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MakeToCare

An ecosystem of user-centered
actors and solutions
for innovation in the
healthcare sector

Stefano Maffei
Massimo Bianchini
Barbara Parini
Elisa Delli Zotti

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*I am always doing that which I cannot do,
in order that I may learn how to do it.*

P.P.

Stefano Maffei
Massimo Bianchini
Barbara Parini
Elisa Delli Zotti

MakeToCare

**An ecosystem of user-centred actors and solutions for
innovation in the healthcare sector**

A research project promoted by:

SANOFI GENZYME 

Fondazione
Politecnico
di Milano 

With the scientific coordination of:

POLIFACTORY
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This publication is the synthesis of a collective work conceived, discussed and developed by the authors **Stefano Maffei** (Scientific Manager, Department of Design, Polifactory, Politecnico di Milano), **Massimo Bianchini** (Lab Manager, Department of Design, Polifactory, Politecnico di Milano), **Barbara Parini** (contract researcher, Polifactory, Politecnico di Milano) in collaboration with **Elisa Delli Zotti**, **Diego Quetti** and **Francesco Leoni** (contract researchers, Polifactory and Department of Design, Politecnico di Milano) contributed in the design and creation phases of the graphical and infographic composition of all the *MakeToCare* research.

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CREDITS

Scientific coordination and project management: **Stefano Maffei**, **Massimo Bianchini**, **Barbara Parini**

Mapping and clustering of data: **Barbara Parini**, **Elisa Delli Zotti**, **Massimo Bianchini**

Infographics: **Francesco Leoni**, **Diego Quetti**

Graphic design and layout: **Diego Quetti**, **Francesco Leoni**

Web design: **Francesco Leoni**

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Contact and information:

stefano.maffei@polimi.it

massimo.bianchini@polimi.it

www.maketocare.it

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infoctr@libraccio.it

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They represent the core supporters of this report.

Examining their work, we discovered a set of innovative solutions for healthcare developed with creativity, passion, curiosity, patience, determination and hope.

Solutions that truly improve the lives of patients: from simple aids that render day-to-day actions enjoyable again to complex prosthesis technology that ensures a better life to whomever uses it.

MakeToCare is certainly the outcome of a work of discussion, analysis and processing of data, but is also a journey of research that started and developed from human relationships above all. Many are the persons we met in these months taking part in research conferences, workshops and meetings, numerous others those we interviewed or from whom we requested information.

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- 3.7.8 - Luca Randazzo, EPFL École Polytechnique Fédérale de Lausanne
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ABSTRACT

MakeToCare (MTC) is a research initiative that started as a spin-off of the first edition of the MAKEtoCARE contest organised in 2016 by Sanofi Genzyme at the European Maker Faire of Rome.

MakeToCare aims to identify, map and represent an emerging ecosystem of patient innovators, independent researchers, research institutions, startups and new entrepreneurs, makers and workshops for digital production. All these subjects work for the development of concrete design solutions capable of improving the everyday life and health of persons living in situations of disability.

This first edition of the *MakeToCare* report proposes a journey of *in-progress* exploration and mapping formulated in three interrelated and complementary directions:

1. the construction of a general scenario containing the principal directions of transformation in the healthcare sector, from social changes to the emerging role of patients as active subjects in the healthcare system, from the spread of enabling digital technologies to the transformation of care products and services in which to position *MakeToCare*;
2. the definition of *MakeToCare* as an *Ecosystem* of research, experimentation and innovation, characterised by the increasing diffusion and integration of collaborative practices developed by patients, family members and patient associations, centres of care and research with the *open* design culture of makers, shared production spaces and workshops, and the world of technology startups;
3. the first mapping of the *MakeToCare Ecosystem* referred to the Italian context, with identification of a first representative sample of 120 innovative solutions in the care sector created by 188 subjects mapped in the *Ecosystem*. The data and information on the projects and subjects were analysed and re-processed through infographic interpretative maps supporting the multilevel reading of the *Ecosystem*.

The results of this research represent the basis for building and developing the *MakeToCare Ecosystem*, validating it in institutional, cultural, scientific and economic contexts as a possible new scenario for the development of innovation in the healthcare sector.

AN EMPATHETIC JOURNEY IN EXPERIMENTAL KNOWLEDGE

Enrico Piccinini, General Manager Sanofi Genzyme Italy and Malta

Filippo Cipriani, MAKEtoCARE Project Lead

For more than 30 years, Sanofi Genzyme has been carrying forward the development of highly complex therapies, in line with a simple but concrete philosophy, i.e., letting itself be guided by scientific evidence and technological expertise, while never losing sight of patient needs (*science driven and patient focused*). Indeed, the experience alone of the scientist who first understood the mechanisms behind some rare diseases, and at the time without treatment, would not have been enough without the determination of the mother of a young patient. Only thanks to the union between strictly scientific aspects and the patient perspective did a start-up become a reality of reference in the biotechnical research panorama and, emboldened by this first experience, in the years to follow other therapies developed, transforming the quality of life of thousands of persons. These same modern therapies have allowed patients to live longer and live better, but more is needed in the day-to-day.

Thanks to the trip made by photographer Aldo Soligno (www.rarelives.com) we were able to know the story of a father who, for the love of his daughter, improvised himself as a maker and found an ingenious solution to a real problem. The guardian that father and daughter developed not only allows more effective rehabilitation but also playing with the siblings. Unfortunately the development of the brace took away, at an individual level, time and resources and we came to a conclusion, talking with patients and their associations, to find together the convergence between technical skills and the needs of those (both at the individual and family level) who deal with complex situations every day due to any form of disability. But not having direct experience of this type of challenge, we turned to young entrepreneurs, makers, FabLabs, academic laboratories, finding valuable travelling companions. In 2015, the Innova Camera team received us at the European Maker Faire of Rome; in 2016 we launched the MAKEtoCARE contest and our collaboration with ASTER and its initiative in Silicon Valley began; in 2017, together with Fondazione Politecnico and Polifactory, we want to systematise actors, locations and projects developed with and for patients. In these years, we have been able to count on passion, on professionalism and the commitment of many Sanofi Genzyme colleagues, in Italy and abroad: David Meeker and Robin Kenselaar, respectively CEO and European President for Sanofi Genzyme, believed in the project from day one.

MAKEtoCARE (www.maketocare.it or www.maketocare.org) began as a contest to share original solutions and support them in their further development. Now, with this first report, we plan to contribute in a real way to the debate on an ecosystem that is still emerging but already consolidated, and that will have an increasing importance in the future.

Without the story of Fabio and Roberta - and the account of Aldo - MAKEtoCARE would not now be a reality.

This first report is dedicated to them.

THE PATIENT ACTIVATOR AND THE EMERGENCE OF A HEALTHCARE ECOSYSTEM

Stefano Maffei, Associate Professor, Department of Design, Politecnico di Milano and Scientific Head of Polifactory

Massimo Bianchini, Researcher, Department of Design, Politecnico di Milano and Lab Manager of Polifactory

Barbara Parini, Associated Researcher, Department of Design, Politecnico di Milano

Elisa Delli Zotti, Associated Researcher, Department of Design, Politecnico di Milano

What happens if at first with hesitation and then with ever more conviction, a sector such as that of care is shaken by a new force to change?

The new element resides above all in the change of role of patients or of those who relate patient needs and activities, the so-called *caregivers*. In fact, they are increasingly becoming the *subjects of the change* rather than the *objects* of the innovative action. The same etymon of the word *patient*¹ relates the starting point to us: what characterizes it is the reference to the words *suffer* and *patience*, or the fact that the *patient* is attributed the role of a *passive element of the action*.

On the contrary, one of the essential facts highlighted by the *MakeToCare* research is, in fact, the entry on the scene of the subject of care and his system of needs as a propulsive factor in the field of innovation of the healthcare sector. The role of the *user* as a carrier of needs or, of specific *personal* and *sensitive* knowledge, generates a world of knowledge, relationships, opportunities and actions that goes beyond the traditional mechanisms of production of *technology* or *market-driven* innovation.

The field, processes and same subjects that occupy this area are irredeemably affected by it in a positive sense. Simultaneously, the intervention of technology as a system that resolves problems exceeds the simple idea of performing result and approaches a system of needs expressed by subjects and their care environment. This intervention materialises a series of tangible and intangible solutions that we would define as *design-driven* and *user-centered*. But more than this, we can define them as empathic, personal or that can be personalised, and potentially generative of innovative models of care intervention, which relate diversity as a potential generator that creates social and economic value in original forms.

Connection-Learning, *Coalition-Collaboration* and *Diversity-Exploration* are three keyword pairs that seem to emerge from the overall image of the *Ecosystem* and from all the projects that we mapped.

Connection-Learning, because from the cases or subjects or places mapped is developing a network of innovators that progressively confront each other in formal and informal arenas (*challenge*, *contest*, *research*) where the emergence of experiences and activities builds an imaginary collective composed of knowledge, resources and challenges able to generate a positive process of acceleration of the *MakeToCare Ecosystem*.

¹ Item "Patient". Treccani Dictionary.

See: www.treccani.it/vocabolario/paziente [last accessed: 07 November 2017]

Coalition-Collaboration, because in the *MakeToCare Ecosystem*, there are individuals deeply involved as active protagonists but also involved is a group consisting of coalitions of actors (large and small, both numerically and organisationally) where the *caregiving system* and its representation play a significant role. It would be interesting to understand which activation *triggers* are most effective to increase the impact of many experiences that already have an advanced degree of collaborative interaction and, learning from this, how to enhance the individual experiences and paths.

Diversity-Exploration, because the collection of projects we have mapped configure an overall vision of the experimental research processes of the *MakeToCare Ecosystem*, that may be considered as a great spontaneous initiative and open to public-private innovation. This collection makes diversity and inclusivity a fundamental *innovative characteristic system* that is growing actively, and that prospectively will generate a significant social, economic and technological value.

This research, therefore, represents a first attempt to organise (in a not-yet systematic and thorough way) the study of this promising collective of experimental ideas, initiatives, collaborations, transformations into something that we can begin to describe, which we can discuss.

Indeed, like all new survey procedures, it is hopeful and still immature and frail, but at the same time promises to become a shared and participatory system of knowledge. We believe that this allows us to imagine a positive impact on the daily life of persons and on the world of the public and private organisations dealing with care.

The open and collaborative processes of innovation have arrived in the city. To bring out and enhance even in an entrepreneurial key a repertoire of innovative care products and improve the conditions of disability in persons.

PREMISES OF THE RESEARCH:

THE MAKEtoCARE CONTEST

This was the objective of the first edition of *MAKEtoCARE*, the contest organised by Sanofi Genzyme within the European Maker Faire of Rome of 2016. A *call for ideas* designed to select and reward projects developed by makers and innovators able to identify needs related to the daily life of patients, their family members or caregivers, and to propose innovative solutions that improve their quality of life. Thirteen projects were selected with the possibility, for the two placed first, to visit Silicon Valley to meet companies specialising in digital production and innovative startups operating in the healthcare sector, Fab Labs and incubators, with the purpose of implementing the solutions at the productive and entrepreneurial level with the support of ASTER (the Consortium for innovation and technology transfer of Emilia-Romagna).

The initiative saw the participation of a large and diverse community of designers, *makers*, innovators with many projects received by the scientific secretarial office of Innova Camera, Agenzia Speciale della Camera di Commercio di Roma [Special Agency of the Chamber of Commerce of Rome] that managed the selection of the project finalists². The projects underwent inspection by the Assessment Committee³ chaired by Giuseppe Novelli, the Dean of the Università degli Studi di Roma Tor Vergata, in which personalities participated from the academic and scientific world, from the *makers* community, entrepreneurial area, from politics and patient and *caregiver* associations, leading to the announcement as winning projects Nicholas Caporusso's *dbGLOVE* and *click4all* from the team coordinated by Nicola Gencarelli from Fondazione ASPHI Onlus.

The success of the first *MAKEtoCARE* contest, run again this year in its second edition, has therefore led to the development of the *MakeToCare* research, presented in this volume, in fact a spin-off projecting the name, theme and spirit of this initiative in a programme of exploration and study.

² The thirteen project finalists:

1) *TooWheels* developed by Fabrizio Alessio; 2) *PD-WATCH* developed by Luigi Battista; *dbGLOVE* developed by Nicholas Caporusso; 3) *click4all* developed by Luca Enei, Nicola Gencarelli and the Fondazione ASPHI Onlus team; 4) *IntendiMe* developed by Alessandra Farris, Giorgia Ambu, Antonio Pinese, Leonardo Buffetti; 5) *Glassense* developed by Luca Giuliani, Luca Brayda, Francesco Diotallevi of the Istituto Italiano di Tecnologia [Italian Institute of Technology]; 6) *SoundSight Training* developed by Irene Lanza, Marco Manca, Henrik Kjeldsen; 7) *MOLBED* developed by Davide Marin of Lumi Industries; 8) *UNICO - The other design* developed by Opendot and Fondazione TOG Onlus; 9) *Io Kitchen* developed by Valerio Monticelli; 10) *DISABILITY MOUSE* developed by Fortunato Domenico Nocera; 11) *Talking Hands* developed by Francesco Pezzuoli, Dario Corona, Simonetta Borja, Simone Sileoni of Limix; 12) *Hubotics - Robotics for Human Beings* developed by Luca and Chiara Randazzo.

³ The Assessment Committee chaired by Giuseppe Novelli, the Dean of the Università degli Studi di Roma "Tor Vergata", consisted of: Laura Bianconi, XII Commission – Hygiene and Health – from the Senate; Paola Binetti, XII Commission – Social Affairs – from the Chamber; Paolo Bonaretti, Director of ASTER; Antonella Cimaglia, Vice-Chairman of UNIAMO; Bruno Dallapiccola, Scientific Director Ospedale Pediatrico Bambin Gesù; Maurizio Decastri, Professor of Corporate Finance, Università degli Studi di Roma Tor Vergata; Federica Draghi, Genextra Director; Fabio Gorrasi, father caregiver and maker; Bruno Lenzi, Co-founder of the Open Biomedical Initiative; Stefano Maffei, Director of Polifactory, the makerspace of the Politecnico di Milano; Andrea Piccaluga, Professor of Innovation Management, Scuola Superiore Sant'Anna di Pisa and NETVAL Chairman; Zoe Romano, blogger and co-founder of WeMake

GENERAL INTRODUCTION

The first edition of the *MAKEtoCARE* contest worked as a first aggregator of solutions materialised by a diverse range of subjects developing open and collaborative innovation activities: patient innovators and patient associations, individual researchers and research teams, startups, *makerspaces*, creative professionals and designers. That was the embryo, the incubator of the next work of exploration at the basis of this research. The results of the *MAKEtoCARE* contest in fact, first on the occasion of selection and then presentation, allowed a glimpse of innovative activities and potentially worthy of further investigation. The initial objective of the research was, therefore, to verify if and how the collection of solutions identified through the contest were part of a larger phenomenon or not, or part of an area definable as *MakeToCare*.

The idea of developing a research began in the first months of 2017, with the construction of a theoretical framework and a methodological system to identify, map and consolidate the first repertoire of study cases reported in the Italian context. This work configured itself immediately as a phenomenological survey based on a work of exploratory mapping and study of projects, experimental initiatives, experiences and tangible product-service solutions having as a characteristic that of being solutions developed through a collaborative dimension that combines scientific culture, *design-driven* technological innovation and *makers* approach.

The survey then further probed and fathomed the national landscape looking for subjects who populate this sector: the world of patient associations and caregivers, that of scientific research, the world of manufacturing in the biomedical sector, the network of *makerspaces* and Fab Labs, the world of entrepreneurial startups.

From the methodological perspective, it is therefore essential to emphasise that the results of this phenomenological analysis represent an exploratory work that produces qualitative elements of knowledge without the pretence of representing statistical and quantitative value.

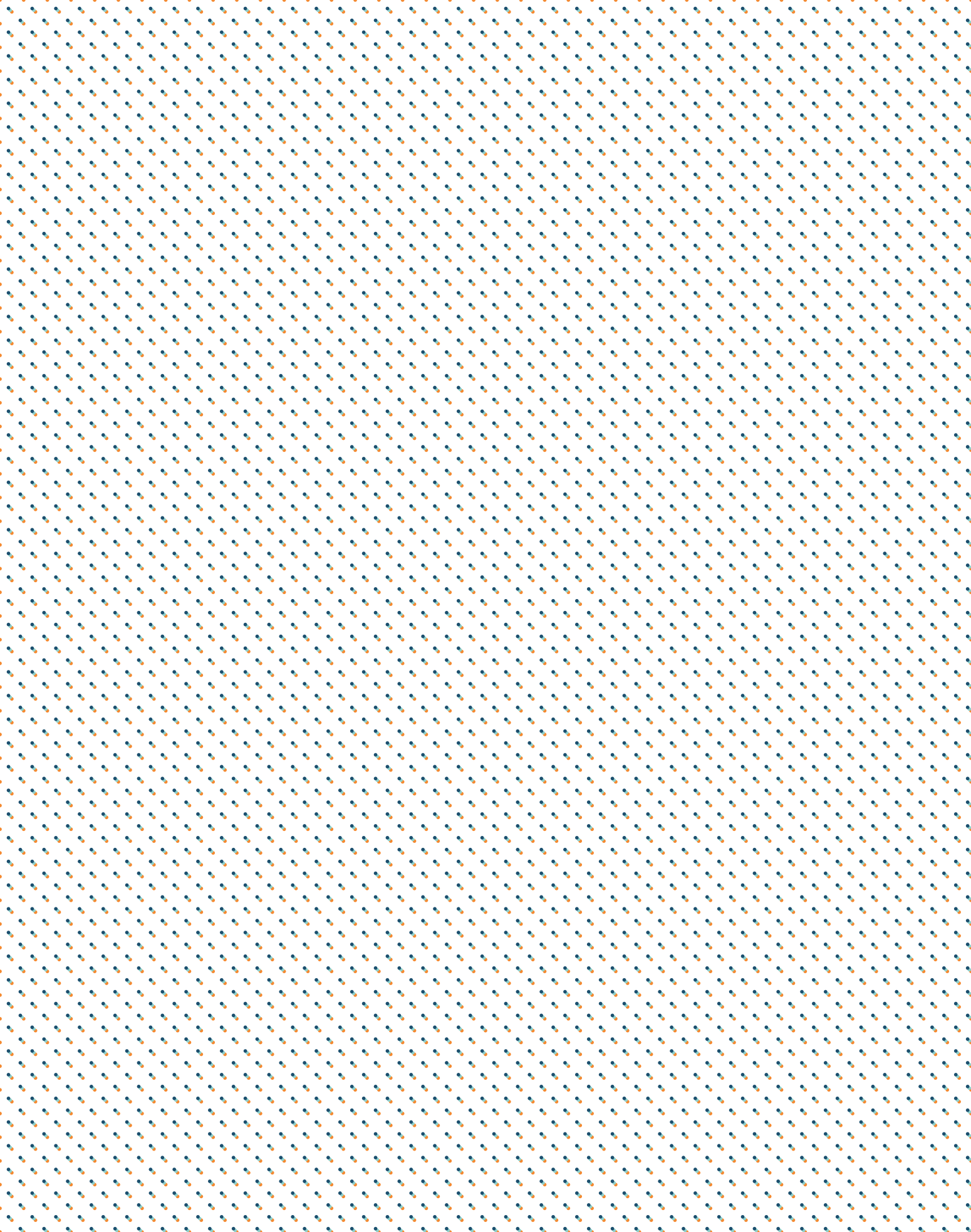
This allowed a dialogue to start with the authors of these solutions, to identify the experts on this theme from various disciplinary perspectives, to participate and analyse significant arenas such as conferences, workshops and research meetings (especially in the *making* and healthcare areas) allowing a process of reconstruction of the network of the subjects who developed it.

The first step of the research allowed to isolate, on a country basis, a corpus of 120 experiences that belong to the *MakeToCare Ecosystem*. In the second phase this grouping was interpreted, analysing its geographic and social dimension, the collaborative-productive nature, and the specific area of design application.

The second phase, that of synthesis, produced a sequence of different outputs generating a stratified reading of the results. We start with the infographic representation of the results: the data were first clustered and then displayed through an infographic atlas on the 188 mapped subjects and on 120 projects. The purpose is to represent through the map the composition of the *MakeToCare Ecosystem*, in order to understand who the subjects are who are part of it, how they relate with each other and coalition between each other, where they are geographically concentrated or distributed, in which areas of healthcare they operate and what the product-service solutions they are developing are. This reading is accompanied by a repertoire of case studies considered particularly relevant to exemplify to the reader what the *MakeToCare*

solutions are, enriching the information with a series of interviews, and to explain the perspective of some of the protagonists in the developed and mapped projects.

The data and information produced by the research that represent the *MakeToCare* subjects and projects have been published and info-visualised on the website www.maketocare.it. This will allow all the *MakeToCare* Ecosystem subjects access to these experiences. They represent a source of inspiration and knowledge that may also activate opportunities for entrepreneurial initiatives, the connection with professional and productive activities, or a vehicle to promote at the institutions applications concerning the social and economic value of this area, further stimulating the chances of developing new research.



PART 1

DEFINITION OF THE CONTEST

1.1 THE TRANSFORMATIONS OF CONTEMPORARY SOCIETY

Understanding the transformations of contemporary society is the key to understanding the emerging scenarios of innovation in the healthcare sector. An introductory passage is useful to calibrate the framework of the *MakeToCare* research.

We are older, live longer, increasingly victims of chronic diseases and more in need of individualised care treatments. But in the near future also increasingly connected, technologically enabled and reinforced to manage our health.

The OECD in *OECD Health Statistics 2017*⁴ provides an interesting series of key indicators.

The first figure concerns the relationship between healthcare expenditure and GDP: the OECD reports a figure of 9% as an average healthcare expenditure figure, which considers the major European countries like Italy, Germany, France and the UK to be aligned, while in the US this value nearly doubles, and is half in BRIC countries. The OECD average figure regarding life expectancy is at about 80 years, with average life expectancies for persons over 65 respectively 21 years for women and 18 for men. Data that consider the hope of life are also significant are the data that consider the hope of life in good health⁵: the EUROSTAT and ISTAT [Italian National Institute of Statistics] statistics with data reported in 2011 measure the life expectancies of women and men *without limitation in activities* (7 and 8 years, respectively 31% and 43%), with *moderate limitations* (9.4 and 6.8 years, respectively 42% and 36%) and with *serious limitations* (6.1 and 3.8 years, respectively 27% and 20%). So, contemporary society, especially Western, characterised by a rapidly ageing population, is individually and socially looking for continuous improvement of the health of persons. A goal that, despite the progress and achievements delivered, contrasts with an immanent general figure: a healthcare expenditure with costs which are still extremely high. The EU estimates the daily healthcare expenditure in Europe (OECD Future Health Paper; Kelley and Hurst, 2016)⁶ to be €4 billion⁷. The OECD addressed the issue of the ageing society under different aspects, from the social impact to the structuring of health services, within a report⁸ published in 2015 and estimated that in 2,050 persons over

⁴ For a full consultation of the OECD database, see: www.oecd.org/els/health-systems/health-data.htm

⁵ For further details on the indicator refer to Nova A., Pintaui, E., Donzelli A. (2012). *The indicators of hope of life in good health*, Health Policies, Vol.13(4)

⁶ See: <https://ec.europa.eu/futurium/en/content/future-health-care-deep-data-smart-sensors-virtual-patients-and-internet-humans>

⁷ The OECD online database www.oecd.org/els/health-systems/health-data.htm contains a set of comparable statistics on healthcare systems across the different OECD countries, with an update to 2017

⁸ See: www.oecd-ilibrary.org/social-issues-migration-health/aging_9789264242654-en;jsessionid=3ekd97bvuiqn7.x-oecd-live-03

60 will move from one-tenth (12%) to one-fifth of the global population (21%), highlighting that healthcare systems are not ready to manage this situation. According to the ISTAT report *The demographic future of the country. Regional forecasts of the resident population in 2065* (ISTAT, 2017) Italy will end up with a third of its population consisting of persons over 65. An Italian figure that fits into the general scenario of the OECD countries, where a combination of low birth rates and low mortality (therefore a low rate of population replacement) with increasing longevity of individuals, enabled by more healthy lifestyles and medical advances. A demographic change that, in the political landscape and scientific discussion, generates a concern on the social and financial sustainability of welfare systems with these characteristics. A phenomenon of this scale, in fact, involves great challenges for the public finance and requires an adjustment of social policies, particularly those in countries where there is a significant public health expenditure for the elderly (Vogt and Kluge, 2014). The *new elderly* contemporaries are subjects that, although healthier than previous generations, will increasingly potentially have to cope with chronic degenerative diseases, with a large impact on healthcare systems.

For this reason, the system of indicators focused on analysing the number of years that a person may hope to live without debilitating diseases is of interest, such as the *HLY – Healthy Life Years (or disability-free life expectancy)*, or with limitations such as the *Global Activity Limitation Indicator* (Jagger et al., 2010). In particular, HLY is an indicator of recent definition (2012) but is already considered as one of the key European structural indicators, and is recognised in the Lisbon Strategy. HLY serves to monitor health as a productive/economic factor, introduces the concept of quality of life, measures the occupational potential of elderly workers, and checks the progress accomplished regarding accessibility, quality and sustainability of healthcare assistance. Yet according to the OECD, the ageing of the population may also bring benefits: the *new elderly* will be a population of persons still in working age or still employable with an ever-higher level of education that, performing intellectual and physical work less strenuous than previously, may have good expectations in terms of health and quality of life. A change that will reshape the life of individuals, networks and family relationships regarding the needs of assistance and will impact on the re-design of services for healthcare assistance, moving the centre of gravity of care from emergency situations to the management of increasingly chronic clinical situations.

A specific and significant phenomenon highlighted in the OECD report concerns the theme of ageing of the population that lives in the cities. Despite an emerging trend pushing pensioners to transfer abroad to countries financially and climatically considered more favourable, almost half of the over-sixty-fives in the OECD area *live in the city*. A similar concentration makes one think that in the cities we need an overall re-thinking of the services that range from assistance to mobility and accessibility to locations and products. But even in imagining the elderly as an increasingly valuable resource in next generation⁹, socially useful, training and productive activities, changing thereby the 20th century urban model that saw the growth of rest homes and the separation of the old and sick from the rest of society. The ageing of the population together with the change in lifestyles and work of persons will then have a direct consequence on the development of new diseases or the dissemination of already existing diseases - of the chronic and degenerative type - that require a new approach and a different organisational model of the healthcare system.

Chronic diseases are now, in fact, the majority of the disease burden in Europe, and are responsible for 86% of all deaths. According to the 2016 Osservasalute Report of the *Osservatorio Nazionale sulla salute nelle*

⁹ The OECD report provides interesting examples of initiatives related to ageing in the city. For example the city of Yokohama uses the frequent flyer airline model to encourage persons of all ages to improve their health by walking more: the more you walk, the more you get points that are converted to discounts at the local stores

*regioni italiane*¹⁰, which analyses the population's state of health, 4 in 10 Italians are afflicted with chronic diseases for a total of 23.6 million persons (with data relative to 2015). Among these, the most frequent are arterial hypertension, ischemic stroke, ischaemic heart disease, congenital heart failure, diabetes, bronchial asthma, osteoarthritis and thyroid disorders. The report also highlighted the important and growing territorial gaps between the North and South of Italy. In Southern Italy mortality under 70 years is increasing, and imbalances in per capita public health expenditure are also observed¹¹.

In countries with advanced economies, and in Europe in particular, there is therefore a growing awareness regarding the limits related to current pharmacological therapies and prevention - predominantly statistically based - to which a healthcare system corresponds that is, on the whole, still centred on the *treatment of disease*. The switch to a system centred on systemic and intelligent forms of *prevention* will require profound transformations based on technical developments linked to monitoring of *citizens-patients* and the management of the data (*big and open*) they generate, the introduction of individualised therapies and technologically enabled for the changes in the organisational methods of healthcare services. Surrounding the personalisation of care and related development of *predictive medicine* there is for this reason much discussion: a global one involving governments, institutions and companies committed to questioning themselves about the future of healthcare, with an eye to future generations who should be healthier than their predecessors in order to keep the social security system in equilibrium.

A recent 2016 white paper of the European Commission entitled *The Future of Health Care: deep data, smart sensors, virtual patients and the Internet-of-Humans*¹² (Lehrach and Ionescu, 2017) tells of the development of new methods to know the *citizen-patient* based on advanced genetic analysis techniques that supply a systemic process of digitisation and virtualization of patient data. The base idea is that through a continuous monitoring of persons, obtained by the combination of sensors and data that model the biology of the patient and their diseases in real time, the personal data can be transformed into predictions that work on both the individual and the population, also with the support of *machine learning* and AI. It is a vision of an individualised, digitised and predictive healthcare system that uses a mix of advanced technologies that made the profiling of the *citizen patient* and their level of wellness or health possible.

Putting patients in the driving seat: A digital future for healthcare is the slogan announced by the European Commission, via the *advisory board eHealth Stakeholder Group*, for the development of a series of study reports and initiatives centred on key challenges for the future of healthcare. Particularly, the topic of *e-Health* concerns the development and diffusion of digital tools and solutions for citizens for interoperability with the healthcare services and with a greater level of inclusion of disadvantaged patients

¹⁰ See: www.osservatoriosullasalute.it. This observatory began on the initiative of the Istituto di Sanità Pubblica [Institute of Public Health] – Hygiene Section of the Università Cattolica del Sacro Cuore di Milano. It collaborates with the Institutes of Hygiene of other Italian universities to collect data useful to monitor the state of health of citizens in the different Italian regions and spread information through dedicated reports and events

¹¹ In 2015, despite the first signs of economic recovery, Italy was still one of 32 countries in the OECD area with the lowest per capita public health expenditure, with levels comparable to Eastern European countries. For example, the per capita public health expenditure varied from €2,255 in the Autonomous Province of Bolzano to €1,725 in Calabria. The distribution of the expenditure between the regions and its dynamic in 2014-2015 is dishomogeneous and a North-South and Islands decline is recorded with the Northern regions (except Piedmont and Veneto) which have higher values than the national figure and the Southern regions (with the exception of Basilicata, Molise and Sardinia) that have lower values

¹² See: www.futurehealthurope.eu

and groups. The European Commission provides the following definition of *e-Health*:

*“...e-Health means using digital tools and services for health. eHealth covers the interaction between patients and health-service providers, institution-to-institution transmission of data, or peer-to-peer communication between patients and/or health professionals. Examples include health information networks, electronic health records, telemedicine services, wearable and portable personal health systems and many other information and communication technology (ICT)-based tools assisting disease prevention, diagnosis, treatment and follow up...”*¹³

The purpose of the *eHealth Action Plan 2012-2020: Innovative healthcare for the 21st century*¹⁴ (European Commission, 2012) is the development of actions for the diffusion of digital devices and technologies as part of a European *e-Health policy* that extends and enhances the link between healthcare operators and patients in a future scenario that focuses on personalised medicine.

The first of these reports entitled *Patient access to the electronic health record* (eHealth stakeholder group, 2013) focuses on the access of the patient to the *Electronic Health Record* (EHR). It provides an overall picture of the possibility of access to these tools by patients in the European Union and focuses on both critical issues such as privacy and *cybersecurity* and on other issues such as the increase of accessibility and *usability* of eHealth solutions. The second report entitled *Widespread deployment of Telemedicine Services in Europe*¹⁵ (eHealth stakeholder group, 2014) aimed to show, through a series of best practices, how the European healthcare systems can benefit from telemedicine services, removing a series of bottlenecks of the legal, financial and performance type that make these new health services less reliable, safe and efficient in the eyes of citizens compared to traditional services.

The Horizon 2020 Programme stimulates the development of scientific research in *eHealth* working on four areas: ICT solutions for digital, personalised and predictive medicine; data management tools and methods for advanced, diagnostics and decisional analysis; new digital technologies and tools that complement healthcare and social assistance systems and support health promotion and health prevention; finally, *e-Health* systems and services characterised by a strong involvement of users for cost-beneficial healthcare assistance. The European Commission, in 2017, via the DG Health and Food Safety, published a report linked to a workshop entitled *Strategic investments for the future of healthcare*. The report highlights how the growth of chronic diseases, the ageing population and lack of healthcare staff are three factors that should contribute to the re-thinking of care models (that require new investment strategies based on the involvement of public and private subjects and on a combination of *top-down* and *bottom-up* approaches). In particular, this report declares the need to create collaborative ecosystems where the critical element becomes the development of *partnerships between the purchasers and providers of assistance services* characterised by new models of participation and *ownership*. Finally it certifies, therefore, an irreversible move of the patient to the centre of the scene with a greater allocation of power and accountability (Belliger and Krieger, 2016). The latter is a topic that directly refers to the development of *health literacy*, which must be seen in both the key of potentiation of individual knowledge and the key of a system of collective-public

¹³ See: http://europa.eu/rapid/press-release_MEMO-12-959_en.htm

¹⁴ See: <https://ec.europa.eu/digital-single-market/news/ehealth-action-plan-2012-2020-innovative-healthcare-21st-century>

¹⁵ See: http://ec.europa.eu/information_society/newsroom/cf/dae/document.cfm?doc_id=5167

knowledge (Freedman et al., 2009; Grandolfo, 2015)¹⁶.

The future of *e-Health* is also the focus of the World Health Organization, highly interested in the future use of healthcare services in a global scenario full of inequalities: an increasingly ageing population in a world of advanced economies contrasted by a rapidly growing young population in developing countries. A first global monitoring on the results obtained with the introduction of digital healthcare services in different countries generates both positive and negative potential. In countries such as the UK, that have introduced programmes of *e-Health* a decade ago, there was a discussion on topics of centralisation and accountability. The citizens of Western countries, for historical and cultural reasons, are generally more resistant to the centralisation of services, fearing the potential misuse by governments or companies of sensitive personal data. At the same time, in a system with abundant services and technologies, the issue of interoperability becomes complex to manage and requires the development of new coalitions. In developing countries, the lack of electronic infrastructure is a barrier, however, to effective digitisation of services, for which reason the focus is directly on developing low-cost applications able to work on the diagnosis phase of very widespread diseases. The World Health Organization, through the *Six Lines Of Action To Promote Health In The 2030 Agenda For Sustainable Development*¹⁷ (World Health Organization, 2015), looks to promote, by 2030, healthcare/a healthcare system for the future linked to a sustainable development model that begins from a clear principle: the strengthening of existing healthcare systems for the broadest access and the development of *Universal Healthcare Coverage* (UHC).

Even the main reports on the future of healthcare produced by the principal global consultancies such as PricewaterhouseCoopers, McKinsey and Deloitte, while using the industry perspective and with a clear reference to the market, focus the attention on transformation of the *consumer* into a more active individual and protagonist in the healthcare sector, and at the same time on the transformation of care in a *daily activity* that becomes measurable with data, indicators, performance shareable through new tools and processes.

PricewaterhouseCoopers in the dossier *Top health industry trends and issues 2017*¹⁸ underlines the increasing availability and propensity of patients to share with healthcare sector companies (particularly pharmaceutical) information regarding their state of health not only during care treatment or in the case of chronic disease, but also during any daily monitoring. The ability of companies to understand how patients manage their care and increase the ability of healthcare organisations to collect, analyse and understand their patients' health data, becomes so important. Naturally, in this direction, the related issue of how to build trust between patients, companies and institutions, and the administrative and legal processes with which these develop, takes on great relevance.

¹⁶ Grandolfo, in the article *Public health literacy* published in 2015 in the *Journal Evidence*, compares the definition of public health literacy coined by Freedman (PHL) that it is "...the level of competence of the persons and community in obtaining, managing, understanding, assessing the information and deducing its consequences for the action required to ensure benefit to the community with decisions of public health..." that contrasts with that of health literacy (HL), defined by the Institute of Medicine (IOM) as "...the degree to which persons have the ability to obtain, manage and understand the base health information and services needed to make appropriate decisions about health..." in order to better adhere to physician instructions

¹⁷ World Health Organization (2017). *World Health Statistics 2017: Monitoring health for the SDGs, Sustainable Development Goals* (www.who.int/gho/publications/world_health_statistics/2017/en/#story-01)

¹⁸ See: www.pwc.com/us/en/health-industries/top-health-industry-issues.html

An international survey conducted in 2014 by McKinsey on the *digital future of healthcare*¹⁹ had in this sense the goal of helping healthcare organisations to plan their transition to complete digitisation. From the research it emerges that persons are generally favourable to the use of digital services of quality in combination with the most traditional physical services, in a blended rationale. The digitisation of healthcare services also moves through the development of innovative applications (see for example *PatientsLikeMe*²⁰) useable by patients of all ages and are therefore simple, efficient, capable of ensuring better access to information that can be supplemented with other channels and connected with the availability of a place or a person of reference. Even the reports produced by Deloitte in recent years on the topic of health and social care have been focused on the role of digital technologies as an enabler of transformation of this sector. In the *Connected Health: how digital technology is transforming health and social care* report of 2014 highlights how the convergence of health technology, digital media and mobile devices constitutes the basis for the development of a system of digital services defined as technology enabled care. A digital infrastructure that includes professional services of *mobile health* (or *m-Health*) and *e-Health* and that finds in the exponential diffusion of *personal health wearable devices* – from increasingly performing smartbands to low cost *IoT devices* for the autonomous and instantaneous monitoring of values such as pressure or concentration of glucose in the blood – a first interesting repertoire of cost-effective solutions for a growing population of patients connected, but still apart for quality, reliability and safety of the standards that healthcare organisations and the future personal and autonomous control of patients require or need (*empowered patient awareness*).

¹⁹ See: www.mckinsey.com/industries/healthcare-systems-and-services/our-insights/healthcares-digital-future

²⁰ See: www.patientslikeme.com

1.2 EMERGING SCENARIOS IN INNOVATION IN THE HEALTHCARE SECTOR

1.2.1 The transformation of the products-services system and technological transition: transformation of care into service and predictive medicine

The emerging transformation scenario for the healthcare sector described above is strongly influenced by the development of an epochal technological transition characterised by an acceleration of the innovation processes in all fields of human activity. This can be called *Great Transformation* (Brynjolfsson and McAfee, 2014), or *Fourth Industrial Revolution* (Schwab, 2015), but the key element of this emerging paradigm is a technological convergence unprecedented in history: biotechnology, nanotechnology, Artificial Intelligence, Virtual Reality and Augmented Reality, ICT technologies, robotics and drones, 3D printing, *Internet of Things*, *blockchain* interact and work together. A *continuum* that enables the evolution of socially and technologically augmented individuals, who may develop new skills and abilities to act (*agency*) as *citizen designers* and co-producers of goods and services. In this regard, Bertalan Mesko with his book *My Health: Upgraded* (Mesko, 2016) developed a scenario of transformation of the world of healthcare within which he places a series of future big challenges that begin from considering the development of new forms of care enabled or enhanced both socially and technologically. In Mesko's vision the digitisation of patient data and information or the dissemination of disruptive technologies in the healthcare sector – Artificial Intelligence, robotics, genomics, cryonics – have a sense only if they put the patient at the centre of his own actions, enhancing his personal knowledge and skills. In this way patients become experts able to manage autonomously the front line of prevention and self-diagnosis and to collaborate with the doctor or healthcare system, actively participating in the development of his own care. According to Charles Auffray, Chairman of *European Institute for Systems Biology & Medicine Projects Team*²¹ the future scenario of development of medicine could be implemented on four pillars: participation, personalisation, prevention and prediction (Auffray et al., 2010). If the first pillar is based on the development of a partnership between the patient and the healthcare system, the other three pillars require a combination of scientific experimentation and research, technological innovation and availability of data. In 2017 the European Public Health Alliance published a discussion paper entitled *Digital Solutions for Health and Disease Management*, which reflects on the importance and influence of user-centred and participatory digital solutions in the healthcare sector. Within an increasingly technological healthcare system, co-creating digital tools with patients and caregivers means balancing market needs with the actual needs of persons, improving the level of expansion of these skills between professionals, patients and the general population. The digital technology infrastructure of citizens-users-patients is already under way and sees the increasing use of a wide range of mobile devices with applications linked to sensors and technologies able to support access to *m-Health* services in different contexts and situations. The *Quantified Self* is an emerging social trend affecting the auto-acquisition of personal data through wearable technological devices fitted with sensors and microprocessors for self-monitoring and detection of body functions or daily behaviours: “...the quantified self (QS) is any individual engaged in the self-tracking of any kind of biological, physical, behavioural, or environmental information. There is a proactive stance toward obtaining information and acting on it. A variety of areas may be tracked and analyzed, for example, weight, energy level, mood, time usage, sleep quality, health, cognitive performance, athletics, and learning strategies...” (Swan, 2009 and 2013). The technologies for the future of healthcare position themselves today at different levels of a hypothetical *hype* cycle: some are at the point of take-off such as biotechnologies and nanotechnologies, other at the growth phase such as robotics, others finally in large-scale use such as the *health apps* and *activity trackers*. An area certainly already the subject of technology

²¹ See: www.eisbm.org

applications that reason on principles of sharing is linked to the transformation of care into a service. The era of *open information* in the healthcare sector is becoming characterised by the transparent digitisation and aggregation of information referring to clinical records or research databases (Grol et al., 2013).

If we frame this topic in a financial and market perspective, and we cross from one side with the trends of population ageing and from the other with the rapid evolution of technological democratization and mass personalisation (Kumar, 2007), we obtain the fact that even in the healthcare sector its interest emerges in the manufacture of personalised medical devices, e.g. also within hospitals or other locations, configuring business models focussed on new *product-service systems for patient-centered care* (Lundberg et al., 2013; Minvielle et al., 2014; Pourabdollahian and Copani, 2015).

To date, the experimental use of advanced medtech services is still circumscribed (Schröter and Lay, 2014) because the functioning of the equipment remains under the management of doctors for reasons of legislation and *expertise*. Still staying in an experimental context, differentiated business models have been developed however that are characterised by the different modes of relationship between suppliers of medical technologies, hospitals and patients (Robert et al., 2015). For example, patients may take advantage of products-services for healthcare (even free of charge) managed in cooperation between hospitals and medtech manufacturers, or use the devices managed directly by companies within the hospitals.

In a rationale of transformation of care into services, patients become thereby both the centre and the agent who pushes for changes of services related to care. In a rationale of *continuous innovation* (McGinnis et al., 2011), healthcare providers need both to capitalise on the patient experience and stimulate them to increase his level of *expertise* on his own state of health. In this sense, the value of this research is in highlighting how much in the future the transformation of care into service will be important not only of the product but also of the process and manufacturing technologies. A transformation that has many points in common with the process that is happening in the *digital manufacturing on-demand and on-site* area or in the development of new service locations such as Fab Labs and *makerspaces* (Baines et al., 2009; Maffei and Bianchini, 2013).

An emerging area is then the one that sees the development of *precision medicine* and *predictive medicine*. Precision medicine is a term used today to describe individualised treatment that includes the use of new diagnostic and therapeutic tools, targeted at the needs of a patient according to his genetic characteristics (Jameson and Longo, 2015). In the definition made by the *National Institute of Health US* (NIH), precision medicine focuses on the identification of more effective approaches for patients according to genetic, environmental and lifestyle factors.

Predictive medicine instead developed from the exponential innovation of technologies for molecular biology, starting from the first human genome sequencing in 2000. The developments of biotechnologies, nanotechnologies and bioinformatics allowed cell analysis to arrive at a previously unimaginable level of extension and detail. A search conducted on Scopus database using the term *precision medicine* clearly demonstrates how this is influenced by the interaction between the fields of medicine, genetics, molecular biology, of neuroscience, pharmacology, pharmaceuticals and informatics.

In fact, this last aspect, the combination of molecular biology and IT, transforms the idea of the human body in a *data factory* that can be investigated and used to understand both the biological mechanisms of the person and to organise personalised care assistance (Lehrach et al., 2011; Wolfe, 2015).

The possibility of obtaining and managing a huge quantity of data deriving from a greater understanding of diseases and the state of health of persons, together with the use of monitoring devices, allow development of a systemic and almost panoptic vision of the individual in his complexity and all his dimensions, including that of time, or his genetic history, his present and his future.

This is the step that feeds the development of predictive medicine and predictive genetics, or the prediction on the individual predisposition to develop a particular disease based on the analysis of genetic heritage, and therefore the opportunity to prevent its onset or reduce its impact when it occurs.

Nature defines it as “...a branch of medicine that aims to identify patients at risk of developing a disease, thereby enabling either prevention or early treatment of that disease. Either single or more commonly multiple analyses are used to identify markers of future disposition to a disease...”²².

1.2.2 The artificialisation of the human body and the future of disability

The development of a general scenario of technological transformation of medicine and healthcare cannot be made without a focus on robotics. The focus is to understand how this sector is stimulating the change of activities in these areas from operating rooms to hospital corridors, from systems of prevention to services for rehabilitation to those for home care. In parallel, also how it is influencing the process of artificialisation and personalisation of the human body, changing the individual and social perception of disability and the future of human possibilities in terms of quality of life for patients and disabled persons. A report produced in 2008 for the European Commission - DG Information Society entitled *Robotics for Healthcare* (Butter et al., 2008) provides an effective overview on key themes and directions of the development of robotics in the healthcare sector, defining it in general terms as “...the domain of systems able to perform coordinated mechatronic actions (force or movement exertions) on the basis of processing of information acquired through sensor technology, with the aim to support the functioning of impaired individuals, medical interventions, care and rehabilitation of patients and also to support individuals in prevention programmes...” (Butter et al., 2008).

This study tried to classify the robotic technologies in the healthcare sector, identifying some key areas of innovation:

- robotics for medical interventions and precision surgery;
- support robotics for professional care, from devices that help nursing staff, to robotized systems for patient monitoring, to the equipment that is moving towards *home care robotics* and the development of *robot caregivers* specialising in assistance and paramedical tasks;
- support robotics for preventive therapies and diagnosis, from the analysis of movement and motor coordination to smart fitness systems, from robotics for monitoring to the smart robotic capsules that explore the human body;
- assistive robotics, an area with many solutions that support humans in the performance of daily activities, from robotic applications that support patients in eating to robotized systems that help them to move independently (the exoskeletons) up to smart prostheses that replace body parts;
- rehabilitation robotics, i.e. all therapies assisted by robots to stimulate motor coordination, physical, mental, cognitive and social rehabilitation.

The rehabilitation professionals have, and increasingly will have available, a growing number of robotic assistance devices to improve the independence and quality of life of persons with disability: *robotic feeder*, *smart wheelchairs*, *mobile and independent robotics*, *socially assistive robots* (Brose et al., 2010).

The creation of gyms for rehabilitation via robotics or the introduction of robotics for rehabilitative purposes in nursery schools (Pennazio, 2015) are the first examples of this path (Stahl and Coeckelbergh, 2016).

The birth and development of *care and disability robotics* if on the one hand contributes to a change in approaches to care, on the other, the patient view towards technologies and devices for the care

²² See: www.nature.com/subjects/predictive-medicine

or overcoming of disability is also changing. In this regard the diffusion of *personal smart devices* or implantation of RFID²³ devices is only the first evidence of a larger social and cultural process of active transformation: from the passive acceptance of devices inserted in the body or connected to it for reasons of care or reduction of disability we move to the progressive spontaneous request of connection or installation of bionic devices that produce not only an action of monitoring, prevention or care, but also a work of physical and cognitive enhancement in an overall direction of *Human Enhancement* (Wasserman, 2012; Bose, 2014; Eilers et al., 2014). This transition begins an ethical and social discussion: from the concept of de-humanisation of the body to the redefinition of what is human and to what alters this condition (Butter et al., 2008). In a speech that moves the focus from cultural and related issues to the figure of the *cyborg* (Haraway, 2009; Leaver, 2014): the era of technological prostheses, bionic implants and the diffusion of the processes of artificialisation of the body has put up for discussion the theme of social acceptance or exclusion of patients or persons with disability (*ableism*, Wolbring, 2009). Thanks to future developments in medicine and technology persons with disabilities could be increasingly considered as cyborg, individuals technologically (re)habilitated and enhanced who experience the boundaries of what it means to be human (Tomas, 1995; Swart and Watermeyer, 2008).

Science fiction has always represented the reluctance of *cyborgs* to reveal their hybrid nature. Instead, the world today offers us the autonomy of individuals participating in the *Cyathlon*²⁴ and the pride of Neil Harbisson²⁵ who exhibits to the world the antenna that changed his perceptual disability, transforming him in fact in a *cyborg* with an artificial new sense. Therefore, there are many reasons that make it interesting to explore the topic of the artificialisation of the human body in the *MakeToCare* research, to verify if the technological development in healthcare can find a valid response in reality.

The issue of *human enhancement* is certainly an emerging issue, even if in the popular imagination it still appears suspended between science and science fiction.

Perceptions change, however, if we try to relate this issue with the statistical data on disability. The first *World Report on Disability*²⁶ finalised in 2011 by the World Health Organisation and the World Bank, reports the following data: more than one billion persons, 15% of the world's population, live with some form of disability. Of these, at least one fifth has significant difficulty²⁷. In Italy, according to the portal *Disabilità*

²³ Acronym for: Radio-Frequency IDentification, in Italian "identificazione a radiofrequenza"

²⁴ Cyathlons are an international competition organised for the first time in 2016 by ETH Zurich and reserved for disabled competitors with assistive bionic technologies such as robotic prostheses, brain-computer interfaces and enhanced exoskeletons

²⁵ Wikipedia reports the following profile: Neil Harbisson (Belfast, 27 July 1984) is a British composer, painter and photographer with Spanish citizenship known for his extended skills to hear and feel colours beyond the possibility of human vision. In 2004 he became the first person in the world to wear a Cyborg Antenna. The inclusion of the antenna in his passport photo was interpreted by some as official recognition of Harbisson as cyborg. In 2010, he founded the Cyborg Foundation, an international organisation to help humans to become cyborg; see the TED video: www.ted.com/talks/neil_harbisson_i_listen_to_color?language=it

²⁶ See: the World Health Organization WHO, www.who.int

²⁷ Globally then we can see that in many countries rehabilitation services are inadequate. In some countries in Southern Africa, only 26–55% of disabled persons received appropriate medical rehabilitation, while barely 17–37% obtained the necessary healthcare devices (wheelchairs, prostheses, acoustic devices). But even in high-income countries, a percentage ranging from 20%–40% of disabled generally do not find solutions for their day-to-day needs. The difference between the proportion of children with disabilities and percentage of able-bodied children attending elementary school ranges from 10% in India to 60% in Indonesia. The deficiency in the school integrative system has a direct impact also on the reality of work. Rates of work are lower for men (53%) and women with disabilities (20%) compared to able-bodied men (65%) and women (30%). In countries in the OECD area for example, the percentage of work of persons with disabilities is 44%, compared to 75% of able-bodied

in *Cifre* of ISTAT²⁸ in the period 2013–2015 persons with disabilities were more than three million overall²⁹. Of this number, as highlighted by the document *Note on the “After us” law* of ISTAT (2017), we know that 2 million 500 thousand are elderly. The share among women is higher, 7.1% (against 3.8% among men). In most cases (55.5%) persons accumulate more types of functional limitations (1 million 800 thousand persons are considered seriously handicapped) and approximately 540 thousand are aged under 65 years. In Southern Italy and the Islands the proportion of persons with functional limitations is significantly higher compared to other territorial areas. Italia spends approximately €430 per capita/year on disability (EUROSTAT data), placing itself below the European average (€538). Less than one out of five disabled persons works. The municipalities (EUROSTAT 2012 estimates) spend €8 per day (less than €3,000 per year per inhabitant) on average for disability, with profound territorial disparities (the Piedmont expenditure is eight times higher than that of Calabria). Regarding care and support received, about half of seriously handicapped persons aged under 65 years do not receive anything from public services, nor do they use payment services, nor can they count on help from non-cohabiting family members. The burden of serious care, therefore, falls completely on cohabiting family members. Two hundred thousand adults are living in institutions or in Nursing Homes (Residenze Sanitarie Assistenziali, RSA). 70% of families manage the relative autonomously (*caregiving* family member) not taking advantage of any service at their home. Less than 7 disabled people out of 100 can count on forms of support at home. Finally, always according to ISTAT, students with a disability in Italy in 2015 were 233,477 (absolute values).

This statistical snapshot on disability in Italy, together with topics of new assistive and rehabilitation technologies and of change in the social acceptance of disability, generates an area of reflection which is useful from the prospective of the *MakeToCare* research.

What would happen if a national system started to organise itself from the design, social and financial perspective not only to reduce the condition of disability but to transform it in forms of citizenship socially and technologically enabled? Some reflections and initiatives open interesting perspectives in this regard. The first level of reflection addresses the concept of disability.

The ICF – *International Classification of Functioning, Disability and Health*³⁰ model of 2001, connotes disability no longer as an attribute of the person but as a situation, even occasional, that presents whenever the person senses a gap between their skills and environmental factors - which factors can then place themselves for or against the person, giving rise to situations of functioning or disability - such as to determine restrictions in the quality of life of the person or in the full development of their potential.

