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

FIT4MEDROB

D4.2.1

REPORT ON AWARENESS AND REGULATORY GAP ANALYSIS WITH STAKEHOLDERS #1

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

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HISTORY OF CHANGES

VERSION	SUBMISSION DATE	CHANGES
1	30/11/2024	
1.1	09/12/2024	Submitted version

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1 EXECUTIVE SUMMARY

The present deliverable D4.2.1 aims to initiate a measurement process of the level of awareness among relevant stakeholders in the robotic rehabilitation ecosystem, with respect to currently applicable major regulations on medical devices. The measurement process will last more than one year, generating two deliverables (the present one, at month 24, and its second instalment, D4.2.2, at month 36). The objective of this deliverable (and its iteration) is of key importance within the initiative, because its achievement requires the active engagement of all the consortium's stakeholders, including the industry, both for the measurement of their awareness and for the consequent provision of feedback and support based on the results. The involvement of the project's community, like it was done in this deliverable, is necessary to reach Fit4MedRob's objective to successfully uptake rehabilitation robotic technologies.

D4.2.1 is a result of the activities of Task 4.1 "Legal gaps and enablers for biorobotic devices and allied digital technologies" within Activity 4. Activity 4 aims to remove the roadblocks at regulatory, policy, and socio-economic levels and contribute to the upcoming effort to set up an EU dataspace and the continuously evolving regulatory framework (e.g., Clinical Trials Regulation and Medical Device Regulation, Artificial Intelligence Act, Machinery Products Regulation, Product Liability Directive, civil liability rules, etc.).

This deliverable acquired information from past deliverables of Activity 4, in particular D4.1.1 "Report on the regulatory frameworks analyses #1" and D4.8.1 "Report on the ethical and legal compliance of healthcare and personal care robots #1". In addition to that, D4.2.1 also took into account the insights provided by other Activities, namely Activity 2 "Clinical protocols and trials", Activity 5 "Healthcare robots", Activity 6 "Personal care robots", Activity 8 "Robot bodyware", Activity 9 "Robot intelligence, human-machine interfaces and interaction" and Activity 10 "Biohybrid interfaces and biomaterials".

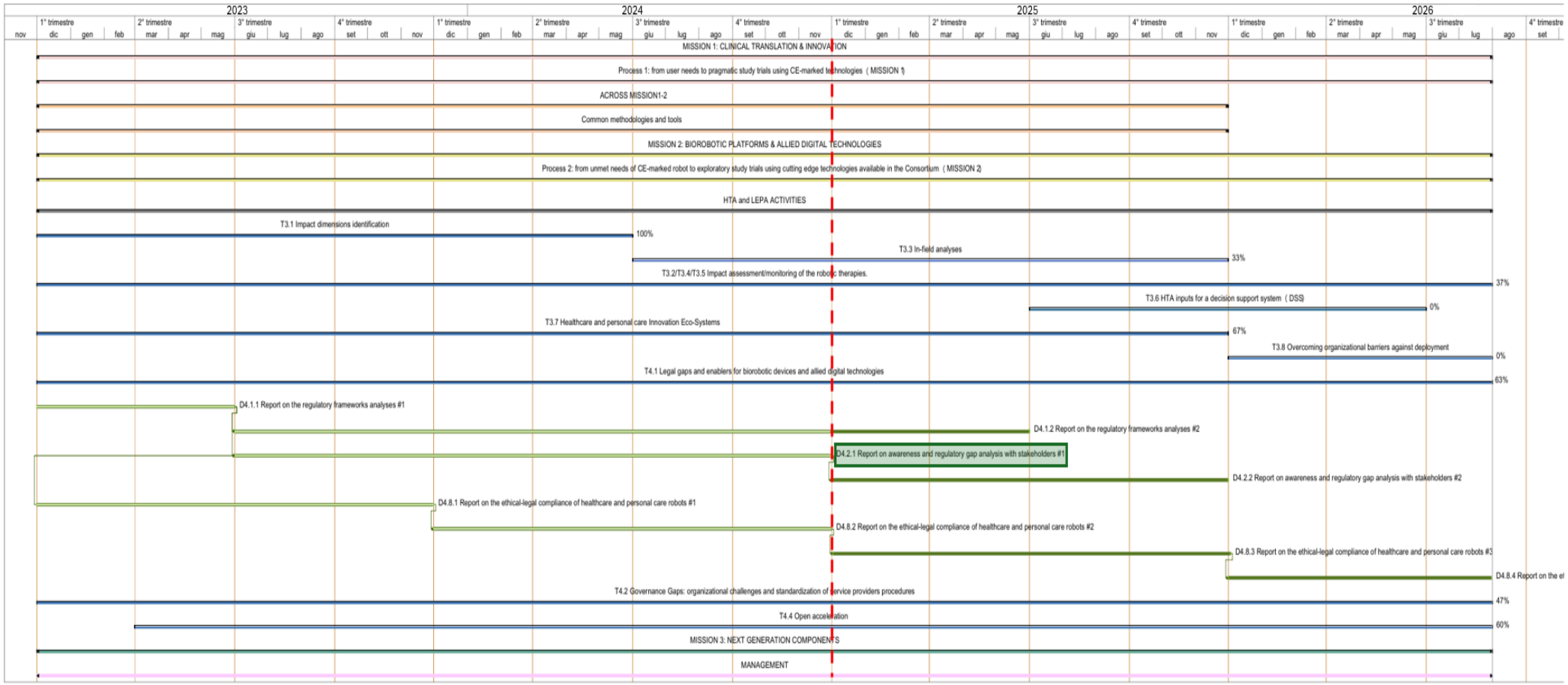
To reach the objectives of this deliverable, Activity 4 selected a range of target stakeholders based on their activities within the project's consortium. The stakeholders came from all three Missions of Fit4MedRob, including consortium companies, R&D labs and university research centres that are developing or testing technologies in the pragmatic or match-making trials of the project. The stakeholders were pinpointed along the development chain according to the Technology Readiness Levels (TRLs) of the solutions they are designing in the Fit4MedRob project.

An anonymous survey of 38 questions was designed and circulated with the aim to analyse in more detail the level of awareness that stakeholders really have about regulatory requirements and to identify any regulatory gaps or issues that have not been found yet in the previous work. The questions were designed in a way to allow the analysis of both the "perceived" awareness of the regulatory framework and the "measured" awareness, meaning the actual knowledge of it. The survey focused specifically on the MDR, but also addressed intersections with other European legislation, such as the GDPR, the Data Act and the proposal for the European Health Data Space (EHDS).

The survey was completed by 30 responders. The findings showed how some topics addressed by the MDR can lead to uncertainty and only partial knowledge of stakeholders – especially the non-industrial ones – sometimes in contrast with a quite optimistic self-perception. This highlighted the need of a training programme and support instruments to ensure a better compliance with the regulations. The results also suggested a correlation between the actual level of knowledge of stakeholders regarding the regulatory landscape and the level of maturity (TRL) of the technologies they usually work on.

This deliverable provides key input for the fine-tuning and enrichment of the web-based platform for Open Acceleration to be initially delivered within Deliverable 4.9.1 and later in D4.9.2, with the aim to become a key support tool for the community of practice of Fit4MedRob and a long-lasting heritage of the project.

The GANTT chart (below) suggests a **completion rate** for this task (4.1) of **63%** and progressing according to schedule.


