Regions4PerMed

Interregional Coordination for a fast and deep uptake of Personalised Health

Regions4PerMed

Best Practices Booklet

Key Thematic Area 5: Tackling ethical, economical, legal and social aspects of Personalised Medicine

This project has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 825812.

PROJECT INFORMATION

GRANT AGREEMENT NUMBER	825812
PROJECT FULL TITLE	Interregional coordination for a fast and deep uptake of personalised health
PROJECT ACRONYM	Regions4PerMed
FUNDING SCHEME	CSA
START OF THE PROJECT	01/11/2018
DURATION	54 Months
CALL IDENTIFIER	H2020-SC1-2018-Single-Stage-RTD
PROJECT WEBSITE	http://www.regions4permed.eu/

Booklet of Best Practices

1. Data Diverse Initiative

Project | Initiative title		Data Diverse Initiative
Organization name		Genomic England
Country		United Kingdom
Region		/
Contact person		Dr Maxine Mackintosh (s/h)
Contact email		-
Website		https://www.genomicsengland.co.uk/initiatives/diverse-data
Keywords		Inequalities, genomic research, diversity, inclusion, personalised medicine
Duration		On going
Area of application		Genomics
DESCRIPTION	Main challenges tackled	Addressing the gap in diverse genomic data Reduce health inequalities Improve diagnosis, prognosis, treatment and care for diverse populations Improve patient outcomes in genomic medicine for minoritised communities Trust of diverse communities in personalised medicine
	Objectives	• Trust of diverse communities in personalised medicine • Expand and improve genomics research with diverse populations • Improve diagnosis, prognosis, treatment and care for diverse populations
	Main concept and methodologies involved	• **Understand the Data Gap:** Improve our understanding of genomic diversity by reviewing, stimulating and conducting research into diversity and its impacts on scientific, clinical and health system outcomes. • **Close the Gaps, Together:** Work with patient and data communities to design, develop and implement equity-enhancing strategies • **Fill the Data Gaps**: Increase the volume and depth of genomic data available on individuals from under-represented groups through sequencing a diverse cohort • **Bridge the Data Gaps:** Work with clinicians, analysts, researchers, patients and community groups to develop tools, and processes to improve research, service-delivery practices, recruitment and care.
	Impacts (health, scientific, industrial, socio-economic or others enabled by the project/initiative	Change (within Genomics England's control) happens from: Acting …to address the imbalance in genomic datasets by sequencing genomes from diverse populations, developing new tools and approaches, and implementing and integrating new data and ways of working into what we do. Influencing and enabling … key groups and organisations, creating the conditions for others to do similar work, setting an example, helping set ambitious goals to rally the community around and always pushing the genomic community to do better. Monitoring … awareness of the need for, and impacts of genomic data diversity and improvements and performance across the ecosystem to ensure our work is relevant, appropriately networked and collaborative where possible.
	Funding and Investments (pleasespecify the source: public, private, Structural or other types of funds)	UK Government
	Key stakeholders involved	UK Government, clinicians, analysts, researchers, patients and community groups

