What is your role within the Fit4MedRob project ? You can choose more than one option.



4. When you have a legal or ethical question, what do you usually do? You can choose more than one option.



5. Regulation of medical devices - Please rank the importance of the following services for your organization



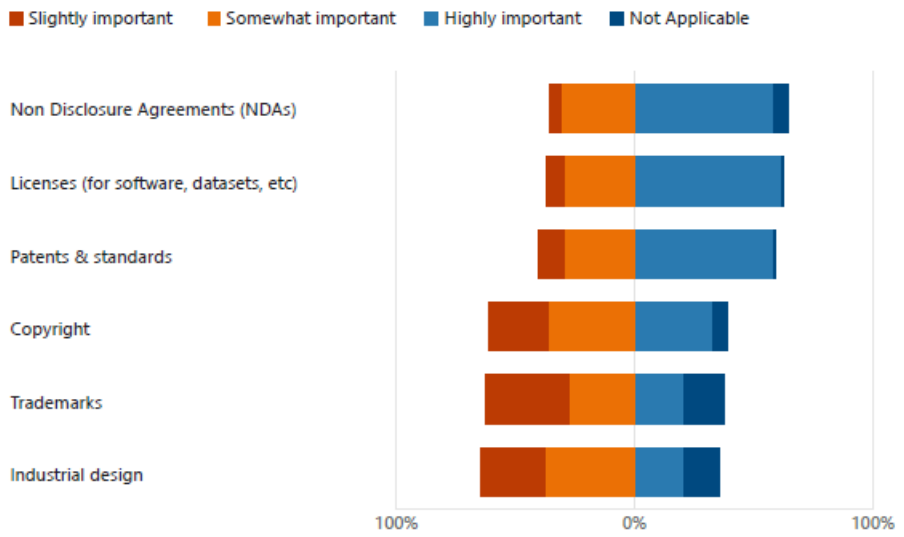
6. If none of the previous options fits with your situation, specify the services you consider highly important.

