Kick-off Conference Milan 28.11.2018

Report

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Acknowledgment

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Interregional collaboration for a fast and deep uptake of personalised health – Regions4PerMed

Kick-off conference report

Summary

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	Participant organisation name	Short Name	Country
1	**Toscana Life Sciences (Coordinator)**	**TLS**	**IT**
2	Sächsisches Staatsministerium für Wissenschaft und Kunst	SMWK	DE
3	Axencia Galega para a Xestión do Coñecemento en Saúde	ACIS	ES
4	Lower Silesia Voivodeship Marshal Office	LS	PL
5	Fondazione Regionale per la Ricerca Biomedica	FRRB	IT
6	Wroclaw Medical University	WMU	PL

Regions4PerMed

D7.1-Kick-off Conference Report

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Background

The European report on the state of Health in the EU[1] concluded that only by fundamentally rethinking our health and care systems can we ensure that they remain fit-for-purpose. This means systems that aim to promote health, prevent disease and provide patient-centred care, meeting citizens' needs. Health and care systems require reforms and innovative solutions to become more resilient, accessible and effective in providing quality care to European citizen.

«Europe's health and care systems face serious challenges. Such as ageing, management of patients with multi-morbidity, health workforce shortages, and the rising burden of preventable non-communicable diseases caused by risk factors such as tobacco, alcohol, and obesity, and other diseases including neuro-degenerative and rare diseases. Public spending on health and long-term care is steadily rising in EU Member States and is expected to continue to do so».

Digital solutions for health and care can improve health and wellbeing of EU citizen and radically **change the way health and care services** are delivered to patients, whether designed purposefully and implemented in a cost-effective way[2]. Digitalisation can support continuity of care strategies, even across borders, an important aspect for those who spend time abroad for business or leisure purposes. Digitisation can also help to promote health and prevent disease, including in the work place. It can support the reform of health systems and their transition to new care models, centred on people's needs and enable a shift from hospital-centred systems to more community-based and integrated care structures. Digital tools can translate scientific knowledge into helping citizens remain in good health, thus helping to ensure that they do not turn into patients. They also have the potential to enable a better use of health data in research and innovation to support personalised healthcare, better health interventions and more effective health and social care systems.

Data, in this context, is a **key enabler** for digital transformation. Health data may be available in various forms; it is not managed in the same way in all EU Member States or within national health systems. It is often not even available to the patients themselves or to public authorities, medical professionals or researchers to help them develop and deliver better diagnosis, treatment or personalised care. Even where it exists, health data often depends on technologies that are not interoperable, thus hindering its wide use.

In terms of efficiency and efficacy of health systems, prevention has been estimated to offer an enormous return on health expenditure, be it through better health outcomes, higher productivity and employability, or saved treatment costs. At the moment, Member States and regions continue to devote only a small fraction of their attention and resources to preventive interventions (roughly 3%).

1 1 State of Health in the EU "Companion Report 2017", https://ec.europa.eu/health/state

2 Brussels, 25.4.2018 COM(2018) 233 final COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society {SWD(2018) 126 final}

Non-communicable diseases account for the vast bulk of the money spent by health and social systems (up to 80% of health care costs according to a 2012 report), but they are, to a large extent, preventable. Many non-communicable diseases share the same behavioural risk factors, such as smoking, alcohol consumption, unhealthy diets and physical inactivity. And the EU as a whole is not doing well when it comes to these risk factors. For instance, almost one in five 15-year-olds is obese or overweight and Europe is the region with the highest alcohol consumption in the world.

According to estimations reported in each of the Country Health Profiles, 30% of the overall burden of diseases across the EU can be attributed to such risk factors. In fact, due to dietary risks alone EU citizens collectively lose nearly 15 million life years – each year[3]

No discussion on risk factors, determinants of health or prevention is complete without a better understanding of their intricate relation to broader inequalities within society at large. Life expectancy across EU Member States has increased by more than six years since 1990, rising from 74.2 years in 1990 to 80.9 years in 2014. However, as became clear from the **State of Health in the EU profiles**, not all population groups have benefited in the same way from these advancements: major inequalities persist not only across but also within countries.

It is clear that medicine and medical research is becoming highly data intensive and we need new methods and new tools to analyse this data for the whole benefit of citizen and patients. It is also clear that technologies like Artificial Intelligence, HPC has the potential to radically advance personalised health and medicine and it is fair to say we are at the verge of a revolution. For the first time it is possible to integrate continuous data from different medical disciplines, different organ systems and genetics towards a comprehensive scientific and clinical understating of health trajectories of individuals so that we can make tailored preventive decisions in time.

This is a worldwide race, and this race will be strongly determined by technology and analytical capabilities, availability of health related data of high quality, the capacity of the industry to generate innovation and the capacity of health care systems to promote and absorb these innovations into clinical practice.

In Europe, Regions are the key element to build the bridge from data driven discoveries & hypothesis driven science to innovative solutions and healthcare systems. In many Countries regions are responsible of health budget, and bear the political responsibility of the quality of care that is delivered to patients and citizens. They have the political power to reform and invest in the infrastructures which are at the core of good science and qualitative care

They can leverage a wide range of financial instruments and enable transformations in line with the geographical, academic and industrial structure.

[3] 2017 report of the European Observatory on Health Systems and Policies.

Connected to the advances that science and technology are enabling, new challenges are posed to law and ethics by genetics, genomics and the possibility of achieving meaningful personalized medicine in the future. Personalised Health and medicine also involve complex issues such as privacy, liberty, discrimination and market economics, which will need to be tackled and addressed by Regions4PerMed.

Why Regions?

The health care decision-making and innovation studies literature has shown that the role of science in decision-making on health innovation is influenced by the characteristics of evidence, e.g. accessibility of economic evaluation[4], and processes at the individual level. Regional ecosystems, for which we intend the collaboration and continuous dialogue between regional decision-maker and local health stakeholders, is more and more characterised by strong leadership, a culture of openness and learning, and commitment to being 'data-driven'[5].

As in many European areas health policies are responsibilities of local (regional) decision makers, the use of evidence is enormously influenced by local pressure (e.g. professional groups tend to use local systems to legitimise innovations, while local systems can frame evidence in particular ways to influence activity at lower levels[6]).

This leads us to suggest that, when it comes the implementation of personalised health and medicine (which encompasses the integrated collection of health related data for research purposes, reorganisation of the healthcare system, investments in shared data infrastructures, facilitation of the market placement of innovative heath technologies, etc.), the dimension of regional ecosystem becomes essential in the national and European landscape.

In this context the project Regions4Per Med has been shaped and it was launched on November 28th 2018, during the inter-regional conference in Milan.

4 Merlo G, Page K, Ratcliffe J, Halton K, Graves N. Bridging the gap: exploring the barriers to using economic evidence in healthcare decision making and strategies for improving uptake. Appl Health Econ Health Policy. 2015;13:303–9.

5 Teng F, Mitton C, MacKenzie J. Priority setting in the provincial health services authority: survey of key decision makers. BMC Health Serv Res. 2007;7:1–10.

6 Simon Turner, Danielle D'Lima, Emma Hudson, Stephen Morris, Jessica Sheringham, Nick Swart and Naomi J. Fulop; Evidence use in decision-making on introducing innovations: a systematic scoping review with stakeholder feedback

The workshop 0 in April 2018[7].

On **11 April**, 2018, healthcare stakeholders and policymakers from different backgrounds, including several Interreg Europe partnerships (see below) as well as key institutions such as the Lombardy Ministry of Health, gathered in Milan (Italy) for a workshop regarding some of the major societal challenges facing Europe such as personalised medicine, ageing, use of data, artificial intelligence and modernising health systems. Apart from enhancing interregional cooperation the main themes of the meeting were **dissemination**, **investment** and **sustainability**.

Personalised health is a cross-cutting field exploring how to use different kinds of data (medical and other) for preventing, diagnosing or treating diseases; explaining for example why there are differences in treatment effectiveness between persons having the same disease, or what a genetic profile can tell about a person's health risks.

The workshop involved members of ICPerMed[8] (International Consortium for Personalised Medicine), the Mario Negri Institute – represented by Silvio Garattini (scientific director), Telbios (represented by Maria Romano - director of research), and partners of the Interreg Europe project TITTAN. In addition, partners of four other health and ageing oriented Interreg Europe projects (ELISE[9], ITHACA[10], HELIUM[11] and the recently approved Medtech4Europe[12]) also joined the event.

Addressing different challenges relating to healthcare policies, the various projects took the floor to capitalise upon their experiences on health innovation and share them with a wider audience outside the Interreg Europe community.

The project participants were able to disseminate and showcase their experiences and their use of innovative policy approaches and relate them directly to challenges being faced by healthcare professionals:

1. HELIUM, put the spotlight on the living lab approach and the placement of people (patients) at the centre of the innovation process.

2. ITHACA, working on personalised solutions for elderly and dependent people, highlighted issues related to accessibility for patients, education among healthcare professionals, and

7 This is the report was published by the interreg policy learning platrform at https://www.interregeurope.eu/policylearning/news/3468/personalised-medicine-and-health-brings-project-communities-together/

8 The International Consortium for Personalised Medicine (ICPerMed) was initiated during several workshops organised by the European Commission throughout 2016. ICPerMed aims to provide a flexible framework for cooperation between its member organisations. Together, they work on fostering and coordinating research as a driver of personalised medicine.

9 https://www.interregeurope.eu/elise/

10 https://www.interregeurope.eu/ithaca/

11 https://www.interregeurope.eu/helium/

12 https://www.interregeurope.eu/medtech4europe/

used the workshop to develop and present ideas regarding proper data usage and ideas regarding co-creation mechanisms with patients;

3. ELISE, with a life science ecosystem perspective, stressed the value of influential and inspirational leaders for improved cross-disciplinary collaboration and exchanged with the other workshop attendees on the issues related to accelerate and translate medical discoveries into clinical use for medical and patient level innovation;

4. Medtech4Europe emphasised the theme of connected healthcare and telemedicine, both as an important sector for investments, and from a policy perspective, and used the workshop to exchange concerning the reimbursement for telemedicine services and its integration in national health systems.