Renzo Andrich (Polo Tecnologico Fondazione Don Carlo Gnocchi Onlus of Milan in *General concepts on aids*³¹, repeats the definition of technical aid and accessibility of the ICF model³² and proposes a classification of

²⁸ See: <http://dati.disabilitaincifre.it/>

²⁹ 3,167,000, of which 1,251,000 in the North, 625,000 in the Centre and 1,290,000 in the South and Islands

³⁰ The International Classification of Functioning, Disability and Health (ICF) is part of the WHO Family of International Classifications together with the International Statistical Classification of Diseases and Related Health Problems 10th revision (ICD-10), of the International Classification of Health Interventions (ICHI). See: www.reteclassificazioni.it

³¹ Andrich, R. (2011), *General concepts on aids*, Milan SIVA (Servizio Informazioni e Valutazione Ausili) Portal, Fondazione Don Carlo Gnocchi Onlus

³² According to the international standard ISO 9999 updated in 2011, an assistive product is considered to be: “Any product (devices, equipment, tools, software, etc.), of specialised manufacture or trade, used by (or for) persons with disability for purposes of: improving participation; protection, support, development, control or replacement of body structures, bodily functions or activities; prevention of impairments, limitations in activities, or obstacles to participation”

aids based on their role in the process of rehabilitation and social inclusion of the person with disability³³. Linked to this theme, there are therefore reflections regarding user autonomy in choosing their aids and the question of the forms of relations and enabling emerging between humans and the new types of tools. The European Commission has developed a strategy for 2020 on disability that focuses on topics such as accessibility to goods, services and assistive devices, the full participation in society, occupation and economic autonomy, inclusive education and continuous training. To these we add the latest taken from the document *Human right: a reality for all* of the Council of Europe Disability Strategy 2017–2023 (European Council, 2017), or the following new priority areas: equality and non-discrimination, awareness, accessibility, equal recognition before the law, freedom from exploitation, violence and abuse. The cross-sectional issues highlighted by the new European strategy are: participation, cooperation and coordination; universal design and reasonable accommodation, the prospect of equality of gender, multiple discrimination, education and training.

If we analyse in detail the second point we can see three interesting indications for the *MakeToCare* research. The first is that disability is the result of the interaction between individual impairments and/or disabilities and the existing attitudinal and/or environmental barriers. Disability may hinder the full enjoyment of human rights and fundamental freedoms and prevent effective and equitable participation in society.

Persons with multiple, complex and overlapping problems and disabilities, have to face further barriers and are at higher risk of institutionalisation, exclusion and poverty.

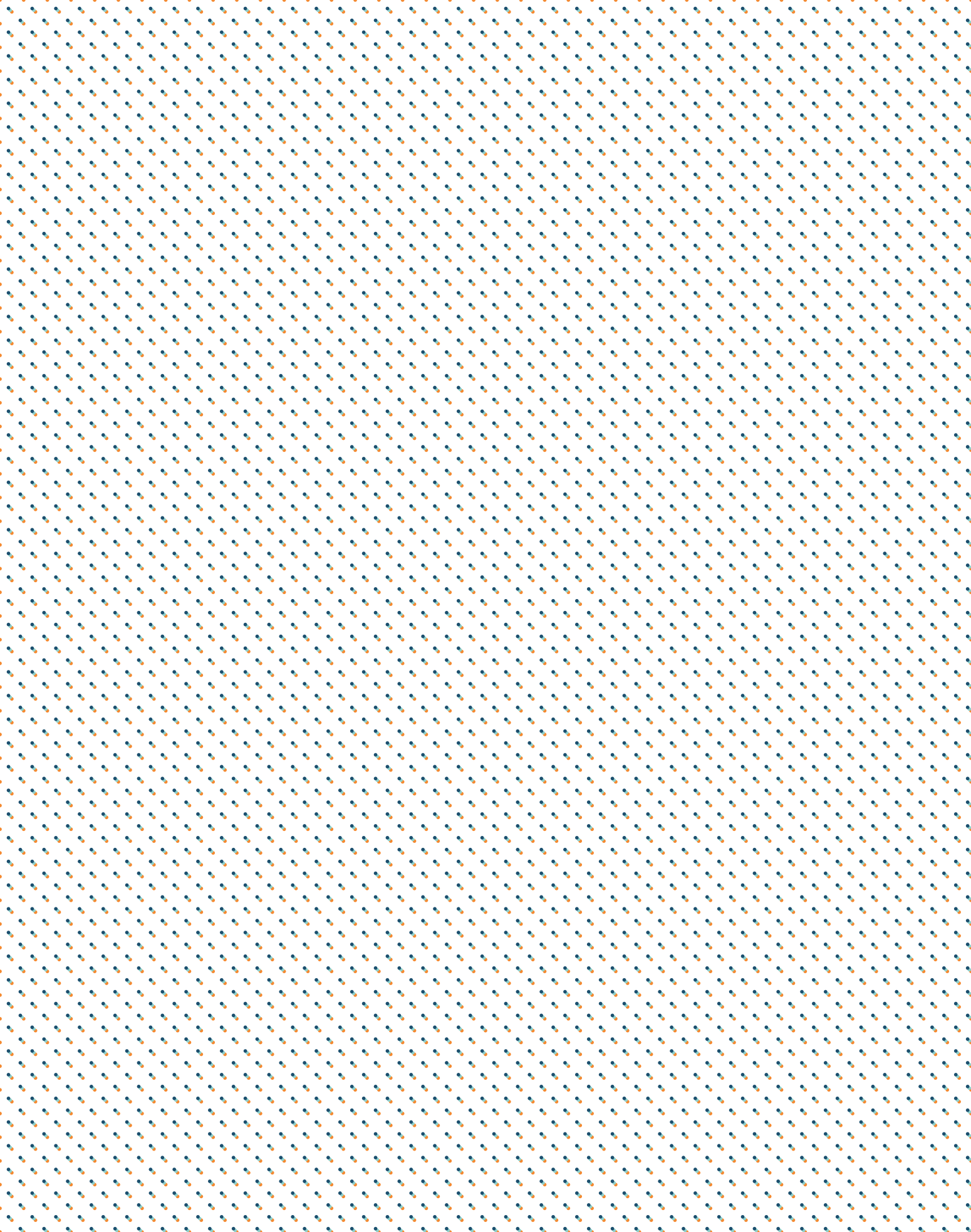
The measures that prevent or remove the existing barriers for sustainable development and to enhance accessibility are therefore necessary investments. The second consideration that emerges is that the challenges of accessibility can be prevented or greatly reduced through the use of smart and not necessarily expensive applications originating from *universal design*. In addition to the necessary measures of accessibility regarding groups, the individual barriers can be overcome individually with reasonable *tailored* accommodation. Refusal of reasonable accommodation and denial of access may be a discrimination. Both these concepts are defined and described in the *United Nations Convention on the Rights of Persons with Disabilities – UNCRPD* (Articles 2 and 4). As the third and final reflection the *universal design* and promotion and development of *affordable* assistive technologies, of devices and services intended to remove existing obstacles should be increasingly promoted.

³³ Distinguishes and describes thereby prosthetic, orthotic, adaptive, environmental, assistential, therapeutic and cognitive assistive products. It proceeds in the analysis of the significant aspects to consider for a proper evaluation of the individual needs of the person, in relation to the objectives to pursue (daily, school, work, free time activities, etc.) in the family context and physical environment in which the person is inserted. From this analysis emerge the methodological recommendations and work tools to organise the work of evaluation, selection and prescription of the assistive products in the context of the rehabilitative process

1.3 EMERGING RESEARCH TOPICS

The collection of information and reflections contained in this chapter provide a series of concrete stimuli and themes for the work of analysis and mapping of the *MakeToCare* research:

- *healthcare tailored to an ageing population.* Is the topic of ageing from the quantitative (growing number of elderly) and qualitative (change of quality of life in ageing) point of view and from the perspective of its social implications on an individual (impact on patient and familial caregiving) and collective (social sustainability of welfare) scale;
- *healthcare for the new generations, between prevention and prediction.* Is the topic of the digital transformation of healthcare and the development of virtualized medicine and immersive environments, but also of new forms of health literacy (the confidence with medical and scientific language) and evolved levels of knowledge and awareness of their own body (from external manifestations to genetic structures);
- *healthcare on a metropolitan scale.* Is the topic of the concentration of population of the city seen from the perspective of citizens (growing number of elderly and disabled in cities) and the perspective of the care system, the city as poles of reference for activities of research, experimentation and provision of services;
- *technologically enabled and enhanced healthcare.* Is the topic of the technological development that potentiates persons and systems of products-services for care, changing the body's limits and barriers, the limits and extensions of the objects and characteristics of the care and life environments;
- *healthcare and the challenges of disability.* Disability is no longer seen as a condition but as a gap between the person and the environment, a situation that can be reduced or closed with design-focused interventions through the breaking down of barriers that hinder the quality of life and personal development and greater autonomy in managing their own situation, including the possibility of designing and experimenting personalised solutions;
- *personal and collaborative healthcare.* It's the topic of the approach to care observed in transformations of diseases of the person (and therefore of their care habits) and the democratisation of technologies for diagnosis, monitoring and psycho-physical support. These are the prerequisites for an open and participatory model of care, for the enhancement of the operational and decision-making relationships between patient and physician, and for the connection with relational and collaborative networks between patients and the community of patients, experts, caregivers and institutions.



PART 2

DEFINING MAKETOCARE

2.1 MAKETOCARE: AN EMERGING RESEARCH, PROJECT AND PRODUCT-SERVICE AREA

2.1.1 The starting point: sketch out a work of research in progress

It often happens that, at the start of a research, beginning from the original meaning of the major keywords related to the topic to be explored offers the possibility to identify the initial coordinates that guide the investigation.

The title of this research, *MakeToCare*, is based on the combination of the words *make* and *care* that refer however to a third word: *patient*, the patient. Examining its meaning briefly, both as individual headwords and as concept-related triads, the first word we will review is *make*, which has always meant to create, produce or manufacture. Actions that in contemporaneous society are mainly associated with the worlds of craftsman or industry, whose sense however, is enriched today by new connotations through the transformation produced by the digital revolution. In particular, the term *make* connotes the idea that individuals or groups who do not possess the means of production - whether simple citizens or professionals - can use technology for digital production transforming themselves into *makers*, or subjects characterised by the ability to invent and materialise independently and then market-share product-service solutions. The term *care* or *cura*, in English and Italian, is associated with a plurality of meanings in both languages. If in the most common acceptance *care* is a “...set of therapeutic means and medical activities used to fight and resolve a disease...”³⁴, on the other hand it also concerns “...the assiduous and responsible commitment in pursuing in the first person a proposal or in practising an activity, in providing for someone or something to which importance is given or of which consideration is taken...”³⁵ Finally, the term *patient*. According to different vocabularies it is a “...subject with a disease who relies on the care of an expert...”³⁶. In doing this, he is certainly the passive element of the action of the same care, the one who receives it, but also the one who has a virtue or a quality that is at the base of an “...attitude or predisposition to operate with care, accuracy and constancy...”³⁶

Considering these three words together helps us to outline the profile of an area of research where we can try to define the care and the research of methods to mitigate disabilities as a set of solutions that can be responsibly invented or performed with varying degrees of participation and collaboration by individuals or groups - such as patients or their associations - capable of materialising them independently by developing

³⁴ See: Vocabulary Treccani online: www.treccani.it/vocabolario/cura

³⁵ See: www.merriam-webster.com/dictionary/care

³⁶ See: Vocabulary Treccani online: www.treccani.it/vocabolario/paziente

a professional, scientific and entrepreneurial attitude.

But to what extent does this initial affirmation find confirmation in the scientific field, in society and in the world of innovation? Beginning from the general framework of social, technological and financial transformation emerging in the healthcare sector, a parallel work of *literature review* (to be considered as *in progress*) and identification of seminal experiences that have a dual purpose, was sketched out and initiated:

- identify interpretative approaches, issues, questions and filters that can support a qualitative - analytic and multi-level - reading of *MakeToCare* as a research area: from the criteria for identification of subjects and projects to the most interesting or important topics to explore, from the role of the subjects involved in the development of projects to the models and processes of innovation they put to use;
- framing the *MakeToCare* area of research from multiple perspectives, from that of individual user innovators to the community of innovators to end up at the participatory approaches of research centres and collaborative production practices of *makers* and *makerspaces*.

To sketch out the research we therefore started by considering in an extended and inclusive way the transformation of the role of the patient and the impact generated by this transformation: from the recipient of innovation developed for him by research centres and companies, to the proponent of solutions designed by him and (self)-produced. Starting from this *statement*, the *literature review* and research of cases was developed in these directions:

- identify the models of innovation where the user-patient is the activator or where there is an open and participatory planning between the patient and other subjects with different expertise;
- identify the research projects and experimental initiatives where the user-patient and his caregiver surroundings develop bottom-up solutions, replacing or as an alternative to a consolidated official system;
- identify the research projects and experimental initiatives in which the user-patient is involved and where there is a propensity to the use and experimentation of innovative technologies or independent development of technology solutions.

Three research and innovation projects developed in Italy corresponding to these characteristics were identified on this basis. These experiences were analysed from the perspective of themes, objectives, methodologies, work processes and output: *SMART-map*, *CREW* and *OpenCare*. They are three initiatives either ongoing or at an advanced development phase having the following characteristics:

- *SMART-map* (sheet 2.1), is characterised by the involvement of the cultural, scientific and entrepreneurial world with the goal of raising awareness and providing tools (guidelines) for the socially responsible and inclusive use of innovative technologies in the healthcare sector;
- *OpenCare* (sheet 2.2), is characterised by an *open* process of construction and activation of a physical and digital platform at the service of an ecosystem of stakeholders such as elderly, patients, institutions, *makers* and *makerspaces*, researchers, and designers. All these subjects are interested in highlighting individual and social issues stimulating the development of bottom-up innovative solutions exploring the potential of digital technologies in the production of material and social innovation;
- *CREW* (sheet 2.3), is characterised by a systemic activation process of different subjects with different expertise (technical and scientific, medical and social, psychological and relational), and having the goal of developing, prototyping and experimenting innovative technology solutions to improve the conditions of disability.

SHEET 2.1 SMARTMAP

Country	Europe
Year	2016–2018 (ongoing)
http	projectsmartmap.eu
Beginning and type of initiative	<i>SMART-map (RoadMAPs to Societal Mobilisation for the Advancement of Responsible Industrial Technologies)</i> is a project (Coordination and Support Action) funded by the European Commission within the Horizon 2020 programme. Its specific aim is the definition and implementation of <i>roadmaps</i> for the responsible development of technologies and services in the fields of precision medicine, synthetic biology and of 3D printing in biomedicine.
Subjects involved and their role	The research consortium encloses a multidisciplinary collection of organisations and experts in technology, medicine, social sciences, biology, management, journalism with their experience of interaction with industry in common. The project is coordinated by Aarhus University and sees the participation of three other Universities – Central European University, Manchester Metropolitan University and University of Manchester, research institutes such as Fraunhofer Institute and Zentrum für Soziale Innovation GmbH, Fondazione Giannino Bassetti that focuses on responsible and inclusive innovation, and two companies specialised in communication science and biotechnology, Formicablu and Genómica Institute of Medicine. The project takes advantage of the skills and indications of an <i>advisory board</i> composed of a group of subject experts in Responsible Research and Innovation (RRI Angels) and a group of subject carriers of the perspective of civil society (among these the <i>Patient Innovation</i> platform).
Mode of collaboration	The <i>SMART-map</i> project actors are focused on the co-design and development of collaborative tools that can help the innovators to use the new technologies for healthcare responsibly.
Research, design and materialisation of the product-service solutions	The heart of the <i>SMART-Map</i> project relies on building an innovative format to build an open and collaborative dialogue between the industrial world and social actors (<i>Industrial Dialogues</i>) and organise training workshops for industry on themes of inclusive and responsible innovation. The tool of <i>industrial dialogues</i> is therefore used to build interpretative maps of three different fields: precision medicine, synthetic biology and 3D printing. The three maps are then made to interact with each other to identify cross-disciplinary innovation challenges on the topics of Responsible Research and Innovation.

Final results

Starting from the development of the *Industrial Dialogues* the result expected from the project is the co-design of the *SMART-map* tool, a tool that will support companies in the task of managing the issues of social and environmental responsibility in their innovation processes more effectively.

SHEET 2.2 OPENCARE

Country	Europe
Year	2016–2018
http	opencare.cc
Beginning and type of initiative	<i>OpenCare</i> is a research project funded by the European Union through the Horizon 2020 programme. It began with the intent to experiment innovative solutions for care needs, i.e. products-services able to respond in a tailored way to the needs of citizens, as an alternative to the high standardisation of traditional services.
Subjects involved and their role	The <i>OpenCare</i> research consortium sees the participation of the Municipality of Milan in involving local communities, of the Universities of Bordeaux and Stockholm for the development of analysis technologies and study activities and ethnographic mapping, and of the WeMake <i>makerspace</i> for designing and developing the prototypes and documenting and communicating their processes. Finally Edgeryders and Fondazione Scimpulse [sic: SCIMPULSE] with a management role of the communities and stimulation for the diffusion of the collaborative practices.
Mode of collaboration	<i>OpenCare</i> configures itself as a project that collaborates with citizens to identify problems and define their needs and then to co-design possible solutions and build <i>open</i> prototypes to share with the communities. The research is therefore characterised by a model of participatory and <i>bottom-up</i> innovation, with a particular focus on the open source dimension of the co-designed processes and solutions.
Research, design and materialisation of the product-service solutions	The development of the <i>OpenCare</i> project passes through a phase of meeting and listening to citizens to identify, define and analyse the problems and needs related to care. The activation of citizens is then stimulated through workshops open to the public, where persons can try to create products-services for care using digital technologies. Subsequent co-design meetings are focused on more specific needs and lead to the development of concepts that are then prototyped and experimented also involving <i>makers</i> , designers, researchers and user

	groups. The testing phase is considered very important in the process, as the growth of the user community promotes the modification of prototypes, thus increasing their efficiency.
Final results	The <i>OpenCare</i> research has led to the development of a first project, <i>InPè</i> , a <i>wearable open source device</i> that measures an extraordinary event such as the fall of a person, generating as a response the forwarding of emergency calls and the <i>Open Rampette</i> initiative, that generated <i>low-cost</i> solutions to improve physical accessibility to commercial activities for persons with disabilities. Another important deliverable of the research is the <i>Playbook</i> , an open source guide explaining the approach and methodology of work of <i>OpenCare</i> : involvement of citizens, co-design and shared prototyping of the solutions and documentation.

SHEET 2.3 CREW

Country	Italy
Year	2014–2018 (ongoing)
http	progettocrew.it
Beginning and type of initiative	<i>CREW (Codesign for Rehabilitation and Wellbeing)</i> is a pilot project of research that began within an Action Plan promoted by the Fondazione Cariplo [Cariplo Foundation] to stimulate the design and prototyping of technological solutions and innovative devices in the sector of enabling, of motor and cognitive rehabilitation and the social inclusion of persons with permanent, temporary or age-related disability.
Subjects involved and their role	<i>CREW</i> counts approximately 50 stakeholders grouped into five categories. The <i>Research and Clinical</i> category brings together clinicians (neurologists, psychologists, geriatricians, psychiatrists, neuropsychiatrists, paediatricians), technicians (physiotherapists, therapists, orthopaedic specialists, teachers) and researchers (computer and telecommunications, physical sciences, engineering, bioengineering, architecture, design, teaching) who operate in hospitals, research centres and workshops. The <i>Enterprise and Startups</i> category brings together SMEs and large companies, <i>makerspaces</i> , startups and spin-offs active in the areas of automation, home automation and building installations, building, production of technological aids, graphics, design, software development. The <i>Civil Society – Third Sector</i> category includes the associations and

representatives of patients, families, and caregivers and volunteer associations that provide services to patients and families. To these three categories, perfectly coinciding with the areas of *MakeToCare*, we add *Education and Training* (teachers, educators, sports coaches, occupational therapists) and *Policy Makers* (public administrators who work in healthcare and education).

Mode of collaboration

The stakeholders, coordinated by Fondazione Cariplo, collaborate at the definition phase of the areas of intervention, in the construction of design workshops. A web TV dedicated to innovation (*Triwù*) supports the communication and dissemination of projects. *CREW* declares to take as a starting point the paradigm of Responsible Research and Innovation (RRI) and to have a *bottom-up* approach to innovation, founded on processes of co-design that integrate the multidisciplinary clinical, technical and scientific expertise with that produced through the experience of individuals and organisations working in the field of care.

Research, design and materialisation of the product-service solutions

The stakeholders, coordinated by Fondazione Cariplo, were involved in the definition of the areas of intervention and in the establishment of design workshops. A group of stakeholders participates in each design workshop that, self-managing, has the objective of co-designing innovative concepts of products and services for care and disability, accompanied by a feasibility and business plan (with the support of the accelerator Fondazione Filarete [Filarete Foundation]). The final phase anticipates the development of prototypes and an activity of experimentation of the same.

Final results

The workshops developed eight project ideas for rehabilitation, well-being and improvement of quality of life of persons with permanent, temporary or age-related disabilities. The shortlisted ideas are supported with a view to a course of development and putting into production.

These three projects, observed in their totality, provided elements of reflection to the *MakeToCare* research, outlining some first conceptual starting points, i.e.:

- the development of innovative solutions at the interception formalised and official research processes and tacit/explicit participatory and social activities;
- the development of innovative solutions in the healthcare sector involving different categories of subjects, obviously including patients;
- digital technologies cover the entire process of innovation, from the collective identification of needs to the design and prototyping phases of solutions.

These are the elements on which a literature review was made and articulated in the next sections (2.1.2, 2.1.3 and 2.1.4). The aim is to arrive at the theoretical and exploratory definition of *MakeToCare* and its sphere of intervention.

2.1.2 Bottom-up models of innovation in the healthcare sector

“...innovation is dynamic problem-solving among friends...” (Aleinikoff, 2014).

This is the easiest and perhaps most effective explanation that can be given to the concept of *bottom-up* or *grassroots innovation*, an approach to innovation that has produced cases and experiences for decades but that has only recently begun transforming into a true and proper field of study.

An article published in 2016 by Hossain Mokter in the *Journal of Cleaner Production* and entitled *Grassroots innovation: A systematic review of two decades of research* (Hossain, 2016) systematised two decades of scientific literature on the topic to better define what *bottom-up* innovation is and how it develops. The main reasoning of this work maintains that bottom-up innovation is characterised first by being generated from civil society instead of from public institutions or companies. It is therefore derived from knowledge, experience and competencies incorporated in individuals and communities located outside of the formal and institutional settings of education, research and industry. Bottom-up innovation attempts to solve complex local or located problems and situations that concern above all the interests and values of the communities directly involved. It is often associated with the issue of sustainability and is characterised as an elective field for socio-technical, *low cost* innovation, because it combines formal and informal science with an experimental dimension developed through *low-tech* (or even *no-tech*) technologies and—unlike mainstream innovation—tends to operate without having economic interest as a substantial dimension. This model emerges when the dominant innovation models are blocked and sustainable changes occur within niches (Seyfang and Haxeltine, 2012). Among the most common examples we can cite community energy projects, local systems for recycling of materials and community healthcare or care facilities (Smith et al., 2014).

The world of official research has always considered this type of process with interest in terms of potential impact of participation and results. This filter allows us to look at a much more varied collection of innovation processes that share its effective approach, to read connections and opportunities of the experiences that we wish to analyse in the healthcare sector.

Bottom-up innovation generated from user participation. The evolution and transformation of the user in the design of goods and services has a tradition that started in the 1960s and accompanies the progressive development of organisations and socio-technical systems, speeding the process of democratisation of technologies. This intertwines with both the increasing level of participation of users in social innovation processes and with the growing importance of design in the company. It is *participatory design*, understood as a methodological approach but also as an emerging spontaneous practice, that studies, analyses and proposes the engagement of the *user-stakeholders* within the design processes, in order to develop usable products and services that respond to needs defined together with users.

This approach over the decades also found models of informal intervention—diversifying even to operate on micro or macro systems—and can transform the design activity into a community activity that shapes the same goals, processes and organisations, and that is characterised by its open and distributed form (Bødker and Pekkola, 2010).

This is true even when talking about those disciplinary areas that operate on human-technology relationships, i.e. the ways in which persons may interact with technologies (especially digital) generating relevant interdisciplinary research areas such as *User-Centered Systems Design*, *User Experience (UX)*, *User-Centered Design (UCD)*, *Interaction Design (IxD)* and *Human-Computer Interaction (HCI)*.

The progressive evolution of these forms of design in an increasingly independent and participatory logic is behind the development of *user centered innovation* (von Hippel, 2006 and 2008) and of *participatory innovation* (Buur and Matthews, 2008). Given the centrality of this topic in the *MakeToCare* research, the relationship between these approaches and the sector of healthcare is the subject of a specific in-depth

investigation in the next sections 2.1.3 and 2.1.4.

Bottom-up innovation and open innovation. Talking about *bottom-up* innovation referring to the paradigm of *open innovation* means talking about a willingness or need for change that begins within organisations to compete in a global marketplace, for which it is no longer sufficient to rely on the internal knowledge of the same organisation because the knowledge is produced and distributed through organisations and individuals in an open manner (Chesbrough et al., 2006). The principle is very simple: the best ideas and knowledge do not begin only in companies or the University but may be proposed from a broad range of persons connected in *scope networks* (citizens, professionals, inventors, etc.). In a sector such as healthcare, that is characterised by an increasing involvement of patients, a major challenge for healthcare organisations is collaboration with the same patients or *caregivers* to innovate and allow knowledge and ideas to flow from the innovation process (Chesbrough et al., 2006; Wass and Vimarlund, 2016). The mix of *bottom-up* innovation and open processes generates - from a new form of relationship between individuals, companies and marketplace - a model around which the world of company incubators and accelerators grew and where large companies, large consulting agencies, centres for innovation, but also entities and institutions, may develop collaborative platforms and *specialised arenas* such as *contests* or *challenges*. All these initiatives aim to stimulate both the connection with new ideas and talents, and the development of new potential entrepreneurial opportunities.

But in what way did the topic of *open innovation* enter the healthcare sector?

Naturally, there are multiple themes and areas of activity, even if these dynamics of experimentation are to date at an early development stage in the healthcare sector. Much attention is placed on understanding the factors that enable, block or slow down the development of *open innovation* in the healthcare sector, and on the study of the transformation of companies thanks to the introduction of organisational models based on this type of innovation (Bianchi et al., 2011). Other contributions, starting from the increasing role played by the alliances in the innovation process (Dittrich and Duysters, 2007), highlight the importance of building networks that increasingly include weak links with external subjects working outside of their key areas (Fascia and Brodie, 2017). Another theme is the management of the processes of innovation in the healthcare sector, involving a new generation of labs that enables the solutions developed by companies with citizens and institutions, such as for example the *Living Lab*³⁷.

Finally, the study of the enabling tools for open innovation: from the platforms and digital services that play a role both of mediators between different actors (Yoo et al., 2010 and 2012) and that of intermediaries for *patient empowerment*, up to the role of *contests* and *competitions* in developing technology solutions (e.g. *hackathon*). A report of 2017 published by NESTA entitled *Open innovation in health. A guide to transforming healthcare through collaboration* (Gabriel et al., 2017) provides an overview of examples on how open innovation operates in the healthcare sector, highlighting how companies, governments, researchers and citizens collaborate to improve the innovation processes, from the way problems are identified to when new products-services are created and used by healthcare providers.

Bottom-up innovation and social innovation. Talking about *bottom-up* innovation, referring to social forms of invention and co-design of products-services in the healthcare sector, also means talking about *social innovation*. It is not easy to contextualise social innovation because it is a widely available and diffuse network of complex phenomena for which there are many different definitions. For one of the maximum experts of social innovation, Geoff Mulgan, one of the founders of NESTA “...*Social innovation refers to new ideas that work in meeting social goals (...) innovative activities and services that are motivated by the goal*

³⁷ Like for example Healthcare Living Lab Catalonia (<http://healthcarelivinglab.cat>); eCareLab (www.ecarelivinglab.eu); Living Lab ActiAgeing (www.actiageing.fr); MEDICALPS (www.medicalps.eu)

of meeting to social need and that are predominantly developed and diffused through organisations whose primary purposes are social...” (Mulgan et al., 2007). Social innovation therefore refers to collaborative and bottom-up actions, experiments and initiatives that formulate a response to specific local needs or social challenges of a global nature. It is a multidisciplinary research area that encompasses economic, social and project disciplines such as design. The SIHI – Social Innovation in Health network³⁸ defines social innovation as “...A solution (processes, product, practices, market reviews) implemented through different organizational models. The solution has been developed by a range of actors in response to a systemic health challenge within to geographic context. It profoundly challenges the current system status quo and has enabled healthcare to be more Inclusive, effective and affordable. Social innovation uses a people-centered perspective...”

This aspect emerges auditing the contribution of social innovation in the healthcare sector. In this field there are studies that argue on affordable efficient and quality health services, experimenting new organisational methods to improve efficiency through the coproduction of services based on *community health* (Hussein and Collins, 2016), the design of structures and open source digital products-services for care, and using funding or investment services such as *pay-for-success* (Van Herck, 2010) or developing new forms of *social entrepreneurship*. The *policy paper Social Innovation In Health And Social Care* (Davies and Boelman, 2016), released as part of the *Social Innovation Europe*³⁹ research and identifies a collection of important themes and priority challenges for social innovation in the health and social care sector: the enhancing of patients in the design and delivery of service phases; the development of *peer to peer* forms of support; the development of new professional roles within the healthcare sector; the development of applications for *m-Health*. The construction of initiatives in this area should take account of the ability to manage risks, the ability to negotiate the expectations and requests of citizens-patients, and the need to measure costs and benefits of the innovations.

Bottom-up innovation and frugal innovation. Talking about *bottom-up* innovation, referring to methods of auto- and coproduction of *frugal* solutions in the healthcare sector, means talking about *frugal innovation* (Radjou et al., 2012). The *frugal innovation* proposes in fact an auto-generated and auto-produced vision of innovation where solutions are for resolving specific problems in a quick and easy way. These are solutions often generated in low-resource settings and guided by the concept of austerity but able to scale very quickly in commercial or entrepreneurial terms (Bianchini and Maffei, 2104). Indeed, the *frugal innovation* can also be considered as “...a process to discover new business models, reconfigure value chains, and redesign products to serve users who face extreme affordability constraints, in a scalable and sustainable manner. It involves either overcoming or tapping institutional voids and resource constraints to create more inclusive markets...” (Bhatti, 2012). More simply, doing frugal innovation means providing functional solutions for many subjects who have few means using scarce resources (Maric et al., 2016).

Some interesting topics and approaches of frugal innovation explore the future of an *affordable* healthcare, conceiving products having a disruptive potential in terms of the cost/performance impact: i.e simplified, convenient and accessible to large population groups and low-income markets (or for the *bottom billion*, Mani and Danasekaran, 2014; Ramdorai and Herstatt, 2015). More specifically, considering the approach of *frugal innovation* in the perspective of the *MakeToCare* research, two interesting areas of analysis emerge:

³⁸ See: <https://socialinnovationinhealth.org>: The Social Innovation in Health Initiative is a network of passionate individuals and institutions combining their skills and resources in support of key activities to promote social innovation in health

³⁹ See: www.si-drive.eu/wp-content/uploads/2016/02/social_innovation_in_health_and_social_care_january_2016.pdf

the first concerns *low-tech* solutions with high potential diffusion, better able to respond to the challenges of citizens in health and care matters compared to traditionally designed digital technologies, the second concerns the solutions understanding the potential of *reverse innovation* (Govindarajan and Trimble, 2012). In other words, simple, smart and *low-cost* solutions developed to meet the needs of developing countries with limited technologies, industry and infrastructure, can be re-manufactured and digitized as innovative goods in Western countries.

Bottom-up innovation and processes of auto and micro production. Talking about *bottom-up* innovation, referring to *independent, collaborative* and *digitally enabled self* and *micro production* processes means on the one hand talking about *open* or *common-based peer production* (Benkler, 2007) and *distributed production* and on the other hand talking about the diffusion and evolution of *hacker and maker culture*. The *open production* refers to an emerging collaborative production model which may be web-based or in physical locations such as Fab Labs. Often this productive model is connected to *open design* approaches leading to the development of projects (under free *Creative Commons* IPR license) based on the sharing of digital files of design released freely to allow its replication or *distributed production*. The *distributed production* is essentially a form of decentralised production developed by organisations or individuals using a network of productive structures and technologies located geographically far apart through ICT technologies. This form of production is behind the *Maker movement* (Anderson, 2013; Dougherty, 2016) or *Do-It-Yourself* culture, and allows an open, distributed and local production of objects, on a microscale close to the end user. In technologically more advanced forms, distributed production is present today in the concepts of *Industry 4.0* (Europe) and *Smart Manufacturing* (USA) thanks to the introduction of cyber-physical systems or the development of automation systems managed by Artificial Intelligence.

The relationship between *hacker culture*⁴⁰ and the healthcare sector is configuring as a territory of exploration and practice that has different points of interest and contact with the *MakeToCare* research area. Within this relationship different investigation initiatives coexist, aiming to explore the role of the *hacker culture* (Thimbleby, 2013; Himanen, 2013) in an *open health* perspective (c). These initiatives aim to implement *open source devices* that facilitate the collection and sharing of data on the health of persons, which aggregated may help in the development of epistemological studies, diagnosis and management of chronic diseases or, simply, improvement of lifestyle. The *hacker culture* is also interested in exploring the biology area giving life to *biohacking* or *Do-It-Yourself Biology* (Delfanti, 2013 and 2014; Goysdotter, 2015) intended both as development of a lab culture connected to the principles of *open science*, and also as the ability to manage the human biology independently, combining medical and nutritional techniques, electronics and cybernetic devices, and synthetic biology. From a *trans-human* perspective, *hacker culture* and ethics push as far as exploring the theme of the human body as an organism to be changed and improved thanks to continuous design and implantation of self-designed cybernetic devices (Barfield, 2015). Making the theme of *hacking mainstream* and relating it more closely with the theme of *MakeToCare*, it is interesting to observe how the hacker culture in healthcare (Day et al., 2017) is already used by associations, informal networks and large institutions to develop experimental initiatives. *Hacking Health* (hackinghealth.ca) is a social organisation with chapters worldwide that promotes the organisation of

⁴⁰ See: <http://hackerspaces.org> “...hackers: persons interested tinkering with technology, meet, work and still their projects, and learn from each other...”

*hackathons*⁴¹, cooperative initiatives where innovators from diverse disciplines and healthcare experts confront each other to develop creative solutions exploring the use of emerging technologies. Even the MIT through the *Hacking Medicine* group⁴² (hackingmedicine.mit.edu; Gubin et al., 2017) composed of students, and members of the *hacker* community, operates to stimulate and accelerate medical innovation by organising hackathons that work on designs of product solutions and networking sessions to discuss entrepreneurship in the healthcare sector. Moving from *hacker* to *maker* culture, the main topic becomes the use of digital fabrication technologies by citizens-innovators and the role of Fab Labs/*makerspaces* and *maker* communities in developing healthcare solutions. Currently, a lot of interest revolves around the theme of *3D printing* and all its possible applications, starting from the development of prostheses and orthoses (Hurst, 2016) then moving to understand what the challenges for the *makers* are (e.g. users and designers). Finally, it is places such as the Fab Labs that are becoming facilitators and enablers for the personal manufacturing of tools and devices needed for the self-management of care (Dreessen et al., 2014 and 2016). This phenomenon takes place not only working on the transformation or hacking of existing objects but also re-thinking the participatory activities of design and manufacturing performed in these spaces, in order to support non-expert users⁴³ who need to design and materialize their own healthcare solutions.

Bottom-up innovation and Responsible Research and Innovation. Talking about *bottom-up* innovation, referring to ethical and social issues that enter the sphere of patients and care systems, primarily means referring to the topic of *Responsible Research and Innovation (RRI)*. The European Commission, strategically focused to incorporate this topic in programmes such as Horizon 2020, defines RRI as “...an approach that anticipates and assesses potential implications and societal expectations with regard to research and innovation, with the aim to foster the design of Inclusive and sustainable research and innovation...”. Von Schomberg defines Responsible Research and Innovation as “...a transparent, interactive process by which societal actors and innovators become mutually responsive to each other with a view to the (ethical) acceptability, sustainability and societal desirability of the innovation process and its marketable products in order to allow a proper embedding of scientific and technological advances in our society...” (von Schomberg, 2011 and 2013). RRI involves processes based on collaboration and ample involvement of social actors – researchers, citizens, enterprises, *policy makers*, organisations and associations – throughout the development of the innovation processes aligning it to results, values and expectations of society (Stilgoea et al., 2013; Kerr et al., 2017). Re-stating the definition of the European Commission, RRI is also conceivable as “...a package that includes multi-actor and public engagement in research and innovation, enabling easier access to scientific results, the take up of gender and ethics in the research and innovation content and process, and formal and informal science education...”.

In general terms, auditing the theme and approach of RRI within the healthcare sector, an interest also emerges in those disciplinary areas strongly based on the relationship between science and technology. RRI includes ethical issues that concern the behaviour of non-human agents in the field of *robotics care* (Stahl

⁴¹ The hackathon are short-lived events (from one day to a week), open to participation of programmers and designers from diverse disciplines committed to developing software and Internet of Things in a collaborative and competitive dimension. Organising a hackathon in the healthcare sector means for example involving IT designers and developers but also physicians, patients and caregivers to develop solutions and prototypes that may then be tested in clinical practice and hospitals

⁴² See: <http://hackingmedicine.mit.edu>. Health. The group declares on its site to have organised over 150 events in 15 countries and 5 continents, with over 40 new companies created and 150 million US dollars in venture funds collected

⁴³ Some examples are the Waag Society MakeHealth project – FabLab Amsterdam (<https://waag.org/en/project/makehealth>) and MakeHealth US (<https://makehealth.us>)

and Coeckelbergh, 2016), and the social impact the introduction of exoskeletons in the field of disability may have (Sadowski, 2014) or even the impact of *blockchain* technology in the healthcare sector. Other topics push to research the ethical and social limits linked to the development of precision medicine or the social, historical and anthropological perspectives of synthetic biology. More specifically, verifying the approach of RRI in a *MakeToCare* perspective, a first reflection soon emerges: if patients are increasingly becoming an integral, autonomous, or propulsive part of the innovation processes, it is important to understand how the topic of RRI evolves and transforms with respect to their method of developing innovation and the transformation of their responsibility. In this sense, it becomes interesting to explore *MakeToCare* as a possible area through which to explore the different dimensions of RRI in a structured way. Another option is to consider the *MakeToCare* as laboratory-observatory to explore the ethical and social impact of *bottom-up* innovations in the healthcare sector and within health services, or integrated in a *policy* dimension and compared with the institutional culture and leadership, or with the processes of openness and transparency.

2.1.3 The birth of the citizen-designer and the participation of users

One of the characteristics of *bottom-up* innovation models is to stimulate new forms of civic and social responsibility in the figures of designers and other creative professionals, thus contributing to the formation and the development of the figure of the *citizen-designer* (Heller and Vienne, 2003; Boland, 2012; Manzini, 2015; Resnick, 2016). Because if it is true that the citizens over the decades have developed increasingly complex design skills up to be considered *free innovators* (von Hippel, 2016), it is also true that the designer - whether a *professional* or *educator* - has extended their presence and role in society and involvement in public participatory design processes. In this regard Ezio Manzini in *Design when Everybody Design* (Manzini, 2015) talks of *diffuse design* (with shared processes in which everybody participates) and *design by experts* (performed by persons trained as designers). He explains how the design skills that unite design, technology and communication interact with the forms of cultural activism and *problem solving* developed by the *grassroots organisations* through emerging forms of open, distributed and *peer-to-peer* collaboration.

As Milton Glaser says “...*Good design is good citizenship*...”, design can add not only economic value to society but also heighten the level of social and cultural challenge. For this, the *design approach* and *concept of citizenship* should go hand-in-hand. The designer should be professionally, culturally and socially responsible for the impact that their action generates on citizens in the same way as each citizen should understand that the design actions will have a certain impact on the environment and socioeconomic system (Heller and Vienne, 2003).

The *design citizenship* is then an emerging condition that brings together and connects the *citizen as designer* with the *designer-citizen*. A hybrid status that, as sustains Elizabeth Resnick, author of *Developing Citizen Designers*, requires a moral responsibility in uniting social applications with professional practices (Resnick, 2016). A practice that is complex and rich in diversity, in which there are no a priori right methods but only scenarios to be transformed from the design point of view, developing an experimental and prototyping dimension characterised by inclusive and emphatic forms of social activism. This means acquiring the ability to build pilot initiatives selecting chosen and extended partnerships that allow designers and citizens to listen and learn, cultivate values, including the ability to assess the transformational outcome and its impacts. An article entitled *Citizen as designers* published in 2012 in the *Stanford Social Innovation Review*, (Boland, 2012) addresses the topic of the shifting of the citizen's responsibility in the step from *deciding* to *designing* in the challenges that society is called to resolve. Among these one of the most important is certainly of ensuring the health of citizens, that today requires

greater recourse to processes of creativity and pragmatic innovation rather than extended analytical and deliberative discussions. The article maintains that *mass collaboration* and *user innovation* are often used to design products, generate knowledge and create markets, but still have a limited role in socio-political transformation. This generates the need to re-define the role and activity of citizens within the socio-political system to involve them in the expression of their energy and their best ideas to make them act as citizen-designers.

But how does this discourse identify with the healthcare sector? In general, the transformation of services in the healthcare sector has followed the same paradigm changes of other sectors, with the slow transition from centralised and Taylorist organisational models to more distributed and open paradigms, where citizens are considered co-creators of their own well-being. It is the switch from the original *centralistic-paternalistic* model of *mass-production* of health services, going through the *mass-customisation*, or a model of *mass personalisation* of products-services, to arrive at the current paradigm of *mass-collaboration*, characterised by a participatory model of health care (Freire and Sangiorgi, 2012) and therefore to the idea of *mass-innovation* (Leadbeater, 2009).

The healthcare sector has since several years been a privileged area of experimentation for *user-centered design* and co-design applied at different levels and scaled to product-service solutions. There is a robust multidisciplinary scientific literature on this topic (medicine, social sciences, design, engineering, economy and management) that ranges from the design of product interfaces or the configuration of care settings up to the redesign of health services adopting participatory or *patient-driven* perspectives (Bannon and Ehn, 2012). It is also the exact idea of *patient engagement*, i.e., individuals, groups or communities motivated and determined from a design point of view, technologically enabled, legally informed or aware and taking moral responsibility, who consciously take a partnership or even leadership role (personal or collective) in treatment and care, arriving at the co-design of products-services characterised by the construction of collaborations with patient associations and healthcare sector companies.

The evolution of participatory design models and processes and the integration between designer-citizens and designing citizens leads to a general reflection: a vision of care as an individual and/or collective strategic project of social value (case in point is the case of Salvatore Iaconesi and his project *La Cura*, Iaconesi and Persico 2016). Finally, the concept of the patient as *health-maker* and of *MakeToCare* as an area of choice for *health-making*, or a process that hosts approaches to the anticipation, design and management of care characterised by collaborative processes and the ability to capitalise the community assets with the purpose of building an area of innovation that promotes and projects the well-being and health of persons.

2.1.4 The patient innovator

The role of patients as protagonist subjects of the innovation processes in the healthcare sector is a certainly emerging issue but still poorly documented in the scientific literature, which may be placed for now along three main guidelines, between the *user innovation*, *participatory* and *design driven innovation* and *new public management*.

Within this framework the *patient-innovator* (Cepiku, 2016; Oliveira et al., 2015) is therefore the last evolutionary stage of a journey that has brought patients (to be considered also as individuals, users-citizens and consumers) to increase their own assurance and role as bringers of new product-service solutions in the healthcare sector.

The patient was for a long time considered primarily the *recipient* (passive) of the processes of innovation

proposed by public and private healthcare systems or by healthcare sector companies, i.e. the *providers* of products and services. Therefore a subject considered more as reference for the *human factor* than as *human actor* (Bannon, 1991). This situation progressively transformed with the development of the global media communication network (now above all social networks) and with the same change of the social and political context: there is increasingly a question of forms and cultures of activation and participation of citizens linked to the growth of an increasingly design⁴⁴ and productive user-centered culture (Buur and Matthews, 2008; Frank et al., 2014).

This worked as a substrate advantageous to the progressive transformation of the patient into an increasingly aware and informed subject with regard to their condition and increasingly able to become active themselves to promote instances or resolve issues regarding their health. The cultural globalisation and enabling technologies have made persons increasingly informed and socially connected, allowing the figure of the *prosumer* (Toffler, 1980) and *lead user* (von Hippel, 1986) to become established in different fields and sectors of the production of goods and services. The last decade finally has seen the pervasiveness of the digital transformation, that has further accelerated the possibility to build social organisations able to innovate on a global level (Benkler, 2007; Murray et al. 2010), further lowered the barriers that separated the processes of innovation between companies and society (*open and democratized innovation*, von Hippel, 2006) and finally provided the possibility that the user may develop innovation and produce it independently (*free innovation*, von Hippel 2016). Within such a connective context, the *patient-innovator* is an individual with an enhanced *agency* and therefore that can be integrated potentially in the cycle of innovation as co-producer, due to the possibility of:

- connection and experimentation with centres of care and centres of research, in turn culturally sensitive and increasingly likely to develop structured and technologically enabled forms of collaboration with patients and *caregivers*;
- access or interaction with resources or means of production (e.g. shared production workshops, platforms for *digital manufacturing*, technology startups) managed by subjects characterised by an evolved culture of collaboration and personalisation.

Visualizing User Innovation in Health Care is in fact the title of the research developed by the University of Innsbruck, Catholic University of Lisbon and the Università degli Studi di Roma Tor Vergata with the aim to study the user innovation developed by patients and *non-professional* caregivers within a complex and professionalised sector such as healthcare (Cepiku and Giordano, 2014). This research built the foundations for the development of the *Patient Innovation* initiative (<https://patient-innovation.com>, sheet 2.4), the online collaborative platform that stimulates the sharing of solutions for care and disabilities developed by patients and *caregivers*. The survey - an online survey conducted in Italy in 2012–2013 with more than 350 participants - highlighted the existence of patients able to invent and (co)-produce product-service solutions without a direct intervention of the medical research system. The results then, discussed with patients, physicians, health managers and ministerial officials, showed products and solutions developed primarily by adults with a prevalent altruistic motivation and a willingness to offer the solutions more extensively. A second survey, conducted in 2013 by the management of the same platform on 500 patients with rare diseases, was a first empirical exploration explicitly confined to *patient innovation* (Dreier et al., 2016). The survey focused on the level of uniqueness of the solutions proposed, on the positive impact in patients' lives, on the factors associated with the development of the innovation, and the method of sharing

⁴⁴ In the 1970s all those research areas where design operated with technologies and systems designed for human use had a large and rapid development: User-Centered Systems Design (UCSD-HCSD) User Experience (UX), User-Centered Design (UCD), Interaction Design (IxD) and Human-Computer Interaction (HCI)

developed by the patients. The cases proposed (90% are service solutions) were analysed by experts who found how 36% of the sample of *patients* and *non-professional caregivers* had developed an autonomous management of their diseases, and how the use of solutions developed autonomously had significantly improved their quality of life.

The research also showed that approximately 10% of the solutions were completely new, while the rest re-proposed solutions that had already been developed, even if not by the same patients or caregivers. Solutions that in approximately 90% of cases were shared with other patients rather than with healthcare professionals (5%) and companies (10%). All this means that there is an innovation potential with wide sharing among patients, but little collaboration between patients, physicians and professionals.

A subsequent work of analysis in 2015 processed by Aalborg University on patients participating in the design of digital media for the care of diabetes, was the opportunity to develop an accomplished definition of *patient innovation* (Kanstrup et al., 2015; Zejnilović et al., 2016). The perspective from which this work of definition begins is that of *user innovation* proposed by von Hippel, a model however that is also viewed critically insofar as thought to focus predominantly on the market (*market-oriented perspective*).

An additional contribution to this definitional work is from the perspective of *participatory design* with the introduction of the concept of *participatory patient* (Andersen, 2010) and therefore “...patients as particular users or workers and force organizers of participatory design in healthcare...”.

The originality and planning of patient innovators is expressed in original solutions that have as principal feature the design willingness to combine technological solutions for the internal care of objects and environments of daily life and to build connections with family members, care service providers, healthcare professionals, friends. Projects of socio-technical networks incorporating dynamics of family cooperation in the design of technologies for the *self-management* of chronic diseases, artefacts associated with personal meaning and technology solutions that support the patient to express their identity. The patient innovation is therefore defined as “...patients’ development of ideas, practice or objects that are perceived as new by themselves and/or others within the social system of adaptation in comparison with high-technology innovations or market share...” (Kanstrup et al., 2015).

It is characterised therefore by the patients’ and *non-professional caregivers*’ ability to build personal product-service solutions that generate or connect to socio-technical networks composed of persons and technology solutions participating in the process of innovation. These networks are strongly oriented to a purpose and have a flexible structure that can evolve and transform according to the patient situation or development of the socio-technical network. The patients through the socio-technical networks become thereby competent actors able to self-manage their own care, also lightening the *caregiver* burden.

SHEET 2.4 PATIENT INNOVATION

Country	Portugal
Year	2014
http	patient-innovation.com
Beginning and type of initiative	<p><i>Patient Innovation</i> is an online platform to which patients and caregivers worldwide can access to share solutions for addressing health problems developed directly by themselves or with the help of collaborators. <i>Patient Innovation</i> began in 2014 at the end of the research entitled “<i>Visualizing user innovation in the healthcare</i>”, developed by the Catholic University of Lisbon with the Università degli Studi di Roma Tor Vergata and the University of Innsbruck with the aim to study <i>user innovation developed by patients and non-professional caregivers</i>. A research supported by the Pieter Pribila Foundation, The Portuguese Science and Technology Foundation and Carnegie-Mellon Portugal Program.</p>
Subjects involved and their role	<p>The <i>patient-innovation.com</i> platform, launched in 2014, started by reflecting on the result of research carried out in 2013. The online platform is managed by the Catholic University of Lisbon together with the Faculty of Medicine at the University of Lisbon (to which some physicians of the design team of the same platform belong). <i>Patient Innovation</i> enjoys the support of foremost scholars participating on the <i>advisory board</i>: Katherine Strandburg, Robert Langer, Lee Flaming, Eric von Hippel and the Nobel prize winners Richard Roberts and Aaron Chiecanover, while other important faculty and researchers operate finally as <i>supporters</i> (patient-innovation.com/who).</p>
Mode of collaboration	<p>The system of actors who manage the platform enables the user-innovators interested in sharing their own product-service solutions that are reviewed by the <i>Patient Innovation</i> medical team. Only validated solutions are published on the platform.</p>
Research, design and materialisation of the product-service solutions	<p>The user interested in sharing an idea or a solution registers on the platform, decides to identify an existing specific <i>Patient Group</i> or create a new group, and can post multimedia information and content that can be implemented over time.</p>

Final results

Since the launch of the platform, more than 650 product-service solutions for care and disability from more than 40 different countries have been submitted by patients (not professionals) or caregivers, validated and then shared online under different categories (*conditions, activities, device, body locations, symptoms, therapies*). *Patient-innovation.com* has obtained numerous rewards and recognition internationally, in turn manages its own award reaching the second edition. The project was then invited by the London Science Museum to be part of “*Beyond the Lab: The DIY Science Revolution*”, an itinerant exhibition that can be visited in 29 European countries from 2016 to 2018.

2.2 DEFINITION OF MAKETOCARE: BUILDING THE RESEARCH MODEL AND PROCESS

2.2.1 MakeToCare: a first definition

The experience of the first *MAKETOCARE* contest was correlated with the work of *literature review* on emerging trends and subsequently with some experiences of significant research in the healthcare sector. This initial work allowed two key areas of *MakeToCare* to be identified: the first one related to scientific research and the second one related to product and technology innovation. Subsequent research on scientific literature focused on participatory and bottom-up innovation models, to the *citizen-designer* and the *patient innovator*, then allowed us define its third characteristic area. This completed the collective view and allowed us to define the boundaries of three areas within which to construct a complete definition of the *MakeToCare* contexts as an innovative space for research, experimentation and materialisation of products for the care and disability of persons:

MakeToCare is a set of practices and processes of innovation originating from the interaction between the healthcare sector with the areas of *making* and new manufacturing and the whole world of patients as carriers of needs and/or product-service solutions invented, designed and created to resolve or improve situations of discomfort and issues related to temporary/permanent diseases or disability.

MakeToCare is an area that is an outcome of the convergence between activities of research, experimentation and (co)design based on the collaboration and coalition between patients and groups/communities of interest, family members and *caregivers*, medical healthcare operators and centres/research laboratories, independent designers and innovators, workshops for shared production, innovative startups.

MakeToCare is an ecosystem that enables *bottom-up* innovation to dialogue with applied scientific research in the biomedical sector, and that in digital production technology finds an enabling platform for the democratization and diffusion of product-service solutions dedicated to care.

This scope of definition was used as the basis to hypothesise the first *MakeToCare Ecosystem* model (or *MTC Ecosystem*) within which to structure the first executive phase of the research, that envisaged a work of exploration conducted within a country context: Italy.

2.2.2 MakeToCare: the research model and process

As anticipated, we defined *MakeToCare* as an area of convergence that begins from the interaction between the *official healthcare* sector, *making* and *new manufacturing* and patients as carriers of needs. The research activity, as we will see in the next chapter, was then structured from a dual level of analysis, which had as its subject of investigation on the one hand those we defined as projects, and on the other those we defined as subjects. The two levels are naturally closely connected and explicit the relationship between who does what, or between the same subjects (who develop the projects) and solutions.

The methodology and research used was based on the construction and fine tuning of a theoretical and operational framework articulated in the following phases.