2023
2024
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MISSION 1: CLINICAL TRANSLATION & INNOVATION
Process 1: from user needs to pragmatic study trials using CE-marked technologies (MISSION 1)
ACROSS MISSION1-2
Common methodologies and tools
MISSION 2: BIOROBOTIC PLATFORMS & ALLIED DIGITAL TECHNOLOGIES
Process 2: from unmet needs of CE-marked robot to exploratory study trials using cutting edge technologies available in the Consortium (MISSION 2)
HTA and LEPA ACTIVITIES
T3.1 Impact dimensions identification
100%
T3.3 In-field analyses
33%
T3.2/T3.4/T3.5 Impact assessment/monitoring of the robotic therapies.
37%
T3.6 HTA inputs for a decision support system (DSS)
0%
T3.7 Healthcare and personal care Innovation Eco-Systems
67%
T3.8 Overcoming organizational barriers against deployment
0%
T4.1 Legal gaps and enablers for biorobotic devices and allied digital technologies
63%
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 stakeholders #2
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 personal care robots #3
D4.8.4 Report on the et
T4.2 Governance Gaps: organizational challenges and standardization of service providers procedures
47%
T4.4 Open acceleration
60%
MISSION 3: NEXT GENERATION COMPONENTS
MANAGEMENT

2 INTRODUCTION

2.1 CONTEXT AND OBJECTIVES

The awareness of regulations concerning the development and commercialisation of medical devices in Europe is a crucial piece of knowledge that stakeholders of the robotic ecosystem must have. Without a proper know-how in this field, they risk missing fundamental factors in designing (research labs), developing (research labs and/or companies), marketing (companies) and even adopting (healthcare service providers) such powerful and innovative technologies.

The present deliverable (D4.2.1) aims at initiating a measurement process of the awareness degree by relevant stakeholders in the robotic rehabilitation ecosystem, with respect to currently applicable major regulations on medical devices. The measurement process will last more than one year, generating two deliverables (the present one, at month 24, and its second instalment, D4.2.2, at month 36).

We chose to focus this deliverable on the major and ineluctable regulation to be applied, that is MDR – Medical Device Regulation (EU 2017/7459) [1], while the next deliverable in the series (D4.2.2) will be mainly devoted to the application of the recently approved – and thus still liable today to steering interpretations – European Artificial Intelligence Act ("AI Act" – EU 2024/168) [2]. We consider these two European regulations as a perhaps not completely exhaustive, but definitively sufficient set of know-how to properly orientate the training support to be provided by Fit4MedRob to the technology providers' community in the field of this project.

2.2 LOGICAL DEPENDENCY WITH THE OTHER DELIVERABLES

The present deliverable has a precise place within the network of information flow in Fit4MedRob.

D4.2.1 is a product of the activities of Task 4.1 "Legal gaps and enablers for biorobotic devices and allied digital technologies", lasting from Q1 to Q15.

Even if this is not immediately evident from the general Gantt of the project, which has a lower level of detail, to work on this deliverable we acquired some information from previous pieces of work in different Activities and even Missions of the project, and the D4.2.1 itself will do the same towards other tasks and deliverable along the whole project timespan.

In particular:

- PREDECESSORS
    - M1, A2 "Clinical protocols and trials", supplied the list of technology providers and associated *commercial devices*, to be tested within the clinical trials foreseen in this action by the clinical centres.
    - M2, A5 "Healthcare robots" and A6 "Personal care robots", supplied the list of technology providers and associated *prototypal devices* that will be transferred along the project timeline to M1 clinical trials.
    - M3, A8 "Robot bodyware", A9 "Robot intelligence, human-machine interfaces and interaction" and A10 "Biohybrid interfaces and biomaterials" supplied the list of research labs and technology providers and associated *prototypal components* that will be made available to the robotic-rehab community if and as soon as they will reach an adequate TRL.
    - M1, A3-4, D4.1.1 "Report on the regulatory frameworks analyses #1" provided a helicopter view of the regulatory body of knowledge involving robotic-assisted rehabilitation technology, on which the present D4.2.1 will check the actual uptake.
    - M1, A3-4, D4.8.1 "Report on the ethical and legal compliance of healthcare and personal care robots #1" provided an initial mapping of the main legal and ethical requirements that the Fit4MedRob partners need to consider while developing a new generation of healthcare and personal care robots.

- SUCCESSORS
    - M1, A3-4, D4.9.1 “Web-based platform for open acceleration #1” and its second instalment D4.9.2 will profit from the results illustrated in D4.2.1 to shape the contents of the web-based platform that will be made available to the entire stakeholders’ community, by giving accurate tips on the gaps of their information in the domain of applicable regulations when designing, developing, registering and using robot-related technology for rehabilitation.
    - M1, A3-4, D4.2.2 will be the second round of the present deliverable and will build on it to extend the assessment of awareness and the gap analysis to more recent regulations, e.g. AI Act, most probably well stabilized at that time and enriched by authoritative interpretations given by high-level groups, as it has been for MDR with MDCG (Medical Device Coordination Group).
    - The present deliverable and its next edition D4.2.2 will provide key insights for the creation of a community of practice felt as meaningful by stakeholders.

3 METHODOLOGY

3.1 CHOICE OF TARGET STAKEHOLDERS

To reach the objectives of this deliverable, Activity 4 selected a range of target stakeholders based on their activities within the project’s consortium. The stakeholders come from all three Missions of Fit4MedRob: Mission 1 on Clinical Translation and Innovation, Mission 2 on Biorobotic Platforms and Allied Digital Technologies and Mission 3 on Next Generation Components. The consortium companies are included, as well as R&D labs and university research centres that are developing or testing technologies in the pragmatic or match-making trials of the project.

The first aspect that was taken into consideration when selecting the stakeholders was that their solutions are at very different stages of maturity and cover the whole pathway to innovation. Their activities in fact range from the prototyping of innovative components in Mission 3 to clinical translation of established technologies in Mission 1 and 2.

Activity 4 used the Technology Readiness Levels (TRLs) in order to pinpoint the level of development of the stakeholders’ solutions. TRLs are an internationally recognised scale used to measure the maturity of an evolving technology, and therefore to help understand whether the solution is ready to be launched on the market as a commercial product. Figure 1 briefly describes the TRLs and shows how the maturity levels reflect on the activities of each of the Missions. Lower TRLs (1-4), for example, are well represented within Mission 3, aimed at laying the foundations of the next generation of health care and personal robots through the prototyping of new structural materials, sensors and batteries, and the development of new interfaces and algorithms for human-robot interaction. Intermediate TRLs (5-8) are reflected in Mission 2, where already available and validated robots are refined, adapted to the target groups’ needs and further tested in match-making clinical trials, as well as complemented with digital infrastructure environments and services. The highest TRL (9) is represented well in Mission 1, where commercial solutions are tested in pragmatic clinical trials not only to test their clinical efficacy with the target groups, but also to measure their cost-effectiveness and economic sustainability.

