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

FIT4MEDROB

D1.1 REV

NEEDS OF TARGET GROUPS

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

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Editors: I.G. Aprile (IRCCS Fondazione Don Carlo Gnocchi Onlus), S. Quaglini (Università degli Studi di Pavia), G. Sgandurra (IRCCS Fondazione Stella Maris)

PIs: I.G. Aprile, M.C. Mauro, F. Falchini, M. Germanotta; A. Fasano (IRCCS Fondazione Don Carlo Gnocchi Onlus); S. Quaglini, E. Parimbelli (Università degli Studi di Pavia), G. Sgandurra, E. Beani (IRCCS Fondazione Stella Maris), E. Gruppioni, F. Buganè (Istituto Nazionale Assicurazione Infortuni sul Lavoro - INAIL), G. Comandè, G. Turchetti (Scuola Superiore Sant'Anna di Pisa)

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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
v1	20/05/2023	
v2	15/05/2024	The deliverable underwent a thorough revision in line with the suggestions provided by the reviewers. The structure was significantly modified to enhance clarity, while the actions undertaken were more rigorously justified in alignment with the scopes of the Initiative.

TABLE OF CONTENTS

1 EXECUTIVE SUMMARY

Fit for Medical Robotics (Fit4MedRob) aims at overcoming existing barriers hindering the seamless integration of robotic and digital technologies within the field of rehabilitation and personal care of people with reduced or absent motor, sensory, or cognitive functions. For this purpose, Mission 1 of Fit4MedRob has as its fundamental goal to lead extensive, in terms of number of patients and/or duration, multicentric, pragmatic clinical trials using healthcare or personal care robots available on the market, as well as exploratory trials involving the robotic devices and digital tools developed by the Consortium within Mission 2. The findings from these trials will inform clinical practice, help evaluate the sustainability of those technologies, guide the development of future interventions, and ultimately improve the quality of life for individuals with clinical conditions targeted by the Initiative.

To design and implement effective interventions, it is fundamental to understand the diverse requirements of target populations, across various clinical conditions. The needs of individuals with motor, sensory, or cognitive impairments are indeed highly diverse. Factors like the specific pathology, its severity, and the age range (childhood to elderly) significantly influence these needs. Matching these diverse needs with appropriate technology, and appropriate technology-based treatment, can improve the clinical outcome. Furthermore, the current generation of robots and allied technologies may not fully meet the expectations of healthcare practitioners (rehabilitation practitioners as physicians, physical therapists, occupational therapists, prosthetists, nurses, etc.), preventing their penetration into clinical practice. For instance, sophisticated robots are difficult to use, as they are designed without enough attention to usability, or simply hospitals lack adequate and up-to-date information technology systems.

For all these reasons, the development of surveys aimed at understanding the needs of various target groups, including patients with neurological diseases, amputations, or oncological diseases, frail individuals and workers, as well as healthcare practitioners was imperative. The insights gained from these surveys, i.e., the identification and analysis of these needs, would have a pivotal role in informing the planning of pragmatic as well as explorative trials. Therefore, as shown in Figure 1, Mission 1 is marked by a timeline of activities that begins with the assessment of users' needs and progresses with the design of clinical trials using innovative methodologies based on Health Technology Assessments (HTA).

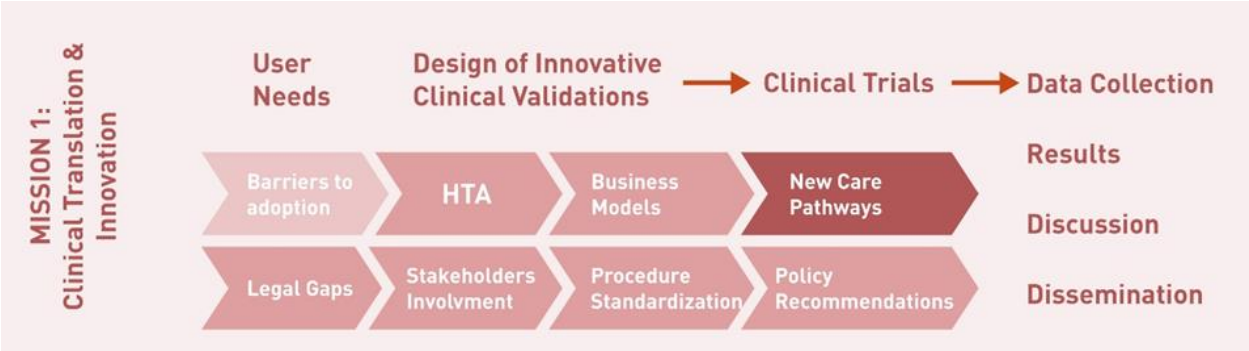

Figure 1 – Activity timeline of Mission 1.

In the first six months of the Initiative, two sets of preparatory activities have been conducted:

(i) a census of available devices, performed trials, and current scientific production of the Fit4MedRob Consortium, allowing us to gain an understanding of the overall scenario in which the clinical studies would have been conducted, and (ii) the development of dedicated surveys assessing the needs of users (both patients and practitioners). The latter activity was preceded by a systematic review conducted on scientific literature regarding the available tools to assess patients' and healthcare practitioners' experiences and perceptions on robotics in rehabilitation, laying the groundwork for survey development.

In this revised version of the deliverable D1.1, we present:

1) an overview of the consortium through the above-mentioned census, in particular:

- inventorying commercial healthcare robots and allied technologies available within the Fit4MedRob Consortium to facilitate the planning of multicentric pragmatic trials;
- identifying expertise (i.e., recent clinical trials and scientific production) within the Consortium regarding robotic rehabilitation for patients with the targeted clinical conditions, essential for identifying expert groups responsible for trial planning;

2) the results of the literature review preparatory to the surveys development;

3) the development of the surveys aimed at collecting the needs of patients (adults and pediatric patients).

The survey targeting healthcare practitioners' needs will be detailed in the revised version of the deliverable D1.2.

2 CENSUS OF DEVICES, CLINICAL TRIALS, AND SCIENTIFIC PRODUCTION

2.1 OVERVIEW OF THE CONSORTIUM CLINICAL PARTNERS

In order to get a clear overview of all clinical partners belonging to the Fit4MedRob Consortium, three different censuses have been designed and conducted:

1) inventorying of commercial healthcare robots and allied technologies available within the Fit4MedRob Consortium;
2) identification of clinical trials concerning the aim of the Initiative that are ongoing or have been conducted within the last 5 years;
3) identification of scientific publications concerning the scope of the Initiative produced in the last 5 years.

The first census aimed at listing the devices or related technologies readily available for the first clinical trials of the Initiative. This endeavor serves as groundwork for orchestrating multicentric pragmatic trials, facilitating the recognition of centers already equipped with similar technologies, including specific devices or categories of devices tailored for treating particular functions such as balance and mobility.

The second and third censuses aimed at detecting the level of expertise of each center about the treatment of diseases targeted by the Initiative: Post-Stroke, Multiple Sclerosis, Traumatic Brain Injuries, Cerebral Palsy, Mild Cognitive Impairment, Parkinson's disease, Spinal Cord Injuries, Polyneuropathies, Amyotrophic Lateral Sclerosis, Muscular dystrophies, Amputees, Oncological patients with limb impairments. The examination of clinical trials and scholarly publications generated recently by clinical groups associated with the Consortium provided insights into the collective scientific proficiency in robotic rehabilitation among Consortium affiliates. This step was crucial in identifying expert groups tasked with devising pragmatic trial plans for the target populations within the Initiative. Leveraging past expertise will play a pivotal role in formulating study protocols, particularly in defining primary and secondary outcomes and endpoints for individual trials.

The tool used for the implementation of the censuses is illustrated in the following section.

2.2 METHODS

2.2.1 KoboToolbox

Among the many tools available to perform online censuses, our choice was *KoboToolbox* (https://www.kobotoolbox.org/) because of its worldwide diffusion, flexibility, and powerfulness. On the website, it is defined as "the free & open-source data collection standard", and its reliability lies in the fact that it is used by several national and international organizations, particularly humanitarian ones, e.g., the United Nations High Commissioner for Refugees and Médecins Sans Frontières.

KoboToolbox supports over 25 types of quantitative or qualitative question types, as well as implementing skip logic to improve user experience (by shortening the questionnaire and hiding not-applicable questions) and data validation rules to increase the quality of collected data, which is useful for the further statistical analyses.

The language chosen for census completion and implementation was Italian. The majority of the questions were closed-ended, including multiple-choice, drop-down, and checkbox options. When appropriate, the "Other" option was included at the end of the list, allowing the user to enter free text when the pre-defined answers were insufficient. Some logic has been implemented to skip parts of the questionnaire if not pertinent according to previous answers. When numerical values were required as an answer (e.g., age of patients, square meters required for the device setting), logic was also implemented to check for abnormal values.

2.2.2 Census of Devices

As mentioned above, the first census proposed to the Fit4MedRob clinical centers, shown in Figure 2, was devoted to acquiring information about the devices currently available for immediate use in clinical studies. Question items have been meticulously chosen in order to get alignment of partners participating in future clinical trials. The census, built in Italian, was structured into 4 main sections as follows:

a) Registry
    - clinical center,
    - device name,
    - responder email;
b) Device information
    - rehabilitative/assistive or both,
    - manufacturer,
    - certification level,
    - risk class according to the EU Medical Device Regulation 2017/745,
    - cost range (known or estimated);
c) Medical features
    - body part addressed,
    - usage destination (as per manufacturer manual),
    - intended future usage destination,
    - target population (adult/children or both),
    - pathologies on which the device has been tested and on which it will be tested,
    - instrumental measurements the device can provide;
d) Features useful to assess study feasibility
    - number of available devices within the center,
    - personnel assistance required to carry out the rehabilitation sessions,
    - setup time and overall rehabilitative session time,
    - occupied space,
    - usability at the patient's bed, wheelchair, and home.

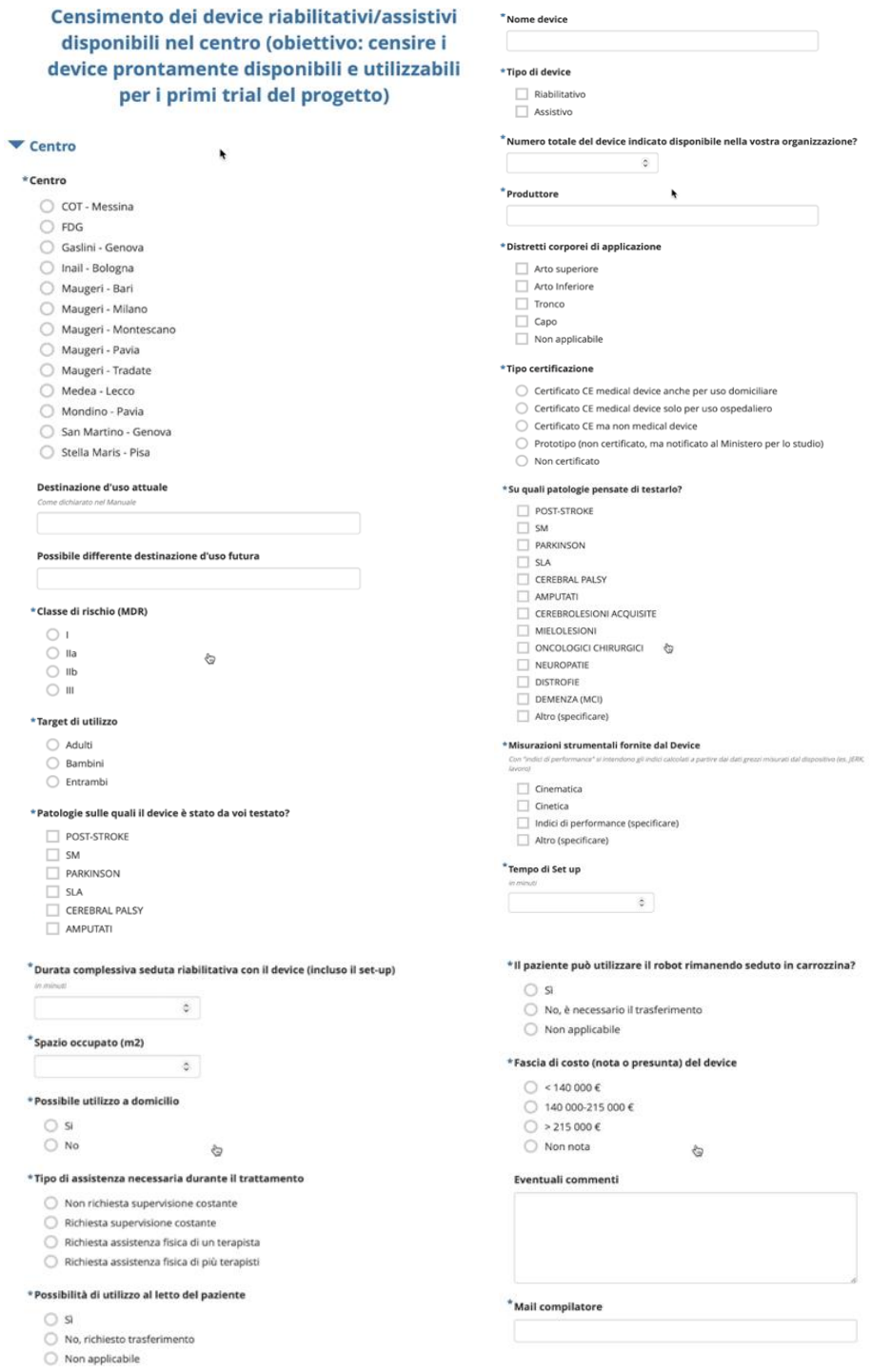

Figure 2 – Census of devices currently available within the Fit4MedRob Consortium for immediate use in clinical studies. Produced via KoboToolbox.