The construction of the first Ecosystem MakeToCare model. First, the fine tuning of the definition of *MakeToCare* in an *Ecosystem* dimension, or an emerging field of innovators and experimenters of solutions in the context of care that begins from the convergence and interaction between the carriers of needs area (defined as *Patient & Caregiving System*), the area of institutional care and scientific and technology research applied to the healthcare sector (defined as *Healthcare & Research System*) and the area of new companies and the professionals who operate in the field of design, prototyping and production of products-services (defined as *Making, Manufacturing & New Entrepreneurship System*).

The scouting of projects and subjects. Or the first research of projects and subjects and the refining of the first *MTC Ecosystem* model. This phase began with the *desk* and *field* research of the more easily identifiable projects, aligned with the structure and areas of the first *Ecosystem* model. These projects were analysed and broken down at their base levels (goals, subjects involved, relational system, activity and output) in effect performing a first *training* for the next phase of mass and systematic *scouting* of other projects. The first activator was therefore the *project*: isolation of an initial core of cases also allowed us to identify the collection of subjects who developed them and therefore the opportunity to re-build their categories of reference. The progressive iterative research of projects cultivated the subject database and vice versa. In this way it was possible to start to populate the *MTC Ecosystem* beginning from its three main areas. The density of projects and subjects therefore facilitated the understanding of the relationship dynamics of the three areas and enabled us to identify overlapping (or secondary) areas, and therefore to define the final *MTC Ecosystem* model.

Data gathering and the interpretation of projects. Implementing the logical passage of the research _ from projects to subjects _ we implemented the *scouting* phase, ending up increasing and mapping a significant number of projects. The solutions identified were analysed and interpreted in accordance with three different levels:

- *subjects*, the solution as the result of a design process in which the patient is central, not only as a carrier of needs but also as activator or in any case an integral part of an open and participatory approach that sees them connected with other subjects with different skills for the development of the final solution;
- *design process*, the solution developed within a collaborative and/or *bottom-up* generated design process, often proposing itself as an alternative proposal to more established and institutional processes;
- *technologies and production*, the solution involves innovative technologies and skills that support its development in the phases of design, and/or prototyping and/or final development.

The populating of the MakeToCare Ecosystem model. The interpretative model of the scouting phase was therefore the guide to make a first positioning of projects and subjects within the *MTC Ecosystem*. The performance of audits and validation of the correct allocation of the projects and subjects mapped was consolidated in the final populating of the *MTC Ecosystem* in all its main and secondary areas. The collection of subjects identified, according to types and categories of reference, was deployed within the *MTC Ecosystem*, populating the three main areas (*Healthcare & Research System*, *Making, Manufacturing & New Entrepreneurship System* and *Patient & Caregiving System*) and the subsequent secondary areas (or of overlap: *Medtech System*, *Public & Community Innovation System* and *Advanced DIY System*), including the central area that we defined as the *MakeToCare Area*.

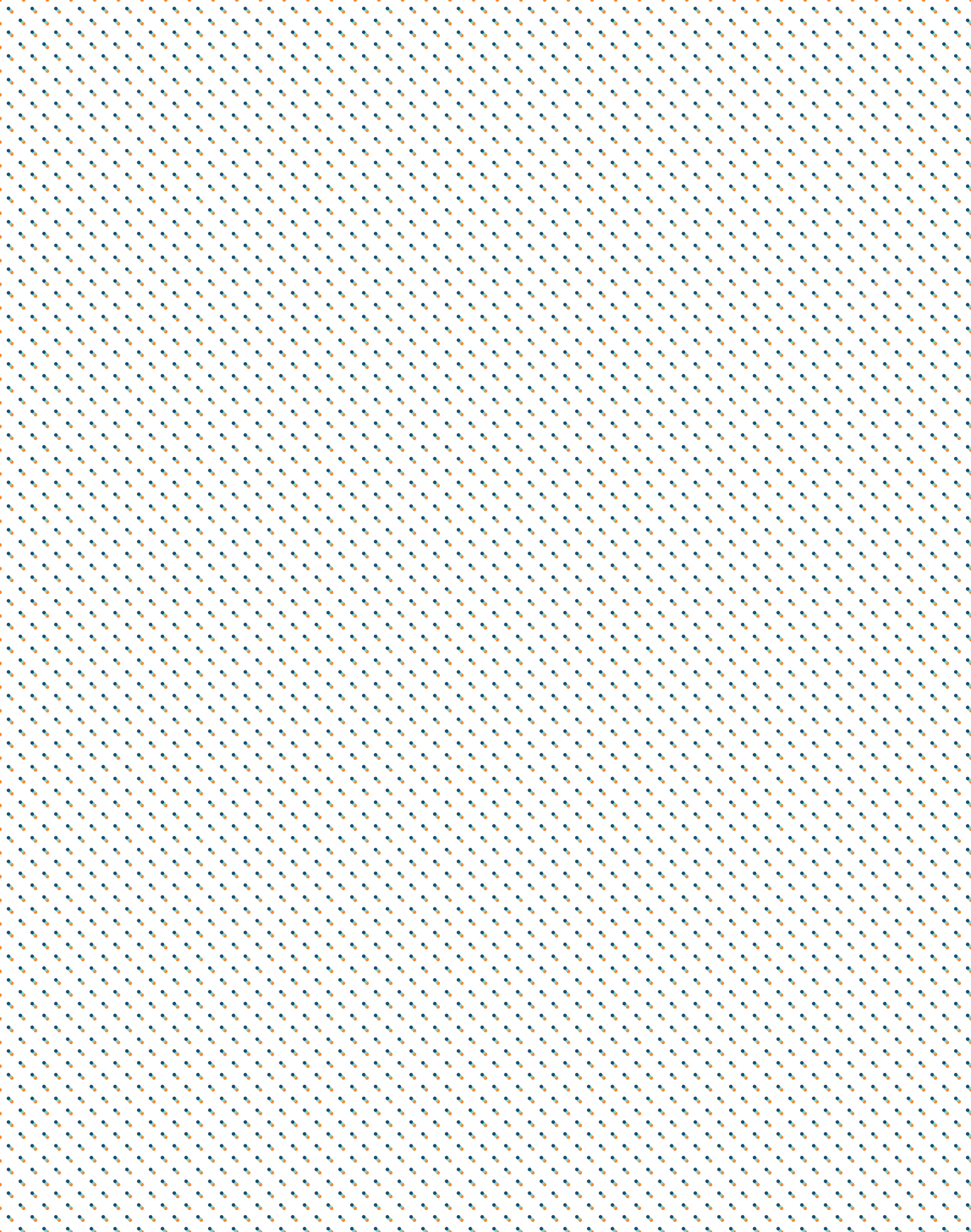
The interpretative analysis of the subjects and projects of the MakeToCare Ecosystem.

The phase of reporting of the *MTC Ecosystem* cases began, by narrative logic, with the analytical representation of subjects and then of their projects.

The interpretative analysis of the subjects and projects was conducted on the following levels:

- *distribution and polarisations*, positioning of subjects in the *MTC Ecosystem*;
- *coalitions and collaborations*, identification of groups of subjects active in the design process and ability of different types of subjects to connect between them to develop the projects;
- *planning*, relationships between actuator subjects (inventors and developers of the solutions) and the projects and products developed;
- *solutions*, types of solutions developed compared to resolved needs.

The allocation of a project to one or more areas of the *Ecosystem* was made taking into account the category to which the subjects who developed it belonged, who naturally may also belong to different categories (and areas) when it comes to coalitions of actors (see part 3).



PART 3

MAKETOCARE ECOSYSTEM: A MAP IN PROGRESS

3.1 METHODOLOGICAL NOTES ON THE MAPPING: AREAS OF RESEARCH AND EXPERIMENTATION FOR MAKETOCARE

The mapping activity of the research was structured from the definition of *MakeToCare Ecosystem* anticipated in the previous chapter, i.e. from the assumption that this Ecosystem defines an emerging area of innovation in the care area, characterised by relational dynamics and renewed design processes. All of this originates innovative solutions that outline an innovative image of a sector routinely considered only as an official system of coded subjects and processes. However, this is an area characterised by transformative causes, which on the one hand see the patient no longer (only) as a passive end user, but rather, see the centres institutionally dedicated to healthcare as part of a system that is more complex and open to the external world, characterised by relationships with subjects and processes of original experimentation and *bottom-up* design initiatives.

If the *MakeToCare* research begins from the assumption of a transformation of the healthcare sector, the mapping can also only start from an analysis of the traditional system of reference for the care of a person, that includes hospital institutions, research centres and places of recovery and rehabilitation. The Sistema Sanitario Nazionale (SSN) “...is a system of facilities and services that are designed to ensure for all citizens, in conditions of equality, universal access to the equal delivery of healthcare services...”⁴⁵ and includes approximately 26,700 subjects⁴⁶ classified in 2013 by ISTAT as care facilities, divided according to the type of care delivered. Among these are the *IRCCS Istituti di Ricovero e Cura a Carattere Scientifico*, considered hospitals of excellence and specialised centres with research purposes, that perform services of hospitalisation and specialised care and are classified as Institutes of Research of the *National Health System*. Among the Institutes of Research of the SSN is also included the Istituto Nazionale Assicurazione Infortuni sul Lavoro (INAIL) with its Centro Protesi of Vigorsio Budrio (Bologna), a state-of-the-art facility specialised in orthopaedic techniques for the care of persons with very serious disabilities (caused by

⁴⁵ See: Ministry of Health, Health Research, www.salute.gov.it. The [Italian] National Health Service (SSN) was established with Law No. 833 of December 1978. The concise abbreviation of SSN includes the complex of functions, facilities, services and activities that the State guarantees to all its citizens, without distinction, for the maintenance and recovery of physical and psychic health, and the implementation of systems to protect the same, as per Article 32 of the Constitution

⁴⁶ See: Ministry of Health, National Health Service Statistical Yearbook, www.salute.gov.it/statistiche. In 2013, the Ministry of Health surveyed the facilities of hospitalisation, dividing them in public facilities, equivalent to those public and private facilities accredited with the SSN. The facilities were also divided by type of care delivered (inpatient, specialist outpatient, community residential, community semi-residential, rehabilitation and other community)

congenital and/or traumatic diseases) and children who require prosthetic interventions. In this way it was possible to identify a coded system of institutional subjects who, by nature and vocation, are oriented to research and experimentation and, each with their own skills, to the development of projects for the study, care and improvement of the health and quality of life of persons. It connects to the larger national system of *Scientific and Technological Research*, composed of public and private subjects who in Italy perform, indeed, research activities (scientific and technological). Universities, Public Research Institutes and other types of public or private subjects (defined *other bodies of research*⁴⁷), operate within this system supported by the Ministero dell'Istruzione dell'Università e della Ricerca (MIUR) to “*produce new knowledge and create new products and production processes of high knowledge added value*”⁴⁸. Universities and Institutes therefore perform, with different objectives and methods, research of an essential or basic type, often working together and developing synergies according to a systemic logic that the same MIUR supports and nourishes.

The identification of those subjects belonging to the *National Health System and National System of Scientific and Technological Research* is therefore the first methodological step implemented to construct the framework of reference for the mapping. This step enabled the first area of the *MTC Ecosystem* to be defined, what we called the *Healthcare & Research System*, i.e. the collection of subjects accredited institutionally who, in collaboration and synergy with other subjects, also develop activities of research, helping to define possible future scenarios and methods of development also (but not only) in the healthcare sector.

Within this system a first nucleus of subjects was then isolated, characterised by an approach, research and project activity in line with the definition of the *MTC Ecosystem*: subject carriers of a different vision capable of implementing methods, practices and processes of experimentation that lead to the development of unreleased solutions, often thanks to the support of technologies and skills from other disciplinary areas.

A second phase was added to this first step of research, focused on subjects involved with productive processes and who intervene in varying measures in developing the process of innovation, from the initial invention phase to the phase of materialisation and production of the final solution. One of the goals of this survey, in fact, was to identify and clarify the how, or the method of interaction between the *MTC Ecosystem* of subjects and system of projects, and any rules that support it. Indeed, the collection of subjects assigned to the production of solutions coincides with the entrepreneurial system of small and mid-size enterprises, including those evolved or technological craft businesses⁴⁹.

A system made of a new generation of producers fits into this traditional productive network and emerges with ever greater visibility. They are the so-called *innovative startups* (7,854 companies on 30/09/2017)⁵⁰,

⁴⁷ See the MIUR website: www.miur.gov.it/web/guest/sistema-della-ricerca, the definition (of Community origin) “other research bodies” defines subjects, public or private, who do not fit into the above categories while part of the national research system

⁴⁸ See the MIUR website: www.miur.gov.it/web/guest/sistema-della-ricerca

⁴⁹ In the phase of construction and definition of the MakeToCare Ecosystem and its categories of subjects, the mapping activity brought us to identify, among the productive realities involved in the production processes analysed, only two (out of 188) companies classifiable as companies part of the system of SMEs that we can define as *traditional*

⁵⁰ See: Third quarterly report of the Ministry of Economic Development, InfoCamere (La società consortile di informatica del Sistema camerale [The Consortium of Information Technology of the Chamber of Commerce Network]) and UnionCamere (Unione italiana delle Camere di commercio, industria, artigianato e agricoltura [Italian Union of Chambers of Commerce, Industry, Handicraft and Agriculture]): www.sviluppoeconomico.gov.it

principally engaged (approximately 70% according to the previously mentioned report) in the production of software, services, IT consultancy and research and development activities. To this 70% we can add approximately 20% of realities engaged in industrial production: manufacture of electronic equipment, computers and products, electrical equipment. Finally, other new productive and small-scale realities can be added to this type of enterprise, able however to redefine the manufacturing scenario through the construction of unreleased processes. It is the world of FabLabs and *makerspaces*, but also of individual designer-makers that reconfigure the traditional processes of artefact materialisation through a collaborative approach, characterised by a strong sense of belonging to the community with which to share their work and the design solutions created for it. In Italy, the development of FabLabs and makerspaces is recent but already positioned among the firsts in the world with over 100 spaces who have these characteristics⁵¹. This area of research has enabled the second system defined as *Making, Manufacturing & New Entrepreneurship System* to be structured.

The third phase of the construction of the mapping attempted to connect the two systems identified previously, *Healthcare & Research System* (system of institutional subjects dedicated to research and innovation) and *Making, Manufacturing & New Entrepreneurship System* (system of subjects protagonists of the productive area) with a third system of actors, that we list here last but in reality are at the heart of the *MTC Ecosystem*: that of patients and their caregivers, defined as *Patient & Caregiving System*. This is a system of subjects that combines the patient and the different figures that assist him in the family context⁵². In fact, they are the protagonists around which both the system of research and the system of production of solutions revolves.

However, the finding and identification of the single *patient/caregiver*, although central in our research, is not a simple operation: trivially but realistically, within the *MTC Ecosystem*, we are all potential patients⁵³.

⁵¹ See: M. Menichinelli, A. Ranellucci, “*Censimento dei Laboratori di Fabbricazione Digitale in Italia*”, 2014 (http://makersinquiry.org/data/italy/2014/Censimento_Laboratori_2014.pdf, last accessed: 22 November 2017)

⁵² As indicated in the draft legislative act of 10/11/2015 “Provisions for the recognition and support of activities of care and assistance” that is now recorded in the official files of the Chamber under the number 3414, “the caregiver family member is the person who, voluntarily and without any pay, assists a person who is not self-sufficient because of advanced age, disability or disease”. In fact, the figure of the caregiver family member forms coalitions and is often part of a wide care network, which also includes representatives of the social welfare system, specialist support services, volunteer associations and cooperatives

⁵³ The concept of the *patient* coincides with that of the *user*, used by the discipline of design

3.2 THE MAKETOCARE ECOSYSTEM

3.2.1 MakeToCare Ecosystem: the key areas

The methodology described in the paragraph above outlined three areas that are at the base of the *MTC Ecosystem* (Fig. 01). Each area brings together a specific collection of actors, and that we defined as:

- **Healthcare & Research System**
- **Making, Manufacturing & New Entrepreneurship System**
- **Patient & Caregiving System**

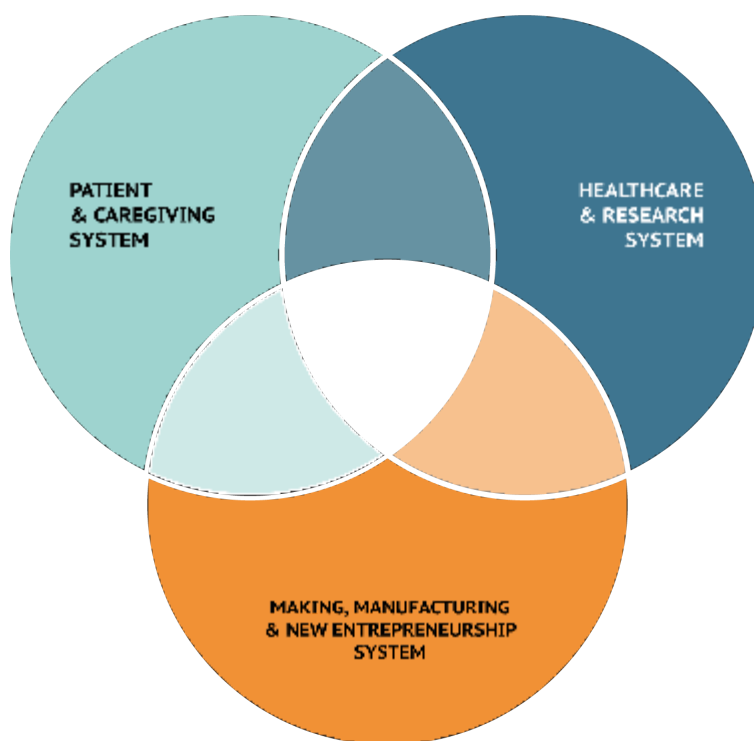


Fig. 01 | MakeToCare Ecosystem: main areas

Healthcare & Research System is the system that identifies the more institutional area of the *Ecosystem*, in fact bringing together the subjects who are part of the national system of care and research. The reference is on the one hand the *Servizio Sanitario Nazionale (SSN)* including, for example, subjects such as hospitals, centres of care and assistance institutes; on the other is the *Sistema Nazionale della Ricerca Scientifica e Tecnologica* (MIUR) which includes the Universities, the Public Research Institutes (for example the CNR (Consiglio Nazionale delle Ricerche) and its different institutes and other qualified research bodies. The

type, role and field of activity of the subjects within this area are always defined officially: the subjects who are part of the *Servizio Sanitario Nazionale* are based organisationally in different sectors connected to healthcare; the subjects belonging to the system of research, while by their nature not being occupied exclusively with the care of the person, carry out their activities of research and experimentation often in the healthcare sector, developing projects of a scientific and technological type oriented to the improvement and/or strengthening of care of the person.

Making, Manufacturing & New Entrepreneurship System is the system that identifies the complex productive world, formed by subjects who develop and control the processes intended for product-service solutions production enabling. This system combines the *individual* (single designer) and *micro-small company* dimension, alongside more traditional forms of design and production (we think for example of craft companies or SMEs in general) and sees the simultaneous presence of processes of invention, development and materialisation of mostly experimental solutions in the FabLabs, *makerspaces* and startups. The system brings together in this way a part of subjects coded within the traditional system of reference of Italian SMEs and a part of protagonists of the new productive scene (especially urban) such as FabLabs and *makerspaces*. *Making, Manufacturing & New Entrepreneurship System* identifies therefore subjects who, while different for structure, size and type, share an attitude for innovation (regarding the process or the product-service, both technological and also social) and the ability to move from a dimension of invention and design to the material production of the final solution. Therefore within this area we can recognise:

- traditional productive enterprises capable of implementing an innovative approach and way of thinking;
- dynamic and productive startups that often start from an idea, an intuition or an innovative technology;
- FabLabs and *makerspaces* that redefine traditional productive processes using technologies for digital manufacturing and open and shared production models;
- *makers* and designers in the dual roles of *creator*-designers and micro-entrepreneurs (*makers* or self-producers).

Patient & Caregiving System is the system that brings together both the figure of *patients*, or carriers of interests and needs, and that of *caregivers*, or the extended network of family members and subjects that daily take care, assist and share the problems and challenges of who is living in a condition of disability (see note 52). It is a category of ever more active subjects, involved not only in the phase of focusing and explicating needs, but often also in the (co)design and materialisation of final solutions.

3.2.2 MakeToCare Ecosystem: the secondary areas and the MakeToCare Area

The *MakeToCare Ecosystem* defined according to its three main systems just described (see Fig. 01) generates an added level of classification of subjects who are part of it (and, as we will see, also of the classification of the projects developed). In fact, the overlap of the three main systems generates three secondary systems, and a fourth and last central area in which the three main areas and the three secondary areas merge (Fig. 02 and Fig. 03).

It is often in these secondary areas, however, that the real protagonists of the *MakeToCare* research emerge: subjects who sometimes are not well known but identified by an exciting mix of innovative skills and practices.

The three areas are:

Medtech System. Corresponds to the area of intersection between *Healthcare & Research System* and *Making, Manufacturing & New Entrepreneurship System*; identifies the subjects who perform activities within the ideal area of overlap between the world of institutional care/scientific research and the real world of making of the productive system. It is therefore the system that identifies different types of subjects capable of uniting a vision of research with a more operational approach focused on the creation of product-service solutions in the healthcare sector. Compared to the subjects who operate in the *Healthcare & Research System*, those in the *Medtech System* in addition have an operational capacity focused on the world of production; compared to the subjects who operate within the *Manufacturing & New Entrepreneurship System* they are instead characterised by a component of research that integrates and

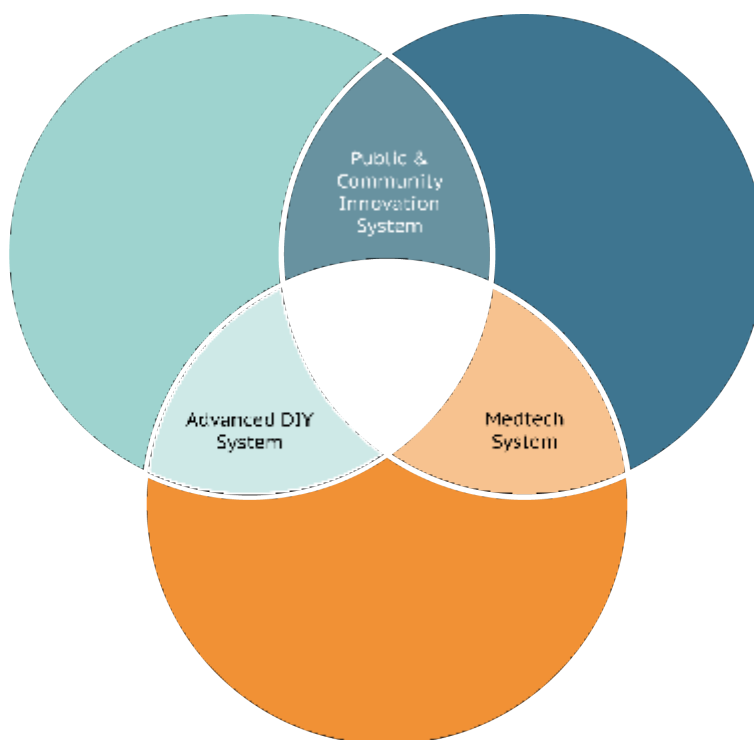


Fig. 02 | MakeToCare Ecosystem: secondary areas

qualifies their operational approach.

Public & Community Innovation System. Corresponds to the area of intersection between *Healthcare & Research System* and *Patient & Caregiving System*; it is the system that ideally overlaps the institutional environment of care and research with that of the patients and their caregivers, identifying primarily the world of *Patient Associations*, that represent by their nature the link between the world of patients and their needs and the medical and institutional world.

Advanced DIY System. Corresponds to the area of intersection between *Manufacturing & New*

Entrepreneurship System and *Patient & Caregiving System*; identifies the *patient* and *caregiver innovators*, persons who have known how to transform a specific need linked to a personal disease or disability (or a loved one) into a design solution more or less developed from the productive process point of view. They are the subjects in which the figure of the *carrier of need* coincides with the *designer-maker*. The overlap between the three main areas within the *MakeToCare Ecosystem* outline a *helix with three blades*. For the purposes of our research, this represents the area of greatest interest, where the categories of subjects and projects characterised by a dual vocation and a mix of both innovative and traditional skills position themselves. At the centre of it all, as an overall area of overlap, the central nucleus or *linchpin* of the *MTC Ecosystem* that identifies an area populated with subjects who we can define as *100% MakeToCare*: subjects of the complex type presenting, although with different levels and methods, skills characteristic of the subjects of the three main systems (Fig. 03).

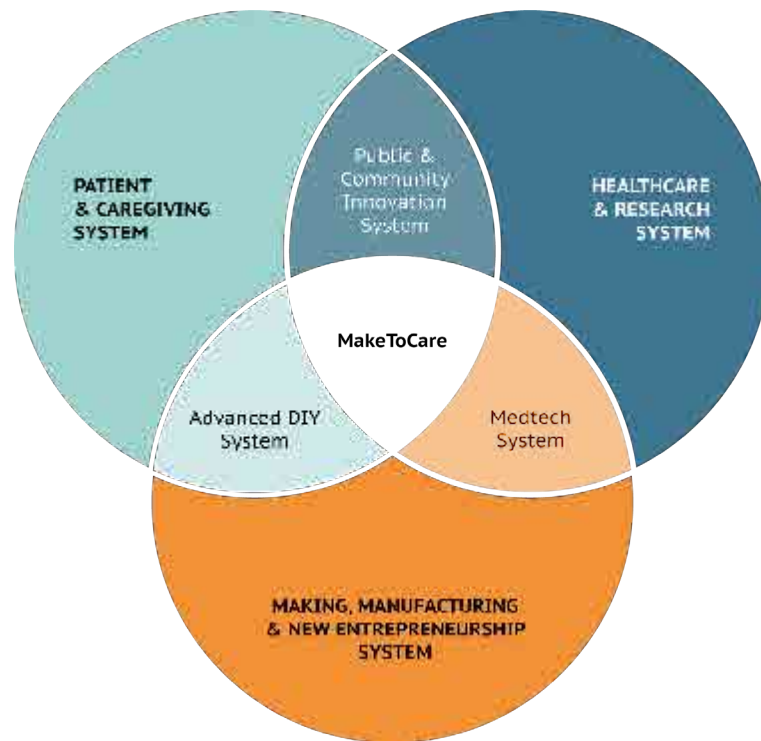


Fig. 03 | MakeToCare Ecosystem: overall summary vision

MakeToCare Area (MTC Area). Corresponds to the area of overlap between the *Healthcare & Research System*, *Making, Manufacturing & New Entrepreneurship System* and *Patient & Caregiving System* systems. This area is the central nucleus of the *MTC Ecosystem* and identifies a specific category of subjects, who have as the common denominator these three elements:

- they are *patient-innovators* or form coalitions with *patients* and *caregivers* (single or combined within a multidisciplinary team or an association);
- have or have acquired medical and scientific competencies;
- have known how to develop a *design solution* in response to *precise needs and requirements*.

3.2.3 MakeToCare Ecosystem: the categories of subjects

It is important to emphasise how, in the methodology applied, the number relative to the subjects included in the *MTC Ecosystem* is closely connected to the number relative to the solutions produced. This first mapping developed (for subjects and their respective categories) is in fact closely related to the mapping of the cases by which it was possible to identify the subject protagonists in the invention and development of innovative solutions. The seven systems of the *MakeToCare Ecosystem* interact with each other in different ways: the subjects who remain within each system can be organised according to different categories that present specific operational methods and fields of interest.

Each subject of the *MTC Ecosystem*, acting individually or liaising with other subjects (in their own category or in other categories and systems) contribute to the implementation of a shared solution or project, invented to improve, resolve or treat a temporary or permanent type of disease or a condition of disability. The following categories therefore identify the subjects which, from our first survey, give origin to the *MTC Ecosystem* and contribute, each with its own team and expertise, to defining the solutions subsequently mapped.

Healthcare & Research System subject categories.

The categories of subjects identified in this main system are five:

- *Hospital Institutes*: identifies the hospital trusts, hospitals, polyclinics, SSN or SSN-accredited care homes;
- *Servizio Sanitario Nazionale (SSN) Research Institutes*: identifies the *Scientific Institutes for Research/Hospitalisation and Health Care* (IRCCS), that combine the world of scientific research and that of the care and treatment of patients; to the IRCCSs we add the INAIL Prosthesis Centre, also an institutes recognised and accredited by the National Health System;
- *Institutes of Care and Assistance*: identifies the Foundations, the NPOs, the Institutes that carry out activities of care, assistance and research complementary to and integrated with the SSN.

To these first three categories, which refer to the institutional system of healthcare, we add the subjects belonging to the *National Scientific Research* system, divided in turn into:

- *Universities*: identifies the University institutes, that range from the scientific area to the humanistic area, including the Universities of Medicine (with overlapping subjects such as the University Hospital Institutes);
- *Public Research Institutes*: identifies the nationally recognised Institutes that carry out scientific and technological research in the main areas of development of knowledge and its applications in technical and scientific sectors, including (but not only) in the healthcare sector.

Making, Manufacturing & New Entrepreneurship System subject categories.

The categories of subjects identified in this main system are four:

- *Innovative Startups and Enterprises*: identifies both the entrepreneurial realities of recent origin (startups) but also more consolidated enterprises that are characterised however by the propensity to the use or development of digital technologies and innovative services and applications (for

- example *Internet of Things* and *digital manufacturing*)⁵⁴;
- *Craftspeople, SMEs and Enterprises* include micro, small and mid-size enterprises and craft companies, therefore productive realities using innovative technology or developing innovative product and process technologies and subjects with a specific technological know-how and innovative approach. In this category there are also subjects who, while not in possession of state-of-the-art technology, significantly contribute to the development of an innovative product: using collaborative approaches and sharing their know-how with other design and productive realities, they interact with other actors and participate in the construction of cross-sectional coalitions composed of many subjects;
- *Designers*: identifies a wider category of project professionals (designers, planners and makers), or subjects who work in various fields – design, art, architecture, computer engineering, electronics and mechanics – and use—individually or in groups/networks—their design, technical and technological skills necessary for the invention, prototyping and development of product-service solutions;
- *FabLabs*, identify the private and public shared manufacturing spaces, workshops equipped for digital manufacture and physical computing such as makerspaces and indeed the FabLabs.

Patient & Caregiving System subject categories.

The categories of subjects identified in this main system are two:

- *Patient*: identifies all the persons with a disease, who because of their specific condition (that may be either transient or permanent) must in general interface with the institutional system of care (SSN);
- *Caregiver*: identifies the so-called *family member assistants*, or the persons who at no charge help their relative or intimate to manage the day-to-day aspects of their condition of incomplete self-sufficiency (which may be related to different issues such as age, disability or other pathologies).

After the categories of subjects of the three main systems come the categories of the subjects of secondary systems that, as we anticipated, identify the more sizeable and interesting areas of the *MTC Ecosystem*.

Medtech System subject categories.

The categories of subjects identified in this secondary system are five:

- *Biomedical/Medical Startups and Enterprises*: identifies entrepreneurial realities of recent inception (startups) and more consolidated enterprises active in the biomedical and medical sector, involved in the creation of tools for care and therapy; often these are productive realities beginning from a clear idea of a device or solution that is then developed and transformed into a concrete

⁵⁴ Although connected to the world of startups and new entrepreneurship, and therefore theoretically subjects who belong to the *Making, Manufacturing & New Entrepreneurship System*, the incubators and accelerators of innovative startups were not included in this first activity of mapping. In this first mapping, in fact, although present in the system of subjects analysed in the scouting phase intended for the research of projects, there were no subjects classifiable as subjects who were actuators of the solutions mapped within the *Ecosystem*. From a legal standpoint the regulation describes this type of subject as “limited company that complies with certain requirements and which offers, also not limited to, services to support the inception and development of innovative startups.” (Source: Decree-Law 18 October 2012, No. 179). In particular, “...the incubator is an organisation that implements and makes systematic the process of creating new enterprises providing them with a wide range of support services that include physical spaces, activities for the development of the business and integration and networking opportunities; the accelerator operates in the very first period of life of the company and supports it with services of mentorship and physical locations in which to operate, as well as services needed for its growth; it is managed principally by entrepreneurs and mentors and is a place where assistance for the creation of a business model is received...” (See VentureUp, website promoted by AIFI (Associazione Italiana del Private Equity, Venture Capital and Private Debt) and Fondo Italiano d'Investimento dedicated to the start-up and venture capital ecosystem: www.ventureup.it)

entrepreneurial reality;

- *University Spin-offs and Startups*: identifies productive realities belonging to the world of startups and new entrepreneurship that developed in an academic environment, which are dedicated to applied scientific research and experimentation with synergies and direct reports with the academic environment from which they originate;
- *Laboratories and Research/Experimentation Centres*: identifies a cross-sectional category of subjects characterised by a strong connection with the world of university or institutional research: FabLabs and university laboratories, research/experimentation centres associated with Public and/or University Research Institutes, realities connected to the world of healthcare and/or scientific research (*platform-initiatives*, laboratories for *open science* and *open biology*);
- *Training centres*: identifies training institutes not belonging to the coded system of mandatory instruction but equally qualified in specific areas of application (for example: Scuola di Robotica of Genoa⁵⁵) and training centres part of the system of mandatory instruction specialised in specific areas (example: technical institutes);
- *Multidisciplinary teams (of design)*: identifies design teams formed by single individuals-professionals with different skills, able to implement a mix of medical-scientific and design skills. These are therefore design microcosms, formed by subjects able to mix medical and scientific knowledge and skills with a capacity for project development aimed at creating a solution.

Public & Community Innovation System subject categories.

The category of subjects in this secondary system is that of *Patient Associations*, that identifies the realities that represent and provide support to *patients* and their *caregivers*, either through processes of public advocacy or through the collection and disclosure of information and the concrete commitment in support of scientific research and the care of individual diseases.

Advanced DIY System subject categories.

In this case there is also one category present, the *Innovator Patients/Caregivers* that identifies those who design by themselves (either by a family member or someone assisted), sometimes self-producing the product solutions to improve a condition of disability. It is therefore actors who actively operate in the design and production area.

MakeToCare Area subject categories.

Two categories of subjects were identified that correspond to the central nucleus of the *MTC Ecosystem*.

Both define an original mix of skills and attitudes that qualifies them as fully *MakeToCare* subjects:

- *Medtech Innovator Patients/Caregivers*: is essentially a variation of the previous category (*Innovator Patients/Caregivers*) whose subjects however also have medical and scientific competencies. Essentially we are talking about the core category of the *MakeToCare* system: individuals representing simultaneously the *patient/caregiver* system, the system of care and scientific research and that of *making*;
- *Medtech Startups and Enterprises/Associations*: identifies startups, enterprises and associations developed by persons who were patients or *caregivers* and who knew how to transform an individual problem into a solution or proposal for an enlarged community of patients with the same

⁵⁵ The Scuola di Robotica of Genoa is a non-profit association founded on the initiative of a robotics group and human science academics, with the objective of promotion of the culture through activities of instruction, training, education and diffusion of the arts and sciences involved in the development process of this new science/technology (see: www.scuoladirobotica.it)

problems. To these we add certain types of *Patient Associations*, starting from the development of a solution (around which the Association was subsequently incorporated) or who developed a specific project or a solution with internal skills.

3.3 THE MAKETOCARE ECOSYSTEM SUBJECTS

3.3.1 The dimensions of the MakeToCare Ecosystem

The identification, detection and subsequent mapping of the subjects of the *MakeToCare Ecosystem* was structured from the previously shown methodological system.

The seven systems and their categories allowed a first phase of desk research to be set, then supplemented by additional levels of research and analysis.

The area defined as *Healthcare & Research System*, with its coded system of subjects, constituted the initial area of survey. In particular, the 49 IRCCSs currently recognised by the Ministry of Health⁵⁶ were considered identifying, among them, those whose activity is intended for the development of innovative projects (products-services) in the healthcare sector and in line with the *MTC Ecosystem*, for approach, methodology and/or technologies used. The attention was initially focused on the ability of the single subject institutes to activate and develop a system of collaborations, that we defined as coalitions activating synergies with other actors even outside their own sector and thus creating connections necessary for the development of the solutions. A first reading indicated 12 IRCCS institutes out of 49 (approximately 24% of the national IRCCSs) involved in projects of research and care in line with the *MTC Ecosystem*. This first encouraging number is indicative of a sector that, although highly structured, is today strongly stimulated by innovative pushes from the world of technological and social innovation. This area of survey finally was extended to include other institutes of care and the principal research centres in Italy. This very broad database (if the system of IRCCSs with its 49 components may be considered a delimited system, the same cannot be said either for the remaining SSN Care Institutes, or for the system of the Universities or national Research Centres) was crossed with some continuous filters of reading, which little by little allowed us to limit the field of investigation, identifying the subjects most important for the research purposes.

Among sources consulted for the scouting there is first the collection of awards and contests dedicated to innovation in the scientific and healthcare sectors. Among these the *Premio Gaetano Marzotto* for innovative startups; the *Think for Social* initiative promoted by Fondazione Vodafone Italia with the *Polihub* incubator of the Politecnico di Milano; the *WithYouWeDo* crowdfunding platform promoted by TIM; the *open innovation M4Life* project promoted by Merck to support the inception and use of new technologies in the healthcare sector; lastly the *Innovation S@lute* award promoted by Aris-Allea, FPA and Motore Sanità. Next to the awards and contests we report the portals and platforms developed in the academic area such as the *Knowledge Share* portal developed by the Politecnico di Torino with Intesa San Paolo to distribute information on patents and technologies that constitute the national scientific know-how excellence and the *T3LAB*, initiative and platform founded by the Università di Bologna and Unindustria Bologna to enable collaboration between researchers and lecturers in order to develop research projects in the field of electronics and ICT.

Finally the system of accelerators and incubators⁵⁷, such as *PNICube*⁵⁸, that operates to support the inception

⁵⁶ See: Ministry of Health, www.salute.gov.it, Research and Innovation, Scientific Institutes for Research/Hospitalisation and Health Care – IRCCSs

⁵⁷ See note 54

⁵⁸ *PNICube* is the Italian association of University Incubators and Business Plan Competitions and the organiser of the Premio Nazionale per l'Innovazione e l'Italian Master Startup Award; see: www.pnicube.it

and development of innovative enterprises formed in the academic area and platforms, such as *BioUpper*⁵⁹, that support new ideas of enterprise in the healthcare and life sciences sectors, or the *FORUM PA Challenge*, an initiative which promotes challenges open to companies, citizens, research centres and administrations to locate, collect and share innovative solutions to small and large collective and social problems. The database managed by Assobiomedica, that collects information on more than 300 startups active in Italy in the biomedical sector, is of particular interest in the healthcare sector, to which can be added the quarterly report of the Ministry of Economic Development on innovative startups⁶⁰.

In relation to the *Making, Manufacturing & New Entrepreneurship System*, we recall the national database of FabLabs and *makerspaces*⁶¹ and some exhibitions that show cases of technological innovation in the healthcare sector, such as *Technology Hub* and the *European Maker Faire of Rome*.

With regard to the *Patient & Caregiving System*, the sector most closely connected to the patient and end user, we mention two important initiatives based on the hackathon model, such as *Hackability* and *Hacking Health*, the online platform related to the international movement of the same name involved in innovation in the world of health and care. Finally, related to the *Public & Community Innovation System*, we recall *HANDImatica*, national conference and exhibition designed and created by the Fondazione ASPHI NPO and dedicated to the inclusiveness of digital technologies.

The desk research permitted thereby to identify 188 subjects that can be included in the *MTC Ecosystem* and divided into three main and three secondary systems plus the *MakeToCare Area*. Of the 188 subjects mapped, 6 do not fully belong to any of the categories, and therefore have been included into the “Other”⁶², category, not represented within the displays for the MTC Ecosystem areas.

The data indicate (see Fig. 04) a greater percentage of subjects belonging to the *Healthcare & Research System* (57 subjects out of 182, equal to approximately 31%), followed by those belonging to the *Medtech System* (54 subjects out of 182, equal to approximately 30%): together two systems combine 60% of the total of subjects mapped, and the categories of subjects belonging to them are those more based, by type, in the research and care sector and dedicated to research and experimentation in the healthcare sector. These subjects naturally represent reference points that are capable of directing and guiding the evolution of the sector through their activities and expertise. But it is the subjects belonging to the *Medtech System* who are most relevant to our research: they in fact, adding also a pragmatically applied *attitude to making* to the component of research, succeed in agreeing on the creation of real solutions for the end user/patient final while often anticipating new scenarios applied to care. The distance of these two first systems compared to those remaining is very deepened.

⁵⁹ *BioUpper* is the first Italian platform of training and acceleration, beginning from the partnership between Novartis and Fondazione Cariplo, that finances new ideas of enterprise in the field of life sciences in order to participate actively in the economic development of the country; see: www.bioupper.com

⁶⁰ For a more in-depth reading please refer to the Ministry of Economic Development website: www.sviluppoeconomico.gov.it

⁶¹ In this regard see the list of Italian FabLabs and makerspaces on: www.fablabs.io

⁶² These are 6 subjects (Associazione Culturale MenoMale, Municipality of Milan, DUC - Distretto Urbano del Commercio – Isola [district of Milan] ADA - Associazione Stecca degli Artigiani, Fondazione Cariplo, DeAgostini Editore), who participated in the development of the mapped solutions but cannot be included in the MTC Ecosystem area given their type and heterogeneity of activities. Of these, as we will see in the chapter regarding the projects, two subjects in particular (Municipality of Milan and Fondazione Cariplo) while not belonging specifically to the Ecosystem, play an important and significant role in the development of some of the mapped solutions

In fact, the *Making, Manufacturing & New Entrepreneurship System* with its 27 mapped subjects (approximately 15%) follows, then moving gradually to the 20 subjects in the *Patient & Caregiving System* representing within our research one of the most difficult subject categories to identify: the 20 subjects discovered are in fact all patients or caregivers identified only because they are active within the design processes mapped where they were involved first hand in the development of the design solutions. The remaining data see the 12 subjects of the *MTC Area* accompanied by 9 subjects of the *Public &*

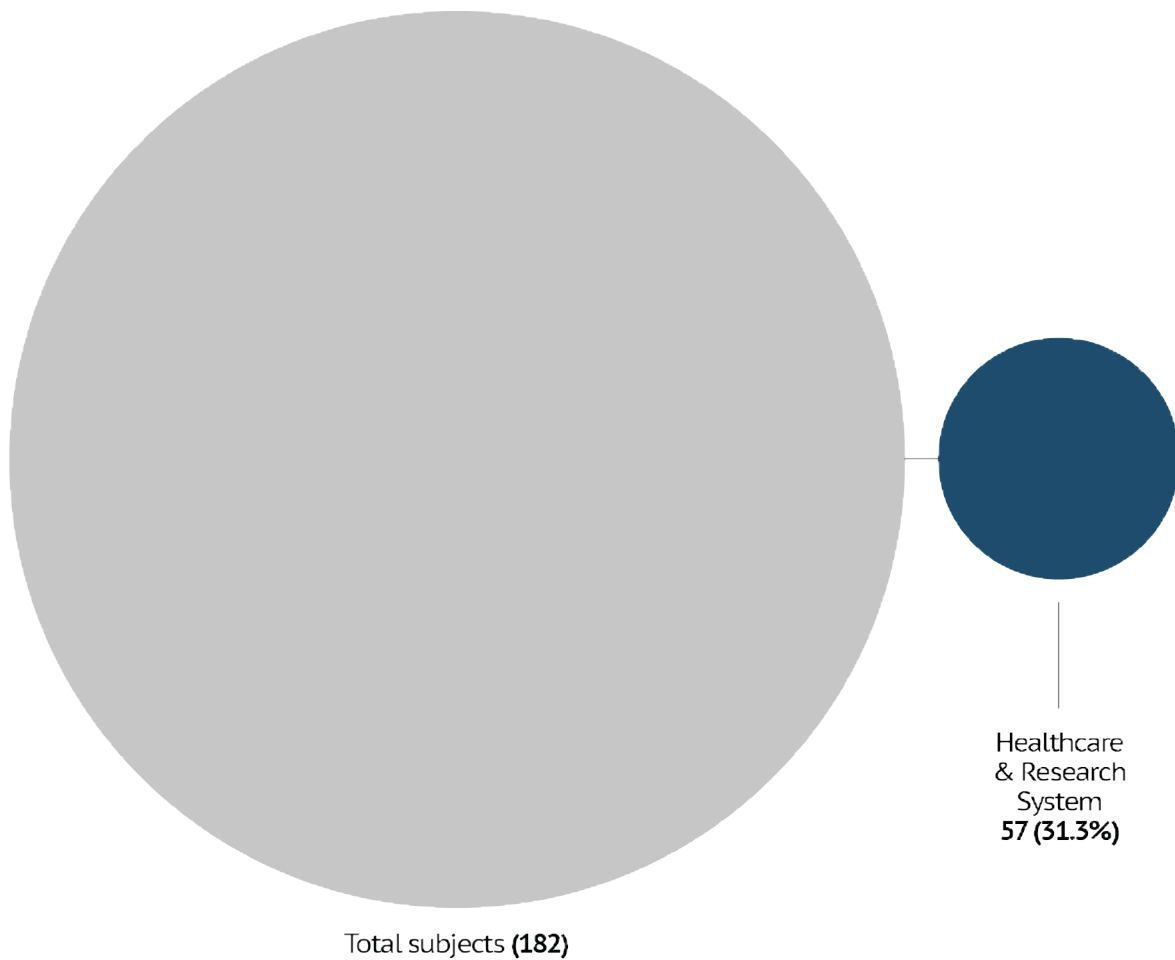
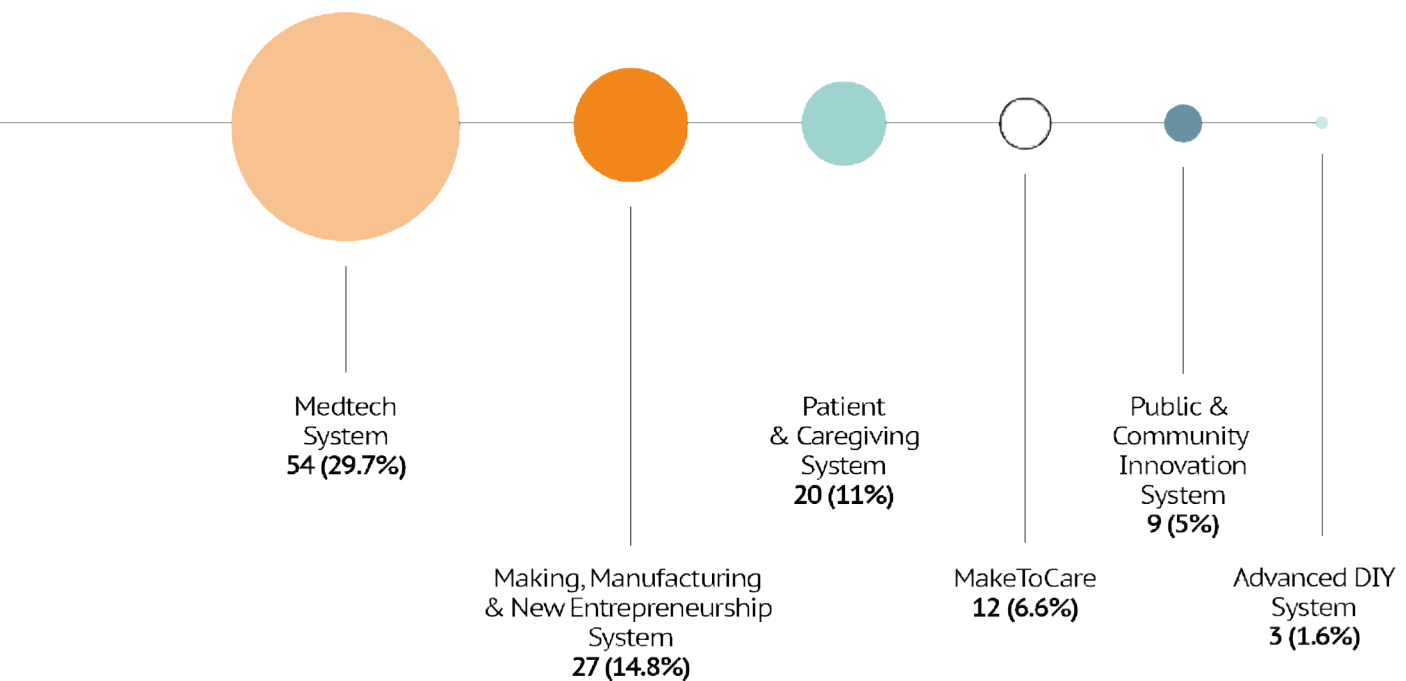


Fig. 04 | The dimensions of the MakeToCare Ecosystem (base data: 182 subjects)

Community Innovation System and, finally, the 3 *Advanced DIY System* subjects. Despite the reduced numbers, these last three subject categories together represent the most interesting nucleus of the *Ecosystem* and identifying amongst other things the subject categories most difficult to identify, whose activity, although intended for the creation of effective solutions related to real needs, does not always succeed in emerging and becoming visible.



3.3.2 The composition and populating of the MakeToCare Ecosystem

The 182⁶³ previously identified subjects can be further sub-divided, based on the individual membership categories of each of the seven *Ecosystem* areas, thus identifying the typological composition of each system (Fig. 05).

For the *Healthcare & Research System*, the main figure to highlight is that related to the *Universities* (20 subjects out of 57, equal to approximately 35%) followed, with a very similar number, by *Public Research Institutes* (12 out of a total of 57, equal to approximately 21%), *SSN Research Institutes* (11 subjects, equal to approximately 19%, of which 10 IRCCSs and the INAIL Prosthesis Centre) and *Institutes of Care and Assistance* (10 subjects out of a total of 57). Lastly, there follows the distinctly lower figure related to *Hospital Institutes* (4 subjects out of 57).

Universities, *Public Research Institutes* and *SSN Research Institutes* with a total of 43 subjects out of 57 (equal to approximately 75%) identify the most qualified component from the scientific perspective of the *MTC Ecosystem*. It is a collective that brings together some of the main national IRCCSs and some of the main CNR Research Institutes that represents the primary research institute nationally, with more than 100 institutes specialised in the main scientific and technological areas.

In relation to the *Medtech System*, out of 54 subjects mapped, 28 are represented by biomedical startups or enterprises. To these we add 13 *University Spin-offs and Startups*⁶⁴, i.e. innovative entrepreneurial realities supported by and closely connected to academic centres. Together, these two categories reach a total of 41 subjects (equal to almost 76% of the *Medtech System* total). Often these are realities beginning from the focus on a specific problem from which it was then decided to develop a design solution. In particular, regarding the academic spin-offs, the mapped realities are in many cases the evolution or continuation of internal research programmes also developed in partnership with other institutes. Interesting examples are, as we will see later, the *qbrobotics* spin-off that developed from a collaboration between IIT Istituto Italiano Tecnologia and Centro Ricerca E. Piaggio Università di Pisa and *Movendo Technology*, spin-off again from the IIT and its *Rehab Technologies Lab*, initiative in turn beginning from the collaboration between IIT and INAIL. There follows the figure related to the 7 subjects who we included in the *Workshops and Centres of Research and Experimentation* category. It is a category with undefined limits, but of great interest for the *MakeToCare* research, which brings together subjects of different types sharing a strong connection with the academic world and/or the world of institutional healthcare and/or scientific research. There are therefore present university laboratories of research applied to the digital manufacturing sector (for example the realities of the Politecnico di Milano such as *Polifactory*, the *makerspace* of the Ateneo and *+Lab*, the research laboratory on *additive manufacturing*) and realities such as *Open BioMedical Initiative* (see section 3.6.11), an *initiative-platform* created to support the traditional biomedical sector through the design, development and distribution of projects of open source solutions accomplished with the help of new technologies of digital manufacturing. The remaining 6 subjects are evenly divided between training centres and multidisciplinary project teams. As anticipated, the *Healthcare & Research System* and *Medtech System* together constitute approximately 61% of the subjects mapped within the *Ecosystem*. The remaining 26% is distributed fairly evenly between the *Making*, *Manufacturing & New Entrepreneurship*

⁶³ As anticipated, of the 188 subjects, 6 do not come under any of the categories and were excluded from this count and related display

⁶⁴ The academic startups and spin-offs identified in the mapping are: BixBis (Catanzaro), CCO – Cover a Conduzione Ossea (Naples), EasyLife (Reggio Calabria), Epinova Biotech (Novara), IN SIGHT (Palermo), IUVO (Pisa), Limix (Camerino), M3DATEK (Parma), mHealth Technologies (Bologna), Movendo Technology (Genoa), qbrobotics (Navacchio Cascina, PI), TOOTECO (Venice), Wearable Robotics (Ghezzano San Giuliano Terme, PI)

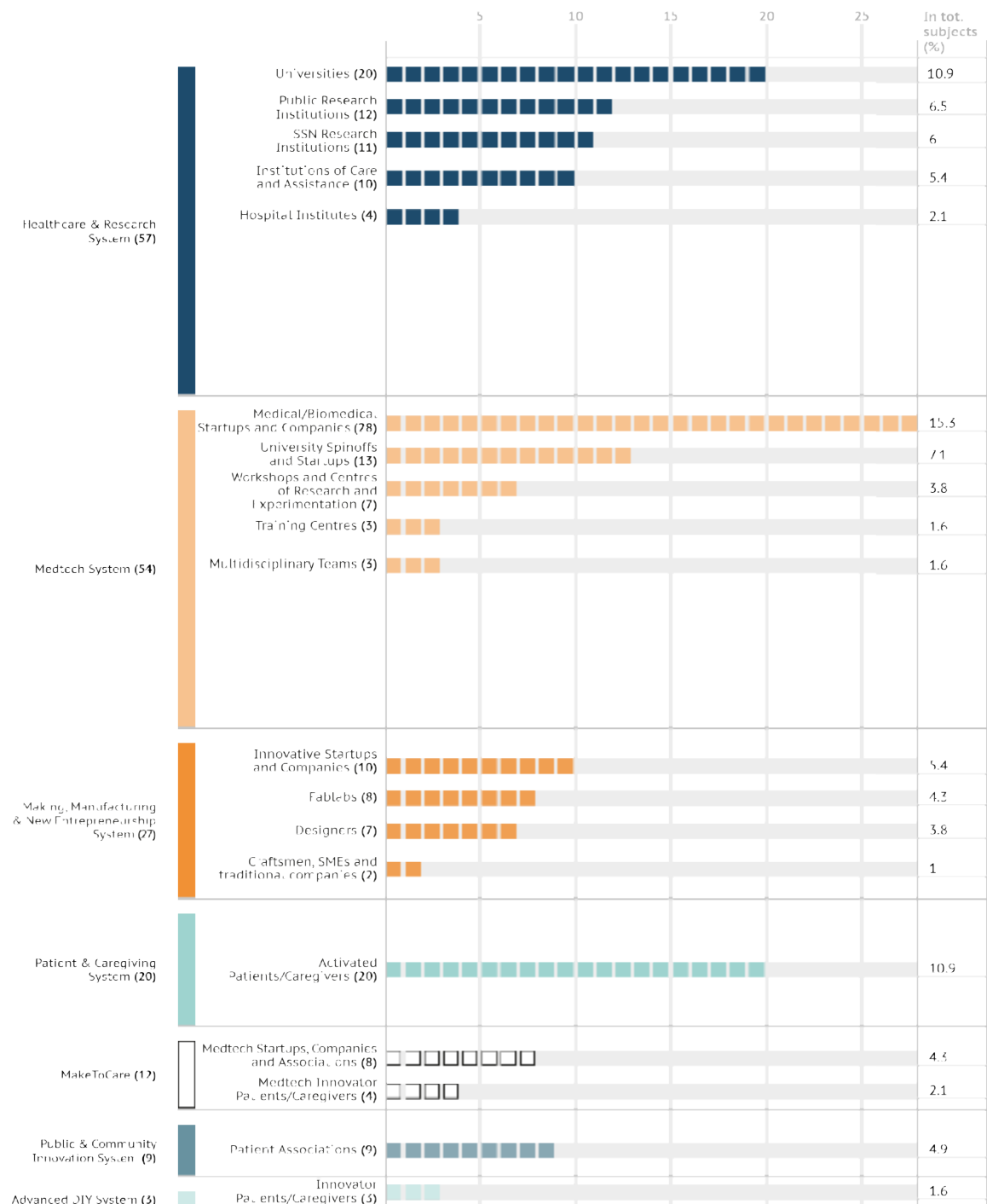


Fig. 05 | MakeToCare Ecosystem: systems, a mosaic of categories and subjects (base data: 182 subjects)

System area (27 subjects) and the *Patient & Caregiving System* area (20 subjects) with a very small remaining percentage (13%) divided between the *Public & Community Innovation System*, *Advanced DIY System* and the *MakeToCare Area*.