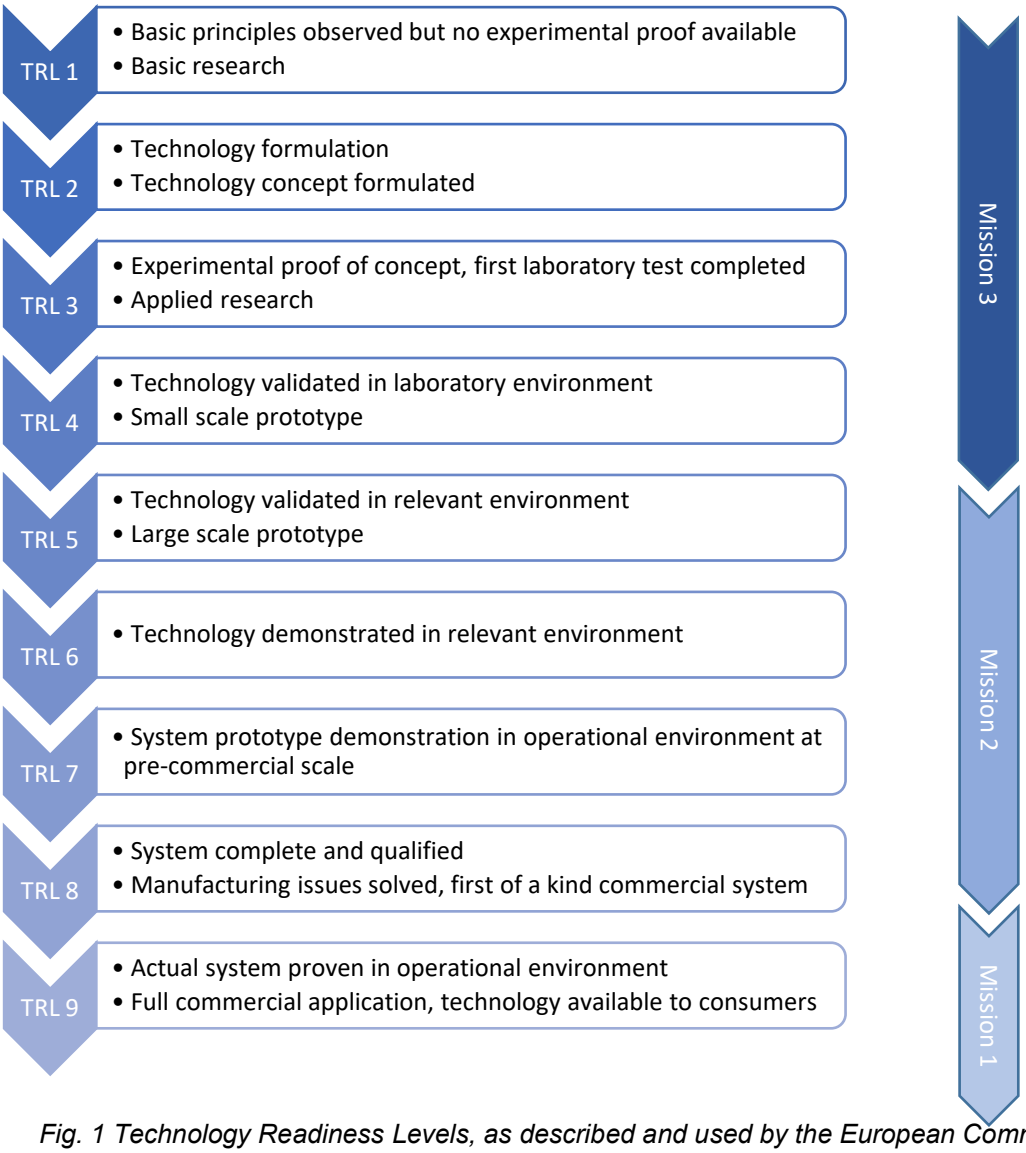

Fig. 1 Technology Readiness Levels, as described and used by the European Commission, and how they are reflected in the three Fit4Med Missions.

The second aspect considered when choosing the stakeholders is that all of them are developing or testing solutions that already are – or are going to be – subject to European regulations that were analysed and presented in previous deliverables of Activity 4. In particular, deliverable D4.1.1. and D4.8.1 are a useful reference, because they both contributed to mapping the relevant legal and ethical framework, presenting the legal acts in a comprehensive way and collecting insights on the legal blocks and needs of members of Fit4MedRob.

The need to be aware of the regulatory obligations and constraints, as well as the more practical details regarding the certification procedures, is still a challenge that all these stakeholders have in common. The "urgency" to be well informed about the regulatory framework of course increases when the technology is at a higher TRL, and therefore closer to be ready to enter the market. However, it is equally important to provide practical information right from the start to stakeholders carrying out activities at low TRLs and to raise awareness among them of the key regulatory requirements that they might need to address in the future is equally important. By including in the activity of this deliverable also actors from Mission 3, they can have a first reality-check about what they know and what they will need to learn in terms of regulations in order to continue developing their solutions up to market access.

3.2 THE SURVEY DESIGN

The basis of the results later discussed in this deliverable is a survey that Activity 4 decided to design and circulate among the target stakeholders. The survey's aim is to analyse at a deeper level of detail the level of awareness that stakeholders really have about regulatory requirements and to identify any regulatory gaps or issues that have not been found yet in the previous work.

The questions of the survey focus specifically on the MDR. The reason for this is that the previous survey carried out in D4.8.1 showed that Fit4MedRob members are particularly interested in compliance with the MDR, which is the regulation – together with a few others like GDPR [3] – that they perceive as most pressing in their everyday work within the project. The survey of deliverable D4.8.1 and the input provided to it were an important basis for the design of this survey, which will add useful insights that will feed into the web-based Open Acceleration platform to be launched in deliverable D4.9.1 and the future (I)URAT centre of excellence.

In addition to the MDR, results of the previous survey in D4.8.1 pointed out that consortium members are sometimes concerned also by issues linked to cybersecurity and personal data. For this reason, the current survey includes questions on topics of regulatory intersections (Fig. 2), namely clinical data (related to GDPR, Data Act [4] and future European Health Data Space [5]) and secondary use of health data (also linked to EHDS), cybersecurity (linked to the future Cyber Resilience Act [6]), and the distinction between a medical destination of use and a wellness or fitness purpose, which is relevant for wearables, sensors and hardware components used together with software devices, and determines the application of the MDR rather than other product safety legislation. These questions are useful to assess whether respondents in the consortium are aware of the connections among different regulations and the need to ensure that all the relevant laws are taken into account when developing a specific product.

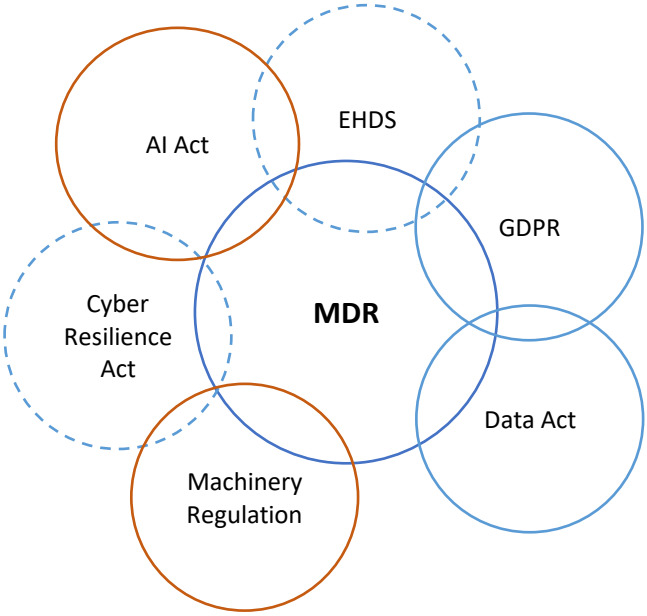

Fig. 2 Intersections among EU regulations that were identified (dotted lines indicate Regulations that are not adopted yet). Intersections in blue were addressed by the survey, while the orange ones will be addressed in the second round of this Deliverable (D4.2.2)

The survey is composed of 38 questions divided into four sections and can be found in the Annex. Section 1 gathers information on the type of stakeholder that is filling the survey (for example whether they are a large company, a SME or an academic institution) and the level of experience they have in R&D in the medtech sector.

Section 2 investigates the perceived awareness of respondents regarding a variety of aspects of the MDR. In this section all questions start with "are you aware that…", because the main aim is to find out whether stakeholders know, or they have at least heard of the topics mentioned or not, and not yet to what extent or at which level of detail they do. In fact, respondents can reply simply with "*yes*", meaning that they have heard of it and think they have an overall good understanding of the topic, "*no*", meaning that they not aware of it and have never heard of

the issue, or "*I am partially aware*", meaning that they have heard something about it and are somewhat aware that this topic is mentioned by the regulations, but would need more information to fully understand it.

