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D1.1.3

PLAN FOR DATA ANALYSIS AND FIRST RESULTS OF SURVEYS

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Website: www.fit4medrob.it

Editors: Irene Giovanna Aprile (FDG), Silvana Quaglini (UNIPV), Giuseppina Sgandurra (FSM)

PIs: Irene Giovanna Aprile (FDG), Maria Cristina Mauro (FDG), Francesca Falchini (FDG), Marco Germanotta (FDG), Alessio Fasano (FDG), Silvana Quaglini (UNIPV), Enea Parimbelli (UNIPV), Giovanna Nicora (UNIPV), Giuseppina Sgandurra (FSM), Elena Beani (FSM), Emanuele Gruppioni (INAIL), Francesca Buganè (INAIL)

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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	

HISTORY OF CHANGES

VERSION	SUBMISSION DATE	CHANGES
1.0	15/05/2024	First version
1.1	20/09/2024	Executive summary modified following reviewers' suggestions.

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1 EXECUTIVE SUMMARY

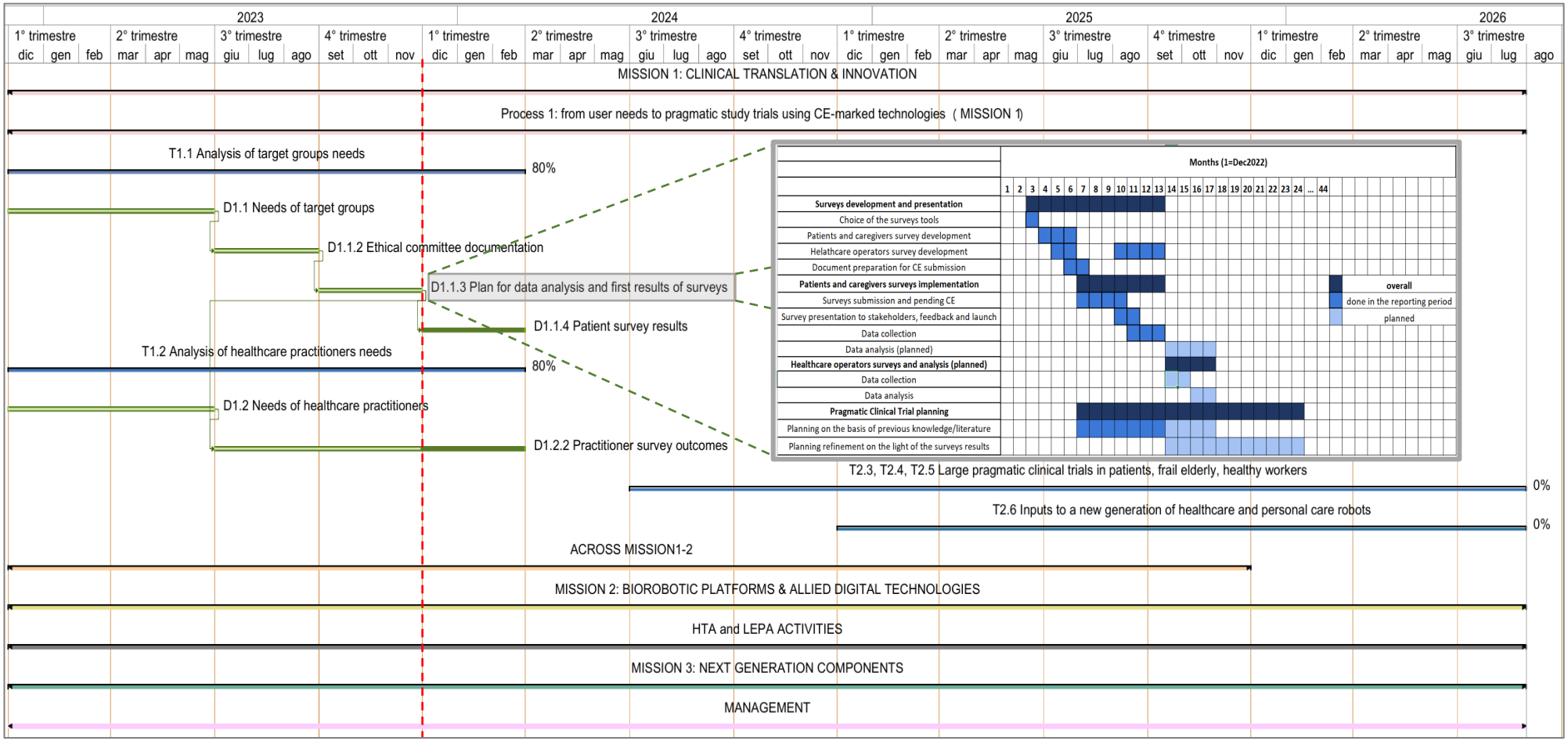
This deliverable describes the status of the surveys for the target users' needs as of mid-December 2023. Moreover, it describes how the collected results will be exploited to guide the planning of the upcoming clinical trials. Three surveys, addressing patient populations were launched on October 18th, 2023, and the final deadline is December 31st, 2023. In particular, the targeted groups were (i) caregivers of children, (ii) adult patients, and (iii) caregivers of adult patients who were not able to answer autonomously. Surveys addressing healthcare operators' needs will be launched in January 2024. Surveys dissemination, initially foreseen during the first half of 2023, was delayed due to the finalization of all the necessary legal steps and Ethical Committees' approval, which took longer than expected. Once the approval was obtained, dissemination has been promptly promoted by the Fit4MedRob clinical centers, patients' associations, and scientific societies.

