WHITE PAPER AP8
HEALTH, CARE AND WELL-BEING (HWB)

Engineering and ICT solutions for personalised medicine, health and well-being

EXECUTIVE SUMMARY

AP HWB focuses on the design, development and evaluation of ICT and engineering solutions for diagnosis and therapy in medicine, empowering citizens towards healthier life styles and preventing or managing chronic conditions. To this aim, it applies engineering design and analysis principles to biological systems and biomedical technologies.
In the last few years, as part of the preparation of the forthcoming Horizon Europe, AP HWB research mainly focused on two keystones: personalized medicine and digital transformation.
Personalized medicine has been defined by the Horizon 2020 Advisory Group as "a medical model using characterization of individual phenotypes and genotypes (e.g. molecular profiling, medical imaging, lifestyle data) to tailor the right therapeutic strategy for the right person at the right time, and/or to determine the predisposition to disease and/or to deliver timely and targeted prevention".
Digital transformation of health and care process strongly supports this vision by providing important instruments to exploit innovative ICT solutions in terms of advanced devices and systems, high performance computing, data analytics and artificial intelligence to help design and test new healthcare products, provide faster diagnosis and better treatments.
Together with these two keystones, other issues have been identified at international level as those on which the research in health engineering must invest in the near future. Among them, one can find service robotics, technologies for health and environment protection, modelling and computational approach to medicine, tools and equipment necessary for the advancement of diagnosis and therapy, and technologies for the management of health systems.
AP HWB is aligned with this trend by studying, designing and developing tools, technologies, devices and services at the cutting edge of the knowledge, able to effectively implement the 4P paradigm: a Predictive, Preventive, Personalized and Participatory medicine.
This document presents the current activities of AP HWB, divided into 7 pillars fully in line with the priorities identified at European level:

- Digital solutions for health throughout the life course (DIGHEALTH)
- Service robotics (S-ROB)
- Environmental and social health (ENVHEALTH)
- In silico models for health (MODEL-H)
- Tools, technologies and devices for advanced diagnosis and therapies (HTECH)
- Tools for personalised medicine (T-PERMED)
- e-Health and health care systems (E-HEALTH)

After a short description of the state of the art of each pillar, the current activities of AP HWB will be described, together with their impact and the identification of the specific challenges of the next future. The description of CNR effort in terms of personnel, active projects, available infrastructures and facilities are described in the annex.

1. STATE OF THE ART OF THE RELEVANT SCIENTIFIC AREA

DIGHEALTH

One of the main focus of H2020 SC1 is to support ageing populations and the increasing number of subjects affected by multiple chronic and/or degenerative diseases by promoting innovative solutions for active and healthy aging, able to assist people in their living environments. In the last few years, also an increasing interest is emerged in solutions able to address other vulnerable stages of life, like childhood and adolescence, including people with disabilities or specific health needs. In this case, the definition of personalised solutions able to promote healthy life styles and social inclusion, even from the early stages of life, can help reduce the risk of mental and physical diseases later. Solutions originally developed for health monitoring and support of elderly can be further improved and customised for different user categories and pathologies, also enabling the integration of different solutions, including self-monitoring and Ambient Assisted Living (AAL), in order to provide a complete analysis of the health status of each subject. In addition, those solutions should be developed on scalable, re-usable and adaptive architectures, be interoperable and concretely evaluated in real-world scenarios.

S-ROB

The European Commission is investing in Robotics as one potential technology that could transform health care in the coming years. In particular, service robotics are being developed, tested and implemented in order to enable novel rehabilitation and surgical procedures, to assist impaired people in performing tasks of daily life, to encourage social interactions and active and healthy ageing. The 2020 Multi-Annual Roadmap (MAR) for Robotics in Europe identifies the Assisted Living sub-domain as the one addressing robotic solutions and technologies that aim to improve the quality of life by enriching the environments where humans live and work. These new technologies need to provide end-users, especially older adults, with dependable, acceptable and sustainable support and assistance including, where necessary, individually tailored systems.

