[ITA] Manifestazione di interesse rivolta a produttori di robot health care o personal care – Annex I

[ENG] Expression of interest targeting healthcare and personal care robots and technology producers – Annex I

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Fit4MedRob
Fit for Medical Robotics

A new generation of biorobotic and digital technologies for a sustainable welfare

Abstract

Fit for Medical Robotics aims to revolutionize current rehabilitation and assistive models for people with reduced or absent motor, sensory, or cognitive functions, by means of novel **(bio)robotic** and allied digital technologies and of **continuum of care** paradigms that can take advantage of the novel technologies in all the phases of the rehabilitation process, from the prevention up to the home care in the chronic phase. This will be possible by carefully identifying the **unmet needs** of patients and healthcare practitioners, and by tackling them with current and novel (bio)robotic/bionic technologies, via multi-centric **clinical trials** jointly conceived by bioengineers, neuroscientists, physiatrists, psychologists and functional/preventive limb surgeons. Such a new continuum-of-care paradigm will start from the prevention and will target all phases of the disease, from acute (bed-side) to chronic (home-rehabilitation) and will contribute to the design of new pre-habilitation protocols and of diagnostic tools for fragile individuals or workers exposed to occupational diseases or repetitive stresses. *Fit for Medical Robotics* will focus both on already available technologies not yet fully validated, and on emerging technologies or breaking-through ideas to be explored throughout the project. Hence, **foundational studies,** involving new materials, algorithms, smart sensing and actuation technologies, as well as sustainable power sources, will sought to overcome the limitations of current robotic solutions, which have prevented their massive spread as *physical* care providers, in order to pave the way to the next generation of biomedical robotic systems. Not less important, the clinical, scientific, and technologic efforts will be matched on the **policy, regulatory** and **organizational** sides in order to **accelerate** the setup of an adequate framework apt to incorporate (in a sustainable manner) current and future technologies and protocols in the healthcare system as well as to sustain the innovation they will bring about.

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Motivation and Relevance

Fit for Medical Robotics aims to address a major clinical, socioeconomical and humanitarian issue which stems from the demand of rehabilitation and personal care of people with reduced or absent motor, sensory, or cognitive functions due to injuries or congenital reasons. Current rehabilitation and assistive models offered by the national healthcare system lack in personalization and adequate *continuum of care* through-out all the phases of the rehabilitation process. Hence, excluding few exceptions nationwide, rehabilitation outcomes are typically unsatisfactory for the patients albeit expensive to the system.

Biorobotics i.e., a *melting pot* of technologies spanning from bioengineering to robotics, including artificial intelligence, controls, sensors, smart materials etc., has been proposed as an appealing option to improve the clinical outcome of physical rehabilitation and personal care treatments in a sustainable manner. This because of the unique combination of features offered by robots: they host sensors and computational reasoning to understand and decipher environmental or patients' intentions, and they have physical bodies that *do actions* in response to such reasoning. In turn, rehabilitation robots could offer patient-specific physical treatments, by performing repetitive movements, automatically adapting to evolving conditions, and could do this continuously, and both in parallel and individually. Robotic prostheses or exoskeletons seamlessly controlled and felt by the individual could efficiently restore lost or weak locomotion or prehensile functions, improving the patient autonomy. Personal care robots, integrated with wearable or environmental IoT devices, may assist frail individuals in their daily living, and, at the same time, extrapolate digital biomarkers and behavioral features for prevention, therapy adaptation and monitoring. These few examples enlighten why such technologies have been considered by researchers and healthcare policy-makers, as promising and possible solutions to improve, or eventually aid more conventional therapies.

In the past two decades, robotics fulfilled the promise indeed, albeit only in specific cases, i.e. where patient, therapy and robot were matched. An aphorism depicting the situation argues: "*There is no* one patient, *no* one therapy *and no* one robotics: *there is the* just right *robotics and therapy for the* just right *patient."* Sadly, even where robotic technologies clinically succeeded, and gave rise to investments towards the creation of new business and products, they crashed against legal and procedural barriers, thus failing in being included in the national and regional healthcare policies and regulations or adopted by rehabilitation hospitals. As a fact up-to-date rehabilitation robots and treatments as well as assistive robots like prostheses or exoskeletons, may enter the Italian healthcare system in a scattered rather than systematic manner, with a dramatic delay with respect to other European countries, and if/when this happens, they become available only in few clinical centers, typically to the wealthiest portion of the population. Similar difficulties were faced by those robotic systems meant to provide preventive treatments like personal care or occupational robots. This is due to a blend of reasons: the lack of their clinical evidence, of standards and of their long-term sustainability, their cost – still relatively high and not yet supported by ad-hoc social services or business models –, the reluctance by healthcare providers to change the way they provide social and health care, and finally, the still partially immaturity of certain technologies to enable robots co-existing (interacting) with humans in domestic or working (unstructured) environments.

