Regions4PerMed

Interregional Coordination for a fast and deep uptake of Personalised Medicine

Regions4PerMed

Key Area 1: Big Data, Electronic Health Record and Health Governance

Report

HORIZON 2020

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DESCRIPTION

This report summarises the content elaborated within the International Conference and the Interregional Workshop which took place in Milan in May and September 2019

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1. Overview of the KA1

The relentless pace of technology, fuelled by the advancement in genome sequencing techniques and the digitalisation process within health systems has led to a significant increase in data production. The quality of data itself is changing, with "big data" now offering multiple possibility for using and sharing information.

By definition, big data in healthcare refers to health data sets whose management is not possible with traditional software and/or hardware or data tool, especially because, besides their volume, they present a high level of variety and differences (Raghupathi, 2014). However, it is on their volume and in their multiple use that a personalised medicine approach can rely, since a huge amount of information is needed for every single patient.

This raises a number of challenges that need to be overcome. On the one hand, new ways of collecting, storing and managing big data need to be thought, bearing in mind the issues of privacy and security.

Furthermore, especially for health data, new actors have a role in the process of governance: not only patients, carers and medical staff, but also decision makers who, through data, can shape more effective policies and reorganise services, and can provide support to industry and innovation stakeholders, for whom data can bring information necessary to drive new advancements.

The role of regions has therefore become pivotal in the health governance system.

In this Key thematic Area (KA1) Regions4PerMed tries to shed light on the most important issues of big data in health, presenting an overview of the current state of art of big data and suggestions, coming from all experts involved in the work, that can support research, regional policies and innovation programmes in Personalised Health and Medicine in order to accelerate the deployment of PM for citizens and patients.

2. KA1 Technical conference

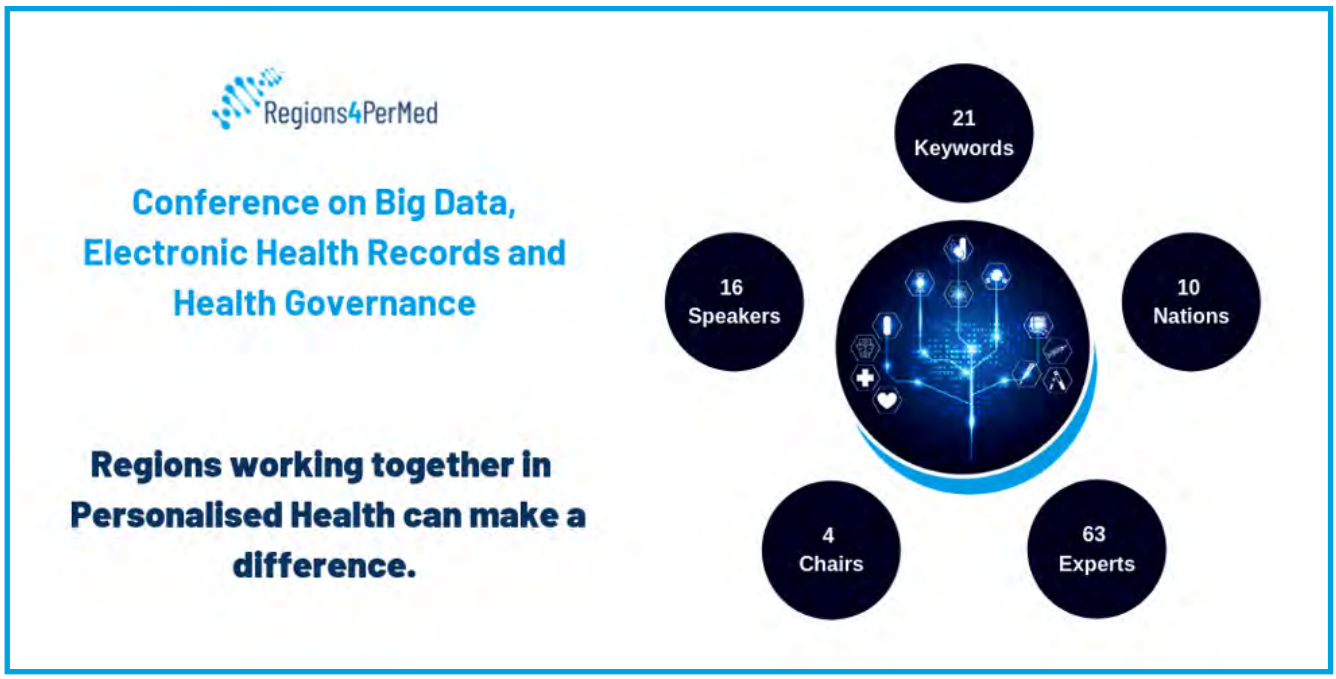


Figure 1: *Conference in a nutshell*

In May 2019 the first technical conference on "Big data, electronic health records and health governance" was organised in Milan.

The aim of the conference was to explore the first key thematic area of the Regions4PerMed project, which is to understand how big data and digitalisation can support measures to promote health, to initiate a reform for health system, easing the transition to new **patient-centred care** models and to integrate care structures. Specifically, the discussion was about the potential, risks and role that all actors involved can play in the governance process of health data, focusing in particular on the current state of art and the next challenges.

The attendees of the conference were regional and governmental entities involved in health policies coming from all Project's partner's countries (Italy, Poland, Germany and Spain), big data experts from academia, research hospitals and patients' organisation. The conference participation is summarised in Fig. 1

The first part of the morning was dedicated to *"Setting the Scene"* introducing the main challenges that national and regional health systems need to tackle to foster the translation of personalised health and medicine into real life settings. A

strong focus was put on how the valorisation of heath data can help European systems to become resilient, effective, equitable, accessible, sustainable and comprehensive, so to provide a framework for coordinating healthcare systems in Europe.

The session was chaired by **Sergio Abrignani** (Member of the Advisory Board of Regions4PerMed) from the National Institute of Molecular Genetics (INGM) and University of Milan.

Pietro Barbieri (Lombardy Region) introduced the topic of personalised health governance from the perspective of a Region. He explained that Regions and policy makers base their decisions on the efficacy of health services.