The topics that are mentioned in these questions cover very practical information that Activity 4 expects to be particularly useful for the stakeholders' activities within and outside of the project. They range from potential sources of guidance to implement MDR requirements provided by the Medical Device Coordination Group [7,8], to questions about the classification and certification procedures for medical device software, to concrete actions to take during the clinical evaluation of a device. Questions cover also cybersecurity, with links to both MDR and the upcoming Cyber Resilience Act, and the secondary use of health data, specifically as provided by the agreed text of the EHDS that was published at the time of writing the deliverable. These questions were included also based on the results of the survey carried out in D4.8.1, where respondents showed interest in these two topics. In that same survey, less interest was shown for post-market surveillance requirements, probably because respondents are developers of solutions at low or medium TRLs and therefore perceive this stage still quite distant. However, it was deemed useful to learn about their awareness of it as well, to make sure that stakeholders do not overlook this important stage in the assessment of medical devices.

Section 3 addresses the topics raised in Section 2 in a bit more detail, this time with the aim to confirm the level of awareness that was stated previously. Participants are requested to indicate if a statement is true or false, or to select the option(s) that they think are correct. In this Section there are references to other European regulations, both already implemented and upcoming, like the GDPR and the EHDS.

Lastly, Section 4 aims at collecting insights on the experience of stakeholders with MDR and, more generally, the perceptions that they have on the certification process, both in terms of time needed and the main obstacles.

The survey was sent to the target stakeholders via email. The email addressed were collected from the internal database of contacts of the Fit4MedRob consortium. Before circulating the survey, a Legitimate Interest Assessment was carried out and a disclaimer was prepared and then included in the text of the email together with a brief description of the activity and its purpose. The survey was anonymous and did not collect personal data.

Stakeholders were given 2 weeks to fill in the survey. The replies were then collected and analysed. The results are presented and discussed in Chapter 5.

4 RESULTS AND DISCUSSION

4.1 RESULTS OF THE SURVEY

The survey was completed by a total of 30 responders. The program used was Microsoft Forms as it guaranteed the anonymous reception of the participants' replies. Among these, 10 came from the industry (both SMEs and large companies), 10 from healthcare facilities and 10 from the world of research (both academia and RTOs – research and technology organisations).

In order to analyse the findings, the replies were grouped by the topics of questions and by the categories of stakeholders. Then, they were converted into numerical values through the following steps. Each answer to questions about the perceived awareness of stakeholders was given a score based on the declared level of awareness: 0 (not aware), 0.5 (partially aware) and 1 (aware). Each answer to questions verifying the actual knowledge (measured awareness) was given a score obtained by summing 0 for each wrong answer and $1/n$ for each of n correct answers to the question. In this way, also the questions about the measured awareness had a total score between 0 and 1.

If a topic was covered by more than one question in the survey, the scores were obtained by calculating the average of results to the individual questions. The scores for the single topics, regardless of the results of different stakeholders, were obtained by calculating the average of stakeholders' answers to each topic.

The results showed that the level of experience in R&D in the medtech sector, in terms of years of activity and experience of device certification under MDR, are proportional to the perceived awareness of stakeholders, while it doesn't seem to influence the level of coherence between the perception and actual measure of their awareness.

4.1.1 Awareness as perceived by stakeholders

With regards to the perceived awareness covered by questions in section 2 of the survey, a first overview (Figure 3) shows that the industrial component (both SMEs and large companies) believes to have a rather high awareness of regulatory aspects, while the research actors (academia and RTOs) and healthcare providers perceived only a partial awareness.

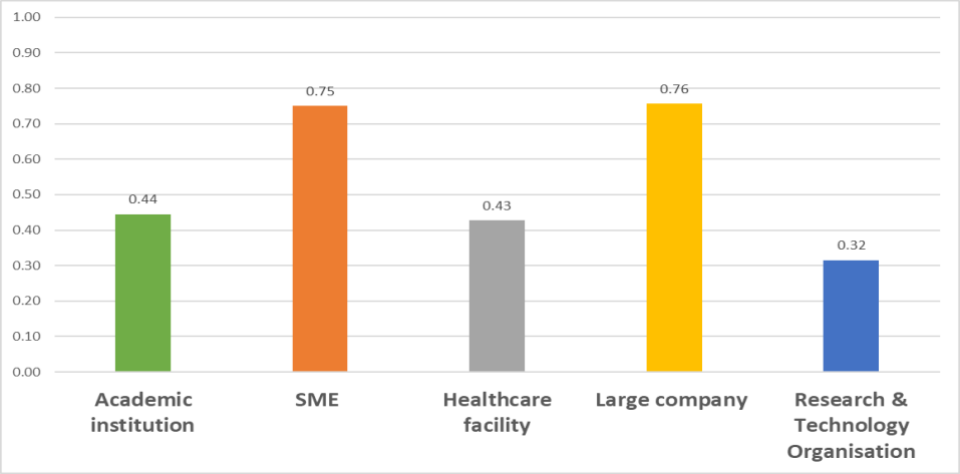

Fig. 3 Perceived awareness by category of stakeholders (average across topics)

A more detailed analysis of the perceived awareness is presented in Figure 4, where the results take into account both the macro-topics and the type of stakeholder. It is interesting to point out that all stakeholders have a rather high perceived awareness on topics related to medical device classification and clinical evaluation, while they all share more uncertainty when it comes to the secondary use of health data. The gap between the awareness perceived by the industry and the uncertainties perceived by research and healthcare actors is again highlighted in topics related to the compliance, cybersecurity and the so-called “in house” devices.

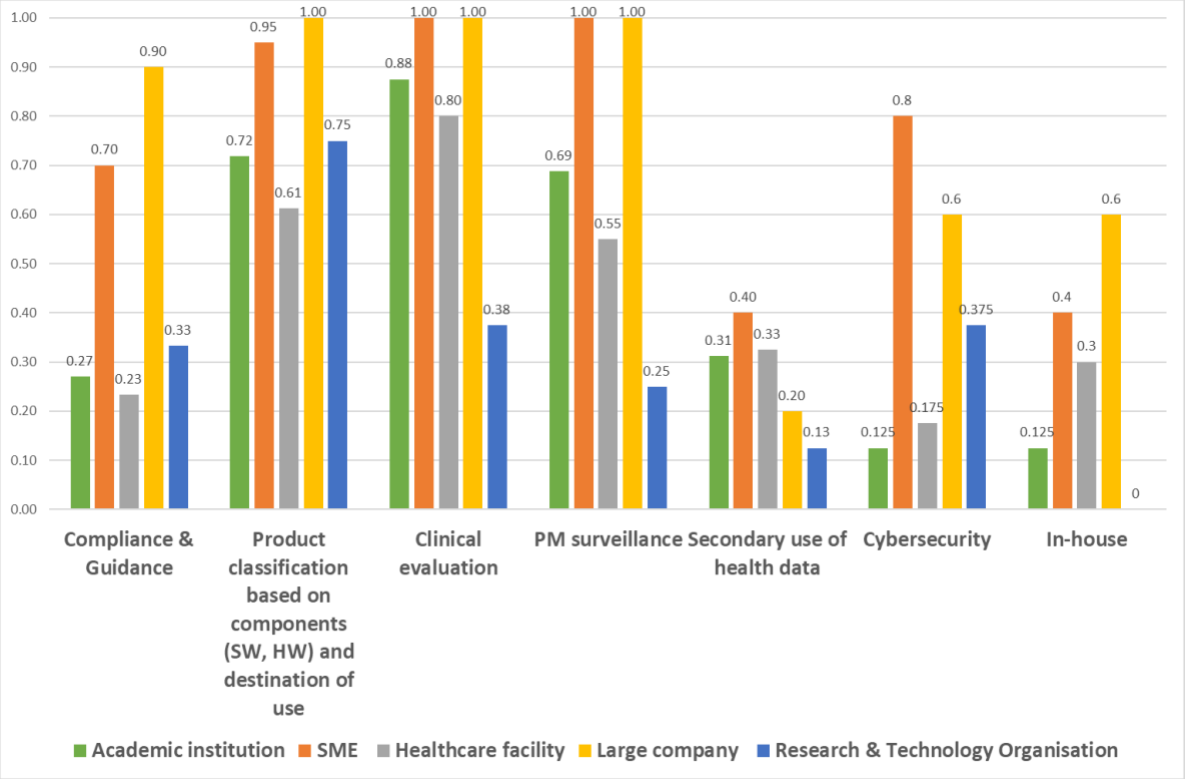

Fig. 4 Perceived awareness by category and topic

4.1.2 Measured awareness

Section 3 of the survey aimed at verifying the real knowledge of stakeholders of the topics on which they had declared their level of perceived awareness in section 2. The results are presented by categories of stakeholders in Figure 5 and by both types of stakeholders and relevant topics for the analysis in Figure 6.