As of mid-December 2023, 750 respondents were collected: 55% from adult patients, 31% from children's caregivers and the remaining from caregivers of adult patients. Most respondents were from specific Italian regions, in particular Lombardia, Lazio, and Toscana. Familiarity with technology varies in the different subgroups. Most children were reported to have a good relationship with technology (86.2%). The same percentage for autonomous adults drops to 67% and 60% for non-autonomous adults. Most caregivers are female (70%) and 63% dedicate more than 5 days in a week to take care of the patient. Note that these results are preliminary, as the survey will be closed at the end of December.

The document is organized as follows. In the Introduction Section, we briefly explained the rationale behind the survey development and dissemination. In the Section "Ad Interim status of the surveys", we report the preliminary analysis of the collected respondents for each of the three disseminated surveys. Section 5 ("Model for patients' survey data analysis") and Section 6 ("Model for healthcare operators survey data analysis") outline the research questions driving the analysis of the surveys, and how they might impact clinical trial development.

In the following page is represented the GANTT chart showing the activities related to target population surveys with respect to Fit4MedRob project timeline. We included the activities related to clinical trials planning because, as mentioned above, this planning will be informed by the survey results. Activities ending/starting in the middle of the same month appear in parallel. The gap in the "Healthcare operator survey development" row is due to the need for alignment with the presentation of the patients' surveys to the scientific societies and patients' associations, which required a longer time due to the Ethical Committee procedures.

While the needs collection took longer than expected, we believe this should not significantly alter the progress of the Initiative. The surveys outcomes, necessary for pragmatic clinical trials planning only (Process 1) and **not for the exploratory trials** (Process 2), will be available by Q5 (month 15). Moreover, while waiting for the surveys' results, working groups dedicated to specific diseases were organised. This is essential to reach the (time-consuming) consensus across partners about the different issues (organisational and scientific) involved in a clinical trial planning. Notably, the census performed at the beginning of the Initiative, about the specific expertise available in the clinical centres of the Consortium, is playing an important role to accelerate the debate within the specific-disease working groups.