In relation to the *Making, Manufacturing & New Entrepreneurship System*, the first figure that emerges is that for the so-called innovative startups that in Italy currently represent approximately 7,850 realities⁶⁵. These are (new) forms of enterprise that in the *MTC Ecosystem* perform research and development activities tending to the objective of the production of innovative products or services with high technological content.

This first figure is followed by that relative to FabLabs and *makerspaces*, other subjects of particular interest to this research. It is a community consisting of subjects who exchange and collaborate in the name of an *open source* logic and sharing approach that makes them capable of truly making an innovative contribution within the traditional design process intended for care solutions (see for example the projects developed by the Milan area *WeMake* and *OpenDot* FabLabs).

The *Patient & Caregiving System* (20 subjects) and the *Public & Community Innovation System* (9 subjects) are two homogeneous areas, because within them there is only one subject category (respectively patients and caregivers in the first, patient associations in the second). The 20 *patients* and *caregivers* represent *individuals* identified because active in the development of specific design solutions.

The *Advanced DIY System* and the *MakeToCare Area* identify the subjects who in the *MTC Ecosystem* represent the figures most significant and consistent with the very concept of *MakeToCare*. In the first there are the *Innovator Patients/Caregivers*, a category of subjects difficult to identify, as in most of the cases these are persons who develop their own solutions by themselves, often without sharing their journey with others outside of their family and circle of closest friends and acquaintances. There are in fact only three subjects we mapped⁶⁶, that we could identify through participation in contests and competitions.

Finally, for the subjects grouped in the *MakeToCare Area*, we have 12 mapped subjects divided into the two categories of *Medtech Innovator Patients/Caregivers* (4) and *Medtech Startups, Enterprises and Associations* (8): the true essence of the *MTC Ecosystem*. Four of these are highly specialised *Patient and Caregiver* innovators⁶⁷, with *medical and scientific skills* that qualify them as of *individuals-systems* capable of combining scientific research activities, expertise in patient care and ability to invent and create *MakeToCare* solutions.

⁶⁵ See: Third Quarterly Report 2017 INNOVATIVE STARTUPS, authored by UNIONCAMERE, Ministry of Economic Development and InfoCamere startup.registroimprese.it. On 30/09/2017 the number of innovative startups registered in the special section of the Companies Register under Decree-Law 179/2012 was equal to 7,854. By startups we mean “any newly-formed enterprise but only those who operate in the area of technological innovation. Outside of this distinction, there is no limitation in terms of the type of sector: the regulations are open to the whole world of production, from digital to manufacturing, from trade to agriculture”, as reported within the summary document “*The national policy in support of innovative startups*” authored by the Ministry of Economic Development, 23/02/2017

⁶⁶ In the mapping appear: Fortunato Domenico Nocera (already finalist in the MAKEtoCARE 2016 contest) with Giuseppe D’Angelo and Emiliano Valente, both participants in the Ausili Creativi contest promoted by the Ospedale di Montecatone

⁶⁷ In the mapping appear: Davide Mulfari, Rehabventure Team – Slobodan with Bojana Miletić, Laura Rossi and Luca Randazzo

The other 8 subjects are an interesting mix of *MedTech* startups, enterprises and associations. These are realities developed by *patients/caregivers* who have transformed an individual challenge into a product solution distributable to a wider community of patients (see for example *D-Heart* in section 3.6.4 and *Ópponent* in section 3.6.13) or by the team who developed a solution in parallel with the development of an association (such as the *FightTheStroke* Association of Social Promotion and the *MirrorAble* project, see section 3.6.10).

Beginning with the classification of subjects based on the 19 previously-shown categories, the 182 subjects mapped were finally sorted in descending order thus displaying the most relevant *MTC Ecosystem* categories (Fig. 06).

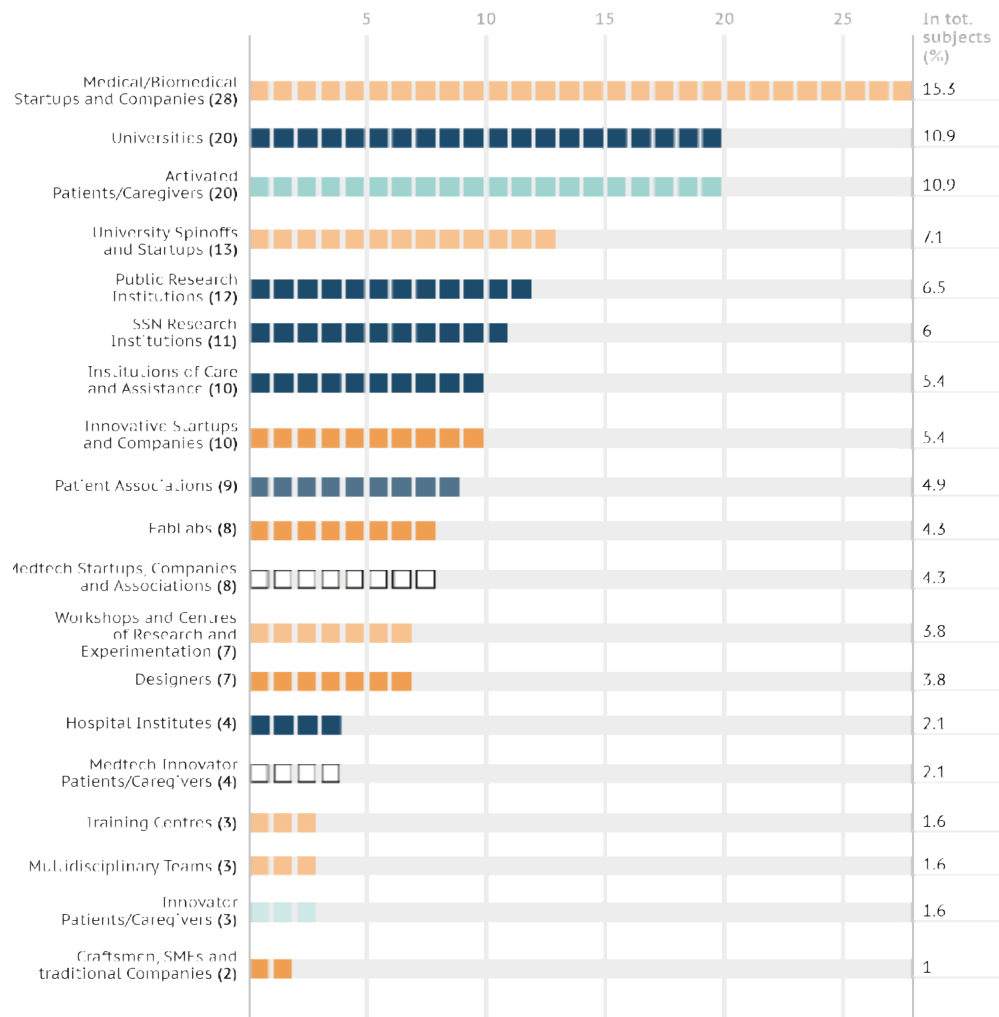


Fig. 06 | MakeToCare Ecosystem: number of subjects (base data: 182 subjects)

3.4 THE MAKETOCARE ECOSYSTEM TERRITORIES

3.4.1 The MakeToCare macro areas and regions

The 188 subjects, after being identified, were geolocated identifying thereby the most active territorial areas, i.e., those most heavily populated with subjects belonging to the *MTC Ecosystem*.

This activity was structured on two levels: first dividing the subjects in the three Italian macro-areas *North*, *Centre* and *South and Islands* (Fig. 07)⁶⁸ and then organising the same regionally (Fig. 08). Before moving to the data analysis, a clarification is needed: 20 of the 188 subjects mapped were identified as *patients/caregivers* but it was not possible to geolocate them because their identity is not known⁶⁹. The following data therefore are based on a set of 168 subjects.

Total subjects **168**

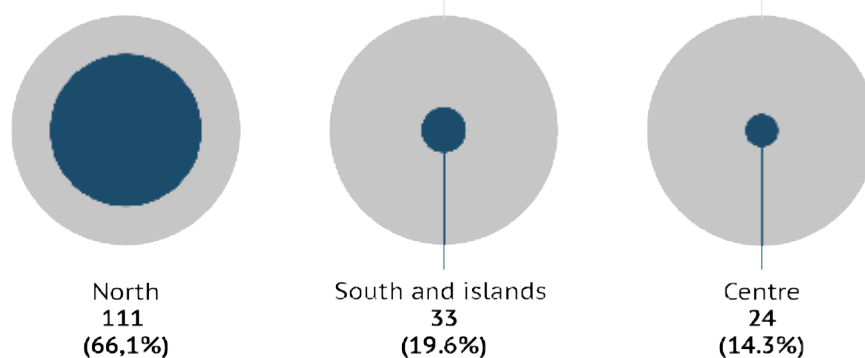


Fig. 07 | The Italian geography of MakeToCare (base data: 168 subjects)

The picture that emerges sees an ecosystem strongly unbalanced in the *North* and *Centre-South and Islands* ratio: 111 of the 168 subjects mapped (approximately 66%) are in fact located in Northern regions, with a further high concentration in Lombardy that, alone, combines more than 50% of subjects in the North macro-region (61 out of 111). To this first figure follows that for the Centre-South area: 33 subjects out of 168 (about 20%) are located in the South and Islands regions, while 24 subjects out of 168 (approximately 14%) are located in Centre regions.

Organising the data regionally, after Lombardy already highlighted as leader region with 61 subjects out of 168 (equal to 36.3%), follows, although with a certain distance, a group headed by Emilia Romagna (20 subjects out of 168, equal to 11.9%), Puglia (15 subjects out of 168, equal to 8.9%), Liguria (14 out of 168) (equal to 8.3%), Piedmont (13 out of 168) and Tuscany (12 out of 168). A third grouping follows formed by Lazio (9 out of 168), Campania (8 out of 168), Sicily (4 out of 168), Veneto and Marche (3 out of 168), Calabria, Basilicata and Sardinia (2 out of 168).

⁶⁸ The North macro-region includes the regions of Valle d'Aosta, Piedmont, Liguria, Lombardy, Veneto, Friuli Venezia Giulia, Trentino Alto Adige and Emilia Romagna. The Centre macro-region includes the regions of Tuscany, Lazio, Umbria and Marche. Finally the South macro-region includes the regions of Abruzzo, Molise, Campania, Basilicata, Calabria, Puglia, Sicily and Sardinia

⁶⁹ As already anticipated at the end of Section 3.3.2

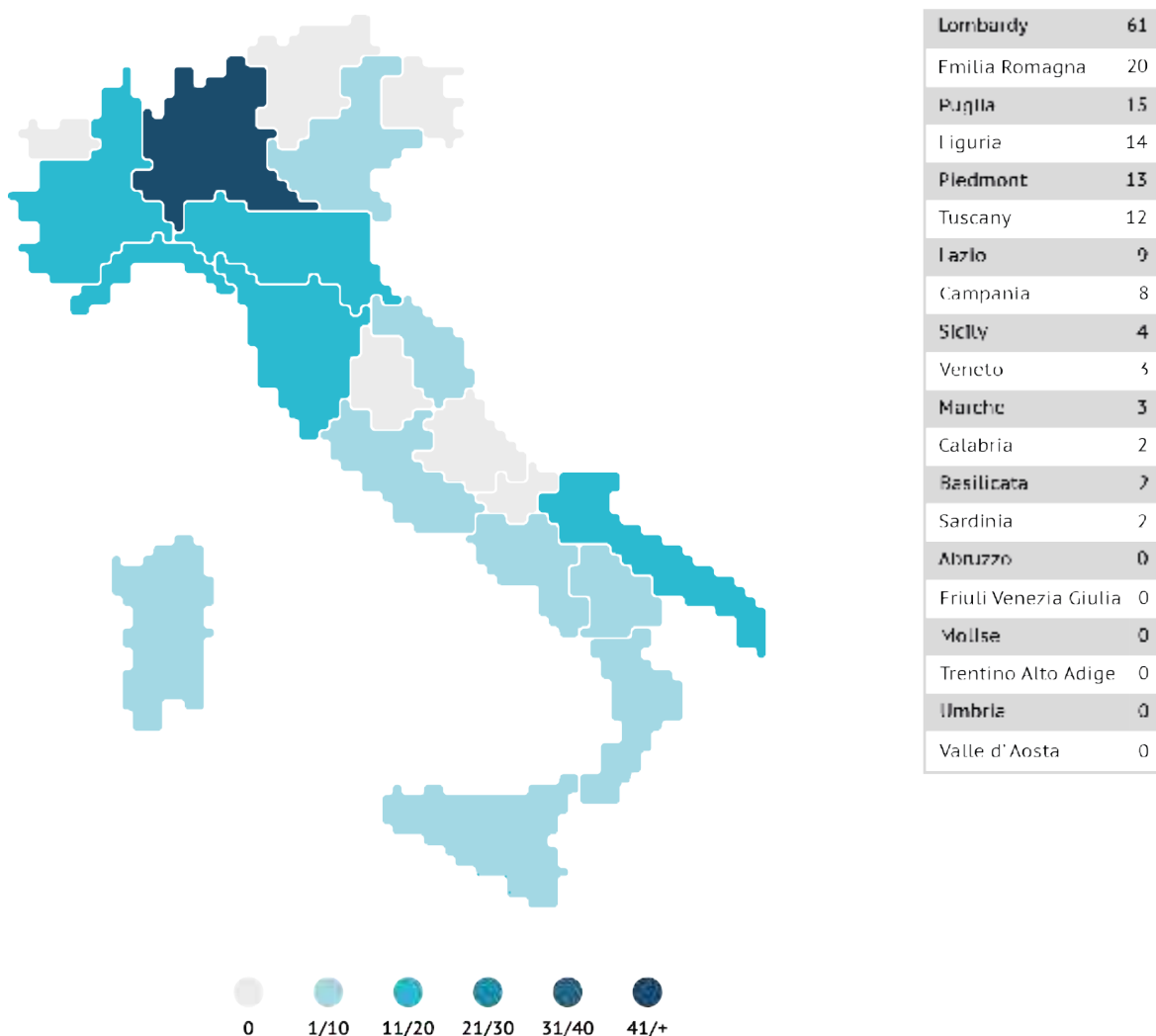


Fig. 08 | MakeToCare Ecosystem: regional distribution (base data: 168 subjects)

Finally, within the *MTC Ecosystem* the mapping does not assign any subject active in the three Autonomous Northern regions (Valle d'Aosta, Trentino Alto Adige and Friuli Venezia Giulia⁷⁰) or to a Centre block composed of Umbria, Abruzzo and Molise...

⁷⁰ It is possible perhaps to hypothesise a condition of independence of the Autonomous regions even relative to circuits of promotion, advocacy and information

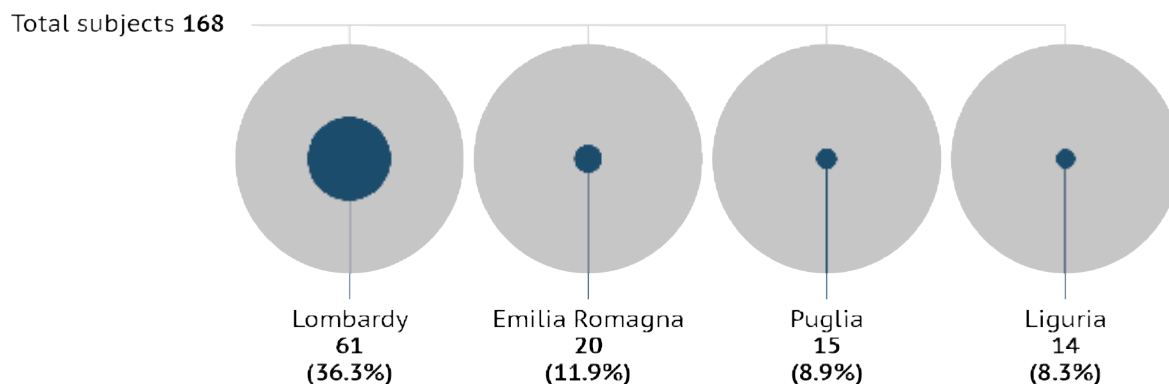


Fig. 09 | MakeToCare Ecosystem: the most active regions (base data: 110 out of 168 subjects)

Lombardy alone accounts for over one-third of Italian subjects (36.3%, 61 out of 168, Fig. 09). Within what we can define as the *Lombardy ecosystem* there are a good 16 of the 19 categories of subjects identified within the *MakeToCare Ecosystem*: this means that in Lombardy it is possible to locate almost all of the categories specified (Fig. 10).

If *Lombardy* is the region leader in Italy, as we will see in the next section, 57 of the 61 subjects mapped within it are located in the Milan area: Milan and adjacent areas (including the nearby provinces of Como and Lecco) therefore stimulate an *MTC mini-system* of subjects and experiences, unique in the national panorama.

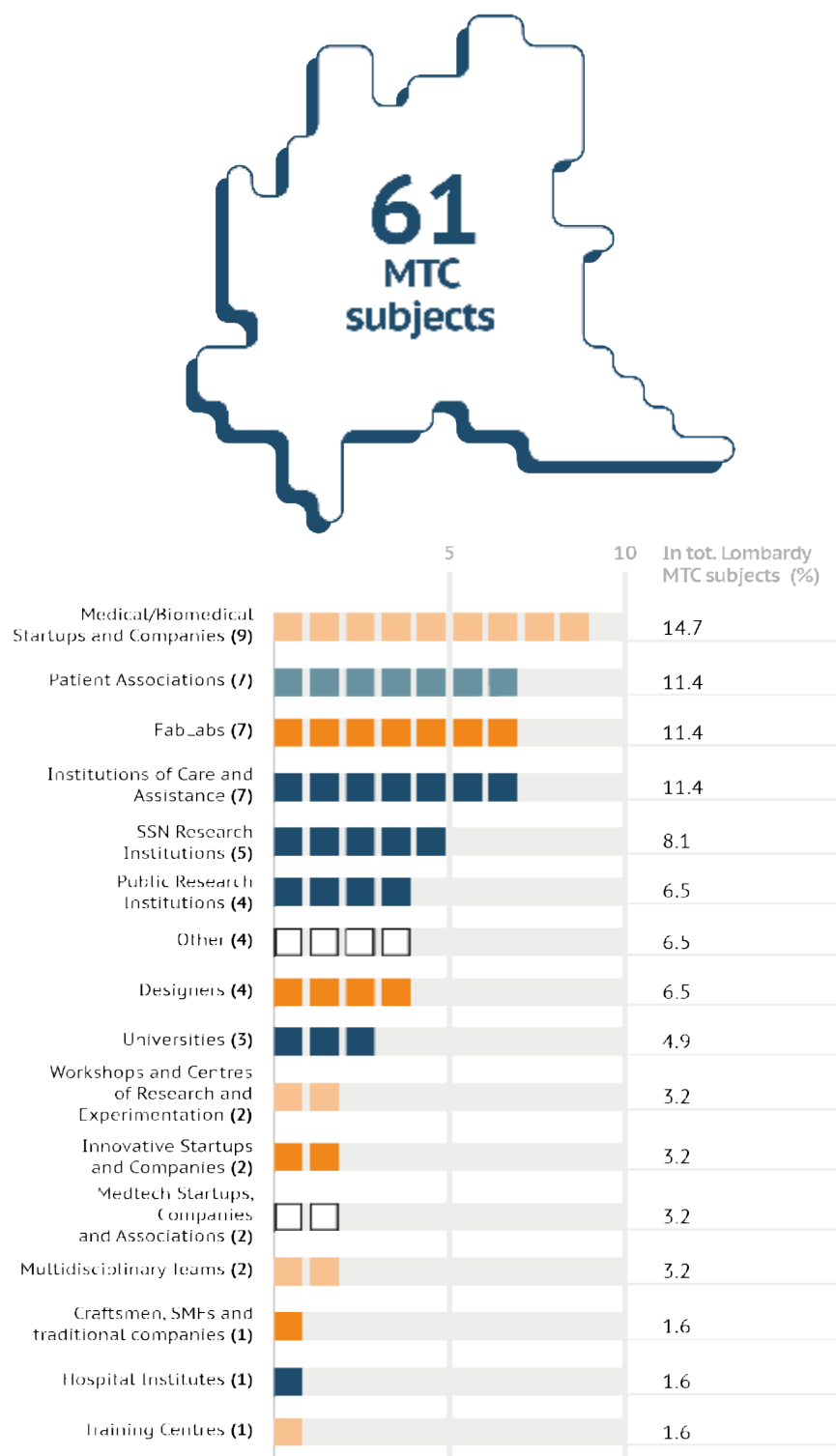


Fig. 10 | Lombardy and MakeToCare: a system in the Ecosystem (base data: 168 subjects)

3.4.2 The MakeToCare attractor poles

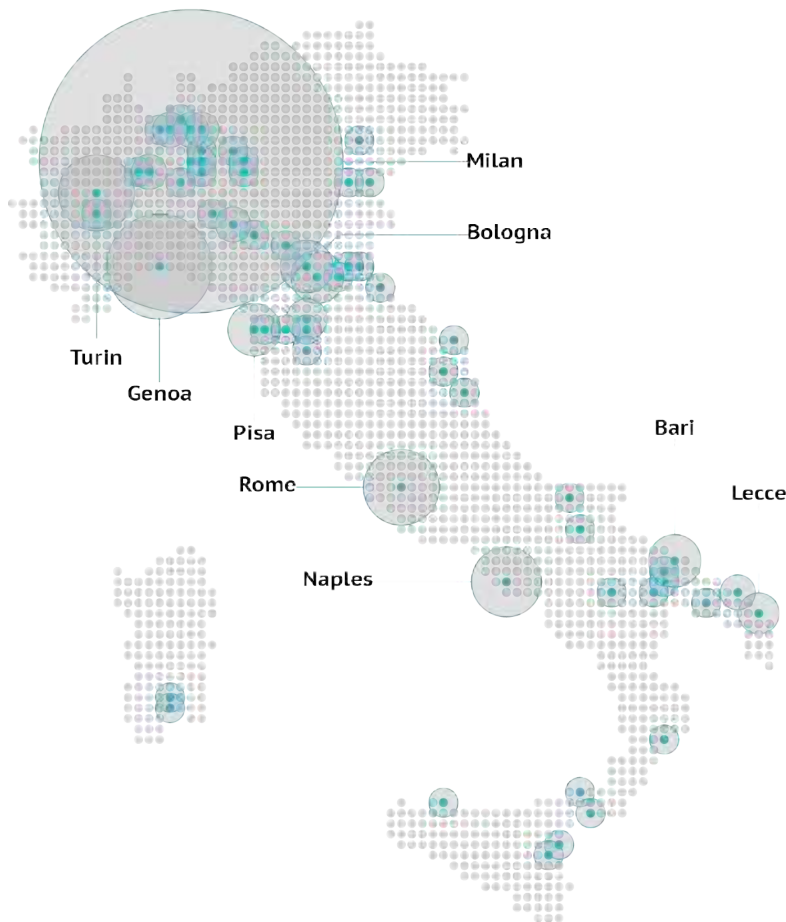
Positioning the 168 subjects geographically (Fig. 11) highlights some areas denser than others: these are *polarised* territorial areas, or characterised by the presence of one (or more) urban or metropolitan poles that we defined as *attractor poles*, cities and provinces around which real and proper ecosystems of active subjects configure and, consequently (as we will see in the next chapter), more easily succeed in activating *MakeToCare* solutions.

As anticipated in the paragraph above, Milan and its province makes a really unique case: alone it accounts for almost 30% of the subjects mapped in Italy (48 out of 168, equal to 28.6%) reaching a total of 57 subjects, also including subjects who locate in nearby Monza and the adjacent provinces of Como and Lecco⁷¹. Lombardy is therefore a highly active area, characterised by a high number of subjects distributed in the different categories and areas of the *MTC Ecosystem*: in the city of Milan alone there is a mix of Universities, IRCCSs, Research Centres, Patient Associations, startups and FabLabs active in the healthcare setting. The Milan FabLabs seem to be characterised by a true and proper vocation towards healthcare issues: out of 37 design solutions in the central nucleus of the *MTC Ecosystem*, 11 (approximately 30%) include the participation of a Milan FabLab or academic spaces dedicated to digital manufacturing such as the two Politecnico di Milano spaces⁷². Among the foremost FabLabs we point out WeMake that we find among the subjects involved in the *CREW* project (see sheet 2.3) promoted by Fondazione Cariplo and among the protagonists, with the Municipality of Milan, of the European *OpenCare* project. Still with regard to the FabLabs we refer to the collaboration between *OpenDot* and *Fondazione TogetherToGo (TOG) NPO*: since 2015 it has undertaken a journey of research for the production of aids and objects for daily use for children with complex neurological diseases (see section 3.7.15).

Within the context of digital manufacturing analysed in the healthcare setting we also include *Secondo nome: Huntington* (see section 3.6.15) a rather unique initiative promoted by an association of patients involving other patients, *caregivers*, designers, researchers and different Milan FabLabs and makerspaces with effect also from the design point of view on a degenerative disease such as *Huntington's Chorea*. Even the figure related to some of the actors external to the *MTC Ecosystem* (the 6 subjects previously defined *Other*) here represent a very important figure: we think about the role of the Municipality of Milan as partner in the *OpenCare* European project, or that of Fondazione Cariplo promoter of the *CREW* project, in their function of institutional subjects who can enable the building of coalitions that become points of strength and activators of the same design process. Still in the Milan area, also important is the role of some of the more active IRCCSs such as *Fondazione Don Gnocchi* with its portal *SIVA – Servizio Informazione Valutazione Ausili* (see section 3.7.5) that, with multiple years of experience in aids, offers itself as a service for the community with the objective to safeguard the pathway, assessment and selection of aids up to their prescription by the ASL (Azienda Sanitaria Locale [Local Health Authority]). Or again the *Medea IRCCS* of Bosisio Parini (see section 3.7.4), a state-of-the-art institute for the research and rehabilitation of patients of advanced age, particularly attentive to the prototyping, development and experimentation of innovative products-services targeting the diagnosis, care and rehabilitation of patients and support of *caregivers*. Last significant figure for the Milan area is the presence of the CNR Research Institutes: 5 out of a total of 12 mapped are included in this area. Among these, the *ITIA, Istituto di Tecnologie Industriali e Automazione*,

⁷¹ Inside the Milan area pole, in addition to the 57 subjects identified in the city of Milan and province, 7 subjects located in the nearby provinces of Como and Lecco were also included, because these are subjects who, in the development of the mapped design solutions, perform their activities predominantly in synergy with subjects in the Milan area

⁷² *Polifactory* (www.polifactory.polimi.it), the makerspace of Politecnico di Milano, with headquarters at the Bovisa Campus, and *+Lab* (www.piulab.it), laboratory on additive manufacturing located at Department of Chemistry, Materials and Chemical Engineering



Milan	48
Genoa	14
Rome	9
Turin	9
Naples	8
Bari	5
Bologna	5
Pisa	5
Imola	4
L'lorence	3
Lecce	4
Bosisio Parini (LC)	2
Brindisi	2
Como	2
L'Aquila (AQ)	2
Iecco	2
Modena	2
Novara	2
Acquaviva Delle Fonti (BA)	1
Altamura (BA)	1
Ancona	1
Ascoli Piceno	1
Brescia	1
Cagliari	1
Cambiano (TO)	1
Camerino	1
Catania	1
Catanzaro	1
Foggia	1
Ghezzano - S Giuliano Terme (PI)	1
Martina Franca (TA)	1
Massa Lombarda (RA)	1
Matera	1
Messina	1
Mirandola	1
Montebelluna (TV)	1
Montecatone Imola (BO)	1
Monza	1
Navacchio-Cascina (PI)	1
Padova	1
Palermo	1
Parma	1
Pavia	1
Piacenza	1
Perugia	1
Reggio Calabria	1

Fig. 11 | MakeToCare Ecosystem: the attractor poles (base data: 168 subjects)

that also is involved with the development of projects and devices for neurorehabilitation with the direct involvement of patients (see section 3.7.9). Like the *RIPRENDO@HOME* project, platform for the home rehabilitation of the upper limbs, designed to improve the quality of the same rehabilitation in a more comfortable context for the patient, by direct support of family members and caregivers therefore with better rationalisation and optimisation of the resources of the traditional inpatient care system (Fig. 12). Moving from Lombardy to the adjoining Emilia Romagna, it is possible to identify another *attractor pole* in the Bologna and province area, with particular attention to Imola. Here there are 11 mapped subjects (out of a total of 168, equal to approximately 6.5% of the total), mostly active in the orthopaedics and motor rehabilitation sector, with particular attention and sensitivity for the world of disability. Bologna is the site of *Istituto Ortopedico Rizzoli*, Scientific Institute for Research/Hospitalisation and Health Care IRCCS, specialising in the orthopaedics and trauma field. The research and experimentation conducted by this Institute is intended for the development and implementation of advanced surgery devices but also of solutions ever more centred on personalisation (up to *custom-made* implants and prostheses, see section 3.7.6). Still in the advanced orthopaedic sector, the *Centro Protesi INAIL* is active in Vigorso di Budrio (Bologna), a research Institute accredited by the SSN and unique of its kind, specialising in the research and advanced technology experimentation intended for the production (and supply) of orthopaedic prostheses and devices. The centre is also a rehabilitation facility: it is in fact involved in training the patients in the use of the prostheses, also taking into care children in the first years of life. It has signed numerous agreements of collaboration with the principal centres of research and Institutes, some already mentioned. These include the agreement of collaboration signed with the *IIT Istituto Italiano di Tecnologia* for the study and development of a mechanical upper limb of robotic derivation, also made with the contribution of *3D printing* technology and intended for the recovery of the overall functionality of upper limb amputee patients. Or again the collaboration with the *Istituto di BioRobotica* that led to the foundation of the *REPAIR Lab* (Rehabilitation Engineering and Prosthetics Applied Innovation & Research), laboratory of the *Scuola Superiore di Sant'Anna* that pursues activities of research and study in bio-robotic, prosthetic and neuro-robotic areas. A partnership with the specific objective of creating a synergy between the scientific research conducted by the Institute and the activity of rehabilitation and training in the use of the prostheses developed by the Vigorso di Budrio INAIL Centre, for developing next-generation prostheses for patients with amputations or neurological injury. Still in the rehabilitation sector we recall the *Istituto di Montecatone*, *Ospedale di Riabilitazione* of Imola, the main regional pole of reference for the intensive rehabilitation of

Total subjects 168

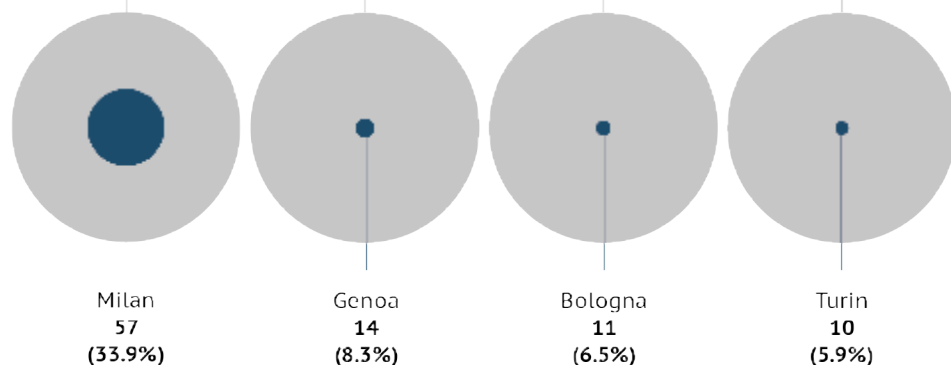


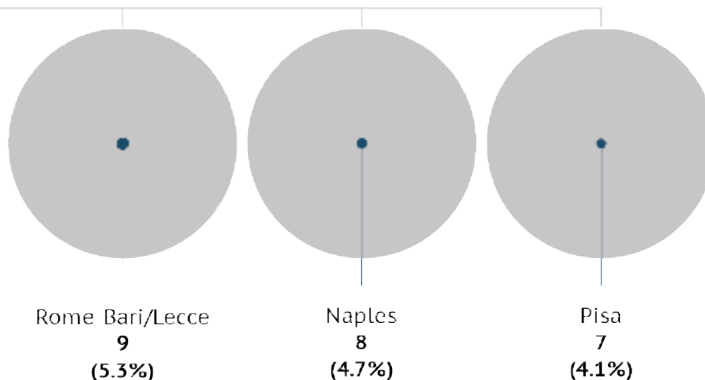
Fig. 12 | The attractor poles and forces in play (base data: 116 out of 168 subjects)

persons affected by medullary disorders and regional centre of reference for acquired brain injuries (see section 3.7.7). Since 2014 the Institute promotes the *Ausili Creativi* competition beginning from the direct experience of Institute staff who observed how patients (and *caregivers*) once discharged, tried their hand at building aids that are not commercially available or otherwise only available at a too high cost. From here the idea of diffusing and sharing aid solutions *made at home*.

These are primarily highly personalised solutions that cannot be applied to other patients, but that in any case, may represent a base or starting point for the development of other solutions of improvement. There is then the case of *HANDimatica* designed and made by the *Fondazione ASPHI Onlus* of Bologna (see section 3.7.14). It is a national exhibition-conference dedicated to digital technologies and technological innovation designed for the school, work and social inclusion of persons with disability.

The attractor pole of Bologna is followed by an ideal geographic triangulation involving the city and areas of Genoa, Turin and Pisa. Among these three poles it is possible to trace signs of collaborations by now consolidated and activated over the years by some of their more significant subjects.

Genoa (and adjacent areas) sees the presence of 14 located subjects (out of a total of 168, equal to approximately 8%) among whom we identify, as anticipated, the *IIT Istituto Italiano di Tecnologia* that collaborates with a network of Universities, spin-offs, biomedical startups and research centres. A network that contributes to configuring this area as an attractor pole and nerve centre for technological research and innovation applied to the care sector with a specialisation in both the context of research and treatment of visual disability and the field of robotics used for development, rehabilitation and body/motor integration. Some of the projects dedicated to patients with visual impairment that we mapped (Glassense, project already finalist in the 2016 edition of the *MAKEtoCARE* contest) or again *ABBI* (see section 3.6.2) position themselves in this disciplinary area and are often the result of coalitions that see the participation, in addition to the already mentioned *IIT*, of other specialised subjects active in situ such as biomedical companies specialised in the optical sector or the *Istituto David Chiossone Onlus*, national centre of excellence that has an agreement with the SSN, involved with visual disability in all ages, from the youngest to the eldest.



The IIT also hosts *Rehab Technology*⁷³, a centre of excellence of applied research in the robotics sector, started in 2013 from an agreement between IIT and INAIL, with the goal of initiating a highly specialised workshop for the development, implementation and transfer to market of rehabilitation prostheses, orthoses and aids with high content of technological innovation. From the activities of research by *Rehab Technology* began a first series of solutions (a prosthetic hand, a motorised exoskeleton and rehabilitative robot) and a spin-off (*Movendo Technology*) that together aim to transfer the skills of a highly qualified research programme to product solutions intended for a competitive marketplace and sustainable from the perspective of costs for the end user patients and national health systems. Among the many collaborations developed by the IIT we also reference the *Joint-lab* activated with the already-mentioned *Fondazione Don Gnocchi* of Milan, dedicated to the development of technology solutions for the rehabilitation and improvement of the quality of life of the most vulnerable persons. The objective is the implementation of solutions that, associating clinical practice and technological research, enable innovative applications in rehabilitation and support through increasingly tailored processes of care of the patient. Finally, always in reference to the IIT, within the Polo Scientifico e Tecnologico Erzelli will appear the future *Center for Human Technologies*, a new IIT infrastructure of research specialising in the development of technologies dedicated to the human being, with a focus on the increase in life expectancy and improving its quality.

Outside of the connection with the IIT but still in Genoa, during the recent Forum on Innovation for Health⁷⁴ it was announced that at the *Istituto Gaslini* will begin the first *Neonatal and Paediatric Stroke Centre*, thanks to the willingness to collaborate with the *FightTheStroke Association* (see section 3.6.10). Based on the experience of existing international *Stroke Centres*, the *Istituto Gaslini* will be the foremost in Italy for the diagnosis, research and assistance for infants and children on the pathology of the paediatric stroke. After Genoa comes Turin with 10 subjects located (almost 6% of subjects mapped), among which it is important to remember the *Hackability* experience (see section 3.7.12). It is an *initiative-platform* that sees the participation and collaboration of an enlarged community of actors, including some FabLabs, Research Centres, Social Cooperatives and Patient Associations, with the objective to devise, co-design and create innovative, *open source* solutions⁷⁵, improve the quality of life beginning from the specific needs of patients and *caregivers*.

Finally, to Genoa and Turin Pisa and its province are connected (with a total of 7 subjects out of 168, equal to approximately 4%), the first of the attractor poles belonging to the Centre macro-region. With the presence of *Scuola Superiore Sant'Anna* and of its *Istituto di BioRobotica*, Pisa is ideally connected to Genoa and its robotic vocation. The *Institute of BioRobotics* of *Scuola Superiore Sant'Anna* is in fact a university centre of excellence specialising in projects with high technological innovation. Highly specialised productive realities were developed from the consolidated experience of scientific research applied to the area of wearable technologies that characterises this institute. From the *Laboratorio di Robotica Percettiva* (PERCRO) began for example the *Wearable Robotics* spin-off, a company specialising in the development and commercialisation of wearable robotic exoskeletons to support the manual moving of materials and for walking or rehabilitation of subjects either elderly or with disabilities (see section 3.6.3). Or again *IUVO*, founded by a team of lecturers and researchers which is located inside the *HUMANufacturing Innovation Center Comau* of Pontedera (PI), that also with the objective of developing wearable tools capable of

⁷³ See: www.iit.it/it/research/lines/rehab-technologies-inail-iit-lab

⁷⁴ S@lute 2017 (Rome, 21-22 September 2017); see: www.innovazioneperlasalute.it

⁷⁵ The project results are then shared and available on the Internet (www.hackability.it) with Creative Commons license; the initiative, after a first experimentation started at the Turin FabLab, has been re-proposed in other sites

improving the mobility and quality of life of persons. Active in the sector of robotics and bioengineering there is also the Centro di Ricerca E. Piaggio of the Università di Pisa. From the collaboration between this centre and the IIT of Genoa began the *qbrobotics* spin-off, active at the *Polo Tecnologico di Navacchio* and specialising in the production of actuators and artificial hands based on the latest research in neuroscience on motor control. *Qbrobotics* developed the *qbhand*, the commercial version of the *SoftHand Pro* prosthetic hand (see section 3.6.16), part of the *SoftPro*⁷⁶ project involving 13 European partners (entrepreneurial and University realities) funded by the European Community in the Horizon 2020 Programme. Confirming the fact that Pisa is a pole of excellence recognised internationally, with a unique territorial concentration of subjects, activities and research programmes applied to the robotics sector, there is then the *Festival Internazionale della Robotica*. It is an initiative inaugurated in 2017 and promoted by the leading city Institutions and the Region of Tuscany in collaboration with Universities and research Institutes, with the goal of presenting the most interesting developments in robotics and its multiple applications in the service of humans.

Another attractor pole in the Centre macro-region is the city of Rome, with 9 subjects mapped out of a total of 168, including the *Ospedale Pediatrico Bambino Gesù*, a Scientific Institute for Research/Hospitalisation and Health Care (IRCCS) and largest Polyclinic and Paediatric Research Centre in Europe. Active in multiple programmes of research and experimentation, also in connection with other facilities, the hospital has recently initiated a unit dedicated to *Innovation and Clinical Pathways* equipped with technologically advanced technologies and processes such as a framework for the *3D modelling* of diagnostic imaging (see section 3.7.3). Still in Rome there is the Università Campus Bio-Medico, with a research unit highly specialised in the *Biomedical Robotics* and *Biomicrosystems* sector and with an attention to *Rehabilitation Bioengineering*.

In the South macro-region, lastly, we can identify two poles: Naples and the Bari-Lecce territorial axis. The first, with 8 subjects mapped out of 168, sees the presence of the *Città della Scienza*, a facility composed of a scientific interactive museum, an entrepreneurial incubator and a space dedicated to innovation and new technologies for digital manufacturing. *Corporea* is the first example of a museum entirely dedicated to the theme of health, science and biomedical technology and prevention. The *Design and REsearch in Advanced Manufacturing (D.RE.A.M.)* includes a FabLab, spaces for training, dedicated areas for co-working and places for the experimentation of innovative projects. For the exhibition spaces of *Corporea* the FabLab developed an adaptation of the open source *TINA* and *BOB* projects with *Open BioMedical Initiative* (see section 3.6.11) and *GALENO* with *BIOlogic* (see section 3.6.5), the first *Bio FabLab* in Southern Italy initiated thanks to an incubation programme promoted by *Campania in Hub* (initiative intended to enhancing the regional ecosystem for enterprise creation) and created by the Municipality of Cava de' Tirreni. The *Bio Fablab* configures as a state-of-the-art centre of research and uses *biological fabrication* technologies to implement new processes of manufacture and new solutions in the healthcare sector. Still in Naples, the *eHealthNet Workshop* is in operation, that began from the aggregation of Institutes of Research, Universities, SMEs and large enterprises that represents the best of the entrepreneurial material and research institutes present in the Campania territory for the creation of the industrial research project *eHealthNet* (i.e. a software *Ecosystem for Electronic Healthcare*).

⁷⁶ See: www.softpro.eu

Finally, the last attractor pole highlighted within our mapping is the Bari-Lecce micro-axis, with the presence overall of 9 subjects identified including three universities (Università degli Studi Di Bari Aldo Moro, Politecnico di Bari and Università del Salento) and an area of interest particularly developed in the context of telemedicine systems.

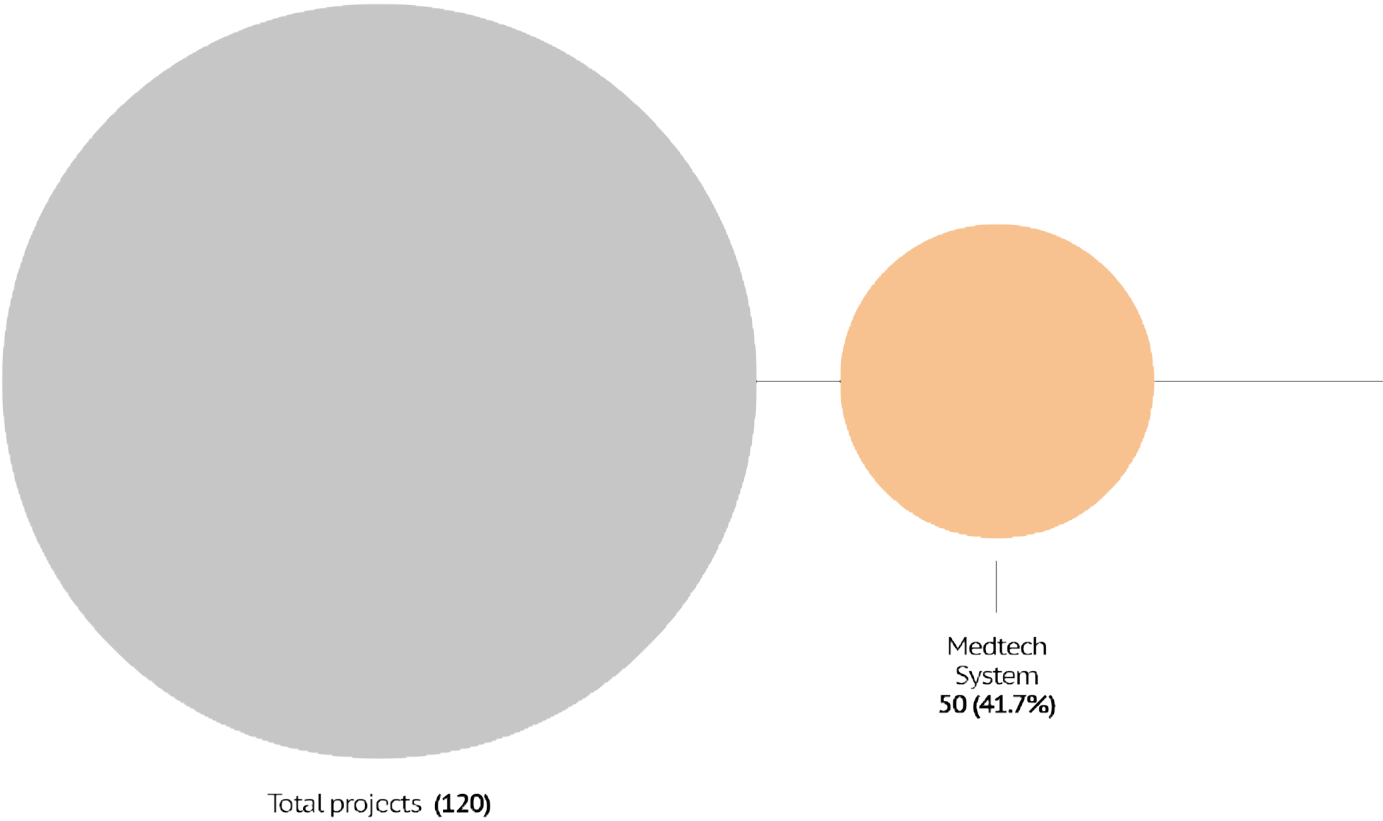


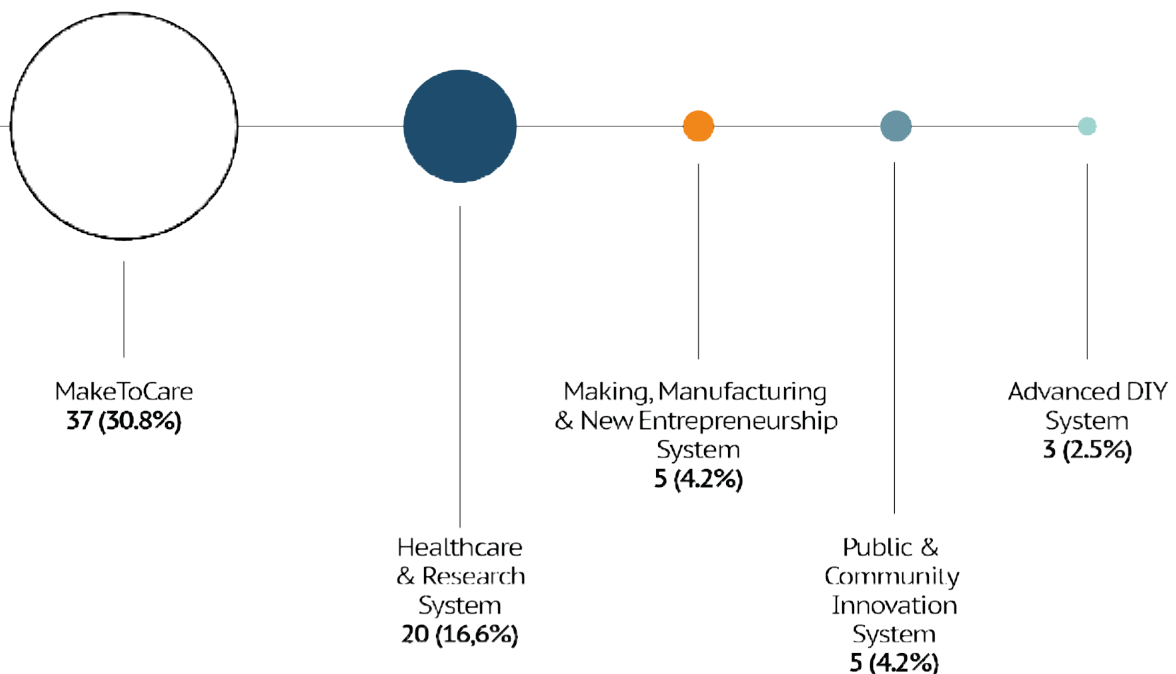
Fig. 13 | The distribution of projects in the MakeToCare Ecosystem (base data: 120 projects)

3.5 THE MAKETOCARE ECOSYSTEM PROJECTS

3.5.1 MakeToCare Ecosystem: a broad laboratory with 120 projects

The principle of definition of the *MakeToCare Ecosystem* is based on the identification not only of subjects active within it, but also the product-service projects and solutions that constitute the results of their activities. *MakeToCare* configures as a *complex ecosystem* that, as we have seen, combines not only subjects who we have defined as *MakeToCare* (subjects belonging simultaneously to the sector of healthcare, new manufacture and patients who then develop solutions that we can *automatically* define as *MakeToCare*) but also and especially subjects who, while positioning themselves in *different* areas of the *Ecosystem*, develop synergies translatable into *MakeToCare* design solutions through the building of design coalitions with other subjects.

Through the placing of perimeters around its areas the *Ecosystem* allows the mapping of each project identified, defining the characteristics that most qualify it. A project that positions itself in the *Healthcare & Research System* area is characterised, for example, by a strong content of research; if positioned instead in the *Making, Manufacturing & New Entrepreneurship System* area, it will have instead a prevalent design-technical-productive content⁷⁷. The *Ecosystem* especially to identify projects that position themselves in the *MTC Ecosystem* secondary areas that, together with the *MakeToCare Area* are the most significant areas for research purposes. The placement of 120 mapped projects with respect to the areas *MTC Ecosystem* (Fig. 13) sees the following division:



⁷⁷ Obviously this practice of allocation involves a process of qualitative interpretation of the same characteristics of the projects-solutions mapped

The *MTC Ecosystem* was analysed weighing the numerical consistency of its different components: the main systems (*Healthcare & Research System*, *Making, Manufacturing & New Entrepreneurship System* and *Patient & Caregiving System*), the secondary systems (*Medtech System*, *Advanced DIY System* and *Public & Community Innovation System*) and the *MakeToCare Area*. Three areas of reference emerge in order from the numeric perspective: the first, exactly in line with a trend already found in the analysis of subjects, is composed of the *Medtech System* area where more than 40% of the solutions are concentrated (50 out of 120 projects); the second is the *MakeToCare Area* with approximately 30% of the solutions (37 out of 120), and finally the *Healthcare & Research System* that accounts for approximately 17% of the total (20 out of 120). The *Making, Manufacturing & New Entrepreneurship System* (5 out of 120), *Public & Community Innovation System* (5 out of 120) and the *Advanced DIY System* (3 out of 120) areas constitute a minority within the *Ecosystem*. Obviously, since in this case it is analysis based on projects, the absence of the *Patient & Caregiving System* area is justified, identifying only one subject category (patients and caregivers, in fact).