Nevertheless, from a broader perspective, in the last decade we have witnessed massive technological and scientific advances: the rise of wearable and implantable devices, of robotics into factories, AI and big data, phygital services, new materials and biomaterials, functional surgical techniques, all complemented by a significant reduction of the costs to afford them. This suggests that robotic rehabilitation/treatment represent a terrific opportunity (up to now untaken) to offer a better and more efficient health care, improve the quality of life of millions of individuals, potentially generating new jobs, contributing, in parallel, to knowledge – in the neuro-robotic fields – that may have important spill overs into many other sectors of technology, services and industry, such as more durable batteries, faster and more efficient microcomputers and algorithms, AI techniques, novel manufacturing techniques, and so on.

In the past few decades, the members of the Consortium have significantly contributed to these areas and gained a significant international reputation, as proven by hundreds of scientific papers, prestigious grants/awards (e.g., ERC grants), clinical trials, and spin-offs. Such past projects, however, to small in size and rarely pooled, could tackle the problems only marginally (technically or clinically, or focusing on specific technologies) and seldom failing in capturing the overall picture, not including the legal and economic aspects.

For all the above considerations, a major national initiative capable of bringing together all the interested parties, addressing these challenges in a systematic and comprehensive way can not be delayed anymore. **This is the right time.**

We believe that healthcare and personal care robots can address the clinical, socioeconomical and humanitarian demand they are called for. Yet we believe that there is space for a substantial change in the legal and economic policies for which such robots/systems enter and are adopted by the Italian healthcare system(s), within a continuum of care paradigm. To this end it is imperative to set an interdisciplinary initiative including physicians (raising clinical questions), bioengineers (finding technical solutions) and social scientists (ensuring the solutions can be adopted).

Societal, scientific, technological and clinical goals

Fit for Medical Robotics aims to cover technological, economical, legal and policy gaps currently present in the Italian healthcare system, that have prevented nationwide clinical adoption of first-class, patient-specific therapies/treatments, **robotic and digital treatments**. This will be possible by tackling the following Objectives:

- **O1**: **Identifying** the **needs** of the patients and rehabilitation practitioners/therapists, associated to specific selected pathologies, unmet with current robotic technologies.
- **O2**: **Tailoring** the most advanced and **ready-to-use** (i.e., available today) families of rehabilitation, assistive-, and occupational- robots to the aforementioned needs and patients, and to neuroscientific-based protocols.
- **O3: Clinically assessing** such available robots and thus provide conclusive clinical evidence of their efficacy when tailored to different target groups of patients/individuals.
- **O4: Performing** a detailed cost-benefits analysis of such clinical assessments in order to assess their **sustainability**.
- **O5: Optimizing** the clinical protocols in order to create specific paradigms for boosting the inclusion of healthcare and personal care robots in the medical, rehabilitation and occupational environments.
- **O6**: **Developing** and promoting with **policy** makers and stakeholders the inclusion and democratization of sustainable robots and treatments in the national healthcare system also by developing specific economic, business and reimbursement models as well as by shaping them in a way that fit also in existing private law tools used in the welfare system.
- **O7**: **Preparing** for the **next generation** of healthcare and personal care robots (and to robotics in general) by promoting the investigation of new hypotheses/ideas and technologies, including nanoengineered smart (bio)materials, and sustainable power sources attempting to overcome the main limits faced by current robots used as physical care givers.

These objectives represent an enormous challenge, with a potentially formidable impact for the patients, the healthcare system, the scientific and technological domains, the citizens and, in general, for the entire socio-economic system of our country. The partners of the initiative are well aware of this and as such have been built a highly multidisciplinary Consortium made of clinicians, scientists, engineers, economists and entrepreneurs to address the problem from all relevant perspectives (social, industrial, clinical and social). To address these objectives, the initiative is organized in three interconnected research Missions (M) (Fig. 1), each one conveniently overseen by one Spoke, following what the Call is asking:

- Mission 1: Clinical Translation & Innovation;
- Mission 2: Biorobotic Platforms & Allied Digital Technologies;
- Mission 3: Next Generation Components.