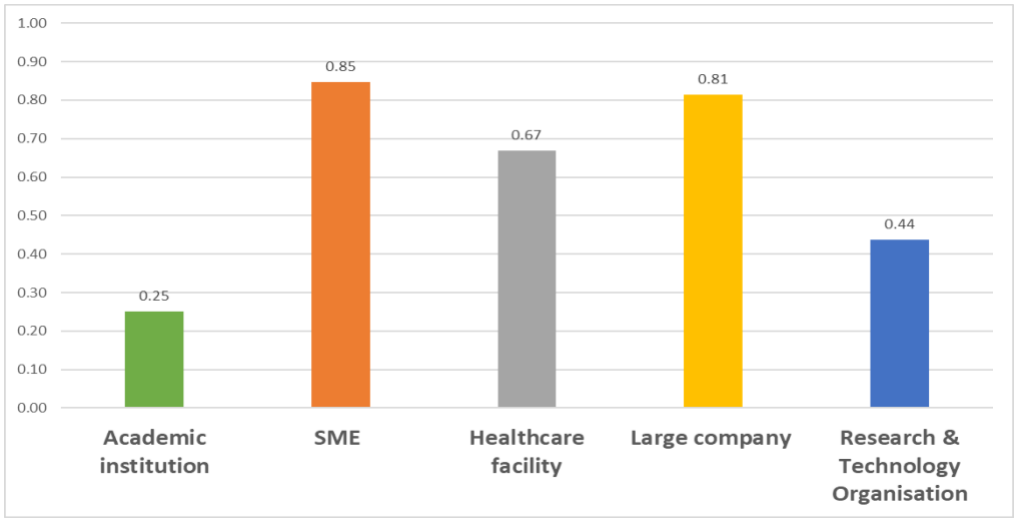

Fig. 5 Measured awareness by category of stakeholders (average across topics)

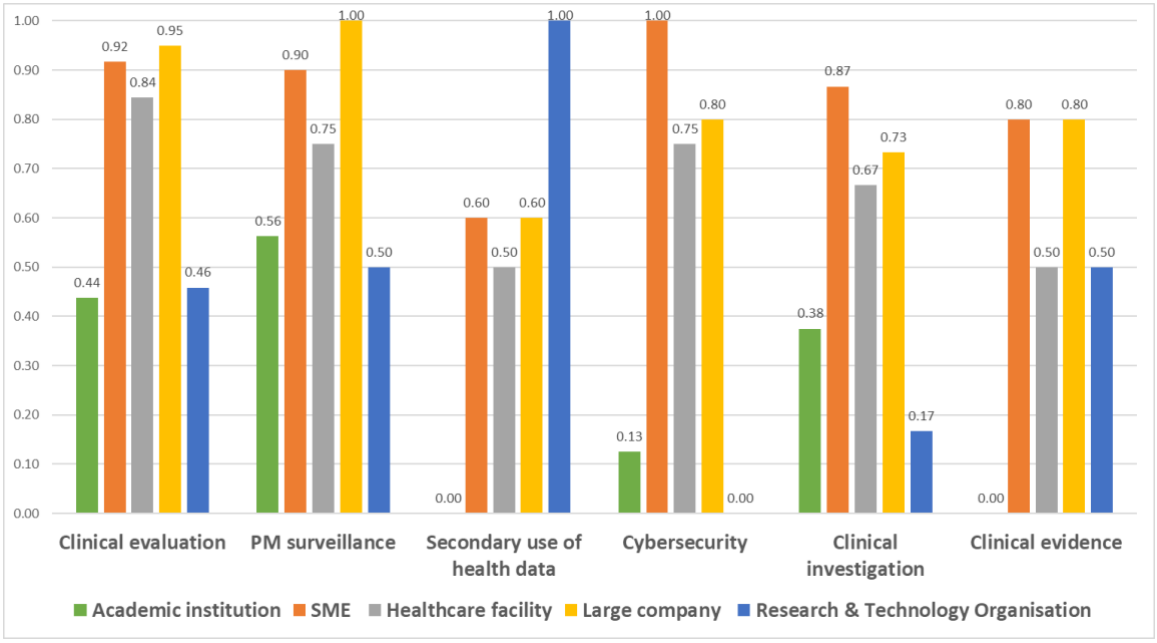

Fig. 6 Measured awareness by category of stakeholders and topics

In order to better highlight the coherence (or lack of) between the perception and the measurement of knowledge, an "overestimation index" was calculated by the difference between perceived awareness and measured awareness. The index is positive in case of overestimation of a responder's knowledge and negative in case of underestimation. Figure 7 presents the overestimation index by typology of stakeholders, which reveals that the industrial component has a higher coherence between self-perception and actual knowledge, while clinicians tend to underestimate their knowledge of the regulatory framework. Within the research component, RTOs tend to slightly underestimate and the academics to slightly overestimate their knowledge.

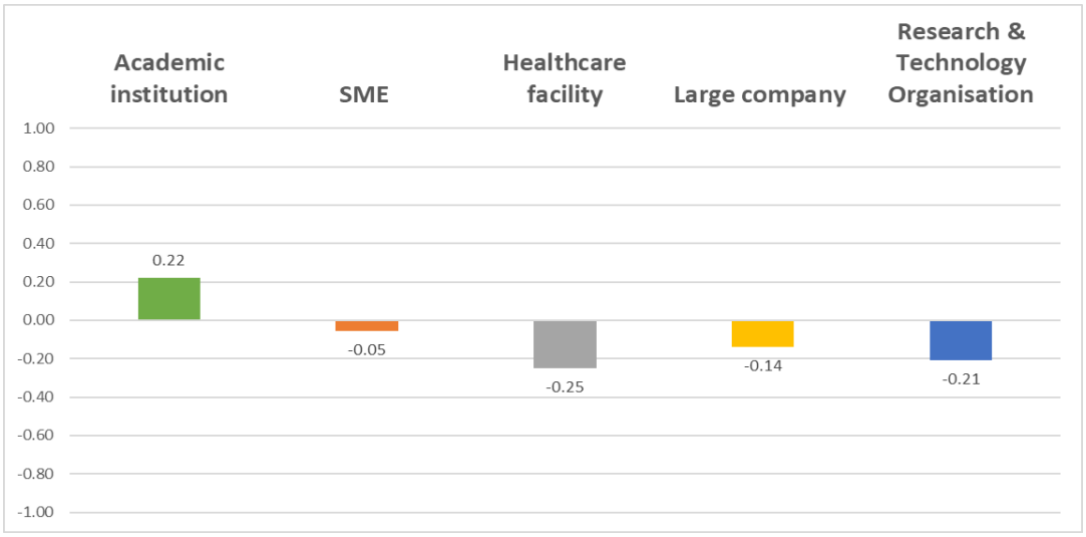

Fig. 7 Overestimation index by category of stakeholders (average across topics)

Figure 8 presents more in the detail the overestimation index by stakeholders and topics. The topics that create more variability in the coherence of stakeholders with self-awareness are cybersecurity and the secondary use of

data, which both require some knowledge of different EU regulations (adopted or in the negotiation process) beside MDR, such as the European Health Data Space Regulation and the Cyber Resilience Act.