2.2.3 Census of Clinical Trials

The second census aimed at collecting, for each center, the characteristics of the clinical trials conducted by affiliated partners in the last five years or ongoing, in terms of:

- Objectives (primary and secondary endpoints as reported in the study protocol);
- Timing: start date and duration;
- Whether the trial was conducted on a technological device or not (if yes, which device);
- Type of study:
  - Prospective observational (descriptive/analytical);
  - Retrospective observational (descriptive/analytical);
  - Non-randomized controlled trial;
  - Randomized controlled trial;
  - Uncontrolled experimental trial;
- Phase of study:
  - Phase Pre-market Pilot (limited number of patients to evaluate performance/safety);
  - Pivotal (sample size sufficient to provide statistical significance for final certification purposes);
  - Post-market;
- Involved pathology (to be selected among those that are planned in Fit4MedRob);
- Number of patients;
- Age range;
- The clinical scale adopted for the outcome evaluation: this could be selected, if present, among the ones provided in Table 1; if not present, the user could enter the used clinical scale as a free text.

Table 1 – Clinical scales adopted for outcome evaluation in the recorded clinical trials, and used for adults, children, or both adults and children.

Adults	Children	Adults and Children
10m Walking test	AbilHandKIDS	6-Minute walking Test
2-Minute Walking Test	ACTIVLIM-CP	Box and Blocks Test
50m Walking Test	AdAHA	Fugl-Meyer Assessment
Abbey Pain Scale	Ages and stages questionnaires (ASQ-3)	Galveston Orientation and Amnesia Test (>=15 years)
AbilHand Assessment	Alberta Infant Motor Scale	Modified Ashworth Scale
Action Research Arm Test	APL Medea (children-Test for pragmatics)	Motor Assessment Scale
Agitated Behaviour Scale	Behavior Rating Inventory of Executive Function (BRIEF P; BRIEF 2)	Nine-hole Peg Test
American Spinal Injury Association Impairment Scale	Canadian Occupational Performance Measure	Timed Up and Go
Barthel Index	Cerebral Palsy QoL	
Berg Balance Score	Child Behavior Checklist	
Braden	Children's Hand-use Experience Questionnaire	
Braden Scale Pressure Ulcer	Conners-3	

Bristol stool scale	Developmental Test of Visual–Motor Integration	
Caregiver Needs Assessment	Edinburgh Handedness Inventory	
Chedoke-McMaster Stroke Assessment	Glasgow Coma Scale Pediatric version	
Coma Near Coma	Glasgow Outcome Scale Pediatric version	
Coma Recovery	Goal Attainment Scaling	
Disabilities of the Arm, Shoulder, and Hand	Grammar Comprehension Test for Children	
Disability Rating	Gross Motor Function Measure	
Dizziness Handicap Inventory	Infant Motor profile	
Dysphagia Outcome and Severity Scale	Jebsen Taylor hand function test	
Early Rehabilitation Bartel Index	Language evaluation battery (BVL 4-12)	
EUROQUOL-5 - Dimension Questionnaire	Leiter Intern Performance Scale (Leiter-3)	
Expanded Disability status Scale	MD CRS R 0-3 and 4-18	
Five Time Sit to Stand	Melbourne Assessment 2	
Flow State Scale	Movement ABC-2	
Freezing of Gait Questionnaire	MOXO dCPT Continuous Performance Test	
Functional Ambulation Categories	Neurops Eval Battery (BVN 5-11; BVN 12-18)	
Functional Independence Measure	Neuropsychological assessment (NEPSY II)	
Glasgow Coma Scale	North Star Ambulatory Assessment	
Glasgow Outcome Scale	PANAS - pediatric version	
Intrinsic Motivation Inventory	Parenting stress index	
MDS-Unified Parkinson's Disease Rating Scale	Particip-Env Meas for Children and Youth	
Medical Research Council	Peabody Developmental Motor Scales	
Mini Mental State Examination	Peabody Picture Vocabulary Test	
Modified Ranking Handicap Scale	Pediatric balance scale	
Montreal Cognitive Assessment	Pediatric Evaluation of Disability Inventory	
Morse Scale	Quality of Upper Extremity Skills Test	
Motor Activity Log	Rivermead Behavioural Memory Test - pediatric version	
Motricity Index	Shriners Hospital Upper Extremity Evaluation	

NASA Task Load Index	System Usability Scale children adaptation	
Neurogenic Bowel Dysfunction score	System Usability Scale-children adaptation	
Norton-Stotts	Test di Ripetizione Caselli	
Numerical Pain Rating Scale	Test for reception of Grammar	
Orthotic and Prosthetic User Survey	Test Neuropsicologico Lessicale	
Parkinson's Disease-Cognitive Rating Scale	Test of Visual Perceptual Skills (TVPS-4)	
Phycological General Well-Being Index	TFL (Phono-Lexical Test)	
Positive Affect and Negative Affect Scale	Visual perc and visual-motor integration test	
Rivermead Behavioural Memory test	Visual&spatial Memory eval battery (BVS-Corsi)	
Rivermead Mobility Index	Wechsler Intelligence Scale for Children (WISC-IV)	
Spinal Cord Independence Measure	Wechsler Preschool Prim scale of Intell (WPPSI-III-IV)	
Stroke Impact Scale	WeeFim	
Stroke Specific Quality of Life scale	Woods and Teuber scale	
System Usability Scale		
Technological Acceptance Methods		
Technology Affinity of Electronic Devices		
Tinetti Falls Efficacy Scale		
Trunk Control Test		
Unified theory of Accept&Use of Technology		
User Experience Questionnaire-Short		
Walking Index for Spinal Cord Injury II		
Wolf Motor Function test		
World Health Organization - Quality of life - BREF		

2.2.4 Census of Scientific Production

The following questionnaire (Figure 3) was submitted to collect the scientific publications concerning the topics of the Initiative, and produced in the last five years by the research groups involved in Fit4MedRob. In particular, DOI and the paper title were requested.

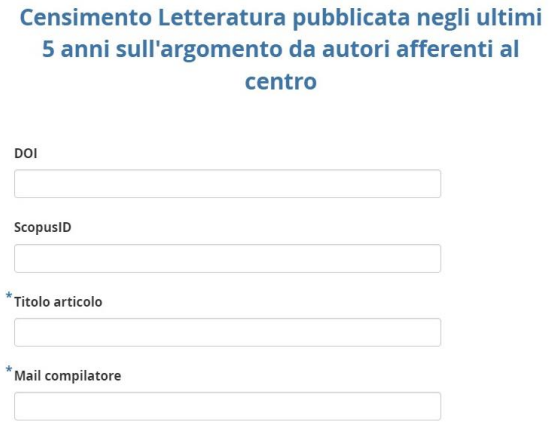

Figure 3 – Census of literature published in the last 5 years about the topics of the Initiative, by authors affiliated with the Fit4MedRob Consortium.

2.3 RESULTS

2.3.1 Results of Census of Devices

The census of devices showed 111 types of technologies in the Fit4MedRob Consortium, 49 of which are robotic systems and advanced digital technologies for sensory-motor and cognitive rehabilitation, while the remaining ones are not strictly robotic devices or advanced digital technologies for rehabilitation. The 49 different robotic devices and advanced digital technologies for sensory-motor and cognitive rehabilitation identified are shown in Table 2. The total number of devices available in the Consortium is equal to 202. Since different centers may use the same device and a center may have multiple copies of the same device, Table 2 displays the number of centers that own the same device as well as the total number of copies available in the Consortium.

Table 2 – Robotic systems and advanced digital technologies for sensory-motor and cognitive rehabilitation (ordered by the number of devices available overall).

n	Device (company)	n. of centers with the device	n. of available copies within the Consortium
1	VRRS HOME (Khymeia)	4	28
2	Dividat SensoFlex (Dividat AG)	1	15
3	Motore (Humanware)	4	13
4	Amadeo (Tyromotion)	3	13
5	Pablo (Tyromotion)	3	12
6	Oculus Quest 2 (Facebook Technology)	3	12
7	Diego (Tyromotion)	2	11
8	Homing (TecnoBody)	1	10
9	Walker view (TecnoBody)	5	7
10	The Grid 3 (Smartbox)	1	5
11	Hunova (Movendo)	3	4
12	Riablo (Euleria Health)	2	4
13	Lokomat (Hokoma/Motek)	4	4

14	VRRS EVO (Khymeia)	2	4
15	VRRS TR (Khymeia)	4	4
16	NIRVANA (BTS)	3	3
17	KARI (Euleria Health)	1	3
18	Myro (Tyromotion)	3	3
19	Prokin (Technobody)	2	3
20	Comunicatore eye-tracking (helpicare)	1	2
21	Geo (Reha Technology)	1	2
22	Gloreha Sinfonia (Idrogenet)	2	2
23	Ekso (Ekso Bionics)	1	2
24	D-wall (TecnoBody)	2	2
25	WREX (Jaeco)	1	2
26	Icone (Haexel)	1	2
27	C-mill (Hocoma/Motek)	2	2
28	CareLab (Vitamin) - FDG	1	2
29	Erigo (Hocoma/Motek)	2	2
30	ALEx RS (Wearable robotics)	2	2
31	Dividat Senso (Dividat AG)	1	1
32	Armeo Spring (Hocoma/Motek)	1	1
33	Armeo(R)Spring pediatric (Hocoma/Motek)	1	1
34	Armon (Ayura)	1	1
35	AV DESK (Linari Medical)	1	1
36	BioXtreme (BioXtreme)	1	1
37	Lexo (Tyromotion)	1	1
38	Ultra+ (Humanware)	1	1
39	Uango (U&O Technology)	1	1
40	keoogo (B-temia)	1	1
41	Myosuit (Myosuit)	1	1
42	GEAMASTER (Vertigomed)	1	1
43	YouGrabber (YouRehab)	1	1
44	Lambda (Lambda Health System)	1	1
45	Jaco (KinovaRobotics)	1	1
46	InMotion wrist (InMotion)	1	1
47	Hand, Arm, leg Tutors (MediTouch)	1	1
48	GRAIL (Hokoma/Motek)	1	1
49	Pepper (Softbank robotics)	1	1

Table 3 reports the list of devices not strictly robotic or advanced digital technologies available within the Consortium. These technologies might be useful for carrying out accurate measurements and/or therapeutic interventions.

Table 3 – List of devices not strictly robotic or advanced digital technologies.

Device
Brainstim
Transcranial direct current stimulation (tDCS)
HSMonitor+ wristband as activity tracker, blood pressure, scale
automatic ICD, pacemakers
Easydom Kit
ELITE 3D
Hand tests system
MAG VENTURE
Motomed
VIBRA 3.0
NEUROTRAVEL EP/ERP
MY LAB OMEGA
biofeedback liberty
PHYACTION 780
Wrist Boat
PRIMUS RS
smart pants
SW markerless analysis of spontaneous neonatal movements
tDCS-BRAIN STIM
tDCS-HDCstim
TechARM
Vibramoov

2.3.1.1 Devices' Classification and Distribution

Tables 4 (a-d) show the classifications of the robotic devices and advanced digital technologies according to different attributes of interest in the Initiative.

Table 4a shows their distribution according to the device function (rehabilitative/assistive/both) and Table 4b according to their functional category (treadmill, exoskeleton, end-effector robot, sensor-based, etc.).

Table 4a – Distribution of devices according to general function.

Device function	n. of devices	%
Rehabilitative	36	12.2
Assistive	6	73.5
Rehab/Assist	7	14.3

Table 4b – Distribution of devices according to specific functional classification.

Class	n. of devices	%
Advanced treadmill	3	6.1
Assistive (generic)	3	6.1
LL End Effector	4	8.2
LL Exoskeleton	5	10.2
Proprioceptive/stabilometric/balance platform	5	10.2
Sensor-Based/VR/cognitive	16	32.7
UL Assistive & UL End Effector	8	16.3
UL Exoskeleton	5	10.2

UL = Upper Limb; LL = Lower Limb; VR = Virtual Reality

Table 4c shows the distribution of devices according to the same functional classification as in Table 4b, but considering all the devices available (in number of copies and percentage) within the Consortium.

Table 4c – Functional classification of devices considering the total number of available copies.

Device class	n. of copies	%
Advanced treadmill	10	5
Assistive (generic)	8	4
LL End Effector	6	3
LL Exoskeleton	9	4.5
Proprioceptive/stabilometric/balance platform	27	13.5
Sensor-Based/VR/cognitive	91	45.5
UL Assistive & UL End Effector	43	21.5
UL Exoskeleton	8	4

UL = Upper Limb; LL = Lower Limb; VR = Virtual Reality.

As shown in Table 4d, almost all of the devices - as expected given the census objective - are certified for medical use, with a good percentage also being certified for home use.

Table 4d – Distribution of devices according to the certification level.

Certification	n. of devices	%
CE-certified medical device for hospital use only	34	68
CE-certified medical device also for home use	13	28
Uncertified	1	2
CE-certified but not as medical device	1	2

The risk class item in the census file showed some missing values, which have been filled in using the information provided by the Italian Ministry of Health at the following weblink: https://www.salute.gov.it/. The risk class item of all devices is shown in Table 4e.

Table 4e – Distribution of devices according to the risk class.