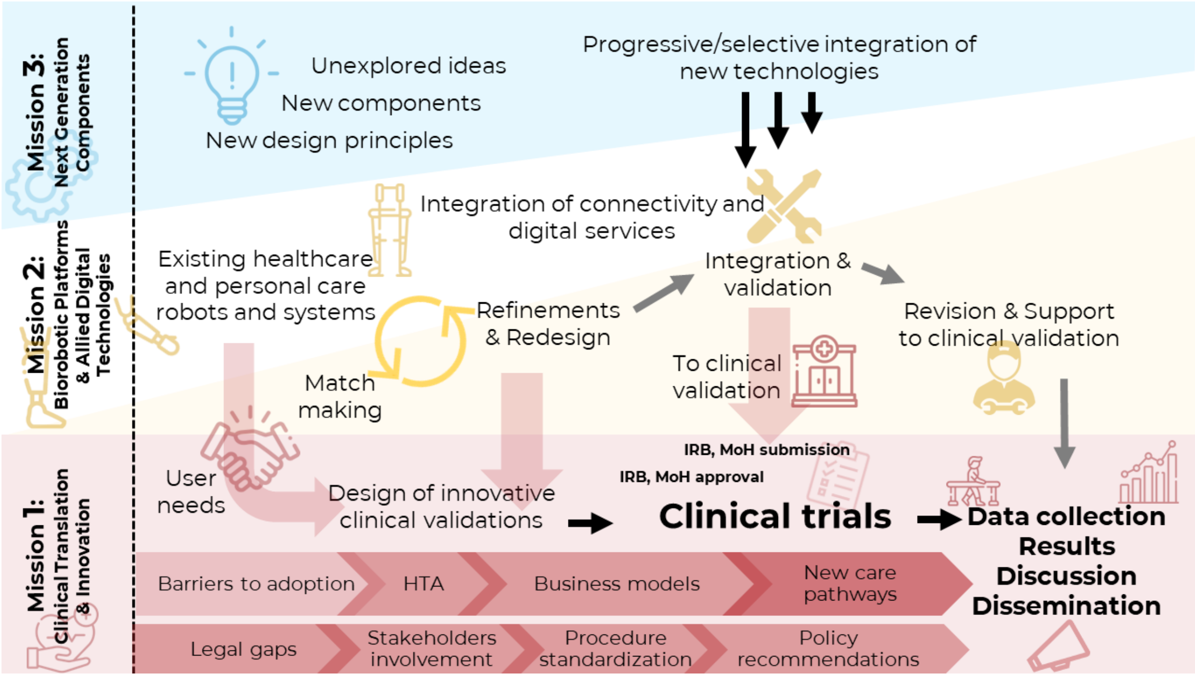

Fig. 1 Graphical representation of the interactions and main activities within the three Missions of Fit4MedRob.

Mission 1 – Clinical Translation & Innovation – Spoke 1

The first Mission, handled by Spoke 1, is the core of the Initiative and is devoted to translational, technology assessment and legal activities. It aims to run extensive, in terms of number of patients and/or duration, multi-centric, clinical trials using **healthcare or personal care robots** available to or developed by the Consortium within Mission 2. Besides identifying their clinical efficacy and evidence (and limits), such treatments will also be assessed in terms of generated value from the perspectives of the involved stakeholders (final users and their families, workers and healthcare professionals, hospital facilities, payers, e.g., insurers, healthcare systems, etc.). In parallel, pivotal actions aimed at understanding and overcoming current legal barriers within the healthcare system will be implemented.

Clinical validation of robotic rehabilitation and treatment

The initiative is tailored around two target groups:

1. patients at all ages with reduced sensorimotor and/or cognitive functions requiring for rehabilitation, assistance and/or support;
2. individuals at risk exposed to aging processes or to muscle-fatiguing working conditions, that could improve their quality of life/job by means of preventive treatments or measures

Hereafter we will refer to them as *target individuals*, *target groups*.

At a glance, clinical activities aim to:

- Identify the technological, societal and methodological barriers to the adoption of healthcare, personal care robots and allied digital technologies into real-life rehabilitation/pre-habilitation scenarios;
- Identify the age-related unmet needs of target groups and their practitioners and translate these in functional and technical requirements which could be fulfilled by specific robotic treatments;
- Define suitable neuro-scientific experimental protocols and metrics;
- Prepare the ethical clearance documentation;
- Run clinical trials of the (healthcare and personal care) robots made available by Spoke 2;
- Provide scientific and clinical evidence of the benefits of healthcare and personal care robots tailored to specific target groups;
- Provide evidence-based feedback to bioengineers involved in the design of the next generation of healthcare and personal care robots.

