e-ISSN 2544-1620

Medical Science Pulse 2019 (13) 3

Reviews

DOI: 10.5604/01.3001.0013.5497

INTERREGIONAL COORDINATION FOR A FAST AND DEEP UPTAKE OF PERSONALISED HEALTH (REGIONS4PERMED) – MULTIDISCIPLINARY CONSORTIUM UNDER THE H2020 PROJECT

Gianni D'Errico[1]
Paola Giulia Cormio[1]
Paola Bello[2]
Marta Duda-Sikuła[3]
• ORCID: 0000-0003-1715-8958
Antoni Zwiefka[4]
• ORCID: 0000-0002-1300-9229
Dominik Krzyżanowski[4,5]
• ORCID: 0000-0003-0255-7163
Eva-Maria Stegemann[6]
Beatriz Allegue Requeijo[7]
José María Romero Fidalgo[7]
Donata Kurpas[8]
• ORCID: 0000-0002-6996-8920

[1] Fondazione Toscana Life Sciences, Siena, Italy
[2] Fondazione Regionale per la Ricerca Biomedica, Milano, Italy
[3] International Scientific Projects Section, Wroclaw Medical University, Poland
[4] Lower Silesian Voivodeship Marshall Office, Wroclaw, Poland
[5] Division of Medical Social Sciences, Wroclaw Medical University, Poland
[6] Saxon State Ministry for Higher Education, Research and the Arts, Dresden, Germany
[7] Galician Health Knowledge Agency ACIS, Santiago de Compostela, Spain
[8] Family Medicine Department, Wroclaw Medical University, Poland

A – study design, **B** – data collection, **C** – statistical analysis, **D** – interpretation of data, **E** – manuscript preparation, **F** – literature review, **G** – sourcing of funding

ABSTRACT

Personalised medicine (PM) represents a paradigm shift away from the 'one size fits all' approach to the treatment and care of patients with a particular condition, to one which uses emergent technologies such as diagnostic tests, functional genomic technologies, and molecular pathway profiling to better manage patients' health and employ target therapies. The current challenge for national and regional authorities is to facilitate the shift from a reactive healthcare system based on episodic and acute care models to a personalized health (PH) system that uses preventive and predictive measures, where at-risk individuals are stratified to intervene before the onset of symptoms or risk is predicted using cutting-edge technologies before symptoms appear. While PH is paving the way toward better and more efficient patient care, it still lacks the cooperation and coordination needed to organise the fragmented field, which is a severe drawback to its development and to the placement of effective financial investments. For this reason, it is crucial to direct major efforts towards coordinating and aligning relevant stakeholders across Europe and beyond, creating a participatory approach, building trust, enabling a multi-stakeholder process, and channeling investments towards PH. Thus, Regions4PerMed aims to coordinate regional policies and innovation programmes in PM and PH to accelerate the deployment of PH for patients.

KEYWORDS: personalised medicine, personalised health, prevention, regional policies interregional cooperation

Background

The Horizon 2020 Advisory Group has defined personalised medicine as "a medical model using characterisation of individuals' phenotypes and genotypes (e.g. molecular profiling, medical imaging, lifestyle data) for tailoring the right therapeutic strategy for the right person at the right time, and/or to determine the predisposition to disease and/or to deliver timely and targeted prevention" [1].

Scientific evidence shows that a change in the model from "high-risk population models" to a "whole population model" [2] would allow huge gains, both for patients in term of health and for healthcare systems in terms of cost reduction. In this context, personalised medicine becomes a basic/translational research approach. Moreover, as we develop a system that uses data and technology to provide personalised care, the concept of personalized medicine broadens and needs

to include variables such as policy, regulation, industry, technologies, and patient associations. A better use of data and technology has the power to improve health and to improve the quality of health and care services while simultaneously reducing the cost.

Regional ecosystems are increasingly characterised by strong leadership, a culture of openness and learning, and commitment to being 'data-driven'. This is a critical observation because in countries where health policies are shaped and applied at the federal level, regions are the focal point in the process of transforming European health and care policies towards sustainable and resilient systems.