2. Developing best practices for conducting equitable genomics research with underserved and racialized populations.

Project | Initiative title		Developing best practices for conducting equitable genomics research with underserved and racialized populations
Organization name		Yvonne Bombard, PhD directs the genomics health services research program at St. Michael's Hospital. She is a member of the ASHG Board of Directors, the CIHR Institute of Genetics Advisory Board, and the Ontario Genetics Advisory Committee, which provides funding recommendations to the Ministry of Health for new genetic technologies. Vernie Aguda, MSc candidate, is a trainee who is currently enrolled in the Genetic Counselling MSc program at Cardiff University and is completing a thesis research project with Dr. Bombard. She is involved in the systematic review, qualitative interviews, best practices guide development, and community engagement activities for the project. Marc Clausen, MA, is the Associate Director of the Genomics Health Services and Policy Research program at St. Michael's Hospital. He is involved in oversight of the best practices development and community engagement activities. Emma Reble, MSc, is a research program manager with Dr. Bombard's team in the Genomics Health Services and Policy Research program at St. Michael's Hospital. She is currently managing all aspects of the project, including study design, qualitative data collection and analyses, best practices development, and community engagement activities. The Equity in Genomics Project Team consists of Melyssa Aronson (MSc, CCGC), Dr. Andrea Eisen (MD, FRCPC), Dr. Harriet Feilotter (PhD, FCCMG), Dr. Jordan Lerner-Ellis (PhD, FACMG), Dr. Aisha Lofters (MD, PhD, CCFP), Dr. Nav Persaud (MD, MSc), Dr. Aaron Pollett (MD, MSc, FRCPC) and racialized community/patient members.
Country		Canada
Region		-
Contact person		Yvonne Bombard, PhD
Contact email		yvonne.bombard@utoronto.ca
Website		-
Keywords		Equitable genomics research, health inequities
Duration		January 2023-December 2023
Area of application		Genomics, Personalised Medicine, Ethic research
DESCRIPTION	Main challenges tackled	Underrepresentation of genomes from individuals of diverse ancestries results in uncertainty about what constitutes benign and disease-causing genetic variation, leading to a higher rate of inconclusive results from clinical genetic testing and risk prediction models (e.g., polygenic risk scores) that do not transfer across genetic ancestries. Without a genetic diagnosis, access to high-risk surveillance, risk-reducing surgeries, cascade testing, and clinical trials is restricted, often in populations who are already under-referred to genetics. Such exclusions reinforce inequities in health outcomes. As genomics is increasingly used in research and clinical care, it is critical to promote equity in all aspects of genomics research to prevent further exacerbation of existing health disparities.
	Objectives	**1) Synthesize evidence & best practices for conducting equitable genomics research,** **2) Identify barriers and solutions to conducting equitable genomics research, and,** **3) Develop a practical guide for conducting equitable genomics research.**
	Main concept and methodologies involved	Aim 1: **Design**: systematic review of the literature to identify best practices for conducting equitable genomics research. Methods: The systematic review will follow methodological recommendations from the Joanna Briggs Institute. Aim 2: **Design**: key informant interviews to determine barriers and solutions to implementing these best practices using interpretive description which generates interpretive, thematic accounts of participants' perspectives to inform practice.

		Population and sampling: We will purposively sample individuals from racialized and other underserved communities (up to n=30) as well as up to 30 genomics researchers and research leaders across Canada. *Data collection & Analysis*: We will conduct semi-structured, in-depth interviews to directly elicit participants' experiences, concerns, barriers and enablers to participating in and conducting equitable genomics research. The interview guide will be informed by a literature review and will explore topics including attitudes and experiences toward participating in research, preferences for recruitment and communication methods, and reciprocity in research. We will follow an interpretive description approach and analyze data thematically through constant comparison. The results of this study will provide rich, contextual evidence to contextualize the practical guide on conducting equitable genomics research. Codes (descriptive and thematic labels) will be applied to transcripts. The coding framework will be iteratively updated as data collection and analysis progress. Data will be compared across interviews, through constant comparison, to identify relationships between codes and to form themes. Data collection will continue until themes are cohesive and well-supported by interview data from multiple participants, and new interviews confirm existing findings. Aim 3: Develop a practical guide for conducting equitable genomics research. Methods: Based on the findings of the systematic review and stakeholder engagement, we will develop a practice guide for conducting equitable genomics research. The development of a best practices for conducting equitable genomics research will be guided by the quality domains of the internationally recognized Appraisal of Guidelines for Research and Evaluation (AGREEII) tool. *Group Recruitment and Composition*: We will form a guideline development group (GDG) of 8-12 racialized community members/patients, genomics researchers and decision-makers that will guide all stages of the guideline creation. We will follow recommendations set by the World Health Organization (WHO) on appropriate and efficient GDG composition. Formulating Recommendations: Recommendations for meaningful, equitable, and respectful engagement of diverse populations will be developed across each phase of the research continuum. A preliminary list of these recommendations will be sent to the GDG prior to the consensus process. Patient engagement strategies: Previous work4 has shown that successful patient engagement tended to arise in settings where more active levels of engagement (e.g., codesign) are used. We will refer to community engaged research principals rooted in advancing social justice and decreasing health inequities as a foundation to guide strategies for mitigating common barriers faced by diverse populations to participation in genomics research, improving resources used in recruitment, diversifying incentives for participation, and engaging in meaningful trust and partnership building. *Consensus Process and Voting*: Consensus on the recommendations will be formally achieved through Nominal Group Technique, a structured variation of a small-group discussion. The GDG will be provided with a preliminary list of recommendations prior to the meeting. Members will have a chance to add additional recommendations to the list. Each recommendation will be voted on for inclusion into the guideline, and subsequent discussion will evaluate and clarify the recommendation within the context of conducting equitable genomics research. The recommendations will then be modified accordingly. Members with a conflict of interest for specific topics will be excused from participating in the discussion. A final draft of the guidelines will be sent to each member of the GDG for approval.
	Impacts (health, scientific, industrial, socio-economic or others enabled by the project/initiative	Our best practice guide to conducting equitable genomics research will address these inequities by providing a resource to genomics researchers and funding agencies so that this issue may be addressed from all angles. This guide will allow for improvements to genomics research that will aim to inform culturally competent clinical interventions, and impact genetic data sources and analytical approaches used to make clinical decisions. Only by addressing the underlying inequities at the genomics research level can we begin to develop personalised medicine interventions that ensure fair and equitable access to genetic testing, and subsequent personalised management and treatment. Development process: To