2023
2024
2025
2026
1° trimestre dic gen feb
2° trimestre mar apr mag
3° trimestre giu lug ago
4° trimestre set ott nov
MISSION 1: CLINICAL TRANSLATION & INNOVATION
Process 1: from user needs to pragmatic study trials using CE-marked technologies (MISSION 1)
T1.1 Analysis of target groups needs
80%
D1.1 Needs of target groups
D1.1.2 Ethical committee documentation
D1.1.3 Plan for data analysis and first results of surveys
D1.1.4 Patient survey results
T1.2 Analysis of healthcare practitioners needs
80%
D1.2 Needs of healthcare practitioners
D1.2.2 Practitioner survey outcomes
Months (1=Dec2022)
Surveys development and presentation
Choice of the surveys tools
Patients and caregivers survey development
Helathcare operators survey development
Document preparation for CE submission
Patients and caregivers surveys implementation
Surveys submission and pending CE
Survey presentation to stakeholders, feedback and launch
Data collection
Data analysis (planned)
Healthcare operators surveys and analysis (planned)
Data collection
Data analysis
Pragmatic Clinical Trial planning
Planning on the basis of previous knowledge/literature
Planning refinement on the light of the surveys results
overall
done in the reporting period
planned
T2.3, T2.4, T2.5 Large pragmatic clinical trials in patients, frail elderly, healthy workers
0%
T2.6 Inputs to a new generation of healthcare and personal care robots
0%
ACROSS MISSION1-2
MISSION 2: BIOROBOTIC PLATFORMS & ALLIED DIGITAL TECHNOLOGIES
HTA and LEPA ACTIVITIES
MISSION 3: NEXT GENERATION COMPONENTS
MANAGEMENT

2 INTRODUCTION

In this deliverable, we first present the status of the surveys as observed on December 15th, 2023. These surveys were launched on October 18th, 2023, with a deadline of December 31st, 2023, to gather information on patients and their caregivers needs. Additionally, we outline the planned analysis of the collected data after the survey closure to extract insights into patients' needs and discuss how the results could guide the next steps of the Initiative, specifically clinical trial planning.

Considering that not all the patients are able/allowed to answer a survey, based on their age or disability level, Mission 1 launched three different surveys to be answered by different target populations:

1. caregivers of children;
2. collaborative adults (i.e., adult patients who are able to answer the survey autonomously);
3. caregivers of adult patients (i.e., for adult patients who are not able to answer autonomously).

As outlined in Deliverable D1.1 (Needs of Target Groups), the three surveys were designed to assess patients' needs based on their functional abilities rather than specific diseases. Accordingly, the surveys include distinct sections with questions covering the following functional domains: upper limb function, mobility, cognition, communication, posture, and self-care. These domains were selected in alignment with the International Classification of Functioning, Disability, and Health (ICF), a framework developed by the World Health Organization in 2001.

Surveys are anonymous and have been disseminated using different channels, including mailing lists of the patients available to the Fit4MedRob clinical centers, patients' associations, and the publication of the links in the centers' websites.

With respect to the surveys for healthcare practitioners, two different surveys were developed, one for healthcare professionals who carry out rehabilitation sessions, and one for prosthetists and orthotics. Dissemination of these surveys is planned for January 2024. The final structure of the surveys, including all the questions, is available in the appendix of the revised version of deliverable D1.2 (Needs of Healthcare Practitioners).

3 AD-INTERIM STATUS OF THE SURVEYS

In this section, for each survey, we will report the following preliminary results:

- the number of respondents until 15/12/2023 (included);
- the pathology;
- the age range;
- the gender distribution;
- the Region where respondents receive the rehabilitation treatment;
- the level of confidence with technology in general.

Those data correspond to the information collected in the general part of the questionnaires.

3.1 CAREGIVERS OF CHILDREN SURVEY

Up until December 15th, 2023, there were 234 respondents to the survey dedicated to children. Among them, 196 (84%) respondents learned about the survey directly or by email from their rehabilitation centers, 33 (14%) discovered it through social media, and 5 (2%) found out about it thanks to patient associations.

Figure 1 shows the evolution of the participation across the weeks.