Scientific and technological advancements need adequate, community-tailored policy frameworks that enable uptake of personalised medicines and health. Deep knowledge of the demographic, epidemiological, academic and industrial context of the healthcare system, together with its financial capacities, allows regions to plan and implement strategic investments to adapt and modernise key enabling health infrastructures. The possibility to establish joint collaborations with other EU regions reinforces their capacities and multiplies impacts while minimising risks. In addition, these collaborations can pave the way to the setting of transnational and transregional models for healthcare that can be replicated in less developed regions and countries thus empowering citizens and patients. At a regulatory level, cross-regional collaborations are the key to increase data interoperability and to multiply the impact of health investments while ensuring adequate levels of training for health professionals. This effort will eventually result in a reduced burden from chronic disease, enhanced capacity for disease prevention, and it will support the development of new medicines and treatments.

Taken together, then, the real challenge for national and regional authorities is to tackle the shift from a reactive healthcare system based on episodic and acute care models to a preventive and predictive health care system. The preventative and predictive health care system is one that stratifies at-risk individuals and ensures that preventive action is taken to intervene well before the onset of symptoms and one that leverages and integrates cutting-edge technologies to not only stratify risk but to predict risk and intervene even before symptoms appear.

In the face of this potential huge leap forward, personalized health (PH) lacks the cooperation at the regional, interregional, and intergovernmental level to coordinate and to organise an adequate level of policy and investments. This represents a severe drawback to effective PH development. For this reason, major efforts need to be directed toward coordinating and aligning regional stakeholders like public institutions, governments, industry, civil society, and patient organisations into action across Europe and beyond in order to create a participatory approach, build trust, enable a multi-stakeholder process, and channel investments towards PH.

The administrative structure of countries, i.e. the competencies and the autonomy of the regions, accounts for the diversity of the regional innovation strategy for smart specialization (RIS3s). For example, regions that have responsibilities in the healthcare system can address PH more globally, linking research and health policies. One recognised added value of RIS3 is the association of policy makers, industries, public stakeholders and the breaking up of data silos through top-down strategies.

These considerations are taken into account by European policy makers. In order to assess the status of interregional coordination in PM, a workshop was organised in Brussels on May 4, 2017, by the European Commission with the aim to compare the regional strategies on PM and to:

- Disseminate information on the role of personalised medicine in regional R&I Smart Specialisation Strategies (RIS3) on European PM activities and on the International Consortium for Personalised Medicine (ICPerMed).
- Exchange information and views on how PM is prioritised at the regional level and on how R&I activities are being implemented at a regional level.
- Identify needs and possibilities for interregional cooperation and synergies for PM R&I.
- Identify information gaps and needs for further data collection/analysis.

Within the workshop, some main challenges have been identified which Regions4PerMed will address:

- Establish a platform and initiative to facilitate interregional cooperation in PM.
- Organise and employ infrastructures, programmes and financial instruments in a way that brings together all relevant stakeholders (public authorities, SMEs- Small and Medium-sized Enterprises, universities, healthcare providers, etc.) and that creates a favourable ecosystem for the development and the implementation of personalised medicine.
- Support the ICPerMed network (the International Consortium for Personalised Medicine) in facilitating a fruitful dialogue between regions, health ministries and research funders.
- Implement reflection and actions to organise the flow of information, share experience, identify barriers, spread good practice, and facilitate dialogue and cooperation between regions. This should include the organisation of similar events that involve more regions.
- Seek tighter contacts between the regions and the Programme Committee for the specific programme implementing H2020 (Configuration 'Health, demographic change and well-being') [3].

Objectives of the Project

Regions4PerMed's overarching goal is to set up the first interregional cooperation on PM, align strategies and financial instruments, identify key investment

areas and release a European regional agenda in order to foster the delivery of PH services to patients and citizens. The consortium was established to:

- Support the coordination of regional policies and innovation programmes in PM in order to accelerate the employment of PM for citizens and patients.
- Strengthen cooperation between Horizon 2020 and ESIF on PM aspects.
- Ensure complementarity between RIS3 diagnostics priority and RIS3 personalised medicine priority mappings.
- Establish a permanent dialogue between European regions regarding a fast and full implementation of PM.
- Strengthen industrial specialisation areas in Europe and allow PM to flourish as an emerging industry.
- Enable interregional joint investment on PM including a stable link with the Vanguard Initiative and with the European Innovation Council.
- Provide guidance to the EC for the next Multiannual Financial Framework (MFF) as well as Research Framework Programme.
- Provide guidance to EC, Member States and regional authorities on the next European Structural and Investment Funds (ESIF) Operational Programme.