		many, the solution to the lack of diversity in genomics is to seek out diverse patient populations to sample from. However, without proper training and best practices to guide researchers, attempts to diversify datasets can often leave lasting damage to the communities and individuals who are the focus of sampling efforts, which often makes other communities wary to participate in future research initiatives. Before the genomics field can successfully achieve access to diverse samples, it is paramount that work is done to identify guidelines for how genetics research with diverse patient populations can be done in a manner that is culturally safe, equitable and ultimately benefits all involved by advancing personalised genomic medicine. Our best practice development process includes a multi-step approach by synthesizing the current knowledge, evidence and initiatives, while also understanding the needs and concerns of racialized patients and community members through qualitative stakeholder engagement. This approach is fundamental to fostering collaborative research partnerships and increasing research engagement, all of which have downstream effects on clinical practice and personalised medicine advancement. Scalability & Research and project organization: Our work will help to advance equitable genomics research by providing a roadmap that will help diversify our datasets in ways that are respectful, sustainable and equitable towards underserved and racialized communities. Our best practices guide will serve as a resource for genomics researchers designing, recruiting and interpreting the science, and will be scalable to be used by genomics researchers of all disciplines across multiple organizations. This resource will inform both researchers who conduct genomics research, as well as funding agencies to ensure that they support genomic research that is equitable, diverse and inclusive.
	Funding and Investments (pleasespecify the source: public, private, Structural or other types of funds)	N/A
	Key stakeholders involved	Population minorities, genomic researchers, funding agencies

3. Capacitation of "Centro" Region of Portugal on Personalized/Precision Medicine, based on Genomics

Project | Initiative title	Capacitation of "Centro" Region of Portugal on Personalized/Precision Medicine, based on genomics.
Organization name	University of Coimbra (coordinator), Coimbra University, Aveiro University, Beira Interior University, Hospitals, "Centro" Regional Education Delegation, Portuguese Press Association, Genomic and Biology Portuguese Teachers Association
Country	Portugal
Region	Centro
Contact person	Fernando J Regateiro (PI)
Contact email	fregateiro@fmed.uc.pt
Website	-
Keywords	Personalized Medicine, Genomic Medicine, Genomic Medicine capacitation, regional strategy, guide to good practices, technical training, knowledge dissemination
Duration	01/07/2021-30/06/2023
Area of application	Genomic medicine, citizen education, regional policy, regional infrastractures