The first significant detectable figure is that in the *MTC Ecosystem* (relative to the projects), the size of the secondary areas including the *MTC Area* (95 out of 120 solutions, equal to 79%) is clearly greater than the primary areas (25 out of 120 solutions, equal to 21%). This aspect characterises the *MakeToCare Ecosystem* and sees the design solutions positioning themselves primarily in the areas of overlap between disciplinary subjects and settings. The second figure is that within the *MTC Ecosystem* the presence of a supporting axis made up of the *Medtech* system and the *MakeToCare Area* is highlighted (87 out of 120 solutions, 72.5%) defining in practice a macro-category of solutions that, while positioning themselves on different points of this hypothetical axis, are characterised by the convergence of scientific, technology and human expertise: a space where in various ways, the patient plays a significant role and finds an enabling environment. What are the characteristics of the solutions that position themselves in these areas of intersection? Is it possible to identify the prevalent types and/or areas of intervention? From the perspective of the solutions created, we can say that the *Medtech System* is characterised by a high degree of heterogeneity. The first clear figure, in fact, is that the 50 solutions positioned within this system cover a very broad range of types that goes from implantable devices to prosthetic, orthotic and mechanical aid solutions, wearable IoT devices, up to more complex systems of platforms and augmented reality. Even for the 37 solutions of the *MakeToCare Area*, that we will analyse more thoroughly in the next sections we have a variety of solutions that range from orthoses, exoskeletons, wearable devices, mechanical-analogue aids up to enabling systems and platforms also.

Finally a significant, but obvious figure, is that of the 20 solutions positioned inside the *Healthcare & Research System*. It is in this area, in fact, that we can detect the highest concentration of solutions with *high technological content*, with a clear predominance of solutions that involve the engineering sector and particularly that of *robotics*. Of the rest this is the sector where the studies and experimentations of the most accredited care centres, Research Institutes and Universities, find application.

3.5.2 The coalitions that give life to the MakeToCare Ecosystem projects

The first level of reading investigated the subjects who developed the 120 design solutions, highlighting the numbers and weights of *coalitions* where a group of more than one subject active in the design process that gave rise to the final solution was found (Fig. 14).

The first significant figure emerges from the percentage weight corresponding to the projects developed within the *Ecosystem*: 62 out of 120 solutions (approximately 51.7%), in fact, were created by subjects who operate *individually* without having formed significant coalitions within the design process. The remaining 48.3% of projects (58 out of 120) were however developed by coalitions composed of at least two subjects.

The 62 individual projects were developed by subjects who work primarily in the *Medtech System* (38 solutions, equal to approximately 61.3%). There follow 6 solutions (equal to approximately 9.7%) developed by subjects belonging to the *Health & Research System*, 10 solutions developed by subjects belonging to the *MakeToCare Area* (16%), 5 from *Making, Manufacturing & New Entrepreneurship System* (8%), and finally 3 solutions developed in the *Advanced DIY System* (5%). Additionally, a significant figure is that related to the 48 solutions (equal to 77.4%) that position themselves in the *Medtech System* and the *MakeToCare Area* supporting axis (formed by 87 projects out of a total of 120) representing—similar to what happens for all of the solutions—a little more than half of the sample (48 out of 87, equal to 55.2%).

In the analysis, the coalitions were divided into three categories corresponding to three different sizes: *mini* (coalitions from 2 to 3 subjects), *medium* (from 4 to 6 subjects) and *large* (more than 7 subjects). 69% of the coalitions belong to the *mini* category, the *medium* coalitions are 8, and lastly, those defined as *large* are 10.

The projects developed by *mini* coalitions (40 solutions out of 58) position themselves predominantly in the *MakeToCare Area* (16) followed by the number of solutions developed within the *Healthcare & Research System* (12), in the *Medtech System* (7) and finally in the *Public & Community Innovation System* (5). Projects developed by *medium* coalitions (8 out of 58) position themselves in a fairly balanced way between *Healthcare & Research System* (2 out of 8) and *Medtech System* (2 out of 8) with a slight prevalence of the *MakeToCare Area* (4 solutions out of 8).

Finally, the projects developed by *large* coalitions (10 out of 58) position themselves predominantly in the *MakeToCare Area* (7 out of 10) and to a lesser extent in the *Medtech System* (3 out of 10).

Considering the *MakeToCare Area* alone (37 projects out of 120), we can therefore detect a majority of subjects who work in collaboration with others (27 out of 37 projects are the result of coalitions) and a minority of projects developed by subjects who work independently (10 out of 37). A relevant figure is certainly the high presence of *mini* (16 out of 37) and *large* coalitions (7 out of 37), less prominent is the figure for *medium* coalitions (4 out of 37). It is thus highlighted that approximately 70% of the solutions consist of partnerships of small size, while 19% are oriented to create *large* coalitions.

This causes a double vision to emerge:

- inside the *MTC Ecosystem*, considered in its totality, a dimension of autonomous subjects and *mini* coalitions is prevalent; the sum of *individual* subjects (62 out of 120) and those involved in *mini* coalitions (40 out of 120) is the basis for development of 85% of the solutions (102 out of 120);
- in the *MakeToCare Area*, however, the trend changes with the prevalence of *mini* and *large* coalitions, which means that the subjects who develop the solutions opt more for the co-creation of solutions, with a predisposition for *large* coalitions (out of 120 projects, 10 are the result of coalitions with more than 7 subjects; of these 10, 7 position themselves in the *MakeToCare Area*).

From the analysis, it emerges how, between subjects who work individually, those more productive are naturally the *Biomedical/Medical Startups and Enterprises* (18 subjects covering 29% of the subjects), followed by *University Spin-offs and Startups* (14; 22.6%), *Medtech Startups and Enterprises/Associations* (8; 13%) and the *Universities* (6; 10%). These are cases where the subjects have in common the fact that they operate in conditions of apparent autonomy and self-sufficiency in expertise and resources.

Finally, for the *coalitions system* which developed 37 solutions of the *MakeToCare Area*, it is possible to observe that the 10 subjects who work individually correspond to the same number of subjects who we defined as *100% MakeToCare*. That is, *Medtech Startups, Enterprises, Associations and Patient and Caregiver Innovators*, subjects who combine within them that mix of medical and scientific and technical-design skills. In particular, regarding the startups specifically, often these are realities formed after a phase of work in teams to develop a specific solution that was subsequently structured into startups, in fact.

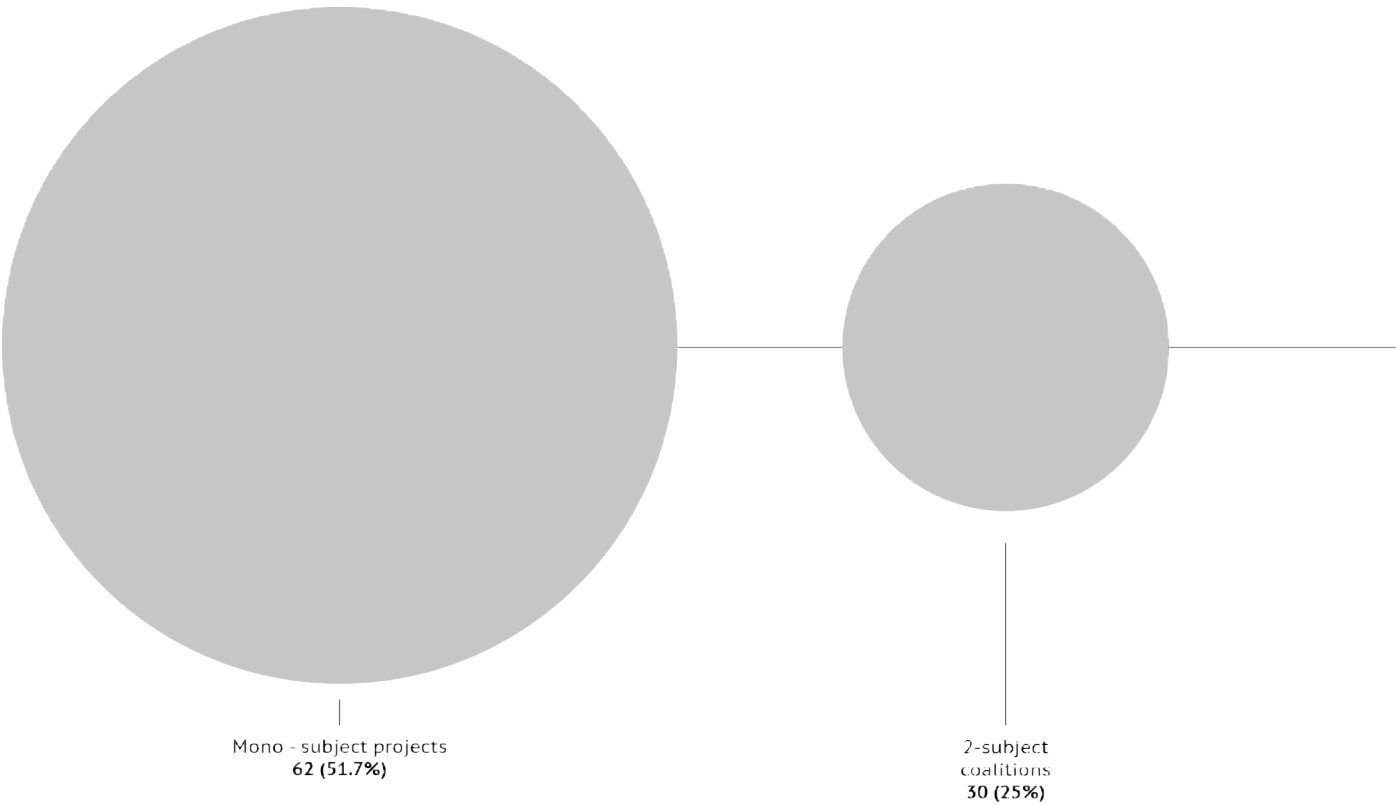
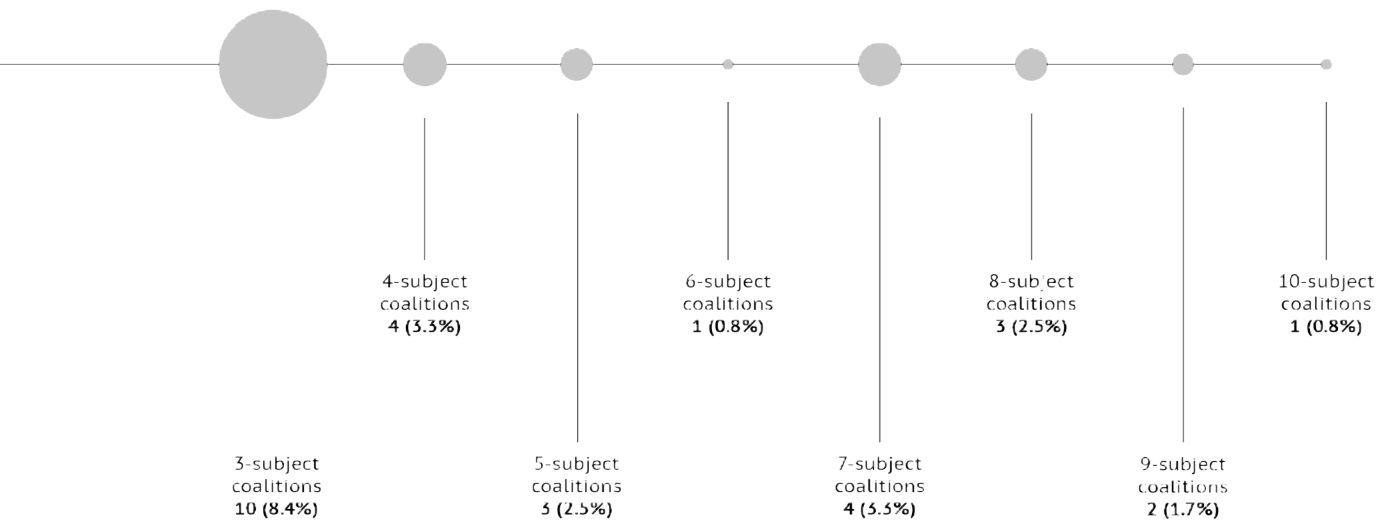


Fig. 14 | MakeToCare Ecosystem: structure of the coalitions (base data 120 projects)



3.5.3 The planning of the MakeToCare Ecosystem

The second level of reading of the 120 design solutions investigated the between the different types of *actuator* subjects (i.e. subjects who invented and/or developed the solution) and the type of project/solution developed/produced.

In the *flowchart* (Fig. 15) is displayed therefore the ratio between the numbers of *connections* activated by the 188 subjects mapped divided by category of belonging to the *MakeToCare Ecosystem* compared to the 120 solutions identified and divided according the area of positioning within the same. The *flowchart* therefore has the objective of analysing the dimension of the development potential of the categories of subjects mapped compared to the different areas of *MTC Ecosystem* (i.e. the 120 projects), investigating the participation of the different categories of subjects/projects compared to the specific planning areas of the *Ecosystem*. The different density of the coalitions of the categories of subjects/projects with respect to the different areas of positioning of the *Ecosystem* is given therefore not by the number of subjects and projects actually found, but by the number of connections activated by all the subjects in the development of individual projects. It is important to emphasise that in this analysis phase, the *Other* category was also displayed, because the analysis of the projects under the topic of *coalitions* showed the relationships that exist between the different subjects in the development process of the same design solutions, in this way making possible and correct to include the subjects external to the *Ecosystem* (excluded in earlier displays). It is clear how the activity of some types of subject focus within some specific areas, while the tendency of other categories is more diversified and distributed in more areas. The *Universities*, for example, operate largely in the areas of the *Healthcare & Research System* and *Medtech* with a much more contained presence in the *MakeToCare Area* and in the *Public & Community Innovation System*.

The startups are instead characterised by a greater diversity: their presence in fact is divided into additional design areas based on type: the *biomedical Startups* together with the *university Spin-offs* have as territory of reference almost only the *Medtech*, whereas innovative startups (generic, not specific to the biomedical sector) have as the territory of choice *Medtech*, but activate connections also in *Making, Manufacturing & New entrepreneurship System* and, to a lesser extent, in the *MakeToCare Area*. The startups originating in the *MakeToCare Area*, and therefore that have that area of application exclusively, close the category.

Also the *Public Research Institutes*, with respect to the production of projects, develop their own activities in several areas following a fairly consistent and equally allocated distribution between the *MakeToCare Area*, *Medtech System* and the *Healthcare & Research System*. Similarly, the designers, even if much lower numbers, follow the same pattern proportionally, resulting as equally distributed between the *MakeToCare Area*, *Medtech System* and *Making, Manufacturing & New Entrepreneurship System*. The *MakeToCare Area*, lastly, presents as main point of reference for *Institutes of Care*, *patient Associations* and *FabLabs*.

If we instead use the areas as a starting point to observe the pattern of the connections activated by the solutions compared to all 20 types of subjects (19 present in the *Ecosystem*, to which we add a special category defined as *Other*), it is possible to see some trends. The *MakeToCare Area* is that which catalyses, more than all the others, the participation of a diverse collection of subjects (17 out of 20 of the categories present form coalitions with each other in developing solutions within this area).

The 37 solutions mapped in the *MakeToCare Area* are mostly the outcome of the work of several subjects and in a small proportion generated from the same nucleus, because there are 12 subjects contained within it. The *Medtech System* follows, with a similar pattern, which contains 14 subject types out of 20.

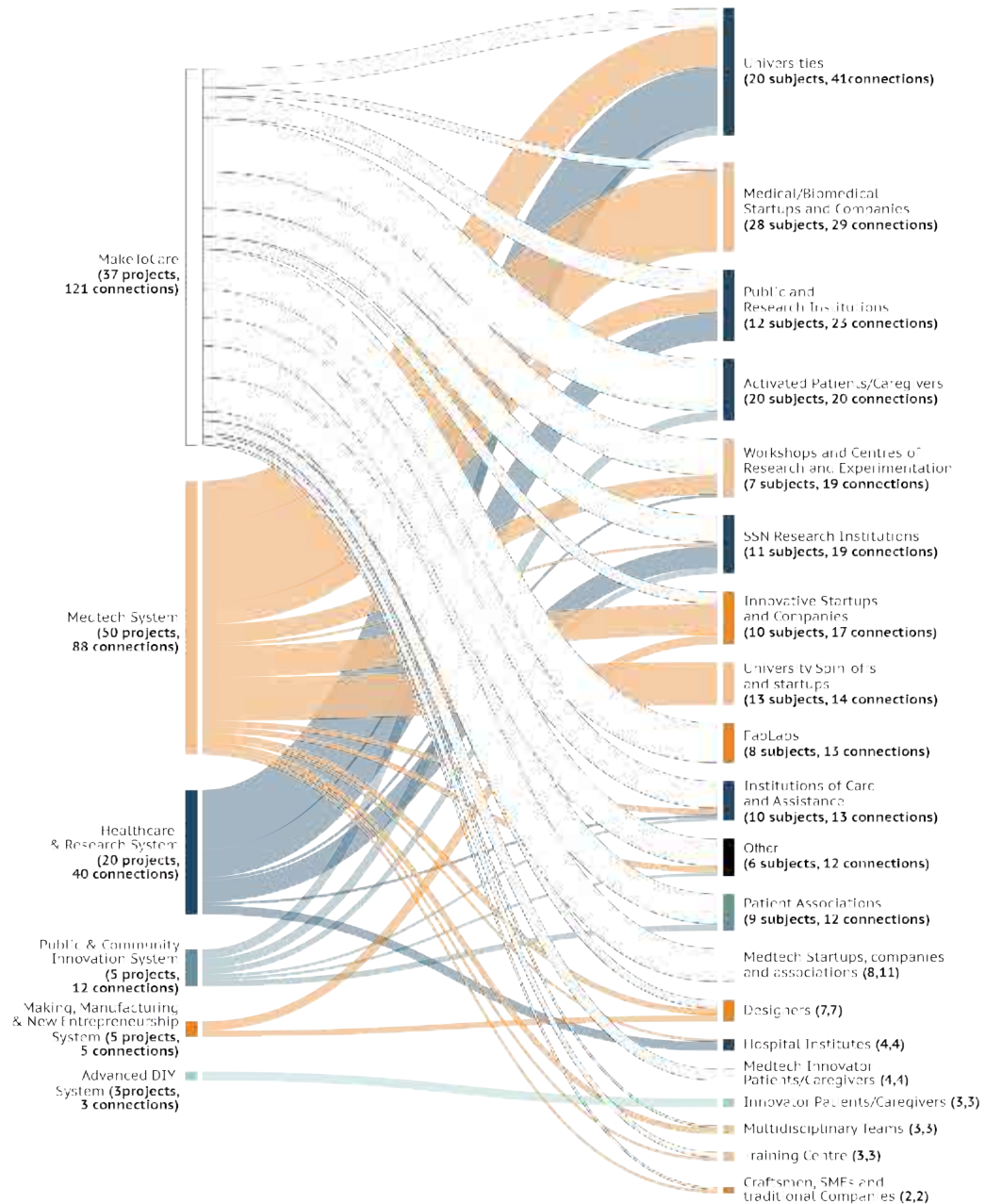


Fig. 15 | MakeToCare Ecosystem: type and weight of the coalitions

3.5.4 The relevance of relationships in the MakeToCare Ecosystem

The third level of reading investigated the *methods* with which the different types of subjects act and collaborate for the development of the final solutions. *Collaborations* between different subjects give life to those we have previously defined as coalitions.

The *chord diagram* aims to highlight the system of relations activated by the 188 subjects mapped in the development of the 120 solutions produced. Essentially, the diagram aims to highlight the coalition between the different types of subjects and their ability to form *coalitions* with other subjects to develop projects, identifying at the same time also the subjects who work in a more isolated and autonomous way. The *dimension* (displayed by the *length* of each arc) of the categories of subjects distributed along the perimeter of the *chord diagram* varies therefore according to the number of collaborations activated by that specific category, and evaluated proportionally compared to the development of the 120 solutions (see Fig. 16). Reading of the diagram is twofold: on the one hand it illustrates for us the *numbers of the coalitions*

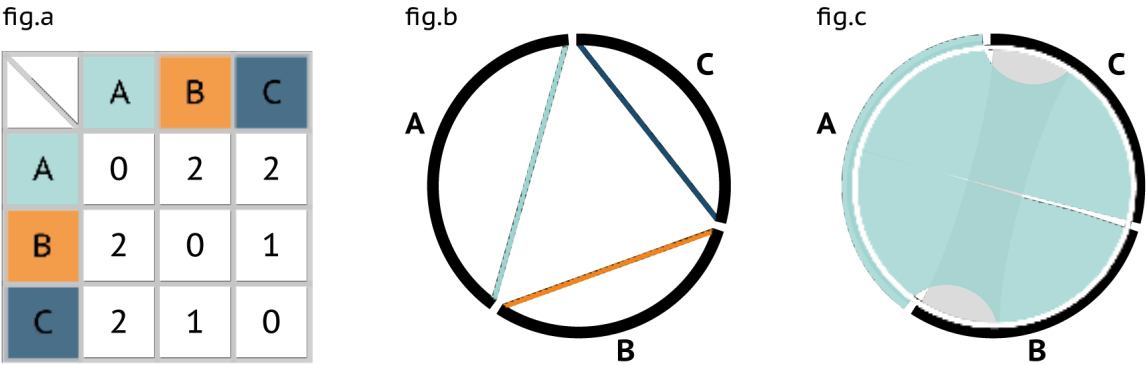


Fig 16 | The chord diagram is a data visualization method used to show relationships in a network. If we hypothesise a network whose nodes are the subject categories “A”, “B” and “C”, the relationships that exist between them can be shown in a matrix (Fig. A). The graph represents the nodes placing them as arches on a circumference. The cord of these arches—the segment that attaches their ends—is proportional to the number of relationships: in the example, the category “A” has more relationships with the others, so it is represented by an arch longer than “B” and “C”, because its cord is longer (Fig. B). The composition of this relationship is then displayed with the links between the arches: in fig. C the links of the category A (in blue) were highlighted, that divide equally between the other categories.

(through the number given in the diagram next to each category starting from Fig. 17), or the number of times in which a subject belonging to a category forms a coalition with another subject (belonging to another or the same category); on the other it tells us the *diversity of the coalitions*, or the number of different categories with which the subject of that single category connects (figure evidenced by the key present in the focus boxes of Figs. 18–24). The two data in most cases have a proportional pattern (a higher number of coalitions corresponds to a higher diversification of the same), but there are some exceptions (as we will see later with the category of *Startups and Biomedical/Medical Enterprises*, see Fig. 22).

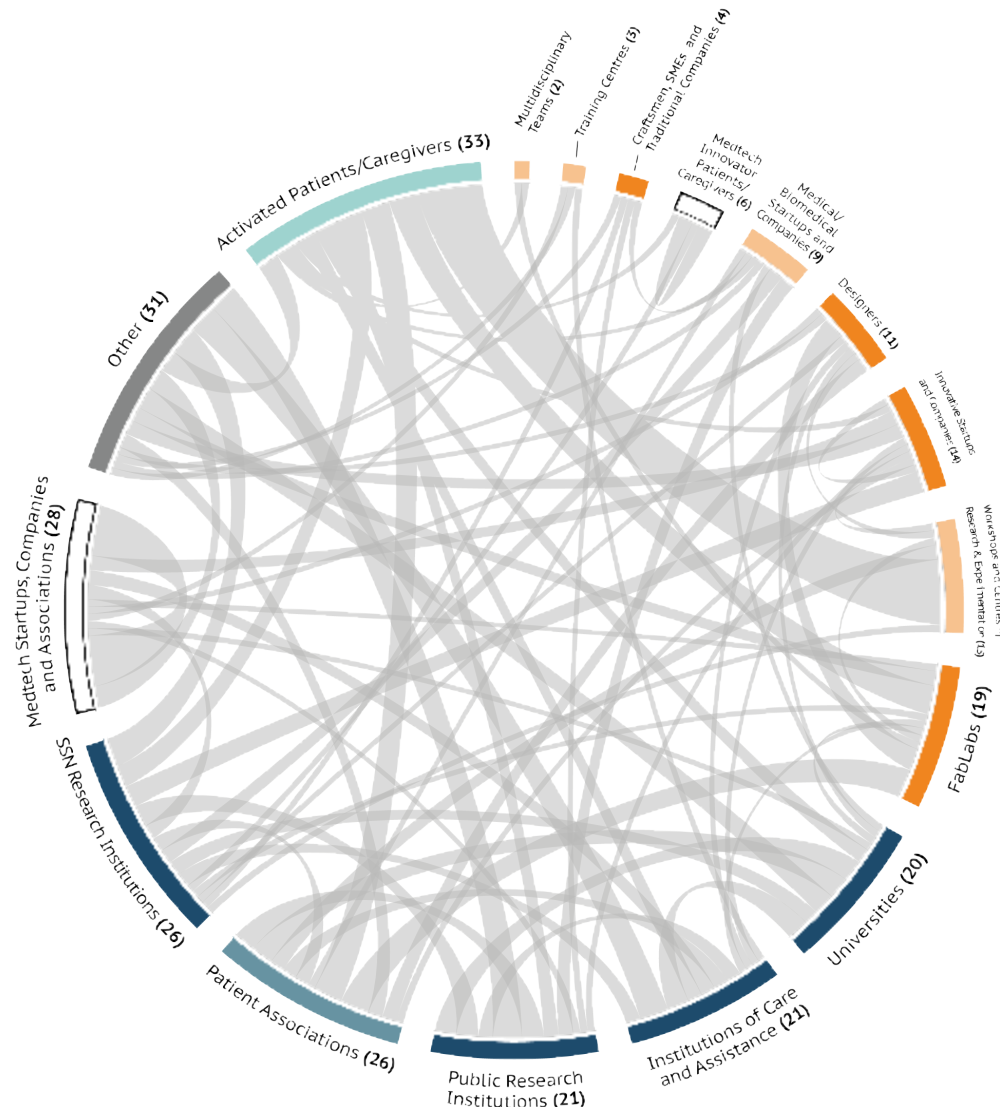


Fig. 17 | MakeToCare Ecosystem: the relationships of the subjects in the coalitions

At the general level it is possible to observe how all types of subjects, although with different propensities, developed coalitions with other types. We can therefore assess the networks of coalitions developed as an indicator of the fact that the *Ecosystem* overall has a good level of interactivity, presenting a *reticular* structure characterised by a coalitional biodiversity similar to that found within the networks that are lubricated by *open innovation* processes.

Within this network of coalitions, we can then apply different analysis filters to highlight and analyse the network of some categories of subjects (see for reference Fig. 05).

It is possible to observe, for example, (see Fig. 18) the degree of connectivity of the *Activated Patients/Caregivers* category that is characterised by the more numerous and diverse network of coalitions (20

“Activated Patients/Caregivers” category partnerships

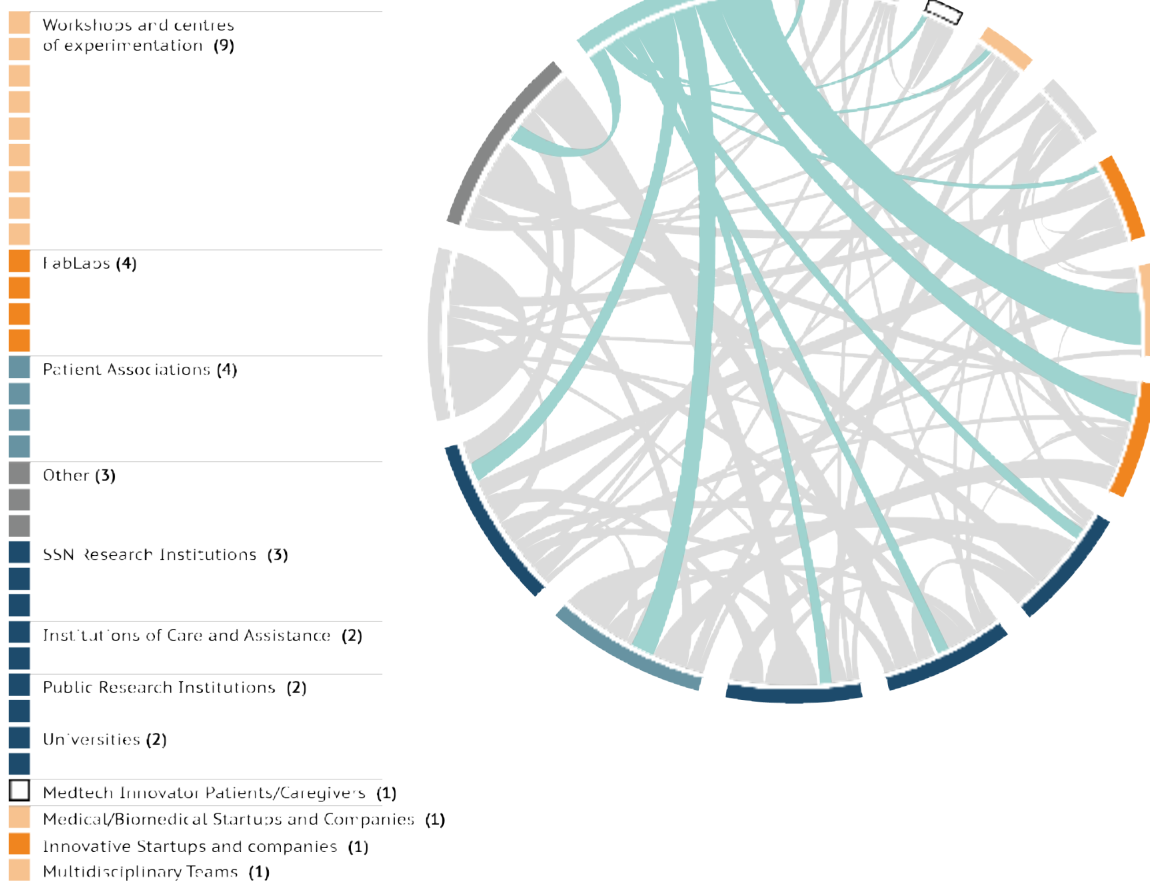


Fig. 18 | MakeToCare Ecosystem: activism of Patients and Caregivers

subjects belonging to the category, 33 coalitions activated with other categories, 12 other categories with which it connects). The connectivity of this category tells us that the presence of the patient has represented an important reference, which has been widely taken account of in the selection of mapped projects. The figure also tells us that, in addition to *Patient Associations* (subjects we naturally think of when speaking about patients), the subjects in this category were able to form coalitions with the locations and facilities of new digital manufacturing, such as the *Workshops and centres of experimentation* and the world of FabLabs and makerspaces (as highlighted in detail in Fig. 18). Even the category of *Patient Associations* (see Fig. 19) is strongly connected (9 subjects in the category, 26 coalitions activated, 11 other categories with which it connects) and in strong coalition with the world of *FabLabs* and digital experimentation workshops: the coalitions activated with the FabLabs category even have the most weight, after that of the category of patients.

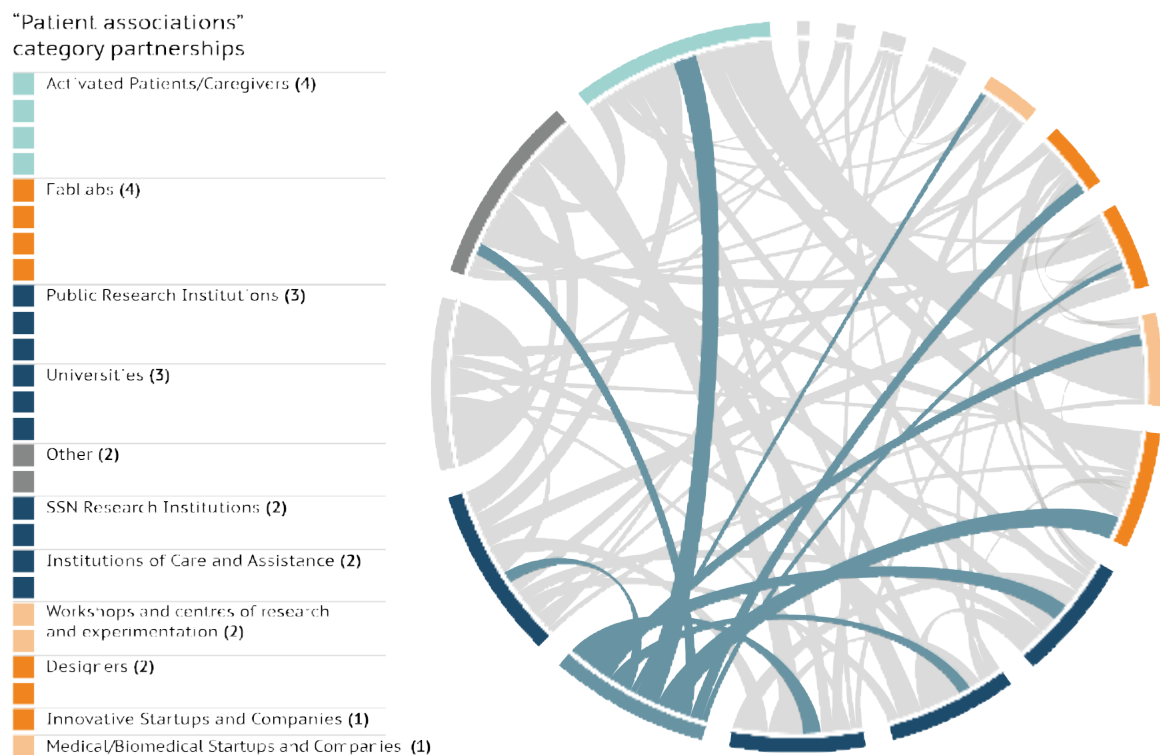


Fig. 19 | MakeToCare Ecosystem: activism of Patient Associations

In parallel, observing the specific pattern of the *FabLabs* category (8 subjects in the category, 19 coalitions activated, 10 other categories with which it connects), we see in fact a prevalence of coalitions activated with patients, caregivers, and patient associations (see Fig. 20).

This appears to highlight the importance of FabLabs in developing *MakeToCare* solutions, not just for the technological competency and contribution given in the creation phase of the final solutions (also displayed in the diagram of the coalitions with the category of *Designers*).

What emerges is their ability to develop a system of direct coalitions with the carriers of needs, which is aligned with a capacity for dialogue developed with institutional subjects such as Centres of Research and Universities. An additional insight for the connectivity of the world of digital manufacturing and experimentation (FabLabs and makerspaces) is given by the connectivity relative to the category that we defined as Workshops and *Centres of Experimentation* (see Fig. 21). It is in fact a cross-sectional category of subjects (7 subjects in the category, 15 coalitions activated, 6 other categories with which it connects) who

"Fabl abs" category partnerships

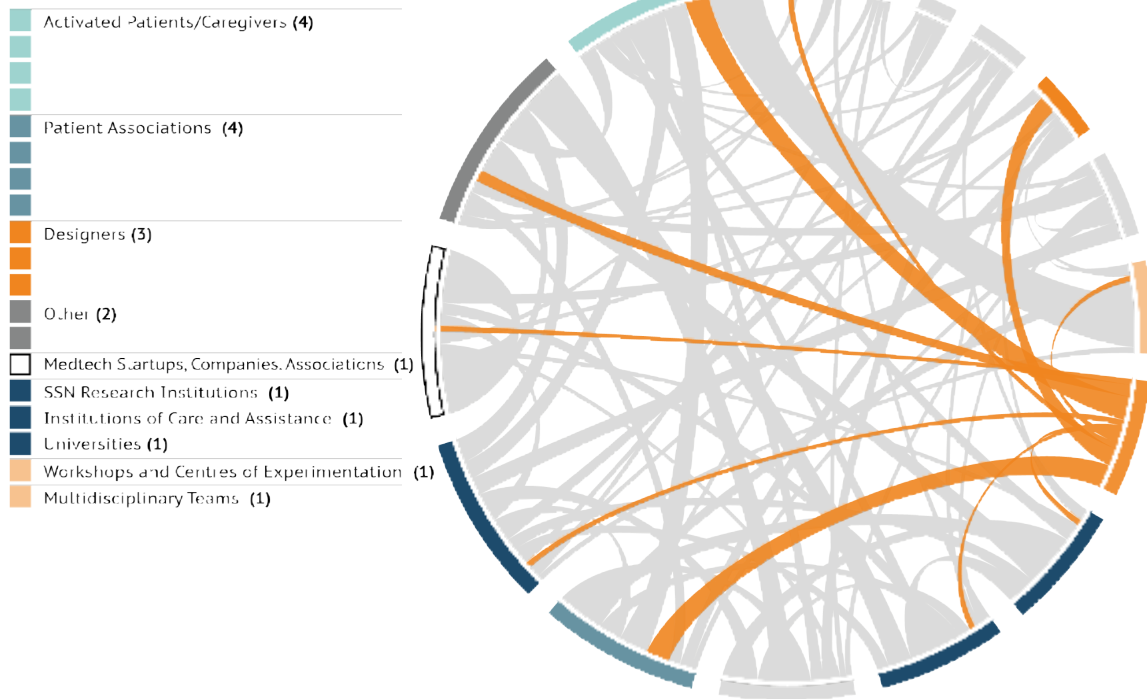


Fig. 20 | MakeToCare Ecosystem: the role of FabLabs and makerspaces

are characterised by a vocation for experimentation related to digital technologies, but also by a strong connection with the world of Universities and/or Institutional Research. Academic workshops or FabLabs are therefore part of this category, realities connected to both the world of digital manufacturing and that of scientific research and institutional healthcare, workshops and platforms for open science and open biology (as for example *Open BioMedical Initiative* or *BIOlogic*). As observed, it is a category of subjects strongly connected with the world of *activated patients/caregivers* and *Patient Associations*. The flows displayed are testimony to the projects developed in initiatives such as *Hackability* or *+Ability*.

As anticipated at the beginning of the section, the category relating to *Startups and Medical/Biomedical Enterprises* (see Fig. 22) is characterised by a different pattern compared to the majority of other categories: a rather low number of connections with other types of subjects corresponds in fact to a high number

“Workshop and Centres of Experimentation” category partnerships

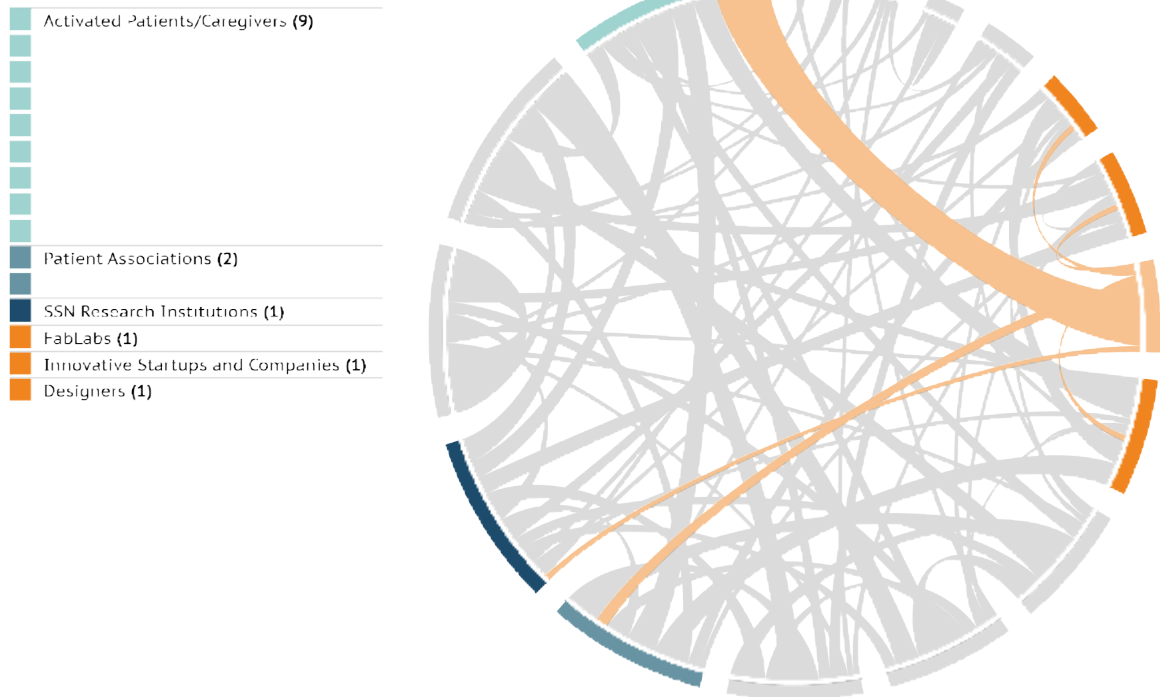


Fig. 21 | MakeToCare Ecosystem: micro-networks of research and experimentation

of different types with which coalitions are made (7 out of 20). This indicates that in the development of the projects mapped, this category of subjects expresses an elevated ability to form coalitions with other categories.

Finally, it is interesting to observe the course of the partnerships that activate the categories of the *MakeToCare Area* subjects. Subjects belonging to the category of *Medtech Innovator Patients/Caregivers* (see Fig. 23) act in a strongly independent way, they only weakly form coalitions with other categories (actually limited to two categories only, *Activated Patients/Caregivers* and *SSN Research Institutes*). Regarding instead the *Medtech Startups, Enterprises and Associations* category (see Fig. 24), still part of the *MakeToCare Area*, it is possible to highlight how the minimal connections with 9 other categories probably indicate that a mix of qualified expertise used for the development of specific solutions is already active within these realities.

"Medical/Biomedical Startups and Companies"
category partnerships

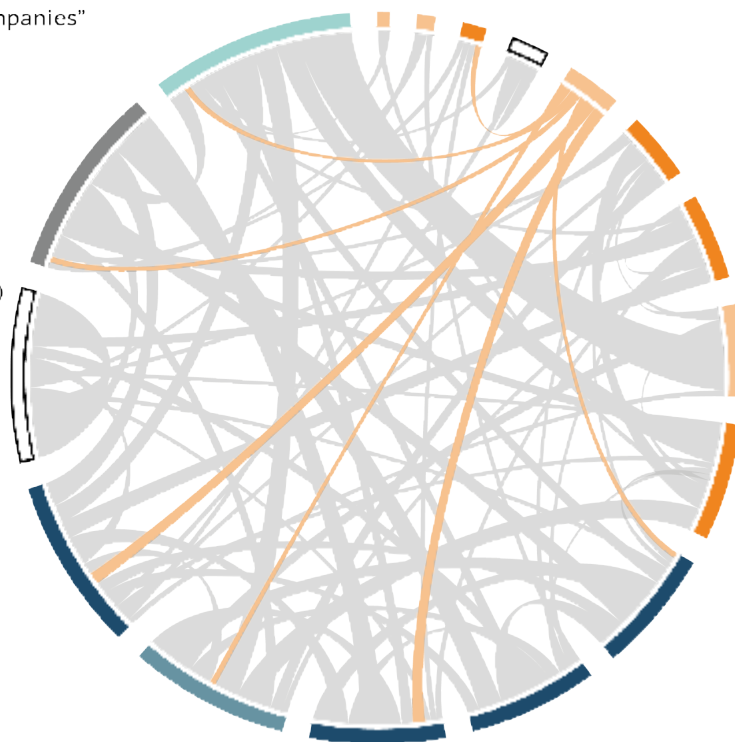


Fig. 22 | MakeToCare Ecosystem: biomedical startups and enterprises collaborations

"Medtech Innovator Patients/Caregivers"
category partnerships

- Medtech Innovator Patients/Caregivers (2)
- Activated Patients/Caregivers (1)
- SSN Research Institutions (1)

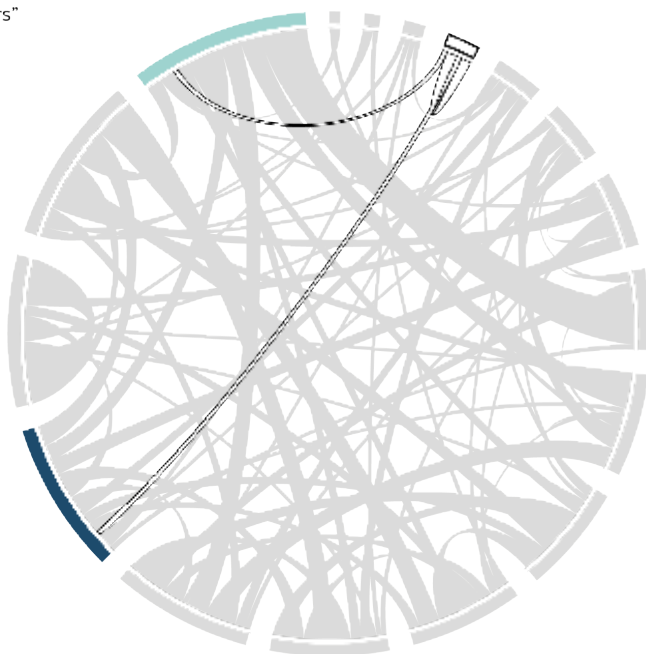


Fig. 23 | MakeToCare Ecosystem: activism of the MakeToCare Area (the white squares show the self-referential relations, the actual weight of the relationship is therefore represented by half the displayed value)

"Medtech Startups, Companies and Associations"
category partnerships

- Medtech start ups and companies/associations (2)
-
-
-
-
-
- Other (3)
- SSN Research Institutions (2)
- Institutions of Care and Assistance (2)
- Innovative Startups and Companies (2)
- Public and Research Institutions (1)
- Universities (1)
- Fab Labs (1)
- Designers (1)
- Training Centres (1)

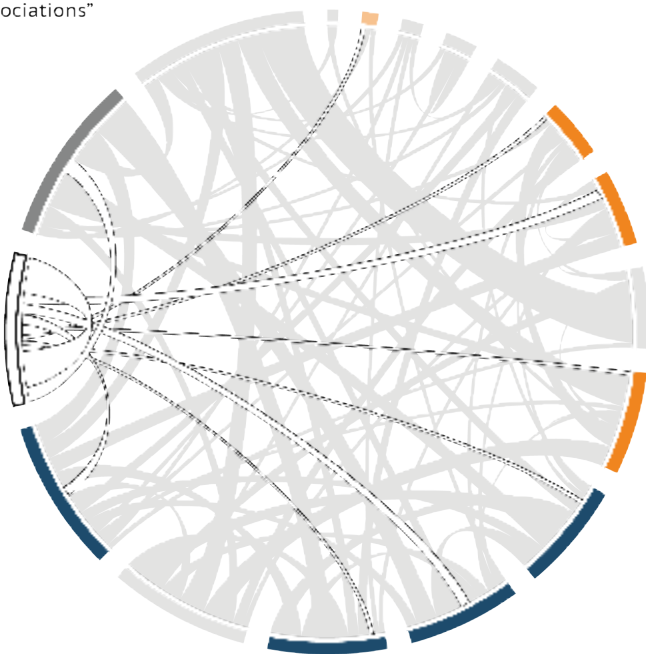


Fig. 24 | MakeToCare Ecosystem: activism of the MakeToCare Area (the white squares show the self-referential relations, the actual weight of the relationship is therefore represented by half the displayed value)

3.5.5 The planning of the MakeToCare Area

The fourth level of analysis focuses specifically on the *MakeToCare Area* projects. First a brief presentation of the 37 solutions positioned in the *MTC Ecosystem* central nucleus that we defined as *100% MakeToCare*, here presented in alphabetical order with a brief description (Tab. 01).

Project name	Summary description
+TUO	Analogue aids and small objects for daily activities created with 3D printer: corkscrews, two-way zippers, spoon holders, kitchen accessories, keychains, supports for the wrist.
AGO E FILO	Cases for insulin pumps created with 3D printer: holder and cover for insulin pumps.
AMIKO	Platform for digital health composed of medical sensors, mobile-app technology, cloud-based and real time data monitoring management system, and analytics.
AQTIVO	Wearable, modular aid that can be reconfigured, for enabling flotation and swimming in safety for persons with disabilities.
BABY CREW	Postural system: modular and functional sitting accompanies the baby in growth and allows him/her to participate in family life.
BASIC COMMUNICATOR	Brain-Computer Interface (BCI) with augmentative and alternative communication (AAC) device controlled by brain waves.
CAMBIO	Multifunctional manual pram with facilitated traction and variable framework, equipped with use sensors, and affordable.
CLICK4ALL	Self-construction computing kit based on interfaces with personalised sensors and able to make technology affordable for everybody.
D-HEART	Pocket electrocardiograph to perform and transmit ECGs in real time via smartphone.
DANDY	Robotic aid for daily activities: robotic arm which enables the person to eat independently.
DU' SPAGHI	Electrical spaghetti winder: mechanical ergonomic fork with a personalised shell created with 3D printer.
E-MOTION	Shock and vibration absorbing backrest for wheelchair to control and soothe involuntary body movements.

EAT-EASY E TAKE-IT-EASY	Analogue aids for grooming: height-adjustable support for the raised plate and wearable orthoses for the hand with diverse grips.
GIOCABILE	Enabling, accessible and inclusive video game with adaptive aids, for play and fun with friends and family.
GRIPPOS	Online platform for the personalisation and 3D printing of tailored adaptive aids in everyday use.
H-MAPS	App with infographic maps (hard copy and digital) that display the therapeutic course and orients cancer patients in their disease.
HUBOTICS	Motorised robotic exoskeleton for the arms, created with open source hardware and 3D printer.
IL TAVOLINO DI ANDREA	Analogue aid for everyday and work activities: table with adjustable and removable supports for smartphone.
INTENDIME	Digital bracelet with sound and light display to sense and issue pre-coded sounds and alerts (alarm, oven timer, telephone).
LA BICICLETTA DI LORENZO	Three-wheeled bicycle with lowered pedal cranks, ergonomic saddle, support for the back and adjustable handlebar.
LA BOTTEGA DEI DOTTI	Therapeutic customisable puppets to encourage eye-hand exploration in children with complex neurological diseases.
LA MIA SCARPA DIY	Personalised shoes that can be adjusted with corrective insoles and guardians.
LA TAVOLA PITAGORICA DI GAIA	Teaching aids: analogue compensatory tool for the study of mathematics in the first years of instruction.
MIRRORABLE	Domestic interactive rehabilitation platform for children in a post-ictal state.
MIV	Portable multifunctional computer/biomedical aids: voice interface, apps with touchscreen aid and optic tracking viewer (notes system, date and time, satellite navigator and home automation solutions).
MOSAIC	Tool-game for accompanying children with autism in primary school.

OPEN RAMPETTE	Integrated system for overcoming architectural barriers: a service, a web-app platform, a bell and mobile small ramp for access to stores in the Isola District of Milan.
ÓPPONENT	Orthoses that support the ankle and block supination and internal rotation of the foot.
REED	Wearable and stabilising guardian that may be built at home for tetraplegic fingers.
ROBOT4CHILDREN	Technology, software and innovative methods applied to S.A.R. (Socially Assistive Robots) automatons for the integration and play of autistic children.
SECONDO NOME: HUNTINGTON	Multidisciplinary initiative of awareness raising and reflection (with design contest and exposure) on Huntington's Chorea, hereditary degenerative disease of the Central Nervous System.
TERZOCCHIO PROJECT	Low-cost artificial vision system with wearable aid composed of board and webcam applied on the glasses and voice synthesis software.
TOOWHEELS	Open source and low-cost sports buggy, self-producible either do-it-yourself or with digital manufacturing technologies.
TUTORI PER PRONTO SOCCORSO	Wearable and personalised orthoses for hand rehabilitation created with 3D printer.
VEYES WEAR	Open source software-hardware platform for transduction equipped with wearable technology (glasses and belt).
WATCH-ME	App and set of devices for paediatric rehabilitation: viewers and aids that help shared attention in children with a delayed emotional, behavioural and social development.
Z/2	Aid for transduction: Braille 3D printer for the tactile reproduction of graphics and images.

Table 01 | MakeToCare Area: the 37 projects

First we investigated the system of specific *coalitions* in this area (see Fig. 25).

An interesting figure is related to the 16 *mini* coalitions (2–3 subjects). Half of the solutions developed by *mini* coalitions (8 out of 16) involve a FabLab or a space dedicated to digital manufacturing in collaboration with a patient or patient association. It is the case for instance of *TooWheels* (project finalist in the *MAKEtoCARE 2016 contest* and developed with the participation of *FabLab Turin*) or again of three projects developed with the participation of the Milan area FabLab *OpenDot* (*The MY shoe DIY*, *Lorenzo's Bicycle*, *The Bottega of Dotti*). Finally, the four projects developed within *+Ability*, the *+Lab* programme, experimental workshop on additive manufacturing of the Politecnico di Milano.

Of the remaining 8 solutions produced by *mini* coalitions, 6 out of 16 represent coalitions structured within platform projects, such as *Hackability* (*The Small table of Andrea*, *Eat-Easy and Take-It-Easy*, *E-motion*, *Du' Spaghi* projects) or *Hackathon Health* (*WATCH-ME*, project started by a research team of the IRCCS Medea then developed thanks to the 2016 edition of *Hackathon Health* held in Milan). In these cases, also, these are coalitions that we defined as *mini*, where however one of the subjects is actually a subject platform (that internally brings together subjects of different typologies). The last two *mini* coalitions (that developed the *H-Maps* and *Hubotics* projects) involve the *innovator patients/caregivers* who we defined as *Medtech*. Finally, a particularly significant figure is that for the coalitions that we defined as *large* (with the involvement of more than 7 subjects) and that concern the development of 7 *MakeToCare* solutions out of 37: of these 5 (*AQTIVO*, *CAMBIO*, *GiocAbile*, *Grippos* and *Mosaic*) are solutions developed within the *CREW* project.