The other specific objectives of the project are:

- Organise the technical dialogue among regions around five Key Strategic Areas (KA) and through five thematic workshops.
- Provide a final action plan of strategic areas of investments.
- Establish a HUB of European initiatives and partnerships on personalised medicine (PerMed HUB).
- Contribute to the realisation of the IC PerMed action plan.
- Provide guidelines in the form of a report to regional authorities on how PM can boost local economies and keep the EU competitive.
- Provide guidelines in the form of a report on how to address PM within the Smart Specialisation Strategies (RIS3).
- Build and maintain a database of PH research and innovation and monitor programmes and projects that can be easily replicated elsewhere [4].

Methodology

At the core of the project are five regional authorities and organisations representing European regions strongly committed to PM and the Wroclaw Medical University as an academic partner of the consortium. These authorities act as the Executive Board for the interregional coordination and are mainly responsible for the implementation of the project activities concentrated around the five key strategic thematic areas: medical big data and health medical records, connected health in terms of better system integration and patient management, health industry in the context of healthcare innovations, facilitation of the innovation flow in the healthcare and socio-economic aspects rationale.

Regions4PerMed establishes a continuous dialogue among the European PM community. It brings together regional authorities that primarily take decisions, academics and stakeholders within organised cross-sectoral and cross-regional workshops and conferences on the five key thematic areas.

This dialogue is organised into five steps:

1. Elaboration of a preparation paper which analyses the state-of-the-art aspects and highlights the challenges of each Key Strategic Area.
2. Organise a thematic interregional workshop around the topic. Carry out five capacity-building workshops for regional authorities in order to build up expertise and skills within the regional authorities about the use and exploitation of the knowledge created within Regions4PerMed.
3. Organise five conferences in different regions and cities in order to have a wider geographical outreach, plus the kick-off and the final conference.
4. Carry out two *in situ* visits for each Key Strategic Area to highly innovative labs, institutes or companies and gather innovative models and best practice examples.
5. Issue a workshop report containing, among others:
   a. Policy recommendations for European, national and regional policy makers.
   b. R&D investment recommendations.
   c. Innovation models and best practices.

The methodology sought in order to achieve the project objectives is based on the organised technical dialogue with relevant stakeholders [4].

Key strategic thematic areas undertaken in the project

1. Medical Big Data, Electronic Health Records and Health Governance

Technological innovation has triggered an explosion in data production that will soon reach exabyte proportions. There is great potential for "big data" to improve health, but at the same time, "big data" also engenders new challenges. One emerging challenge is the issue of capacity, where the amount of data generated will strain the infrastructure of an individual hospital or institute. Integrated solutions for data sharing and analysis will need to allow for the combination of data coming from multiple sources and potentially different research disciplines. At the European level, one of the main hurdles is the construction and sharing of a common data storage platform for research purposes. Service models need to be developed in order to deliver better health care and strengthen the health industry.

Big data technology has many applications in healthcare, such as predictive modelling, clinical decision support, disease or safety surveillance, public health, and research. Big data analytics frequently exploit analytic methods developed in data mining like classification, clustering, and regression. Technologies that can extract large quantities of data from samples or biopsies are permitting discovery of previously unknown disease factors, which may be utilised as drug targets or disease biomarkers. Data is also able to expose the complexity of a disease, especially cancer, and it can highlight the fact that there will never be one drug or treatment option that works for every patient. Through the "datafication" of patient tissue samples and genomic fingerprints, clinicians can systematically extract more information from each patient without requiring multiple rounds of testing. By having all available information at the same time while determining diagnosis and the patient prognosis, the best treatment decisions can be made on an individual basis at a faster rate. National health systems are heterogeneous in terms of the level of government influence, main source of financing, and main levels of organization. Some systems, for example, are self-governed as in Germany, some have regional autonomy, while others are national systems. Moreover, some systems are tax-financed and some deduct a fee from monthly income. Hence, solutions and fundamental approaches differ between European member states and are not entirely portable and scalable.

As recalled in the EC Communication on digital health, health care systems in Europe face serious challenges [5] such as ageing, chronic disease, multi-morbidity, health workforce shortages, the rising burden of preventable, non-communicable diseases caused by risk factors such as tobacco, alcohol, and obesity, as well as other neuro-degenerative or rare diseases [6]. Public spending on health and long-term care is steadily rising in EU Member States and is expected to continue to do so. In 2014, the EU-28's total healthcare expenditure was €1.39 trillion (10% of the EU's GDP). This is expected to increase to 30% by 2060. These trends pose significant problems for the sustainability of EU Member State health care systems.