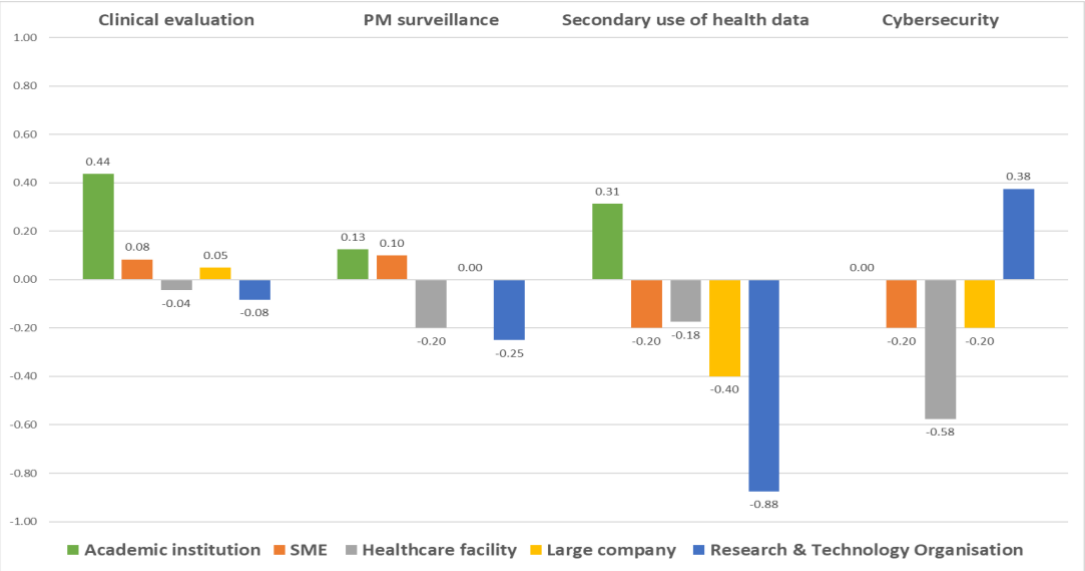

Fig. 8 Overestimation index by category of stakeholders and topics

4.1.3 Perceived barriers in the certification process under MDR

As shown in Figure 9, the main factors that stakeholders see as obstacles to the certification process under MDR relate to the long timeline needed for the process of certification (29%) and the costs (26%), followed closely by the difficulty to prepare the technical documentation (21%) and the relations with notified bodies (20%, of which 11% related to the difficulty to interact and communicate with the notified body and 9% related to the challenge to find the right notified body for the type of device – perhaps correlated to the overall lack of knowledge of the European database of notified bodies NANDO [9], addressed in Q.5 of the survey).

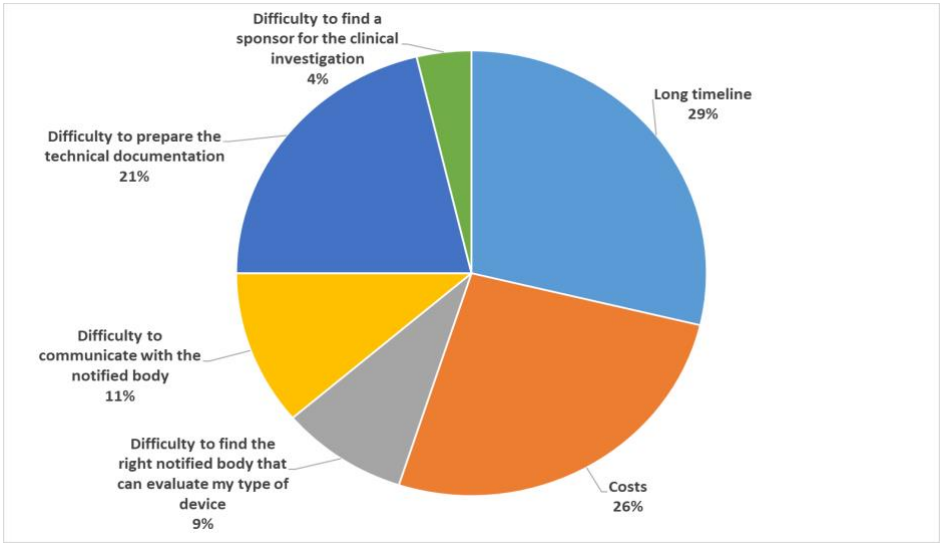

Fig. 9 Main obstacles of the certification process for a manufacturer as perceived by stakeholders

4.2 DISCUSSION

The findings analysed above point out how some topics addressed by the MDR can lead to uncertainty and only partial knowledge of stakeholders – especially the non-industrial ones – sometimes in contrast with a quite optimistic self-perception. This highlights the need of a training programme and support instruments to ensure a better compliance with the regulations. The results also suggest a correlation between the actual level of knowledge of stakeholders regarding the regulatory landscape and the level of maturity (TRL) of the technologies they usually work on, in ascending order academia (low TRLs), RTOs, healthcare providers and industry.

The fact that healthcare providers ranked second only to the industry when it comes to the knowledge of the regulatory framework is reassuring, considering the different roles that they – and especially IRCCS, Scientific Institute for Research, Hospitalization and Healthcare – can play along the innovation pipeline, starting from the ideation stage of new devices to the role of test beds in clinical trials and final users of the solution once it is on the market.

Regarding the topics, as presented in Figure 10, actors have still partial knowledge on cybersecurity (nearly half of them didn't know which are the regulations of reference), clinical investigation (e.g. only half of respondents knew all the conditions to meet to start a clinical investigation of a device that is not CE-marked yet) and clinical evidence (more than half of them didn't know who has the role of defining the level of sufficient clinical evidence to demonstrate conformity of a device).

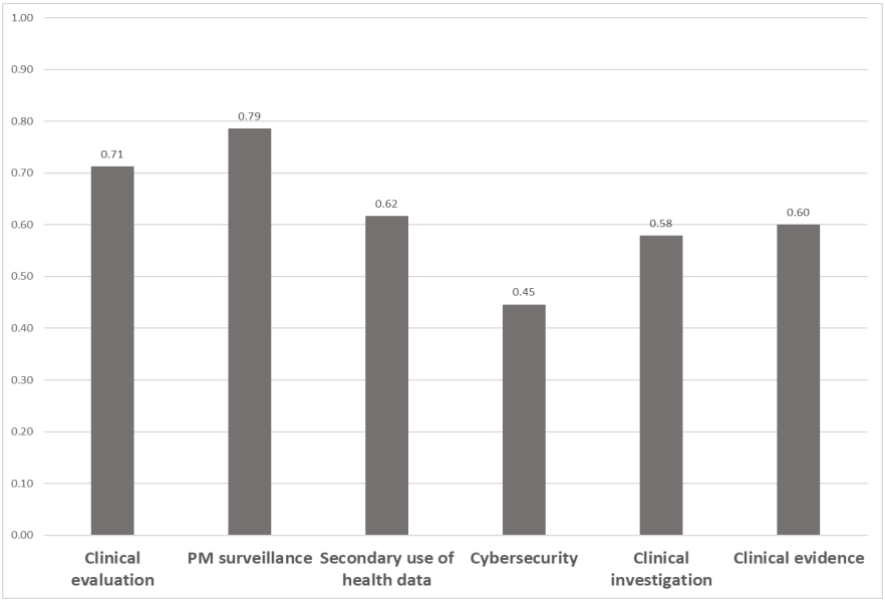

Fig. 10 Measured awareness averaged across category

4.3 TAKE-HOME MESSAGES FOR THE UPCOMING DELIVERABLES

Future training activities organised within the Fit4MedRob consortium should address the topics highlighted above, where knowledge still needs to be consolidated. Furthermore, they should also include aspects where stakeholders initially declared a low level of awareness, or whose awareness was not coherent with their actual knowledge. Two practical examples relate to the sources of materials and guidance on compliance and specific aspects of MDR, like the guidelines published by the MDCG, the future provisions on the secondary use of health data and the specific conditions to be met in case of *in-house* devices.