DESCRIPTION	Main challenges tackled	This proposal responds to some of the structural constraints and respective challenges already identified as important for the strategy of "Centro" Region, for the period 2021-2027, namely the demographic decline, the chronic challenge of qualifications and the shortcomings in terms of infrastructure and advanced services to support internationalization and competitiveness. Involving the three public universities in the Central Region and having as one of its activities the capacitation for Genomic Medicine, this proposal also responds to the great challenge of territorial cohesion, encouraging the balanced distribution of technology and knowledge, the innovation and the promotion of highly qualified human resources.
	Objectives	The definition of a regional strategy for Genomic Medicine, for the period 2021-2030, represents an opportunity for the international consolidation of the health sector, an area in which "Centro" Region is recognized as an innovation leader. Moreover, it is urgent to implement this initiative, so that "Centro" Region can accompany international initiatives, thus reinforcing its status as an Innovative Region. This initiative marks the beginning of this strategic definition, based on mapping of innovation ecosystems, writing a Regional Strategy Report for the period 2023-2030, training in Genomic Medicine, knowledge transferring and dissemination among health professionals and general public and educational actions dedicated to general public and high schools to support and encourage an adequate perception of the scope and limits of Genomic Medicine and its proper use.
	Main concept and methodologies involved	**The definition of a regional strategy** implies the existence of an operational regional infrastructure network, based on (1) creation of a Page for Genomic Medicine (2) a network of trained and certified laboratories, (3) a regional network of computer platforms; (4) creation of a regional network of Genomic Medicine integrating biobanks, cohorts of patients, genomic and clinical databases and computational resources from the various hospital units in the Region, (5) creation of Genomic Medicine units in hospitals of the Region; (6) promotion of high-precision, genomic-based clinical trials, (7) assessing the benefits arising from a clinical practice in the Region based on Genomic Medicine, (8) forecasting the production of patents and startups, (9) provision of ethical-legal support.
	Impacts (health, scientific, industrial, socio-economic or others enabled by the project/initiative	**Technical training** ensures skills to main areas of diagnosis, therapy and research linked to Genomic Medicine, namely those with the greatest impact: (1) stratification in cancer situations, (2) characterization of genetic diseases and (3) pharmacogenomics. The project includes (1) technical training in genomic sequencing, (2) the preparation of a Good Practices Guide, (3) and the training and internalization of genomic methodologies in hospitals, mainly in the fields of cancer, chronic respiratory diseases and diabetes; **Biolaw contribution** will ensures (1) the production of a Manual of Good Practices aimed at health professionals, concerning ethical and legal aspects on genetic information, (2) providing patients with an adequate understanding of Genomic Medicine, (3) proposals for legislative change at national and European level, where the need for this is demonstrated, (4) construction of adequate procedures to obtaining consents, (5) analysis of ethical, legal and social aspects, (6) promotion of literacy among high school students, (7) contribution to capacitation of patients associations. **Promoting the creation of start-ups** will (1) encourage entrepreneurship, (2) transfer and enhance knowledge, (3) support managemt of intellectual property, (4) support "seed" phase of the "startup", (5) support procedures to fundraising. **Dissemination activity directed to health professionals and health students** includes (1) six cycles of "webinars" for academic community and health professionals, (2) six internships for health students in sequencing laboratories of the universities involved, (3) a congress on Genomic Medicine to bring together health professionals (doctors, researchers, nurses) and health students from the health areas. **Education for genomics at non-university schools** includes (1) four "webinars" for secondary school teachers of Biology, including topics on genomics and its applications in medicine, ethics and biomedical law, (2) six summer internships for secondary school students and selective visits to genomics laboratories, (3) four multimedia production for high school students and teachers concerning concepts and perspectives in the field of genomics, and (4) a

		"Genomics Medicine Day" for students and teachers from diverse levels of non-university education. **Education aimed at the general public** includes (1) the publication of eight texts in newspapers of the Region, (2) the publication of a cartoon in a national newspaper to raising awareness of the community on Genomic Medicine, (3) the production of a cartoon as a book, (4) five press releases concerning activities developed by the Project, (5) using social networks, (6) writing and performing a play addressing themes of Genomic Medicine, to be presented on the "Day of Genomic Medicine" and at the Congress
	Funding and Investments (pleasespecify the source: public,private, Structural or other types of funds)	This Project was approved and financed by "Centro" Commission for Coordination and Regional Development (CCDRC), with around 1.2 million euros
	Key stakeholders involved	health professionals and general public

4. From molecular targets to personalized care. Towards a comprehensive educational training to clinical research in oncology