Risk class	n. of devices	%
I	29	58
IIa	18	38
Not applicable	2	4

Figure 4 shows the geographical distribution of the available devices in the different Consortium centers.

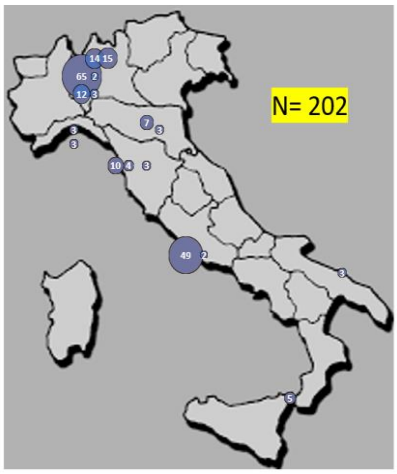

Figure 4 – Geographical distribution of the robotic devices available within the Fit4MedRob Consortium.

Figure 5 shows the geographical distribution of devices within the Consortium according to their functions (rehabilitative device, assistive device, rehabilitative and assistive device).

Figure 5 – Geographical distribution of the robotic devices available within the Fit4MedRob Consortium, according to their function (rehabilitative devices in orange; assistive devices in blue; rehabilitative and assistive devices in green).

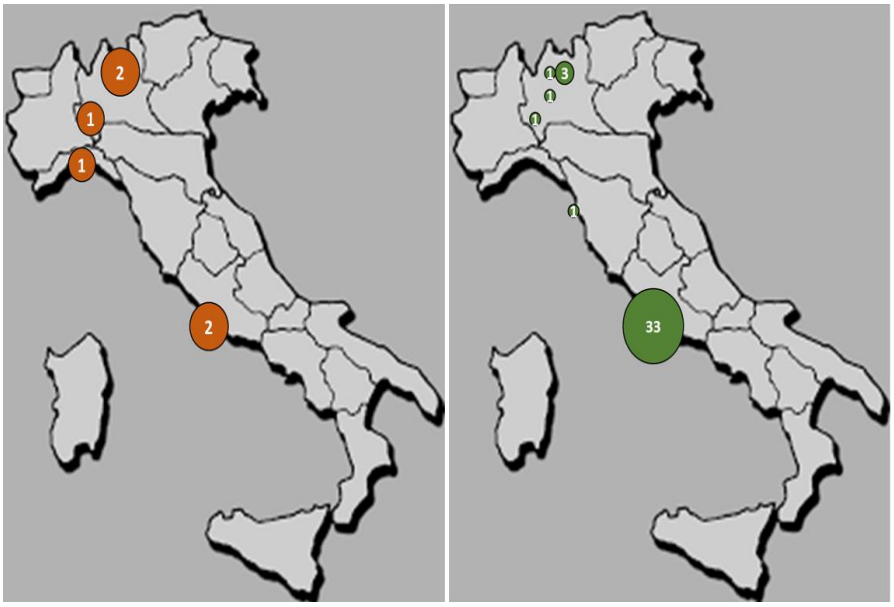

Figure 6 – Distribution of lower (left) and upper limb end-effector (right) devices within the Fit4MedRob Consortium.

Further statistics were performed describing the distribution of the end-effector devices for the lower (LL) and upper limbs (UL), as shown in Figure 6.

2.3.1.2 Devices' Usage Scope

In the following tables, statistics on other features collected through the census and related to the usage scope of available devices are shown. These items were chosen for getting an alignment of clinical partners for future multicentric clinical trials.

Table 5 reports the number of devices used for the treatment of the different body segments. The results show the prevalence of devices for the treatment of the upper limb.

Table 5 – Distribution of devices according to the body segment treated.

Segment(s) of the body treated	n. of devices	%
Upper limb	69	34.16
Upper limb, Lower limb, Trunk, Head	37	18.32
Lower limb	30	14.85
Upper limb, Lower limb, Trunk	23	11.39
Lower limb, Trunk	15	7.43
Head	3	1.49
Trunk	2	0.99
Upper limb, Trunk, Head	1	0.5
Upper limb, Trunk	1	0.5
Not applicable	20	9.9

Table 6 shows the distribution of devices according to the target population. While adults are the primary target audience, some devices are also used for children.

Table 6 – Distribution of devices according to target population.

Target population	n. of devices	%
Adults	122	60.4
Both	75	37.13
Pediatric	5	2.48

Table 7 highlights three key potential future trends of the devices' usage, as suggested by the responders. In particular, three suggestions are relevant to trial planning in the future: (i) extending to a pediatric population a device currently used for adults, (ii) translating into clinical practice a device used only for research, and (iii) extending the use at home for a device currently used in hospital.

Table 7 – Suggested further use of the devices.

Current use of a device	Desired further use	n. of devices
Rehab at the hospital for research purposes	Rehab at the hospital for clinical purposes	5
Adults	Implementation for childhood	4
Clinical use	Usage at home	3
Interaction with humans	Geriatric (orthogeriatric)	1
Clinical use (unilateral)	Bilateral	1
Home rehab post arthroprosthesis	Post-stroke	1
Shoulder rehab	Lower limb	1
Arthoprosthesis (knee-shoulder-hip)	Neuro proprioceptive rehab (Parkinson, SM)	1

Table 8 shows the diseases that have been treated so far using the available devices. As can be seen, the majority of devices are used for post-stroke rehabilitation, followed by acquired cerebral lesions and Parkinson's disease.

Table 8 – The treated diseases and the corresponding devices used.

Disease	n. of devices	%
Post-stroke	34	59.65
Acquired Cerebral Lesions	30	52.63
Parkinson	30	52.63
SM	29	50.88
Cerebral Palsy	28	49.12
Spinal cord injury	18	31.58

Dystrophies	15	26.32
Neuropathies	15	26.32
Post-onco-surgery	13	22.81
Multiple Sclerosis	11	19.3
Mild cognitive impairment	8	14.04
Amputees	4	7.02

Tables 9-12 show the possibility of using the device at home, at the patient's bedside, with the patient in the wheelchair, and different needs for assistance during the rehabilitation treatment. Note that in the tables the total number of devices is greater than 49 because, for the same device, different centers provided different answers probably according to their specific expertise on the device itself. This could foster collaboration among centers to achieve a consensus after sharing the different expertise.

Table 9 – Use at home.

Possible usage at home	n. of devices	%
No	33	59
Yes	23	41

Table 10 – Use at the patient's bed.

Possible usage at bed	n. of devices	%
Yes	12	21
No, transfer required	36	61
Not applicable	11	18

Table 11 – Use at the patient's wheelchair.

Possible usage at wheelchair	n. of devices	%
Yes	31	55.5
No, transfer required	15	27.5
Not applicable	10	17

Table 12 – Needs for assistance during the device usage.

Assistance during rehabilitation treatment	n. of devices	%
Continuous assistance not required	28	42.42
Assistance from more than one therapist required	2	3.03
Assistance from one therapist required	12	18.18
Continuous assistance required	23	34.85

2.3.1.3 Devices' Features

Table 13 reports instrumental measurements provided by the currently available devices and the distribution within the Consortium expressed as a percentage of devices offering that measurement.

Table 13 – Type of measurements provided by the available devices.

Instrumental measure	n. of devices	% of devices
Other (physiological parameters, time of reaction, % of success or not applicable)	69	34.16
Performance indices	50	24.75
Kinematics (raw data)	23	11.39
Kinematics (raw data), kinetics (raw data)	16	7.92
Kinematics (raw data), kinetics (raw data), performance indices	16	7.43
Kinematics (raw data), performance indices	18	8.92
Kinetics (raw data)	5	2.48
Not Applicable	3	1.49
None	1	0.5
Kinetics (raw data), performance indices	1	0.5

The devices' performance indices can be classified based on the type of data used (kinematic or kinetic raw data) and the investigated limb/function (upper limb, lower limb, and balance).

Kinematic performance indices, in particular, can be distinguished and classified according to different aspects:

- According to the literature [1], the performance indices derived from upper limb kinematic data can be categorized according to the following movement quality characteristics: movement planning, interlimb coordination, accuracy, temporal efficiency, efficacy, ease, smoothness, efficiency, intralimb coordination, and range of motion;
- Lower limb kinematic performance indices are spatiotemporal parameters of gait (step length, step number, walking time, etc.);
- Kinematic performance indices exploring balance are those related to the Center of Pressure (CoP) displacement during static or dynamic balance tests (CoP anteroposterior or mediolateral displacement, CoP speed, CoP area, Limits of stability, etc.).

Kinetic performance indices reported in the census are mainly related to the maximum value of the strength at the hand in different grip configurations, or at the ankle joint.

Table 14 and Table 15 show the observed ranges of setup time and space occupation, respectively for each device. These question items have been proposed in order to investigate the feasibility of future multicenter clinical trials and the requirements to set up and harmonize organizational models of technological areas in the different clinical centers.

Table 14 – Setup time of each device (minutes) and corresponding number of centers within the Consortium.

Device	n. of centers	Setup min	Setup max
NIRVANA	3	0	30
Walker view	5	2	15
Erigo	2	10	20
Prokin	2	2	10
D-wall	2	2	10
Motore	4	2	10

Pablo	3	2	10
Amadeo	3	3	10
VRRS EVO	2	5	10
VRRS	2	5	10
Oculus Quest 2	3	5	10
ALEx RS	2	5	10
VRRS TR	2	5	10
Myro	3	1	5
C-mill	2	2	5
Riablo	2	8	10
Hunova	3	3	5
Diego	2	4	5
Geo	1	7	7
GRAIL	1	15	15
GEAMASTER	1	30	30
Hand, Arm, leg Tutors	1	10	10
Ekso	1	10	10
Gloreha Sinfonia	2	10	10
Armeo Spring	1	10	10
Dividat Senso	1	5	5
Armeo(R)Spring pediatric	1	10	10
AV DESK	1	5	5
HomeKit	1	5	5
Armon	1	5	5
Lambda	1	5	5
eye-tracking dialog	1	120	120
CareLab (Vitamin)	1	5	5
BioXtreme	1	5	5
Dividat SensoFlex	1	5	5
Telecockpit/Homekit Khymeia	1	10	10
WREX	1	5	5
VRRS TR/EVO	1	10	10
VRRS TELECOCKPIT	1	1	1
VRRS HOME TABLET	1	5	5
VRRS HOME KIT	1	5	5
VRRS Home full set	1	5	5
Ultra+	1	10	10
Uango	1	10	10
KARI	1	10	10
The Grid 3	1	30	30
Homing	1	10	10

Myosuit	1	5	5
Lokomat pro	2	15	15
Lokomat	2	15	15
Lexo	1	15	15
YouGrabber	1	10	10
keoogo	1	15	15
Jaco	1	2	2
InMotion wrist	1	10	10
Icone	1	2	2
Pepper	1	N.A.	N.A.

Table 15 – The space occupied by each device (m^2).

Device	n. of centers	Minimum Space	Maximum Space
NIRVANA	3	2	15
Motore	4	1	10
VRRS EVO	2	3	10
Lokomat	2	6	12
Hunova	3	3	9
Diego	2	1	6
Erigo	2	2	6
ALEx RS	2	3	6
VRRS TR	2	2	5
Myro	3	1	4
Amadeo	3	0	3
Gloreha Sinfonia	2	3	5
Walker view	5	3	5
Lokomat pro	2	10	12
D-wall	2	9	10
Pablo	3	1	2
Oculus Quest 2	3	0	1
AV DESK	1	1	1
HomeKit	1	1	1
Hand, Arm, leg Tutors	1	3	3
GRAIL	1	25	25
Armeo Spring	1	3	3
Armeo(R)Spring pediatric	1	5	5
Geo	1	6	6
Ekso	1	1	1
Armon	1	1	1
Lambda	1	9	9

BioXtreme	1	2	2
CareLab (Vitamin)	1	30	30
C-mill	2	4	4
eye-tracking dialog	1	1	1
Dividat Senso	1	1	1
Dividat SensoFlex	1	1	1
GEAMASTER	1	3	3
Riablo	2	2	2
WREX	1	1	1
VRRS TR/EVO	1	3	3
VRRS TELECOCKPIT	1	3	3
VRRS HOME TABLET	1	4	4
VRRS HOME KIT	1	0	0
VRRS Home full set	1	0	0
VRRS	2	4	4
Ultra+	1	1	1
Uango	1	1	1
KARI	1	3	3
Telecockpit/Homekit Khymeia	1	5	5
Homing	1	0	0
Prokin	2	3	3
Pepper	1	1	1
Myosuit	1	1	1
Lexo	1	1.5	1.5
YouGrabber	1	3	3
keoogo	1	1	1
Jaco	1	2	2
InMotion wrist	1	6	6
Icone	1	0	0
The Grid 3	1	0	0

Table 16 shows the distribution of devices according to their cost range.

Table 16 – Devices' cost.

Cost range	n. of devices	%
< 140 000 €	41	72
> 215 000 €	3	5.3
140 000-215 000 €	10	17.5
Unknown	3	5.2

In Table 17, devices are classified and matched with the centers that own them, and the number of available samples in each center.

Table 17 – Devices and their availability in the different centers (blue/green color alternation is to improve the readability of rows referring to the same device).