ENVHEALTH

Human health is closely linked to the quality of the environment, as it is influenced by the interaction between environmental conditions and biological systems. This interaction is extremely complex to be understood, varying not only in relation to the physical agent to which an organism is exposed but also to the characteristics of the agent itself. The knowledge of interaction plays a crucial role in the assessment of the possible health risks due to exposure of the population. Additionally, there is a need to contextualize health data from patients as a function of the environment, to better assess the risk of diseases and the health at large.

MODEL-H

In medicine, the natural extension of in vitro and in-vivo experimentation is represented by in-silico modeling, in which physical-mathematical models are used to understand physiological and pathological processes, to define and evaluate the diagnostic pathways and their effectiveness, including pharmacological processes. The prime mover of their diffusion and enormous use is certainly the explosive increase of computing power at continuously decreasing costs, which allows the implementation of computational models unimaginable until a few years ago. The in-silico models allow the evaluation of systems and processes of a virtually unlimited number of parameters and possible conditions, finding in biomedical applications a fertile and exponentially growing field. Only through this approach it has been possible to come to an understanding of previously unknown physiological and pathological mechanisms in all sectors of medicine, to design and develop medical devices and technologies that not only prolong life but significantly improve quality, create sensory, motor and cardiovascular prostheses, implement oncological models able to give fundamental answers for the development of therapies and diagnostic approaches, modeling entire organs and systems. Last but not least, in silico models play a key role in computational planning tools for personalized treatments.

HTECH

Engineering for health, by exploiting all the most innovative available techniques and technologies, is called to design, develop and implement tools and devices achieving previously unimaginable progresses in diagnosis and therapies.

Innovative biomedical applications of electromagnetic fields (EMF), the increasing interest in magnetic nanoparticles and multifunctional nanocomposites, which enable multiple selective therapeutic and diagnostic approaches, contrast enhanced microwave imaging and thermally induced drug delivery are among the evidences of this innovation process. Formulation of a rapid diagnosis and identification of the most suitable therapy are made available by Point of Care Testing (POCT) devices, able to monitor bioanalytes at the patient's bed. Plasma medicine, by using low-temperature, atmospheric pressure plasma, interacts with living matter in cancer treatment, non-thermal blood coagulation and transfection of genetic material.

T-PERMED

The nowadays availability of complex, very large and high-dimensional datasets, coupled with the last advances in artificial intelligence tools, from network analysis and machine/deep learning to statistics and graph theory algorithms, is pushing the transition toward Personalized Medicine. Even though this novel paradigm is promising virtually infinite possibilities for advancing healthcare systems, some aspects still need to be tackled for its concrete realization. First, effective techniques to interpret and correlate vast amounts of heterogeneous data (from biomedical 2D/3D images and signals until omics, radiomics, connectomis and epigenetics data and clinical documents), need to be devised and tailored, allowing comparative analysis among known or similar cases and statistical analysis over significantly large populations. Second, advanced algorithms to mine, from this information, explainable predictive models for treatment, diagnosis and prevention of diseases of different specialties need to be realized. Finally, solutions to enable physical or virtual interactions with patients/doctors in supporting and monitoring daily care activities have to be developed.

E-HEALTH

One of the main priorities of European governments is to make health systems easily accessible, interoperable, secure and trusted, especially with respect to health information and personal data. Indeed, the integration of the large amounts of valuable health data, generated and collected during citizens' medical examinations in different clinical settings, offers enormous possibilities of reuse for research and better care purposes. To this aim, several national and European ICT systems have been realized to support exchange and analysis of huge amount of health data produced daily by clinical organizations, employing health standards, coding systems and medical terminologies. However, the partial and often trivial adherence of native data, typically stored in silos, to syntactic and semantic standards, as well as the heterogeneity of health processes and security measures, represent open and challenging problems not solved yet.

2. CONTRIBUTION TO THE RELEVANT SCIENTIFIC AREA

DIGHEALTH (IFAC, IIT, ISTI, ISTC, STIIMA)

Consolidated expertise in personalized and self-monitoring solutions, based on remote monitoring, m-health and AAL. Specifically, on: (i) scale-up and integration of IoT platforms for smart environments; (ii) multi-dimensional, personalized coaching system and persuasive technologies to stimulate and empower citizens towards healthier life style and prevent physical and cognitive decline; (iii) personalised services for remote and self-monitoring. This generates a big amount of real-world data to be collected, related to daily activities, physiological data, social interactions, dietary habits, motor and cognitive behaviour of each subject. The integration and analysis of this data on medium and long-term monitoring sessions allow the detection of anomalous behaviour, possible physical and cognitive decline, stress conditions and to prevent high risk situations, especially in chronic conditions and multi-morbidities.