Project | Initiative title		From molecular targets to personalized care. Towards a comprehensive educational training to clinical research in oncology
Organization name		Department of Oncology and Hemato-Oncology (DIPO), University of Milan (UniMi), European Institute of Oncology (IEO), Fondazione IRCCS Istituto Nazionale Tumori (INT), ASST Fatebenefratelli Sacco (FBF).
Country		Italy
Region		Lombardy
Contact person		Dr Virginia Sanchini
Contact email		virginia.sanchini@unimi.it
Website		-
Keywords		Clinical Trials – Research Ethics – Precision Oncology – Training – Regulation
Duration		From 2020, no end
Area of application		Ethic research, clinical trials, personalised medicine
DESCRIPTION	Main challenges tackled	Applying non-personalised approaches in clinical research and practice still represents an open critical issue. To address this issue, not only HCPs should develop robust scientific and methodological knowledge, but also develop an expertise on the ethical and psychological issues related to CTs in oncology, so that, by implementing also patients' values, preferences and lifestyle, precision medicine can be translated into personalised care. To date, however, this twofold demand for patient's inclusion and for multidisciplinary training of HCPs remains largely unfulfilled. In the context of a rich national training framework, there is a gap in the current training horizon, since, at the time in which this project was set up, there was no advanced course developed for HCPs, able to address, at the same time, issues related to clinical research methodology, as well as ethics, regulatory, and psychological issues related to CTs in oncology.
	Objectives	Integrate biomedical skills and philosophical-humanistic-social skills on the other. Underlying the whole project is a holistic approach, responding to the idea of a medicine oriented to the understanding and care of the person in its entirety and complexity. This approach is reflected both by the content of the training activities - ethics and methodology of clinical research (in oncology) - and by the choice of profiles involved in the design of the project and in the delivery of the training activities themselves. Promoting a real process of patient inclusion in the daily practice of CTs, Training "patient advocates", with expertise in oncological CTs.

Main concept and methodologies involved	**1) Promoting a real process of patient inclusion in the daily practice of CTs:** By setting-up a basic training course for patients at IEO ("Basic Course") on the scientific, methodological and ethical aspects of the CTs in oncology. The course will take place at IEO and then it will be possible to export it to the other institutions participating in the project. It will be structured in weekly meetings (2h each) for a total duration of 4 months, with the aim of providing patients with the fundamental knowledge to make informed decisions regarding the CTs in which they are or will be enrolled. The course will also allow patients to create a network of relationships with other participants, in a time of significant emotional fragility. (b) By setting-up an advanced training course on the methodology, ethics, and regulation of CTs, directed to HCPs involved in oncological CTs. **2) Training "patient advocates", with expertise in oncological CTs:** By setting-up an Advanced training course for patients and former patients ("Patient Advocates' Course") on the scientific, methodological and ethical foundations of the CTs in oncology. The course will be structured in modules, with interventions from the major experts on the topics of clinical research. The lessons will be recorded and uploaded on the IEO website as well as on the websites of other institutions participating in the project, so as to reach an audience as wide as possible. The course aims to provide participants with an advanced knowledge of CTs in oncology and it will be functional to the training of patient advocates who can work in patient associations, ethical committees, or regulatory tables.
Impacts (health, scientific, industrial, socio-economic or others enabled by the project/initiative	The Project has a **threefold impact**: at the healthcare level, promoting patients' inclusion in CTs, ethical committees and regulatory tables; at the educational level, promoting change in the specialized training offer for researchers involved in CTs in oncology; at the academic level, strengthening awareness about precision medicine, personalised medicine, and personalised care. It will contribute to the debate on personalized medicine and clinical research in the era of precision oncology. The project, in fact, will lead to the publication, in scientific journals, of its results; the programming of a dedicated discussion day, where, alongside an academic intervention on the topic of ethics of the clinical research, the results of the project will be presented. Participants of the three courses will also be invited to participate. Finally, the project is also aimed to the publication of a university manual about the ethics of clinical research in the age of high precision oncology. The hope that animates this project is that precision oncology, based not only on the various 'omics' sciences, but also and above all on the values, preferences, and lifestyle data of patients, will represent a way for personalising care, from multiple points of view, not only scientific, but also ethical, to consolidate the humanitarian vocation of the medical profession. Secondly, the project allows its transferability to several levels. Not only the online course for patient advocates, but also the other two training courses, as they are characterized by a modular and replicable format, which can be exported to other institutions where CTs in oncology are carried out. In this regard, if the courses receive positive feedback, they could be implemented in other institutes involved in the project, which have a profile like IEO (for example, the INT). It is then possible to adapt the proposed package for setting-up courses in other institutions, in order to deal with the topic of the methodology and ethics of CTs but taking into consideration the impact in different fields of application, specific to the institution involved.
Funding and Investments (pleasespecify the source: public,private, Structural or other types of funds)	N/A
Key stakeholders involved	Lombary Heathcare institution,