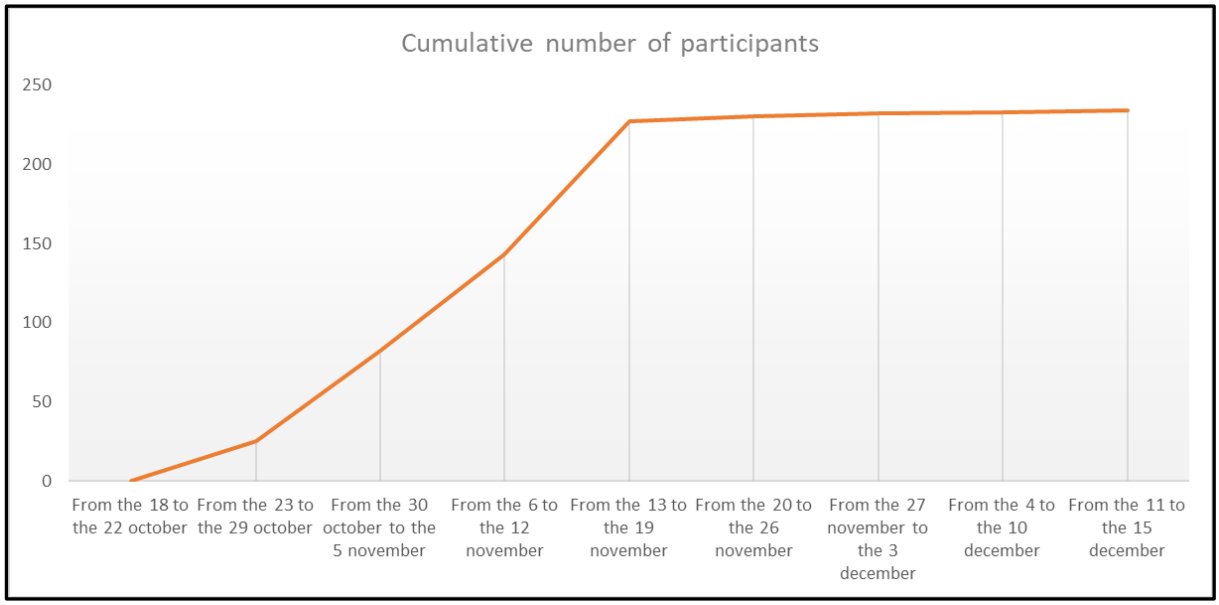


Fig. 1 Cumulative number of respondents (children's caregivers) since the launch of the survey

About gender distribution, 80 (34%) children are females and 154 males (66%). The distribution of age range is reported in Table 1:

Table 1 – Age distribution of the children

	Number	Percentage
0-5 years old	81	34,6%
6-13 years old	132	56,4%
14-18 years old	21	9%

The most prevalent diseases were Cerebral Palsy (111 respondents, 47.4%), genetic diseases (34 respondents, 14.5%) and autism (28 respondents, 11.9%) (see Table 2).

Table 2 - Clinical condition of the children

	Number	Percentage
Cerebral Palsy	111	47.4%
Genetic diseases	34	14.5%
Autism	28	11.9%
Other	26	11.0%
Psychomotor/cognitive disorders	10	4.3%

Neuropathy	8	3.4%
Learning Disease	6	2.6%
Attention-Deficit/Hyperactivity Disorder	4	1.7%
Oncology surgery sequelae	3	1.3%
Acquired cerebral lesion	2	0.85%
Myelolesion	2	0.85%

Ninety-seven respondents (41%) are receiving treatment within the National Health System while also attending rehabilitative sessions in private centers; 62 (26%) are attending day-hospital sessions. Twenty-one (9%) are not undergoing any form of rehabilitation.

Regarding the Italian Region where the patients were treated, the distribution is shown in Table 3:

Table 3 – Geographic distribution of the children

	Number	Percentage
Lombardia	78	33.3%
Toscana	32	13.7%
Veneto	26	11.1%
Liguria	18	7.7%
Puglia	15	6.4%
Friuli Venezia Giulia	12	5.1%
Campania	11	4.7%
Sicilia	10	4.3%
Piemonte	8	3.4%
Calabria	5	2.1%
Sardegna	4	1.7%
Emilia Romagna	4	1.7%
Marche	4	1.7%
Abruzzo	3	1.3%
Lazio	2	0.8%
Umbria	1	0.4%
Trentino Alto Adige	1	0.4%

Most of the respondents believe that their children have a good enough relationship with technology in general:

Table 4 – Relationship of children with technology, as reported by their caregivers

	Number	Percentage
Totally	28	11.9%
A lot	86	36.7%
Enough	88	37.6%
A little	28	11.9%
Not at all	4	1.7%

3.2 ADULT PATIENTS SURVEY

Until December 15th, 414 individuals responded to the survey. Regarding how the participants heard about the questionnaire, 365 (88.2%) received it directly by email from their rehabilitation centers, 26 (6.3%) learned about it from patient associations, and 23 (5.6%) discovered the survey through social media. Figure 2 shows the evolution of participation across the weeks.