Type of device	Class	Device name	Center	n. of devices for each center	n. of devices for each organization	n. of devices within the Consortium
1 - Rehabilitative	Advanced treadmill	C-mill	FDG - Firenze	1	2	10
1 - Rehabilitative	Advanced treadmill	C-mill	FDG - Milano	1		
1 - Rehabilitative	Advanced treadmill	GRAIL	Medea - Lecco	1	1	
1 - Rehabilitative	Advanced treadmill	Walker view	FDG - Milano	1	7	
1 - Rehabilitative	Advanced treadmill	Walker view	Maugeri - Bari	1		
1 - Rehabilitative	Advanced treadmill	Walker view	Maugeri - Milano	1		
1 - Rehabilitative	Advanced treadmill	Walker view	Maugeri - Montescano	1		
1 - Rehabilitative	Advanced treadmill	Walker view	Maugeri - Pavia	3		
2 - Assistive	Assistive (other)	eye-tracking dialog	UniMoRe - Modena Reggio E.	2	1	2
2 - Assistive	Assistive (other)	The Grid 3	UniMoRe - Modena Reggio E.	5	1	
1 - Rehabilitative	LL End Effector	Geo	FDG - Roma	2	2	6
1 - Rehabilitative	LL End Effector	Lambda	Valduce - Como	1	1	
3 - Rehabilitative/Assistive	LL End Effector	Erigo	Maugeri - Pavia	1	2	
3 - Rehabilitative/Assistive	LL End Effector	Erigo	Valduce - Como	1		
3 - Rehabilitative/Assistive	LL End Effector	Lexo	Gaslini - Genova	1	1	
1 - Rehabilitative	LL Exoskeleton	Lokomat	Maugeri - Montescano	1	4	8
1 - Rehabilitative	LL Exoskeleton	Lokomat	Medea - Lecco	1		
1 - Rehabilitative	LL Exoskeleton	Lokomat	UNIPI - Pisa	1		
1 - Rehabilitative	LL Exoskeleton	Lokomat	Valduce - Como	1		
1 - Rehabilitative	LL Exoskeleton	Uango	Valduce - Como	1	1	
3 - Rehabilitative/Assistive	LL Exoskeleton	Ekso	Valduce - Como	2	1	
3 - Rehabilitative/Assistive	LL Exoskeleton	keoogo	Valduce - Como	1	1	
3 - Rehabilitative/Assistive	LL Exoskeleton	Myosuit	Valduce - Como	1	1	

2 - Assistive	Mobile Servant	Pepper	San Martino - Genova	1	1	1
1 - Rehabilitative	Proprioceptive/stabilometric/balance platform	Dividat Senso	FDG - Milano	1	1	27
1 - Rehabilitative	Proprioceptive/stabilometric/balance platform	Dividat SensoFlex	FDG - Milano	15	15	
1 - Rehabilitative	Proprioceptive/stabilometric/balance platform	Hunova	FDG - Roma	2	7	
1 - Rehabilitative	Proprioceptive/stabilometric/balance platform	Hunova	Inail - Bologna	3		
1 - Rehabilitative	Proprioceptive/stabilometric/balance platform	Hunova	Valduce - Como	2		
1 - Rehabilitative	Proprioceptive/stabilometric/balance platform	Prokin	FDG - Milano	2	3	
1 - Rehabilitative	Proprioceptive/stabilometric/balance platform	Prokin	Maugeri - Bari	1		
3 - Rehabilitative/Assistive	Proprioceptive/stabilometric/balance platform	GEAMASTER	San Martino - Genova	1	1	
1 - Rehabilitative	Sensor-Based/VR/cognitive	AV DESK	UNIPI - Pisa	1	1	90
1 - Rehabilitative	Sensor-Based/VR/cognitive	CareLab (Vitamin)	FDG - Milano	2	1	
1 - Rehabilitative	Sensor-Based/VR/cognitive	D-wall	FDG - Milano	1	2	
1 - Rehabilitative	Sensor-Based/VR/cognitive	D-wall	Maugeri - Pavia	1		
1 - Rehabilitative	Sensor-Based/VR/cognitive	Hand, Arm, leg Tutors	Medea - Lecco	1	1	
1 - Rehabilitative	Sensor-Based/VR/cognitive	Homing	FDG - Milano	10	1	
1 - Rehabilitative	Sensor-Based/VR/cognitive	KARI	COT - Messina	3	1	
1 - Rehabilitative	Sensor-Based/VR/cognitive	Myro	FDG - Roma	1	3	
1 - Rehabilitative	Sensor-Based/VR/cognitive	Myro	Maugeri - Pavia	1		
1 - Rehabilitative	Sensor-Based/VR/cognitive	Myro	Valduce - Como	1		
1 - Rehabilitative	Sensor-Based/VR/cognitive	NIRVANA	Maugeri - Pavia	1	3	
1 - Rehabilitative	Sensor-Based/VR/cognitive	NIRVANA	Medea - Lecco	1		
1 - Rehabilitative	Sensor-Based/VR/cognitive	NIRVANA	San Martino - Genova	1		
1 - Rehabilitative	Sensor-Based/VR/cognitive	Oculus Quest 2	FDG - Milano	10	11	

1 - Rehabilitative	Sensor-Based/VR/cognitive	Oculus Quest 2	FPUCBM - Roma	1		
1 - Rehabilitative	Sensor-Based/VR/cognitive	Pablo	FDG - Roma	10		
1 - Rehabilitative	Sensor-Based/VR/cognitive	Pablo	Gaslini - Genova	1	12	
1 - Rehabilitative	Sensor-Based/VR/cognitive	Pablo	Maugeri - Pavia	1		
1 - Rehabilitative	Sensor-Based/VR/cognitive	Riablo	COT - Messina	2		
1 - Rehabilitative	Sensor-Based/VR/cognitive	Riablo	Maugeri - Pavia	2	4	
1 - Rehabilitative	Sensor-Based/VR/cognitive	VRRS EVO	FDG - Milano	1		
1 - Rehabilitative	Sensor-Based/VR/cognitive	VRRS EVO	Medea - Lecco	1	3	
1 - Rehabilitative	Sensor-Based/VR/cognitive	VRRS EVO	Stella Maris - Pisa	1		
1 - Rehabilitative	Sensor-Based/VR/cognitive	VRRS HomeKit	FDG - Milano	8		
1 - Rehabilitative	Sensor-Based/VR/cognitive	VRRS HomeKit	FDG - Milano	10		
1 - Rehabilitative	Sensor-Based/VR/cognitive	VRRS HomeKit	Medea - Lecco	2	26	
1 - Rehabilitative	Sensor-Based/VR/cognitive	VRRS HomeKit	Stella Maris - Pisa	6		
1 - Rehabilitative	Sensor-Based/VR/cognitive	VRRS Telecockpit Khymeia	FDG - Milano	1		
1 - Rehabilitative	Sensor-Based/VR/cognitive	VRRS Telecockpit Khymeia	Maugeri - Bari	1	2	
1 - Rehabilitative	Sensor-Based/VR/cognitive	VRRS TR	FDG - Firenze	1		
1 - Rehabilitative	Sensor-Based/VR/cognitive	VRRS TR	FDG - Milano	2		
1 - Rehabilitative	Sensor-Based/VR/cognitive	VRRS TR	Maugeri - Pavia	1	5	
1 - Rehabilitative	Sensor-Based/VR/cognitive	VRRS TR	Stella Maris - Pisa	1		
1 - Rehabilitative	Sensor-Based/VR/cognitive	YouGrabber	Medea - Lecco	1	1	
3 - Rehabilitative/Assistive	Sensor-Based/VR/cognitive	Ultra+	Stella Maris - Pisa	1	1	
2 - Assistive	UL Assistive	Armon	Medea - Lecco	1	1	2
2 - Assistive	UL Assistive	Jaco	Medea - Lecco	1	1	
1 - Rehabilitative	UL End Effector	Amadeo	FDG - Roma	11		
1 - Rehabilitative	UL End Effector	Amadeo	Maugeri - Pavia	1	13	
1 - Rehabilitative	UL End Effector	Amadeo	Valduce - Como	1		41
1 - Rehabilitative	UL End Effector	BioXtreme	Valduce - Como	1	1	
1 - Rehabilitative	UL End Effector	Diego	FDG - Roma	10	11	

1 - Rehabilitative	UL End Effector	Diego	Valduce - Como	1		
1 - Rehabilitative	UL End Effector	Icone	FDG - Roma	2	2	
1 - Rehabilitative	UL End Effector	InMotion wrist	Medea - Lecco	1	1	
1 - Rehabilitative	UL End Effector	Motore	FDG - Roma	10	13	
1 - Rehabilitative	UL End Effector	Motore	Maugeri - Milano	1		
1 - Rehabilitative	UL End Effector	Motore	Stella Maris - Pisa	1		
1 - Rehabilitative	UL End Effector	Motore	UNIPI - Pisa	1		
1 - Rehabilitative	UL Exoskeleton	ALEx RS	FDG - Roma	1	2	8
1 - Rehabilitative	UL Exoskeleton	ALEx RS	UNIPI - Pisa	1		
1 - Rehabilitative	UL Exoskeleton	Armeo Spring	Maugeri - Montescano	1	2	
1 - Rehabilitative	UL Exoskeleton	Armeo(R)Spring pediatric	Medea - Lecco	1		
1 - Rehabilitative	UL Exoskeleton	Gloreha Sinfonia	FDG - Firenze	1	2	
1 - Rehabilitative	UL Exoskeleton	Gloreha Sinfonia	Valduce - Como	1		
2 - Assistive	UL Exoskeleton	WREX	Medea - Lecco	2	2	

2.3.2 Results of Census of Clinical Trials

There were 140 responses to the census of clinical trials. Maps in Figure 7 show the trials' distribution among the centers, considering all the trials (left) and the trials on a device (right).

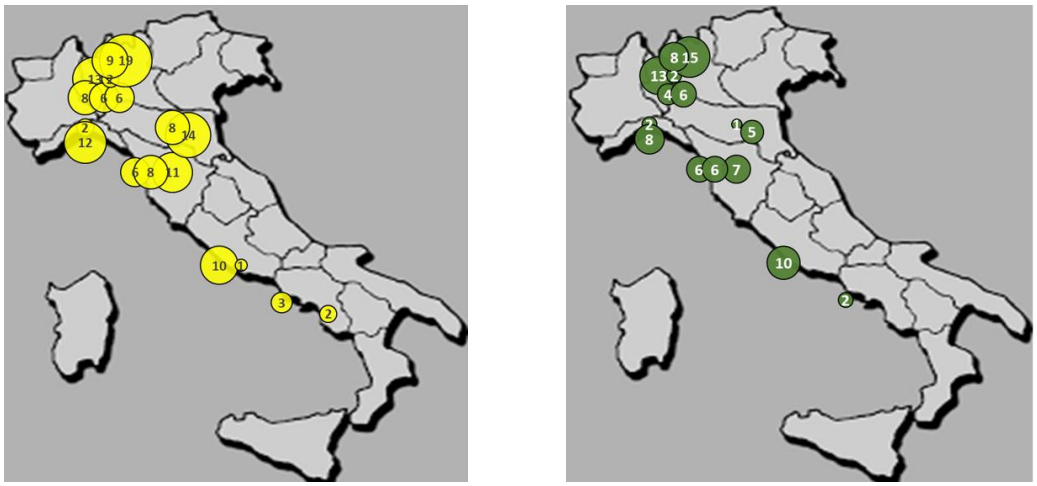

Figure 7 – Number of trials in the different centers (left: all trials, right: trials on device).

Table 18 shows the devices used in the census-reported trials, and the number of trials in which each device was involved. Some devices did not appear in any of the reported trials, namely Armon, AV DESK, BioXtreme, CareLab (Vitamin), eye-tracking dialog, Dividat SensoFlex, D-wall, Erigo, GEAMASTER, InMotion wrist, KARI, keoogo, Lambda, Myro, Pepper, RiabloThe Grid 3, Uango, Ultra+, Walker view, WREX.

Table 18 – Devices and number of census-reported trials in which they were used.

Device	n. of trials
Amadeo	2
Armeo Spring	4
Armeo Spring pediatric	1
C-Mill	2
Diego	2
Dividat Senso	1
Ekso	1
Geo	1
Gloreha Sinfonia	1
GRAIL	4
Homing	1
Hunova	2
Icone	1
Jaco	1
Lexo	1
Lokomat	7
Motore	8

Myosuit	1
NIRVANA	1
Oculus Quest 2	1
Pablo	2
Prokin	1
VRRS EVO	2
VRRS HomeKit	4

The census of trials also allows us to capture the expertise of the different centers in each pathology included in the Initiative. For instance, Figure 8 shows where post-stroke censed trials were or are located within the Fit4MedRob Consortium.

Figure 8 - Geographical distribution of clinical trials conducted on post-stroke patients (n=50).

2.3.3 Results of Census of Scientific Production

The census of literature reports the scientific papers, coherent with the scope of the Initiative, published by each center in the last five years (see Table 19).

Table 19 – Number of scientific papers published by each center.

Center	n. of papers
FDG Firenze	102
Valduce Como	88
UniGE (San Martino) Genova	51
FDG Milano	46
FDG Roma	30
MONDINO Pavia	22
UNIMORE Modena-RE	21

ICSM Pavia	18
MEDEA Lecco	17
Stella Maris Pisa	15
Campus Biomedico Roma	11
COT Messina	9
Inail Volterra	9
FDG Santangelo dei Lombardi	7
UniPI Pisa	6
ICSM Bari	5
Inail Bologna	5
GASLINI Genova	4
UNINA Napoli	3
ICSM Milano	2
ICSM Montescano	1

2.4 CONCLUSIONS

The census of robotic devices and allied digital technologies allowed us to get a "picture" of the current scenario of available technological equipment within the Consortium. Information regarding the number of devices per each center and per each device's class, as well as their functional category and specific features, provided important suggestions on how the potential organizational models of technological areas for the future clinical trials could be devised and what is still needed for harmonizing partners' equipment in the light of multicenter studies to be conducted within the Fit4MedRob Consortium.