Subsequently the entire system of the coalitions activated within the *MakeToCare Area* was investigated (see Fig. 26). In particular, examining the development potential of the sample of 37 projects belonging to the *MakeToCare Area*, we can observe that the majority of the solutions (30 projects out of 37, approximately 81%) directly activate *Patients*, *Caregiver* and/or *Patient Associations* in the development and experimentation of the final solutions. Of these 30, furthermore, 4 are the results of operating involvement of those who we defined as *Medtech innovator Patients and Caregivers*, i.e., innovator patients who also have scientific, medical and technical-design skills. They represent simultaneously the *patient/caregiver* system, the system of care and scientific research and the system of production of *MTC* solutions. But perhaps the even more significant figure, still related to the 37 *MakeToCare Area* projects, is that for the 11 projects in which there is an innovative start-up or enterprise in the biomedical sector (approximately 30% of the sample), even if with different methods. It is interesting to note especially how 8 projects out of 11 are the result of a process of construction of a new legal entity (biomedical start-up, in fact) that evolved starting from a need identified by a patient or caregiver or association that developed a specific solution.

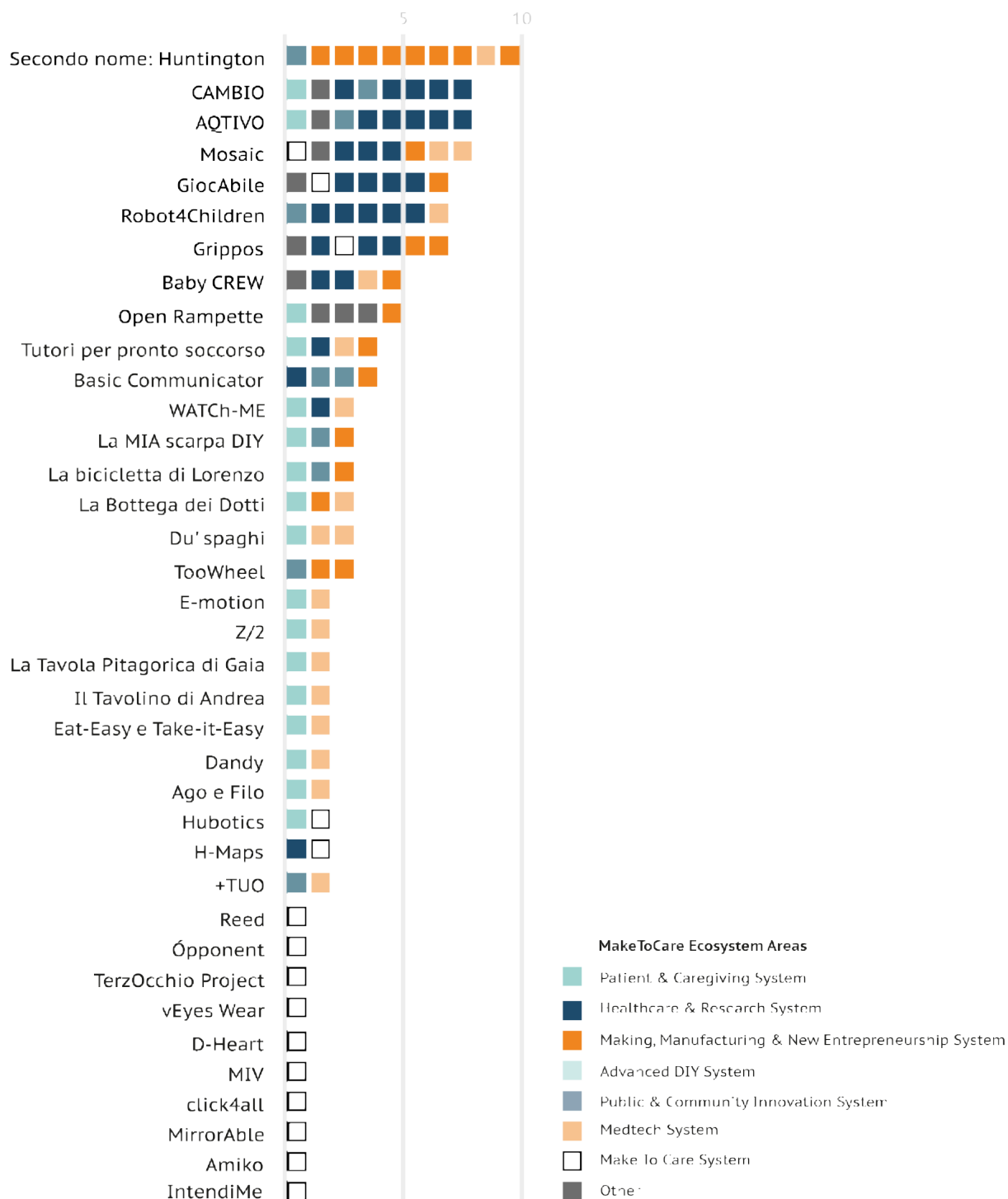


Fig. 25 | MakeToCare Area: structure of the coalitions (base data: 37 projects)

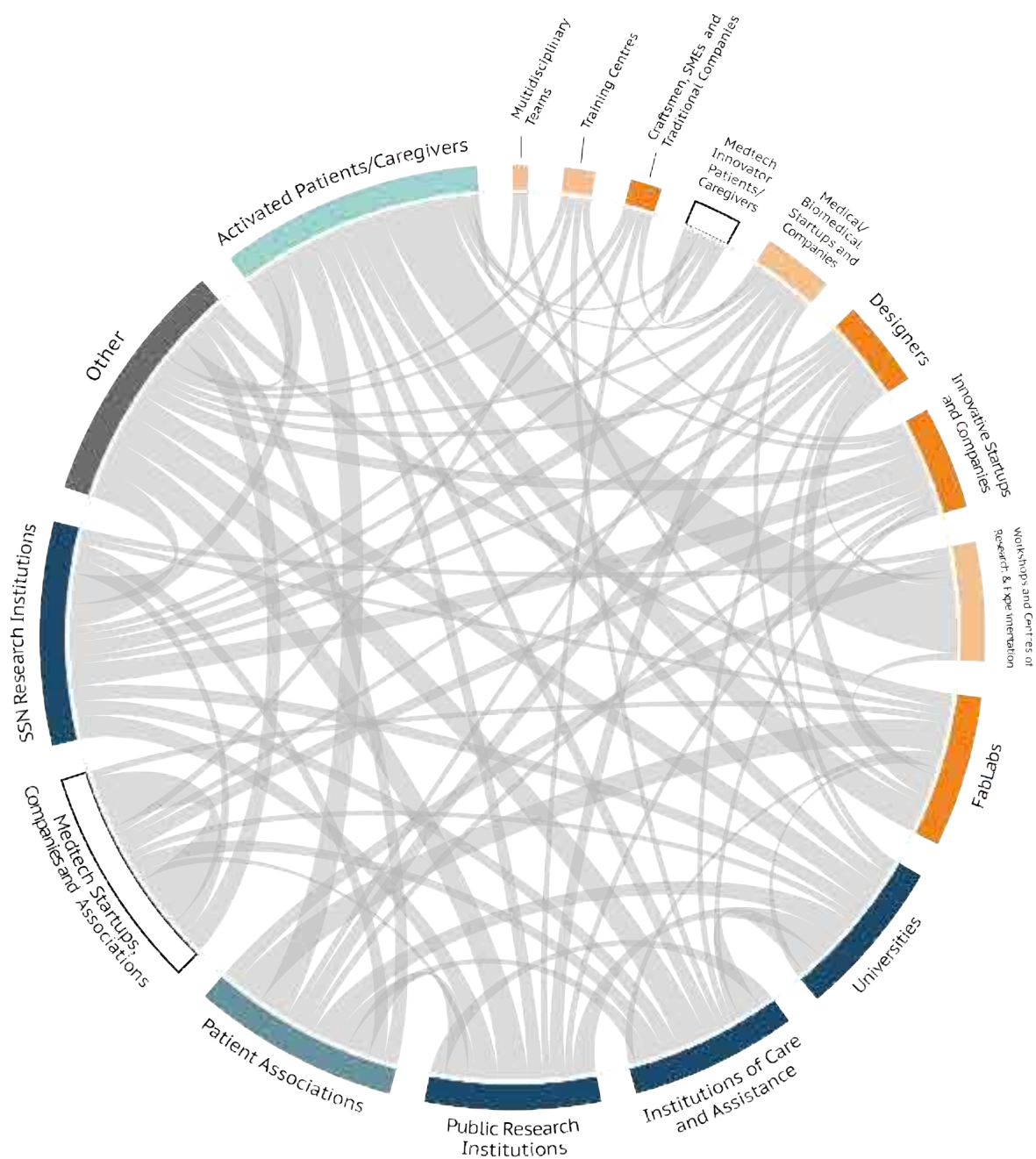


Fig. 26 | MakeToCare Area: the network of coalitions (base data: 37 projects)

Finally, we investigated the geographical areas where the subject protagonists of the design process who developed the 37 projects of the *MTC Area* (Fig. 27) are located. As anticipated, the display confirms the figure already highlighted that sees Milan as the main attractor pole: 21 projects out of 37, in fact, were developed either totally (or partially) by subjects active in the Milan area or surrounding areas. The most interesting system of activators is also located in Milan: a system of subjects who, even though positioning themselves outside of the *Ecosystem* (see *Other* category), support it and supply the production process of *MTC* solutions. This is the case, already anticipated, of subjects such as the Fondazione Cariplo and Municipality of Milan.



Fig. 27, Fig. 28 | MakeToCare Area: the project geography (base data: 37 projects)

The figure for the city of Milan is followed by that for the city of Turin, whose weight is one-third compared to Milan: 7 out of 37 solutions (and compared to the 21 situated in Milan), in fact, were developed by subjects (totally or partially) located in Turin.

Compared to the population of city of Turin projects, it is important to remember the figure related to the solutions (5 out of 37) developed within the *Hackability* initiative. The third and final figure is for the city of Genoa: 3 solutions out of 37 were developed by subjects (totally or partially) located in the main city of Liguria.

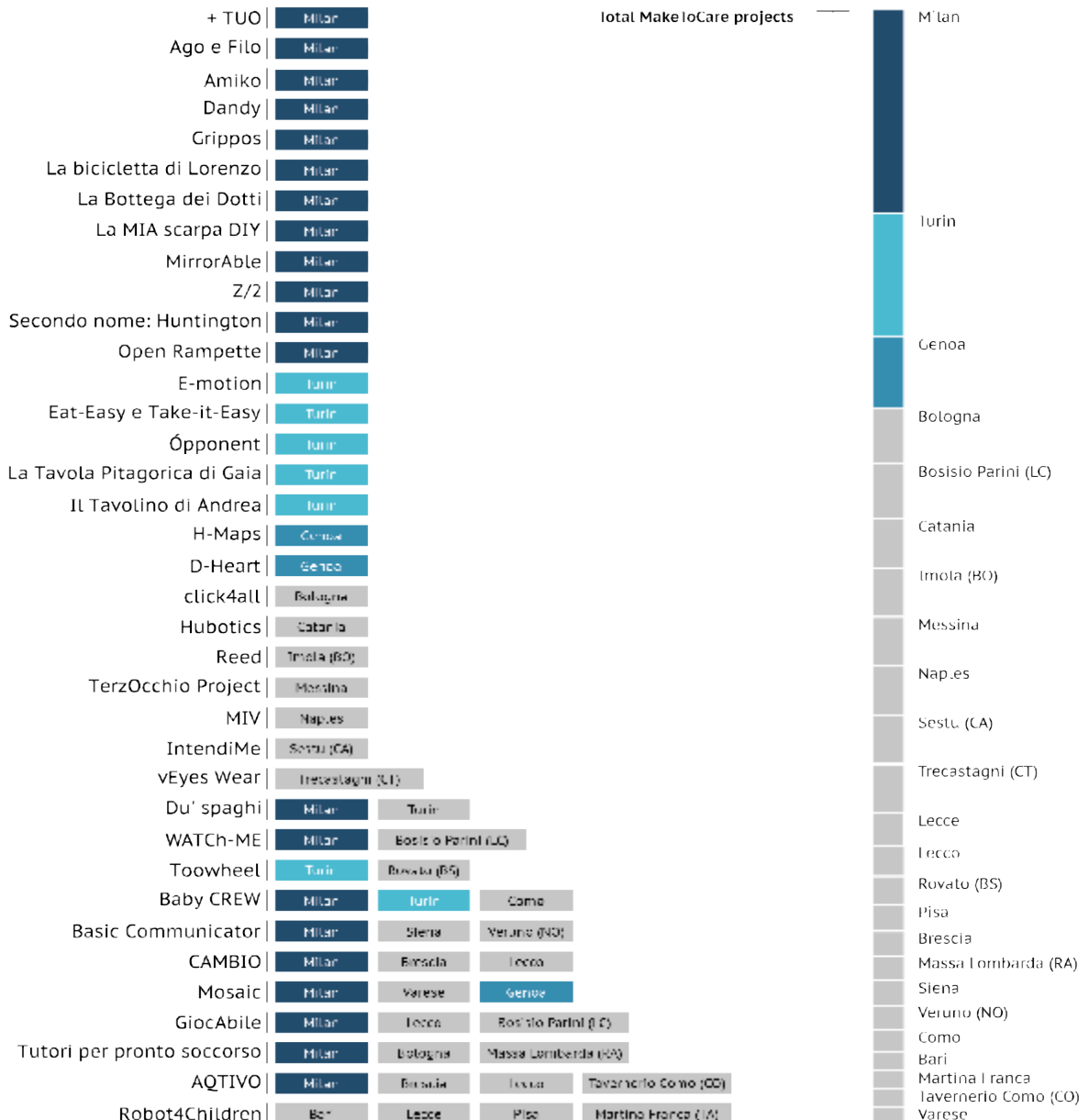


Fig. 28 | MakeToCare Area: the project geography – detail (base data: 37 projects)

3.5.6 The MakeToCare Area projects: a typological reading

An additional level of analysis classified all 120 projects based on the positioning and proximity of the solutions compared to the *areas of the body* (and *outside the body*), thereby allowing a typological reading and interpretation of the project outputs (Fig. 29). Based on this reading it was possible to extrapolate, visualise and analyse in detail the data on the 37 design solutions of the *MakeToCare Area* (Fig. 30).

The construction of the *typological* reading occurred in two phases.

The first step was the classification of the design solutions based on an official national source such as the *New National Health Care Range of Fees* distributed by the Ministry of Health⁷⁸, then integrated with other categories that emerged from the mapping. This work produced the definition of the following list:

- *aid*, intended as a tool, utensil or equipment that allows the handicapped person to perform an action that could not be performed under normal conditions;
- *prostheses*, intended as equipment that replaces missing body parts;
- *orthoses*, intended as equipment that improves the functionality of an impaired body part;
- *devices or medical-health equipment*, intended as objects, tools, products that help prevent and/or treat certain diseases;
- *digital platforms, applications (apps) and environments*, intended as digital tools and online services that enable the collection, systematisation and sharing of data and information on the patient and/or enable the patient in the performance of activities related to the care of the person and the enhancement of autonomy in home and work activities.

The second phase saw the positioning of the design solutions on the human body developing a classification scheme using a *design-driven* reading (Archer, 1995; Cross, 2006) and identify four levels of positioning of the solutions on the human body going from the internal to the external body, up to a gradual moving away to involve the surrounding environment:

1. *inside the body* (level “IN”), solutions that insert into the body or assimilate internal parts of it;
2. *on the body* (level “ON”), solutions that connect and/or are worn and support the body.
3. *with the body* (level “WITH”), solutions with which the body interfaces physically;
4. *outside the body* (level “EXTRA”), external solutions, mostly intangible and digital, and that can be connected to the previous solutions.

In the table below (Tab. 02), the types of products and services mapped are assigned to the corresponding four levels, connected by keyword (tag cloud) relative to design disciplines and areas.

⁷⁸ For the most recent version see the OJ General Series No. 65/ 18-03-2017 (www.gazzettaufficiale.it/eli/gu/2017/03/18/65/so/15/sg/pdf)

Level	Positioning	Solutions	Keywords
1 - IN	INSIDE THE BODY	From body grafts to biotech supplements: surgical tissues and implants, aids and devices, bionic prostheses (e.g.: implantable cardiac device, biocompatible orthopaedic equipment, multi-volumetric pharmaceutical capsules with timed release, etc.).	#Neuroscienze #Bionica #MicroChirurgia #RoboticaSoft #MedicinaDiPrecisione #BiologiaSintetica #Ortopedia #Impiantologia #LifeScience
2 - ON	ON THE BODY	From MedTech postural systems to wearable IoT: analogue, mechanical and robotic (exoskeletons) orthoses, wearable contact aids and smart devices (e.g.: curative arch support, stabilising guardians, clothes with sensors, bracelets and viewers for augmented reality, etc.).	#Robotica #InterazioneUomoMacchina #NewAgency #Ergonomia #Fisioterapia #Riabilitazione
3 - WITH	WITH THE BODY	From biomedical aids to platforms in augmented reality: enabling components and equipment, technologies (e.g. buggies, rehabilitative robotic gyms, aids for independent eating, educational and recreational aids); interfaces, enabling and immersive environments (e.g. augmented reality video games, systems and applications for tracking care, etc.).	#InternetOfThings #PredictiveMedicine #InteractionDesign #ServiceDesign #Infovisualization #BigData #ArtificialIntelligence #TecnologieAssistive #Psicologia #Education
4 - EXTRA	OUTSIDE OF THE BODY	From rehabilitative gyms to treatment automatons: biomedical equipment, enabling technologies, urban equipment, indoor fixtures, services, exhibitions, educational-training methodologies and robot caregivers (e.g.: diagnostic kit, tailored kitchens for the disabled person, ramps for access to public spaces, initiatives of disclosure and awareness raising for rare diseases, etc.).	#Architettura #Urbanistica #ServiceDesign #Codesign #Education #InteractionDesign #CollaborativeNetwork #RoboticaAssistiva

Table 02 | Levels of positioning of the MakeToCare solutions

Level of solutions

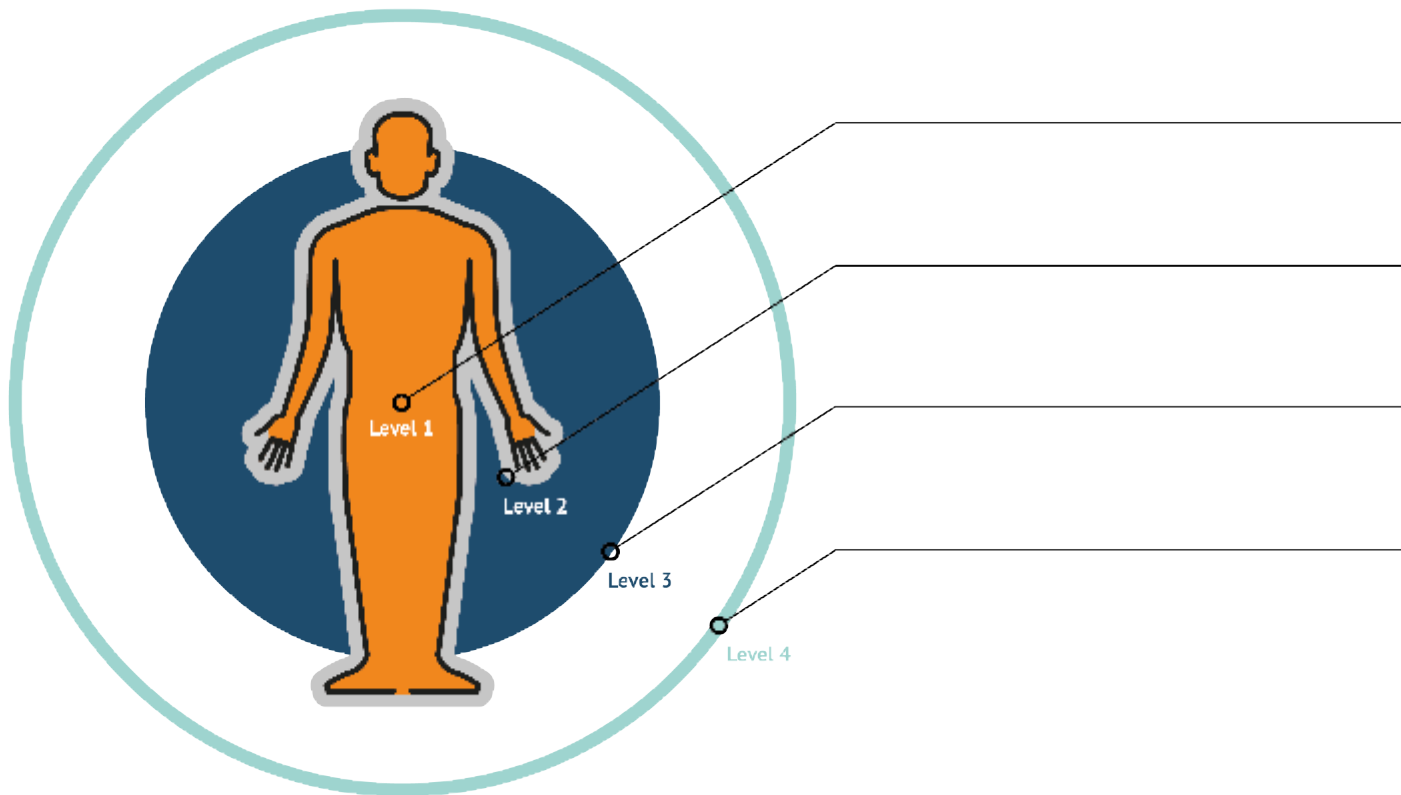
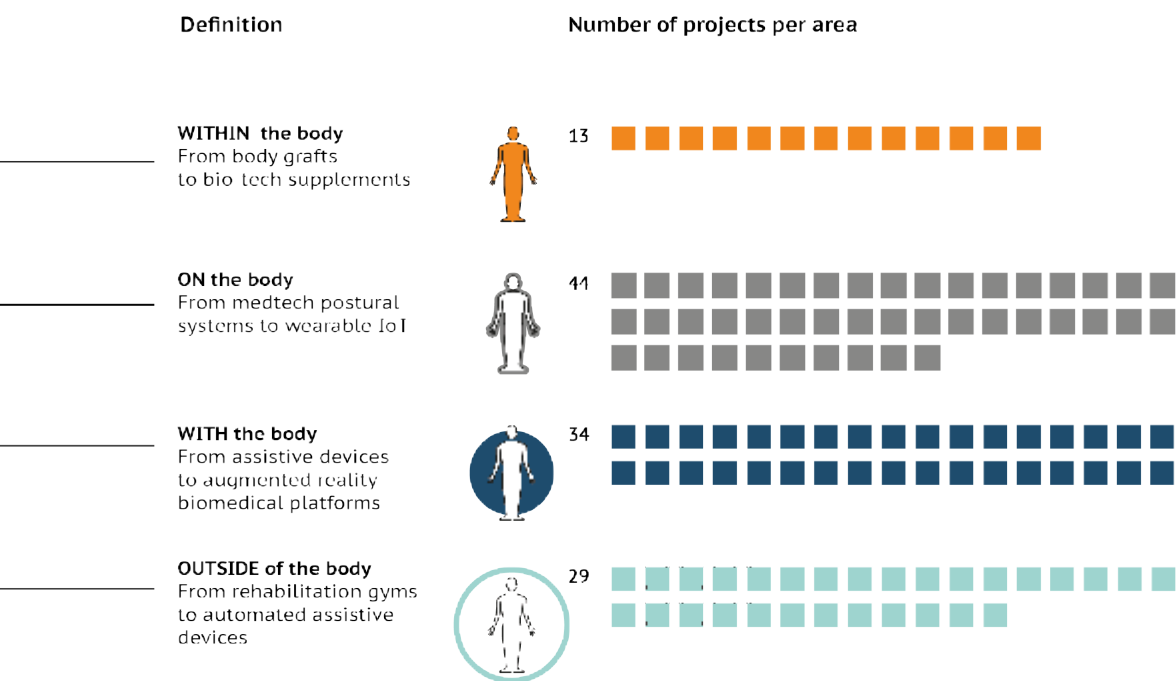


Fig. 29 | MakeToCare Ecosystem: positioning of the solutions (base data: 120 projects)





12

ON the body

From medtech postural systems
to wearable IoT

AQTIVO
Baby CREW
Basic Communicator
Hubotics - Robotics for Human Beings
IntendiMe
La MIA scarpa DIY
Opponent
Reed
TerzOcchio Project
Tutori per pronto soccorso
vEyes Wear
Watch-Me



16

WITH the body

From assistive devices to
augmented reality
biomedical platforms

+IUO
La bicicletta di Lorenzo
La Bottega dei Dotti
CAMBIO
click4all
Dandy
D Heart
Du' spaghi
Eat-Easy e Take-it-Easy
E-motion
GiocAbile
MIV - Modulo di Interfaccia Vocale
La Tavola Pitagorica di Gaia
Il Tavolino di Andrea
TooWheel
Z/2



9

OUTSIDE of the body

From rehabilitation gyms to
automated assistive devices

Ago e Fito
Amiko
Grippos
H-Maps
MirrorAble
Mosaic
Open Rampette
Robot4Children
Secondo nome: Huntington

Fig. 30 | MakeToCare Area: positioning of the projects (base data: 37 projects)

From the overall reading of the 120 projects on the four levels of body placement, those who work *On the body* (44 out of 120, 36.7%) and *With the body* (34 out of 120, 28.3%) emerge as design areas. 29 solutions out of 120 operate *Outside the body* (24.2%) and finally, the most complex area of intervention sees the 13 projects that operate *Inside the body* (10.8%).

If we therefore try to apply also the levels of body positioning to the 37 projects in the *MakeToCare Area*, we see that 16 solutions out of 37 (43.2%) belong to the third level *With the body*, 12 to the second level *On the body* (32.5%) while the remaining 9 projects (24.3%) belong to the fourth level *Outside the body*. Among the cases mapped in this area, therefore, no solutions belonging to first level (*Inside the body*) are detected. Comparing this last figure with the overall figure on the first level, compared to 120 projects (13 solutions present) we see that two of these were developed by subjects operating in the *Healthcare & Research System*, while the other 11 by subjects operating in the *Medtech System*. In the *MakeToCare Area*, the total absence of projects belonging to first level is indicative of how this area of experimentation and innovation requires medical and scientific expertise and very advanced technology, and is therefore today still difficult to approach by subjects who develop *open source* and *bottom-up* innovation.

An interesting area of consideration finally is that regarding the projects that position themselves on the second and third level: these are indeed projects that act in direct contact with the person, inserting inside the space closest to the body and therefore the most personal. The *MakeToCare Area* constitutes 75.7% of the sample (28 out of 37 projects) while the general area is represented by 65% (78 projects out of 120). A therefore similar pattern that potentiates in the *MakeToCare Area*, perhaps because of the type of development potential and resources involved in the processes of prototyping and production of solutions.

The 37 projects of the *MakeToCare Area* were also analysed from the point of view of the need, and disease or deficit to which they respond, and then placed in connection with the levels of body placement and categories of the typological reading. The following table (Tab. 03) summarises this correlation.

Level	Project	Category	Need	Pathology and deficit
2 - ON	Reed	Orthoses	Easy handling to use technology aids and tools	Motor neuron and trauma diseases and deficit
2 - ON	Tutori per pronto soccorso	Orthoses	Physical rehabilitation and postural maintenance	Motor neuron and trauma diseases and deficit
2 - ON	Ópponent	Orthoses	Physical rehabilitation and postural maintenance	Motor neuron and trauma diseases and deficit
2 - ON	Baby CREW	Aid	Physical rehabilitation and postural maintenance	Motor neuron and trauma diseases and deficit

2 - ON	Hubotics	Orthoses (exoskeleton)	Physical rehabilitation and postural maintenance	Neurological, cognitive and relational diseases and deficits
2 - ON	La MIA scarpa DIY	Orthoses (accessory for)	Personalisation of orthoses	Sensory diseases and deficit
2 - ON	IntendiMe	Medical healthcare device	Communication, safety and independence of the person; autonomy in mobility	Neurological, cognitive and relational diseases and deficits
2 - ON	WATCH-ME	Digital platform, apps and environment (with aids)	Cognitive, sensory and emotional development (triangulation of attention)	Miscellaneous diseases and deficits
2 - ON	AQTIVO	Aid	Physical rehabilitation and postural maintenance	Sensory diseases and deficit
2 - ON	TerzOcchio Project	Digital	Orientation and autonomy in mobility; communication and interaction (transduction)	Sensory diseases and deficit
2 - ON	vEyes Wear	platform, apps and environment (with aids)	Orientation and autonomy in mobility; communication and interaction (transduction)	Motor neuron and trauma diseases and deficit
2 - ON	Basic Communicator	Digital platform, apps and environment (with aids)	Communication and interaction mediated with device (transduction)	Chronic disorders (heart disease, rheumatosis, respiratory failure, diabetes)
3 - WITH	D-Heart	Digital platform, apps and environment (with aids)	Monitoring and prevention; communication	Motor neuron and trauma diseases and deficit

3 - WITH	TooWheels	Medical healthcare device	Mobility	Motor neuron and trauma diseases and deficit
3 - WITH	CAMBIO	Aid	Mobility	Rare or inherited oncology diseases
3 - WITH	E-motion	Aid	Grooming and postural maintenance (alleviating involuntary body movements)	Neurological, cognitive and relational diseases and deficits
3 - WITH	La bicicletta di Lorenzo	Aids (component)	Mobility	Motor neuron and trauma diseases and deficit
3 - WITH	Du' Spaghi	Aid	Grooming (autonomy in eating)	Chronic disorders (heart disease, rheumatosis, respiratory failure, diabetes)
3 - WITH	+TUO	Aid	Grooming (autonomy in daily movements)	Motor neuron and trauma diseases and deficit
3 - WITH	MIV	Aid	Communication and interaction (transduction)	Miscellaneous diseases and deficits
3 - WITH	GiocAbile	Digital platform, apps and environment (with aids)	Placing & inclusion in school	Sensory diseases and deficit
3 - WITH	Z/2	Digital platform, apps and environment (video game with aids)	Placing & inclusion in school and communication (transduction)	Sensory diseases and deficit
3 - WITH	La Tavola Pitagorica di Gaia	Aid	Placing & inclusion in school	Neurological, cognitive and relational diseases and deficits

3 - WITH	La Bottega dei Dotti	Aid	Cognitive, sensory and emotional development; communication and interaction	Neurological, cognitive and relational diseases and deficits
3 - WITH	Il Tavolino di Andrea	Aid	Autonomy in daily activities and in work	Motor neuron and trauma diseases and deficit
3 - WITH	Eat-Easy e Take-it-Easy	Aid	Grooming (autonomy in writing and eating)	Motor neuron and trauma diseases and deficit
3 - WITH	Dandy	Aid	Grooming (autonomy in eating)	Motor neuron and trauma diseases and deficit
3 - WITH	click4all	Aid	Accessibility to technology and autonomy in daily activities and in work	Motor neuron and trauma diseases and deficit
4 - EXTRA	Secondo nome: Huntington	Platform, apps and environment (contest and exhibition)	Raising of public awareness	Rare and hereditary oncology diseases
4 - EXTRA	MirrorAble	Digital platform, apps and environment	Neurological and neuromotor rehabilitation; monitoring	Motor neuron and trauma diseases and deficit
4 - EXTRA	Robot4Children: Pleo, Nao e Zeno	Digital platform, apps and environment (with automatons)	Cognitive and relational development; communication and interaction	Neurological, cognitive and relational diseases and deficits
4 - EXTRA	Ago e Filo	Medical healthcare device (accessory)	Personalisation of medical healthcare aids	Chronic disorders (heart disease, rheumatosis, respiratory failure, diabetes)
4 - EXTRA	Mosaic	Digital platform, apps and environment (game)	Placing & inclusion in school	Neurological, cognitive and relational diseases and deficits

4 - EXTRA	Open Rampette	Digital platform, apps and environment (with product-service system)	Overcoming architectural barriers and accessibility to services; raising public awareness	Motor neuron and trauma diseases and deficit
4 - EXTRA	Grippos	Digital platform, apps and environment	Personalisation of aids	Motor neuron and trauma diseases and deficit
4 - EXTRA	H-Maps	Digital platform, apps and environment (with aids)	Communication and interaction (information for therapeutic courses)	Rare and hereditary oncology diseases
4 - EXTRA	Amiko	Digital platform, apps and environment (with aids and medical healthcare devices)	Monitoring and prevention; communication	Chronic disorders (heart disease, rheumatosis, respiratory failure, diabetes)

Table 03 | The typology of the 37 MakeToCare solutions

The most representative solutions category is that of *Aids* with 15 projects out of 37 (40.6%). Next are the *Digital platforms, apps and environments* where 14 projects out of 37 are concentrated (37.8%) and *Orthoses* that represent 13.5% of the solutions in the *MakeToCare Area*. Finally, the *Medical-health equipment* present in 3 units (see Fig. 31). A relevant figure: in the *MakeToCare Area* the *Prostheses* are absent.

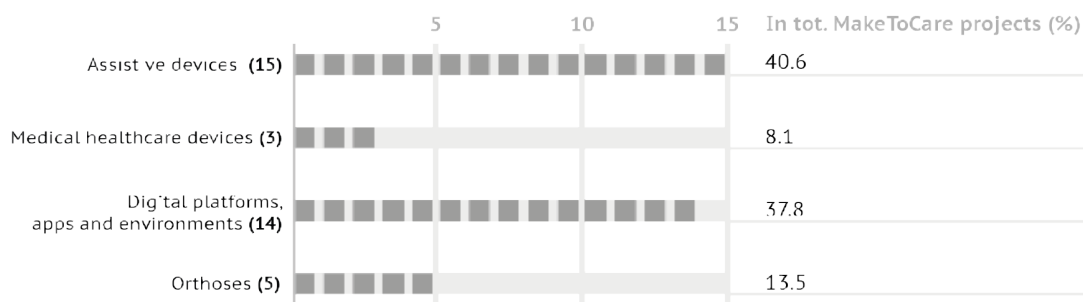


Fig. 31 | The categories of the MakeToCare solutions (base data: 37 projects)

If we analyse the projects from the perspective of answered needs we notice the coverage of a broad and diverse range of requirements, summarised below:

- *solutions related to communication and interaction needs*, 14 projects out of 37 focus on improving the people's ability to express themselves and interact with others and with domestic and work environments;
- *solutions for the rehabilitation of the person*, 10 projects out of 37 help persons in pathways and activities of physical, neurological and neuromotor recovery and postural maintenance and/or activities that boost the development of cognitive, sensory, emotional and relational abilities;
- *solutions that improve the degree of autonomy of the person*, 9 projects out of 37 make the persons more self-sufficient in the performance of daily activities related to work, to study and to free time;
- *solutions that improve the level of mobility and independence of the person*, 7 projects out of 37 help the person to move safely, making spaces or places more accessible;
- *solutions related to care of the person*, 5 projects out of 37 involved with needs related to activities such as eating, cleaning and getting dressed;
- *solutions for monitoring and prevention*, 3 projects out of 37 provide support in the collection and sharing of biometric data on the patient's state of health.
- *personalisation of the solutions*, 3 projects out of 37 enable patients or caregivers in personalising aids, orthoses, prostheses and medical-health devices and equipment.

Considering finally the beneficiaries of the projects, we can then observe that almost half of the *MakeToCare Area* solutions are designed to improve the condition of life and autonomy of persons with degenerative diseases such as ALS or from impairment due to stroke or accidents (16 out of 37, 43.2% of solutions). 7 projects out of 37 (19%) propose as solutions for neurological, cognitive, sensory and relational conditions and deficits. 5 solutions are intended for sensory diseases and deficits (13,5%). Then come 4 (10.8%) intended for chronic diseases (heart disease, rheumatosis, respiratory failure and diabetes) and 3 for oncological, rare or inherited diseases (8.1%). 2 solutions (5.4%) adapt to multiple conditions or are potentially usable by subjects suffering from multiple diseases.

One last interesting figure: 11 solutions out of 37 (30%) are specifically dedicated to children who have neurological disability that is manifested in motor disability.

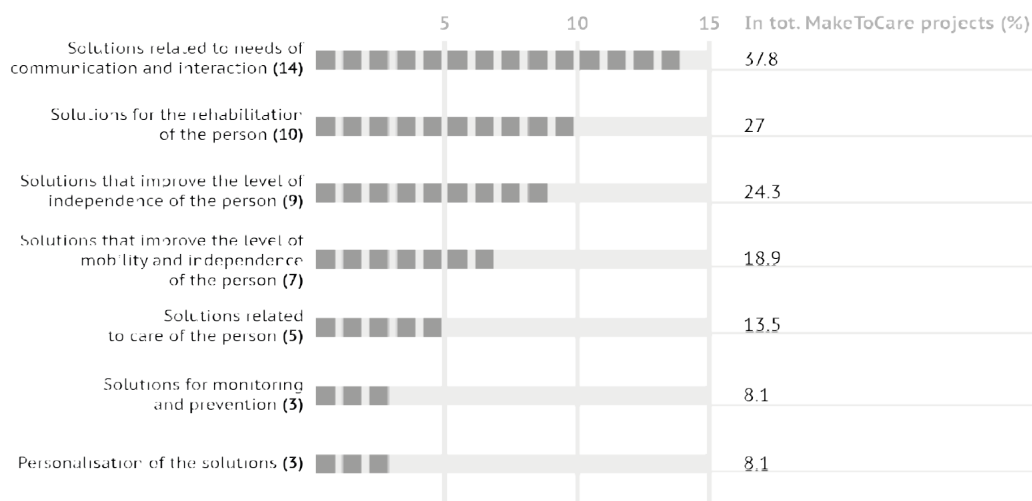


Fig. 32 | The needs to which the MakeToCare solutions respond
(base data: 37 projects; some solutions may belong to multiple categories)

3.5.7 The MakeToCare Area projects: from concept to clinical validation

To each of the 37 projects of the MakeToCare Area was applied a final level of analysis that measures its *degree of maturity*, or the level of development reached and the consequent relation with the market and end users. This aspect was investigated attempting to map the process of invention, design, materialisation of the products-services and their eventual marketing, wherever possible isolating the conditions favourable for the generation of other *MakeToCare* solutions.

Two parameters were used to evaluate the 37 projects:

- *generation of ideas*, with the aim of identifying determining conditions and factors for the launch of product/service ideas and the development of new entrepreneurial realities;
- *evolution of the project*, with the aim of identifying prospects and possibilities of implementation also in terms of the adaptability/replicability/scalability of the project compared to other contexts and needs.

Concerning the generation of ideas, what emerges above all is the connection between the design phase of the solutions and the world of digital manufacturing and *making*.

Seven projects were invented and developed within a FabLab or makerspace or in collaboration with it⁷⁹.

Another four projects were the outcome of primary Degree or Doctorate theses developed in a university research laboratory dedicated to digital manufacturing, the *+Lab* of the Politecnico di Milano. Also devised in the *+Lab* was the *Tutors for First Aid project*, subsequently developed in collaboration with WASP, manufacturer of 3D printers, and the IRCCS Rizzoli of Bologna.

Six other projects were developed as part of *contests* and *hackathons* (five of these began from participation in the *Hackability*) initiative, that stimulates the phases of invention, experimentation and prototyping of solutions involving designers and makers.

One last interesting figure is the connection between the *MakeToCare* solutions and the world of competitive research. Two projects (*Robot4Children* and *Open Rampette*)⁸⁰ are in fact the products of research funded through national calls for tender or European programmes (e.g. Horizon 2020) conducted with coalitions of national and international subjects.

Concerning the evolution of the projects, it is interesting to observe the following itineraries:

- *from design solutions to the formation of an association*, two projects launched an association that aims to promote the solution or implement it in an open and distributed way (*MirrorAble* and *vEyes Wear*);
- *from design solutions to the establishment of an enterprise*, nine projects launched a start-up, often thanks to the participation in a *contest* and subsequent funding or support offered by incubation and/or acceleration programmes (*Hubotics*, *WATCH-ME*, *Robot4Children*, *BrainControl – Basic*

⁷⁹ *La bicicletta di Lorenzo* (FabLab Opendot), *La mia scarpa DIY* (FabLab Opendot), *La Bottega dei Dotti* (FabLab Opendot), *Grippos* (WeMake), *Open Rampette* (WeMake) and *TooWheels* (FabLab Turin).

Secondo nome: Huntington initiative instead saw the active involvement of 8 Milan spaces dedicated to digital manufacturing

⁸⁰ *Robot4Children* stems from an innovative startup that started its journey of research and experimentation with the SARACEN – “Socially Assistive Robots Autistic Children Education” – project funded by the P.O.N. (Programma Operativo Nazionale) “Research & Competitiveness” 2007–2013 call for tender.

Open Rampette instead is a project that grew from the OpenCare European research funded by the Horizon 2020 programme

Communicator, Opponent, D-Heart⁸¹, H-Maps, Amiko, IntendiMe e MIV);

- *from design solutions to the deposition of a patent and/or to marketing*, two solutions are awaiting a patent (*MirrorAble, H-Maps*), one is at the marketing phase (*IntendiMe*) while another two (*Opponent* and *Amiko*) are registered products already on the market;
- *from design solutions to the open source product*, the topic of openness characterises many of the 37 projects of the *MakeToCare Area*, but only two are distinguished by being invented or created for distribution to the public with open source methods (*Grippos* and *TooWheels*⁸²).

The concentration of projects in the implementation and testing stage confirms that the *MakeToCare Area* is an area of strong experimentation. The overall picture shows that 25 of the 37 projects (67.5%) were prototyped while 12 (32.4%) are already on the market or are completing the final phases of clinical or bureaucratic validation.

Another meter of the degree of innovativeness of the *MakeToCare Area* solutions is readily observed by the good number of awards and recognition obtained nationally and internationally (15 projects out of 37 with awards, 46%). Two projects in particular – *D-Heart* and *MirrorAble* – are distinguished for multiple award wins and have obtained important recognitions⁸³, while others are distinguished for winning:

- *awards and competitions related to the healthcare sector* such as *eHealth Solution Award* (*Basic Communicator* winner), the *OPBG Innovation Award in Paediatrics 2017* (*TerzOcchio Project* winner), the *Hackathon Health Milan* (*WATCH-ME* winner) and the *Creative Aids* contest organised by the Ospedale di Montecatone (*Reed* winner);
- *awards and competitions for innovation and entrepreneurship* such as the *National Innovation Award* (*Robot4Children* winner), *Marzotto Award* (*Basic Communicator* winner) and more local initiatives such as *NASStart-up* (*MIV* winner);
- *design awards* such as the *Compasso D'Oro ADI* (Associazione per il Disegno Industriale) won by *TooWheels* in 2017;
- *awards and competitions in social innovation and open innovation*, such as *Think for Social* of Fondazione Vodafone (*click4all* and *vEyes Wear* winners, in addition to *D-Heart*), *Telecom WCAP* [corporate accelerator] (*Hubotics* winner) and the crowdfunding platform *WithYouWeDo* – Fondazione TIM (*H-Maps* winner).

⁸¹ The *D-Heart* project is concluding the process of certification to move to the marketing phase of putting the product on the market. It began collaborations internationally in the experimentation phase, applying and testing its technologies outside the original context

⁸² The *TooWheels* project has been (re)produced also in an Ecuadorian FabLab and a remote collaboration to develop pram models for daily mobility was started in India. The inventor of the same project is then collaborating with the Italian Badminton Federation (recognised by the CIP – Comitato Italiano Paralimpico [Italian Paralympic Committee] – as a Paralympic Sporting Federation), that manages Para-Badminton. For *TooWheels* the development of the most advanced digital and mechanical electronic solutions is anticipated

⁸³ *D-Heart*: winner of the BNP Cardiff Award 2016, winner of the Corman Award 2016, winner of the Think4Social Fondazione Vodafone contest; *MirrorAble*: 2013 – participation in TED Global and TEDMED Ambassador for Live Events, 2014 – Eisenhower Fellowship for Innovation; 2015 – first Italian Ashoka Fellowship, 2015 – participation in the World Business Forum, 2017 – Seif Award for Digital Healthcare supported by Johnson & Johnson, and Digital360Awards with the award by the jury, the award for social impact while is a finalist in the Machine Learning, AI, Augmented and Virtual Reality category

3.6 THE MAKETOCARE PROJECTS: A SELECTION OF CASES

3.6.1 Introduction to cases

Below is proposed a selection of the study cases considered particularly representative of the *MakeToCare Ecosystem*, taking account of the following selection criteria:

- *coverage of the disciplinary areas*, with the objective of providing a simultaneously synthetic and analytical framework of the areas of intervention of the *MakeToCare Ecosystem*, and with a focus on the choice of projects and solutions that constitute the point of convergence between the three *Healthcare & Research System*, *Making, Manufacturing & New Entrepreneurship System* and *Patient & Caregiving System* areas;
- *type of subjects who invented and produced the solutions*, with the objective of returning a portrayal of the variety of subjects involved with a focus on more innovative profiles present in the *MakeToCare Ecosystem*, such as for example innovator patients who developed solutions transforming into entrepreneurial initiatives, or again unpublished coalitions of actors belonging to different systems;
- *type and level of innovation of the solutions*, with the objective of presenting a repertoire of artefacts that range from prostheses to exoskeletons, from orthoses to wearable devices, and offer an overview on innovation, design skills and the technological level contained in them (no-tech, low-tech, hi-tech, robotics, etc.);
- *type of needs of patients resolved through the solutions*, with the objective of understanding the role of mediation of the patients or interest groups in the invention and development of the innovations (from family members to medical and health operators);
- *growth potential of the MakeToCare solutions*, identifying where possible the state of development of the projects and products, checking their level of replicability and scalability at the productive or entrepreneurial level (for example, a multidisciplinary team that produces a biomedical start-up or a prototype implemented and experimented in another context apart from that in which it was initially devised).

Each case study selected was summarised in a sheet for assisting with the reading and comparison between experiences. Each sheet lists the following information:

- name of case;
- summary sentences to identify the type of solution;
- positioning of the project in the *MakeToCare Ecosystem* areas;
- subjects or coalitions involved in the development of the solution;
- motivation of the selection;
- concise technical description of the solution;
- publications, awards and recognition obtained;
- website.

Each case is accompanied by a keyword and a picture of reference.

A summary table is shown below (Tab. 04) that lists the cases in alphabetical order and their positioning in the *MakeToCare Ecosystem* areas (Fig. 33).

Case study	Position in the MakeToCare Ecosystem
ABBI (3.6.2)	Healthcare & Research System
ALEX (3.6.3)	Medtech System
D-Heart (3.6.4)	MakeToCare Area
Galeno (3.6.5)	Medtech System
H-Maps (3.6.6)	MakeToCare Area
Hu.GO (3.6.7)	Medtech System
La Bottega dei Dotti (3.6.8)	MakeToCare Area
Look Of Life (3.6.9)	Public & Community Innovation System
MirrorAble (3.6.10)	MakeToCare Area
Open BioMedical Initiative (3.6.11)	Medtech System
Open Rampette (3.6.12)	MakeToCare Area
Ópponent (3.6.13)	MakeToCare Area
Robot4Children (3.6.14)	MakeToCare Area
Secondo nome: Huntington (3.6.15)	MakeToCare Area
SoftHand Pro (3.6.16)	Healthcare & Research System
sensewear (3.6.17)	Medtech System

Table 04 | MakeToCare Ecosystem: 16 study cases

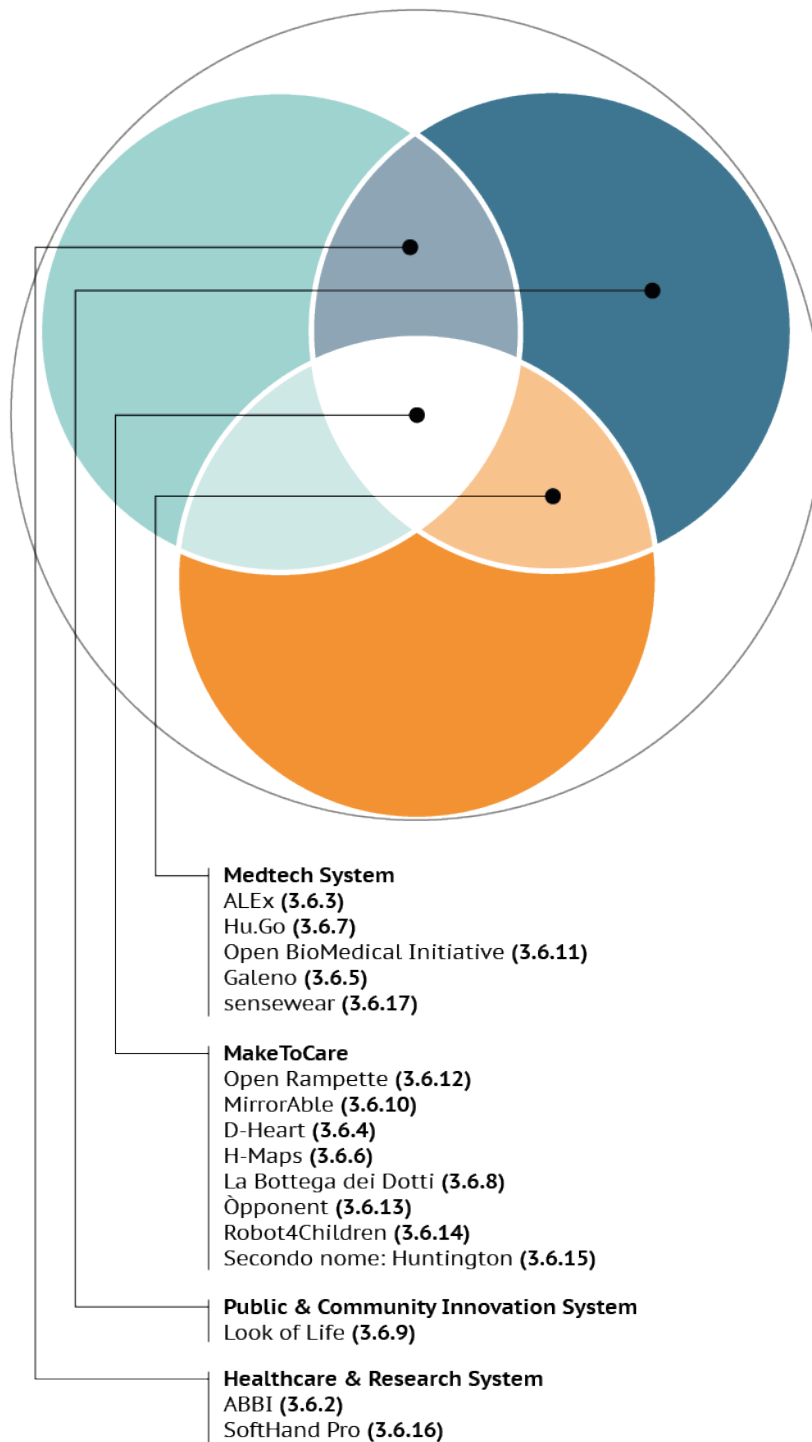


Fig. 33 | MakeToCare Ecosystem: positioning of 16 study cases

3.6.2

ABBI - AUDIO BRACELET FOR BLIND INTERACTION

Wearable bracelet for the sensorimotor rehabilitation of blind children



Healthcare & Research
System

2014: initiation of project

#AudioFeedbackAid
#SensoryMotorRehabilitation
#WearableDevice



photo credit: L. Taverna© 2017 IIT

The device is part of the outputs of the *ABBI* research project carried out by *IIT* and funded by the European Commission within the Seventh Framework Programme [for Research and Technological Development] (FP7-ICT-2013-10). The research had the objective of developing and validating a new set of devices for cognitive-spatial and motor rehabilitation to improve the social interaction of children and adults with visual impairment, through the natural combination of audio-tactile-motor stimuli.

ABBI is a bracelet which helps children to navigate in the space and explore the dimensions of their body, basing themselves on the origin of the emitted sound. The technology works by making use of the plastic and adaptive ability of the brain in pre-school/school age. The wearable device, providing audio-tactile information, can be used to create proper sound networks to be deployed in the environments in which the children live, allowing them through hearing—and not through vision—to create a spatial map in which they can move in full autonomy, enhancing their ability to integrate with the environment, and social interactions. The device is worn while the child plays or in general is performing an activity, switching itself on and off automatically when it is in movement or is still. A defining and innovative element is that *ABBI* does not require learning a new language, but listening to a simple audio signal that allows the child to know how both his/her body and the bodies of others move in the space.

“A new technology for visual impaired children”

IIT Istituto Italiano di Tecnologia (Unit for Visually Impaired People U-VIP)
Istituto David Chiossone per Ciechi ed Ipovedenti Onlus
University of Hamburg
Lund University
University of Glasgow

Cappagli, G., Finocchietti, S., Cocchi, E., Gori, M. (2017) The Impact of Early Visual Deprivation on Spatial Hearing: A Comparison between Totally and Partially Visually Deprived Children. *Frontiers in Psychology*. Vol. 8

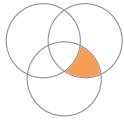
ABBI has begun the first phase of clinical studies to become a marketable medical device

www.abbiproject.eu

3.6.3

ALEX - ARM LIGHT EXOSKELETON

Robotic platform for upper limb neuromotor rehabilitation



Medtech
System

2014: beginning of the start-up

#ClinicalRehabilitation
#EmbodiedMotorLearning
#Rehabilitation4.0



photo credit: www.wearable-robotics.com

The *Wearable Robotics srl* is a spin-off of the *Scuola Superiore Sant'Anna of Pisa*, beginning from the long tradition of scientific research in the field of exoskeletons and wearable robots of the *Scuola Superiore Sant'Anna PERCRO* (Laboratorio di Robotica Percettiva [Perceptual Robotics Laboratory] *Laboratory*). The start-up produces and markets wearable robotic exoskeletons, usable both in an industrial setting to support the manual handling of materials, and in the medical setting for walking or rehabilitation of subjects with disabilities, or elderly subjects.