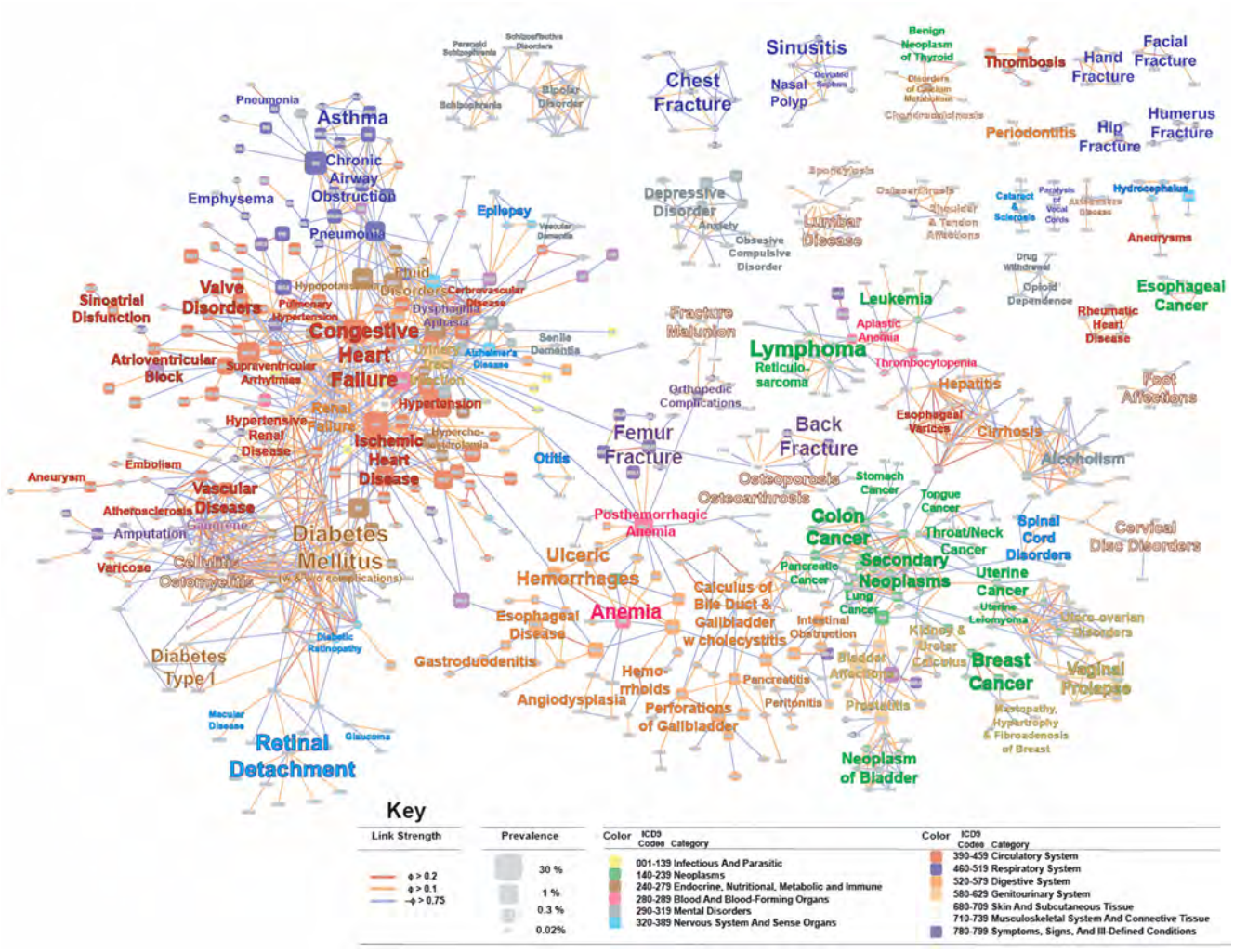


Figure 2: *Network analysis applied to administrative medical data*

He gave an insight of the Lombardy regional health reform, put in place in 2015, elaborated with the aim of responding to new epidemiological issues by leveraging the new technological advancements.

The ongoing work in Lombardy is mostly focused on structured databases which are indexed by individual codes; the high quality of data allows an adoption of deterministic record linkage to maximise information extraction.

Not only digital changes, but also cultural changes have led to an organizational transition towards a "taking care approach"

Through the analysis of medical data, the regional government prioritised, as one of the main challenges for the health system, the management of chronicity - intended as paradigm of complexity and personalized medicine. He highlighted that not only digital changes, but also cultural changes have led to an organizational transition towards a "taking care approach", a system where the synergetic action of different players integrates and personalizes the care path, thus meeting the health requirements of each patient[1].

Significantly, this reform could be applied effectively on the regional territory, and it is now an example for other regions.

Jana Makedonska (European Commission) described how the European Commission is supporting the **transformation of health and care** in the digital single market and how an initiative like the "1 Million Genome" paves the way to a newer and deeper form of European collaboration in health.

She highlighted how the European Commission set the theme of Digital health and Care as a strategic priority in the Mid-Term-Review. An Interinstitutional task force of the European Commission (DG CONNECT, DG RTD and DG GROW) developed the Communication on Digital Single Market Strategy and elaborated the Digital Transformation of Health and Care, which was approved by the European Economic and Social Committee (EESC) in 2018. The main pillars of the strategy were shown in the figure 3 and 4.