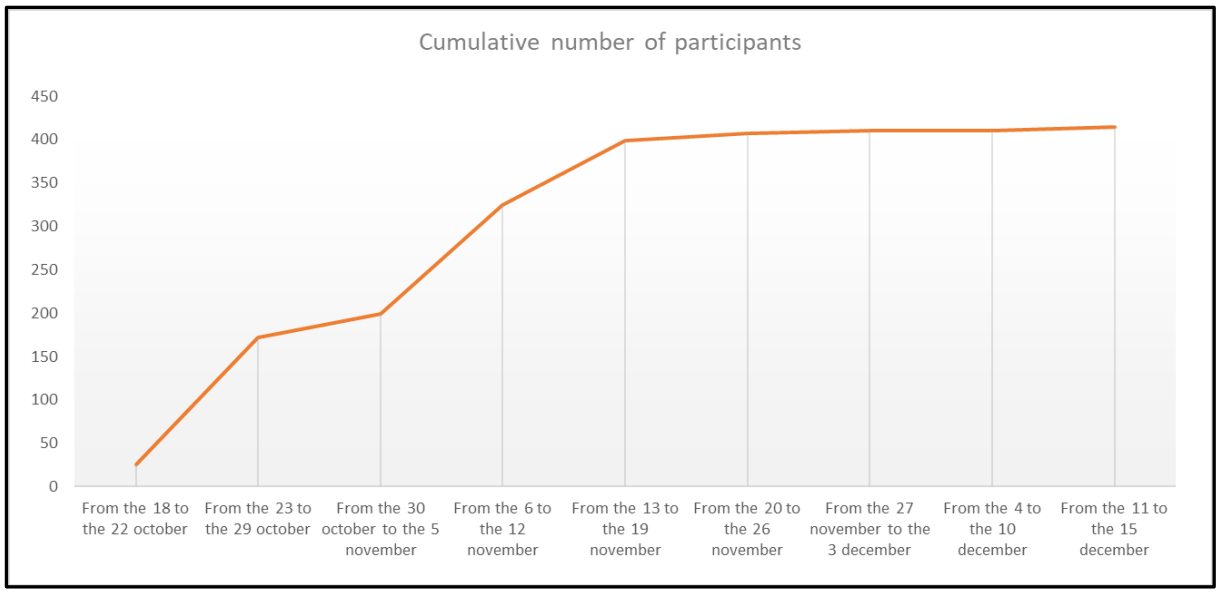


Fig. 2 Cumulative number of respondents (adult patients) since the launch of the survey

About gender distribution, 209 respondents were male (50.5%), 203 were female (49%) and 2 persons preferred not to declare it (0.5%).

About the age of participants, Table 5 reports the range distribution:

Table 5 – Range distribution of collaborative adults

Range	Number	Percentage
18-35 years-old	35	8.4%
36-54 years-old	110	26.6%

55-64 years-old	92	22.2%
65-74 years-old	94	22.7%
75-84 years-old	74	17.9%
>85 years-old	9	2.2%

The most common disease was stroke (94, 22.1%), followed by multiple sclerosis (45, 10.6%), orthopedic diseases (41, 9.6%), neuropathy (32, 7.5%), and Parkinson's (31, 7.2%). Additionally, 60 individuals (14.1% of the respondents) reported suffering from diseases not covered by Fit4MedRob Initiative.

With respect to the clinical setting, the greatest percentage of respondents (172, 38.9%) were inpatients. Ninety-eight (22%) were on a day hospital regimen or were outpatients, 79 (17.9%) were treated within the National Health System but were also undergoing rehabilitation sessions in private centers, and 68 (15.4%) were not undergoing any rehabilitation treatment at all. Additionally, 24 (5.4%) were not treated within the National Health System but conducted all their rehabilitative sessions privately.

About the Region where the participants were treated, the distribution is reported in Table 6.