The workshop brainstorming sessions helped partners to identify areas in which they should prioritise their policy cooperation efforts. These included research and innovation road maps, regulatory issues related to personalised medicine, big data, connected health and to highlight and share **investment** opportunities and new policy tools to be deployed within their Action Plans. Beyond the inspirations given by the Interreg Europe community, the workshop also provided insights into a Vanguard Initiative/Esther pilot on medical technologies, aimed at mobilising joint investments through innovation led interregional collaboration.

By working together, partners argued that they are able to develop a better understanding of the whole health value chain, connect their strengths and enhance their regional innovation performance and overall competitiveness. This may result in:i) establishment of joint Research, Development and Innovation technology road mapping, ii) alignment of regional polices, and iii) unlocking of joint investments. Among others, big-data, connected and integrated health, as well as responsible research and innovation were identified as future themes of cooperation.

The **sustainability** dimension of the workshop aimed to encourage partners to think about the perspective of the creation of an interregional network where exchange of experience, mutual learning models in life sciences are maintained and a common priority agenda on Personalised Medicine is created in the following years.

The workshop attendees also underlined the value of the Interreg Europe Policy Learning Platform for their activities and noted that “sharing helps people design and implement more complex projects”. The good practice database offers the possibility to find successful models, programmes and solutions and reduce the risk of duplication between partners and projects. Lastly, partners noted that the strengthening of sustainable relations between the regions will help lay the foundations for joint innovation and co-investment projects, connecting those regions sharing similar challenges. Such approaches are in line with current policy actions deployed by DG REGIO

seeking to accelerate interregional innovation led cooperation and represents the next challenge for these different health related project communities.

By working together and across projects, partners were able to discover synergies and seek complementarities with other funding programmes. A Horizon 2020 project proposal for "Regions4PerMed - Interregional coordination for a fast and deep uptake of personalised health" was submitted to turn theory into practice.

Policy Brief: European regions and smart specialisation

Under the 2013-2020 multi-annual programming regulations, the principle of *smart specialisation* (S3) was introduced as a legal precondition, also known as ex-ante conditionality, for using the European Regional Development Fund (ERDF). As of 2018, over 120 smart specialisation strategies for research and innovation (RIS3) are in place, guiding research and innovation investments of over EUR 40 billion from ERDF and over EUR 65 billion including national co-financing. These regional and national strategies are being implemented by authorities in charge of regional development and innovation together with relevant stakeholders to be able to develop and match innovation strengths with business opportunities and needs[13].

To realise these objectives, the principle of smart specialisation calls to build on cross-regional cooperation that would advance regional competitiveness while minimising duplication and fragmentation of publicly funded activities across the European Union (EU). In fact, increasing cooperation in innovation investments across regions is supported by the so-called *outward-looking dimension* that is generally expected to be present in a good smart specialisation strategy (RIS3). This dimension calls for exploring possible complementarities with other regions across Europe, thus assessing one's own regional assets and competitive edge while taking into account one's own position with respect to others. However, staying competitive in the global economy increasingly depends on transnational activities and participation in global value chains[14]. In fact, the competitiveness of the EU industry is largely determined by the capacity of Europe's regions to develop and link their innovation eco-systems by continuously supporting and facilitating cooperation among regional actors across the European Union.

The European Commission stresses[15] that Europe's competitive edge largely depends on its ability to develop new regional level growth models by targeting investments in innovative areas. The

13 COM(2017) 376 final, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Strengthening Innovation in Europe's Regions: Strategies for resilient, inclusive and sustainable growth, July 2017

14 Brennan L., R. Rakhmatullin, 2015. Global Value Chains and Smart Specialisation Strategy. Thematic Work on the Understanding of Global Value Chains and their Analysis within the Context of Smart Specialisation

15 Ibid

European Commission recognises[16]that four specific challenges need to be addressed to promote new regional level growth models:

- Further reform of research and innovation systems within regions;
- Increasing cooperation in innovation investment across regions;
- Leveraging research and innovation in less developed and industrial transition regions;
- Harnessing synergies and complementarities between EU policies and instruments.

The originally proposed RIS3 methodology support EU regions in improving the use of any existing and new regional capabilities that help regions spread innovation throughout regional and national economies. In addition, the *new thematic S3 approach* can help regions advance their global competitiveness by working with partner regions in order to create global value chains in new areas of strategic growth. With this in mind, the European Commission established *three thematic S3 platforms*[17] to support interregional partnerships in areas of Agri-Food, Energy and Industrial Modernisation. The *thematic S3 approach* is a strategic framework that brings regional policy closer to thematic S3 policies from a systemic and place-based perspective.

The Regional Smart Specialisation Strategies (RIS3) helps to prioritise and align efforts between public and private stakeholders in EU regions and allocate EU and regional funds in a focused and efficient way. At the same time, there are clear opportunities to engage in strategic interregional cooperation along shared RIS3 priorities in order to complement each other's competences, share infrastructure, and develop joint investment projects. Such interregional cooperation with allow scaling up towards larger impact and more effective collaboration along industrial value chains.

The Smart Specialisation Platform for Industrial Modernisation (S3P-Industry) aims to support EU regions committed to generate a pipeline of industrial investment projects following a bottom-up approach - implemented through interregional cooperation, cluster participation and industry involvement.

The S3P-Industry co-developed and co-led by the regions themselves ensuring an active participation of industry and related business organisations such as clusters, as well as research institutions, academia and civil society.

Under the S3P-Industry regions are already exchanging ideas about joint investments on Personalised Medicine[18] and Medical Technology[19].

16COM(2018) 306 final, communication from the Commission to the European Parliament, the European Council, the Council, the European Economic and Social Committee and the Committee of the Regions A renewed European Agenda for Research and Innovation - Europe's chance to shape its future, May 2018

17 European Commission. (2012). Guide to Research and Innovation Strategies for Smart Specialisation.

18 http://s3platform.jrc.ec.europa.eu/personalised-medicine

19 http://s3platform.jrc.ec.europa.eu/medical-technology

Regions4PerMed - Interregional conference Milan – 28.11.2018

Agenda

Title: Forward together with innovation with the regions at the centre: Regions4PerMed

Background

Welcome to the future - personalised medicine is here, and the regions are vital to its integration into the EU's healthcare systems.

Areas such as genomics, and the explosion in potentially paradigm-changing Big Data streams, should allow Europe to put its millions of potential patients across different regions at the heart of this incredible revolution.

Regional ecosystems offer proximity to the territory and adaptable regulatory and investment capacities which are essential in this phase to transform the way health and care are organised and delivered.

As the European discussion on personalised medicine gathers pace, the project Regions4PerMed was brought together as a response to the need for a wider understanding of priorities and a more integrated approach to bring innovation into healthcare systems.

All sessions of the kick-off conference included a keynote speech plus a panel discussion and are designed to be interactive.

Opening Session: Setting the scene

It is well documented that EU citizens value good healthcare very highly - it is a priority and policymakers generally know this (if they don't, then they should). Equity of healthcare across Europe does not really exist unfortunately, for various reasons, but it is a prime goal that politicians and stakeholders have little choice but to aim for. The large differences in health care expenditure cannot be explained entirely by the demographic, economic or technological differences.

Legal and institutional architecture of healthcare provision and financing is undoubtedly an important factor influencing the public and private spending in the sector. However, the high complexity of the system and variety of its features makes it very difficult to quantify and compare across the EU. This session will feature a chair, plus five speakers representing the Commission and Coordinators of the project as well as one speaker with a specific focus on SMEs.

Institutional Welcome, Maurizio Bersani - Lombardy Region

Introduction: Gianni D'Errico, *Project Coordinator, Regions4permed*

- **Chair: Denis Horgan**, *Executive Director, European Alliance for Personalised Medicine*
- **Gianpietro VAN DE GOOR**, PA to the Director for Health, DG Research and Innovation policy officer, European Commission, DG RTD
- **Gaetano Gugliemi,** Director, DG research and health innovation, Italian Ministry of Health
- **Paola Castagnoli, Scientific Director,** *Toscana Life Sciences*

Q&A

Session I: Coordinating regional policies and innovation programmes in personalised medicine

There is an urgent need to start restructuring care delivery, fuelled by factors such as chronic diseases, Europe's ageing population and health workforce shortages. To tackle the challenges, new care models are needed and their implementation requires essential investments and related strategies. Involvement of a broad range of public and private partners and investors is required, with a combination of bottom-up and top-down approaches to realise necessary new care models.

When it comes to implementation of these, two underlying principles are collaboration and partnerships. When all concerned stakeholders – politicians, care authorities, care professionals, citizens/patients, service providers, technology providers and investors – are committed to working together, this should create a favourable environment for the design and deployment of new care models. **Regions4PerMed** has the overarching goal of acting as a flagship for interregional cooperation in personalised medicine. From this, it will aim to align strategies and financial instruments, identify key investment areas, and release a European regional agenda in order to speed up the delivery of personalised health services to patients and citizens.

Regions4PerMed's expected impact 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 in respect of personalised medicine, exchanging views and concerns, finding fields of cooperation, and committing to concrete joint cooperation actions in the short-to-medium term. Commitment is clearly crucial for any real and lasting impact and says it will maximise efforts and leverage on already established projects and initiatives. As personalised medicine develops, a number of good practices are emerging, not least regionally, which - individually and collectively - offer insights into how to design and implement successful new models.

Once again, this speaker session will encourage debate from the floor with as much interactive attendee involvement as possible.