5. LINNUX - Laboratorio de INNovación y experiencia (User Experience UX)

Project | Initiative title		LINNUX
Organization name		IDIVAL
Country		Spain
Region		Cantabria
Contact person		-
Contact email		-
Website		https://www.idival.org/en/linnux-2/
Keywords		Regional infrastructures, health-tec, patient care
Duration		On going
Area of application		Regional health technology, health tech facilities, patient care improvement
DESCRIPTION	Main challenges tackled	Technological gap in regional infrastructure
	Objectives	Development of innovation projects at the service of the staff of the health environment of Cantabria region
	Main concept and methodologies involved	LINNUX (IDIVAL User Experience Laboratory) is a multifunctional workspace to develop innovation projects at the service of healthcare professionals and with the aim of improving patient care, generating an environment of innovation that facilitates creative work, multidisciplinary and multi-institutional interaction focused on the search for health solutions, which includes working with patients, both new technologies and processes. In these spaces, the usability of the technology will be evaluated, and research and innovation in strategies that contribute to improving the healthcare system will be promoted. It is also expected that these spaces can be used under specific agreements by external institutions.
	Impacts (health, scientific, industrial, socio-economic orothers enabled by the project/initiative	As an experience laboratory, LINNUX will focus on evaluating the usability of technology, software, processes and spaces through observation and testing using specific methodologies including observation, heuristics, usability testing and testing technology such as eye tracking systems. The focus will be on e-Health systems in general and telemedicine in particular, including patients as recipients and end users of all tools. As a creativity laboratory, it will also have the function of raising awareness, research, experimentation, creation and launching of new ideas that are generated from the creative capacities of people through the use of 'design thinking' as a basic tool. In addition, as a prototyping and design laboratory, LINNUX will serve to generate basic designs and prototypes for the conceptualization and testing of equipment as part of the development of new devices that can serve as conceptual tools within the innovation projects of the healthcare system.
	Funding and Investments (pleasespecify the source: public,private, Structural or other types of funds)	This new IDIVAL space has been refurbished thanks to an investment of 60,000 euros from the Directorate General for Digital Transformation and User Relations
	Key stakeholdersinvolved	Healthcare professioanles, patients

6. Trial Nation – one point entry to clinical trials in Denmark

Project | Initiative title		Trial Nation – Clinical trials Denmark
Organization name		Trial Nation is a member-based association. The Ministry of Industry, Business and Financial Affairs, The Ministry of Health, and the five Danish Regions are members representing the Danish healthcare system and the Danish State. The umbrella organisation for patient organisations in Denmark, Danish Patients and the Organization of Danish Medical Societies are members representing their respective spheres.
Country		Denmark
Region		The 5 Regions of Denmark
Contact person		Rasmus Fält (Innovation Consultant)
Contact email		-
Website		https://trialnation.dk/
Keywords		Clinical trials,
Duration		2018-On going
Area of application		Clinical trials, med tech
DESCRIPTION	Main challenges tackled	To provide regional facilities and infrastructure for clinical trials in all therapeutic area
	Objectives	Trial Nation contributes substantially to Denmark's position as the leading public-private ecosystem for clinical trials in Europe – to the benefit of patients, research and both the regional and national economy.
	Main concept and methodologies involved	Trial Nation provides a national set up and governance for facilitating clinical trials in Denmark for all therapeutic areas and phases with a unique network structure within a few selected therapeutic areas. Clinical trials are an example of public-private partnerships – and the strength and potential of common solutions to health care should be capitalised through these public private partnerships. The potential for scale has been shown earlier, as the idea of creating one point of entry started in one of the five Danish Regions (on pharma coordination in few therapeutic areas), and later has expanded to all Danish Regions, more therapeutic areas network structure and also med tech.
	Impacts (health, scientific, industrial, socio-economic or others enabled by the project/initiative	Over the last 2-year period the number of clinical trials has increased by 2.6 times. Furthermore, Trial Nation has, as the first in Denmark, become an Associated Partner on a project of IMI (a EU public-private partnership funding health research and innovation). Trial Nation builds on a Clinical Trial Office from 2012 in the Capital region which became a NEXT (a national Pharma partnership) in 2014 -2018. In 2021 Trial Nation was tasked with overseeing the establishment of the first real-time updated overview of recruiting clinical trials, allowing patients and health-care professionals to find clinical trials that may be suitable for them. Launch is expected 2023. In 2022 Danish Patients and Organisation of Danish Medical Societies changed their status from observatory members to full members on the board of Trial Nation.
	Funding and Investments (please specify the source: public, private, structural or other types of funds)	The 5 regions is paying 6,4 mio. euro in a four-year period (2020-2023). The state payed 2,4 mio. euro. in 2020-2021
	Key stakeholders involved	Regional authorities, citizens