Development and scale-up of those technological solutions and on the integration and analysis of real-world data to provide personalised suggestions and promote healthier life styles, study of big data analytics tools to provide a territorial observatory of societal well-being.
Study and implementation of cyber security methodologies and techniques (defined in the CyberSecurity AP) for the management of personal health data, with particular reference to the new General Data Protection Regulation (EU 2016/679). These techniques are also common to all the other activities described below.

S-ROB (IEIIT, ISTC, STIIMA)
Service Robotics is aimed at integrating smart assistive environments with robotic solutions to help humans. This entails many research efforts in terms of: i) development of sensor networks and semantic interpretation of the gathered data; ii) deployment of robotic solutions able to guarantee safety, reliability, robustness and flexibility; iii) design and implementation of advanced models of Human-Robot Interaction conceived to foster a high positive perception of care presence for the older users; iv) design of user models that allows to build personalized services; v) customization for different scenarios like private homes and public health facilities; vi) continuous self-adaptation of services; vii) user experience evaluation.
Development of robotics solutions for rehabilitation, exploitation of new artificial intelligent algorithms, (immersive) virtual and augmented reality applications, quantitative methods for the evaluation of patients and therapy effectiveness, manufacturing of personalized components by additive manufacturing technologies. These activities are based on economic sustainability and ease of use, to exploit solutions also in non-clinical environments, reduce hospitalization and improve the autonomy in the activities of daily living.

ENVHEALTH (IAC, IEIIT, IFAC, IREA, IMEM)
Development and use of methodologies for the human exposure evaluation: i) measurement environmental campaigns in public and private workplaces; ii) definition of standardized methods of assessment, design of ad hoc instrument chains and development of adequate measurement and data processing procedures; iii) development and use of specialized software for EMF numerical dosimetry; iv) development and use of EMF stochastic dosimetry; v) in-vitro study of the possible induced biological effects for the evaluation of interaction mechanisms with biological systems.
Improving health information and data exploitation by integrating clinical records coming from medical history data and molecular data (including omic-data) in a novel platform, which enables (in respect of the privacy) to geo-referencing all patient data and integrate it with heterogeneous information.

MODEL-H (IAC, IEIIT, IFAC, IMATI, IREA, ISTI)
Development of computational bio-electromagnetics techniques for brain invasive and non-invasive stimulation by electro-magnetic fields for neuro-disorders; bioelectric modeling of nerve fiber for novel sensory-motor prosthetics; modelling of microwave and radar applications for diagnosis, surgery and oncology; EMF characterization of human tissues in vivo, development of electro-physical models to study the interaction between single cells and pulsed electric fields in cancer therapy.
Modeling of: i) physiological and pathological processes, in terms of structural components and their interactions, to derive mathematical expression for simulation and further symbolic and numeric manipulations, with applications in pharmacological investigation and in research on kinetics and metabolism of endogenous substrates and xenobiotics; ii) immune system considering its involvement in the resolution or the exacerbation of human diseases; iii) blood flow in normal and pathological conditions and development of algorithms for EEG/MEG processing in physiology and pathology, iv) of gene regulatory networks (GNRS) by computational frameworks, to facilitate network analysis and design.

HTECH (IEIIT, IFAC, IGI, IMEM, IREA)
Design and development of EMF-based biomedical devices for non-invasive breast cancer and brain stroke diagnosis, thermal treatments guidance and hyperthermia and ablation by microwaves; magnetic nanoparticles hyperthermia and tracking for drug delivery; invasive and non-invasive brain stimulation for neuro-disorders; electrochemotherapy by pulsed electric fields for tumor treatment.