Chair: **Gianni D'Errico**, *Project Coordinator, Regions4PerMed*

- **Paola Bello,** *Lombardy Foundation for Biomedical Research,* Lombardy Region
- **Andrea Belardinelli**, *Digital Health and Innovation* – Tuscany Region
- **Rafael Solana,** *General Secretary for Research, Development and Innovation. Regional Ministry of Health of Andalusia, Seville, Spain*
- **Richard Barker**, *Founding Director, New Medicines Partners*

Q&A

Session II: Coordinating regional strategic investments

Europe's achievements in science and technology have been significant and research and development efforts form an integral part of the European economy. The continent has been home to some of the most prominent researchers in various scientific disciplines, and the raw output of such research in Europe consistently ranks among the world's best. However, the EU and regions have struggled to bring innovation into the bloc's healthcare systems. The regions need to coordinate in a much smarter fashion to help address this issue, and this is at the heart of what Regions4PerMed is all about. This session will touch on the policy initiatives directly involved over the years as well as looking toward the next legislative periods and the frameworks which could add support.

The format will see a chair plus six speakers, once again representing the political, institutional, regulator, patient, medical and scientific perspectives. Discussion from the floor, as well as questions and answers, are key to the session.

Chair: **Richard Barker**, *Founding Director, New Medicines Partners*

- **Diego Tonelli**, Life Sciences Economist, European Investment Bank
- **Paola Pozzi,** *Venture Consultant - Sofinnova Partner*s
- **Anna Sobczak,** *European Commission, Policy expert for clusters and emerging industries at Directorate General for Internal Market, Industry, Entrepreneurship and SMEs (DG GROW)*

Q&A

Session III: Technological challenges for system integration and data interoperability

Innovative solutions can boost people's health and quality of life and enable more efficient ways of organising and delivering health and care services. For this to happen, they must be designed to meet the needs of people and health systems and be thoughtfully implemented to suit the local context. Digital infrastructures and technologies should be seen as an integral part of health and care and geared towards the wider objectives of health systems.

The swift deployment of innovative and digital health solutions can best be achieved by working together at EU level, sharing experiences in deploying, measuring impact and transferring innovation across Member States and regions. The active engagement of all parties is essential to succeed in creating a "triple win" that benefits people, health systems and the market.

Continuous technical dialogue will ensure that EU and Member State policy makers receive the best possible information and advice, thereby minimising barriers to the uptake of personalised medicine at the political level. The Regions4PerMed plan is that regional representatives will be able to understand how other EU regions are tackling the challenges, will have access to state of the art analyses from relevant stakeholders, and will share their views and update policies.

Chair: **Andrea Frosini,** *Head of unit, Toscana Life Sciences*

- **Jan Verheyden,** *VP Traumatic Brain Injury, IcoMetrix*
- **Paolo Gazzaniga,** *Director of Studies Center, Assobiomedica*
- **Cristina Tinti**, *Incubation Manager, Toscana Life Sciences*

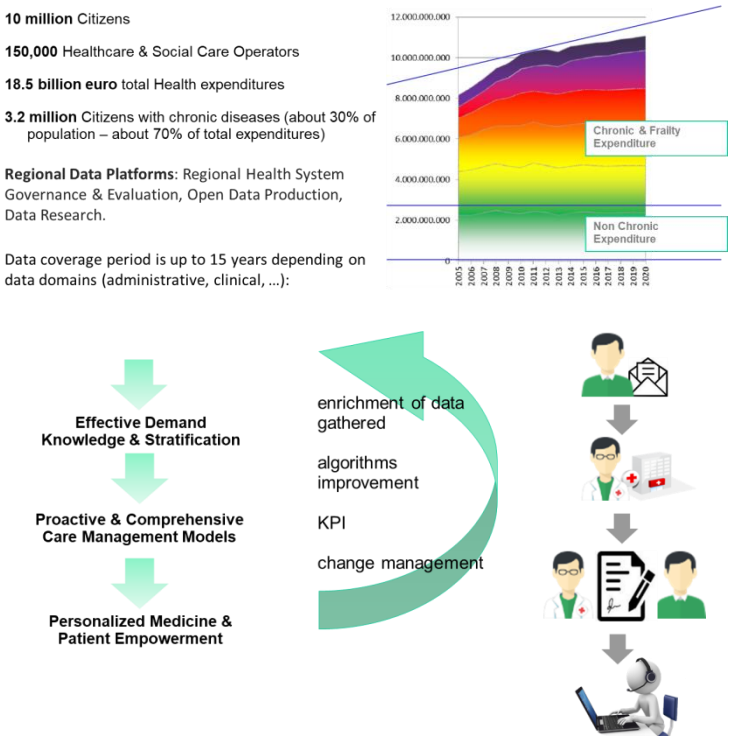
Opening Session: Setting the scene

Maurizio Bersani, Director, DG Welfare – Lombardy Region

Maurizio opened and welcomed the Regions4PerMed conference on behalf of the Lombardy Region, that this year hosted the annual congress of the European Alliance for Personalised Medicine.

He highlighted how Lombardy has been implementing an important health care reform, focused on the stratification of patients 'population with a particular focus on chronicity and frailty.

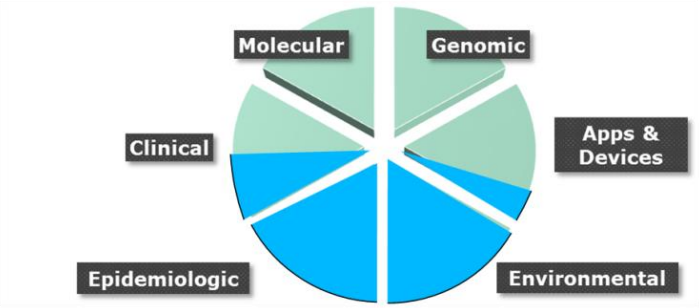
Maurizio emphasised how the regional Healthcare system has adopted an integrated approach for taking care of the patients, which translates into a system where the patients are more engaged in the decisions affecting their healthcare. Lombardy Region- he added- is also developing new forms of support for those, especially elderly population, in a condition of frailty.



The healthcare reform has re-modulated the relation between healthcare professionals and patients, who draft together with their clinicians their own "personalised treatment plan" and a "Personalised Assistance Plan",. The "Taking care approach" includes the role of a "Case manager", who supports patients in the adherence to the therapy, also offering practical support in the planning of all medical appointments. As a result this approach will enable more tailor made therapeutic outcome and significant savings for the healthcare systems.

Maurizio briefly illustrated the role played by the Region in the data collection and data analytics through the in house company LISPA (Lombardia Informatica S.p.A). LISPA is active in integrating

data coming from different sources and EMRs to provide indicators in clinical pathway management.



Current Projects running on Cardiovascular risk, Multitherapy in Older People, Pharmaeconomics, COPD Exacerbations, Prescription Appropriateness in older people, clinical pathways

Lastly, he remarked the importance of seeking interregional collaborations in order to maximise the impacts of investments in the health system. Lombardy is already engaged, since 1988, in a long term commitment with 3 other European regions through the network of four highly industrialized and research-oriented regions in Europe. [**Rhône-Alpes** of France, **Baden-Württemberg** of Germany, Catalonia of Spain] called "4 Motors of Europe" and ready to establish other interregional collaborations.

Gianni D'Errico, Regions4PerMed Project Coordinator, TLS

Gianni introduced the Project Regions4PerMed, stressing the political responsibility that regional authorities bare in many EU countries for delivering better care while ensuring the universality coverage principles.

Many EU regions have been planning, shaping and delivering better health policies; have reorganised the healthcare system and need to further infrastructure investments in order to allow the transition of health system from reactive and hospital centred to a more preventive and community based system.

In many areas regions have re-organised and integrated the so called Regional Health Information Organisations (RHIOs) – by which we mean the regionally linked agency and/or in-house companies that collect, manage and analyse the health related data of the locals.

There are tools that are available at transnational an interregional level that can be exploited jointly. The aim of regions4Permed is to aggregate regions around personalised health key investments leveraging regional, national and European investment schemes.

Gianni reminded that the project regions4PerMed contributes to the achievement of the objectives of the European strategy launched in 2011 with the European Council Conclusion:

Towards modern, responsive and sustainable health systems (2011/C 202/04) and **modernisation of the European Healthcare system**. In the 2011/C 202/04, particular stress is put on the role of strategic investments in healthcare and the importance of an integrated and interoperable health data sharing system.

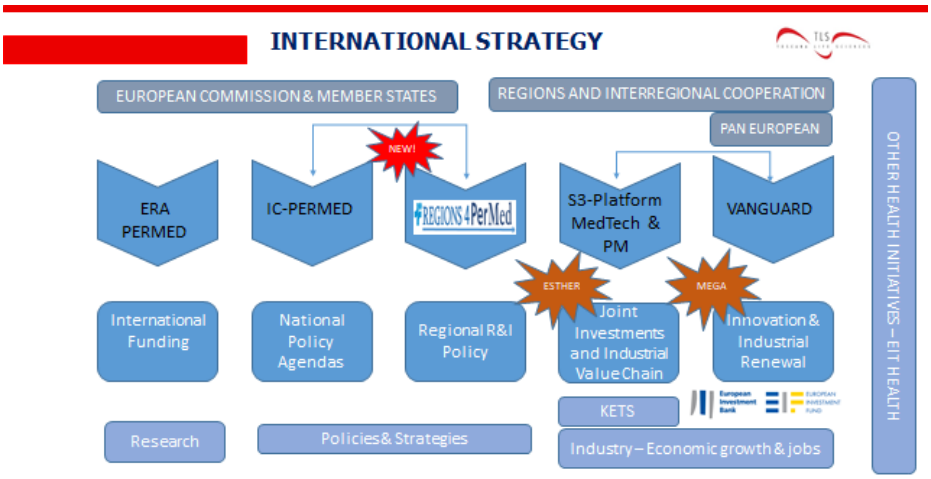
For what concerns the main project features, after having explained the main administrative information (duration, starting date, partners, etc) Gianni presented:

- **Overall Objectives**

Overarching Goals	• Coordinate regional policies and innovation programmes in Personalised Medicine 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 Personalised Medicine • 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 MFF as well as Research Framework Programme • Provide guidance to EC, Member States and regional authorities on the next ESIF Operational Programme
Specific objectives	• Organise the technical dialogue among regions around five Key Strategic Areas 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 IC PerMed Action Plan • Provide guidelines in a form of 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 tackle PM within the Smart Specialisation Strategies • Build and maintain a database of Innovative Personalised Health research/innovation /monitoring programmes and projects that can be easily replicated elsewhere

The international context of Regions4PerMed

He stressed how regions4Permed bridges the European activities at member states level on PM (predominantly focused on national policies and joint investments in basic and translational research), with the activities carried out at regional level and more focused on industrial and innovation policies. He also stressed the important role that regions and the Regions4PerMed can play within the implementation of the human genome declaration and the Million European Genomes Alliance [MEGA].