7. ElderTech

Project | Initiative title		Emerging Technologies and vulnerabilities in aged care (ElderTech)
Organization name		Department of Social and Political Sciences (SPS), University of Milan (UniMi,), Department of Oncology and Hemato-Oncology (DIPO),Emerging Technologies and vulnerabilities in aged care (ElderTech), Faculty of Philosophy (FP), San Raffaele University, Milan (UniSR).
Country		Italy
Region		Lombardy
Contact person		Dr Virginia Sanchini
Contact email		sanchini.virginia@hsr.it
Website		-
Keywords		Emerging technologies, older adults, aged care, ethical issues, active aging, vulnerability
Duration		From September 2021 to August 2024
Area of application		
DESCRIPTION	Main challenges tackled	Currently, a wide range of ETs are designed for the elderly. These are a heterogeneous group, both in terms of age and health condition, requiring personalised services, targeted on the individual's characteristics. In spite of this heterogeneity, bioethical reflection traditionally refers to the elderly as a vulnerable population, whether due to intrinsic (e.g., embodiment) or situational factors (e.g., socio-economic aspects).
	Objectives	ElderTech aims to comprehensively investigate and conceptualize the concept of vulnerability when referred to the ageing population and to study the impact of Emerging Technologies (ETs) on older adults' vulnerability, in the context of care, broadly understood. Considering the multiple facets of vulnerability and the pervasiveness of ETs in the daily management/care of the elderly, ElderTech aims to explore if and to what extent ETs devised for the elderly (e.g. wearables, robots and virtual reality) impact on their vulnerability. The final purpose of the project is to design ethics-oriented policies for the implementation and use of ETs for the elderly, i.e. policy guidelines which are both compliant with ethics and privacy requirements, and respectful of elder's individual preferences, expectations, and principles (as resulting from theoretical and empirical evidences collected during the project).
	Main concept and methodologies involved	Objective 1. Mapping definitions and connotations of the concept of vulnerability in aged care Within bioethics and applied ethics mainstream debates, the concept of vulnerability has been mainly developed in the context of human-subject research and defined in relation to the concept of autonomy: vulnerability refers to conditions of impaired and/or diminished autonomy. According to this interpretation, inasmuch as it is considered as "lack of something", vulnerability presents a negative connotation. Subjects who, following this definition, may be defined as vulnerable should be granted protection. Historically, vulnerability has been associated with several categories of agents, amongst which the elderly are paramount. Older adults represent a vulnerable population both in the research ethics domain (i.e. special provisions apply for their enrolment in clinical research) and in the clinical ethics domain (i.e. they are considered as a special category of agents in clinical practice, deserving "personalised" attention). However, before the start of the ElderTech project, no accepted and well-defined conceptualization of vulnerability, when referred to older adults, especially in the domain of clinical ethics, had been provided. Recognizing this conceptual gap in existing bioethics literature, the first specific objective of the ElderTech project was to shed light on the concept of vulnerability when referred to the ageing population, in particular in the aged care context. Methodology: systematic review (i.e. "argument-based review") of relevant scientific literature in scientific databases. Objective 2. Understanding the experiences undergone and the challenges faced