Development of technologies for early diagnosis and assessment of hearing impairment, of gestural human computer interfaces to automatically assess the neurological status in Parkinson patients and of bioreactors aimed at in vitro testing and validation of novel drug delivery approaches.
Development of invasive optical fiber sensors to monitor biomedical quantities and optical platforms for biomarkers for sepsis and immunosuppressants in transplanted patients; plasma sources for treatment of corneal infections, disinfection, wound healing, cancer therapy killing damaged cells by, non-thermal blood coagulation and transfection of genetic material.
Activities related to Point of Care Diagnosis by developing nano-micro, organics, bio-organic and hybrids hierarchically organized materials, sensors and systems, for diagnosis and therapy; systems for acute, post-operative and chronic pain therapy by drug-delivery by nano-micro containers; detection of neuronal activity and biomarkers by OECT (Organic Electro-Chemical Transistor); tissue engineering by OECT on textile fibers, to monitor the concentration of salts in the sweat, to prevent states of dehydration and malaise; hybrid nanosystems for RX-induced photodynamic therapy.

T-PERMED (IAC, ICAR, IIT, IMATI, ISTI)
Development of tools and algorithms to integrate and process huge amounts of structured data, biomedical images, signals, text, also collected in Virtual Reality environments, by means of machine/deep learning, pattern recognition and natural language processing techniques. Specifically: i) segmentation and annotation of biomedical images and the extraction of 3D geometric descriptions, also supporting new multi-modal visualization modalities; ii) radiomics approaches for the extraction of quantitative features from biomedical images to model their inner information and create reference biobanks meant to support research activities; iii) connectomics approaches exploiting novel complexity measures for the extraction and modelling of features from signals; iv) epigenetics approaches for the identification of the chromatin structure on available human genome.
Modelling of various medical contexts as well as decisional procedures elicited from experts or learned from data to support personalized diagnosis, monitoring and prevention of pathologies, by using both knowledge technologies and artificial intelligence algorithms and tools. Contribution, by network-based analysis, to the discovery and multi-dimensional combination of effective diagnostics biomarkers and, by graph theory, machine learning and statistical inference techniques, to predict treatment response and disease progression. Novel solutions for enabling the interaction of healthcare systems with humans by using gestures and natural language.

E-HEALTH (ICAR, IIT, IMATI, STIIMA)
Launch of specific actions, under the agreement/collaboration with the Agency for Digital Italy, finalized to: i) design and validation of ICT platforms for the interoperability of health critical systems in compliance with the current regulations, especially on Electronic Health Record (EHR); ii) standardization of the structure of clinical documents and the use of terminological systems for coding the clinical content appropriately.
As far as the development of the EHR national system is concerned: i) modelling of health business processes; ii) definition of access control and information integrity mechanisms (cybersecurity); iii) development of technical specifications and health informatics standards; iv) implementation of testing environments.
CNR participates to the EHR National Board, under which the EHR national interoperability framework has been defined and implemented by all the Italian Regions. Other activities: development of coding support web services, based on formal rules; integrated terminology services based on standard semantic interoperability protocols to support the stakeholders in the terminology management and use; optimization of document management and preservation processes within healthcare facilities, including the analysis on conformity to standard specifications; alignment and improvement of models to measure the quality management level of hospitals and highlight best practices; documentation and annotation of patients' data and integration of different exams/data/information to be shared among different specialists.

3. IMPACT

DIGHEALTH

The AP HWB research on digital solutions for health monitoring and promotion have a strong social impact in terms of citizen empowerment through self-monitoring, personalised coaching, persuasive feedback and access to personal data. In addition, it has a strong scientific impact for the health communities, highly increasing the amount of data characterising the individual behaviour and needs, in addition to the definition of new algorithms for data mining and analytics. From a political point of view, this activity contributes to enable EU citizens to: i) lead healthy, active and independent lives while ageing; ii) improve the sustainability and efficiency of social and health care systems; iii) boost and improve the competitiveness of the markets for innovative products and services, responding to the ageing challenge at both EU and global level, thus creating new opportunities for businesses.

S-ROB

Robotics technology in synergy with advanced smart environments has the potential to promote well-being at home and in assisted facilities by implementing both a monitoring and coaching/motivational role. The AP HWB research activities on this topic has a potential impact in the realization of health and well-being services that could help address the demands of an ageing population and an increased pressure on centralised healthcare systems, which entails an increasing interest in multiple functions and continuous monitoring delivered at home. This is in line with the goal of the European Commission of pursuing policy initiatives relevant to the Silver Economy, e.g. on the potential for new markets and economic drivers such as independent living.