Sustainability of robot rehabilitation/treatment is not a choice

Measuring the potential organizational, economic and non-economic impact of the proposed robotic solutions in their advanced phase of development is pivotal for understanding their short- and long-term sustainability. This will be done by health technology assessment experts, by identifying: relevant indicators and KPIs (key performance indicators) pertaining current organization of rehabilitation services and robotic solutions; cost models associated to the short and long run impact of the robotic solutions, and so on. These metrics, combined with quantitative and qualitative data (validated questionnaires, focus groups and structured interviews) will be analyzed using state of the art techniques to assess the sustainability indexes of the robotic solutions for each stakeholder involved (e.g., incremental cost effectiveness and cost benefit analyses, organizational changes analysis, budget impact analyses, probabilistic sensitivity analysis, etc.), in order to provide inputs to improve it, to propose policies for their reimbursement and to define business models and business plans to aid them becoming ready for market.

Building a clear and friendly legal framework

"From research to the bed or to the workplace" has been a constant mantra of the last decades with too many difficulties to overcome while attempting to put it into practice. Indeed, the legal perspective impacts on the entire lifecycle of research and innovation of biorobotic systems, under multi-level grounds of regulation, standardization, and compliance activities. To accelerate the development of a sustainable model, where technologies could be integrated smoothly in healthcare delivery, rehabilitation and prevention the applicable ethical and legal frameworks shall be interpreted through the lenses of the current EU strategies, and harmonized at local, regional, and national levels. Even the domains and procedures left to self-regulation (e.g., to access to the competent ethical committees) are fragmented and in need of harmonization or at least of clear guidelines. These dimensions will be addressed leveraging comparative law methodologies, including a mapping of the EU, national, and regional hard and soft law regulations to comply with, comparing it with the law in action, mechanisms and practices identified at local, regional, and national level in each considered context, involving from the beginning stakeholders and target communities. A combination of top down (desk research) and bottom up (interviews and focus groups with stakeholders via "roundtables") approaches will be applied to identify standards, policies and recommendations to be validated among stakeholders through simulations and focus groups, and among institutional stakeholders to stimulate coherent reforms.

Mission 2 – Biorobotic Platforms & Allied Digital Technologies – Spoke 2

Mission 2 aims to provide validated healthcare and personal care robots already available to the Consortium, and specifically adapted to the unmet needs of the target groups, in order to run the clinical trials.

With **healthcare robots** we refer to those aiding patients with reduced sensorimotor or cognitive functions. Among them we can list: ***assistive robots*** restoring lost sensory and motor functions (like thought-controlled prostheses, assistive exoskeletons, manipulators on wheelchairs, etc.) and ***rehabilitation robots*** providing robotized physical rehabilitation (end-effectors, rehabilitation exoskeletons, gait trainers, etc.).

With **personal care robots** we refer to those offering therapy adaptation, monitoring, empowerment, or pre-habilitation treatments to individuals at risk. These include: ***mobile servants*** *and* ***physical assistants*** able to support and/or monitor frail individuals and ***occupational robots*** for individual exposed to occupational diseases or repetitive stresses.

Providing ready-to-assess robots and systems implies:

- Adapting the available robots in order to address the unmet clinical needs, coping with the evolving needs of patients in various phases of the disease (from acute to chronic) and in different treatment settings (inpatient, outpatient, at home), to guarantee the continuum of care.
- Adapting available personal care robots that can address the unmet identified occupational needs that exist, in the different treatment settings (from working setting to home-based settings).
- Complementing the available healthcare and personal care robots, with advanced digital infrastructure and services in the light of providing modular, dynamically configurable systems, and telecommunication means (telemedicine).
- Continuously updating the development of such technologies based on the outputs of the clinical trials. Iterations between Missions 1 and 2 will enable the clinical assessment of improved versions of robots.

The expected impact of Missions 1 and 2 is **on the healthcare and welfare systems**, brought by conclusive clinical evidence on the use of healthcare personal care robots and allied digital technologies, new business models and a legal framework hypothesis for the adoption of such systems. Missions 1 and 2 will also produce significant contributions from the technological point of view (upgrade and validation of **robots and systems**) and in terms of new knowledge in the areas of translational medicine, physiotherapy, neuroscience, human physiology and technology.

Mission 3 – Next Generation components – Spoke 3

In parallel with the assessment of already existing technologies (Missions 1 and 2), Mission 3 is devoted to support **basic studies** pertaining to physical and computational aspects of robot *bodies*, robot intelligence, and interfaces with the patient. These will include: sensing and interpretation of user volition, haptics or hybrid sensory feedback devices, training environments (incorporating virtual reality, or augmented reality, serious games), bio-cooperative control strategies, computational models, new materials, biomaterials and manufacturing processes, actuators, mechanisms and transmissions, sustainable energy sources. While promoting *blue-sky research* – which is the lifeblood of innovation – new components will be designed and developed with a special emphasis on their sustainability, and in accordance with the regulatory and ethical guidelines, since the very initial stages. Although the focus of this scientific and technological Mission pertains to the above mentioned healthcare and personal robots (and target groups) it will likely produce important contributions to biorobotics science and engineering at large.