Firstly, available devices covered an adequate range of classes and scopes. The census showed 111 types of technologies (49 of which are robotic systems) and 202 total copies of devices available in the Consortium. The majority of the robotic devices are for rehabilitative purposes (mostly post-stroke), CE-certified for hospital use only, and devoted to the upper limb treatment. Exoskeletons or end-effectors for the lower limbs are present but in minor amounts. However, there is a substantial number of devices for all the body segments. Available technologies are targeting adult treatments, while pediatric patients remain poorly covered. Indeed, among suggestions for future use of the devices, implementation for childhood is prevalent, together with ideas of translating into clinical practice the systems so far used in research only, and with the need for devices for home-based use. The geographical distribution of devices among clinical centers on the Italian territory showed a prevalence of availability in the centers of the north and center regions.

These results also suggest the need of harmonization of technological coverage across centers for future stages of the Initiative.

The process of identifying clinical trials and scientific papers, produced over the past 5 years by clinical groups associated with the Consortium, offered a comprehensive view of the individual affiliates' scientific proficiency in robotic rehabilitation. This task served as a preliminary step to pinpoint expert groups with the role of designing pragmatic trials for the clinical conditions to be examined within the Initiative. Previous expertise will play a crucial role in outlining study protocols, and more specifically, in determining primary and secondary endpoints in each trial.

3 LITERATURE REVIEW ON THE TOOLS TO COLLECT NEEDS OF TARGET GROUP

3.1 INTRODUCTION

The primary objective of the literature review was to undertake a comprehensive analysis of the existing qualitative instruments and tools aimed at collecting the needs of both patients and rehabilitation practitioners/therapists, in the context of employing robotic devices within rehabilitation interventions.

With this analysis, we aimed to understand specifically the employed tools, the investigated populations (in terms of clinical conditions and countries), the included type of technological devices used by the responders, and the explored themes. In particular, we aimed to identify any tools based on the International Classification of Functioning, Disability and Health (ICF), according to the Fit4MedRob proposal. Ultimately, our aim was to ascertain whether any instruments aligned with the objectives and scope of the Fit4MedRob Initiative.

3.2 LITERATURE REVIEW

We conducted an initial investigation by thoroughly searching relevant literature related to the existing qualitative instruments and tools aimed at collecting the needs of both patients and rehabilitation practitioners/therapists, in the context of employing robotic devices within rehabilitation interventions. This activity involved exploring several scholarly archives and databases and led us to a recent systematic review titled "Patient, carer, and staff perceptions of robotics in motor rehabilitation: a systematic review and qualitative meta-synthesis" by Laparidou et al. [2].

This study was considered highly relevant to our research topic, since it offers a comprehensive examination of the precise area we are focusing on, as easily inferred from the correspondence between our objective and the title of the systematic review. In fact, the authors had reviewed end-users' (patients, caregivers, and healthcare professionals) experiences with robotic devices in motor rehabilitation using ad-hoc interviews. The exact research question was: "*What are patients', their carers', and healthcare professionals' perceptions of and/or experiences with robotic interventions in motor rehabilitation*?". It is worth noting that this systematic review was published in the Journal of NeuroEngineering and Rehabilitation, which ranks 3rd out of 68 journals in the Rehabilitation category by Journal Impact Factor (IF: 5.1, first quartile, source: Journal Citation Reports).

By delving deeper in the paper, the eligibility criteria encompassed studies focusing on the firsthand experiences and perspectives of patients who underwent motor rehabilitation integrating robotic interventions. Furthermore, perspectives of family members or caregivers of the patients, as well as those of healthcare professionals participating in the intervention's administration (including physiotherapists, neurologists, occupational therapists, etc.), were also considered. Only peer-reviewed studies in English were included. Quantitative studies were excluded, as the emphasis lay on qualitative research providing comprehensive narratives of participants' rehabilitation experiences.

From a methodological point of view, the search strategy was performed in the following electronic bibliographic databases: MEDLINE, CINAHL, Academic Search Complete, The Cochrane Library (Cochrane Database of Systematic Reviews), PROSPERO, Scopus, IEEE Xplore, Knovel, and ACM Digital Library. All databases were searched from databases inception to August 2020. It included a combination of two sets of keywords and related terms: (1) robotic and robot-assisted, interventions, therapy, and rehabilitation; combined with (2) qualitative research, interview, focus group, experiences, perceptions, attitudes, and views. For the full search strategy used for the Medline database, see Table 20.

Table 20 – Search strategy for MEDLINE database [2].

S1	robotic* OR robot* OR robotic therap* OR robot-assisted OR robot assisted OR exoskeleton* OR assistive robotic* OR walking robotic device* OR personal care robot* OR medical robot* OR assistive OR assistive automation OR wearable robot* OR orthotic* OR orthosis OR exoskeletal* OR exo OR end-effector OR haptic* OR robot regulation*
S2	rehab* OR intervention* OR treatment* OR therap* OR program* OR strateg* OR training OR physiotherap* OR physio-therap* OR "physiotherap*" OR "physical therap*

S3	Qualitative research OR qualitative OR interview* OR focus group* OR ethno* OR phenomenolog* OR hermeneutic* OR grounded theory OR narrative analysis OR thematic analysis OR lived experience* OR life experience*
S4	(MH "Qualitative Research") OR "Qualitative research"
S5	S3 OR S4
Searched	**S1 AND S2 AND S5**

The search strategy identified a total of 13.556 citations. After removing duplicates and excluding citations based on title and abstract, the Authors analyzed the full text of 82 articles. A further 52 articles were excluded based on inclusion/exclusion criteria, leaving 30 studies to be included in the review and meta-synthesis. Figure 9 presents a flowchart illustrating the results of the selection process.

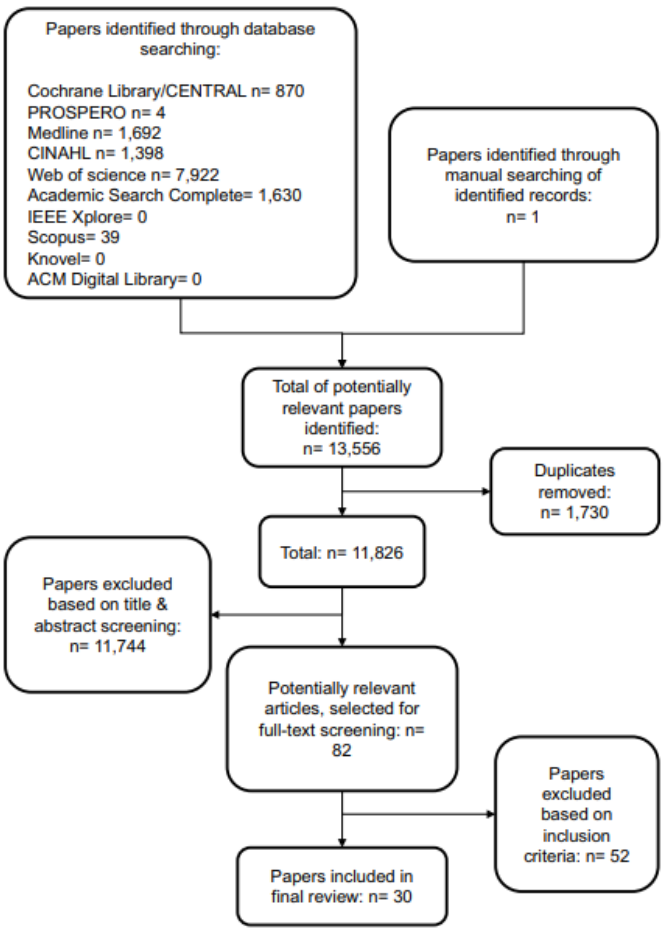

Figure 9 – Flowchart illustrating the results of the selection processes [2].

Prior to delving into the study of the selected paper in the context of our objective, we made the decision to update this systematic review to include the most recent studies, as detailed in the paragraph that follows.

3.3 UPDATE OF THE SYSTEMATIC REVIEW OF LAPARIDOU ET AL.

Given that the systematic review and meta-synthesis mentioned above encompassed studies published up to the year 2020, we endeavored to extend the temporal scope of our investigation to the present year, therefore spanning from 2021 to 2023. We preferred not to conduct a new research, but to update a previous one, since updating systematic reviews is considered, in general, more efficient than starting new systematic reviews when new evidence emerges, as reported in the Literature [3].

Employing an analogous methodology and search strategy to maintain methodological coherence, we sought to ensure that also the most recent papers were included. The only difference was that we restricted our search to PubMed. Although it is usual to perform thorough searches across many databases for systematic reviews and meta-analyses, this technique may not always be required or preferred for research that examines clinical aspects. We are certain that our choice to exclusively use PubMed for this study was reasonable and suitable. This decision showcases our strong dedication to maintaining rigorous methodology and ensuring clinical relevance in our pursuit of evidence-based medicine.

For the full search strategy used for the Medline database with specific filters, see Table 21.

Table 21 – Our search strategy and applied filters.

S1	robotic* OR robot* OR robotic therap* OR robot-assisted OR robot assisted OR exoskeleton* OR assistive robotic* OR walking robotic device* OR personal care robot* OR medical robot* OR assistive OR assistive automation OR wearable robot* OR orthotic* OR orthosis OR exoskeletal* OR exo OR end-effector OR haptic* OR robot regulation*
S2	rehab* OR intervention* OR treatment* OR therap* OR program* OR strateg* OR training OR physiotherap* OR physio-therap* OR "physiotherap*" OR "physical therap*"
S3	Qualitative research OR qualitative OR interview* OR focus group* OR ethno* OR phenomenolog* OR hermeneutic* OR grounded theory OR narrative analysis OR thematic analysis OR lived experience* OR life experience*
S4	(MH "Qualitative Research") OR "Qualitative research"
S5	S3 OR S4
Searched	**S1 AND S2 AND S5**
Applied Filters	*Published*: 2021-2023 *Language*: English *Species*: Humans

Our search strategy identified a total of 7.101 citations. After title screening, 106 papers were included. Subsequent abstract screenings narrowed down the selection to 23 papers for full-text screening. After reviewing the full-text, 7 papers were included in the analysis. Figure 10 shows a flowchart illustrating the results of our selection process.

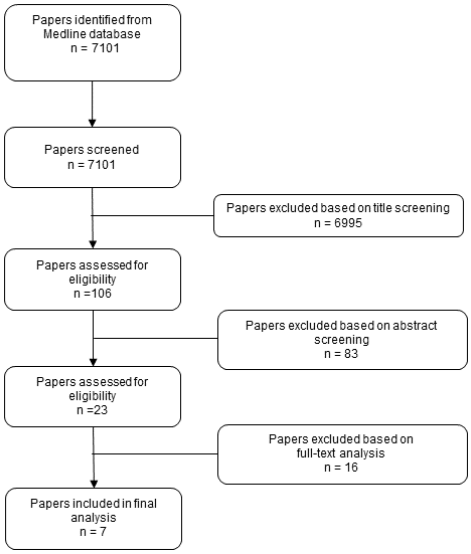

Figure 10 – Flowchart illustrating the results of our selection processes.

In accordance with the Authors' previous work, we create a Table (Table 22) that summarizes the characteristics of all the reviewed studies, namely, the 30 studies incorporated from the systematic review and meta-synthesis [2], as well as the additional 7 studies included in our investigation.

The table collects the aim(s) of the study, the sample (participants, healthcare professionals, caregivers involved), the condition and target area of rehabilitation, robotic devices included, the method of data collection and analysis employed in each study, and the use of tools based on the ICF framework. This table presents the key factors that were important for understanding the types of instruments used in Literature to gather the needs of patients and healthcare practitioners, and to identify any factors that might make them inappropriate for use within the Fit4MedRob Initiative.

Table 22 – Study characteristics of all reviewed studies.