In conclusion, the output of this deliverable can become a rather solid basis for the design and implementation of both the web-based platform for Open Acceleration that will be delivered within Deliverable 4.9.1 and potential training and information activities, managed by Activity 4 in Mission 1 and open to all Fit4MedRob stakeholders (internal and external), with the aim to become a key support tool for the community of practice of Fit4MedRob and a long-lasting heritage of the project.

5 ANNEX: SURVEY TEXT

Fit4MedRob Survey on awareness and regulatory gaps

Conducted by the Team of Activity 4

Grant n. PNC0000007

* Obbligatoria

Objectives of the survey

This survey will gather insights about the level of awareness that stakeholders in the Fit4MedRob project have about regulatory requirements related to medical devices and identify any regulatory gaps or issues that have not been found yet in the previous work of Activity 4. The results will be presented in Deliverable D4.2.1.
The survey is organised into 4 Sections and focuses mainly on the MDR, however there are a few references to other EU legal acts, both already applicable and upcoming. The survey should take approximately 10 minutes of your time.
We encourage you to answer honestly to help us collect truthful and accurate results.
Thank you for your time and contribution!

Who are you?

1. Where do you work? *

- ◯ Large company
- ◯ SME
- ◯ Start-up
- ◯ Research & Technology Organisation
- ◯ Healthcare facility
- ◯ Academic institution
- ◯ Other

2. How many years of experience do you have on R&D in the **medtech sector**? *

- ◯ less than 2 years
- ◯ between 2 to 5 years
- ◯ between 5 to 10 years
- ◯ more than 10 years
- ◯ Not applicable

General awareness on some aspects of the MDR

The aim of this section is to find out whether you are aware of some contents that are addressed by the MDR or not. Topics include software, cybersecurity, guidance material, clinical evaluation, and a few references to other European regulations. Each question includes a reference to the Article of the MDR addressed, so that after sending the survey you can consult the regulation on that topic, if you are interested.
You don't have to elaborate your answers and provide information on your knowledge, but simply choose one of these 3 options:
Yes = you are well aware of the topic mentioned and you have an overall good understanding of it.
No = you have no awareness of the topic (e.g. because you have never heard of it in your experience)
I am partially aware = you are somewhat aware of the topic, but you would need more information for a full understanding
Your honesty is precious, so don't be afraid to select "No"!

3. **REGULATORY COMPLIANCE:** Are you aware that according to Art. 15 of MDR, the manufacturer should have within their organization at least one person responsible for regulatory compliance, with expertise in the field of medical devices? SMEs are not required to have this person within their organization, but they shall have such person always at their disposal. *

- ◯ Yes
- ◯ No
- ◯ I am partially aware

4. **GUIDANCE**: Are you aware that there is a Medical Devices Coordination Group (MDCG), established by Art. 103 of MDR, that has the job to develop guidance for manufacturers and other actors to support the implementation of the MDR? *

- ◯ Yes
- ◯ No
- ◯ I am partially aware

5. **GUIDANCE**: Are you aware that there is a Commission database of notified bodies called NANDO, where you can identify notified bodies in each country and according to the type of devices they assess? (NANDO Database and Art. 43 MDR) *

- ◯ Yes
- ◯ No
- ◯ I am partially aware

6. **SOFTWARE**: Are you aware that the MDR includes specific classification rules for software, which fall under different classes of risks according to their destination of use? (see Annex VIII of MDR, Rule 11) *

- ◯ Yes
- ◯ No
- ◯ I am partially aware

7. **SOFTWARE**: Are you aware that according to these classification rules, most software fall under class IIa and therefore their certification process needs the involvement of a notified body? (Annex VIII, Rule 11) *

- ◯ Yes
- ◯ No
- ◯ I am partially aware

8. **SOFTWARE:** Are you aware that if a medical device software is intended to work in combination with hardware components (e.g. sensors, wearables) that are **not** CE-marked as medical devices, the manufacturer becomes responsible also for the safety and performance of the hardware parts and must describe all configurations in the technical documentation? (MDCG 2023-4 "Guidance on MDSW intended to work in combination with hardware or hardware components") *

- ◯ Yes
- ◯ No
- ◯ I am partially aware

9. **WEARABLES**: Are you aware that, as the manufacturer of a wearable, the destination of use you choose can change the regulatory framework to follow? If the destination of use is medical, the wearable falls under MDR, while if the destination of use is wellness or fitness, it will not fall under MDR (see Art. 2 of MDR) *

- ◯ Yes
- ◯ No
- ◯ I am partially aware

10. **CYBERSECURITY**: Do you know that the MDCG provides guidance on how to fulfil essential requirements needed for conformity with regard to cybersecurity? (MDCG 2019-16 rev.1 "Guidance on Cybersecurity for medical devices") *

- ◯ Yes
- ◯ No
- ◯ I am partially aware

11. **CYBERSECURITY**: The proposed Cyber Resilience Act will introduce a framework of cybersecurity requirements for products with digital elements available on the market. Are you aware that it will apply to, among others, personal wearable products that do **not** fall under MDR but have a health monitoring purpose (such as tracking)? Instead, if the wearable is a medical device, the Cyber Resilience Act will not apply because cybersecurity is already addressed by MDR. (cfr. TA-9-2024-0130 Art. 2 and Annex III) *

- ◯ Yes
- ◯ No
- ◯ I am partially aware

12. **CLINICAL EVALUATION:** Are you aware that the clinical evaluation is a life-cycle process that includes also the post-market stage? *

- ◯ Yes
- ◯ No
- ◯ I am partially aware

13. **CLINICAL EVALUATION:** Are you aware that in the clinical evaluation the safety, performance and clinical benefits of the device must be demonstrated with clinical data? *

- ◯ Yes
- ◯ No
- ◯ I am partially aware

14. **SECONDARY USE OF HEALTH DATA:** Are you aware that the purposes for secondary use of health data allowed by the upcoming European Health Data Space (EHDS) will include scientific research in health, HTA, development and innovation activities for products, and the training, testing and evaluation of algorithms in medical devices, AI systems and digital health apps? (cfr. Art. 34 of agreed text) *

- ◯ Yes
- ◯ No
- ◯ I am partially aware

15. **SECONDARY USE OF HEALTH DATA:** Are you aware that the EHDS will require health data holders to make available health data for secondary use purposes, including personal electronic health data automatically generated through medical devices, data from wellness applications, from clinical trials and from electronic health records? (Art. 33 of agreed text) *

- ◯ Yes
- ◯ No
- ◯ I am partially aware

16. **POST-MARKET SURVEILLANCE**: Are you aware that the post-market surveillance includes the post-market clinical follow up, which is a continuous process that updates the clinical evaluation? *

- ◯ Yes
- ◯ No
- ◯ I am partially aware

17. **POST-MARKET SURVEILLANCE:** Are you aware that manufacturers of devices in class IIa, class IIb and class III have to prepare a periodic safety update report (PSUR) summarising the analyses of the post-market surveillance plan, and that this report has to be updated at least annually for class IIb and III devices and at least every 2 years for class IIa devices? *

- ◯ Yes
- ◯ No
- ◯ I am partially aware

18. **IN-HOUSE DEVICES:** Are you aware that in Art. 5 of MDR it is stated that the provisions of MDR don't apply to the so called *in-house* devices (devices manufactured and used only within a health institution established in the EU), provided that they respect the general safety and performance requirements and meet a series of specific conditions (e.g. not transferring these devices to another legal entity)? *

- ◯ Yes
- ◯ No
- ◯ I am partially aware

Analysis of the awareness on specific contents of MDR

This section addresses the topics covered by previous questions in a bit more detail, this time with the aim to "confirm" and consolidate the level of awareness that you stated previously. There are true-or-false questions, or questions where you have to select the option(s) that you think are correct. In this Section there are a few references to other European regulations, both already implemented and upcoming, like the GDPR and the EHDS.