1. *Regione Lombardia, Lombardia informatica, "Constructor of innovations" www.lispa.it on 20th November 2019.*

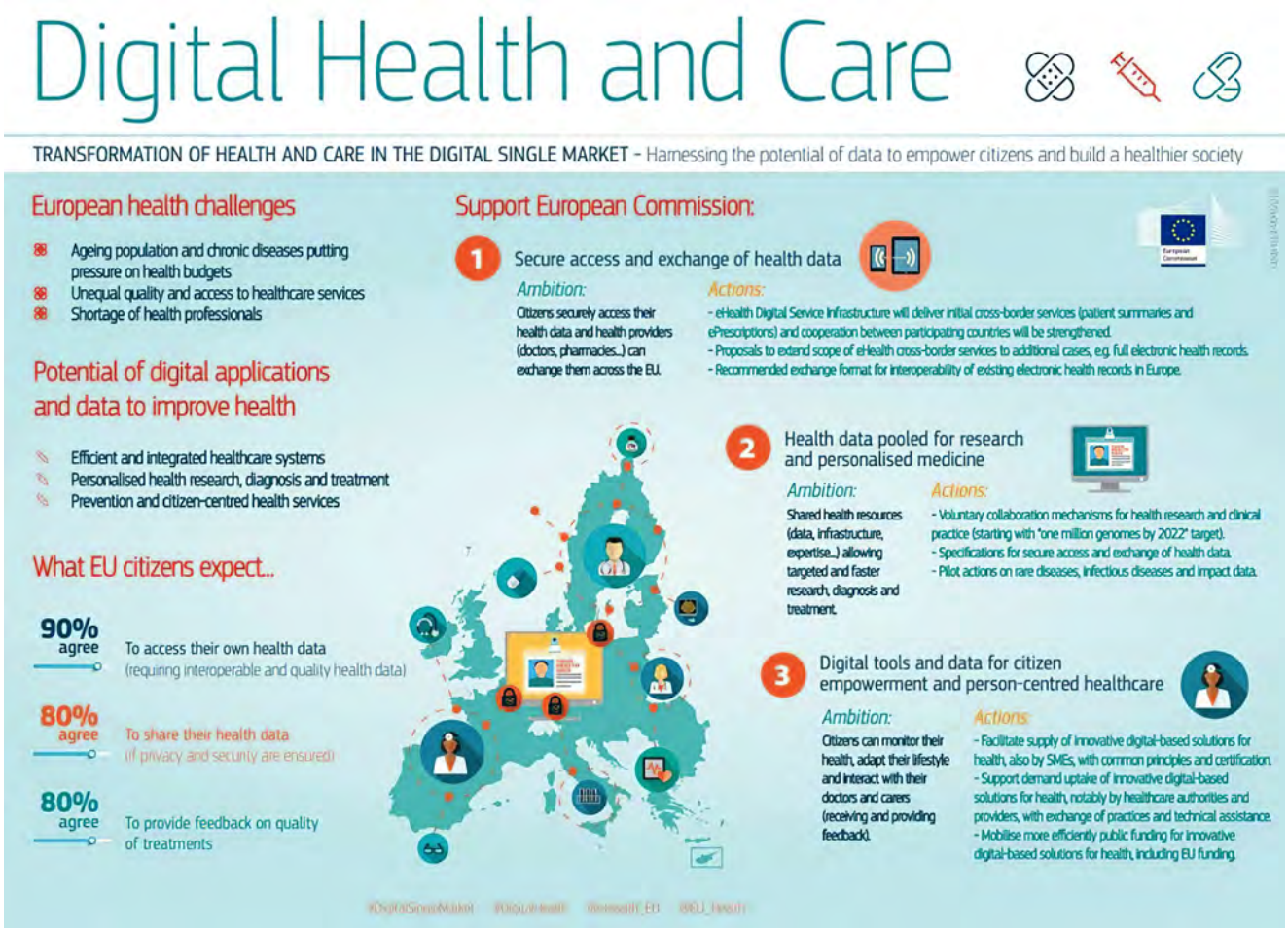


Figure 3: *European Commission, Digital Health and care.*

She provided information about the implementation of the declaration "Towards access to at least 1 million genomes in the EU by 2022", through which the Member States agree to collaborate on the secure and authorised access to national and regional banks of genetic data and other data relevant for health.

With these initiatives the European Commission will support Member States in setting up a **voluntary coordination mechanism** of public authorities to link ongoing genomic medicine initiatives. The coordination mechanism will:

1. Define a governance model of the cooperation, particularly concerning the terms and conditions for distributed access to genomic data across-borders, usage of the data and others;
2. Support the development of technical specifications for secure access and cross-border exchange of genomic datasets within the internal market;
3. Facilitate interoperability of relevant registries and databases to support personalised medicine research.