Study	Aim(s)	Sample	Condition and target area of rehabilitation	Robotic device	Method of data collection and analysis	Use of the ICF framework
Ates et al., 2014 [4]; Three EU countries (unspecified)	To report on the technical challenges presented by the use of SPO and the feedback from therapists and patients	24 patients; no information about the therapists	Stroke; hand impairment	SCRIPT Passive Orthosis	Clinical observation and descriptive summary into themes	no
Basla et al., 2022 [5]; Switzerland	To investigate end-user perspectives and the adoption of an exosuit in domestic and community settings	7 patients; no information about the therapists	Multiple Sclerosis, Spinal Muscle Atrophy, Spastic paresis Bethlem Myopathy, Cauda-equina syndrome; walking rehabilitation	Myosuit	SUS and QUEST and one personalized questionnaire, semi-structured interview	no
Beveridge et al., 2015 [6]; Canada	To explore the experiences and perspectives of parents whose young, ambulatory children with CP were undergoing Lokomat gait training, and consider how parents' values about walking influenced therapy decisions for their children	5 mothers and 1 father of 5 children;	Cerebral palsy; walking rehabilitation	Lokomat	Individual, semi-structured, face-to-face interviews; followed the Dierckx de Casterle approach to analysis of qualitative data: the Qualitative Analysis Guide of Leuven (QUAGOL)	no
Bezmez and Yardimci, 2016 [7]; Turkey	To explore the role of a robotic gait training device and its role in rehabilitation in Turkey	42 participants; 7 doctors, 2 nurses, 2 physiotherapists, 2 non-medical personnel, 20 in-patients, and 9 former patients	Traumatic injury or illnesses; bodily disability and inability to walk	Lokomat	Individual, semi-structured inter- views; no information provided on the method of analysis	no

Cahill et al., 2018 [8]; Ireland	To gain an understanding of the experience of using a RWD within a gym-based setting from the perspective of non-ambulatory individuals with SCI	5 patients	Spinal cord injury; walking rehabilitation	Ekso™	In-depth semi-structured inter- views; thematic analysis	no
Danzl et al., 2013 [9]; USA	To investigate the feasibility of combining tDCS to the LE motor cortex with novel locomotor training to facilitate gait in subjects with chronic stroke and low ambulatory status; and to obtain insight from participants and their caregivers to inform future trial design	8 patients	Stroke; lower limb (gait) rehabilitation	Robotic gait orthosis	Semi-structured interviews; inductive thematic analysis	no
Eicher et al., 2019 [10]; Germany	To identify differences regarding usability, acceptability, and barriers of usage of a robot- supported gait rehabilitation system between a younger and older group of patients with gait impairments	13 patients	Stroke/brain haemorrhage, hemiplegia, other (e.g., acci- dents, falls, not specified); gait rehabilitation	Hybrid Assistive Limb exoskeleton	Structured interviews; qualitative content analysis by Mayring (2010)	no
Elnady et al., 2018 [11]; Canada	To describe users' perceptions about existing wearable robotic devices for the upper extremity; identify if there is a need to develop new devices for the upper extremity and the desired features; and to explore obstacles that would influence the utilization of these new devices	8 people with stroke; 8 therapists: 4 Physiotherapists, 2 Occupational therapists; 2 Rehabilitation assistants	Stroke; upper limb rehabilitation	Wearable Robotic Devices for the upper extremity	Focus groups; thematic analysis	no

Flynn et al., 2019 [12]; Australia	To explore occupational therapists' and physiotherapists' perceptions of robotic therapy for the upper limb and the perceived barriers and enablers influencing implementation	6 occupational therapists and 6 physiotherapists	Stroke; upper limb movement at the shoulder, elbow and hand (with the wrist fixed in neutral or pronation)	InMotion2	Focus groups; data were deductively analysed using the Theoretical Domains Framework (TDF)	no
Gilbert et al., 2018 [13]; UK	To determine whether or not the MUJO System was acceptable to patients with shoulder dysfunction and their rehabilitation professionals	10 patients and 7 physiotherapists	Shoulder instability (n = 6) and rotator cuff related pain (n = 4); rehabilitation of the rotator cuff muscles (bi-articular muscles or multiple axial joints)	MUJO System	Interviews; Directed Content Analysis was undertaken to organise the qualitative data according to the four constructs of Normalisation Process Theory (NPT)	no
Hampshire et al., 2022 [14]; UK	To gather users' and caregivers' perspectives on assistive device	6 patients and 2 caregivers	Stroke, Spinal cord injury, hereditary spastic paraparesis; walking rehabilitation	Assistive devices	Semi-structured interview	no
Heinemann et al., 2018 [15]; USA	To describe clinicians' experiences, evaluations, and training strategies using exoskeletons in rehabilitation and wellness settings	30 healthcare professionals	Spinal cord injuries; Standing and gait rehabilitation	Robotic exoskeletons (Ekso, Indego, ReWalk)	Focus groups; thematic analysis	no
Heinemann et al., 2020 [16]; USA	To describe appraisals of robotic exoskeletons for locomotion by potential users with spinal cord injuries, their perceptions of device benefits and limitations, and recommendations for manufacturers and therapists regarding device use	35 patients	Spinal cord injuries; Gait rehabilitation	Robotic exoskeletons (Ekso, Indego, ReWalk)	Focus groups; thematic analysis	no

Hochstenbach-Waelen and Seelen, 2012 [17]; Netherlands	To identify criteria and conditions that people, involved in development of rehabilitation technology for upper limb training of stroke patients, should take into account to achieve a (more) successful implementation of the technology in daily clinical practice	6 senior physiotherapists and occupational therapists	Stroke; upper limb rehabilitation	Technology-assisted arm-hand	Semi-structured interviews; method of data analysis was not reported	no
Hughes et al., 2011 [18]; UK	To understand the stroke participants' experiences of using the novel combination of a robotic arm and iterative learning control system and to gain greater insight into how systems might be improved in the future	5 patients	Stroke; upper limb rehabilitation	Robotic workstation	Two ways data were collected: comments were recorded during the time when participants were receiving the intervention and immediately following the clinical study, an interview-based question set was used; content analysis	no
Huq et al., 2012 [19]; Canada	To develop a portable robotic system with a haptic interface that facilitates the concept of rehabilitation at a remote location, e.g., at a home; to develop a GUI that integrates different control techniques and VR games in the same screen, and allows therapists to easily interact with the system; and to evaluate the current system with therapists in a focus group study	3 physiotherapists and 4 occupational therapists	Stroke; upper limb rehabilitation	Portable robotic system with a haptic interface	Focus groups; summary of findings	no

Kumar and Phillips, 2013 [20]; UK	To explore the views, experiences, benefits, and difficulties that users of one specific type of PMAS perceive, and deter- mine which areas of daily life they are used in	13 patients	Neuromuscular conditions; upper limb rehabilitation	Powered mobile arm supports	Semi-structured interviews; thematic analysis	no
Lajeunesse et al., 2018 [21]; Canada	To present the perspectives of individuals with ASIA C or D incomplete SCI concerning the usability of lower limb exoskeletons to R&D engineers and clinicians working in motor rehabilitation	13 patients	Incomplete spinal cord injury; lower limb rehabilitation	ReWalk exoskeleton	Individual, semi-structured interviews; inductive thematic analysis	no
Lebrasseur B.Erg et al., 2021 [22]; Canada	To evaluate the usability of an actuated arm support	9 patients; no information about the therapists	Multiple sclerosis Spinal, muscular atrophy, muscular dystrophy; upper limb rehabilitation	Gowing power-assisted arm support	Quebec User Evaluation of Satisfaction with assistive Technology (QUEST) and semi-structured interviews	no
Lo et al., 2020 [23]; Asia, Australia, Europe and USA	To inform rehabilitation clinicians about the various aspects of adopting and integrating robotic stroke therapy into clinical settings	8 rehabilitation therapists	Stroke and other neurological conditions, such as spinal cord injury, multiple sclerosis (MS), brain tumors and traumatic brain injuries; upper and lower limb training	Not defined	Semi-structured interviews; qualitative descriptive analysis	no
Louiea et al., 2022 [24]; Canada	To explore the experience and acceptability of an exoskeleton-based physiotherapy program for non-ambulatory patients from the perspective of patients and therapists	14 patients; 6 physiotherapists	Stroke; gait training	Ekso™	Semi-structured interviews and thematic analysis	no

Manns et al., 2019 [25]; Canada	To explore the expectations and experiences of persons with spinal cord injury, training with the ReWalk exoskeleton	11 patients	Traumatic spinal cord injury; standing and walking training	ReWalk exoskeleton	Semi-structured interviews; thematic analysis	no
McDonald et al., 2022 [26]; Ireland	To explore the usability and acceptance of RAGT in an acute hospital setting and to examine users' perceptions of two different modes of robotic assistance provided during rehabilitation	10 patients; no information about the therapists	Stroke; gait training	Ekso™	Semi-structured interviews of end-user perspectives and two 10-point Likert scales rating	no
Mortenson et al., 2020 [27]; Canada	To explore the experiences of physiotherapists with the introduction of an exoskeleton as a gait retraining device in a Canadian rehabilitation centre	10 therapists	Brain and spinal cord injuries; gait training	Ekso™	Semi-structured interviews; thematic analysis	no
Nasr et al., 2015 [28]; UK, Italy and Netherlands	To examine stroke survivors' experiences of living with stroke and with technology in order to provide technology developers with insight into values, thoughts and feelings of the potential users of a to-be-designed robotic technology for home-based rehabilitation of the hand and wrist	10 patients and 8 caregivers	Stroke; upper limb rehabilitation	Not defined	Application of qualitative methods such as in-depth interviews as well as using diaries and photography activities; thematic analysis	no
O' Brien Cherry et al., 2017 [29]; USA	To determine participants' general impressions about the benefits and barriers of using RT devices for in-home rehabilitation	10 veterans (plus their caregivers)	Stroke; upper or lower limb impairments	Hand Mentor™ and Foot Mentor™ devices	Direct observations and semi structured interviews; inductive thematic analysis	no
Phelan et al., 2015 [30]; Canada	To investigate the expectations and experiences of children with CP in relation to robotic	5 children and their parents (3 mothers and 2 fathers);	Cerebral palsy; gait rehabilitation	Lokomat Pro	Observations during sessions, semi-structured interviews with parents	no

	gait training using the Lokomat Pro				and use of a customizable "toolbox" of age-appropriate child-friendly techniques; thematic analysis	
Read et al., 2020 [31]; Canada	To explore how the training and implementation of using the Ekso robotic exoskeleton with patients affects physiotherapists' work	3 physiotherapists	Individuals with SCIs and hemiplegia due to stroke; gait training	Ekso™	One-on-one semi-structured interviews; thematic analysis	no
Shore et al., 2022 [32]; Ireland	To explore insights expressed by a cohort of older adults related to their life experience, their experiences using or assisting someone with assistive devices, and their perceptions of robots and robotic assistive devices	24 patients; no information about the therapists	Stroke; lower limb rehabilitation	Assistive devices	Semi-structured interviews	no
Sivan et al., 2016 [33]; UK	To evaluate the ICF as a framework to ensure that key aspects of user feedback are identified in the design and testing stages of development of a home-based upper limb rehabilitation system	17 patients and 7 physiotherapists and occupational therapists	Stroke; upper limb rehabilitation	Not defined	Face-to-face semi-structured interviews; analysis based on the updated International Classification of Functioning, Disability and Health (ICF) linking rules and core set categories	only for the analysis
Stephenson and Stephens, 2018 [34]; UK	To explore physiotherapists' experience of using RT in rehabilitation of the upper limb, within a stroke rehabilitation centre	6 physiotherapists	Stroke; upper limb rehabilitation	InMotion2	Semi-structured interviews; thematic analysis	no
Swank et al., 2020 [35]; USA	To describe therapists' clinical practice experiences with robotic gait training (RGT) over	10 physical therapists	Condition not specified; gait training	Ekso™	Semi-structured focus group; thematic analysis	no

	3 years during inpatient rehabilitation					
Swank et al., 2020b [36]; USA	To determine the feasibility of integrating the Ekso Gait Training device into inpatient rehabilitation in a neurologic population	Physical therapists (exact number not reported)	Stroke and SCI; gait training	Ekso™	Semi-structured focus group; thematic analysis	no
Sweeney et al., 2020 [37]; UK	To understand user perceptions in order to explain low uptake of upper limb rehabilitation interventions after stroke in clinical practice within the National Health Service (NHS Scotland)	8 patients	Stroke; upper limb rehabilitation	Not defined	Semi-structured interviews; thematic analysis	no
Tedesco Triccas et al., 2018 [38]; UK	To explore views and experiences of people with subacute and chronic stroke that had previously taken part in a randomised controlled trial involving tDCS and RT for their impaired upper limb	21 patients	Stroke; upper limb rehabilitation	Armeo Spring	Interviews involving open questions; thematic analysis	no
Thomassen et al., 2019 [39]; USA	To generate new knowledge regarding user experiences of standing and walking with Ekso	3 patients	Spinal cord injury (due to traumatic and non-traumatic reasons); standing and walking training	Ekso™	In-depth interviews in a phenomenological tradition; systematic inductive content analyses	no
Waibel et al., 2022 [40]; Germany	To investigate the chances and risks of robotic assistance systems in early neurological rehabilitation	No information about the number of patients; 9 professionals working in physiotherapy and nursing	Stroke; lower limb rehabilitation	Robotic assistance systems	Interviews	no

Ultimately, the current systematic review encompassed 37 studies, 30 studies [4], [6], [7], [8], [9], [10], [11], [12], [13], [15], [16], [17], [18], [19], [20], [21], [23], [25], [27], [28], [29], [30], [31], [33], [34], [35], [36], [37], [38], [39] spanning the period from 2011 to 2020, to which are added 7 studies [5], [14], [22], [24], [26], [32], [40], published between 2021 and 2023.

Studied were mainly from different *countries*: Canada [6], [11], [19], [21], [22], [24], [25], [27], [30], [31], USA [9], [15], [16], [29], [35], [36], [39], the UK [13], [14], [18], [20], [33], [34], [37], [38], Australia [12], Turkey [7], Ireland [8], [26], [32], Germany [10], [40], Switzerland [5], and the Netherlands [17]. One study [23] took place across various geographical areas (Asia, Australia, Europe and USA), one study [28] across three countries (Italy, UK, and the Netherlands), whereas another study [4] mentioned being conducted in three European Union (EU) countries, without specifying the countries.

Overall, the review included 480 subjects (to which must be added the therapists involved in six studies [4], [5], [14], [22], [32], [36], the exact number the number of whom was not reported). For each study, *sample sizes* ranged from 3 to 42 participants and most studies contained both men and women. According to the information provided, there were more male (n=209) than female (n=170) participants, while two studies included only male participants [29], [39]. Participants' ages ranged from 8 to 88 years.

Different healthcare professionals (n=152) were included, such as physiotherapists (n=113) [32], [33], nurses (n=5) [7], [33] and nursing assistants (n=3) [33], doctors (n=7) [7], non-medical personnel (n=2) [7], occupational therapists (n=12) [11], [12], [19], rehabilitation assistants (n=2)[11], rehabilitation therapists (n=8) [23], 6 studies [4], [5], [14], [22], [32], [36] did not report the number of therapists involved.