		by older adults in using unconventional ETs, and their impact on aged care vulnerability. In recent years, a great emphasis has been placed on ETs designed for the elderly. In line with this phenomenon, a vast amount of (both theoretical and empirical) literature has appeared exploring the ethical implications – namely ethical advantages as well as threats – of (already or still to be implemented) ETs in the contexts of daily management and care of (frail) older adults. On the one side, this body of scholarship has contended, for instance, that more conventional monitoring techniques (e.g. telemedicine) may allow (frail) older adults to be assisted and/or cured in their home environments, thus prolonging their independence, while also reducing costs and inconveniences due to prolonged admissions and hospital-based commuting. However, some ethical treats may also occur: by gathering massive amount of data, Ambient Intelligence technologies may for instance violate "informational privacy"; the same technological system, by constantly monitoring the elderly, may also impact on older adults' personal liberties, since evidences report that individuals may modify their behaviours as a consequence of knowing of being monitored. In spite of the consistent body of literature exploring the ethical implications of ETs for the elderly, no comprehensive research has been carried out, as of yet, over the impact of ETs on older adults' vulnerability. Drawing from these considerations, the second specific objective of the ElderTech project is to gain an in-depth understanding of whether and how ETs devised for the elderly impact on – and lead towards a reconfiguration of – traditional accounts of vulnerability. Methodology: (i) market analysis, aimed to map currently available ETs specifically devised for older adults; (ii) review of the qualitative evidence (interviews, focus groups, informal observations) exploring perceptions of older adults about the use of ETs. Objective 3. Providing guidance on (the ethics of) ETs for the elderly population. From a public policy perspective, considerable interest has been devoted to the challenges associated with population ageing and the role that ETs can play in elderly care. Already in 2010, the European Commission commissioned a report entitled ICTs&Ageing. Users, Markets and Technologies reviewing available technologies for aged care, and discussing the ethical issues related to ICTs in the ageing domain. In spite of this early discussion, to the best of our knowledge, to date, no regulations, policy documents or ethics guidelines, have been developed either at national or international level, specifically devoted the use and implementation of ETs in the context of aged care. At the EU level, policy documents have broadly targeted the general population, and not specifically the elderly and their needs. Even the legislative act promulgated by the European Parliament in 2017 on robotic issues, entitled Civil Law Rules on Robotics , does not discuss the use of robotic devices in the context of aged care. At the national and local level, the only available document on this topic is the National Guidelines on Telemedicine (promulgated in 2012 and implemented by the Lombardy Region with the Decree X/2989 of the 23 of December 2014) which has been recently updated, but, however, focuses just on telemedicine and only tangentially tackles ethical issues related to our topic. Drawing upon these considerations and related gaps, the third objective of the ElderTech project is to design ethicsoriented policies for the use and implementation of ETs for the elderly, i.e. policy guidelines which are both compliant with ethics and privacy requirements, and respectful of elder's individual preferences, expectations, and principles (as resulting from theoretical and empirical evidences collected during the project). Methodology: Semi-structured interviews and focus groups will be conducted with all relevant categories of subjects involved in the ElderTech Project, in order to elaborate ethically-oriented policies regulating the use of ETs for the elderly: older adults, geriatricians, stakeholders involved in aged care and/or regulation of ETs in aged care and/or in the development and production of ETs for the elderly. This third objective will be achieved in the course of 2023 and 2024.

	Impacts (health, scientific, industrial, socio-economic orothers enabled by the project/initiative	ElderTech aims to have an impact on three fronts: on the regulatory field, the academic field, and the public field. This means, respectively, creating new policies, conducting research to advance knowledge on the subject, and raising awareness by disseminating the results. The first, practical, impact of ElderTech is the production of ethically-oriented guidelines for the implementation and use of ETs in aged care, which will have regional and national impact, thus bridging the current gap in this area. These guidelines will be committed to the Personalised Health ideal, since they will also be based not only on theoretical investigations but also on the analysis of the perspectives of those who are directly involved in the field of care: the elderly, the treating physicians, and relevant stakeholders. Secondly, ElderTech, through scientific publications in leading national and international journals, aims to contribute to the scholarly debate, in particular to the bioethical debates around vulnerability in aged care, as well as the ethics of ETs in aged care. Finally, ElderTech has organized several dissemination activities and is committed to publishing informative articles for the lay public in order to establish an active dialogue with the widest audience possible, i.e., not only academic experts, but also the main stakeholders involved in aged care and in the production, implementation and regulation of ETs, and the general public. Examples of scientific outreach are two informative articles, one published on the website La Statale-News (link: https://lastatalenews.unimi.it/eldertech-nuove-tecnologie-per-cura-anziani) and one published on the website of Fondazione Giannino Bassetti, whose aim is to foster responsible innovation, in order to facilitate the engagement with the civil society for stakeholders' involvement, for the dissemination of Emerging Technologies and for the promotion of Responsible Research and Innovation (link: https://www.fondazionebassetti.org/it/focus/2022/10/alla_scoperta_dei_risultati_di.html).
	Funding and Investments (pleasespecify the source: public,private, Structural or other types of funds)	The project is funded by the Cariplo Foundation
	Key stakeholdersinvolved	Lombardy Region, citizens, academics, regional policy