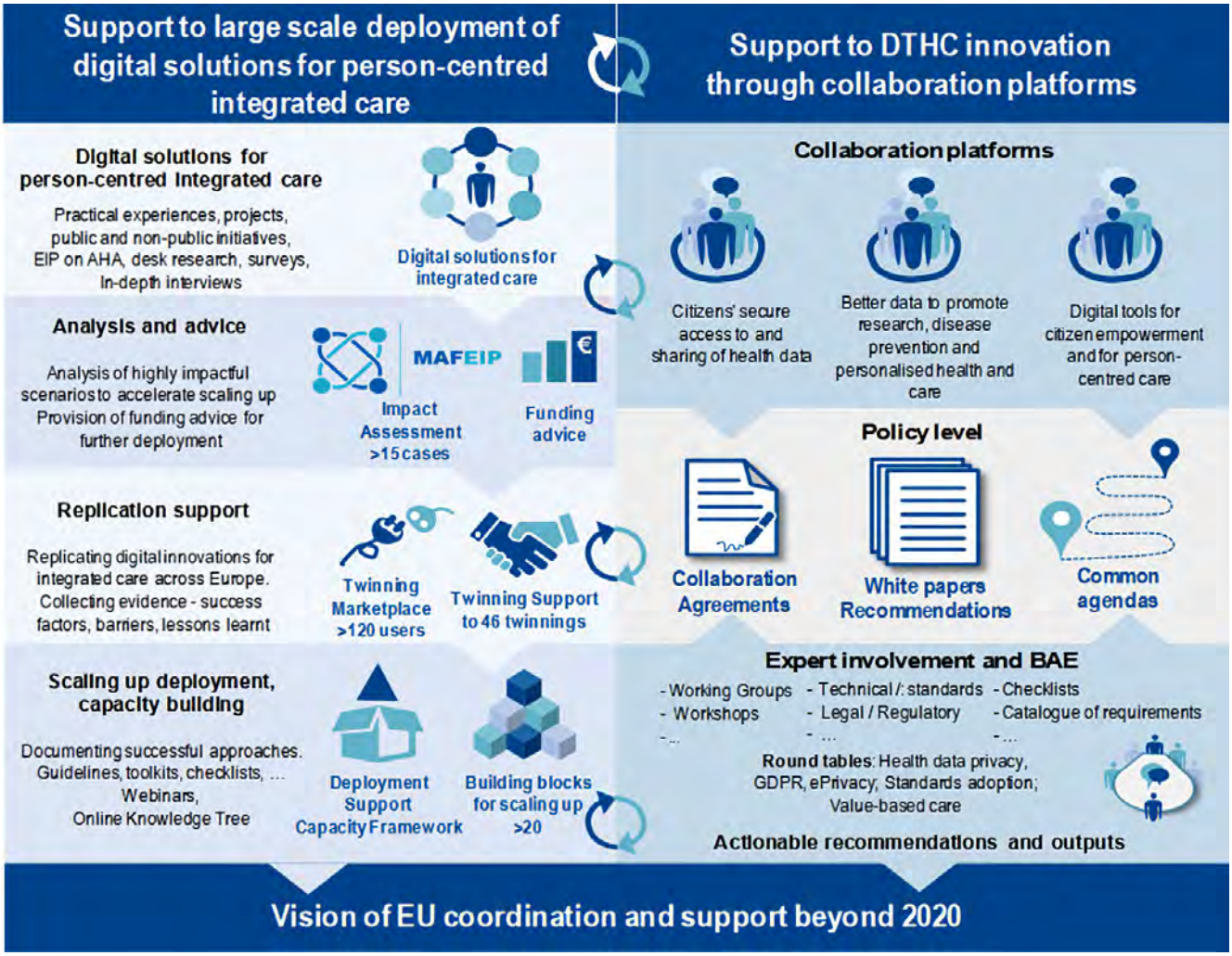


Figure 4: European Commission, Vision of EU coordination and support beyond 2020

Elio Borgonovi (Bocconi University, CERGAS), described the **role and value of regions** for the healthcare of tomorrow, highlighting three steps for the generation and diffusion of personalised health and care:

- Scientific research
- Translational research
- Reorganisation and change in the current health systems.

The governance system is key for managing the whole process, specifically for the definition of **health policies** and **investments**.

A) Scientific research entails interdisciplinary, generation of new knowledge and management of disruptive innovation.

B) Translational research requires a rethinking of the current professional profiles, considering the

interdisciplinary background now needed, and new processes in place.

C) New processes call for a reorganisation of regional provider networks (hub and spoke model, public-private mix) and a change in the management system, not only to face the innovations coming from scientific research but also to adopt new healthcare processes in new settings.

The "traditional management", based on hard knowledge, planning of operational resources, accounting and budgeting, will remain relevant but will have a lower impact on the functioning of a complex system. There will be a need to change a skill mix (big data analyst, medical doctor, cyber security expert and other professional profiles).

According to these premises, the main areas to address are:

- Regulation, at EU Level, or at least among Member States, through coordination;
- Health policy settings, in terms of principles, new needs, new knowledge to implement;
- Adaptation of general policies to different epidemiological, cultural, management and socio economic condition.

Local and Regional Authorities (**LRA**), as well as intermediate institutions, are critical in addressing these issues as they are in charge of translating general regulations in operational and day-to-day activities.

Figure 5: *Three steps for the generation and diffusion of personalised health and care within European LRA*

In particular, there is a need to strengthen collaboration among LRA and between LRA and health delivery organizations, to improve the relation between policy making and management levels so that a) what is needed is clear and b) how the goal can be achieved is defined.

New training programs should be created, in order to train new professionals that will soon be needed: a mix of clinicians, doctors, biologists, nurses, managers, sociologists. Investments in education and training should be made now, or there will be a delay in dealing with relevant technological, organizational and ethical issues.

New processes and new healthcare settings entail also new remuneration schemes. These new schemes, based on the pay for performance model, are necessary for the needs of Personalised health and Medicine. New schemes must overcome the silos funding.

Of paramount importance is the redefinition of **Health Technology Assessment (HTA)** frameworks. LRAs need to try to anticipate and regulate the new benefits coming from personalised health as well as to assess its risks (i.e. new inequality related to how different groups will have different access to new services), as well as the safety issues connected with new professional and people working in the field. This new frameworks will have to include cost-benefit, cost-effectiveness and cost-quality analysis.