19. **CLINICAL INVESTIGATION AND EVALUATION:** Do you know what is the difference between a clinical evaluation and a clinical investigation? Select the **2** correct definitions (Art. 2 paragraphs 44 and 45 of MDR): *

- [ ] Clinical investigation: any systematic investigation involving one or more human subjects, undertaken to assess the safety or performance of a device
- [ ] Clinical evaluation: a systematic and planned process to continuously generate, collect, analyse and assess the clinical data pertaining to a device in order to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer
- [ ] Clinical investigation: a systematic and planned process to continuously generate, collect, analyse and assess the clinical data pertaining to a device in order to verify the safety and performance, including clinical benefits, of the device when used as intended by the manufacturer
- [ ] Clinical evaluation: any systematic investigation involving one or more human subjects, undertaken to assess the safety or performance of a device
- [ ] I don't know

20. **CLINICAL EVALUATION**: in the clinical evaluation of a device, the MDR provides a possibility to use clinical data related to an *equivalent* device. What aspects should be considered by the manufacturer to demonstrate equivalence? There is **only 1** correct answer (Annex XIV, 3) *

- ◯ Only technical characteristics
- ◯ Only clinical characteristics
- ◯ Technical, biological and clinical characteristics
- ◯ I don't know

21. **CLINICAL DATA:** clinical data are information concerning safety or performance that is generated from the use of a device and is sourced from: select the **4** correct options (Art. 2 paragraph 48) *

- ☐ Clinical investigations of your device
- ☐ Scientific literature on any device that is a bit similar to yours
- ☐ Clinical investigations reported in scientific literature of a device that is *equivalent* to your device
- ☐ Publications in the scientific literature on other clinical experience of your device or an *equivalent* device
- ☐ Non-published reports on your device
- ☐ Clinically relevant information collected during the post-market clinical follow-up
- ☐ Informal reviews on your device coming from professionals
- ☐ I don't know

22. **CLINICAL INVESTIGATION:** the main objectives of clinical investigations done during a clinical evaluation are to verify the safety and performance of a device under normal conditions of use and the clinical benefits and collateral effects. *

- ◯ True
- ◯ False
- ◯ I don't know

23. **CLINICAL INVESTIGATION:** clinical investigations are not useful to gather missing clinical data necessary to demonstrate conformity. *

- ◯ True
- ◯ False
- ◯ I don't know

24. **CLINICAL INVESTIGATION**: A clinical investigation on a device that is **not yet** certified as a medical device can start only if... There is **only 1** correct answer (Art. 62 of MDR) *

- ◯ It has only an authorisation by the Member State(s) in which the clinical investigation is to be conducted
- ◯ The ethics committee has issued a positive opinion on the clinical investigation
- ◯ A sponsor was found and it is established in the EU
- ◯ All of the above conditions
- ◯ I don't know

25. **POST-MARKET CLINICAL FOLLOW-UP**: the data gathered in the post-market clinical follow-up is useful to confirm safety and performance and to identify new risks or incorrect use of the device. *

- ◯ True
- ◯ False
- ◯ I don't know

26. **POST-MARKET CLINICAL INVESTIGATION:** a post-market clinical investigation is an investigation conducted on a device that is already CE-marked with the aim to further assess it. *

- ◯ True
- ◯ False
- ◯ I don't know

27. **DATA AND LEGISLATION**: if your medical device collects data (both personal and non-personal data) which further EU legislative acts will you need to consider? There is **only 1** correct answer. *

- ◯ GDPR
- ◯ Data Act, applicable from 2025
- ◯ Future European Health Data Space (EHDS)
- ◯ All of the above
- ◯ I don't know

28. **CLINICAL EVIDENCE**: who has to specify and justify what is a sufficient level of clinical evidence needed in the clinical evaluation? There **only 1** correct answer. *

- ◯ The manufacturer of the device
- ◯ The European Commission
- ◯ The notified body
- ◯ The Ministry of Health
- ◯ I don't know

29. **CYBERSECURITY**: where can you look for information about the cybersecurity level that your medical device should have? There is **only 1** correct answer. *

- ◯ In the MDR and the guidance of MDCG, in state of the art standards (e.g. ISO), and in the future Cybersecurity Act
- ◯ In the Cyber Resilience Act
- ◯ In the ISO standards
- ◯ I don't know

Your experience with MDR

This is the last Section of the survey. The aim is to collect insights on your experience with MDR and, more generally, the perceptions that you have on the certification process, both in terms of time needed and the main obstacles.

30. Have you ever certified a medical device under MDR? *

- ◯ Yes
- ◯ Not yet, but I plan to do it in the future
- ◯ I am right now in a certification process for one or more of my devices
- ◯ No

31. In your opinion, how long does the process take to certify a device with a notified body? *

- ◯ Less than 6 months
- ◯ Approximately 1 year
- ◯ 1 to 2 years
- ◯ Around 2 years or more

32. How much do you find the MDR difficult to navigate? *

- ◯ Very easy
- ◯ Overall easy
- ◯ Overall difficult
- ◯ Very difficult

33. Based on your experience (or on your perception), which are the main obstacles and difficulties of the certification process for a manufacturer? You can select more than one option and add others. *

- ☐ Long timeline
- ☐ Costs
- ☐ Difficulty to communicate with the notified body
- ☐ Difficulty to find the right notified body that can evaluate my type of device
- ☐ Difficulty to prepare the technical documentation
- ☐ Difficulty to find a sponsor for the clinical investigation
- ☐ Altro

34. Have you ever used any of the guidance documents provided by the MDCG? *

- ◯ Yes
- ◯ No

35. If yes, on which topics?

36. Do you think there are gaps that are not adequately covered by the MDR regarding safety and requirements of medical devices? *

List of Abbreviations

AI	Artificial Intelligence
EHDS	European Health Data Space
GDPR	General Data Protection Regulation
IRCCS	Scientific Institute for Research, Hospitalization and Healthcare
MDCG	Medical Device Coordination Group
MDR	Medical Device Regulation
RTO	Research and Technology Organisation
SME	Small and Medium Enterprise
TRL	Technology Readiness Level

References

[1] European Parliament, Council of the European Union, "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 (Medical Device Regulation) (Text with EEA relevance)", OJ L 117, 5.5.2017.

[2] European Parliament, Council of the European Union, "Regulation (EU) 2024/1689 of the European Parliament and of the Council of 13 June 2024 laying down harmonised rules on artificial intelligence and amending Regulations (EC) No 300/2008, (EU) No 167/2013, (EU) No 168/2013, (EU) 2018/858, (EU) 2018/1139 and (EU) 2019/2144 and Directives 2014/90/EU, (EU) 2016/797 and (EU) 2020/1828 (Artificial Intelligence Act) (Text with EEA relevance)", OJ L, 2024/1689.

[3] European Parliament, Council of the European Union, "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.

[4] European Parliament, Council of the European Union, “Regulation (EU) 2023/2854 of the European Parliament and of the Council of 13 December 2023 on harmonised rules on fair access to and use of data and amending Regulation (EU) 2017/2394 and Directive (EU) 2020/1828 (Data Act) (Text with EEA relevance)”, OJ L, 2023/2854, 22.12.2023.
[5] Council of the European Union, “Proposal for a Regulation on the European Health Data Space - Analysis of the final compromise text with a view to agreement”, 2024.
[6] European Commission, “Proposal for a Regulation of the European Parliament and of the Council on horizontal cybersecurity requirements for products with digital elements and amending Regulation (EU) 2019/1020” (Cyber Resilience Act), COM/2022/454 final, 2022.
[7] [Medical Device Coordination Group, “MDCG 2023-4 Medical Device Software (MDSW) – Hardware combinations Guidance on MDSW intended to work in combination with hardware or hardware components”, 2023.
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