KineteK, medical division of *Wearable Robotics*, develops and markets robotic solutions for the physical and functional rehabilitation of movement. The solutions, invented in collaboration with international clinical centres, departments of physical medicine and rehabilitation and subjected to rigorous clinical assessment, allow a personalised and task-oriented rehabilitation using contextualised rehabilitation programmes and exercises in virtual environments and highly motivating and involving immersive interfaces.

ALEX is an exoskeleton with 5 degrees of freedom (4 active and 1 passive) that is intended for post-ictal state and post-operative subjects, particularly indicated in the physical rehabilitation of diseases of the upper limbs due to neurological or musculoskeletal disorders and orthopaedic dysfunction.

ALEX provides guided assistance in the performance of complex movements in the upper limbs and can be adjusted automatically or manually according to the patient's needs.

A highly innovative feature of the device is the technique of implementation and transmission that uses electrical motors in combination with elastic elements, allowing a high reduction in energy consumption, considerable simplification of the control of the device and finally, a reduction of the clutter and weights of the moving parts and therefore a lighter device.

“Designed around human arm capabilities”

KineteK, divisione della Wearable Robotics Srl

Center For Neuroprosthetics Cno, Epfl, Unità Neuroriabilitativa dell'Ospedale Universitario di Pisa

Casa di Cura Villa Serena

Casa di Cura del Policlinico

Pirondini E., Coscia M., Marcheschi S., Roas G., Salsedo F., Frisoli A., Bergamasco M. and Micera S. (2016)

Evaluation of the effects of the Arm Light Exoskeleton on movement execution and muscle activities: A pilot study on healthy subjects. *Journal of NeuroEngineering and Rehabilitation*. Vol. 13 (9).

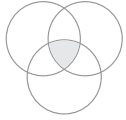
2017 Gaetano Marzotto Award for Innovation

www.wearable-robotics.com/kinetek

3.6.4

D-HEART

Pocket electrocardiograph to carry out and transmit ECG in real time via smartphone



Area
Make to Care

2015: beginning of the start-up

#CardiovascularScreening
#CVmedicine
#MobileHealthTechnology



The project began from the intuition of Niccolò Maurizi, a patient affected by myocardial infarction at the age of sixteen, who decided to make a medical career specialising in cardiology, and involving a fellow student in the development of the *D-Heart* device and in the creation of the start-up of the same name.

D-Heart enables anyone to use a reliable and intuitive medical instrument that enables quick and early diagnosis at low cost. The device converts every smartphone into a portable electrocardiograph using electrodes that, thanks to retractable wires, make it similar to a medical yo-yo. *D-Heart* is manageable by the same patient even remotely: connecting via Bluetooth to any device which has the relevant app, makes it possible to share the person's ECG directly with his/her doctor or with a remote tele cardiology centre. An effective solution for the daily monitoring of heart disease that can be critical in the case of emergency, communicating promptly—to the operators or caregivers present—the resuscitation manoeuvres needed and alerting the local healthcare staff for the emergency treatment. A use is also hypothesized for the device in the insurance sector for which health policies and awards ad hoc may be offered. The start-up has an active partnership with different international NGOs including AMREF and InterSos, with whom it tests its technology in particular projects such as those of healthcare support to young mothers in Kenya or monitoring migrants in Lampedusa and Greece. It is a partner since 2016 in the Pavia-Ziguinchor (Senegal) cooperation.

— **“Anyone, anywhere, anytime,
in any condition can perform
the perfect ECG”** —

D-Heart Srl

2015 Think for Social of Vodafone Foundation Italy, selected project finalist

2016 Polihub, progetto accelerato

2016 ComoNext, BioInItaly Investment Forum di Intesa San Paolo

2016 Programma BNP Cardiff Open Innovation

2016 Adoption Program / Cosmofarma StartUp Village (Corman Award)

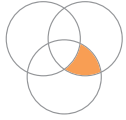
D-Heart is concluding the clinical studies phase to become a marketable medical device.

www.d-heartcare.com

3.6.5

GALENO

3D printer for controlled release multi-volumetric pharmaceutical capsules for the personalisation and temporisation of care



Medtech
System

2016: creation of the FabLab and initiation of the project

#3DopenMedicine
#BiologicalFabrication
#HomemadeCapsule



photo credit: BIOlogic

BIOlogic is a centre of research and experimentation that uses biological fabrication technologies to develop both new paradigms of fabrication with bio matrix, and to implement new making processes in the manufacturing sector, to support the needs of companies and offering—on the FabLab model—consulting and training services to professionals and bodies in the sector. *BIOlogic* is the spin-off of *Knowledge for Business* (company specialising in the promotion of innovative processes and technology transfer), managed in collaboration with *Medaarch* (company specialising in technologies of digital fabrication, whose team formed the first Southern Italy FabLab, the Mediterranean FabLab).

Marco Abbro of *BIOlogic*, through the re-engineering of a 3D printer, originated *Galeno*, a device that digitises the process of creating pharmaceutical capsules allowing its sub-division into modules and making the capsules available for multifunctional care and supplements.

The automation of this process and the regulation of all stages of the care (inhibition, activation, protection) opens new scenarios in the management of diseases. The applications in the healthcare landscape are many, from simple multivitamin supplements to anti-cancer treatments already in place at the *UMaCa* hospital (*Unità di Manipolazione di Chemioterapici Antiblastici [Antiblastic Chemotherapies Handling Unit]*). The printer uses original dispensers, designed and created in the same FabLab (therefore easily replaced) that pre-set the quantity of medicinal product, making the creation process of the medicinal product versatile and controllable. The capsule is designed by establishing the wall thickness of each individual module in order to protect or make immediately available an active ingredient or a supplement. The filament used as excipient is a thermoformable and biocompatible polymer created in collaboration with the CNR Institute for Composite Polymers and Bio-materials.

“From the first BIO FabLab in Southern Italy, the printer for home-made medicinal products”

BIOlogic

Dream FabLab di Città della Scienza

IIT Istituto Italiano di Tecnologia

CNR - Istituto per i Polimeri Compositi e Biomateriali [Institute for Composite Polymers and Biomaterials]

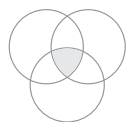
2016 *BIOlogic*, start-up of the “Cradle” incubation programme promoted by Campania In.Hub

www.facebook.com/biologicfablab

3.6.6

H-MAPS

App with infographic maps (hard copy and digital) to view the therapeutic course and orient cancer patients in the disease

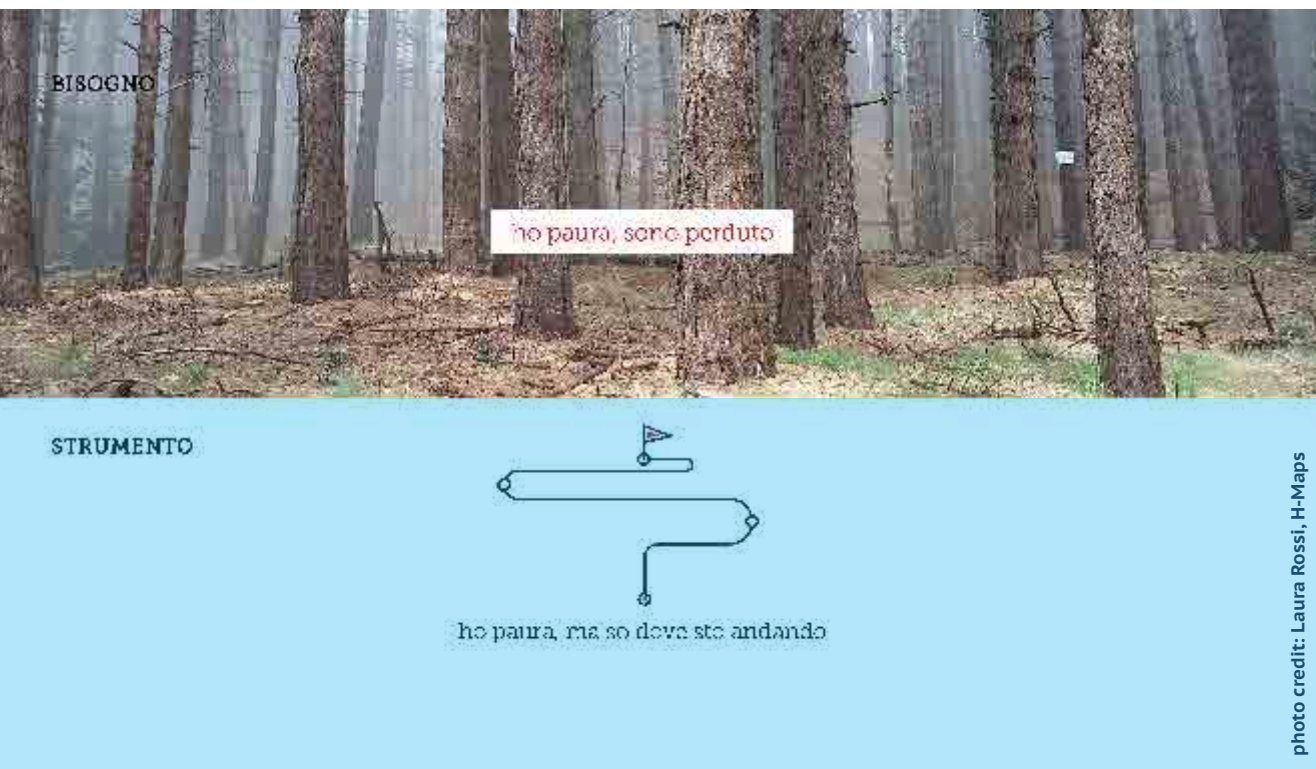


Area
Make to Care

2016: initiation of project and beginning of the start-up

2017: pilot study with patients

#HodgkinLymphoma
#InfographicMaps
#TherapyFeedback



The project began from the field experience of a student of radiology techniques who, following the diagnosis of *Hodgkin's lymphoma*, designed a solution to manage the bureaucratic and psychological course of the disease. *H-Maps* is proposed therefore as a tool of support and guidance for patients and their families, to inform them and try to answer some of the most common questions accompanying the periods of care.

Each course is composed of different stages (procedures, visits, treatments and diagnostic tests), each accompanied by a brief explanation with practical and logistical information, to allow the patient to participate consciously in their own care process without getting lost in the terminology and spatial labyrinths of the hospital environment.

The architecture of the map, however, is designed to be able to render both the therapeutic course expressed in stages, and the main information regarding side effects and the impact of care in physical and psychological terms.

The map is designed to be used in both hard copy and digital media: the heart of the project in fact is in developing an application that allows the patient to follow their own treatment journey, be informed and leave feedback on the effects of therapies and related physical, social and psychological relapses.

The replicability potential of the project—patent pending—lies in the possibility of being applied also to therapeutic courses for other diseases, not only in the oncology or acute contexts, but also for chronic or paediatric diseases, extending the number and type of patients supported. *H-Maps* is a bottom-up project that was supported by crowdfunding.

In its pilot version, it is directed at patients treated at the *Haematology Clinic of the IRCCS A.O.U. [Azienda Ospedaliera Universitaria] San Martino* (San Martino University Hospital) *IST* (Istituto Nazionale per la Ricerca sul Cancro [National Institute for Cancer Research]) of *Genoa for Hodgkin's Lymphoma* (first-line treatment), *Non-Hodgkin's Lymphoma and myeloproliferative diseases*.

— “So we don't get lost” —

Laura Rossi

in collaboration with the Haematology Clinic of the IRCCS A.O.U. San Martino IST of Genoa and ARCI [association for social development and support] Liguria

2016, project funded by the Fondazione TIM WithYouWeDo crowdfunding platform

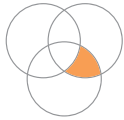
2016, video of winning project of the Sole 24ore Teletopi award (over 10,000 views)

www.h-maps.com

3.6.7

HU.GO - HUMAN GOING

Low-cost robotic exoskeleton for functional recovery of the lower limbs



Medtech
System

2014: initiation of project and first prototyping
2016: beginning of start-up and InLab incubation
2017: tests on focus groups and implementation

#Exoskeleton
#Rehabilitation
#WearableRobotics



U&O™ is a multidisciplinary innovative biomedical start-up in which technical (mechanical, electronic, IT) and application (in this case medical) expertise live together, targeting robotic rehabilitation for persons who have locomotor difficulty caused by different diseases (such as stroke, bone marrow lesions and multiple sclerosis, neurodegenerative diseases or cranial trauma). It proposes a rehabilitative course of the new generation, the technological heart of which is the *Hu.GO* exoskeleton, economically accessible and particularly suitable for use in rehabilitation centres.

Hu.GO has therapeutic objectives and is intended for persons with lower limb disabilities; it allows to stand up and walk and can be used to undertake innovative rehabilitation courses more effective than traditional systems. The device has special software that enables the progressive collection and analysis of the data detected during use. The exoskeleton, battery-powered and equipped with sensors, is particularly indicated to improve autonomy in movement, to support the patient's residual functional capacity (digestive system, respiratory, etc.) and to prevent possible effects due to the condition of immobility (cardiovascular diseases, loss of bone mass, diabetes, etc.). With a much lower cost than that of the current competitors, *U&O™* offers equal macro-functionality proposing a device that is easy to wear, fast to adapt to the morphologic characteristics of the patient, not very invasive and easily configurable thanks to the touch screen on board display, pre-configured with different operational modes depending on the level of familiarity of the patient. Since June 2016 *U&O™* has started a collaboration with the *Startup Piacenza* office, *Urban Hub* and *Area S3 ASTER* (Piacenza location at the *Technopole*), the realities that follow the local startups, part of the *InLab*, Piacenza incubator with a social vocation.

U&O™ is establishing a collaboration with the University of Parma and with other realities operating in the sector with a dual focus: to initiate a pathway of experimentation for validating, finalising and evolving the product based on the clinical data and feedback collected.

— “To walk again” —

U&O srl

2016, Winner of *Premio Provincia* and second place at regional level in the *Start Cup Emilia Romagna*

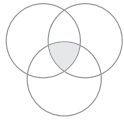
2017, BioInItaly Investment Forum & Intesa Sanpaolo [sic: San Paolo] StartUp Initiative: among the 8 best Healthcare & Medical Devices startups

<http://uando.it/>

3.6.8

LA BOTTEGA DEI DOTTI (THE BOTTEGA OF DOTTI)

Therapeutic puppets to encourage eye-hand exploration in children with complex neurological diseases



Area
Make to Care

2016: initiation of project, currently in the development phase

#CNCsewer
#CognitiveBehaviourTherapy
#DigitalFabrication

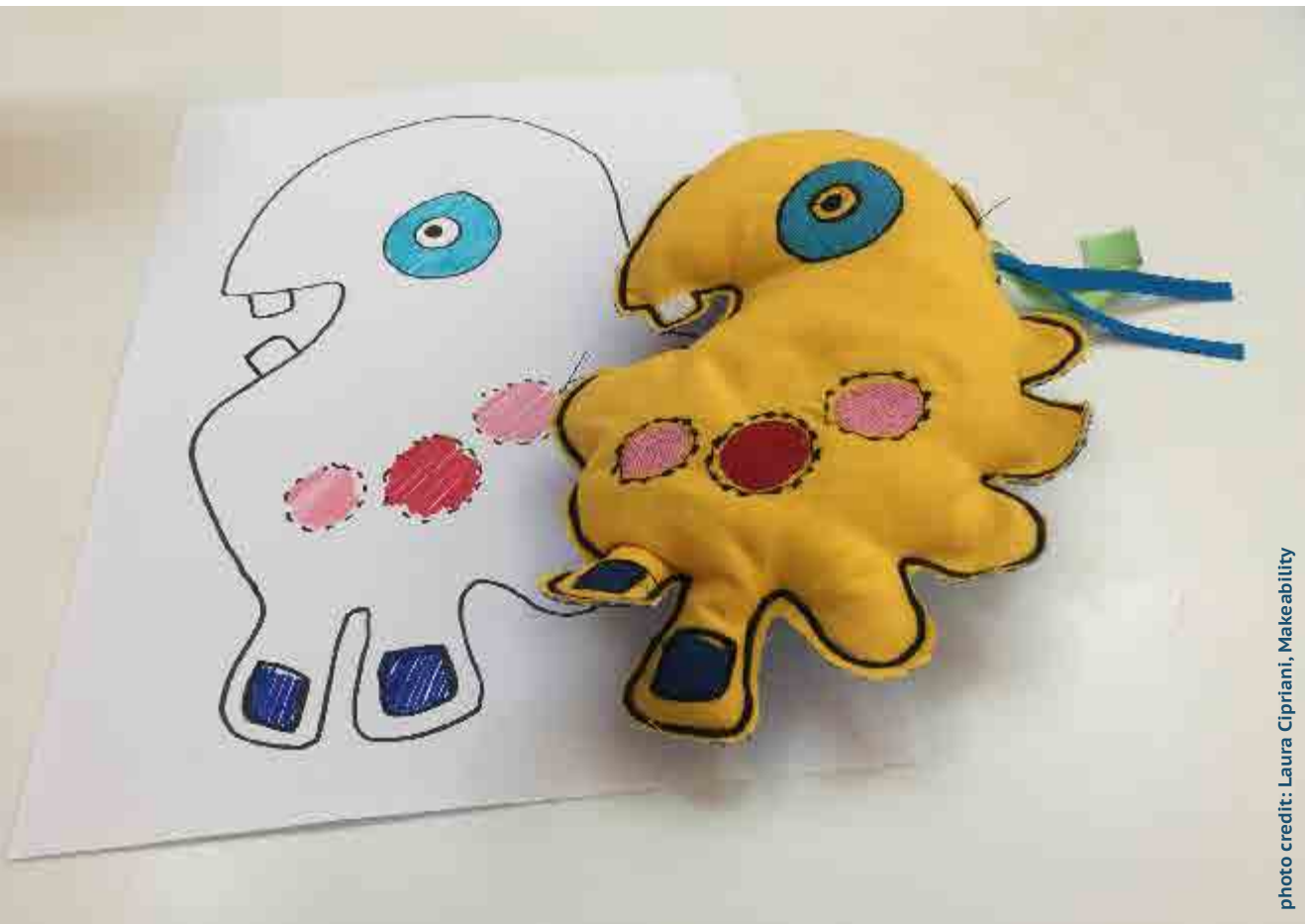


photo credit: Laura Cipriani, Makeability

Makeability is a multidisciplinary team composed of designers and therapists who work in close synergy with the *Opendot FabLab*. The group brings together a mix of cross-sectional skills (designers, educators, psychiatrists and makers) and began in the context of a work group of the *MI-Generation Lab* initiative, promoted by the Municipality of Milan, that had among its objectives the support of creation of innovative startups with a social vocation.

Dotti, the good puppet who comes to you represents the evolution of a previous product developed as part of the *UNICO – The Other Design* project of *OpenDot* with *Fondazione TOG*. It is a *Puppet DIY*, puppets made with a computer-controlled embroiderer from designs of children to develop a completely personalised game, entirely created and fabricated in the FabLab together with families and therapists to stimulate the eye-hand exploration of children with complex neurological diseases.

The *Dotti* puppets thus become therapeutic mediators usable in different contexts: courses of emotional education, *CBT (Cognitive-Behaviour Therapy)* programmes, psychotherapeutic courses intended for children with *PTSD (Post-Traumatic Stress Disorder)*.

The technology used accurately expresses the child's design, transforming the entire process into a tool-experience very effective in the psychotherapeutic context, where design and play are widely used to communicate and connect with children.

The production process involves the vectorisation of the design through open source software (*Inkscape*) that is then re-processed to generate the machine file to program the CNC embroiderer: the file is made so that the machine stops as required, letting the fabric on the frame that will form the back of the puppet be closed prior to carrying out the external stitching.

— “The good puppet
who comes to you” —

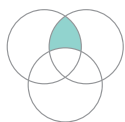
Makeability
in collaboration with Opendot

www.makeability.it

3.6.9

LOOK OF LIFE

Immersive reality at home to reduce the negative impact of the social-sensorial isolation of cancer patients



Public & Community
Innovation System

2016: initiation of project, currently in the implementation phase

#PalliativeCare@Home
#PsychometricSurveys
#VirtualReality



photo credit: Margherita Cecchini

The process of production and experimentation of the project—promoted by *ANT* Associazione Nazionale Tumori, the largest Italian non-profit reality for free specialist and home care with patients with cancer—was assigned a team of psychologists that evaluated the efficacy and impact of VR (*Virtual Reality*) technology in patients' homes, testing with the assisted persons a series of 360° VR videos (whose content were selected among those on the Internet or created ad hoc and personalised based on the wishes expressed by the patients during dedicated focus groups), then analysed through appropriate validated psychometric questionnaires and semi-structured interviews.

The project had the scope of monitoring the clinical outcome and use at home of an innovative technology such as the *Gear* VR viewers, that allow the use of 360° immersive video, proposing experiences that range from music to the arts, from nature to spirituality. The first data obtained from the scientific study provide encouraging results on the use of this technology in the context of home palliative care. Among the parameters of most clinical relevance there are those associated with pain, physical tension and states of anxiety. An increased sense of perceived wellbeing was observed in patients and it is assumed that this mode of interaction could significantly attenuate the worsening of symptoms in the long term. The creation of a universal and inclusive platform is planned to extend the benefits of the VR content to caregivers and other types of patients with equally incapacitating chronic diseases.

— "The therapy of wonder" —

Fondazione ANT Onlus Italy
Associazione Culturale Menomale
HIT - Human Inspired Technology Research Centre dell'Università degli Studi di Padova
Deye VR (partner multimediale)

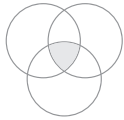
The project is supported by Fondazione Vodafone and Fondazione Cattolica with the collaboration of Samsung 2017 Innovation Award at the Smau of Bologna

www.lookoflife.it

3.6.10

MIRRORABLE

Interactive rehabilitation platform at home for children in a post-ictal state



Area
Make to Care

2011: Mario, patient in a post-ictal state, is born

2013: participation in the TED Talk Global

2014: registration of the association

#MachineLearning
#MirrorNeuron
#OpenMedicine



photo credit: FightTheStroke®

MirrorAble is a project developed from the experience of the founders of *FightTheStroke*®, parents of Mario, child with perinatal stroke. It represents a unique model of home rehabilitation therapy, specifically researched to answer the needs of children who have suffered central nervous system damage in a very early stage of life, with impacts at motor level (e.g. perinatal/paediatric stroke, childhood cerebral palsy, acquired traumatic injuries).

The platform increases the level of efficacy of the healing process as it is usable in a comfortable development environment (their home, their own games, the relationship in the presence of loved ones, and remotely with peers) and is intended for families who want to have an active role in the rehabilitation project of their child. It does not exclude the role of the healthcare operator, in fact it enhances it, providing him/her with a tool for the collection of data useful to measure the patient's status and establish gradually more demanding goals.

The scientific principle on which *MirrorAble* is based is the ability to stimulate the plasticity of the motor system activating the mechanism of the mirror neurons; the process is activated just by looking at video-stories and exercising with other children with similar needs.

MirrorAble for the first time enables a data collection process and unique record of several case histories, becoming a tool able to process statistical evidence useful for studying the different brain lesions and develop new rehabilitation strategies. The availability of these data in the cloud allows their wide diffusion, reducing the costs of distribution and time needed for transfer as well as the crowding of the rehabilitation facilities active in the territory.

FightTheStroke® actively participates in international conversations on themes of scientific and social innovation, is part of the Board of Directors of the *International Alliance for Pediatric Stroke*, and is a supporter of the concept of open medicine; the Association was also the *TEDMED* [independent health and medicine edition of the TED (Technology, Entertainment, Design) conference] *Ambassador* for the Live Event in 2013 and promoter of the first *Hackathon in Medicine* in Italy.

The story of little Mario and *MirrorAble* is told in the book *Lotta e sorrisi* published by Sperling & Kupfer in 2015.

— "Learning while observing" —

FightTheStroke®, Association for Social Development and Support

2014 Eisenhower Fellowship for Innovation

2015 first Italian Ashoka Fellowship

2015 participation in World Business Forum

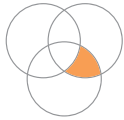
2017 Seif Award for Digital Healthcare supported by Johnson & Johnson and Digital360Awards with the award by the jury, the award for social impact while is a finalist in the Machine Learning, AI, Augmented and Virtual Reality category.

<https://fightthestroke.org>

3.6.11

OPEN BIOMEDICAL INITIATIVE

Global non-profit initiative for the generation and diffusion of accessible biomedical solutions created in *digital fabrication* in a collaborative and *open source* way



Medtech
System

2014: Open BioMedical Initiative is a registered trademark

#CollaborativeDesign
#LowCost
#OpenSource&3DPrintableTechnologies

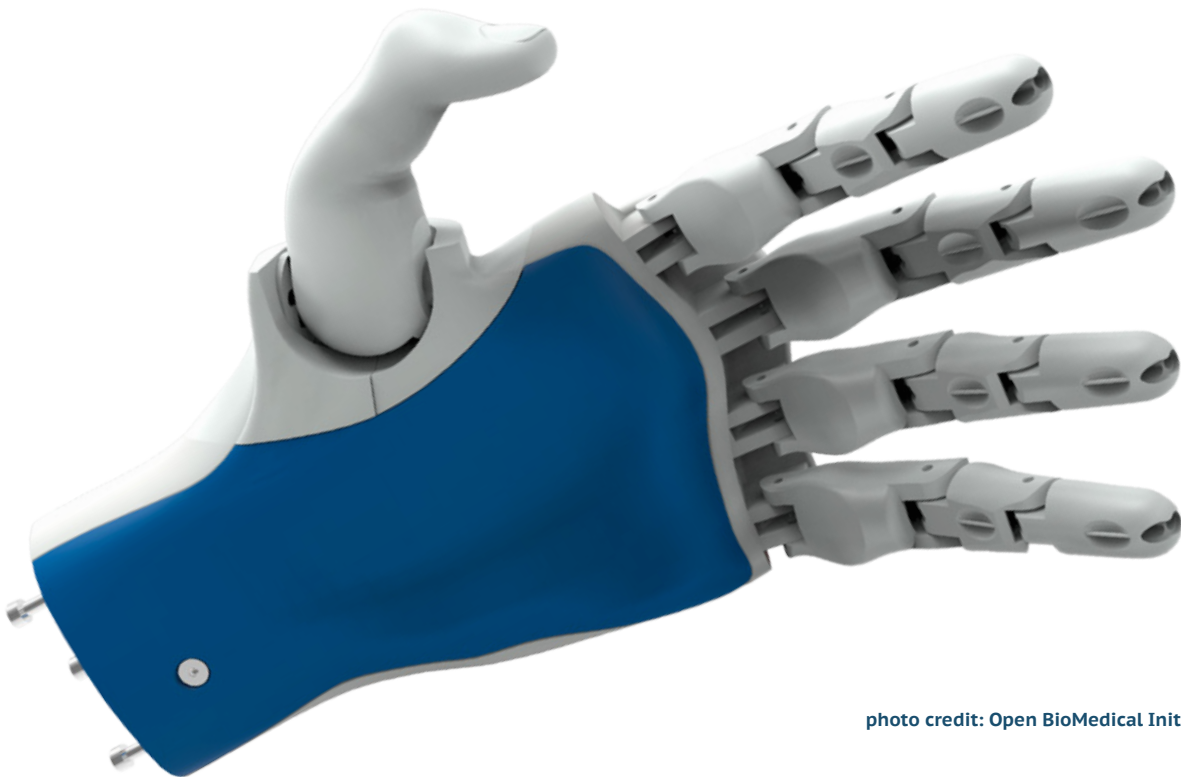


photo credit: Open BioMedical Initiative

Open BioMedical Initiative is a non-profit initiative created by a team of managers and engineers to operate in the biomedical sector with a specialisation in the design, development and distribution of *low-cost, open source* biomedical prostheses and equipment that can be made through a 3D printer. An international design network composed of volunteers specialised in different fields developing *open source* projects of biomedical devices and applications with the aim of making them easily accessible in accordance with an open and distributed manufacturing model.

The NPO Association offers itself as an authority for all the partners involved and has as its goal the distribution of the technology for the creation of the products.

Open BioMedical Initiative operates without physical facilities of reference, targeting the development of projects characterised by open and distributed design and manufacture. A multidisciplinary team composed of designers, engineers, modelling and software experts collaborating in the development of product solutions with strong focus on 3D printing that facilitates their reproducibility. It currently counts four *open source* projects in the development phase: *TINA*, a mechanical prosthesis that can be operated through movement of the wrist and a system of rods; *FABLE*, an electromechanical prosthesis that can be operated through the myoelectric impulses generated by the contraction of the arm muscles; *RAM* a mechanical foot obtained with the 3D printer and *BOB* a low cost neonatal incubator.

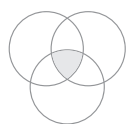
"The development and distribution of Health and Accessibility Supports"

Open BioMedical Initiative

2017 Semi-finalist in the European Social Innovation Competition

www.openbiomedical.org

Pilot initiative for improvement of accessibility to commercial outlets



Area
Make to Care

2016: initiation of project

#CoDesign
#OpenCare
#PolicyMaking



photo credit: www.rampette.opencare.cc

The project began as part of *OpenCare*, a European project funded within the Horizon 2020 programme, which sees the involvement of different partners (Universities, research centres, institutes, *makers*) with the goal of co-designing and creating with open methods final solutions able to meet the care needs expressed by the community. In particular, *Open Rampette* has been set up to solve the problem of users who require the use of ramps to access commercial outlets. The collaborative and participative approach is interesting, able to activate a dialogue within the same design process between different actors often very distant between them (carriers of needs, citizens, *policy makers*, retailers, designers, *makers*).

The project saw an initial phase of testing in the field with collection of data related to the context, interviews with users and meetings between the different stakeholders. It was then developed on two parallel levels: on the one hand supporting the retailers in the dialogue with institutions for completing the documents needed to validate the presence of a ramp (a mini-site prototype allows data to be entered and the procedure monitored until release of the final completed request to be submitted to the municipal offices); on the other hand co-designing and making, thanks to rapid prototyping technologies, all the service elements used in the test and verification phase: from the call signal, that allows users to forward the request for assistance to the stores via smartphone, to the receiver, who informs the requesters with an appropriate signal (light, sound or vibration) of the assistance request, up to the sticker (element of communication) that easily identifies the store accessibility. The idea of developing a product-service system, able to go beyond the size of the artefact (the ramp) and the idea of scalability and replicability of the solution in other contexts and environments, is interesting.

"Co-design the accessibility of urban spaces and services"

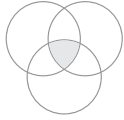
WeMake Makerspace Fab Lab
Municipality of Milan
DUC (Distretto Urbano del Commercio – Isola)
ADA (Associazione di Associazioni – Stecca degli Artigiani)
with carriers of needs

www.rampette.opencare.cc

3.6.13

ÓPPONENT

Orthoses to support the ankle and prevent supination and internal rotation of the foot



Area
Make to Care

2015: beginning of the start-up, currently in the incubation phase

#AnkleFootOrthosis
#FootBiomechanics
#Supination&Pronation



photo credit: Diego Dolcetta, VivacSo srl

The VivacSo srl biomedical start-up (from the Latin Vivax: “durable, vital”) based in the Incubator of Innovative Enterprises of the Politecnico di Torino I3P, stems from a multidisciplinary team that includes a neurologist, always active in scientific research, who, affected by hemiparesis due to a traffic accident, focused his/her interests and studies in the orthopaedic sector.

Ópponent® is the first product that the company launches on the market with the aim to answer complex problems through creation of a product that is performing from both the ergonomic and aesthetic perspectives. The total absence of a specific *Ankle-Foot-Orthosis (AFO)* for this condition in the recent decades of the last century elicited the introduction of new surgical techniques and medical therapies targeted at inhibiting spasticity. *Ópponent*® neutralises it putting effective constraints against supinatory exertion, while supporting the foot.

Ópponent® is an innovative orthosis that address the problem of the foot twisting outward (supination), characteristic of post-stroke hemiparetic patients. This reflex movement in fact hinders and slows the walking of persons with lower limb spasticity. A similar difficulty must be managed by the patient with an unstable ankle due to weakness and atrophy of the calf and foot muscles: in this case the internal rotation is due to body weight and the result may be the recurrent distortion of the ankle. *Ópponent*®, created in fibre composed of carbon, Kevlar and Vectran, is a light and effective product, convenient to slip on even just using one hand. It ensures stability by supporting the falling foot, placing it securely and at the same time providing a useful push forward during the forward phase of the step.

— "A step forward" —

VivacSo srl

Ópponent® is protected by patent and is produced as a Customised Medical Device, pursuant to Directive 93/42/ EC and subsequent amendments, by VivacSo Srl

www.vivacso.com

3.6.14

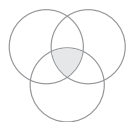
ROBOT4CHILDREN - PLEO, NAO E ZENO

Software solution with innovative method applied to three automaton—two humanoids and a dinosaur—to support autistic children in interaction and play

2007-2013: with the PON SARACEN project

2016: HERO srl initiates the Robot4Children project

2017: implementation and experimentation



Area
Make to Care

#LifeScience
#PatternRecognition
#SociallyAssistiveRobots



photo credit: Giuseppe Palestra

HERO srl is an innovative start-up that develops, manufactures and markets products with high technological value, based on robotics, artificial intelligence (AI) and man-machine interaction with care as the preferred field of application. The start-up in fact has developed internally several robot-software integrated solutions for the support and learning of children with *Autistic Spectrum Disorder (ASD)*. Starting from the specific needs of autistic children and from data provided from the scientific literature in support of *human-robot* interaction for this disorder, an innovative method of treatment application was designed to provide more efficient and better performing technologies to support the progressive improvement in the level of the overall development, verbal and non-verbal skills, social skills and adaptive capabilities of children with ASD. The developed solutions contribute to both the fine-tuning and application of new therapies (including in the home environment) and to the progress of research on debilitating diseases, offering an adaptable, customisable, inexpensive and efficient response.

Robot4Children is therefore a software-robot integrated solution that anticipates the implementation of artificial intelligence and computer vision algorithms inside the top three *Socially Assistive Robots* recognised internationally: *Aldebaran Nao*, the humanoid robot completely programmable in movements and behaviour (with cameras and sensors) designed to make the patient carry out enabling exercises; *Zeno*, humanoid robot able to reproduce and detect facial expressions (feelings of stupor, happiness, sadness) to stimulate the child in expressing its needs and in recognising the moods of others; *Pleo*, robot pet dinosaur (with tactile sensors throughout the body) for entertaining and learning, particularly suitable for very small and/or non-verbal children, that does not require a direct control by a supervisor and is therefore usable in settings outside of the hospital. The automatons speak and understand what is being said to them interacting with children as actual companions of play. They were tested in two autism research and therapy centres and further tests are ongoing for the fine-tuning of the experimental protocols.

— "Children friendly robots" —

Giuseppe Palestra of HERO Srl, Department of Informatics of the Università degli Studi di Bari, Istituto di Tecnologie della Comunicazione, dell'Informazione e della Percezione (TeCIP) of the Scuola Superiore Sant'Anna of Pisa, INO-CNR (Istituto Nazionale di Ottica) IFC-CNR (Istituto di Fisiologia Clinica), Centre of Services for Autism – Association "Friends of Nico" NPO of Lecce, Department of Psychology of the Università del Salento, AbaMI-Milan Centre of Learning, Institut des Systèmes Intelligents et de Robotique (ISIR); Université Pierre et Marie Curie, Sorbonne Universités – Paris, StreamVision – Paris (technology partner), Accompagn'moi – Paris

2016 winner of the Life Science category and overall winner of the Puglia StartCup competition

2016 Special Mention for Equal Opportunity of the National Award for Innovation in Modena

2015 Selected among the first 15 finalists of the Scintille Award of the National Council of Engineers

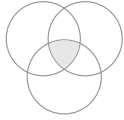
www.robot4children.com

<http://saracenrobot.it/#progetto>

3.6.15

SECONDO NOME: HUNTINGTON

Initiatives of awareness-raising and multidisciplinary reflection on Huntington, hereditary degenerative disease of the central nervous system



Area
Make to Care

2016: contest launch and call for designers
2017: display of the results

#CoDesign
#Design for All
#Fablab&Makerspace



photo credit: Secondo nome: Huntington

Secondo nome: Huntington represents the closing exhibition event of a broad awareness-raising initiative that, actively involving a cross-sectional community of subjects (patients, caregivers, researchers, designers and *makers*) developed an unpublished reflection on a hereditary disease that every year in Italy affects approximately 150,000 persons. Like many diseases, the impact of the disease goes far beyond the single patient, becoming an integral part of the life of all persons who are closest to the affected patient. The initiative started therefore with the intent of structuring a reflection that looks at the disease from different perspectives, even those not closely associated with the world of patients, to provide an image removed from stereotypes and bias. The idea is that the disease concerns not only those affected by it, but can be part of a social reflection and raising of consciousness extended to a much larger community. *Huntington's* is a disease that progressively impacts and changes daily habits, progressively affecting and deteriorating the cognitive abilities and autonomy of the patient, and thereby also involving family members and caregivers.

The exhibition event organised in collaboration with the *Triennale Design Museum* was the culmination of this interesting and unpublished journey of discussion and sharing, that involved the world of digital design and fabrication, thanks to the active participation of the main Milan area FabLabs and *makerspaces*. Designers and *makers* therefore imagined and created a series of products conceived to help persons with this disease, but actually usable by everyone. Items designed therefore to improve some of the small and large problems that the persons with the disease must manage each day, considering that the condition of disability can sometimes be overcome simply by observing the disease from a different view.

"Design for All, Design for Huntington"

AICH Associazione Italiana Corea di Huntington Milano Onlus
Huntington Onlus - La rete Italiana della Malattia di Huntington
Triennale Design Museum
FabLab Milan, Ideas BIT FACTORY, Makers Hub, Opendot, Polifactory, TheFabLab, WeMake, YATTA!
Damiano Alberti, Lorenza Branzi, Tommaso Brillo, Lorenzo Damiani, Daniele Enoletto and Angelo Passariello, Ghigos, Sirine Graiaa with Elodi Malacarne and Giulia Massacesi, Alessandro Guerriero, Claudio Larcher, Nicoletta Morozzi, Claudia Scarpa, Serpica Naro, Brian Sironi, Sovrappensiero, Tecnificio

www.triennale.org/mostra/secondo-nome-huntington/

3.6.16

SOFTHAND PRO

Prosthetic robotic hand



Healthcare & Research
System

2016: project launch

#AnthropomorphousHand
#Cybathlon
#SoftRobotics



photo credit: Centro di Ricerca E. Piaggio - Università di Pisa

SoftHand Pro is a robotic hand for prosthetic uses developed initially by the *E. Piaggio Centre* and experimented in a first phase of testing in collaboration with the *INAIL Prosthesis Centre* and with the US Mayo Clinic, non-profit organisation involved in clinical practice, training and medical research. Since 2016 it is part of the European *SoftPro* project funded as part of the Horizon 2020 programme, involving 13 European partners between Universities, Research Centres and companies. Among the objectives also to bring the *SoftHand Pro* to a *Technology Readiness Level* equal to 8 (*Actual Technology Completed and Qualified Through Tests and Demonstrations*) by 2020. The purpose of the *SoftPro* project is the study and design of innovative technology solutions in the sector of soft synergy-based robotics: specifically, it provides for the creation of prostheses, exoskeletons and treatment devices for upper limb rehabilitation, improving the efficacy of the devices and making them accessible to the largest number of users.

From a joint research activity with the *IIT Italian Institute of Technology* of Genoa, the *E. Piaggio Centre* developed the *Pisa/IIT SoftHand* robotic hand, in its first version available in open source mode on the website www.naturalmachinemotioninitiative.net.

The development of this hand is based on the most recent studies in neuroscience that investigate how the human brain can manage the complexity in the control phases of the hand.

The behaviour of the appendage, therefore, is not predetermined, but subject to the physical interaction between the same hand and surrounding environment. It is a simple and robust orthosis, effective in grasping objects and performing specific actions. The most recent *Pisa/IIT SoftHand 2* developed from this model, and represents an evolution intended to extend its functionality and increase its handling ability. The fact that different solutions intended for different applicative areas were developed subsequently from a single initial project, is interesting. From the *Pisa/IIT SoftHand* also began in fact the *qbhand*, model of robotic hand for applications in the industrial sector, produced and marketed by *qbrobotics*, spin-off company of *IIT* and the *E. Piaggio Research Centre*.

"The hand, more than the brain, has shaped language and culture"

Centro di Ricerca E. Piaggio of the Università di Pisa

IIT Istituto Italiano di Tecnologia

Centro Protesi INAIL

**SoftPro (Synergy-based Open-source Foundations and Technologies for Prosthetics and Rehabilitation)
European project**

2016 Winner Robotic Grasping and Manipulation Competition @ IROS

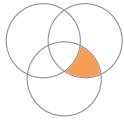
2016 CYBATHLON Finalist 2016 H2020 SoftPro project financing

www.softpro.eu

3.6.17

SENSEWEAR

Line of clothing to communicate the moods of persons with difficulty in sensory integration



Medtech
System

2015: initiation of project

2017: foundation of WITSENSE srl

#Autism&AspergerSyndrome
#SensoryProcessingDisorder
#WearableTechnology



photo credit: Witsense srl

Sensewear stems from the intuition of two parents when analysing the limits of the products currently available for persons with autism. The project objective from the beginning was in fact to develop a collection of therapeutic clothing and accessories with an inclusive design, attractive and wearable by anyone, capable of not stigmatising the persons with this condition. The collection, initially created with materials of high performance but with low technological content, was subsequently implemented thanks to sensors and actuators that extend its functionality, creating interconnections between the various elements, configuring a system adaptable to different needs.

A key element of the system is an undervest that incorporates textile sensors able to collect vital signs, then processed by an application. The signs include heart and breathing rate, indicative of the level of stress of the person wearing it; some articles are activated in fact when a state of anxiety or an attack is detected, others simply communicate this mood, others again activate interactions. The *inflatable jacket* is an example of a product that reacts to a state of anxiety, creating a deep pressure on the body of the person wearing it, producing a soothing sensation and limiting external contact through a pad (in these cases often perceived as unwanted). The inflatable inserts are activated by a micro pump automatically managed by the application when the vital functions are altered. The *chewable necklace* enables the release of a momentary discomfort, in which different textures recall multi-sensory games that educate taste and touch, and a GPS receiver to localise the wearer. Finally, the *musical poncho* stimulates interaction and helps develop the wearer's auditory capability. The fabric is covered in fact by sensors and actuators that emit sounds in response to tactile movements and stimuli, while the two ends equipped with directional microphones allow the surrounding environment to be explored.

In August 2017 *WITSENSE srl* officially began, start-up with the aim of commercialising the collection, enhancing the use of customisable components that can be used for more severe cases of autism (characterised for example by the impossibility to communicate) in addition to transferring the same principles in different areas also. Currently the start-up collaborates with the *Santachiara Lab* of the University of Siena in the context of the European WEARSustain programme.

"Garment and accessories inspired by sensory therapies"

WITSENSE srl

2015 Grand Prix in the Lexus Design Award contest during the Fuorisalone - Milan Design Week

2016 Winner of the Wearable Technology contest during Venice Design Week

<http://sensewear.clothing/wordpress/>

3.7 THE VOICES OF MAKETOCARE: INTERVIEWS WITH THE PROTAGONISTS

3.7.1 Introduction to the interviews

After completing the work of investigation and mapping, we decided to have a brief interview with some of the subjects whose activity was particularly significant in relation to the *MakeToCare* scenario. They represent a significant sample of the different types of subjects highlighted within our *Ecosystem* (Fig. 34).

Beginning from the experience of Fabio Gorrasi, *innovator father-caregiver*, from which the experience of the *MAKEtoCARE* contest started, the main categories of the *MakeToCare Ecosystem* were involved.

- **Area Healthcare & Research System**

Servizio Sanitario Nazionale (SSN) Research Institutes

IRCCS Bambino Gesù Ospedale Pediatrico, Rome

IRCCS Eugenio Medea – The Our Family Association, Bosisio Parini, Lecco

IRCCS Fondazione Don Carlo Gnocchi, Milan

IRCCS Istituto Ortopedico Rizzoli, Bologna

Hospital Institutes

Istituto di Montecatone Ospedale di Riabilitazione, Imola, Bologna

Universities

EPFL École Polytechnique Fédérale de Lausanne, Switzerland

Public Research Institutes

ITIA Istituto di Tecnologie Industriali e Automazione – CNR, Milan

- **Medtech System Area**

Biomedical startups

Neuron Guard, Modena

Witsense, Monza

Workshops, Centres of Research/Experimentation and Platforms

Hackability, Torino

- **Making, Manufacturing & New Entrepreneurship System Area**

Fablabs

WeMake Makerspace FabLab, Milan

- **Public & Community Innovation System Area**

Patient Associations (Foundations)

Fondazione ASPHI Onlus, Bologna

Fondazione TogetherToGo (TOG) NPO, Milan

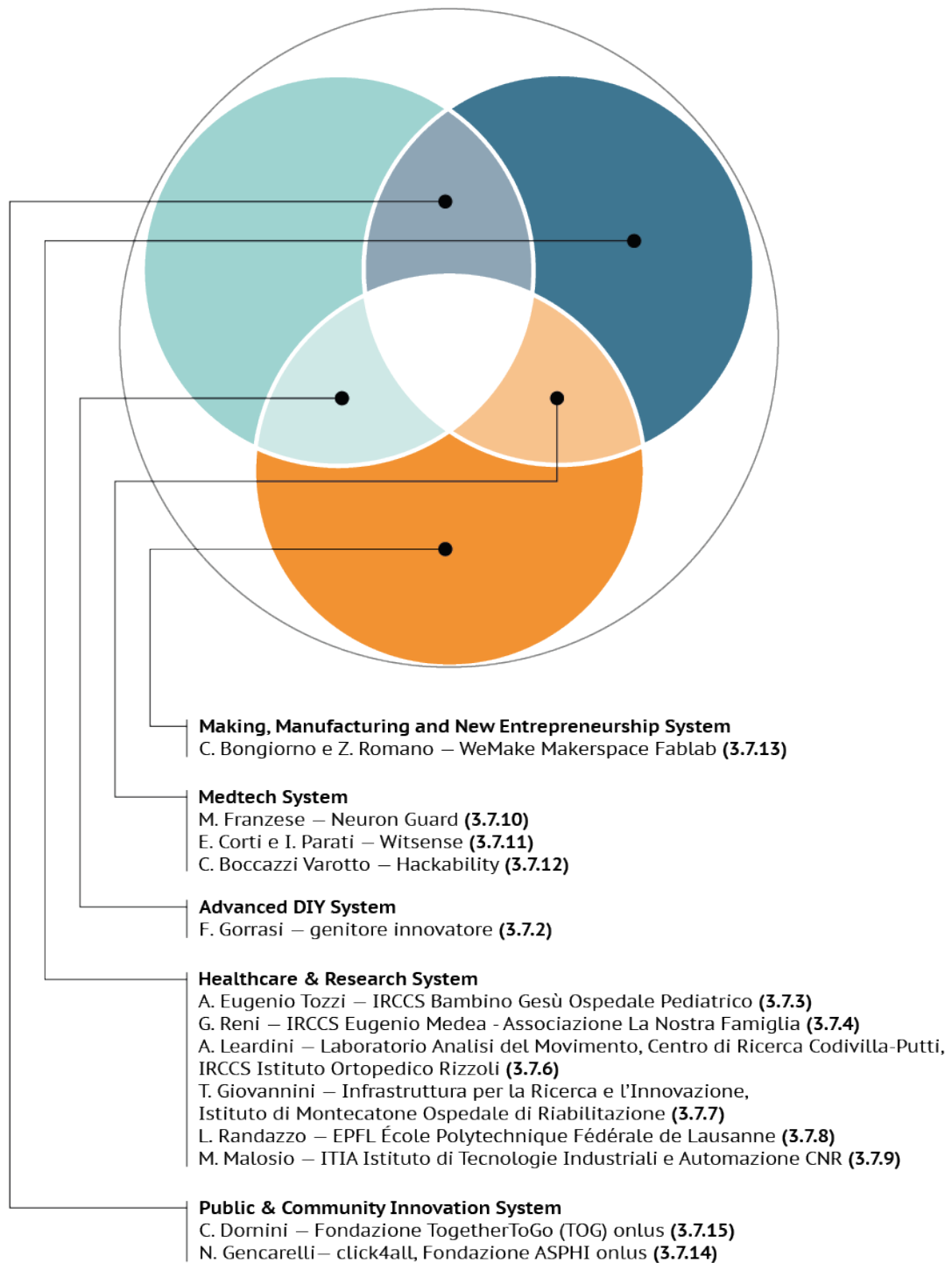


Fig. 34 | MakeToCare Ecosystem: positioning of 14 interviews

3.7.2 Fabio Gorrasi, parent innovator

Do you recognise your activity in the definition of the Make To Care area? If yes, how?

Yes, because my project allowed me to see my daughter happy to be able to make a few steps again, which she was no longer able to do with the other guardian given to us by the ASL. With my solution she has the ability to feel more free in movement, but always supported.

What contribution of innovation do the projects that you developed propose?

What impact do you think they have on care and in the MakeToCare area?

Mine is a coupling for the guardian for which I proposed innovative aspects that concern: greater lightness, because it is children that wear them who, like my daughter, need to stand and at the same time feel more free in some movements; a balance between flexibility and the right fit, or rigidity when it must support the child upright, and flexible when the child is sitting or is taken by the arm by an adult letting him rotate the legs adapting itself to the body of the person who is wearing it; a substantial saving in terms of healthcare expenditure as this guardian may be adapted for a much longer time just by replacing the plastic parts and four poles (paltry cost), without mentioning the endless adjustments that can be made during the growth phase of the patient, something that other guardians don't do.

With regard to your experience, how do you think the care sector and MakeToCare area might evolve in the future (to better accommodate the needs of patients and caregivers)?

For me everything started through listening day-to-day to the needs of my daughter, assessing her and our difficulties when she wore her guardian. I think the fundamental point is precisely that of listening to the patients and to who is near to them and cares for them; they must be listened to carefully because what the patient perceives as priority is often different from the priority of the caregiver, and it is exactly the putting together of the two perspectives that can definitely make the *MakeToCare* area evolve for the best.

3.7.3 Alberto Eugenio Tozzi, IRCCS Bambino Gesù Ospedale Pediatrico, Rome

Do you recognise your activity in the definition of the Make To Care area? If yes, how?

The Bambino Gesù Paediatric Hospital has just built a Unit dedicated to *Innovation* and *Clinical Pathways* of which I am in charge. The *MakeToCare* area is perfectly matched with the programmes of activity of the aforementioned Unit. I would add that the same world of healthcare is sometimes a carrier of needs that deserve to be met. There is no doubt that the meeting of multiple stakeholders with different roles and expertise promotes the recognition of problems and possibly the identification of solutions.

Does your activity involve coalitions or collaborations with other subjects for the development of research and innovation projects in the care sector? If yes, what are the types of subjects (patients, caregivers, associations, institutes of care and research, Universities, centres and laboratories, institutions, enterprises, other) with whom you interact?

Very different professions are represented in the research group that I personally coordinate, from medicine, nursing, legal, communication, and we even have an architect among our researchers. The external coalitions concern the academic world, also for different disciplines, industry, startups, with particular attention to the international scenario. Particularly close to our hearts is the active role of patients and for this we involve them and the Associations representing them directly. In fact we are part of an international network for innovation in Paediatrics.

What specific skills and resources (for example human resources, technology, design, production, etc.) did you implement to develop research and innovation projects in the care sector?

Our Hospital is an IRCCS [sic] and as such it competes for research and innovation resources at the national and international level. As mentioned before, since a short time the innovation activities have been entrusted to a defined group that can count on a large number of clinicians, specialists in their facility. Technologically the most advanced part involves a framework for 3D modelling of diagnostic imaging and an advanced digital strategy for communication on health.

What contribution of innovation do the projects that you developed propose? What impact do you think they can have on care and in the MakeToCare area?

We are trying to find specific solutions for paediatrics. We are involved in a robust activity of international networking so as to cross fertilise the respective experiences. We also embrace solutions that represent a benefit to the patient in terms of quality of care, satisfaction and efficacy and safety of treatments. First of all, we try to express the ideas in solutions usable within our Hospital and then share them more widely.

With regard to your experience, how do you think the care sector and MakeToCare area will evolve in the future?

No medical institution can do without an approach that allows the meeting all the protagonists of health pathways systematically. Whoever is involved with healthcare should acquire methodological expertise on innovation and work increasingly in multidisciplinary groups. There will be an increasing participation in these processes by the patient. This evolution will be unstoppable and somewhat ground-breaking, and will require persons able to take on big challenges and changes so as not to remain behind other international realities.

3.7.4 Gianluigi Reni, Applied Technologies Area (neuroimaging, bioengineering, robotics), IRCCS Eugenio Medea – The Our Family Association, Bosisio Parini, Lecco

Do you recognise your activity in the definition of the Make To Care area? If yes, how?