The expected impact of Mission 3 is a new wave of technologies (proofs of concept or proofs of viability) and of knowledge, at the **basic or component level**, to be integrated into next generation healthcare and personal care robots.

The Consortium at glance

The Initiative is coordinated by the largest research center in Italy, the Consiglio Nazionale delle Ricerche (CNR), which organized a scientific and technical task force **made of committed researchers and innovators**, from **25** additional Institutions. These include **10** academic institutions: Scuola Superiore Sant'Anna (SSSA), Italian Institute of Technology (IIT), Universities of: Genoa (UNIGE), Florence (UNIFI), Pisa (UNIPI), Pavia (UNIPV), Siena (UNISI), Modena-Reggio Emilia (UNIMORE), Campus Biomedico in Rome (UCBM), Naples Federico II (UNINA); **11** clinical centers: INAIL Prosthetic Center (INAIL), IRCSS: San Martino (ISM), Gaslini (IG), Medea (IM), Fondazione: Don Gnocchi (FDG), Stella Maris (FSM), Mondino (FM), Policlinico Campus Biomedico (FPUCBM), Istituti Clinici Scientifici Maugeri (ICSM), Villa Beretta-Valduce (VBV) and COT Istituto Clinico Polispecialistico Messina (COTM); and **3** companies: Eustema (EUS), Item Oxygen (IO), and Tecnobody (TB). Additional -equally committed- players will be included through a cascade calls mechanism that will devote ~27.5% of the budget to external partners for specific tasks.

A multi-disciplinary and complementary team has been assembled around the Initiative. The partners have gained a 30+ years research experience in the rehabilitation robotics, prosthetic and neuro-prosthetic, assistive robotics fields as well as in tightly connected fields such as structural materials and manufacturing processes, tissue engineering, regenerative medicine, sustainable power sources. At a glance, the most important and largest prosthetic center (INAIL), nation-wide multi-centric hospitals (FDG, ICSM), as well as clinical centers (ISM, IG, IM, FSM, FSL, FM, VBV, COTM, 3 of which purely pediatric), or university hospitals (UNIPI, UNIPV, UNIGE, UNIMORE, FPUCBM, UNINA) with a long-lasting research and clinical experience in delivering advanced robotic neurorehabilitation, represent the best available option in the country for this topic. They will contribute to the Initiative by designing neuroscientific based experimental protocols, and delivering world-class treatments. Leveraging from previous research efforts/grants, recognized academic groups of bioengineers and roboticists (CNR, SSSA, IIT, UNIGE, UNIFI, UNPI, UNIPV, UNISI, UCBM, UNINA) will provide "ready to validate" robots and technologies, to the clinical centers, and will develop new ideas and components for future waves of healthcare and personal care robots. Legal and innovation management experts (SSSA, UNIPV, UCBM) will contribute breaking the barriers to the adoption of the technologies in our country. Companies involved in the prosthetic, rehabilitation and assistive robotics will contribute to the R&D activities and will offer pathways for product/service development.

Each partner has a long-term experience in one ore more fields of interest for the Initiative, and has gained international recognition for its work, as demonstrated by the partner sheets hereafter. In addition, strong professional links between partners already exist albeit in smaller groups, they have already collaborated in all sorts of regional, national and European projects.

The Coordination of this Initiative will be managed by Paolo Ravazzani, as the **Scientific Coordinator**, and by Christian Cipriani as the **Scientific Director**. Paolo Ravazzani (PhD in Bioengineering), CNR Director of Research, has a long term experience in coordinating and participating in national and international research projects (coordination of 4 EC Projects). Since 2018 he has been serving as the Director of the IEIIT institute of CNR. He is the author of 202 products (h-index 27, Scopus). Christian Cipriani (PhD in Biorobotics), Professor of bioengineering, has coordinated and participated in many research projects on rehabilitation robotics (coordinator of 3 EC Projects, including an ERC StGr). Since 2018, he has been serving as the Director of the Biorobotics Institute of SSSA. He is the author of 90 journal papers (h-index 40). In addition to the management structure, the scientific coordination will be supported by an **International Advisory Board** (IAB) made of 6 international leading experts in the fields addressed by Fit4MedRob, which will be enrolled through an open call for interests. Two founding members have already agreed to serve the IAB and in contributing to build it: Michelle Johnsson (University of Pennsylvania) and Dario Farina (Imperial College London).