Table 6 - Geographic distribution of the collaborative adults

Region	Number	Percentage
Lombardia	162	39.1%
Lazio	111	26.8%
Campania	27	6.5%
Toscana	25	6.0%
Veneto	15	3.6%
Piemonte	14	3.4%
Basilicata	12	2.9%
Liguria	10	2.4%
Sicilia	10	2.4%
Friuli Venezia Giulia	8	1.9%
Puglia	6	1.4%
Emilia Romagna	4	0.9%
Abruzzo	3	0.7%
Calabria	2	0.5%
Sardegna	2	0.5%

Marche	2	0.5%
Trentino Alto Adige	1	0.2%

The reported relationship with technology in general is showed in Table 7.

Table 7 - Relationship of collaborative adults with technology

	Number	Percentage
Enough	169	40.8%
A little	113	27.3%
Not at all	27	6.5%
A lot	77	18.6%
Totally	28	6.8%

3.3 CAREGIVERS OF ADULT PATIENTS SURVEY

This survey aimed at collecting information about adult patients who are not able to answer autonomously. By the middle of December, 102 caregivers of adult patients answered. Most of them are female (70%).

Figure3 shows the evolution of the participation across the weeks.

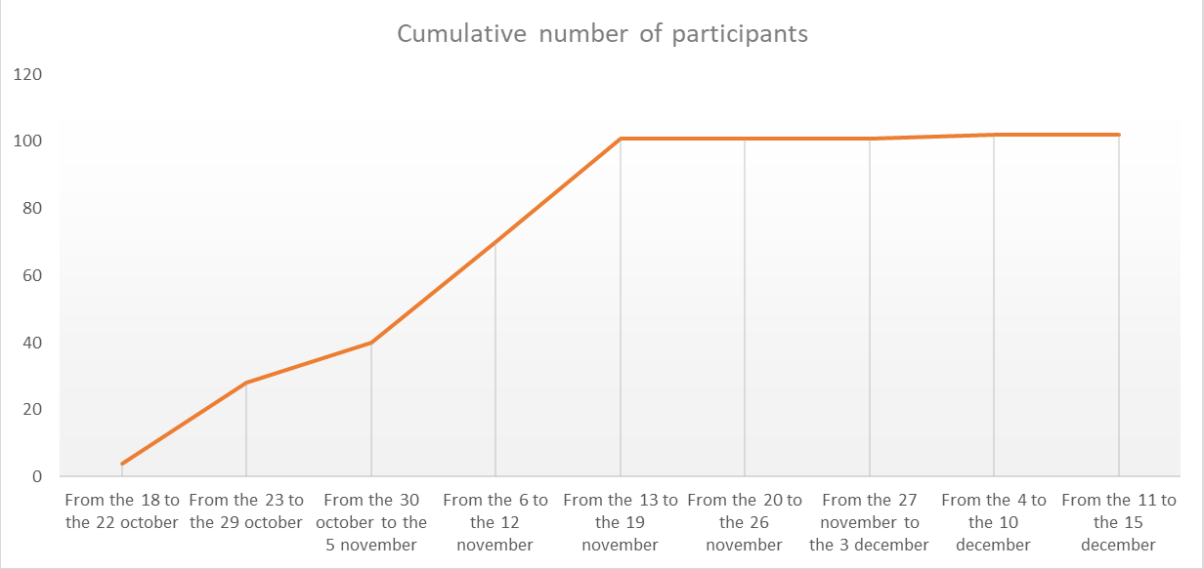


Fig. 3 Cumulative number of respondents (caregivers of adul patients) since the launch of the survey

Most of them knew about the survey from their rehabilitation center, as reported in Table 8.

Table 8 – Sources of Information for Caregivers of Adult Patients Regarding the Survey

	Number	Percentage
Directly or via e-mail from the clinical center to which the patient belongs	79	77.4%
Patient association or scientific society	15	14.7%
Joined voluntarily after looking at post on social channels	8	7.8%

The age distribution of adult patients' caregivers is reported in Table 9.

Table 9 – Age range of adult patients' caregivers

	Number	Percentage
18-24 years	2	1.9%
25-34 years	2	1.9%
35-44 years	11	10.8%
45- 54 years	37	36.3%
55-64 years	28	27.5%
65-74 years	13	12.7%
75-84 years	9	8.8%

The caregivers' level of education is reported in Table 10.