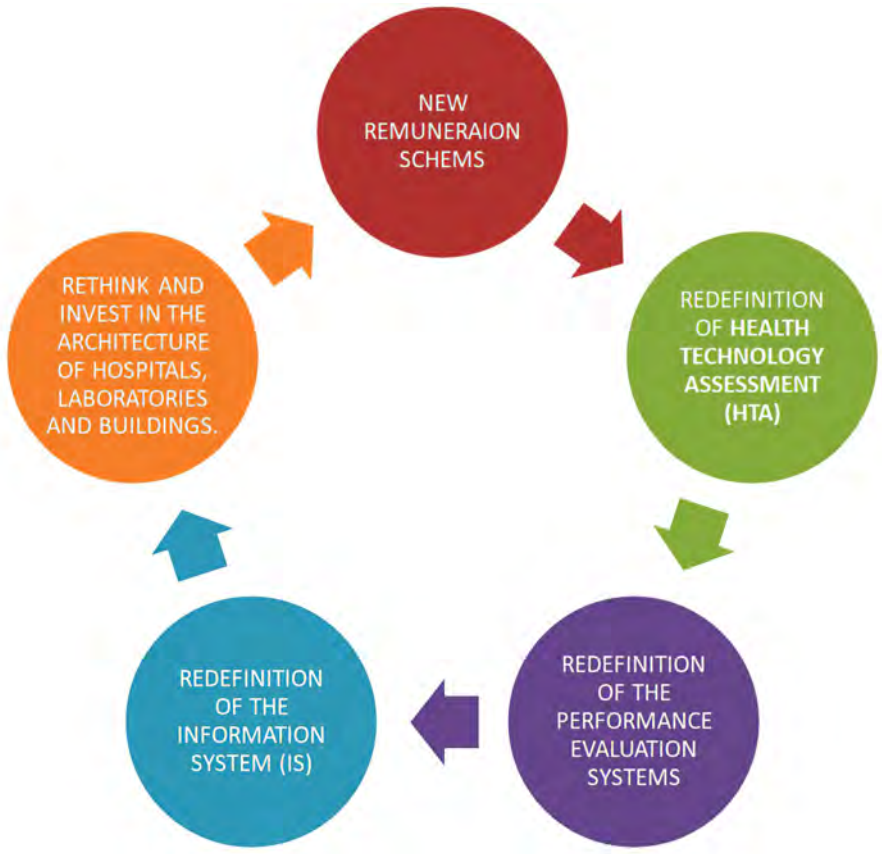


Figure 6: *Five actions to be undertaken by European LRA to implement Personalised Medicine*

LRAs need to play a role in the redefinition of the performance evaluation systems, in particular for dealing with the new mix of public-private players, going beyond the traditional performance evaluations based on efficiency, effectiveness, sustainability, economics.

A redefinition of the Information System (IS) should also be sought, in the perspective of being rapid and effective in collecting and elaborating and interpreting data. The Information systems need to be flexible in order to deal with more and more data, making them accessible, and specific training programmes should be put in place to extrapolate meaningful information from the data.

Finally, LRAs need also to rethink and invest in the architecture of hospitals, laboratories and buildings.

Sabrina Montante (National Institute of Health, Italy) presented the TO REACH Project (to-reach.eu/). Starting from the **common challenges** that health systems across Europe are facing, such as the need for technology to be used effectively, the uneven distribution of health and care professionals, the persistent and rising **health inequalities** and **financial pressures** on economies, the TO REACH project aims at producing research evidence to support healthcare services and systems so that they become more resilient, effective, equitable, accessible, sustainable and comprehensive in Europe.

Healthcare services and systems must become more resilient, effective, equitable, accessible, sustainable and comprehensive

Following this opening session, the day continued with sessions dedicated to different topics.

SESSION I focused on *clinical decision support, data sharing, patients' engagement.* The session was chaired by **Nick Guldemond**, Erasmus School of Health Policy & Management, PANAXEA.

Riccardo Bellazzi (University of Pavia) described the current issues and presented guidelines for predictive data mining in clinical medicine: how to use **data to support clinical decision**. He talked about the potential of big data, highlighting at the same time the importance of the purpose of the collection and use of big data.

Analysing the current publication trends, it is clear that more and more knowledge is based on health data, particularly coming from AI or deep learning, and it seems that this knowledge is ready to be transferred.

New data sources are available in electronic format, including data from wearable devices. Better algorithms and infrastructures are now available while machine learning systems are now able to process data coming from devices or from images.

One of the issues is that the methods applied by the machine learning mechanisms are basically a black box which poses a great risk to the deployment of new technologies.

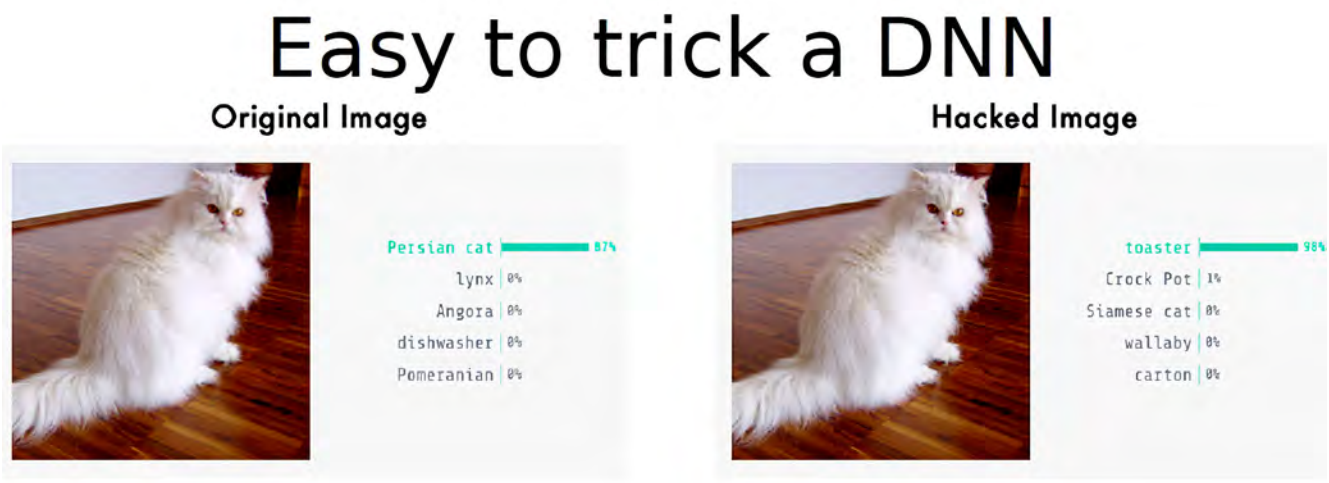


Figure 7: *Original image and image with perturbation: a tiny perturbation on the bits of the second cat image, the deep learning model predicted it as a toaster*

In order to avoid a potential failure of an otherwise essential tool for the medicine of tomorrow, there are four areas to address:

- **Deep understanding:** the data we find in healthcare records may not be constantly precise, and more information on the process that generated the data is needed. There are numbers of errors inside the electronic health records. Data remain significant but we should not consider them as clinical trial data. This means that data stewardship programmes should be in place in order to make this data effective and exploitable
- **Data governance:** the collection of data, and its quality, is of the utmost importance. Sometimes big data without a good stewardship programme does not help researches find the needle in the haystack, only make the haystack bigger. The format and the data should be interoperable: we could share the code instead of sharing the data. In order to tackle this issue, it is important to build and adopt model and data architecture which may mitigate the effect (like i2b2 Academic Users' Group data warehouses for sharing data which is based on specific ontologies, or OMOP Common Data Model)
- **Model Validation:** In deep learning approaches, the models generated can be easily perturbed by mistakes that are then processed and jeopardise the clinical prediction.