Even though the health sector is data intensive, the data has been underutilized for enhancing public interests.

While health data is available in various forms and formats, it is not managed in the same way by all EU Member States, nonetheless within an individual national health system. Furthermore, health data is often difficult to access by patients themselves or by medical staff or researchers that develop and deliver better diagnoses, treatments or personalised care. Even where it exists, health data often depends on technologies that are not interoperable, thus hindering its wide-spread use [5].

Big data is also becoming a crucial tool for leading companies to outperform their peers. This is especially true in the health sector where the quality, availability, and accessibility of health-related data is vital to maintain a competitive stake in the European health industry, in which medical technologies can boost the economy, employment and efficiency of health care system as a whole.

Among the technical challenges to be solved is the lack of standards applicable to collecting, analysing and storing data. Additionally, the potential for health funding agencies to promote standardisation is still untapped even though standardisation also affects the technological developments and the industrial competitiveness of the health industry.

Big data and digitalisation can support measures to promote health and prevent disease, as well as to reform health systems, ease the transition to new patient-centred care models, and to integrate new care structures [7,8].

The aim of this Work Package is to explore all the potential, the risks and the roles that regions can play in the governance process of health data, focusing on Electronic Health Records (EHR) and health research data.

Data can be a key enabler of digital transformation and development of new forms of technology, to benefit patients and healthcare staff, and to aid medical research and health technologies industries. Nonetheless, the increasing amount of data and the collection, storage, access and protection of the data have created numerous legal, economic and ethical issues. Current national legislations struggle to manage these issues and are trying to find a common ground for regulating IT technology and its impact on citizens.

Big data technology has a variety of healthcare applications, such as the creation of electronic medical records (EMRs), predictive modelling and clinical decision support, disease or safety surveillance and research. Big data analytics frequently exploit analytic methods developed in data mining, including classification, clustering, and regression [9]. A recent article published in Science [10] highlighted the potential healthcare applications of big data. The UK Biobank recently made a systematic analysis of the full genotyping data of 500,000 people available to 7000 registered researchers. The UKB data is being used for 1400 projects and has resulted in nearly 600 published papers, focusing on the link between gene variants to a disease or trait such as arthritis, type 2 diabetes, depression, neuroticism, and heart disease, for example.

If PH is to be realised, tremendous amounts of data specific to an individual must be captured, synthesised and presented in an analysed form to clinicians when care decisions are needed. This can only be accomplished by using sophisticated EHR systems that are designed to support this function. By having all available information at the same time while determining diagnosis and patient prognosis, it would be possible to ensure the best and most timely treatment decisions on an individual basis.

On a larger scale, a joint declaration on artificial intelligence was recently signed to create a cloud infrastructure for data sharing to ensure Europe's competitiveness in the research and deployment of AI and to deal with the associated social, economic, ethical and legal questions. On the heels of this declaration, the new General Data Protection Regulation (GDPR) was initiated and it influences the exploitation of big data in healthcare. Among others, some big data challenges to be addressed are 1) how to enable cross-border data exchange, 2) how to promote legal, organisational, semantic and technical interoperability, 3) alignment of the OECD council recommendations and EU privacy regulations, 4) creation and dissemination of codes of conduct on how to handle secondary data use and how to de-identify patient data for secondary use [4]. Other challenges that emerged throughout the year of new big data initiatives were the need to invest in staff and not just infrastructure and the need to demonstrate the benefits of big data.

2. Connected health: Better system integration and patient management

With many personal human genome map initiatives launched worldwide (Personalised Medicine Initiative in the USA, 100.000 Genomes Initiative in the UK and the Million European Genomes Alliance in Europe), it is possible to envision a future where treatments are tailored to individuals' genetic structures, prescriptions are analysed in advance for likely effectiveness, and researchers study clinical data in real-time to determine success. The implementation of these regimens will create a situation where treatments are better targeted, health systems save money by identifying therapies not likely to be effective for a particular patient, and researchers have a better understanding of comparative effectiveness [11].