0

Risposte

Risposte più recenti

7. Intellectual property - Please rank the importance of the following services for your organization

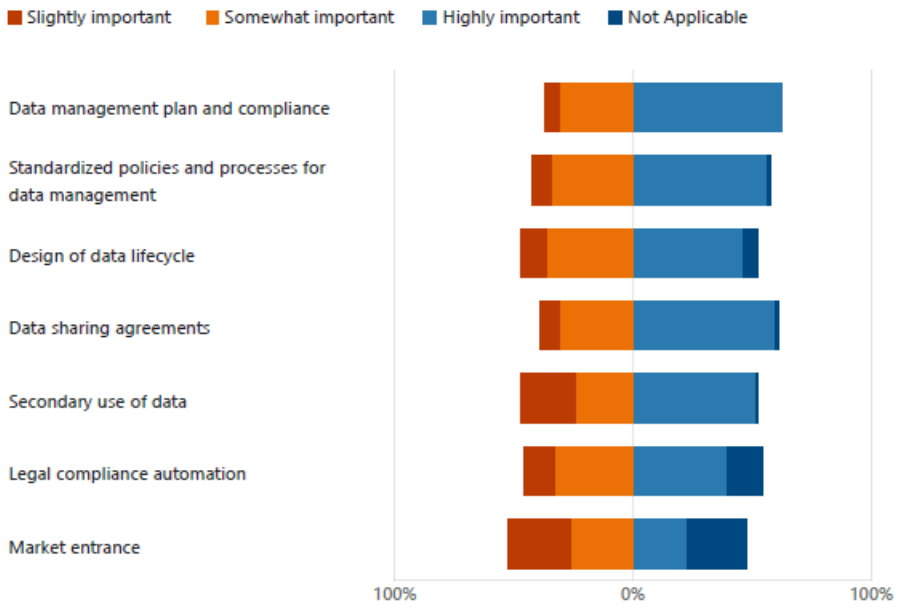


8. If none of the previous options fits with your situation, specify the services you consider highly important.

1
Risposte

Risposte più recenti

9. Data management - Please rank the importance of the following services for your organization

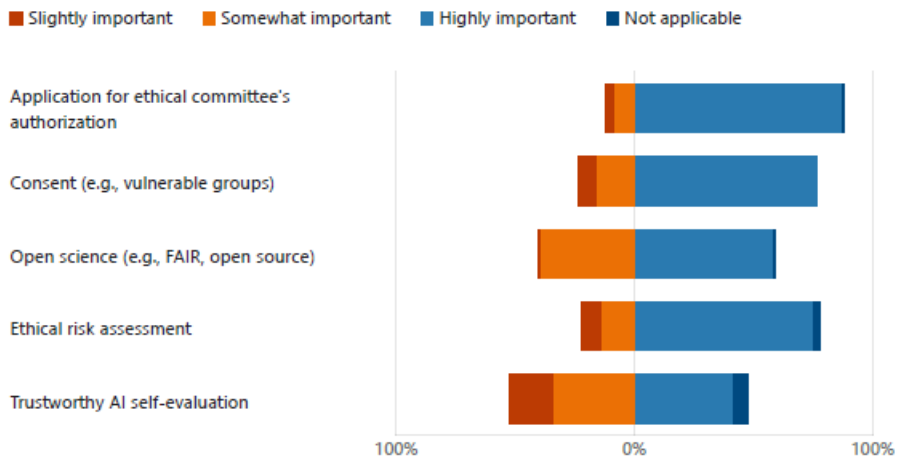


10. If none of the previous options fits with your situation, specify the services you consider highly important.

0
Risposte

Risposte più recenti

11. Ethical compliance of research and product development - Please rank the importance of the following services for your organization