Distortions created through machine learning processes do generate errors that an expert, i.e. a clinician, never does. Therefore it is of utmost importance to support a model validation analysis

- **Explainability:** It is important to always explain the **purpose** of a model. We can start from the regulations that we have, including the new GDPR, that aim to protect citizens from taking decisions without being able to understand the process that lead to a particular result. That is the reason scientists should open the black box.

Giovanni Apolone (Fondazione IRCCS Istituto Nazionale dei Tumori, Milan), tackled the role of Big Data as a driver of clinical decision support system. **Validation** is key, as in the medical practice decisions are based on **evidence**. Big data appear to be an excellent tool (together with **AI**) to support clinical decisions, and they can be used at any level of medicine and healthcare, from primary prevention to rehabilitation, from genomics to real world evidence. In order to be adopted, they have to prove their efficacy and therefore any healthcare technology of these kind has to be assessed in terms of clinical benefits (risk-benefit) and cost effectiveness (cost-utility). In this regard Apolone poses the focus on two main points:

- So far, no evidence based data is available to support the uptake of Big Data in the health care setting (research is ongoing)
- Different potential applications: the most interesting is as a tool (together with AI) to support clinical decisions.

In healthcare decisions are taken on the basis of the best available evidence, and evidence itself can be produced by different methods and can be classified according to the quality of the study: big data and AI based evidence can represent a new layer of the hierarchy of evidences.

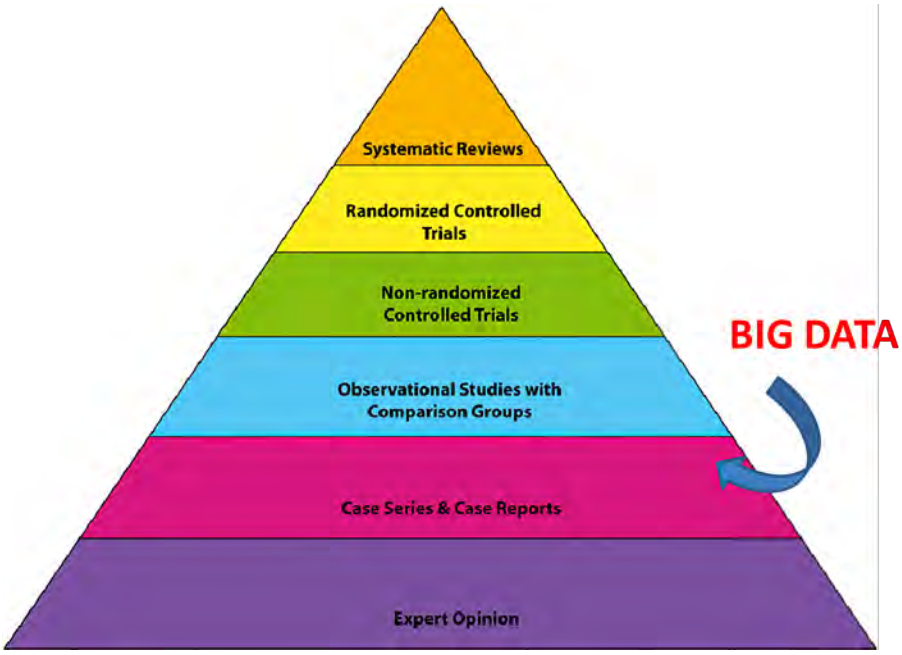
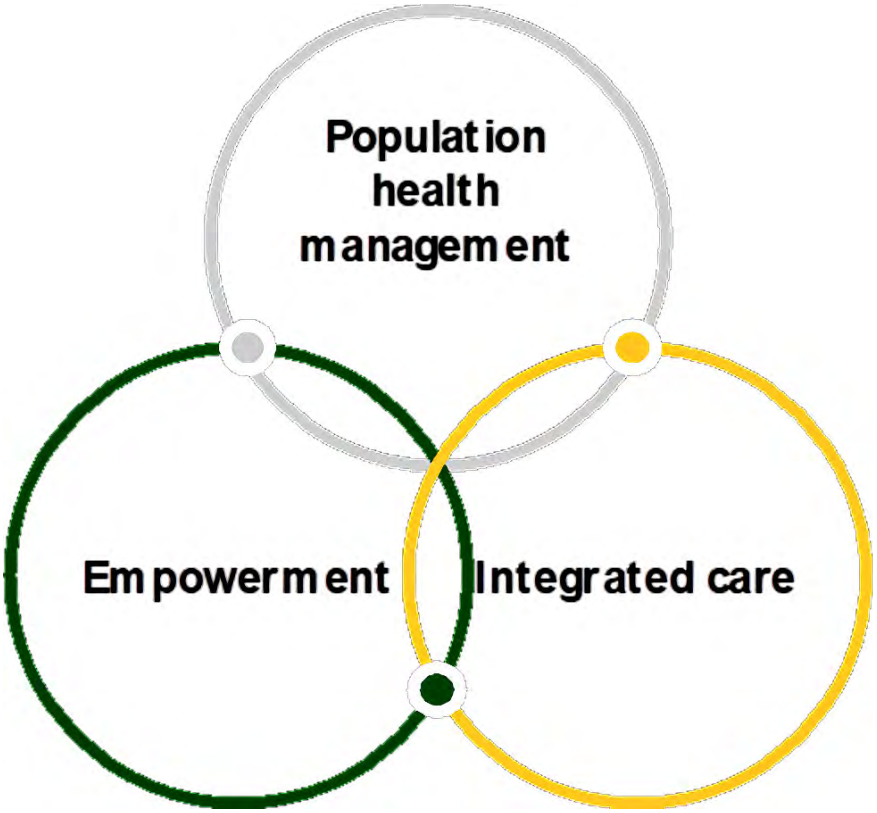
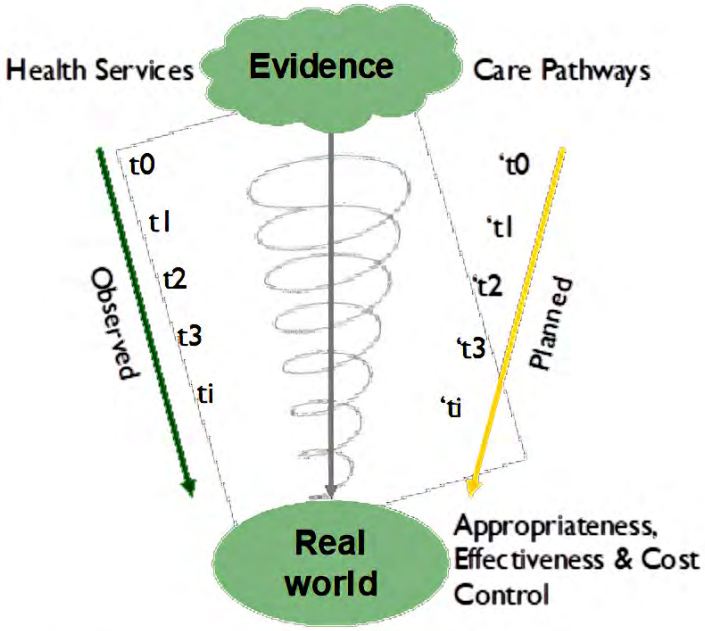