Table 10 – Education level of adult patients' caregivers

	Number	Percentage
High school	48	47.1%
Master	39	38.2%
Middle School	11	10.8%
PhD	4	3.9%

Most of caregivers provide assistance at least 5 days a week (see Table 11), and all of them are patients' relatives.

Table 11 – Level of assistance provided by adult patients' caregivers

	Number	Percentage
Main (at least 5 days a week)	64	62.7%
Other (< 5 days a week)	38	37.2%

The following tables reports statistics about the assisted patients, as reported by their caregivers. Most of them are female, as reported in Table 12.

Table 12 – Adult patients' gender

	Number	Percentage
Female	59	57.8%
Male	42	41.2%
I prefer not to declare	1	0.9%

The patients' age range is reported in Table 13.

Table 13 – Adult patients' age range

	Number	Percentage
18-24 years	14	13.7%
25-34 years	5	4.9%
35-44 years	8	7.8%
45- 54 years	7	6.9%
55-64 years	13	12.7%
65-74 years	14	13.7%
75-84 years	31	30.4%
>85 years	10	9.8%

They are distributed in the Italian Regions as reported in Table 14.

Table 14 - Geographic distribution of adult patients

	Number	Percentage
Lombardia	46	45.1%
Lazio	11	10.8%
Campania	8	7.8%
Veneto	7	6.9%
Piemonte	5	4.9%
Toscana	5	4.9%
Basilicata	4	3.9%
Puglia	3	2.9%
Marche	3	2.9%
Liguria	3	2.9%
Calabria	2	1.9%
Friuli Venezia Giulia	2	1.9%
Emilia Romagna	2	1.9%
Sardegna	1	0.9%

The patients' relationship with technology in general, as reported by their caregivers, is shown in Table 15.

Table 15 - Relationship of adult patients with technology

	Number	Percentage
Not at all	24	23.5%
A little	28	27.4%
Enough	31	30.4%
A lot	13	12.7%
Totally	6	5.9%

4 MODEL FOR PATIENTS' SURVEY DATA ANALYSIS

The preparation of the surveys for collecting patients' needs has been guided by a set of research questions, primarily aimed at planning the Fit4MedRob pragmatic clinical trials. In the following sections, the different research questions are elaborated upon, and potential applications of survey results are highlighted in bold.

4.1 THE OVERALL PICTURE OF THE PATIENT'S SAMPLE

For both children and adult patients, it is important to obtain an overall clinical picture of those accessing Italian rehabilitation services. Additionally, understanding the treatment settings, the type of rehabilitation (conventional

or robotic) and whether patients were treated within the National Health System or privately is crucial. The resulting snapshot may vary across patient groups based on geographical origin, gender, and age range. **These results could potentially foster collaborations among various centers to conduct multicenter clinical trials**

4.2 DISEASE-SPECIFIC INQUIRIES TO DRIVE THE CLINICAL TRIALS DESIGN

For each disease of interest (as stated above), we will analyze relevant information, including the latency (i.e., the time elapsed since the acute event), the treatment setting (both traditional and robotic rehabilitation), and the level of autonomy in the considered functional domains.

The research questions, which will be replicated for different classes of patients, are the following:

1. How many domains are simultaneously affected?
2. Are the patients simultaneously working on different domains within their traditional or robotics rehabilitation? **If the results will indicate that several patients are affected across multiple domains, trials exploring the use of multiple devices addressing different functional domains simultaneously could be promoted.**
3. Among those patients not currently treated with rehabilitation technology, how many of them would like to engage in robotics rehabilitation or learn more about it? **The answer could provide insight into the potential willingness of patients to participate in clinical studies and, consequently, the dropout rate that may be encountered during the trials.**
4. What are the functional domains that patients/caregivers perceive as the most important to be addressed? For example, is the priority for stroke patients addressing motor or cognitive disabilities? These results should also be stratified by latency. E.g. **if more patients report cognitive problems in the mid to long term compared to the short term, trials considering telerehabilitation for home patients could be suggested.**
5. What are the costs associated with the treatment setting, whether within the National Health System or private and the prognosis of the patient? If the survey indicates that costs pose a problem for patients or specific patient categories, we could consider designing **trials with a more precise cost assessment to understand the potential impact of robotic rehabilitation on financial issues.**

4.3 IMPLEMENTATION OF THE PIPELINE FOR DATA ANALYSIS

The complete set of survey responses will be stored in tab-delimited files, which will be analyzed using commonly used statistical tools, including custom-made Python and R scripts, or higher-level software for data analysis such as Tableau, a proprietary dashboard provided by Salesforce (https://www.tableau.com/). In particular, Tableau will be use to obtain a global view of the data and general statistics interactively. The user-friendly interface of Tableau will also enable individual researchers to perform specific statistics of interest at any time.