Expected impacts

To date Number of involved Regions	**Expected number of involved regions*** by the end of the Projects**
48*	180**
To date number of regional stakeholders involved	**Expected number of involved stakeholders*** by the end of the Projects**
336	1260****
**the number of regional authorities covered at the Interregional Workshop on personalised health in Milan on April 2019* ***This number appears feasible if we consider the number of regions in other networks and initiatives (ESTHER, IC-PERMED, Vanguard, etc.)* ****Regional authorities and regional stakeholders* *****INTERREG EUROPE Projects usually involve 7 key stakeholders on average. Using this factor, by the end of the project this number appears feasible*	

Number of RIS3 containing PM priorities	Minimum number of involved regions by the end of the project	Means of Validation
45	120	EYE@RIS3*
*During our events the use of RIS3 will also be promoted.		

Stakeholders already involved

H2020	IC PerMed To Reach ERA-PerMed ESTHER INNOLABS PERMIDES
INTERREG EUROPE	ELISE HELIUM HO-CARE ITHACA TITTAN MEDTECH4EUROPE JAseHN
S3 THEMATIC PLATFORMS	MEDICAL TECHNOLOGIES PERSONALISED MEDICINE

Lastly he touched the methodology of work and the activities planned for the next 4 years of the project.

He then introduced Denis Horgan, manging director at European Alliance for Personalised Medicine, who chaired the rest of the session.

Gianpietro Van de Goor, PA to the Director for Health, DG Research and Innovation policy officer, European Commission, DG RTD

Gianpietro started his speech highlighting the findings of the 2018 OECD and European Commission report[20] where it is referenced that one fifth of the health spending is inefficient and could be used for other care needs – Unnecessary admissions consume over 37 million hospital bed days each year and that prevention is highlighted to be a priority, since over 790000 deaths per year are due to behavioural risk factors.

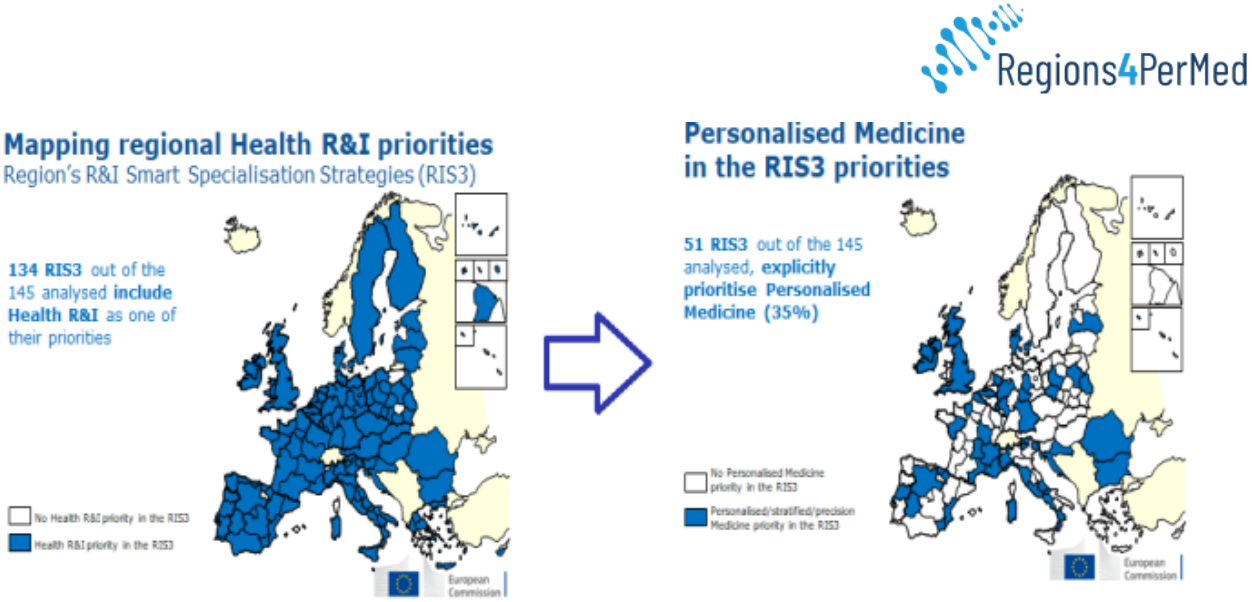
In this context, Gianpietro highlighted the investments in personalised medicine under the 7th framework programme [209 projects, 2756 participants. 1.334 billion € plus EUR 380 million for 31 projects under IMI1] and Horizon 2020 [163 projects – EUR 870 million €].

He then encompassed the policy pathways of the European Commission in personalised medicine:

- 2008: International Cancer Genome Consortium (ICGC)
- 2010: International Human Epigenome Consortium (IHEC)
- 2010: First European PM workshop by EC (towards a funding strategy for PM approaches)
- 2011: Launch of the International Rare Diseases Research Consortium (IRDiRC), 1st European PM Conference
- 2015: EU Council Conclusions on PM
- 2016: International Consortium on PM (ICPerMed):28 countries and 4 regions, 11 Health Ministries, 6 Science and Education Ministries
- 2017: ICPerMed Action Plan
- 2018: 18 MS sign Declaration on linking genomic data across borders, 1st ICPerMed conference

At regional level, a 2017 preliminary mapping of the regional priorities in health and Personalised medicine, showed that 134 regional Smart and Innovation Strategies (RIS3) included health as a strategic investment priority, whilst only 51 RIS3 included explicitly Personalised Medicine as strategic investment area.

20 Health at a Glance, Europe 2018 OECD, European Commission



Lastly, he presented the measures the EC has put in place to support the interregional cooperation in the area of Health R&I, which can be summarised as follows:

- Mapping of regions 'Health R&I priorities (RIS3) and dedicated workshops organised by EC/DG-RTD in May 2017
- Partnering of regions in the IC PerMed initiative (www.icpermed.eu)
- Establishing of 24 European Reference Networks (ERNs)

virtual networks of specialist healthcare providers helping patients with rare or complex diseases

- Thematic Partnerships under the Smart Specialisation Platform for Industrial Modernisation (2 out of 16 are on health)
  - Medical technology (created in 2017)
  - Personalised Medicine (created in 2018)

  To align complementary assets, infrastructures and work to integrate value chains across different technology sectors for PM. It will bring the agenda to implement PM to the next level.
- Horizon2020-funded support actions for regions with interest in the area of personalised medicine: SAPHIRE and **REGIONS4PERMED**.

Gaetano Guglielmi, Director at DG research and health innovation, Italian ministry of health

Gaetano, member of the secretariat of the international consortium on Personalised Medicine, presented the main features of the IC-PerMed, i.e. the European Action plan, the organisation that IC Permed has shaped to implement the Action Plan and the activities carried out so far.

He also presented Era PerMed project, showed the results of the 2018 JTC:

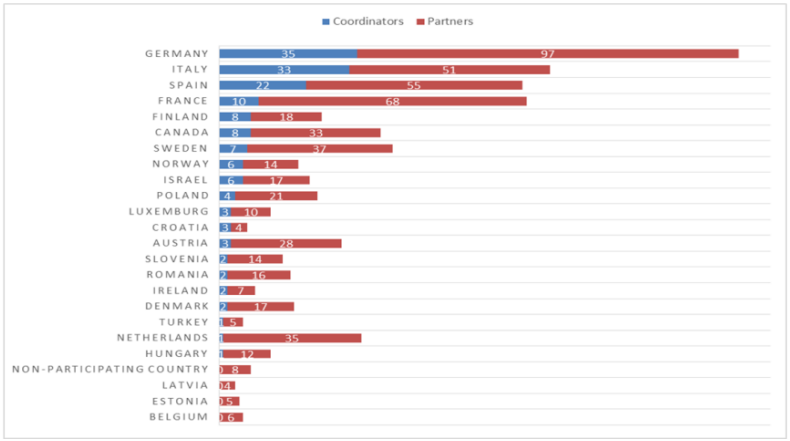
Facts and Figures JTC 2018

- **Pre-proposal stage**:
  - 159/143 submitted projects
  - 741 partners involved from 30 funding organisations
  - 176.21 M € of requested funding
  - 50 Pre-proposals invited to submit a Full proposal
  - 75 evaluators from 24 countries (25% females)
- **Full proposal stage**:
  - 50 submitted projects
  - 252 partners involved from 27 funding organisations
  - 59,86 M € of requested funding
  - 23 evaluators from15 countries

- Funding available: EUR 26.99M

ERAPerMed – EU co-funded JTC 2018

Pre-proposal Coordinators and Partners per Country



and introduced the second Transnational Joint call which will be opened in January 2019 on the topic. Personalised Medicine: Multidisciplinary Research Towards Implementation[21].