Figure 8: *The hierarchy of evidences for clinical decision*

Antonio Barone (ARIA, azienda regionale per l'innovazione e gli acquisti) showed how Lombardy Region used data, and data driven technology to bring the benefits of digitalization in health to patients. He presented the **"taking care approach"**, based on integrated and accountable care model.





Model for the integration of the Evidence-Based Practice and the Practice-Based Evidence for the levels of improvement of the quality of chronic patients' care

Figure 9: Lombardy Chronic Care Model Approach

One of the strategic objectives of the regional government was to tackle the issue of management of chronic patients. Thanks to the data mining of the Lombardy health data, the patients' population has stratified in 5 levels and a specific care programme tailored on their clinical needs.

The taking care approach includes the development of a personalised healthcare plan (PHP) which provides a strategy for each individual around whom the care system is reorganised. It also enables the empowerment of patients and paves the way to a smart use of data for precise need analysis and future personalised treatments.

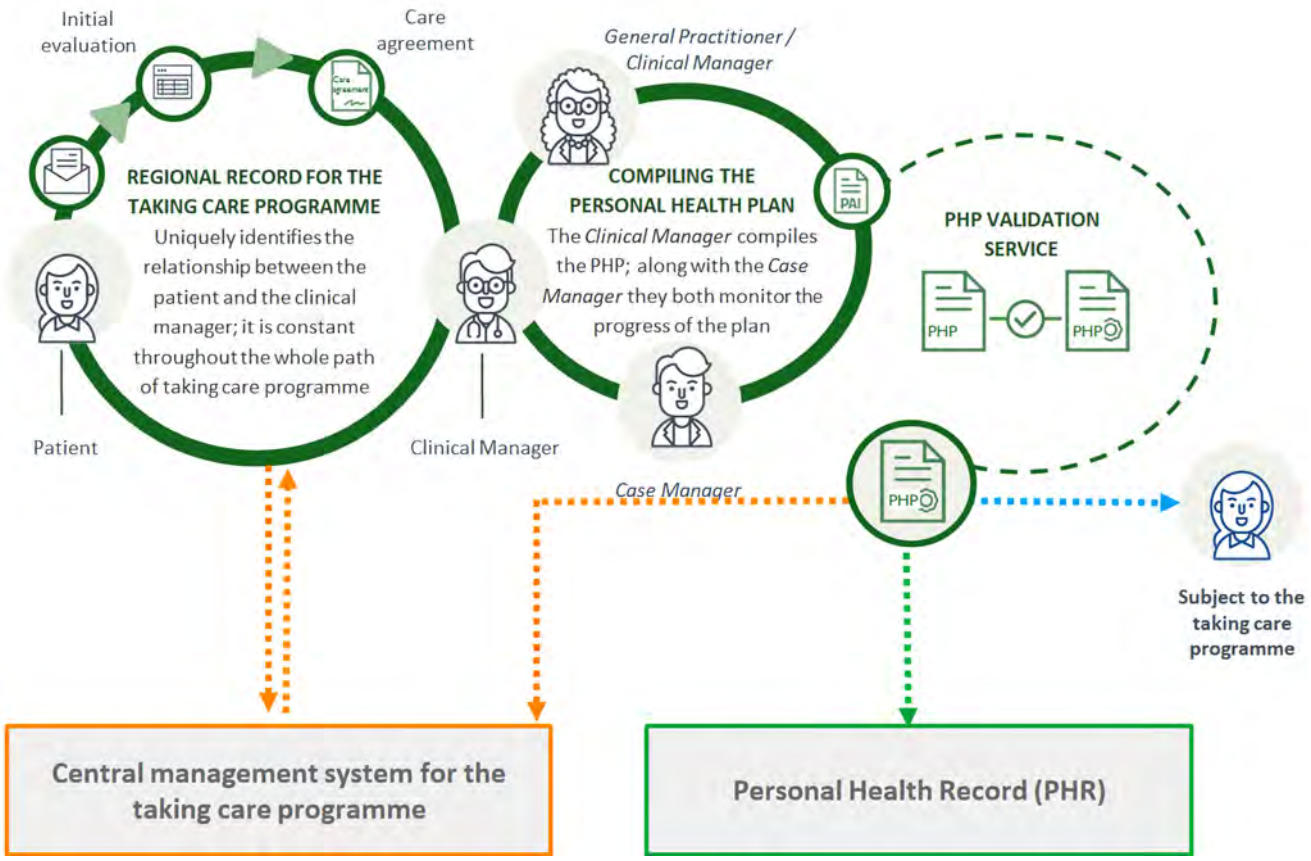


Figure 10: *The structure of Personalised Healthcare Plans in Lombardy*

SESSION II was focused on *Research Data management.* The session was chaired by Denis Horgan, European Alliance for Personalised Medicine (EAPM)