Python and/or R scripts will be developed with three objectives:

1. they will allow us to establish an automatic pipeline for data analysis that can be run with follow-up data in the future;
2. we will be able to develop statistical models (e.g., regression models) to better understand relationships and correlations between variables;
3. since they are open-source tools, they will allow us to share the pipeline with anyone interested in, thus promoting open science.

5 MODEL FOR HEALTHCARE OPERATORS' SURVEY DATA ANALYSIS

The results of the surveys will be considered, as well as those in the previous section, to drive the future activities of the Initiative. In the following, we provide some examples on how the various sections of the survey may be used to draw actionable insights for future activities (as previously, reported in bold).

5.1 OVERALL PICTURE OF THE HEALTHCARE PROFESSIONALS IN REHABILITATION

The first question of our survey asks for the name of the rehabilitative center where the healthcare professional is working. Stratifying the data analysis across centers may suggest systematic differences among hospitals in different Regions, thus highlighting Regional-specific needs. For instance, it may highlight **the heterogenous usage of robotics rehabilitative technologies**. As a matter of fact, we already performed a census of robotic devices available in the clinical center of the Consortium. However, the availability of a device does not guarantee the regular use of the device itself. This discrepancy can be detected by comparing the two results.

Additionally, the survey is addressed to healthcare professional across Italy, not only to those within the Consortium. **By comparing the average usage of robotic devices among healthcare professionals outside the Initiative, with the average usage within the Initiative**, we may quantify any difference between them.

Demographic data, such as gender and age class, could identify **specific barriers to the use of robotic technologies, due to physical constraints**, e.g., robots are heavy to manipulate.

These results can also be stratified across the different types of healthcare professionals (i.e., physiotherapists, physicians, nurses, etc) and/or places of work (i.e., rehabilitative centers or others), and/or disease of interest, in order to understand if **they perceive different needs**. **These findings can guide specific actions tailored to the professionals**. For instance, some groups may undergo **additional training** to bridge gaps. If we face lack of use for particular diseases, we could **suggest actions to the relevant scientific societies**. We could stratify the place of work further distinguishing home care rehabilitation from hospital rehabilitation, and detect which are the **specific needs for home-based settings**. This will be really useful as the Initiative foresees some pragmatic trials that consider the whole patient pathway, from the subacute phase to the long-term home-based rehabilitation.

The perception of robotics devices for rehabilitation will be also stratified across the age range of the patients treated by the healthcare professional, to acknowledge **possible shortcomings in robots for pediatric or elderly rehabilitation**.

Specifically, we aim to address the following research questions:

- RQ1: what is the current landscape of robotics-assisted rehabilitation in Italy?
- RQ2: what are the attitudes of HCPs towards robotic devices in rehabilitation?
- RQ3: what are the HCPs' needs and the barriers to the spread of robotic rehabilitation?
- RQ4: are there differences in attitudes among different HCP groups? HCPs can be stratified according to different characteristics, including (i) gender, (ii) age, (iii) experience, (iv) professional category

5.2 DEVICE-SPECIFIC INQUIRIES

For each device, we can **quantify the spreading of use**. Different barriers can be perceived for the different devices, and the results can be used to design pragmatic trials and/or the development of new solutions, as those reported below.

- Lack of space: this information can be used **to inform centers about this specific need in order to participate in multicenter clinical trials;**
- Lack of scientific literature: this finding can guide the implementation of **new clinical trials** to generate more reliable data about the device;
- Lack of robustness: this finding can suggest the **need for adaptation and updating** of existing devices;
- Lack of time to set-up the device before the rehabilitation session: this information could be **useful for healthcare policymakers** to adjust some regulations about the maximum duration of therapy sessions, taking into account this specific need for robotics rehabilitation.