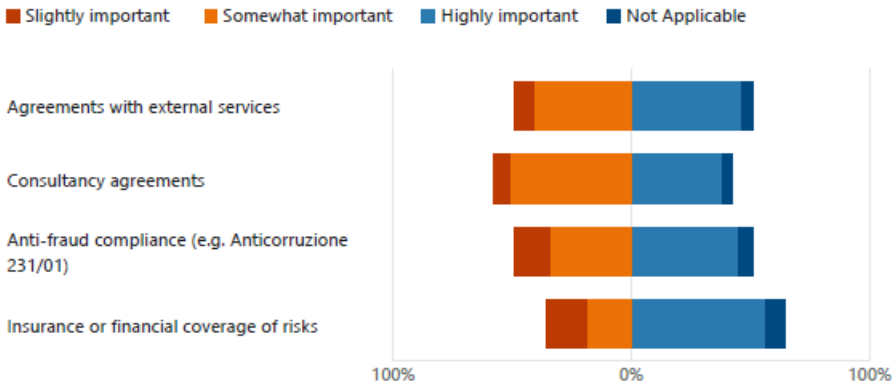


12. If none of the previous options fits with your situation, specify the services you consider highly important.

0
Risposte

Risposte più recenti

13. Contract drafting and other - Please rank the importance of the following services for your organization

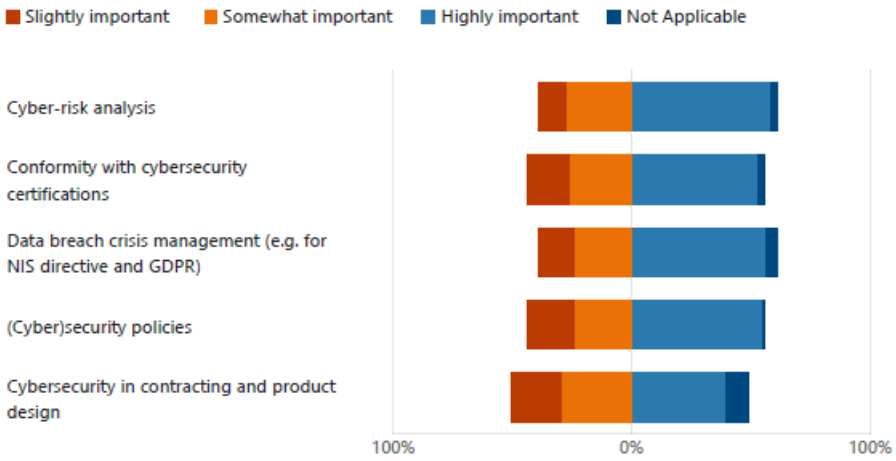


14. If none of the previous options fits with your situation, specify the services you consider highly important.

1
Risposte

Risposte più recenti

15. Cybersecurity - Please rank the importance of the following services for your organization



16. If none of the previous options fits with your situation, specify the services you consider highly important.

0
Risposte

Risposte più recenti

17. To provide legal-ethical support in your activities, what would best serve your organization (e.g., a dedicated role within the company, consultancy services, law firm...)?

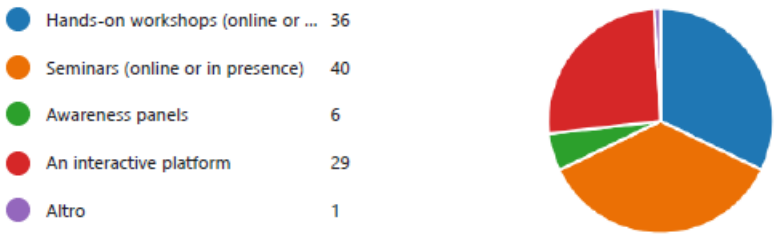
59
Risposte

Risposte più recenti
"A dedicated role inside the company."
"ease to access to a consultancy service"
"dedicated role and external consultancy"

Aggiorna

22 intervistati (**40**%) hanno risposto **dedicated role** a questa domanda.

18. If you have training needs on the mentioned legal and ethical challenges, what is your preferred option(s)? You can choose more than one option.



19. Do you think your organization needs training on one or more of the topics mentioned earlier? If yes please specify

25
Risposte

Risposte più recenti
"yes, a continous training is always important"

Aggiorna

3 intervistati (**13**%) hanno risposto **clinical trials** a questa domanda.

LIST OF ABBREVIATIONS

ML	Mission Leader
AL	Activity Leader
SC	Scientific Committee
BoD	Board of Directors
GA	General Assembly
CoE	Centre of Excellence
CCB	Cascade Calls Board
AI	Artificial Intelligence
CTR	Clinical Trials Regulation
DA	Data Act
DGA	Data Governance Act
EHDS	European Health Data Space
GDPR	General Data Protection Regulation
GSPD	General Safety of Products Directive
GSPR	General Safety of Products Regulation
MD	Machinery Directive
MDR	Medical Devices Regulation
MR	Machinery Regulation
MS	Member State

REFERENCES

[1] European Parliament resolution of 16 February 2017 with recommendations to the Commission on Civil Law Rules on Robotics (2015/2103(INL) OJ C 252, 18.7.2018, p. 239–257.

[2] Regulation (EC) No 765/2008 of the European Parliament and of the Council of 9 July 2008 setting out the requirements for accreditation and market surveillance relating to the marketing of products and repealing Regulation (EEC) No 339/93 (Text with EEA relevance) OJ L 218, 13.8.2008, p. 30–47 (CE Marking Regulation).

[3] Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (Text with EEA relevance) OJ L 11, 15.1.2002, p. 4–17 General Safety of Products Directive (GSPD)

[4] Regulation (EU) 2023/988 of the European Parliament and of the Council of 10 May 2023 on general product safety, amending Regulation (EU) No 1025/2012 of the European Parliament and of the Council and Directive (EU) 2020/1828 of the European Parliament and the Council, and repealing Directive 2001/95/EC of the European Parliament and of the Council and Council Directive 87/357/EEC (Text with EEA relevance) PE/79/2022/REV/1 OJ L 135, 23.5.2023, p. 1–51General Safety of Products Regulation.

[5] Directive 2006/42/EC of the European Parliament and of the Council of 17 May 2006 on machinery, and amending Directive 95/16/EC (recast) (Text with EEA relevance) OJ L 157, 9.6.2006, p. 24–86, Machinery Directive.