Research area 1 "Translating Basic to Clinical Research and Beyond"	Research area 2 "Integrating Big Data and ICT Solutions"	Research area 3 " Research towards Responsible Implementation in Health Care"
Module 1A: Pre-clinical Research	Module 2A: Data and ICT – Enabling Technology	Module 3A: Optimising Health Care System
Module 1B: Clinical Research	Module 2B: Data and ICT - Towards Application in Health Care	Module 3B: Ethical, Legal and Social Aspects

He favoured a closer collaboration between regions and central governments, which is demonstrating already a high value in joint investment in basic and translational research, and that can certainly be essential for the success of IC PerMed.

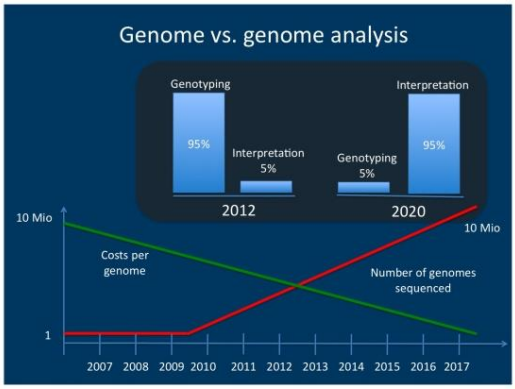
[21] http://www.erapermed.eu/wp-content/uploads/2018/11/1_ERA-PerMed_2019_pre-announcement-FV.pdf

Paola Castagnoli, scientific director - Fondazione Toscana Life Sciences

Paola, highlighted the global panorama around Personalised Medicine, stressing how the pan-European joint commitment on Personalised Medicine recently launched with the human genome declaration[22] the years the Obama PMI and 2 years after the 9 billion Chinese personalised medicine programme.

She also pointed out how the main efforts are switching from genotyping to interpretation of

the collected data.



She also stressed how, in order to make personalised Medicine a reality, there is a need for greater investment in biomedical Research.

On the topic of interregional collaboration, she pointed out that:

Regional ecosystems offer proximity to the territory which is essential to transform health and care

In Italy two regions, Lombardy and Tuscany are willing to promote a fast uptake of Personalized Medicine;

In Italy we have also big health research infrastructure that can be leveraged on, the Human Technopole Foundation. HTF has been recently launched in Lombardy, it's a multidisciplinary research institute, developing personalized approaches in the medical and nutritional fields, coupling large-scale genomics with the analysis of complex data systems and developing new diagnostic techniques, with the aim of fighting cancer and neurodegenerative diseases.

The Human Technopole could be a great opportunity for Lombardy, Tuscany and other Italian regions to support, i.e., the generation of the first genomics databanks and biobank as future node of European initiatives. Paola believes that this new opportunity should lead to the acceleration of personalized medicine.

[22] https://ec.europa.eu/digital-single-market/en/news/eu-countries-will-cooperate-linking-genomic-databases-across-borders

Session I: Coordinating regional policies and innovation programmes in personalised medicine

Gianni D'Errico chaired the session I dedicated to the innovation programmes in place at regional level to support personalised medicine.

Paola Bello, European Funding Officer – Regional Foundation for Biomedical Research (FRRB)

Paola illustrated the support FRRB, as Lombardy Research Funding Agency, is providing to the research and scientific community though their regional calls for proposals and their participation in European Networks (TRANSCAN2, ICPermMed, ERA-PerMed, EJP Rare Diseases) to maximise their impact on the territory of Lombardy.

Lombardy is the Region that invests the most in Italy in Life Sciences[23] and has a 18.6 bl/Euro, Total Health expenditure, including for services to non-resident citizens[24]. There are more than 200 public and private hospitals and 19 research hospitals (Istituti di Ricovero e Cura a Carattere Scientifico -IRCCS), as well as 130.000 healthcare professionals (including 30.000 clinicians and 8.000 GP and paediatricians

Within the project Regions4Permed, FRRB will collaborate with the regional in-house IT company LISPA, in tackling some major problems connected with the use of big data in health, specifically:

- **Citizens and hospital-based Electronic Medical Records** (*Fascicolo Sanitario Elettronico*): Structuring, managing and improving the quantity and the quality of health data. I.e. improving the readability and transferability of heterogeneous data. Currently the objective is to include data on genetics and epigenetics.

- **Continuous care for chronic patients: "taking care" approach** (*Presa in carico della cronicità*): Collection of patients' health data and provisions for access for clinicians, to follow up on the Patient's health conditions step-by step. This is connected to **a Personalised treatment plan** and a **Personalised Assistance Plan**, which keeps track of all treatment procedures and ensures the Patient's engagement and involvement.
- **Data privacy**: All patients' management systems can read relevant data and personal data are treated with a Privacy by design approach (GDPR).

Paola has then presented the work ahead that FRRB will be realising through its operational support to Lombardy Region. Starting from the EC Communication on Data driven transformation of healthcare[25], the next steps will see:

- The Integration of PM into Regional S3 (from health industry to medical technology, etc.)
- Promoting PM through public funding (FRRB) i.e. *Progetti in rete, EU calls*

[23] La rilevanza della filiera Life Science in Lombardia: benchmark tra regioni italiane ed europee, Centro Studi Assolombarda, 2017

[24] Determinazioni in ordine alla gestione del servizio sociosanitario per l'esercizio 2018, DELIBERAZIONE N° X / 7600

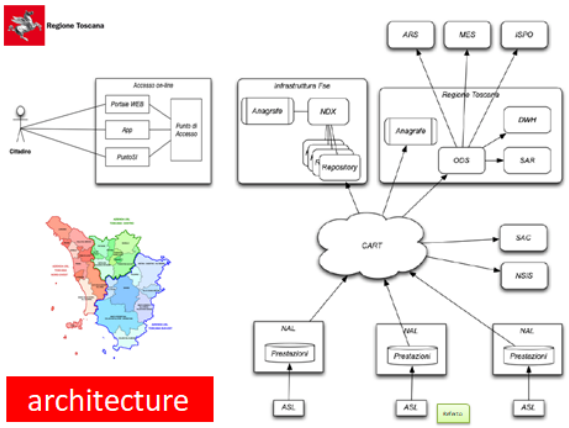
[25] COM(2018) 233 final, Communication from the Commission to the European Parliament, The Council, The European Economic And Social Committee and the Committee Of The Regions on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society {SWD(2018) 126 final}

- An evidence-based improvement of Regional Strategy
- Promoting a PM culture among all stakeholders

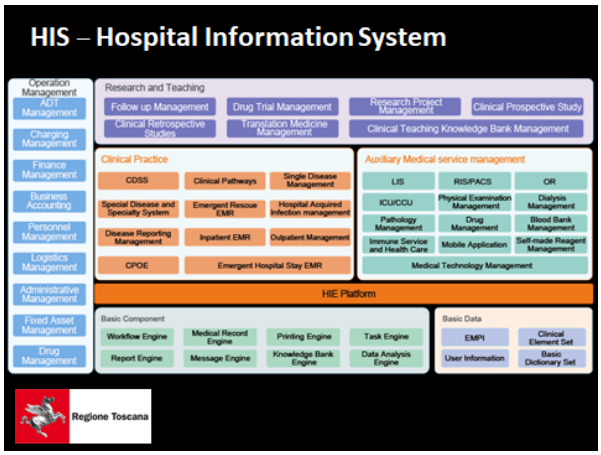
Andrea Belardinelli, Director of Digital Health & innovation at Tuscany Region

Andrea started his speech recalling the 2017 Bloomberg[26] report that shows that Italy, despite its struggling Economy, has the world's Healthiest People, and the 2018 Conferenza Stato-Regioni report that recognises Tuscany as benchmark region in Italy.

He then illustrated the healthcare organisation in Tuscan Healthcare Services (SST), and how the patient system information is organised.



Successively, he described how the Hospital information system is organised and the kind of services that the region delivers to patients and citizen through their Electric Medical Records.



He presented precise and up-to-date e-health records currently collected and analysed by the region (**380.487.453,** of which 39.754.362 form Laboratory, 11.705.680 form emergency room, 15.120.569 from Radiology, etc.**).**

[26] 2017 Bloomberg Global Health Index of 163 countries

He also presented the dashboard accessible to the EMR users and the numbers related to daily medical and clinical practice performed by the regional health system (i.e 411 emergency room visits, 95.000 e-prescriptions, 115.000 outpatients visits etc.)

Towards the implementation of the personalised health system, Belardinelli expressed the regional commitment to integrate omics data within the EMRs, in order to obtain quantitative data on the individual components of the different sets, transcripts, proteins and metabolites that can lead, on the one hand, to the development of increasingly advanced analytical technologies that allow simultaneous measurements of an ever increasing number of biomolecular components, on the other hand to new analytical disciplines that allow to interpret and summarize the enormous quantity of observational data and to identify the relations, latent in the data field, leading to the formulation of new hypotheses for the functioning of the system.

In this sense, Tuscany have some examples to show, like :

- **NIPT** (catchment area: about 2000 samples / year - up);
- **Retinopathies** (catchment area: about 800 patients / year);
- **Cardiomyopathies** (catchment area: about 400 patients / year);
- **Myelodysplastic syndromes** (catchment area: about 100 patients / year);
- **Rare Diseases**: Hypocalmic / Hypercalemic Periodic Paralysis, Amyloidosis, Neuropathies, Hemophilia A, Hemophilia B, Hemochromatosis, Duchenne-Becker Muscle (catchment area: about 300 patients / year)
- **Hereditary tumours** (colon, breast, ovary) (catchment area: about 500 patients / year)
- **DPYD gene polymorphisms** in pre-treatment with Fluoropirimidines of oncological patients;

Strategically the Tuscany Region is working toward a personalised and data driven healthcare service by:

- **funding research** projects with PM approaches
- **training of researchers** who will have to develop specific, biological or computational skills, but everyone should be trained in the complementary field, at least sufficient to interface with colleagues.
- creation of ICT **collaboration and coordination** platforms (Jira, Wrike, etc.);
- creation of **centralized and reusable ICT platforms** (TIX private cloud owned by public authority) to support precision medicine or, in any case, to process the large amount of data produced by analytical technologies

Andrea furthermore presented some results coming from regionally funded projects (ERDF and Regional health budget), and said that over 200 Projects were submitted in response of the 22.5 M€ worth call for proposal on personalized medicine and big data analytics[27], and said that Region has also joined some international networks (Era Permed, IC-Permed and JPI RD) to invest more in transnational excellent health research.