ENVHEALTH

The AP HWB research activities on the interaction between the human health and the quality of the environment has a strong impact at social, scientific, political and industrial level. On the social level they are providing evidence-based information to health authorities and general public about the possible health risks related to EMF exposure and a better awareness of the EMF exposure level to which the general public (and workers at the workplaces) are exposed. Moreover, AP HWB research allows to collect evidence-based information on the link between exposure to physical agents and health status of the involved population. On the scientific level, the impact of the research activities is, at first, in contributing to fill the gaps of knowledge on the effects of EMF exposure on health and to improve EMF exposure assessment techniques. Additional impacts are in providing expertise and input to health risk assessment processes, which are put in place by national and international bodies (WHO, EU-Commission, IEEE, etc.) and in providing real-time cancers/pollutants risk maps (leukemia, myeloma and lymphomas vs chemical pollutants in air and food). The main impacts on the industrial level are in the improvement of technological techniques to reduce EMF exposure and in the development of new hi-tech tools for the measurements of EMF and other physical agents. The identification of scientific evidences to support policy authorities in implementing the actions needed for risk management and risk communication processes, including the possible link between cancers and pollutants, are the main impacts of AP HWB activities on the political level.

MODEL-H

The increase of the knowledge on neural mechanisms and their control, the investigation on brain network dynamics for neuro-prosthetics and the in silico characterization of the EMF quantities induced in neural tissues during brain stimulation are among the main scientific impacts of AP HWB research on in silico models for health. Additional relevant studies are the investigation of the dynamics of the neural processes in normal and pathological conditions, the development and in silico test of innovative drugs (including the determination of dose/schedule therapeutics protocols) and the investigation of multiple therapeutic approaches and diagnostics for oncology.

A relevant social impact is related to the validation of new diagnostic and therapeutic techniques, devices and drugs, to reliably accelerate their use on a large scale to the benefit of the largest possible number of patients, together with the improvement of personalized medical treatments.

Industry is taking advantage by the AP HWB results mainly in the design and prototyping of innovative medical devices and in descriptive and interpretative structural models for pharmaceutical industries.
The reduction of social costs by facilitating the introduction of new devices, the discovering of links between health conditions that were once considered unconnected, the uncovering of shared disease mechanisms and of key drivers of pathogenesis, and the identification of novel therapeutic applications, avoiding drug side effects, are strongly impacting on the health services at political level.

HTECH

The AP HWB results on innovative tools, technologies and devices for advanced diagnosis and therapies are strongly impacting the scientific community, mainly for what concerns the design and development of new EMF-based biomedical applications, including the combination of multiple therapeutic approaches and diagnostics for oncology and the technologies for individualized drug therapy. Moreover, the contribution to the development of novel treatments of tumors and wound healing (e.g., plasma, pulsed electric fields) and the development of novel technologies to apply external stimuli and collect in vitro biological, mimicking the physiology of human organs, are of relevant interest. From the social point of view, AP HWB activities are contributing to provide the health systems with new EMF-based economically-sustainable technologies. Availability of minimally invasive devices at home for a better quality of life of patients, the decrease of the mortality in many pathologies by rapid and reliable monitoring of disease markers (e.g., by Point of Care Testing and Diagnosis) are among other strong social impacts of AP HWB research. On the industrial level, AP HWB research is contributing in providing high-tech opportunities for the biomedical industry to stay at the cutting edge of the technological research and development. Last but not least, the decrease of the costs of the health services by the reduction of the burden of diseases, thanks to the introduction of novel technologies and tools for the advantage of patients and families, are strongly impacting at political level.