The majority of studies included patients (or their caregivers or their healthcare professionals) who had received rehabilitation after stroke (n=19) [4], [9], [11], [12], [17], [18], [19], [24], [26], [28], [29], [31], [32], [33], [34], [36], [37], [38], [40], or brain and/or spinal cord injury (n=8) [8], [10], [15], [21], [25], [27], [36], [39]. Two studies included children with cerebral palsy [6], [30]. Three studies [10], [23], [35] included participants necessitating rehabilitation intervention for different *clinical conditions*, including stroke, spinal cord injury, multiple sclerosis, brain hemorrhage, hemiplegia, or any other condition (e.g., accidents, falls, not specified). Similarly, three other studies [5], [14], [22] focused on participants with various rehabilitation-related conditions, including multiple sclerosis, spinal cord injury, muscular atrophy, muscular dystrophy, Bethlem Myopathy, Cauda-equina syndrome, hereditary spastic paraparesis. The remaining studies included conditions such as shoulder instability or rotator cuff-related pain [13], neuromuscular conditions [10], [20], [23], [35], and physical disability through traumatic injury or illness [7].

Furthermore, in these studies different robotic devices were included: EksoGT in the major of the studies [8], [15], [16], [24], [26], [27], [31], [35], [36], [39], ReWalk in four studies [15], [16], [21], [25] Lokomat in three studies [6], [7], [30], InMotion2 in two studies [12], [34], Indego in two studies [15], [16]. Other types of devices were encompassed such as orthosis in two studies [4], [9], assistive technologies in five studies [10], [14], [17], [32], [40] and various others [5], [11], [13], [18], [19], [20], [22], [29], [38].

To explore user's experiences and perceptions, most of studies utilized individual semi-structured interviews as their primary method. Seven studies performed focus groups [11], [12], [15], [16], [19], [35], [36]. Six studies [10], [14], [26], [40], [41], [42] conducted semi-structured interviews with both open and closed questions, recorded and transcribed verbatim. Two studies [5], [22] supplemented semi-structured interviews with the System Usability Scale (SUS) and the Quebec User Evaluation of Satisfaction with Assistive Technology (QUEST). One study [4] relied solely on clinical observations for data collection. Another study [29] combined direct observations with semi-structured interviews. One study [28] integrated in-depth interviews with diary entries and photography activities. Lastly, one study [30] employed direct observations alongside semi-structured interviews with parents, as well as interviews and activities involving children.

One study only [33] applied the ICF framework to analyze the outcomes of their semi-structured interviews.

In relation to the Analytical and descriptive themes mentioned by the Authors [2], the newly discovered articles might be included into the 6 analytical themes that were previously found (namely, Logistic barriers, Technological challenges, Appeal and engagement, Supportive interactions and relationships, Benefits for physical, psychological, and social functioning, Expanding and sustaining therapeutic options). Nevertheless, we did not prioritize these elements since they are outside the scope of our analysis. Indeed, as previously said, the primary objective of this literature search was to assess the instruments and their applications.

3.4 KEY FINDINGS OF THE SYSTEMATIC LITERATURE REVIEW

Overall, the examination of the current literature suggests developing an interview protocol aligning with the objectives of the Fit4MedRob Initiative. Indeed, some shortcomings of existing tools delineate their inadequacy in meeting the specific aims of our endeavor.

In general, in order to collect the needs of patients and healthcare practitioners regarding the use of robotics in rehabilitation, the literature employs mainly semi-structured interviews targeting small populations often with different pathologies and referring to the use of a single device. No studies used questionnaires/tools based on the framework defined by the ICF. One study only [33] applied the framework to analyze the outcomes of their semi-structured interviews, asserting that the categories of the ICF Comprehensive Core Set could serve as a foundation for structuring interviews to capture user feedback. Nonetheless, as far as we are aware, the Authors have not made similar tools accessible. During the planning phase of the Initiative, we deemed it essential to build surveys that were based on this framework, since it represents a common language to describe the health status of a subject, regardless of the specific disease. The possibility of investigating through ICF the degree of impairment of different functions in a subject is an extremely important aspect. In fact, as emerged from the literature, the acceptability of devices often depends on the level of disability [14]. The level of disability can be referred to individual functional domains (gait, balance, cognitive status, etc.) for patients with different diseases using the ICF.

In addition, various studies in the literature employ the same survey to examine the requirements of both patients and practitioners. In our opinion, to comprehensively capture a broad sample and acknowledge the distinct perspectives and expertise of patients and practitioners regarding technologies, different and specific tools are desirable.

The literature review also highlighted a series of limitations in the current knowledge that could be obtained regarding patient needs in relation to robotic rehabilitation, which we aim to overcome by developing specific surveys to be disseminated through the Initiative. Regarding sample size, the review shows that there are no studies investigating the needs of patients and caregivers on large sample sizes. Each study has a sample size that ranges from 3 to 42 participants. With respect to the investigated clinical conditions, the review shows that the needs of patients with major neurological conditions (stroke, spinal cord injury, multiple sclerosis, traumatic injury, cerebral palsy, neuromuscular conditions such as muscular atrophy, muscular dystrophy), also being studied in our initiative, were explored. It should be noted that there is a lack of specific studies on the analysis of needs in individuals with Parkinson's disease, limb amputation, oncological conditions, and frail individuals (populations also being studied by the Fit4MedRob Initiative). Thus, the current evidence in the literature does not explore the needs of the patients with all specific pathologies included in the Fit4MedRob Initiative. The devices used by the study populations are, when specified, only robotic devices for upper limbs and walking. No studies explored the experience of patients and therapists who used devices for balance treatment or devices for cognitive function treatment. Moreover, no studies have explored the experience of subjects who had used multiple devices simultaneously. Finally, there is a lack of wide studies on the needs of Italian patients and practitioners. The healthcare needs of patients in our country may vary from those of populations in other countries, primarily due to differences in regulations and legal frameworks that govern healthcare services across different regions in Italy, such as the duration of hospital stays and the range of services that can be provided at home.

In summary, the systematic review has not only claimed the lack of a suitable tool to be used for our scopes, but also identified several constraints within the existing body of knowledge concerning patient needs in the context of robotic rehabilitation, underscoring the necessity of addressing these limitations. To address this gap, we intend to develop tailored surveys that are precisely aligned with the target groups of the Initiative. These surveys will serve as a pivotal tool for gathering comprehensive and nuanced insights directly from patients. By disseminating these surveys through the Initiative, we aim to cultivate a deeper understanding of patient needs, with the ultimate goal of enhancing the effectiveness of robotic rehabilitation strategies.

4 DEVELOPMENT OF SURVEYS AIMED AT COLLECTING THE NEEDS OF PATIENTS

4.1 INTRODUCTION

In our effort to comprehensively address patients' needs by means of new developed surveys, we followed a step-by-step approach. We engaged in a systematic process to extract suitable ICF core sets to be employed in the selection of the functional domains to be explored in our surveys. This process was marked by an interactive approach, leveraging the insights of a diverse panel of stakeholders. This panel included clinicians representing various specialties, as well as representatives from parents' and patients' family associations. Through this collaborative effort, we aimed to ensure that the identified core sets accurately reflect the multifaceted needs of the patient population we serve, with the ultimate goal of develop surveys aimed to systematically collect patients need recruited through the Initiative.

The following paragraphs set out the methodological approach employed in drafting the surveys. The overarching aspects crucial for idealising, designing and realising similar questionnaires are first discussed, followed by a detailed account of the specific steps taken to address these aspects (as detailed in paragraph 4.2). Subsequently, a more comprehensive examination of the research and clinical questions that guided our investigation is undertaken, focusing on the development process and the content of our surveys (paragraph 4.3). Finally, in paragraph 4.3, we analyse the legal considerations associated with distributing the survey to patients and detail the corresponding actions taken in response.

4.2 METHODS FOR SURVEY IMPLEMENTATION

Patient care should involve the patient and their family in clinical decision making. This has been shown to play a role in improving health outcomes, increasing satisfaction with the care experience, reducing costs and even benefiting the clinician's experience [43]. In this context, the use of survey methodology to obtain their views about their care allows researchers to obtain information that is not routinely collected in other traditional ways [44]. Where available, the use of validated survey instruments is clearly preferable, but where this is not possible, the construction of an ad-hoc survey may be a solution. Although the design, administration and interpretation of a survey may seem intuitive and straightforward, several biases at the design level may affect the respondent's ability to provide an accurate response or the researcher's ability to interpret the results in a meaningful way [45]. Therefore, clinicians need to be aware of all these issues and try to overcome them. A review of the existing literature on the methodology to be used for surveys (both when using an already validated survey and, in particular, when building them from scratch), did not reveal any available ready-to-use tool suitable for our scopes, so we were prompted to idealize, design and realize ad hoc surveys. We started by trying to summarize the characteristics of surveys used in the health sector [46], with the aim of extracting some sort of guideline to be used in the process of constructing the surveys.

The aspects considered could be listed as follows:

1. the design of the survey;
2. the mode of administration of the survey;
3. the content of the questions of the survey;
4. the effort in filling in the survey;
5. the number of questions of the survey;
6. the pretesting;
7. the surveys distribution.

Each aspect is described in detail below, together with the source of the literature and the solution adopted in the Initiative.

4.2.1 The design of the survey

The first step in survey design is to define the research question and select the appropriate study design, which can be either descriptive or analytical. The American Paediatric Surgery Association (APSA) recognizes the “value of surveying its members to identify practice preferences, changes, and decision making by surgeons and has established its guidelines for surveys of APSA members” [47] .

Action taken: In our case, we opted for a descriptive survey, which does not presuppose any hypothesis, but serves to collect data that will be reported to understand the general trends, incidence and prevalence of the outcome of interest, which in our case was the rehabilitative care provided and the rehabilitative needs, with particular reference to both traditional and technological treatment.

4.2.2 The mode of administration of the survey

There are several potential approaches to administering a survey, including face-to-face interviews, telephone interviews, self-completion questionnaires and computer-assisted methods [46]. There is no clear evidence that responses to sensitive questions differ between these various administration methods. Furthermore, no single method consistently outperforms all others.

Actions taken. In the Initiative, we opted for a self-completion approach utilizing an internet-based tool (Google Forms) that can be readily managed by all users via their personal smartphone, computer or tablet. This approach allows users to select the most suitable time and engage in an interactive process.

4.2.3 The content of the questions of the survey

In order to employ survey methodology to answer a question, it is mandatory to understand how to craft questions in an unbiased, understandable, and inviting way in order to engage the respondents and inspire them to give the most truthful answer possible. Furthermore, completing surveys typically requires the ability to read and comprehend. It is recommended that words such as "usually" or "few" be avoided in favor of phrases that are temporally related, such as "once a week" or "at least once a year" [47].

Actions taken. In order to accommodate the diverse needs of our target population, we have developed three distinct survey instruments: one for collaborative patients, one for caregivers of adults, and one for caregivers of children. In the latter two cases, respondents are asked to express the patient's needs. Additionally, we have incorporated visual aids to enhance the clarity of our questions. The process of review included patients’ associations of both adults and children to ensure that the question was written objectively. Moreover, we selected terms very clear in terms of frequency, as advised.

4.2.4 The effort in filling in the survey

The act of completing a survey inevitably occupies a significant portion of a respondent’s time, and it often necessitates the disclosure of personal feelings and impressions. Consequently, it can be challenging to obtain responses to surveys on sensitive topics. Online study design has been identified as an optimal approach for collecting more responses in surveys where such topics are addressed. The literature recommends the following strategies for overcoming this challenge: the use of financial incentives, the communication of the importance of the survey, and the creation of an easy-to-use survey administration. It is recommended that a 5- or 7-point Likert scale be employed, with 5 points being the most commonly used [44].

Actions taken. An online tool is employed to facilitate the usability of the surveys, which can be completed at a convenient time for the families. Furthermore, the involvement of patients’ associations serves to raise awareness of the importance of data collection. A 5-point Likert scale was selected to collect precise and detailed data, thus avoiding the uncertainty that might arise from using a greater number of points.

4.2.5 The number of questions of the survey

In general, surveys should be relatively brief in order to avoid survey exhaustion and inaccurate responses. Moreover, the order of the questions is of paramount importance. It is advisable to begin with broad, easily answered questions, with subsequent questions regarding the same topic grouped together [48].

Actions taken. In our case, we initiated the survey with general questions and employed a ramification concept with a yes/no choice at the beginning of each section to ascertain whether the respondents found the questions meaningful and to enable them to answer only the question of main interest. We also grouped the questions according to the main functional domains involved (such as motricity, communication, and so on).

4.2.6 The pretesting

Once a survey instrument has been created, it must be pretested. This process should involve an informal administration of the new survey instrument to members of the target population, with the aim of determining the readability and ease of survey administration. This is crucial to ensure the validity of respondents' answers prior to the formal distribution of the survey and to identify any errors in coding or awkward words used. Furthermore, pretesting is essential for gaining insight into the optimal timing of a survey and for determining whether survey questions elicit responses that align with the intended purpose of the question [49].

Actions taken. The surveys were tested with various Fit4MedRob personnel, both clinically oriented (such as physicians or therapists) and non-clinically oriented (such as engineers). Specifically, the surveys were tested by 5 physicians, 8 physical therapists, and 4 biomedical engineers. These personnel were selected to represent a range of backgrounds and expertise. Additionally, feedback was sought from patient associations regarding the readability, length, and potential misunderstandings of survey contents.