Yet, despite these benefits, consumer and system-wide gains remain limited due to an outdated policy regime. With scientific innovation running far ahead of public policy, physicians, researchers, and patients are not receiving the full benefits of the latest developments. Current policies need to leverage new advances in genomics and PM in order to individualise diagnosis and treatment. Similarly, policies creating incentives for the adoption of health information technology should ensure that the invested infrastructure is one that supports new-care paradigms as opposed to automating yesterday's health care practices.

European health systems require a seamless and rapid flow of digital information, including genomic, clinical outcome, and claims data. Research derived from clinical care must feed back into assessment in order to advance care quality for patients. Currently, there is discrete data on diagnosis, treatment, medical claims, and health outcomes that exists in parts of the system, but it is hard to determine what works and how treatments differ across subgroups. As more information on treatment, lab tests, genomics, and costs is integrated into healthcare, it is hard to incorporate data from medical history, vital signs, genetic background, and lab testing into diagnosis and treatment. Predictive modelling represents a way for physicians to move towards systematic and evidence-based decision-making. While the first step toward enabling personalised medicine is to ensure clinicians have access to what is known about patient gene variants, computer models can go beyond this approach and predict which treatments are likely to be most effective given observed symptoms. Public policy should incorporate rapid learning and predictive modelling to gain the full benefits of PM.

Concerning the emergence of Artificial Intelligence (AI), it is necessary to deal with its effects on the transformation of the market in an appropriate and contemporary way. An environment of trust and accountability including analysis of new legal and ethical questions will permit healthcare systems to benefits fully from AI.

Finally, the combined intellect of the leading European experts in e-health and m-health (mobile health) is required to identify future approaches to e-health/m-health that can redefine ways of interaction within the healthcare system. All mentioned connecting systematic approaches and platforms require consented, open and interoperable connections that follow international standards. This does not only apply to existing aspects, e.g. IHE profiling, but also to defining new standards on topics like cross-platform authentication and data exchange. Standardisation in healthcare services is a major requirement for improving patient treatment by way of modern technology.

All this considered, the second phase of the project will address:

- m-/e-health technologies for continuous monitoring and self-empowerment;
- m-/e-health technologies for data integration;
- AI for predictive models;
- Personal data management;
- Remote monitoring and tele-assistance.

One of the main goals of this phase is the employment of medical data registered systems. Additionally, this phase aims to increase big data capacity to solve such problems as the poor quality of collected medical data, like weak or insufficient, incomplete, or incorrect data, or data saved in various formats, for example. Big data could also improve medical professional and patient awareness regarding medical event documentation and could provide diagnostic support and therapy personalisation through the use of AI. It could also support the creation of information and communication technology (ICT) systems for data collection and their enhancement for PM in European regions, enabling a personalised approach to integrated care for the elderly based on the use of intelligent ICT solutions.

The other goal considered in this phase is to increase knowledge and to strengthen the involvement of citi-

zens and communities in the monitoring system; measurable /inadequate use of ICT is the result of inadequate access to medical data and lack of trust in its quality.

Also, integrated care for patients with multiple diseases is going to be discussed in this phase using Multi-Criteria Decision Analysis (MCDA). MCDA will account for understanding care-focused people, improving the health and well-being of citizens through integrated health care, implementation of integrated care systems, innovative models of integrated care and systems, and assessment and improvement of monitoring quality. Implementation of this new model of integrated care needs to occur quickly to meet the increasing demand for such care due to the aging of the European population and the increase in vulnerability, cognitive impairment and chronic diseases associated with the aging process [4].

3. Health industry: Driving healthcare innovations

Currently, a diagnosis is made using tests and investigations of a patient's symptoms. However, while two patients might share the same symptoms, the underlying cause could be different. Knowledge of an individual's complex molecular and cellular processes, informed by other clinical and diagnostic information, will help to more fully determine the true cause of the symptoms. Precision diagnoses can be further optimised when coupled with new technologies such as those that provide rapid and real-time results and those that can be used at the point of care.

These technological developments have the potential to significantly change the way that the health industry operates to the benefit of the patient. Due to an ageing population and the current increase of lifestyle-related diseases, the cost of healthcare is expected to increase significantly. The healthcare industry is among the fastest growing industries and it is expected to continue its significant growth. The further development of PM and especially of PH has the potential to cause a quantum leap in respect to the efficiency of the healthcare system and to ensure its long-term sustainability. The developments in PM and PH may change the entire way the healthcare industry operates, shifting toward prediction and prevention of disease instead of curative treatments.