T-PERMED

AP HWB activities have already generated a relevant impact in healthcare settings. In particular, CNR has formalized: i) agreements with regional and national health organizations and local companies of the health domain to realize ICT solutions for aiding care activities; ii) the constitution of a center for experimenting AI solutions to significantly advance research and care, especially in oncology, with big industry players and health organizations; iii) participations in regional and national scientific committees in the health domain.
Moreover, future expected results can have a significant impact at scientific level. Methods, techniques and tools specifically realized for personalized medicine will be validated in the daily practice, allowing quantifiable measures for the evaluation and the interpretation of their outcome. Thus, more accurate diagnosis of pathologies of different specialties can be achieved. Moreover, links between conditions currently considered unconnected can be discovered, by uncovering shared disease mechanisms and key drivers of the pathogenesis, predicting individual disease outcomes, and identifying novel therapeutic applications also avoiding drug side effects. In addition, consciousness indices can be improved and validated to better classify neuropathological conditions of unhealthy patients by comparing diseased and healthy connectomes. The relevance of the expected results can be also extended to industry, since the proposed solutions could be engineered and integrated in decision support systems. Finally, the clinical validation can also boost pharma companies.

E-HEALTH

AP HWB activities have already produced a significant impact given the strong cooperation with the competent institutions (Agency for Digital Italy, Ministry of Health, Ministry of Economy and Finance), in order to ensure national (among the 21 regional EHR systems) and, potentially, European technical and legal interoperability according to the constraints imposed by the current laws. Moreover, the specifications produced as part of the Italian implementing decrees represent the technical reference for the homogenous implementation of such systems by the majority of the e-health industrial vendors.
In addition, granting interoperability of clinical data has also a strong impact since the comprehensive understanding of health processes and data flows is crucial to plan and manage policies and services, also enabling the meaningful reuse of information for a plethora of secondary scientific, social and political

purposes. It can also ensure EU cross-border interoperability to enable health data exchange and understanding, despite of their native format and language in order to provide EU citizens efficient care, even if they are not in their own country.

4. EMERGING RESEARCH CHALLENGES

Integrated solutions for self-monitoring, health promotion, disease prevention, and management of chronic conditions/multi-morbidities. Personalised and exhaustive coaching based on real world data.

Safe, smart and efficient robotics based on AI. Advanced human-machine interactions and complex embodied systems.

EMF assessment and interaction of 5G technologies. Data integration, analysis and visualization on a geographical scale for health-environment monitoring.

Simulation and multi-scale modelling of systems/organs. Redefinition of intracellular logic for gene regulation. Translation of omic data into medical practice. Personalized treatment planning procedures.

Nanoparticle enhanced contrast for microwave imaging. Enabling key technology for tailored drug therapy. New pulsing protocols for deep seated tumors. POCT for biomarkers monitoring. Selective neural activation for afferent and efferent prosthetics.

Heterogeneous data exploitation for tailored disease diagnosis/treatment. Immersive and tailored rehabilitation, surgery and prosthesis.

Deep analytics for document/knowledge management, optimization of EHR workflows, meaningful organization of clinical knowledge.

5. CONCLUSIONS

AP HWB gathers the scientific activities of CNR DIITET in the area of engineering and ICT for medicine and health. Currently it involves 142 structured personnel units (researchers, technologists and technicians) and 38 assistant researchers distributed over 12 CNR DIITET Institutes.
AP HWB activities are fully in line with the main European and international indications regarding the development of this specific sector. Specifically, the pillars on which AP HWB's research and development activities are based, are in line with the current H2020 program and the preliminary information about Horizon Europe research challenges. In addition, they follow also other international programs, like the NSF program on Smart and Connected Health (SCH), aimed at accelerating the development and integration of innovative computer and information science and engineering approaches to support the transformation of medicine and health.
These activities move, first of all, along the two primary research lines generally identified as the real challenges for medicine and health in the near future: personalized medicine and digital transformation of health and care process.
On a practical ground, AP HWB implements these lines with a system based on the 7 scientific research pillars discussed above.
These activities are made possible by the involvement of extremely different skills: bioengineering, applied electronics, applied electromagnetism and microwaves, computational biology, bio-modelling and control systems, system and communication engineering, information theory, pervasive and mobile computing, artificial intelligence and data analytics, robotics and virtual/augmented reality.

Furthermore, HWB activities are strictly linked but not overlapped with activities performed by other CNR DIITET APs, such as AP Biotechnologies, Cyber Security, Nanotechnologies, Robotics and Automation, Smart Cities, Social Security.

AP HWB, with its research groups, is an international reference point in the various specific sectors, as demonstrated by the large number of multi-centre European and international projects in which AP researchers are involved, and the wide research and industrial network they are maintaining in this field, also through the participation to national and international working groups.

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