[6] Regulation (EU) 2023/1230 of the European Parliament and of the Council of 14 June 2023 on machinery and repealing Directive 2006/42/EC of the European Parliament and of the Council and Council Directive 73/361/EEC (Text with EEA relevance) PE/6/2023/REV/1 OJ L 165, 29.6.2023, p. 1–102 Machinery regulation

[7] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC (Text with EEA relevance) OJ L 117, 5.5.2017, Medical Devices Regulation (MDR)

[8] National Implementation of the MDR D.lgs 137/2022 and decrees 12 April 2023. GU 13 June 2023 n.136.

[9] Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 – MDR and Regulation (EU) 2017/746 – IVDR https://ec.europa.eu/docsroom/documents/37581 accessed 27 October 2023.

[10] Clinical Trials regulation (and its implementation in Italy): Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC Text with EEA relevance OJ L 158, 27.5.2014.
[11] National implementation of Clinical Trials Regulation into the Italian discipline: 26, 27, 30 January 2023 decrees
[12] ALTAI, Assessment list. Trustworthy Artificial Intelligence Self-Assessment https://digital-strategy.ec.europa.eu/en/library/assessment-list-trustworthy-artificial-intelligence-altai-self-assessment . Accessed 25 October 2023.
[13] AI act proposal (general regulation for Artificial Intelligence, COM/2021/206 final), AI act.
[14] Product liability directive proposal (COM/2022/495 final) (PLDU).
[15] AI civil liability directive proposal (COM/2022/496 final) (AILP).
[16] Directive (EU) 2019/770 of the European Parliament and of the Council of 20 May 2019 on certain aspects concerning contracts for the supply of digital content and digital services (Text with EEA relevance.)PE/26/2019/REV/1 OJ L 136, 22.5.2019, p. 1–27 (DCDS).
[17] Directive (EU) 2019/771 of the European Parliament and of the Council of 20 May 2019 on certain aspects concerning contracts for the sale of goods, amending Regulation (EU) 2017/2394 and Directive 2009/22/EC, and repealing Directive 1999/44/EC (Text with EEA relevance.) PE/27/2019/REV/1 OJ L 136, 22.5.2019, p. 28–50 771(SG).
[18] European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) (Text with EEA relevance) OJ L 119, 4.5.2016.
[19] Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety (Text with EEA relevance) OJ L 11, 15.1.2002, p. 4–17 General Safety of Products Directive (GSPD)
[20] D. lgs 193/2003 updated with D.lgs. 101/2018, Italian Code of Privacy
[21] Provvedimento recante le prescrizioni relative al trattamento di categorie particolari di dati, ai sensi dell'art. 21, comma 1 del d.lgs. 10 agosto 2018, n. 101 [9124510] https://www.garanteprivacy.it/web/guest/home/docweb/-/docweb-display/docweb/9124510 Accessed 25th October 2023.
[22] Regole deontologiche per trattamenti a fini statistici o di ricerca scientifica pubblicate ai sensi dell'art. 20, comma 4, del d.lgs. 10 agosto 2018, n. 101 - 19 dicembre 2018 [9069637] https://www.garanteprivacy.it/home/docweb/-/docweb-display/docweb/9069637 Accessed 25th October 2023.
[23] Parere ai sensi del ai sensi dell'art. 110 del Codice e dell'art. 36 del Regolamento - 30 giugno 2022 [9791886] https://www.garanteprivacy.it/web/guest/home/docweb/-/docweb-display/docweb/9791886 Accessed 25th October 2023.
[24] Regulation (EU) 2022/868 of the European Parliament and of the Council of 30 May 2022 on European data governance and amending Regulation (EU) 2018/1724 (Data Governance Act) (Text with EEA relevance) PE/85/2021/REV/1 OJ L 152, 3.6.2022, p. 1–44
[25] Data Act (rules on access and re-use of personal and non-personal data from IoT, COM/2022/68 final)
[26] European Health Data Space (EHDS, secondary use of health Data for research, COM/2022/197 final)