To enable this drastic change in how the healthcare industry operates, several steps need to be taken. First, there is a need to distinguish health research from clinical practice. Mechanisms to connect data from multiple sources into databases for secondary research use and population cohort analysis need to be established. It is nearly impossible to evaluate treatment effectiveness without being able to aggregate data and compare results, thus big data needs to be accessible and usable. Faster knowledge management could enable physicians and public health officials to employ "rapid learning" models and evidence-based decision-making. Fundamental innovations often flow from basic research to clinical studies to different scaling-up stages; it is the task of policy makers to facilitate this process by providing the necessary framework for successful translation especially where innovations may have a disruptive character on current healthcare processes. This holds true for several relevant aspects:

- Exchange of research data, including data interoperability and access to databases.
- Intellectual property rights, its tangibility and exchange.
- Transfer of relevant information between neutral market actors like networking agencies, non-governmental organizations (NGOs), and public or governmental consulting bodies.
- Entrepreneurial activities, foundation of SMEs, exit strategies.
- Private venture capital, public sources of capital to ease market access or change of market.
- Reimbursement policies regarding innovative technologies or processes and their introduction to state-paid or self-governed systems.

It is furthermore necessary to broaden the widely accepted, but narrow view on the costs and benefits of introducing e-health/m-health and of implementing a PH approach. Healthcare industry partners, SMEs and research institutes would greatly benefit from a coordinated European approach to include quality of life and systemic outcome measurements in the cost-benefit analysis. Ultimately, the value of preventive and predicative approaches needs to be assessed in light of possible reimbursement policies for these approaches to make them financially more attractive when compared to the current primarily curative approaches.

Also, even discounting spin-offs, a major share of innovation is created by SME's. SMEs are therefore crucial for the further development of the health industry. They have a significant role in the following fields:

a. Diagnostics such as in vitro diagnostic devices (IVDs), genomic diagnostics, biomarkers, medical devices, and imaging.
b. Technological transfer.
c. Disease management innovative tools.
d. New business models for a wider health market uptake.
e. Payment models.

This key strategic area will be elaborated in the third workshop and will impact clinical studies, joint research, standardisation, Living Labs, training, technology transfer and demonstration activities [4].

4. Facilitate the innovation flow in healthcare

PM must play a decisive role in the long-term sustainability of health systems. The one-treatment-serves-all-patients traditional approach seems unsustainable, inefficient, and it offers low-value interventions to patients. Implementation of PM has the potential to

reduce financial and time expenditures and to increase quality of life and extend the lives of patients. This next technological revolution – the technology redefining the healthcare industry of the future – combines highly powerful biotechnologies like biomarkers, genetics or proteomics with vast amounts of available data, cloud computing services, machine learning, artificial intelligence (AI)-based or similar ICT solutions. Together, these provide expert insights and highly valuable information to support clinical decision at a relatively low cost. Presently, connected medical devices and highly innovative diagnostics together with stratification technologies are already transforming the way the healthcare industry works. The widespread adoption of technology-enabled care will ensure that the concept of the "Smart Hospital" becomes a reality. The industry appears ready to deploy these technologies in large healthcare settings, but open-minded healthcare organisations are also needed in order to pave the way for the future. Some regional and national systems have already created innovation tools like Innovative Procurement and screening programmes to facilitate the adoption of these technologies in routine hospital practices. Other healthcare organisations are creating and refining systems to increase and accelerate the innovation flow around PM in their facilities. Hospitals are also favouring links with industry through their research and innovation infrastructures. Important lessons learned from all these experiences will help to accelerate the adoption of PM technologies across Europe. They should also contribute to the definition of new policies and investment decisions at European, national and regional level. The fourth workshop will invite leading organisations and experts with successful programmes and experience in the adoption of PM technologies by healthcare organisations, and it will be organised around five sub-areas:

a. Research & Innovation infrastructures exploitation models to boost innovation
b. Innovative Procurement Tools (PCP & PPI)
c. Screening and prevention programmes
d. Procurement based on clinical outcomes from PM technologies
e. Smart and future hospitals [4].