Lastly he showed the cloud infrastructure that Tuscany has built and stated that for interregional joint investment also under the Million European Genomes Alliance umbrella.

Rafael Solana Lara, General Secretary for Research, Development and Innovation of the regional ministry of health of Andalusia - Seville

Rafael started his speech by saying that the overall objective of the Andalusia Strategy for personalised medicine is the continuous improvement of patient diagnosis, prognosis and optimization of the treatments, by generation of knowledge and technologies that allow to provide the diagnosis and the most adequate treatment to each patient according to his personal characteristics and peculiarities.

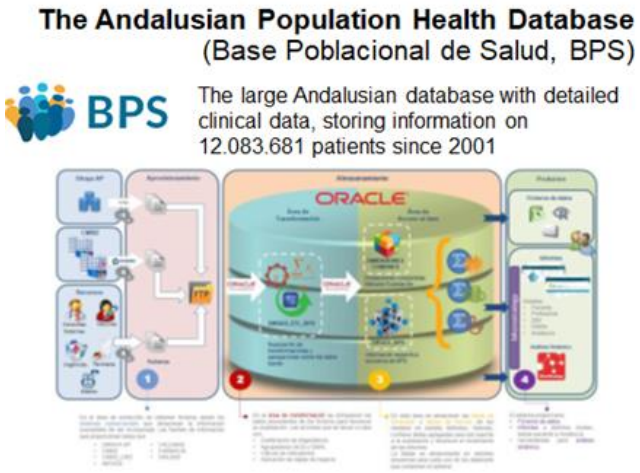
This strategy has resulted in a six goals programme which is encompassing:

- **Objective 1**: Promote and support research in personalized medicine within the Public Health System of Andalusia, identifying and prioritizing research areas.
- **Objective 2**: Provide the Andalusian Public Health System [SSPA] with a bioinformatics infrastructure that allows the development of programs, procedures, techniques and technologies based on knowledge and innovation generated in the area of bioinformatics research in order to improve health.

27 http://www.regione.toscana.it/-/bando-ricerca-salute-2018

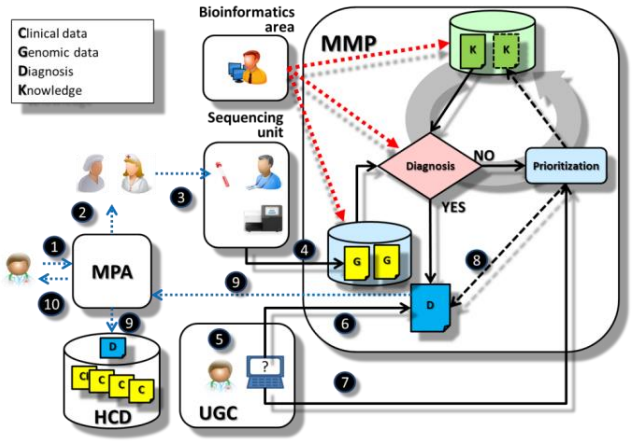
- **Objective 3**: Promote and coordinate the networking of resources available in research to support the entire research community of the SSPA.
- **Objective 4**: Develop and / or adapt the necessary regulations and procedures so that it is possible to address the challenges that arise as knowledge in this area increases, as well as to address and respond to the aspects of bioethics that emerge both in the field of research and assistance.
- **Objective 5**: Adapt the information systems so that they can guarantee the traceability of the biological samples, respond to the information needs of the research and of the health care, considering the normative and the bioethical requirements.
- **Objective 6**: Offer the professionals the necessary continuous training that will enable them to manage the programs.

He also presented the Andalusian Population Health datatbase (BPS), which contains detailed clinical data of over 12 Million people since 2001.



The system has been designed in a way that is compliant with EU and Spanish General Data Protection regulation (see figure below). This system is useful for, among others:

- Clinicians requesting for genomic diagnostics have access to electronic health records [eHR] and only get the result of the test.
- Geneticists have access to eHR and can query the genomic data (but never extract them)
- IT have access to anonymized genomic data but not to her



This system is furthermore being integrated with:

- Other *big data* (medical images, digital pathology, wearable devices, etc.)
- Microbiota (Colorectal cancer screening)
- Clinical data in the BPS dynamically associated to different *big data*
- Immense possibility for data reusability
- Growing genomic DB with increasing study possibilities

Richard Barker, Funding Director at New Medicines Partner

Richard started his speech by referencing the precision medicine definition as "Integration of molecular research with clinical data from individual patients to develop a more accurate molecular taxonomy of diseases that enhances diagnosis and treatment and tailors disease management to the individual characteristics of each patient"[28] which represents the link between stratified medicine – defined as the ability to classify individuals into subpopulations that differ in their susceptibility to a particular disease or their response to a particular treatment[29], and predictive and personalised medicine, defined as patient-specific treatments for different people, tracking the course of health and disease over time and intervening in a personalised manner.

He stressed that core personalised medicine technologies are:

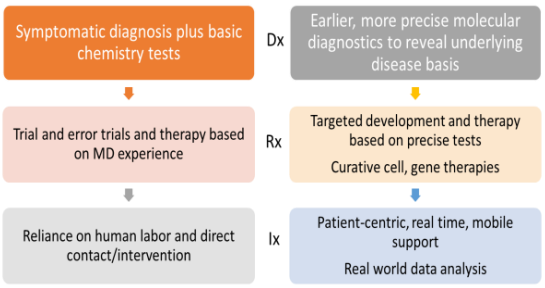
- Genomics and other "omics": technological advances increasing analysis speed and decreasing costs for genomics and other 'omics applications will enable greater insights into disease mechanisms fundamental for setting more personalised treatments and prediction/prevention of disease.
- Advanced therapeutics: new therapeutic opportunities such as gene and cell therapies offer the potential for genuine cures - a paradigm shift from conventional medicines focused on symptoms control and pain management to the eradication of the pathology.

28 US Nat Acad of Sciences report, 2011
29 ABPI White Paper 2009

- Digital health solutions: identified as a wide range of devices and apps, that generate real-time, multi-channel data, providing unprecedented insight into users' health. Increasingly sophisticated data analysis methods enable the transformation of this data into actionable information.

According to Prof Barker, precision medicine will be profoundly disruptive on three levels:

1. Reducing time to accurate diagnosis
2. Tailoring medical treatments to individual patient
3. Real time tracking of patient health parameters



The process of personalisation of healthcare encompasses three different aspects:

1. Psychological and behavioural profile (attitude to health & disease, concerns about treatment implications for adherence, etc.)
2. The biological profile (Genomics, Proteomics, Metabolomics, Microbiomics, etc)
3. Social and ethnic setting (Community based support, Ethnicity, lifestyle differences).

Prof Barker also pointed out the common attitudes of the stakeholders when it comes to innovation in health.

1. Politicians – enthusiastic about health & economic potential
2. Health systems managers – a 'nice to do' alongside priorities
3. Payers – sceptical of the value, especially for high price drugs
4. Physicians – some deeply involved, the majority underinformed
5. Patients - poorly informed and sometimes suspicious.

What should be tackled by specific actions in order to increase the political momentum for personalised medicine and health:

1. Make connections with health policy & funding
2. Demonstrate impact on resource use and economics
3. Construct business cases; focus on cash-saving areas
4. Incorporate genomics/PM into medical education/CPD
5. Launch major education programs in conjunction with patient groups

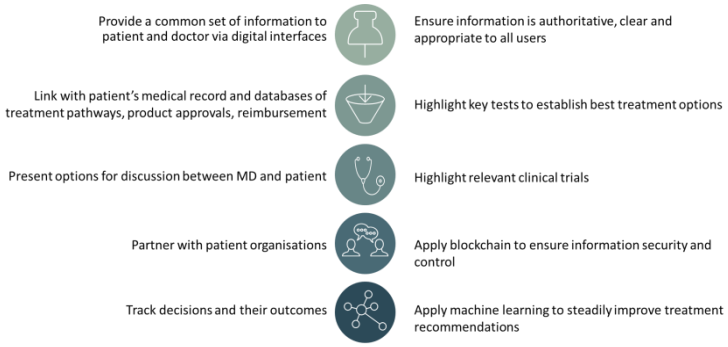
He also provided an overview of EU level challenges that need to be properly addressed[30]:

- Provide further evidence for the benefits delivered by PM to health systems

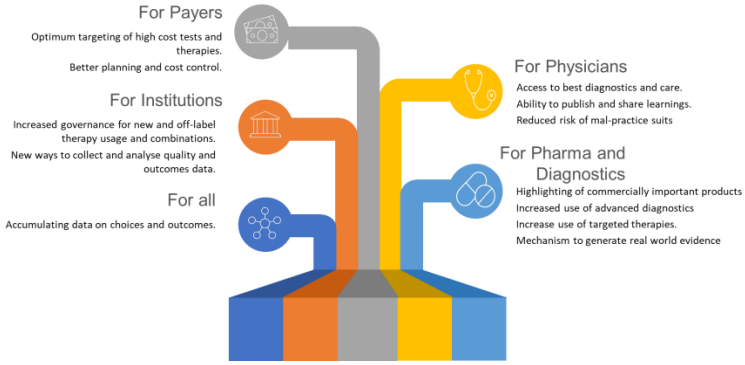
30 Many of these challenges are already tackled by the IC-PerMed action plan.