4.2.7 The surveys distribution

The preliminary evidence indicates that distributing survey links via social media accounts of individual users and organized e-groups with an interest in specific health issues may increase the engagement and accuracy of responses. [50].

Actions taken. We employed institutional channels of all the clinical centers involved in the Fit4MedRob Consortium and of the several patients' associations (see Appendix 1) to enhance participation. Additionally, we leveraged social media of all the clinical centers involved in the Fit4MedRob Consortium and in-person events (such as the Fit4MedRob conferences showing an ad-hoc QR codes) to facilitate engagement. Moreover, we ensured that the visual recommendations [46] were meticulously adhered to, including aspects such as colors, pagination, cover design, and so forth.

4.3 SURVEY DEVELOPMENT

The literature findings, reported in the previous section, provided some insights into the available tools to be used to collect patients' needs. However, due to the limits described above, we proceeded with the creation of ad-hoc surveys that may systematically gather the different perspectives of the target groups. The choice to use user-friendly online tools, such as Microsoft Office Forms, which can be easily accessed and completed on any smartphone, has been taken with the objective of maximizing the inclusion of patients and their families. The primary objective of these surveys was to provide a comprehensive assessment of the rehabilitation needs and their perception about the use of technology in rehabilitation.

The initial requirement was to determine a shared set of user requirements that could address the needs of all users, i.e., regardless of the clinical condition, to encompass as much patients as possible and highlight a wide variety of rehabilitative needs. In this perspective, as previously reported, during the planning phase of the Initiative, it was deemed essential to construct surveys based on the ICF framework. Therefore, we began by reviewing the ICF core set of all the clinical conditions included in the Initiative, when available (https://www.icf-research-branch.org/icf-core-sets/category/8-neurologicalconditions). We conducted a comprehensive analysis of all core sets, including both disease-specific sets available and the generic core set on rehabilitation. Based on the ICF, all of the identified specific needs belonging to different functioning areas (i.e., motor, cognitive, self-care, etc.) have been listed and categorized according to the primary overall domain to which they were referred (for instance, "solving problems" under the cognitive domain). Following the identification of the individual rehabilitation needs, we developed a table to verify which of the needs were the most representative for the target groups (Table 23). The table indicates in green whether each individual ICF core set is associated with one of the diseases covered by the Initiative. Since there were no specific ICF core sets for some pathologies, the generic core set has also been taken into consideration. Additionally, at various stages of the process, professionals within the Fit4MedRob Consortium and patients'

associations (see Appendix 1) were met in person and during online meetings to ensure that all the specific needs were represented.

Table 23 – ICF Core sets analysis

ICF CORE SET			CEREBRAL PALSY	POST STROKE	MULTIPLE SCLEROSIS	ACQUIRED BRAIN INJURIES	SPINAL CORD INJURIES	POST ONCO SURGERY	GENERIC
cognitive	solving problems	d175							
cognitive	making decision	d177							
cognitive	undertaking multiple tasks	d220							
cognitive	carrying out daily routine	d230					EARLY POST-ACUTE		
communication	communicating with - receiving - spoken messages	d310							
communication	speaking	d330							
communication	pre-talking	d331							
communication	producing non-verbal messages	d335							
communication	conversation	d350							
communication	using communication device and techniques	d360					EARLY POST-ACUTE		
posture	changing body position	d410							
posture	maintaining body position	d415							
mobility	moving objects with lower extremities	d435					EARLYPOST-ACUTE		
upper limbs	fine hand use	d440							
upper limbs	hand and arm use	d445							
mobility	walking	d450					EARLY POST-ACUTE		
mobility	moving around	d455							
mobility	moving around in different locations	d460							
mobility	moving around using equipment	d465							
self care	washing oneself	d510							
self care	caring for body parts	d520							
self care	dressing	d540							
self care	eating	d550							
self care	drinking	d560							
communication	basic interpersonal interactions	d710							
communication	complex interpersonal interactions	d720							
communication	informal social relationship	d750							
communication	family relationship	d760							
cognitive	engagement in play	d880							

Within this careful selection of the ICF items, we identified the most common and the most significant functional domains that cover the pathologies and the functional targets of the technologies envisaged in the Initiative by means of the feedback provided by several patients' associations.

In particular, we grouped the specific ICF items in some macro-categories, belonging to a more general domain. For example, all the ICF items related to the activities such as walking, moving around with or without walking aids and so on were grouped in the domain "mobility", referring to all the potential different ways of moving in different environments. The same for every change of posture, describing, for example, the movement from sitting to standing or vice versa, including in the domain "postural function". Following this reasoning, we then identified the following 6 main domains (first column of the figure above), which grouped specific ICF items:

i. mobility function;
ii. postural function;
iii. cognitive function;
iv. communication function;
v. self-care;
vi. upper limb function.

For each domain, we further created an explicative definition to explain it more in detail, also considering the specific potential differences among ages (e.g., the specific needs related to pre-talking and speaking in the "communication function" for very young children).

The objective was not merely to analyze the global clinical picture, but primarily to identify the needs based on the specific functioning of the patients in the six specific domains. Consequently, the surveys were structured with an **initial generic section** containing information on the individual characteristics (such as age range and referral clinical center). This was followed by a 5-point Likert scale analysis of the following topics for each considered domain:

- ***Independence in the considered domain***: based on some common classification systems of the functioning based on different abilities (such as the *Gross Motor Function Classification System*, which describes the ability in performing movements such as sitting, walking and the use of mobility devices, or the *Manual Ability Classification System* for the use of the hands in handling objects in daily activities), we decided to ask for the patient's independence level and the potential need of assistance from others or from assistive aids and devices;
- ***Impact of the limited independence in the considered domain:*** stating the potential impact of the above-described limitations in everyday life tasks, the second question was related to the quantification of the impairment related to the possible solutions and strategies adopted (such as in the case of a device for allowing the communication to non-verbal people);
- ***Current rehabilitation treatment (traditional and technological) related to the considered domain.*** With the aim of collecting data about the details of the rehabilitative treatment carried out, for each domain two different sets of question were included:
    - the first was related to the *traditional treatment*, i.e., rehabilitation without technology. The questions were related to the frequency, the satisfaction and, in case of absence of the treatment, the will and the need of the treatment, and the setting of the current treatment (in-clinic or at home);
    - the second part of the questions were focused on the *rehabilitative treatment involving the use of any technological devices*. As for the traditional rehabilitation, questions were related to the frequency, the satisfaction and, in case of absence of the treatment, the will and the need of the treatment, and the setting of the current treatment (in-clinic or at home). In detail, an open question has been planned to ask the name of the used device, to have an idea of what is more used by patients and to which device the answers were based on.

The questionnaires were structured with a ramification concept, so that the questions appeared on the basis of the previous answers (i.e., if the respondent clicked "no" to a treatment in one domain, he/she automatically went to the next domain). This organisation was defined together with the parents' associations and was aimed, on the one hand, at providing the possibility of obtaining specific data on each specific rehabilitation domain (highlighting tailor-made needs), and on the other hand, at avoiding too long questionnaires that could require too much effort. In the

second step of the construction of the online surveys, some images were added to give an immediate visual impact to the subject of the questions, trying to limit the possible errors due to the redundancy of the sentences.

Recognizing the importance of the economic impact on the families, a final general section of questions was dedicated to the collection of the costs of rehabilitation. Starting with a yes/no question on the provision of rehabilitation (both traditional and technological) by the national health system, in case of treatment paid by the family, specific costs were investigated: for the devices (i.e., walking aids or rental of some assistive devices), home adaptations (i.e., ramps), special food (supplements), transportation, people hired for assistance (both sanitary as a nurse or non-sanitary as a babysitter), as well as the reduction of salary for the need of assistance to the patients by the carers. For each of these questions, different cost ranges have been proposed, based on the general costs traditionally described for rehabilitation.

Finally, at the end of all six domains and the economic part, the subject is asked to rank all the domains described in order of importance, i.e., to list them hierarchically from a subjective perspective.

Therefore, the general structure of the survey has been defined and all the feedback from the various patients' associations has been incorporated. Then, based on the population of the Initiative, including several different diseases and a wide age range, we decided to create different forms of the survey:

- One for the collaborative adults, who could answer themselves, and for the collaborative teenagers, who could choose to answer themselves;
- One for the caregivers of adult patients, who can answer for them or together with them;
- One for the caregivers of young patients (children), who can answer for them or, in the case of teenagers, together with them.

For this reason, QR codes have been created together with the link in order to maximise dissemination and ease of access.

4.4 SURVEY DISSEMINATION: LEGAL ASPECTS

Legal issues concerning the legal aspects related to the survey dissemination were discussed by Fit4MedRob clinical centers in connection to A4. Several interested DPOs of clinical center shared relevant parts of their routine documentation on data processing for suggestions and improvements.

The aims of these actions were: (1) to help determining the possibility to re-contact patients for participation in an anonymous survey for medical research purposes; though the assessment was performed autonomously by each facility the joint efforts within the Initiative enabled forms of harmonized actions; (2) to define how the surveys would be disseminated to patients and caregivers in compliance with the privacy rules; this activity contributed to the drafting of an ad hoc information sheet explaining to the patient the objectives of the Initiative, the surveys and the legal basis justifying the recontact.

Upon the mentioned action 1, it was determined that only patients who had consented to be re-contacted for medical research purposes could be contacted, unless legitimate interest would apply in given cases, exclusively by e-mail containing the link to the survey (and not solicited). Juridically, patients could be contacted by:

- a private entity relying on the legitimate interest (Art. 6(1)(f), Art. 9(2)(j) Reg. EU2016\679) as per the Legitimate Interest Analysis eventually performed by each interested clinical center;

- a public entity to which they have given permission to re-contact them (consent Art. 6(1)(a), Art. 9(2)(j) Reg. 6(1)(a), Art. 9(2)(a) Reg. 9(2)(a) EU2016\679).

Within the second action several alignment meetings with the DPOs of some clinical centers were performed. Given the positive feedback and the availability of patient associations to disseminate the surveys, a single information sheet (common to all clinical centers) was produced to legitimize the invitation to patients from clinical centers, entities, patient associations, or other parties to fill in the survey to be adapted by each contacting entities according to their specificities. The information sheet informs patients about the proposed survey, and their rights, in a clear and intelligible way. In detail, the final information sheet included the following:

- Information on the objective of the Initiative;
- a declaration that the survey is designed to be anonymous (it does not collect personal data within the terms of EU Reg. 2016\679) and explain how this is accomplished;
- a declaration of the different legal bases (necessarily in unified form given the possible different legal bases);
- a clarification of the possible legal bases legitimizing the invitation from clinical centers, entities, patient associations, or other parties in order to reiterate all the rights exercisable in each case against the inviter.

It should be noted that the information sheet is not only distributed (i.e., e-mail) by the individual clinical center contacting the patients, but also has to be reviewed by the patient at point 3 of the surveys. Only upon reading and accepting the information sheet, will be possible to proceed with the survey, thus expressing voluntary and informed participation without ever having to process any personal data. Furthermore, the patient may discontinue the survey at any time and without any repercussions. None of the answers entered up to the moment of abandoning the process will be stored or used in any way, as per the information sheet. At the end of the survey, participants are queried as to their intention to be contacted for further survey-related activities. Only upon the participant's consent will they be asked to provide their contact details, which will never be technically linkable to their survey responses. Their contact details will be only used to contact them for invitations to future research activities or to provide updates on the progress of the Initiative.

4.5 NEEDS OF TARGET GROUPS: NEXT STEPS

All activities carried out from the beginning of the Initiative to month 6, above reported in detail led to the surveys' development in three different versions. They were submitted on 15 May, 2023 to the Ethical committee for their approval before dissemination. The latest version of the surveys, along with all the documentation submitted to the Joint Ethics Committee of the Scuola Normale Superiore and the Scuola Superiore Sant'Anna di Pisa for their evaluation and subsequent revisions, will be detailed in deliverable D1.1.2. The Plan for data analysis and first results of patient surveys will be reported in the deliverable D1.1.3. Finally, the results of the patients' surveys will be reported and discussed in the deliverable D1.1.4. The next steps are summarised in Table 24.

Table 24 – Next deliverables reporting the update of the deliverable D1.1

Deliverable ID	Deliverable name	Month of deployment
D1.1.2	Ethical Committee documentation	M9
D1.1.3	Plan for data analysis and first results of surveys	M12
D1.1.4	Survey outcomes	M15

LIST OF ABBREVIATIONS

Fit4MedRob	Fit for Medical Robotics
HTA	Health Technology Assessments
LL	Lower limbs
UL	Upper limbs
VR	Virtual reality
CoP	Center of Pressure
ICF	International Classification of Functioning, Disability and Health
APSA	American Paediatric Surgery Association

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APPENDIX 1

List of patients' associations involved in the development and dissemination of the surveys:

- Association for patients with acquired brain injury (RISVEGLIO)
- Association for the Fight against Cerebral Stroke for patients with stroke (ALICe)
- FightTheStroke for patients with stroke
- Italian Diabetic Association for patients with diabetes (FAND)
- Italian Federation for Overcoming Handicap for patients with different handicaps (FISH)
- Italian Federation of Voluntary Associations in Oncology for oncology patients (FAVO)
- Italian Multiple Sclerosis Association for patients with multiple sclerosis (AISM)
- National Federation of Traumatic Brain Injury Associations for patients with traumatic brain injury (FNATC)
- Parkinson's Association Lombardia for patients with Parkinson's disease (APM)
- Soft Tissue Sarcoma Patients Association for patients with sarcoma (SARKNOS)