5. Socio-Economic Aspects Rationale

From an economic point of view, personalised health, intended as a paradigm shift from a reactive to a preventive and predictive healthcare, poses some concerns. Massive financial investments are required to modernise the European health systems and personalised health needs to become a new driver for the economy as building and automotive sectors have been in the past century. Investment policies should facilitate the integration of different industrial sectors. The transition to personalized health will also help to achieve healthcare sustainably, which is currently a major challenge.

Another major concern is the possible inner discrimination of personalised health and the necessary mitigation by policy interventions. In fact, as PH potentially offers 1-to-1 services, the costs tend to increase and the access to the best care available might be hampered. Therefore, in order to guarantee the social and economic sustainability of healthcare, according to Prof. Borgonovi [12], PH needs to produce changes in A) training/education, in training new managers and professional figures; B) vertical integration between basic, translational research, technological development and innovation processes; C) empowering patients and citizens; 4) guaranteeing interdisciplinary approaches. In the last ten years, as the technology and promise of personalised medicine developed, bioethics scholars began to contemplate the ethical, legal, economic and social implications of the applications of this approach to medicine, forming the field of investigation known as 'ELSI' scholarship. Some of the foundational issues considered were safety and efficiency, informed consent, access to PH and reimbursement. In recent years, technologies such as next-generation sequencers and gene expression assays have become less expensive and more suitable for clinical application, and as a result, personalised medicine has become established in a growing number of clinical areas. With these clinical applications, however, the implications of personalised medicine have expanded in scope and complexity. This trend is likely to continue in the coming years, with wider adoption throughout the healthcare system creating a need to broaden the focus of ELSI scholarship. Finally, PH needs to guarantee that the criteria of the so-called Responsible Research and Innovation are met regarding public engagement, gender, ethics, and open science. Additionally, principles like social justice/inclusion, sustainability, privacy, transparency etc. are to be respected. According to the 1st Interregional Workshop on personalised health in Milan on April 11, 2018, personalised health in terms of RRI needs to guarantee data access and control, avoid excessive claims and promises from research findings and avoid genetic discrimination and misuse of genetic profiling. This Key Strategic Areas will explore regional challenges from the following points of view:

a. Regulatory
b. Economics
c. Cultural
d. Responsible Research and Innovation
e. Gender discrimination [4].

Expected impact

The most important impact of Regions4PerMed will be a strengthening of links between European regions setting up or planning personalised medicine healthcare approaches. This will be achieved by ensuring regional representatives interact directly with each other, sharing activities, plans and strategies on PM, exchanging views and concerns, finding fields of cooperation, and finally, committing themselves to concrete joint cooperation actions in the short-medium term.

Commitment is crucial for any real and lasting impact. Therefore, the Consortium will maximise its efforts and leverage already established projects and initiatives.

Stakeholders relevant to PM in each region and Europe-wide will come together in the frame of Regions4PerMed and exchange best practice as well as highlight the key challenges ahead. The continuous technical dialogue through preparatory papers, thematic workshops, and on-site visits will thus ensure policy makers receive the best possible information and advice, and in consequence, will minimise risks to PM employment on the political level. Regional representatives will have the opportunity to understand how other EU regions are tackling relevant challenges, get state-of-the-art analyses from relevant stakeholders, share views and update policies, contribute to shaping a common agenda, and identify common investment areas.

Overall, this will result in a coherent, science-founded basis for decision-making [4].

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Word count: 5142 • Tables: – • Figures: – • References: 12

Sources of funding:
The Coordination and Support Action Regions4PerMed has received funding from the European Union's Horizon 2020 research and innovation programme under grant agreement No 825812.

Conflicts of interests: The authors report that there were no conflicts of interest.

Cite this article as:
D'Errico G, Cormio PG, Bello P, Duda-Sikuła M, Zwiefka A, Krzyżanowski D, Stegemann E-M, Allegue Requeijo B, Romero Fidalgo JM, Kurpas D. Interregional coordination for a fast and deep uptake of personalised health (Regions4Permed) – multidisciplinary consortium under the H2020 project. MSP 2019; 13, 3: 60–67.

Correspondence address:
Donata Kurpas, MD, PhD, Assoc Prof.
Wroclaw Medical University
ul. Syrokomli 1, 51-141 Wrocław, Poland
Phone: (+48) 606 323-449
E-mail: dkurpas@hotmail.com

Received: 30.08.2019
Reviewed: 18.09.2019
Accepted: 30.09.2019