- Understand how the changes relating to PM will impact public health and ensure that they can be translated directly to benefits for individual citizens and society
- Incorporate patient participation in the healthcare system and increase the patient's role in all phases of research and development
- Develop and promote models for individual responsibility, ownership and sharing of personal health data
- Improve communication and education strategies to increase patient health literacy
- Develop common principles and legal frameworks that enable sharing of patient-level data for research in a way that is ethical and acceptable to patients and the public
- Develop mobile health applications to maximise engagement of patients with their treatment pathways and track the safety and effectiveness of these interventions
- Integrate Big Data and ICT Solutions
- Promote strategies to make sense of 'big data' Create a European 'big data' framework and adapt legislation
- Develop and encourage the fast uptake of technologies for data capture, storage, management and processing
- Promote the development of high quality sustainable databases including clinical, health and wellbeing information
- Support translational research infrastructures and enforce data harmonisation fostered by specific ICT infrastructures designed to the health data
- Support analytical methods and modelling approaches to develop new disease models, e.g. 'Computerised Twins' or a 'Virtual Patient'
- Develop new decision support tools and methodologies of ICT to analyse and interpret data in order to support physicians in their decision-making process
- Translating Basic to Clinical Research and Beyond
- Develop methods to better integrate and evaluate the information provided by genomic, epigenetic, transcriptomic, proteomic, metabolomic and microbiome analyses
- Develop suitable funding models to enable cross-sector working in PM research
- Support research in preclinical models to validate hypotheses resulting from molecular analyses of patient samples and treatment outcomes

In the last part of his speech he provided what he referred to as **Metadvice Decision Support**, depicted in the figure below.



Lastly, he emphasised that a shared decision making platform has benefits for many healthcare stakeholders:



Session II: Coordinating regional strategic investments

The third session, chaired by prof. Barker, was dedicated to the financial instruments (institutional and private) that can be available for regions to support healthcare value chain innovation.

Anna Sobczak, Policy Expert for clusters and emerging industries at Directorate General for Internal Market, Industry, Entrepreneurship and SMEs of the European Commission (DG GROW)

Anna presented the EU Cluster Initiatives, which are acknowledged to offer a favourable eco-system; host innovative companies, reach out to groups of related SMEs, be well positioned as facilitators and bridge-builders, create strategic partnerships at the level of policy-makers and intermediaries, provide support for innovation activities and facilitate the validation of ideas for joint innovation projects.

She also expressed her favour on cross sectorial industrial focused collaboration because it brings different competences together, offers opportunities for new knowledge combinations and innovation, shapes new products/services, value chains and industries, diversifies specialisation patterns that are more likely to boost economic prosperity.

The cross-regional collaboration, in this context, is important because it mobilises stakeholders and resources around common smart specialization strategies, offers opportunities for strategic use of innovation to develop new industrial value chains, offers further funding opportunities for

possible collaboration ideas; it triggers complementary support via linking sectors and partners to smart specialisation priorities.

She listed the 18 thematic areas around S3 for industrial modernisation, among which there are two focused on health:

1. Medical technologies: participated by 19 regions and which has already delivered some joint investment plans proposals,
2. And the newly launched personalised medicine platform, which is gathering consensus by committed regions

She presented the structure and main results reached by 13 ongoing cluster facilitated projects for new industrial value chains (INNOSUP-1) funded under Horizon-2020 programme (total budget euro 130 million) .

She then detailed the European Strategic Cluster Partnerships for Smart Specialisation Investments (ESCP-S3) funded under COSME programme (total budget EUR 2.8 million) and the main project which have been financed (Tuscany participated in the project AI4Diag – Artificial Intelligence for diagnostics).

Lastly she presented the opportunities to operate with stakeholders outside of the European Union offered by the European Strategic Cluster Partnerships - Clusters Go international (ESCP-4i) funded under COSME programme as well as some main results achieved and examples of success stories, especially those relevant for the personalised health and personalised medicine sector.

Diego Tonelli, European Investment Bank (EIB)– Life Sciences Economist

Diego started the discussion providing some figures on the importance of the Healthcare sector in the overall economy, as it accounts for 8% of total workforce and for 10% of GDP in Europe.

As the EU bank, Diego highlighted the critical role the European Investment Bank has been playing in supporting projects that aim to ensure universal access to effective, safe and affordable healthcare services in Europe. As an example, in 2017 the EIB helped to improve healthcare services for more than **45 million people,** including improved access for more than 30 million people.

He pointed out that the health sector objectives of the European Investment Bank are aligned with the overall EU strategic priorities. In particular, the Bank works on three key principles guiding the selection of projects for financing, notably aimed at:

- enabling universal access to effective, safe and affordable preventative and curative health services;
- providing sustainable health services;
- delivering the highest expected economic value for society, taking into consideration both outcomes and impacts, such as employment creation and social gains.

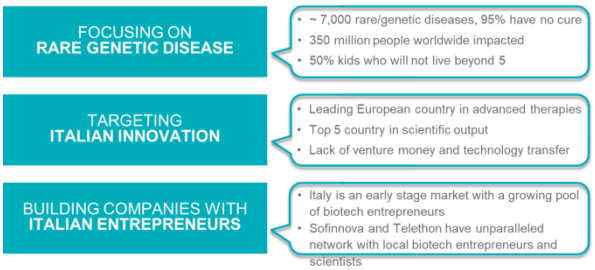
The EIB areas of intervention in the Life Sciences sector cover a wide spectrum, including health infrastructure, research and development for novel medicines and devices, medical education and training, solutions for integrated care, etc. Beneficiaries can be public institutions, private entities, as well as regional stakeholders that set up programmes of investment to support local companies and entrepreneurs, to develop highly innovative products/services.

Regarding the financial tools, the EIB provides also a wide array of products to support public and private investments, offering financial firepower, flexibility and expertise to get projects off the ground. In particular, Diego highlighted some of the most important EIB products for Life Sciences investments, notably project loans, venture debts and specific instruments such as the InnovFin funding programs, developed in the context of Horizon2020.

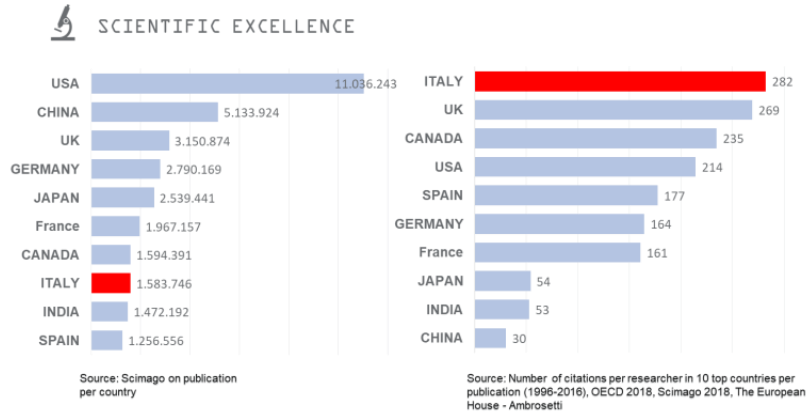
Paola Pozzi, Venture Consultant, Sofinnova Partners

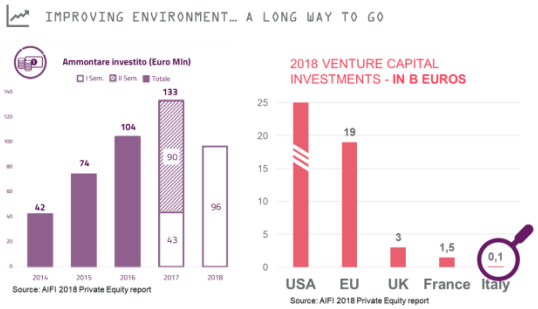
Paola started her speech giving some numbers about the investment Sofinnova has dedicated so far to health technologies, which account approximately to 2 Billion €.

She explained in detail the Sofinnova Telethon Fund (STF), in which European Investment Fund and Italy's Government investment vehicle Cassa Depositi e Prestiti committed 40 million euros to a new venture capital fund focused on Italian biotech startups lauched by Sofinnova Partners with Italian biomedical charity Telethon as advisor.

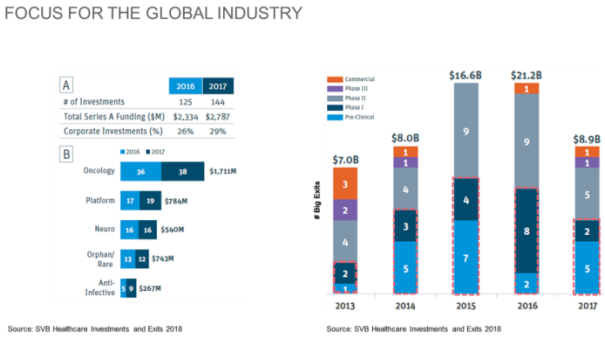


She underlined the need to improve and increase venture capital in Italy, whose scientists are the most cited on global scale, but in terms of investments to bring on the market breakthroughs and marketable ideas for the benefit of EU and global citizens and patients are still very low.





Paola afterwards showed some numbers about their early stage venture programme.



Lastly, she went through their internal peer reviewing process to ensure quality and efficacy of their investments.