The Istituto Scientifico Medea - La nostra Famiglia – is very active in scientific and technological research applied to healthcare, particularly in prototyping, development and experimentation of innovative products-services targeting the diagnosis, care and rehabilitation of patients and support of caregivers. In particular, our Institute is distinguished for the research and rehabilitation in the specific area of advanced age.

Does your activity involve coalitions or collaborations with other subjects for the development of research and innovation projects in the care sector? If yes, what are the types of subjects (patients, caregivers, associations, institutes of care and research, Universities, centres and laboratories, institutions, enterprises, other) with whom you interact?

The Medea institute works with Italian and external partners for the development of national and European research projects, among which patient and parent associations (such as A.I.S.I.C.C. Associazione Sindrome di Ondine and U.I.L.D.M. Unione Italiana Lotta alla Distrofia Muscolare) institutes of care and research (see Centro di Medicina Riabilitativa “Villa Beretta”), the device of the Ospedale Valduce]; Ospedale Pediatrico Bambino Gesù, CNR), Universities (including Politecnico di Milano, Drexel University, University of Southern California, Univerlecco, Scuola Superiore Sant’Anna) and enterprises (such as Sixs, AERIS, Didael).

What specific skills and resources (for example human resources, technology, design, production, etc.) did you implement to develop research and innovation projects in the care sector?

Within the Medea institute, alongside clinical professionals (doctors, nurses, physiotherapists, psychologists, etc.) there are biomedical and mechanical engineers and computer experts involved with the design, prototyping, progress, completion and finally testing of innovative technologies for rehabilitation and healthcare.

What contribution of innovation do the projects that you developed propose? What impact do you think they can have on care and in the MakeToCare area?

The institute has developed and develops projects that offer innovative solutions from the technology and methodological standpoint, aiming to improve the diagnosis, rehabilitation and daily care of patients and support caregivers. In particular, the development and validation of advanced devices and analysis methods in the healthcare sector is central, such as 3D printing of orthoses, the development of advanced devices for diagnosis, monitoring, rehabilitation and empowerment of patients even at home.

With regard to your experience, how do you think the care sector and MakeToCare area will evolve in the future?

We believe that the MakeToCare area will become increasingly accessible and usable thanks to the new systems for low cost, hardware prototyping, of virtual prototyping and 3D printing. We expect that the rehabilitation and home care sector will be increasingly widespread in the future, thanks also to

the noteworthy development of *IoT* and smart sensor systems and that, consequently, the *MakeToCare* sector will increasingly focus on solutions for e-medicine, e-monitoring and e-rehabilitation.

**3.7.5 Renzo Andrich, Centre for Innovation and Technological Transfer (CITT),
IRCCS Fondazione Don Carlo Gnocchi, Milan**

Do you recognise your activity in the definition of the Make To Care area? If yes, how?

Yes, in the *Patient & Caregiving System* and *Healthcare & Research System* areas. Our *SIVA (Servizio Informazioni e Valutazione Ausili)* Project is in fact involved in providing personalised guidance, consultancy and assessments to identify appropriate aids for the specific needs of each person with disability; it also performs research and innovation in the assistive technologies field (development of innovative methodologies, technological assessment of new products).

Does your activity involve coalitions or collaborations with other subjects for the development of research and innovation projects in the care sector? If yes, what are the types of subjects (patients, caregivers, associations, institutes of care and research, Universities, centres and laboratories, institutions, enterprises, other) with whom you interact?

The research projects in which we participate are usually conducted through partnerships with associations, other institutions of care and research, Universities, centres and laboratories, institutions, enterprises, at national and international level. The implementation of these projects sees a close collaboration between clinical (doctors, therapists, etc.) and technical (bioengineers) professionals and users (participation of patients in both the phases of definition of the unmet needs and the assessment of prototypes).

What specific skills and resources (for example human resources, technology, design, production, etc.) did you implement to develop research and innovation projects in the care sector?

A particular feature of our organisation (*Fondazione Don Gnocchi*) is that of having within it – next to its activities of care, rehabilitation and support – a Technological Pole specifically dedicated to research and innovation of technologies in this sector. There is therefore close interaction between clinical, technical and social professionals, between research and clinic, between innovation and support.

What contribution of innovation do the projects that you developed propose? What impact do you think they can have on care and in the MakeToCare area?

The *Fondazione Don Gnocchi* has a broad range of operation in this field. Here we are only talking about the *SIVA Project* in the field of assistive technologies for persons with disability. Our projects contribute to the definition of the *user requirements*, to their engineering in design and concept, from tests of the prototypes with real users, to the creation of new methodologies and the evaluation of the *outcome* (measurement of efficacy, efficiency, cost/benefits).

With regard to your experience, how do you think the care sector and MakeToCare area will evolve in the future?

We are witnessing a decisive evolution towards home services in the area of persons with disability. Increasingly persons want to continue to live independently (or with the support of their family) in

their own home, work if of working age, participate fully in society, and in all this technical aids have an increasingly critical role.

3.7.6 Alberto Leardini, Movement Analysis Laboratory, Codivilla-Putti Research Centre, IRCCS Istituto Ortopedico Rizzoli, Bologna

Do you recognise your activity in the definition of the Make To Care area? If yes, how?

Yes, certainly. The *Istituto Ortopedico Rizzoli* has been developing specific surgical solutions for many of its patients for years, both for highly leading edge treatments needed for the many really critical clinical cases, such as those patients with cancer of the musculoskeletal system (coming from all over Italy and also from abroad) and for personalising the currently standard treatments as much as possible, such as joint prosthetic replacement, that still sees a severely limited design of the aspects related to the size and specific conditions of the individual patient. In this context, I must also refer to the ongoing work in our Institute on the development of databases in the context of *big-data* for rare diseases, with the purpose of better understanding the disease and providing here also more personalised treatments.

Does your activity involve coalitions or collaborations with other subjects for the development of research and innovation projects in the care sector? If yes, what are the types of subjects (patients, caregivers, associations, institutes of care and research, Universities, centres and laboratories, institutions, enterprises, other) with whom you interact?

The activity of my Institute in this context naturally calls for coalitions and collaborations with many other subjects: Centres of Research and Laboratories, Universities, public and private Institutions, enterprises, etc. but also scientific societies and patient Associations. For many of these types, the coalitions are with both Italian and international subjects. The history of *Rizzoli* demonstrates in fact the need not just for the international, but also the intersectoral dimension, indispensable today to obtain significant clinical and research results.

What specific skills and resources (for example human resources, technology, design, production, etc.) did you implement to develop research and innovation projects in the care sector?

The *Istituto Ortopedico Rizzoli* has many human and technological resources to develop projects of research and innovation in orthopaedic treatments. For the first, it assembles physicians and surgeons of different specialities, bioengineers, radiologists and technicians of different areas, biologists and technologists, all absolutely necessary for the projects in this field, as already mentioned. The technologies too are many, and represent the leading edge for radiographic, functional and biomechanical measurements and analysis. The clinicians and bioengineers also have available laboratories to test the devices designed in such a way.

What contribution of innovation do the projects that you developed propose? What impact do you think they can have on care and in the MakeToCare area?

Projects that the Institute is developing, particularly in these past 4–5 years, are necessarily mostly leading edge, so as to provide our patients with the best of the knowledge and techniques available at the orthopedic area. It goes from implantable medical devices to external orthoses, to advanced surgery tools and techniques, to pre-operative planning on computer, up to real and proper complete

and personalised designs. The impact in the future of the orthopedic area will be relevant, once the reliability and efficacy of the new solutions have been demonstrated.

With regard to your experience, how do you think the care sector and MakeToCare area will evolve in the future?

My personal prediction is that of major developments in this field in the coming years. Perhaps we won't arrive at revolutionising the organisation of the most conventional and already successful treatments, such as the prosthetic knee and hip, but *custom-made* implants and prostheses will certainly increase a lot. It will also be critical to manage the training of new professionals involved in this process.

3.7.7 Tiziana Giovannini, Infrastructure for Research and Innovation, Istituto di Montecatone Ospedale di Riabilitazione, Imola, Bologna

Do you recognise your activity in the definition of the Make To Care area? If yes, how?

In the broad sense, yes. In recent years two research studies with *MakeToCare* characteristics have been activated in the medical devices sector in collaboration with a team of University of Bologna bioengineers.

Does your activity involve coalitions or collaborations with other subjects for the development of research and innovation projects in the care sector? If yes, what are the types of subjects (patients, caregivers, associations, institutes of care and research, Universities, centres and laboratories, institutions, enterprises, other) with whom you interact?

Yes. For a long time now, there have been coalitions and collaborations with other Care Institutes (particularly Hospitals), Universities, Centres and Laboratories, Institutions (such as Regional and Local Health Authorities, Ministry of Health), enterprises (those manufacturing medical devices), Patient Associations, Scientific Societies and non-profit Foundations.

What specific skills and resources (for example human resources, technology, design, production, etc.) did you implement to develop research and innovation projects in the care sector?

Human resources; planning capabilities; the high number of inpatients/outpatients at the Institute that may be recruited in research studies and that justifies the need to invest in research and innovation. The Institute in fact is the location of the foremost *Spinal Unit* in Italy for the rehabilitation of persons with *spinal cord injury*.

What contribution of innovation do the projects that you developed propose? What impact do you think they can have on care and in the MakeToCare area?

The projects developed so far are for the following areas, especially for spinal lesion and, to a lesser extent, for severe acquired brain injury: early interventions in the acute phase of neurological injury; validation of tools measuring the clinical results (*outcomes*); functional/neurologic recovery; consequences of neurological injury and subsequent clinical complications.

In general, they are studies with a strong clinical impact. The two that can be included in the *MakeToCare* area are aimed at creating objective systems of measurement of the clinical outcomes, a very important aspect both in care practice and research, for which we anticipate continuing their development in the future.

With regard to your experience, how do you think the care sector and MakeToCare area will evolve in the future?

The technology is definitely a great support in clinical practice and the products that generally will be invented in the future will definitely support the better care and management of patients and their needs. Great innovations may concern on the one hand the development of particularly targeted drugs, on the other the creation of new medical devices and aids, especially if with sensors. In general, the sector of telemedicine may see major developments.

3.7.8 Luca Randazzo, EPFL École Polytechnique Fédérale de Lausanne

Do you recognise your activity in the definition of the Make To Care area? If yes, how?

The *Hubotics* project aims to develop a wearable robotic exoskeleton for persons with upper limb motor disability. The system has two main objectives: reduce the cost of current robotic systems for rehabilitation and support and enable personalisation based on the needs of many users, subjects who have suffered stroke, spine injury, subjects with myopathies or children with cerebral palsy. The development of the exoskeleton requires continuous interactions and tests with the users with motor disability. These tests are primarily targeted at the personalisation of the device to the needs of the individual users, both in terms of protocols of use, and in terms of the physical characteristics of the users (shape, interfaces with orthoses already worn by the users, etc.). Thanks to *open source* technology and *3D printing* it is possible to reproduce various aspects of the design very quickly and with extremely reduced costs.

The project is therefore at the intersection between the three areas identified in *MakeToCare*, i.e. research in the healthcare sector, co-design with users with motor disability, and manufacturing, in order to leverage the open processes and technologies.

Does your activity involve coalitions or collaborations with other subjects for the development of research and innovation projects in the care sector? If yes, what are the types of subjects (patients, caregivers, associations, institutes of care and research, Universities, centres and laboratories, institutions, enterprises, other) with whom you interact?

Currently, I am doing a PhD thesis work at the EPFL in Lausanne, Switzerland, within which I work on the development of robotic solutions for motor rehabilitation and man-machine interfaces to control these devices. Periodically, we test the solutions developed in the university hospitals and rehabilitation centres who are partners of our research team. The continuous interaction with the carriers of needs and with experts in motor rehabilitation, such as physiotherapists and occupational therapists, allow an important expertise to develop for the *Hubotics* team related to the needs of the end users and *caregivers*.

What specific skills and resources (for example human resources, technology, design, production, etc.) did you implement to develop research and innovation projects in the care sector?

The project requires a mix of many skills and resources. The technical aspects and knowledge (engineering skills in mechanical, electronic and software design and development, and knowledge in neurophysiology, the human neuromuscular apparatus and in rehabilitation techniques) are definitely critical. The *soft skills* play an important role in the relationship with end users, in order to identify their main needs and requirements. A vision/understanding of the stakeholders and processes involved in healthcare is also important to develop a product that can reach the users for whom it was created.

Currently, the Hubotics team is composed of Chiara and Luca Randazzo. Chiara focuses primarily on the collection of users' requirements and the design of solutions that are usable day-to-day and aesthetically acceptable. Luca dedicates his time to the prototyping and testing of the devices for end users. In the immediate future, we aim to expand the team with a technical co-founder and an executive.

With regards to the technological resources, we perform the device prototyping in-house using 3D printers, laser cutters and CNC milling machines, available at makerspace locations. Eventual larger scale productions will be done through outsourcing. The prototyping requires financial resources (for purchasing components, materials, etc.) that we currently self-finance.

In a development perspective, we want to access funding by Foundations, Research Institutes or through Awards to be able to expand the team and allow to fund the research, development and testing of devices on a larger and more distributed scale.

What contribution of innovation do the projects that you developed propose? What impact do you think they can have on care and in the MakeToCare area?

Until recently, the development of similar devices was the exclusive prerogative of very specialised Research Centres. Similarly, their use by end users was (and still is) restricted to a few specialised Centres.

The *Hubotics* project aims to demonstrate primarily that it is possible to develop tailored functional devices for rehabilitation and motor support at a low cost, and that these devices can be distributed directly to the end user's home. In this sense, we hope that the biggest innovation and impact that the project may have is cultural. Our biggest success would therefore be to represent, in the common perception, a case of success that demonstrates how healthcare, with its needs of extreme and continuous personalisation depending on the needs of individual users, is a particularly fertile terrain for new open and in-house/distributed manufacturing technologies.

With regard to your experience, how do you think the care sector and MakeToCare area will evolve in the future?

In the future, the distributed and personalised production of healthcare devices, for example through equipped FabLabs and/or workshops, may represent an important solution able to satisfy the typical needs of users with motor disability.

In our opinion and in this regard, however, it is fundamental that the stakeholders involved in healthcare are exposed to successful projects and that they support these projects at various levels (incubating them, allowing in-house testing, through financial support, etc.) to create virtuous

circles able to attract interest/support from foundations and institutions (private and non-private), thereby producing more value for both end users and the various parties involved.

3.7.9 Matteo Malosio, ITIA Institute of Industrial Technologies and Automation - CNR, Milan

Do you recognise your activity in the definition of the MakeToCare area? If yes, how?

Yes. Our group is involved in the development of devices for neurorehabilitation using the support of medical staff and interacting with patients for testing the devices and obtaining data on the therapy sessions. Some of the devices were designed and created paying special attention to aspects such as self-production and personalisation using additive manufacturing, low-cost components and *open source* software.

Does your activity involve relationships or collaborations with other subjects for the development of research and innovation projects in the care sector? If yes, what are the types of subjects (patients, caregivers, associations, institutes of care and research, Universities, centres and laboratories, institutions, enterprises, other) with whom you interact?

Over the years we have collaborated with some rehabilitation centres, especially in the Lombardy region. Some of the projects were developed in partnership with other CNR Institutes and some foreign Universities. In the projects, we interacted with some companies in the rehabilitation sector. Both before and during the experimentation phases we interact with physicians, physiotherapists and patients to guide the device development and therapy planning aspects.

What specific skills and resources (for example human resources, technology, design, production, etc.) did you implement to develop research and innovation projects in the care sector?

The group is composed of six individuals with cross-sectional skills: design/control of machines, industrial design, bioengineering and physiotherapy. For the creation of the prototypes the Institute makes available a mechanical workshop equipped with machinery for the removal of shavings and machines for *additive manufacturing*. Design and simulation software during the design phase, and open source control systems and calculation software for the data analysis phase, is used in other equipped laboratories.

What contribution of innovation did the projects that you and/or Institute developed propose? What impact do you think they can have on care and in the MakeToCare area?

Almost all the devices developed expect interaction with the patient, using appropriate algorithms of control and unconventional mechanical solutions such as creation with *variable stiffness*. In some the possibility of production of the device using low cost 3D printers and easily available materials was particularly taken care of. In almost all cases, nevertheless, the mechatronic solutions proposed are designed to reduce the complexity and overall cost of the devices compared to those already on the market, so as to obtain devices oriented towards the world of home rather than clinical rehabilitation.

With regard to your experience, how do you think the care sector and MakeToCare area will evolve in the future?

The technologies of personalised design and production are continuously improving and are increasingly within the reach of everyone. The possibility by patients or caregivers to develop ad hoc aid solutions will be increasingly relevant. Despite this, the ready distribution on a large scale of solutions developed specifically for a patient will meet a continuous and necessary obstacle in medical regulations and certification procedures, characterised by stringent and high cost limitations.

3.7.10 Mary Franzese, Neuron Guard, Modena

Do you recognise your activity in the definition of the MakeToCare area? If yes, how?

Neuron Guard is developing a medical device for the treatment of stroke, cardiac arrest and head trauma, life-threatening and disabling diseases (every 7 seconds worldwide a person is affected by acute brain damage). We include our activities in the *MakeToCare* area because our goal is to innovate the process of patient care, taking care of them from the location of the adverse event up to the hospital, ensuring the proper and best implementation of care.

Does your activity involve relationships or collaborations with other subjects for the development of research and innovation projects in the care sector? If yes, what are the types of subjects (patients, caregivers, associations, institutes of care and research, Universities, centres and laboratories, institutions, enterprises, other) with whom you interact?

Our activities are the result of continuous coalitions and collaborations with hospitals, research centres, patients, institutions and companies for the definition of the best strategy of care. The continuous comparison is essential for us also for the creation of the device: their involvement is in fact critical in determining the technical characteristics, areas of application and elements such as the wearability of the collar.

What specific skills and resources (for example human resources, technology, design, production, etc.) did you implement to develop research and innovation projects in the care sector?

The development of research and innovation projects in the care sector presupposes the continued use of skills and human, technological and financial resources with the goal of expanding scientific knowledge, and enables their application. In defining these projects, account should be taken of the creation of programmes and methodologies based on an efficient organisation of the work because it is persons, and particularly patients, who are the fulcrum of our decisions.

What contribution of innovation do the projects that you developed propose? What impact do you think they can have on care and in the MakeToCare area?

The project that we developed helps to create an innovation of product and process through the proposition to hospitals and emergency services of a device able to treat the patient early and simplify their care by medical staff. We also estimated that the application of our technology in the hospital context, in particular access to the A&E department, brings a reduction of healthcare costs of approximately 48%.

With regard to your experience, how do you think the care sector and MakeToCare area will evolve in the future?

The evolution and improvement of the care sector assume ongoing challenges such as the scarce ability of our users to assess the technical implications a choice, the lack of an unambiguous treatment guideline, and the real involvement of the users, especially of medical staff and patients. There may be progress only with simplification, persistence (endless perseverance), professionalism and preparation for continuous comparison.

3.7.11 Emanuela Corti and Ivan Parati, Witsense, Monza

Do you recognise your activity in the definition of the MakeToCare area? If yes, how?

The *sensewear* project originates from the identification of a need: improve the daily life of persons with integration sensory disorders that are typical in autism, and not only autism. The key element of the system is an undervest incorporating textile sensors, able to collect the vital signs of the person wearing it, subsequently processed by an application.

The signs include heart, respiratory and motility rate, indicative of stress levels of the person wearing the undervest. Some articles in the collection are activated when a state of anxiety or attack is detected, others communicate the mood of the person wearing the undervest, and yet others create occasions of interaction. *Sensewear* is a project that stimulates the collaboration and integration between worlds until now difficult to reconcile such as those of fashion, healthcare and consumer electronics, that from its initial appearance on the international scene of the world of design has seen a multiplicity of similar experiences. It is a product that also may help who is involved with persons with disabilities to plan and accomplish more effective personalised therapies with immediate results. It is a product that not only reads vital signs in a non-invasive and comfortable way but sets out to automatically activate the response of additional articles in an integrated system. It is a wearable product that, while incorporating advanced technologies, wishes to enter the daily life of persons in a discreet and invisible way. Also, as stress, anxiety and panic attacks are part of the daily life of those who live a frenetic urban reality, the product is aimed at a pool of users that extends beyond disabled persons.

Does your activity involve relationships or collaborations with other subjects for the development of research and innovation projects in the care sector? If yes, what are the types of subjects (patients, caregivers, associations, institutes of care and research, Universities, centres and laboratories, institutions, enterprises, other) with whom you interact?

Our activities began from a design contest where the concept was supported by a personal interest and research that confined itself to a collection of case studies and statistics and a direct approach with some therapists. The visibility obtained from winning the contest has nevertheless allowed us to note an interest by the sector and to activate some specific collaborations. Since then we have established an important partnership with an Italian pioneer in the textile sensors sector. Currently, participation in the European *WEAR Sustain* Open Call for proposals, currently ongoing, has allowed us to bring the development of the product to a subsequent stage and become part of their network of companies and institutes that orbit around the sector of wearables and technological innovation. The opportunity to produce functioning prototypes in small numbers has finally opened the way to experimentation at therapeutic centres with recognised influence nationally.

What specific skills and resources (for example human resources, technology, design, production, etc.) did you implement to develop research and innovation projects in the care sector?

The development of our products involves several skills and, for this, we try to build networks with different institutions. Currently we are working on a European project with the support of the FabLab at the University of Siena in collaboration with Valerio Frascolla, Head of the Department of Research and Innovation at Intel.

Previously we supported the research on possible applications of the product with the help of some Politecnico di Milano students in the *Health Care Management of Faculty of Management Engineering* course. We also support the research pertaining to smart fabrics through an *Ajman University* programme for which we work as lecturers.

Last but not least, and very important as already mentioned, is the work done alongside the occupational therapists of various centres for autism, from the *Dubai Autism Center*, from where the project began, to *Casa San Sebastiano* of Trento and others in the course of definition.

What contribution of innovation do the projects that you developed propose? What impact do you think they will have on care and in the MakeToCare area?

A critical, but often undervalued, input involves the integration of therapies, often performed in hospital or medical settings, in objects of daily use such as clothing or accessories. This allows to avoid the stigmatisation of the subjects and assist their acceptance and integration in a more normal social setting. It also promotes a concept of continuous care that can extend the benefits in the home environment rather than treat a condition at a specialist centre. From the technology standpoint, to date, the development of an integrated system of wearable sensory therapies has not yet been attempted, but *Sensewear* wants to add a further objective to this, i.e. to understand in advance the moment at which to activate depending on the vital signs read from the activity of the person wearing it.

With regard to your experience, how do you think the care sector and MakeToCare area will evolve in the future?

They will evolve heterogeneously following different guidelines, resulting in the erosion of the traditional hospital and pharmaceutical system by the pool of users.

On the one hand prevention and the possibility to monitor your own health autonomously will become an element that increasingly distances subjects from the eventual recourse to hospitalisation. This may be encouraged also by the possibility of creating increasingly less invasive, portable and economic systems of detection and therapy. On the other hand, the sector could focus on the development of individual performance, as in the case of the creation of light wearable exoskeletons that may resolve motor and perceptual dysfunctions.

Another key director is the possibility to incorporate the contributions of different actors and the ability to have a huge pool of case histories available, yet easily interpreted through artificial intelligence. This will help to generate ever more accurate diagnoses in restricted time limits and provide remote, high-quality, personalised therapies breaking down the inequality of offer based on the geographical localisation of patients.

3.7.12 Carlo Boccazzi Varotto, Hackability, Turin

Do you recognise your activity in the definition of the MakeToCare area? If yes, how?

Hackability has three purposes: co-design as a way to identify the most efficient and effective devices; digital fabrication as an opportunity to create them at low cost; the social impact at the territorial level as outcome of the co-design process. In this sense, it cross-sectionally traverses the topics covered by *MakeToCare*.

Does your activity involve relationships or collaborations with other subjects for the development of research and innovation projects in the care sector? If yes, what are the types of subjects (patients, caregivers, associations, institutes of care and research, Universities, centres and laboratories, institutions, enterprises, other) with whom you interact?

Hackability is an open work platform that is sustained with the work of a community with which it has structured relationships, consisting of: 4 FabLabs (Turin, Chieri, Alexandria and Cuneo), 2 research Institutes (Lero The Irish Software Research Centre of Limerick and the CINI Consorzio Interuniversitario Nazionale per l'Informatica), the Young Persons Group of the CNA and Brescia IPASVI (Federazione Nazionale Collegi Infermieri professionali, Assistenti sanitari, Vigilatrici d'infanzia [Italian Federation of Professional Nurses and Medical Workers]). The Consorzio [Nazionale] CGM (Consorzio Nazionale della Cooperazione Sociale Gino Mattarelli), a half-dozen Social Cooperatives and around 10 associations of persons with disability to which *Rokers* (the first Italian community that promotes robotics in all its forms and declinations) is added are also part of our network as permanent activity of co-design.

What specific skills and resources (for example human resources, technology, design, production, etc.) did you implement to develop research and innovation projects in the care sector?

We developed a specific methodology for the co-design and we rely on the network of partners for the creation of the prototypes. In particular, we supply an *open source repository*, in the sense of a directory, of projects.

What contribution of innovation do the projects that you developed propose? What impact do you think they can have on care and in the MakeToCare area?

We have to distinguish between three levels:

- the impact in the world of device *making* and manufacturers: very high for both emulation and direct contact, particularly among professional device manufacturers who are among our biggest stakeholders;
- the impact in the world of disability, which is significant on both an active and cultural level: often the persons with disability ask for devices that already exist in other markets (UK, USA, Israel, etc.) but they don't know it;
- the impact in the third sector: our challenge is to build an organic alliance with the third sector to continue our common battles on certifications and warranties.

With regard to your experience, how do you think the care sector and MakeToCare area will evolve in the future?

It seems to us that there are two interesting and emerging phenomena: the evolution of professional

device manufacturers who increasingly tend to use light prototyping tools and organise themselves around small communities; the *self-help groups* between patients and *caregivers* with similar diseases. We are making a large investment on both the first and second.

3.7.13 Costantino Bongiorno and Zoe Romano, WeMake Makerspace FabLab, Milan

Do you recognise your activity in the definition of the MakeToCare area? If yes, how?

Yes, we recognise our activity because the innovation that occurs in the FabLabs is above all of process. It is possible not only through access to digital manufacturing equipment that allows the creation of customised, *on-demand*, collaborative products with high technological value but, especially, because it gives a reading of the need that involves several stakeholders and has the social impact as an objective so as to reach where “business as usual” does not.

Does your activity involve relationships or collaborations with other subjects for the development of research and innovation projects in the care sector? If yes, what are the types of subjects (patients, caregivers, associations, institutes of care and research, Universities, centres and laboratories, institutions, enterprises, other) with whom you interact?

All the types of subjects mentioned.

What specific skills and resources (for example human resources, technology, design, production, etc.) did you implement to develop research and innovation projects in the care sector?

We implement the skills and resources related to community management, participatory design, management of open technology workshops, design, digital manufacturing, international coalitions, training.

What contribution of innovation do the projects that you developed propose? What impact do you think they will have on care and in the MakeToCare area?

The projects that we have developed add to an innovation of the process in creating *community-based* care.

With regard to your experience, how do you think the care sector and MakeToCare area will evolve in the future?

Increasingly, in the future, care will actively involve patients who had a passive role in the past, and a series of hybrid subjects who could not be recognised as valid carriers of solutions and innovation. This will also bring innovations intended to simplify the bureaucracy and governance.

3.7.14 Nicola Gencarelli, click4all, Fondazione ASPHI NPO, Bologna

Do you recognise your activity in the definition of the MakeToCare area? If yes, how?

Yes. The *click4all* project has the ambition to help build a bridge between the world of carriers of needs (persons with disability, caregivers and social and healthcare operators) and the possibilities offered by prototyping technologies and digital production.

Does your activity involve relationships or collaborations with other subjects for the development of research and innovation projects in the care sector? If yes, what are the types of subjects (patients, caregivers, associations, institutes of care and research, Universities, centres and laboratories, institutions, enterprises, other) with whom you interact?

The *click4all* project began from the *Fondazione ASPHI Onlus*, a non-profit organisation that is involved in computer technology for disability. We are part of the national network of *Centri Ausili Italiani* that provide consultancy on computer aids to persons with disability, Associations of persons with disability, caregivers, healthcare operators, educators and teachers. We collaborate with the Universities for the field experimentation of technologies stemming from research activity. We work with companies on the aspect of company welfare policies and for the definition of projects of experimentation of treatment technologies in the territory.

What specific skills and resources (for example human resources, technology, design, production, etc.) did you implement to develop research and innovation projects in the care sector?

In our team there are skills of the technological type (electronic engineers and computer developers) and educational psychology (pedagogues, educators specialising in disability, counsellors). On the one hand, we have a *centre for technical aids* available supplied with a broad spectrum of computer aids available on the market. On the other, we experiment and modify consumer technologies to adapt them to the needs of persons with disability (accessibility and usability). With regard to the prototyping of original solutions, we use primarily Arduino, Raspberry Pi, Scratch, 3D printers.

What contribution of innovation do the projects that you developed propose? What impact do you think they can have on care and in the MakeToCare area?

We hope to help lower the threshold of access and allow the persons to become creators and not only passive consumers of treatment technology. We believe there is still a large gap between what is being developed and the real use by persons with disability and their caregivers. We try to work on the innovation of the process of use and adaptation of existing technologies rather than on the development of new technologies.

With regard to your experience, how do you think the care sector and MakeToCare area will evolve in the future?

If it is true that the market of traditional treatment technologies will need to open up more to innovation, on the other hand the world of makers and startups needs to get rid of some techno-deterministic trends. There are still many examples of solutions that are prototyped starting from a technology and not a survey of real needs, or ideas originating in the garage but that in fact reinvent the wheel and pay for the ingenuity of not thinking about diffusion and sustainability. The projects

in the *MakeToCare* area that may define the future of the sector are those that, through participatory design, activate a real fusion of the know-how of rehabilitation and care, the life and wishes of the persons with disability, the opportunities and knowledge of digital manufacturing.

3.7.15 Cristina Dornini, Fondazione Together To Go (TOG) NPO, Milan

Do you recognise your activity in the definition of the MakeToCare area? If yes, how?

The *Fondazione TOG* and *OpenDot* since 2015 have been on a journey of research and application of advanced manufacturing techniques of aids and objects of everyday use for improving the quality of life of children with complex neurological diseases.

The *UNICO – The Other Design* project, beginning from this collaboration, is definitely close to the *MakeToCare* vision, as it anticipates a model of interaction and exchange between the patient and caregiver subjects, rehabilitation therapists with their scientific expertise, and the makers and designers with their design skills and knowledge of technologies.

Does your activity involve relationships or collaborations with other subjects for the development of research and innovation projects in the care sector? If yes, what are the types of subjects (patients, caregivers, associations, institutes of care and research, Universities, centres and laboratories, institutions, enterprises, other) with whom you interact?

OpenDot and *TOG* collaborate regularly with the NABA University and Domus Academy to bring designers closer to the world of design of functional and stylish aids, because the aesthetic is a value too often forgotten in disability. One of the *UNICO* mottos is indeed “beauty generates inclusion”. Workshops of co-design of aids were organised with the students (*Glifo*, the treatment tool to write and draw, started from one of these), and workshops involving large companies like IKEA for the *hacking* of everyday objects, modifying them to adapt them to the real needs of children. Another example of virtuous collaboration between *UNICO* and the world of business is the DIY summer shoe project for children who have to wear corrective guardians. *UNICO* involved *Vibram*, the company leader in soles, initiating a co-design work group between their designers, the therapists of *TOG* and *makers* of *OpenDot*, to design a tailored shoe, designed ad hoc for every child and fully customisable from a *Vibram* model.

What specific skills and resources (for example human resources, technology, design, production, etc.) did you implement to develop research and innovation projects in the care sector?

The *UNICO* project engages multiple skills and resources: those of rehabilitators with specialisation and experience in complex neurological diseases, those of figures such as designers and *makers* with design skills and experience of co-design and *know-how* on digital manufacturing technologies. To this the direct experience of the patient is added, who is always involved from the beginning and pro-actively in the design phase, and in this way we intend to shorten the distances between designer and end user.

Then the acquisition of technological equipment such as 3D printers and related software is important, in fact the *3D Laboratory* at *TOG* was built thanks to winning the *Nati per Proteggere Award* promoted by *AXA Insurance* in 2014. The grant won sustained the purchase of the 3D printers and all the orthopaedic aid scanning and computer design devices at the *TOG Centre*. The following

year, in collaboration with the *Fondazione Vodafone Italia*, we were able to fund the project of creation of a software designed ad hoc for the use, by *TOG Centre* therapists, of these machines for the simple and rapid transformation of postural and shower seats for the lower limbs from plaster to coloured and light PLA.

What contribution of innovation do the projects that you developed propose? What impact do you think they can have on care and in the MakeToCare area?

From Design For All to Design For Each, this is the shift that *UNICO* proposes. Digital fabrication and co-design finally become tools at the service of individual needs.

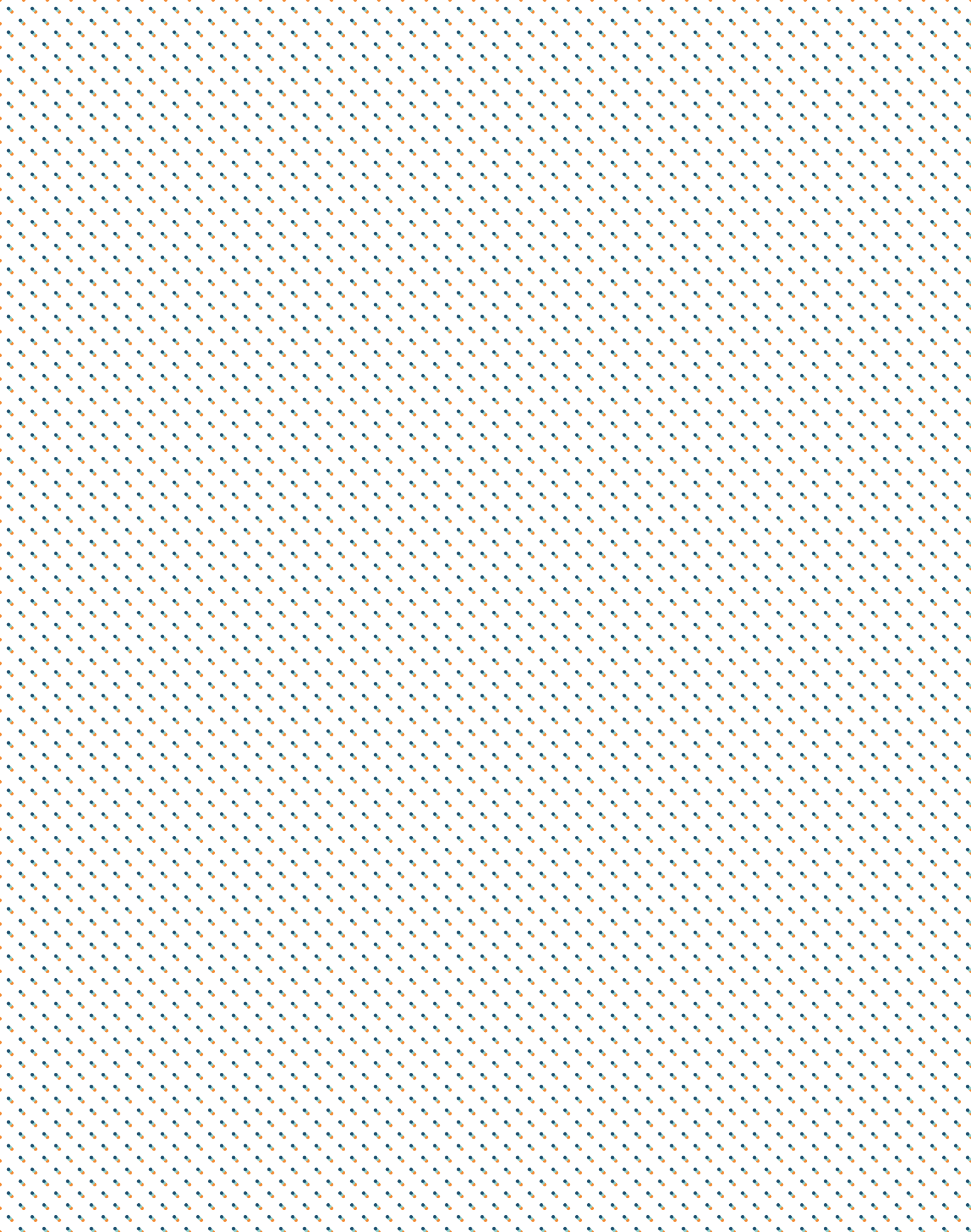
Instead of continuing to discuss and produce standardised objects to be produced in series, digital manufacturing finally leaves a large space for the specific needs of the individual. It is not by chance in fact that in this moment in time, the families and operators involved in the world of childhood disability are the actors who most take advantage of the potential of digital manufacturing and who find great advantage in co-design, in personalisation and low-cost prototyping.

With regard to your experience, how do you think the care sector and MakeToCare area will evolve in the future?

All Western countries have health among the first-line items of expenditure, and in many cases the situation is becoming unsustainable. In this scenario, many countries are beginning to consider alternative systems to the traditional, and it is in such a context that the processes and products that *UNICO* proposes become real practices to innovate healthcare in a *MakeToCare* rationale.

In the Italian context for example, the process for the manufacture of aids foresees a sequence of required passages that slows delivery time lines very much; first you have to go from the approval of the Ministry of Health, only after this can the orthopaedic workshops begin the design and manufacture of the product.

Alternative solutions are ever more urgent, and it is possible to anticipate a greater interest of stakeholders in technologies able to increasingly respond to the need of autonomy of persons with disability and their families, with costs increasingly in reach, we hope.



PART 4

MAKETOCARE: PROSPECTIVES FOR THE DEVELOPMENT OF NEW FORMS OF OPEN AND DISTRIBUTED HEALTHCARE

4.1 CHARACTERISTICS OF MAKETOCARE APPROACHES AND PROCESSES

The final synthesis of this research tells us that the *MakeToCare Ecosystem* is characterised firstly as an extended area of *design biodiversity*. The projects that we identified are a collection of solutions capable of bringing out and materialising, through *real demonstrators*, emerging needs that are unspoken, unsatisfied or hidden in the field of care. The MTC *Ecosystem* is an aggregator of models and processes of social and technological innovation, even if guided by a *design-driven* rationale. It is in fact a sort of *public-private, territorially open and distributed workshop*, that brings out a large repertoire of *forms of collaborative design*: from those of patients and institutes of care to that of Fab Labs and *makerspaces*, from research centres to entrepreneurial experiences. This set of actors, in reality, intercepts and resolves a universe of needs unmet by the official care system: from *ad hoc* solutions for the individual (such as aids developed as part of the *Hackability* initiative) to digital platforms for sharing or personalisation of care products (such as *Grippos*, online platform for personalisation and 3D printing of adaptive aids) up to *low-tech* and *low cost* self-produced solutions, to arrive at those of the scientific research funded with European funds, such as projects developed by Research Centres and Universities. Examples produced by the latter subjects are the robotic prosthetic hand *SoftHand Pro* or *ABBI*, the bracelet for sensor motor rehabilitation for blind children or again the *OpenCare* project, looking for innovative solutions to respond in a personalised way to the care needs expressed by an enlarged community of citizens, through the creation of an open approach and of unreleased coalitions of actors.

Within the MTC *Ecosystem*, the action of the subjects is characterised by a *human (user)-centered* approach to innovation that reduces distances, difficulties, bureaucratic and human barriers, pushing the direct and pragmatic contact between persons, enterprises and institutions. The result is an increase of the *agency of citizens-patients* that brings them to new forms of awareness and *co-responsibility* in the improvement in the healthcare sector. It happens thereby that the organisational hierarchies (and sometimes the power hierarchies) are transformed: the patient can become the partner and collaborator of a MTC *Ecosystem* subject, that he/she then incorporates into his/her experience becoming the actuator that materialises the solution. This approach generates a system of coalitions where there are *processes of consultation and sharing* from the early stages of research and design up to the final stage of concretising the solutions. Many of the cases reviewed in this project can be considered as *anticipations* - through seminal investigational experiences - of what might be a productive, *patient-driven*, open and distributed model, that works on the *design*, the *development* and the *delivery* of personal solutions for healthcare, producible through the network of companies, research and prototyping workshops, and communities of multidisciplinary practice.

We can thus add that the *MTC Ecosystem* is a great and articulated individual-collective system of advocacy where the presentation of the solutions is accomplished through specialised forms of communication that, through the generalist media system, generates information, networking, *storytelling* and accessibility to the documentation on the processes and results (that this *inclusive* and *responsible* approach generates). A new *account of care* that opens to the world of the main stakeholders and that highlights unspoken perspectives that are not only technical-specialist. All of this assumes an essential and strategic value and role, and makes this area a favourable location for the incubation and development of new and more evolved forms of *health literacy*, towards an increasingly *citizen-centric* transformation of the practices, solutions and locations of care (even if activated by private initiatives). In support of this statement there is both the initial exploration phase that the analysis of the cases has brought out a new and different geography of healthcare made up of *urban attractor poles*: a map of national healthcare no longer modelled only with the strategic presence of health authorities and hospitals, but also enriched by the presence of places such as the Research Laboratories and Fab Labs where possibilities of meeting with carriers of needs (for example the initiative *Secondo Nome: Huntington*) are generated. Thinking about the city as a place of service, of the production of care materials and culture thereby becomes an interesting and strategic theme, also considering the current demographic projections on ageing of the population and thinking that in 2030 one-third of the world population will live in the main 750 cities in the world⁸⁴.

Moving the analysis to the centre of the *MTC Ecosystem*, we understood that the *MakeToCare Area* is that which is characterised by a bottom-up approach to innovation: within it are solutions that attempt to resolve concretely a set of problems of care that reduces the rights and possibilities of the everyday life of persons, overcoming or transforming the field of *top-down* and systemic resolution, made of standardised products-services designed to solve healthcare problems of high strategic and political complexity. The *MakeToCare Area* in fact, mainly contains a set of products-services⁸⁵ designed for the needs of individuals, for different diseases or specific conditions of disability. These solutions, critical for the persons for whom they are intended, now generate a residual or unattractive economic value for many operators in the healthcare sector, who instead need to build solutions on a larger scale. There is therefore an *open innovation space* (and to be experimented) for the development of enterprises and processes that deal with personalised, configurable and implemented solutions in time using locations, services, activities and *on-demand* and *tailor-made* design and production tools. It is a space of design, but also economic and social, action by which to put together new *healthcare platforms* that make the creation of an area of public procurement that meets a demand unfilled by the healthcare system as it is now producible, accessible and economically sustainable. All of this may also demonstrate to the most important actors that it is possible to build social and economic value starting from an approach that rewards economies of purpose and transforms in a not only demonstrative sense the *social responsibility* of public institutions and companies.

⁸⁴ See: www.oxfordeconomics.com/Media/Default/landing-pages/cities/OE-cities-summary.pdf and www.who.int/sustainable-development/cities/Factsheet-Cities-sustainable-health.pdf?ua=1

⁸⁵ For the projects mapped in the *MakeToCare Area* see Part 3, especially sections 3.5.5, 3.5.6 and 3.5.7)

4.2 THE MAKETOCARE RESEARCH: RESULTS, LIMITS AND OPPORTUNITIES

The process of construction of the interpretative and research model that we developed on field – although with the limits of method and resources of an exploratory work – allows a series of brief thoughts on future scenarios of investigation and the prospects of research that open up to be expressed.

The research process used was based on the construction and fine-tuning of a framework of reference through a process by phases that included:

- definition of the concept and first model of the *MakeToCare Ecosystem*;
- the *scouting* of projects and subjects;
- the *data gathering* and interpretation of the projects;
- the populating and interpretative analysis of the subjects and projects of the *MakeToCare Ecosystem*.

The first result of the research is the fine-tuning of the definition of the *MakeToCare Ecosystem* concept within which we then derived the definition of the same *Area*:

MakeToCare is an ecosystem that enables *bottom-up* innovation dialogue with applied scientific research in the healthcare sector and that finds in the technology of digital manufacturing an enabling platform for the democratisation and diffusion of product-service solutions dedicated to care;

MakeToCare is an area of convergence between activities of research, experimentation and (co)design based on the collaboration and coalition between patients and groups/communities of interest, family members and *caregivers*, operators and centres/laboratories of healthcare and medical research, designers, independent innovators, workshops for shared manufacture, innovative startups.

To validate this concept, we went *into the field* to carry out the *scouting* of projects, gradually identifying the cases. We repeated this process together with an interpretative analysis of the solutions. The feedback obtained influenced the verification of the *MTC Ecosystem* categories of subjects.

The first thing that we learned is that the representation of the *primary* and *secondary* areas of the *MTC Ecosystem* model (as for the articulated and profound definition of the categories) was defined precisely but in reality, it has a more blurred aspect. That brings us to think that the progressive work of populating the *Ecosystem* model with more projects – through ad hoc scouting campaigns and the engagement of protagonists – will highlight even more the diversity between the categories of subjects, and therefore a more complex collection than what we imagined when we started the research. For example, within the *MedTech System*, with the term *Laboratory and Centres of Research/Experimentation* it was intended to identify a cross-sectional category of subjects characterised by a connection with the world of academic or institutional research and with that of technologies and experimentation applied in the healthcare sector, but not only. This category in fact also brings together Fab Labs and academic research laboratories that explore digital manufacturing with different approaches (such as the *Polifactory* and *+Lab* of the Politecnico di Milano), centres of scientific research and communication-experimentation (such as the *Design and REsearch in Advanced Manufacturing D.RE.A.M.* of the Città della Scienza in Naples), laboratories for open science and open biology (such as *BIOlogic*, Cava de' Tirreni), a reality-platform related to the world of healthcare and scientific research (such as *Open Biomedical Initiative*).

The analysis always enabled us to isolate and study the operation of a small but important set of subjects not specialised in the field of healthcare that for this reason were included in the *Other* category. Among these are important enablers of the design development processes: Fondazione Cariplo (Milan) with the

CREW project, the Municipality of Milan with the OpenCare European project, the Associazione MenoMale (Bologna) with the *Look Of Life* project, have created the foundations and/or provided operating, political and economic tools necessary for the beginning and subsequent development of many care solutions.

The second thing that we learned, still linked by the analysis of the subjects, is that two different dynamics live in the *MakeToCare Ecosystem*: on the one hand is the force of some medium-large *coalitions* (4 or more individuals involved in 58 projects, with an average of 8, and 10 large *coalitions* for a total of almost 120 subjects involved); on the other there is *individual activism* of the single subjects (62 projects out of 120). Among these we can certainly include the patients-innovators (7, summing the *Innovator Patients/Caregivers* and those who we defined as *MedTech Innovator Patients/Caregivers*) and the more structured realities, such as companies, startups or associations involving an innovator patient (the eight *MedTech Startups, Enterprises and Associations* of the *MakeToCare Area*). In this regard, one of the questions that we asked at the start of our research was the following: are the patient innovators really able to enter the official circuits of innovation? If yes, in what way?

The purpose of this question was twofold: on the one hand to see if the patients were actually the activators-generators of a change in the offer of products-services for care, on the other to see if they were also able to develop into entrepreneurs and providers of the products-services designed and made by them. The *MakeToCare* research contributed to clarifying that the *patient innovators* exist but still struggle to enter the official circuits of innovation, because it is often single individuals who have difficulty entering in connection with a system of subjects this complex and enlarged. During the mapping phase, it was difficult to identify them as individuals-innovators while it was easier to identify their contribution within the projects. The *MakeToCare* research in fact identified and analysed a set of startups and companies that constitute the final step of a process that began with the creation of a solution initially designed as a response to the specific need of a person. It is the case for example of *D-Heart*, startup beginning from the idea of one of the founding partners, who, affected in adolescence with myocardial infarction, thought of developing an easy-to-use pocket electrocardiograph; or again the *ViavacSo Srl* [sic: *VivacSo Srl*], company, started for the development and commercialisation of *Ópponent*, a new type of orthosis designed starting from the needs of one of the partners, neurologist, who after being affected by hemiparesis due to an accident, became specialised in orthopaedic solutions.

Others again have known how to transform a personal and specific need into larger projects, like Francesca and Angelo, parents of Mario affected by perinatal stroke, who thought not only of developing a project platform, *MirrorAble*, for the rehabilitation of children with the same disease, but also to become through the establishment of the *FightTheStroke* Association, a reference point both for other families and for the system of conventional care (from the collaboration with the Ospedale Pediatrico Gaslini di Genova is beginning the first Italian *Stroke Centre* for the treatment and care of children affected by paediatric stroke).

In practice, these cases lead us to the idea that may even be a *patient-enterprise* (Maffei and Bianchini, 2016), or a patient who can be considered as an *individual-organisation* who develops processes of care through an entrepreneurial creation process. On this specific topic, the report entitled; *The added value of patient organizations* (Sienkiewicz and van Lingen, 2017), produced by the *European Patient Forum*, explores the historical evolution of organisations of patients (re)defining their type, role, values and activities. Two are the most important things that emerge from the report:

- the overcoming of the idea that the involvement of patients and patient organisations is a purely *symbolic* or *communicative* operation, but that instead their contribution is substantial in determining issues and needs and in designing solutions for healthcare;
- the *change of status of the patient* and of *patient organisations* that transforms them into peers,

subjects considered at the same level of other experts, from scientists to industry representatives, to medical professionals.

According to the authors of the report, the recognition of this *status* means that the patient or organisation that represents the patients can, the same as an expert, be rewarded for innovation that he/she generates or for the knowledge/*expertise* that contributes to generate through the innovation developed by others. This also means that *patient innovation* can have a quantifiable value and that *MakeToCare* can be seen not only as an *Ecosystem of innovation* but also as a potential constructor of the market for this same innovation. This will also transform the balances within the coalitions, ensuring equal dignity or power also to the *innovator patients*, who in this way would become relevant actors not only in the production of social value but also of economic value.

The final consideration is the role of public action to form an *enabling culture and system* that achieves a condition of balanced *subsidiarity* in stimulating the possible actions of private subjects. *Subsidiarity* interpreted as the construction of enabling operational, economic and social conditions that produce an environment favourable for the growth and distribution of the *bottom-up* innovation processes of *MakeToCare*. Processes that can penetrate the logic of the traditional system and produce what patients need. These same processes, while working already at the experimentation and prototype level, are not yet sufficiently generative in the construction of the system of management and diffusion of knowledge (shared) and of new forms of entrepreneurship. The *MakeToCare* research brought out and tried to define an ecosystem that had not been planned and designed, but that emerged thanks to the convergence of enabling conditions: at its internal, in fact, the area that most benefited from public interventions dedicated to innovation in the healthcare sector is the official research system, i.e. the *Healthcare & Research System*. This does not mean however that the public actors are not attentive or active on this front also in thinking about initiatives involving the other two areas, that of *Making, Manufacturing & New Entrepreneurship System* and the *Patient & Caregiving System*. The research has in fact shown us some evidence in this regard: these are forms of action implemented by public subjects in the narrow sense such as the Municipality of Milan or *intermediate subjects* such as the Fondazione Cariplo, that mediated the requests of public and private sectors, building a new approach for the production of *subsidiarity*.

4.3 NEW RESEARCH PROSPECTIVES

Beginning from the explanation of the results and limits reached, we can finally summarise some insights to identify possible prospects of development of the *MakeToCare* research.

A first nucleus of consideration concerns the entrepreneurial potential in the social and inclusive sense of the *MakeToCare Ecosystem* and focuses on the possibility of acting on this network of actors to turn it into a design, productive and economic platform that operates in a circular from patient to patient logic. A logic that can be developed in a dimension of *subsidiarity* thanks also to the change of status of the *patients-innovators* who become entrepreneurs or who simply form coalitions with the articulated networks able to materialise their needs: that is, transforming them *from recipients to proponents of innovation*, certifiable or certified distributors of solutions alternative or complementary to those existing up to being buyers of goods with high perceived individual-social value that currently do not have a market.

Another related reflection concerns the innovation time: from the point of view of a culture of service ever closer to the patient, for both personal and market needs, the need to accelerate the times of development and application of the same innovations emerges.

Often, in fact, we found that these timelines do not tally with those of the procedures of scientific-clinical official validation exactly in the sector of healthcare, that expects or requires lengthy, structured and bureaucratised processes given instead urgent and specific needs.

The last consideration is of the scientific type. To replicate the *MakeToCare* research on an international level, maintaining the same methodological system to render the various ecosystems comparable between them, a preparation work of verification of the conditions of contextuality on the facility and elements of the national ecosystems to be analysed will be required every time. Very probably each country system may be different in the interpretation of some categories of subjects and types of projects, of local laws and regulations, of the arrangements of the policies of research and innovation. Conducting the research in other contexts would mean certainly perfecting and understanding better what are the endogenous and exogenous elements acting to shape a *MakeToCare Ecosystem* in the general sense, or the mix of subjects (and their capabilities and attitudes) and environmental characteristics that promote or inhibit the development of care solutions.

MakeToCare. In the construction of this neologism the result of our research is enclosed/ we can enclose the results of our research. A new word that tries to describe a set of individuals, thoughts, projects, actions and solutions that previously did not exist and that can now be known and therefore discussed. *MakeToCare* activates on different levels—technical and scientific, social-cultural, economic-productive, political and institutional—it constitutes/embodies an exchange of ideas, processes and experiences that may be expressed concretely in new solutions for care.

MakeToCare solutions, precisely.

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Info and contacts:

stefano.maffei@polimi.it

massimo.bianchini@polimi.it

www.maketocare.it

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