Session III: Technological challenges for system integration and data interoperability

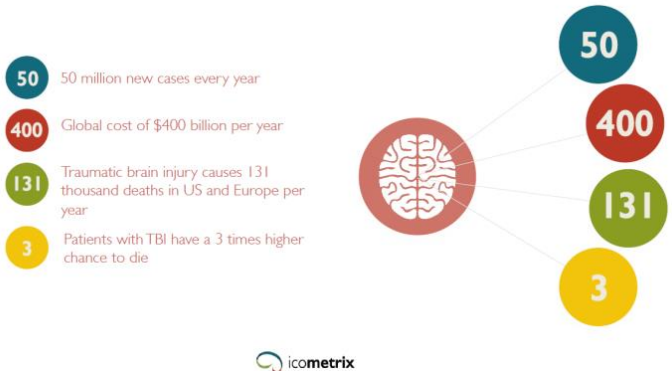
This session was intended to address the main technological challenge to support innovative solutions that can boost people's health and quality of life and enable more efficient ways of organising and delivering health and care services.

The session was chaired by **Andrea Frosini**, Head of UVaR – Ufficio per la Valorizzazione delle ricerca biomedica e farmaceutica – Tuscany Region.

Jan Verheyden, Vice President of Icometrix

Jan presented the challenges and opportunities from imaging point of view and brought the precious contribute of a company in the Personalised Medicine landscape.

He firstly introduced the numbers of Brain Injuries, defined as "an alteration in brain function caused by an external force".



Brain disorders are associated with ageing related chronic diseases, difficult to prevent and costly to manage.

Advancements in imaging biomarkers technologies reduce the time to diagnoses and help clinicians and health professionals to shape better and more preventive care trajectories.

Icometrix is one of the global players in this sector and WP leader in the Center-TBI project[31].

After having touched the main areas of work of the company, Jan tackled the issue of how to make the imaging data usable, whose problem is threefold:

- Data Completeness
- Data Quality
- Extraction Tool for user-friendly access

He then provided some general solution for the data curation:

31 The CENTER-TBI project is designed as a comparative effectiveness research (CER) study with a strong emphasis on evidence translation and communication, aiming to achieve optimal dissemination of results. They conduct a prospective longitudinal observational study in 60 centres from 20 countries including approximately 5400 patients (CENTER-TBI Core Study). They will obtain detailed data on the entire clinical course on injury details, treatment, outcome and health costs, collecting all relevant core Common Data Elements (TBI-CDEs).

- Harmonized and standardized data collection through fixed protocols, harmonized across major vendors and across studies. Reference data via healthy controls and phantom data
- Storage and management -> Findable and accessible via Brain Imaging Data Storage (BIDS) format
- Structured reading -> Central reading with **Common Data Elements**
- Quantitative analysis -> **Standardized quantitative reporting**

Lastly, Jan focused the last part of his presentation on some key challenges still untackled with regard to imaging data:

RESEARCH

- 'Big data' is required for precision medicine research
- 'FAIR' (Findable, Accessible, Interoperable, Reusable) principles are required to pool data
- Harmonized and standardized data
- Data curation: Data Completeness, Data Quality, Extraction Tool for user-friendly access

CLINICAL

- Reimbursement (Europe vs US) is a difficult story and need to be streamlined
- Slow clinical uptake -> AI is not replacing the radiologists, but rather support them
- Information Security (ISO27001) is needed.

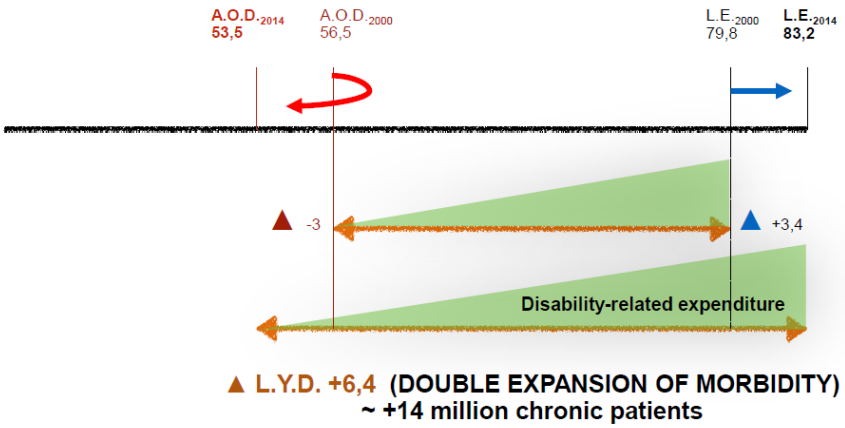
Paolo Gazzaniga, Director of Studies Center at Assobiomedica

Bringing the voice of the national federation of medtech companies, Paolo gave his view about technological challenges for system integration and data interoperability stating preliminary that innovation is not a stand-alone mater of supply, but it needs a market (demand), a value-based procurement as well as smart settings.

On the same side, Paolo reminded the so called trajectories of performance improvement, according to which "The pace of technological progress may exceed the rate of improvement that customers want or can absorb. When this happens, innovation overshoots the performance that market demand" which may lead companies to fail and stop the innovation flow in the healthcare sector.

Another bottleneck identified by Paolo is that research in medical devices often **not** based on public needs", but medical research priorities are based primarily on scientific and technological preferences, with little explicit regard for public health needs".

The global forum on health research to highlight the fact that **only** 10% of global health research expenditure is devoted to conditions that together account for 90% of the global disease burden"



Another very significant aspect for companies, is their capacity to adopt new technologies to improve the quality of their products and services. In this terms, Gazzaniga stated that technological innovation is faster than organizational innovation. If we talk about improving the market placement of better health technologies, we should also find a way to facilitate a faster internal organisations of companies.

These issues can be tackled ad different level: in this sense he presented a list of challenges to undertake in a matrix frame which encompasses all the business related aspects:

	COMPANIES	POLICY MAKERS	PURCHASERS	MEDICAL SOCIETIES
FUNDING		GIVE UP THE SILO MENTALITY		
REIMBURSEMENT		SHIFT FROM FEES FOR SERVICES TO PATIENT-BASED FEES		TAKE UP THE CHALLENGE OF PERSONALIZED DIAGN.-THER. PROTOCOLS
PROCUREMENT	TAKE UP THE VALUE-BASED-PROCUR. CHALLENGE		TAKE UP THE VALUE-BASED-PROCUR. CHALLENGE	
CLINICAL TRIALS & HTA	TAKE UP THE CHALLENGE OF RISING INVESTM. IN STUDIES	TAKE UP THE IN-ITINERE-HTA CHALLENGE		TAKE UP THE CHALLENGES OF CLIN. EXCEL. PLATFORMS & MD REGIST.
MANAGED ENTRY AGREEMENT	TAKE UP THE OUTCOME-BASED-PRICE CHALLENGE		TAKE UP THE OUTCOME-BASED-PRICE CHALLENGE	
FOCUS ON PRIORITIES	COMMITMENT TO BE PRIORITY-FOCUSED-INNOVATION DRIVERS	COMMITMENT TO BE PRIORITY-FOCUSED-INNOVATION FRIENDS	COMMITMENT TO BE PRIORITY-FOCUSED-INNOVATION FRIENDS	COMMITMENT TO BE PRIORITY-FOCUSED-INNOVATION DRIVERS

Cristina Tinti, Bio-incubation manger, Toscana Life Sciences

The final speaker of the regions4PerMed conference was dr. Cristina Tinti, bio-incubation manager at Toscana Life Sciences.

She presented the regional precision medicine project, an experimental model for precision medicine in Tuscany, which has the aim to:

- Sharing technological platforms (analytical and –omics platforms, research and clinical labs, bio-banks, data science facilities)

- Supporting the regional health system to implement a personalised approach to diagnosis and care
- Promoting the economic growth of life sciences companies
- Engaging patients, clinicians, scientists

After having illustrated the main features and bio-incubation activities, she described, based on the needs raised by TLS incubated companies, the challenges that an organisation like Toscana Life Sciences is tackling in order to facilitate access to more and better health related data, data use, reuse and exploitation for the delivery of better and more patient cantered technologies.

Specifically she pointed out the following messages:

- Development of bioinformatics tools, infrastructure and centralized facilities to enable the integration, analysis and interpretation of heterogeneous data (-omics data; medical records, other)
- Multidisciplinary skills for scientists and clinicians
- Preservation of patient-generated health data for further analysis and research purposes (legal and ethical issues)
- Legal and Regulatory issues concerning Public-Private Partnership

Closing remarks

Regions and regional innovation ecosystems are deeply active in fostering personalised medicine and heath innovation in Europe. They are becoming an essential element to collect, store and provide access to health related data as well as for providing important investments to a different range of activities such as:

- Central and connected biobanks;
- Creation of Regional Health Information Systems, to implement centralised and regulatory compliant health data management systems.
- Local healthcare reforms, aimed at rearranging the healthcare offer based on the stratification of patients by level of chronicity and its health demand;
- Personalised medicine pilot projects, which are often disease specific and aim at reduce time to diagnosis, provide better treatment response, improve the efficacy of the treatments based on genomic profiling, patient lifestyles etc
- Health Technological clusters, which are facilitating regional public private partnerships for health infrastructure investments.

Health is no more intended as a simple value in itself and it is becoming a public policy priority in the EU. For this reason, it is more and more important also to focus on the economic aspects of Health. Investing in the efficiency of Health system and especially on prevention will bring also increases in work productivity and will reduce social inequalities

As all these example of personalised health and medicine approaches need to be included in a integrated and complementary frame, the interregional collaboration is acknowledged as key tool to leverage upon local investments, and connect different technologies for more personalised, preventive and even predictive treatment strategies. Regions can join forces, expertise and capacities to create wider schemes able to deliver innovative services with a twofold effect:

1. Improve the quality of care and the efficiency of healthcare systems;
2. Boost the competitiveness of local health industry.

Specific attention should be put on the regional inequalities in Health R&D investments and the so called the within-countries regional polarisation, which might imply a minor capacity of some Health innovation systems to respond adequately to societal contextual needs taken into consideration by regions4permed.

This work represents only the authors 'view and the European Commission is not responsible for any use that may be made of the information it contains.

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