Lisa Licitra (Fondazione IRCCS Istituto Nazionale Tumori), presented a Pilot project in oncology as an example of application of the big data technology. BD2DECIDE is a project dedicated to build and validate an Integrated Decision Support System linking together: patient-specific multiscale data from genomics, pathology, clinical and imaging (radiomic) data, population-specific epidemiologic, behavioural and environmental data, available multiscale prognostic models and graphical visualization tools. Lisa Licitra highlighted how all information collected from data, due to the mathematical model built to uncover clinically relevant inferences, fall within the concept of **black box Medicine.**

The main lesson learnt from the project is that precision medicine in oncology is becoming more and more an interdisciplinary field which, in terms of capacities, encompasses medicine, engineering, physics and computer science.

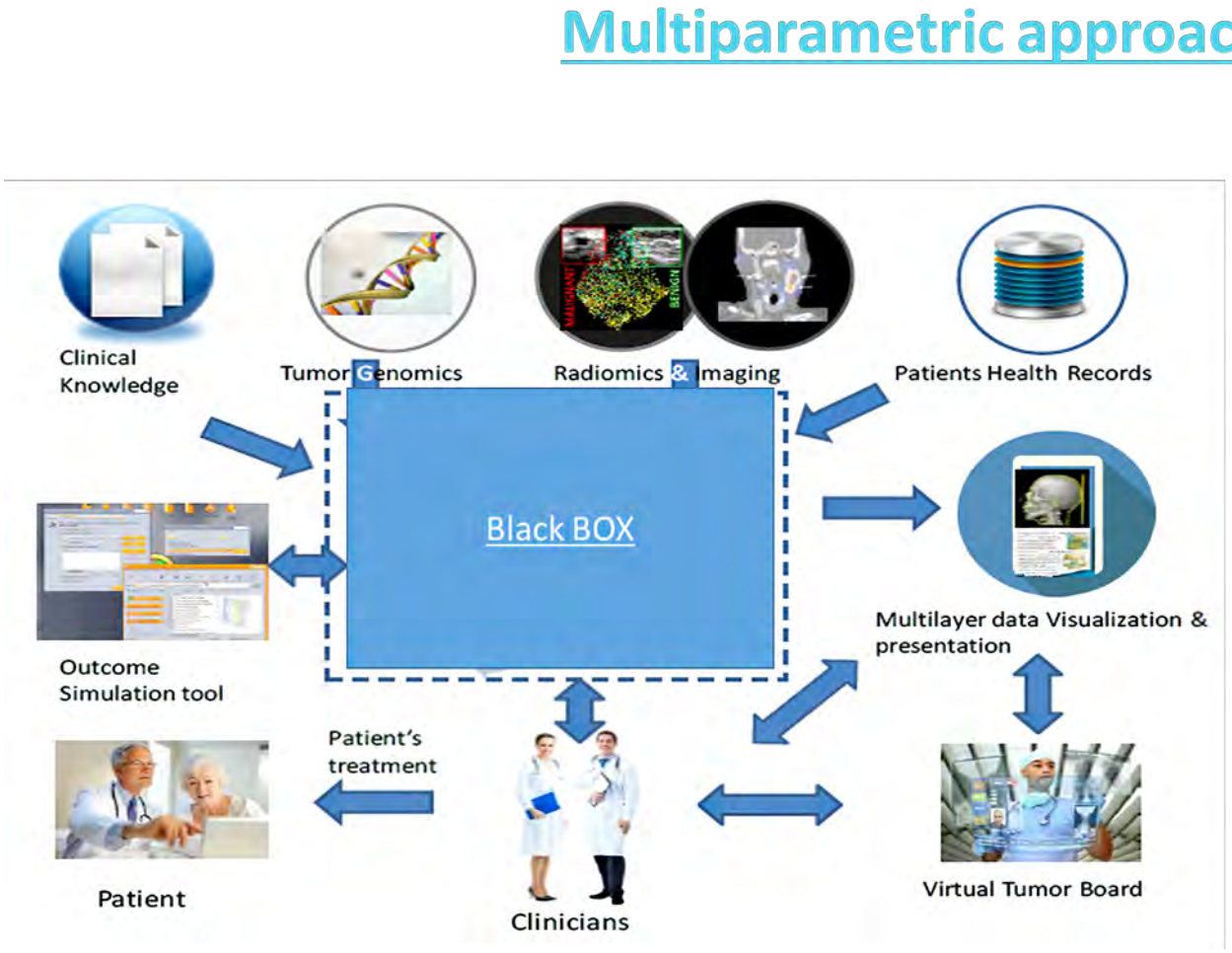


Figure 11: *Multiparametric approach in Black-Box Medicine*

In this regard, Licitra stressed the increasing importance of applying mathematical methods, models, and simulations in the pursuit of personalised medicine to better meet the urgent need to leverage the massive amounts of currently underutilized data to a clinical benefit.

SESSION III: *Data and Patients* addresses the social issues related to the topic of big data in health: the **patients' perspective**, the impact of algorithms on daily life. The session was chaired by **Christos Lionis**, University of Crete.

Technology can now be considered as an actor in healthcare

Mauro Turrini (University of Nantes) described what algorithms can do and what is their impact, especially on data-driven devices in health care. He explained that technology can now be considered as an actor in healthcare, since the one-to-one doctor-patient relationship has now become a **three-way relationship, with the third party being technology.**

There are currently discussions on the possibility to have algorithms replacing doctors' diagnosis. Beyond the actual possibility for this to happen, these discussions do generate a political impact.

In the perspective of implementing personalised medicine, digital technologies and big data are highly valuable, but along with them the following conditions must exist:

- Allowing more time for clinicians to look at, and talk to, patients;
- Maintaining meaningful human control over the use of machines
- Investing in the education of professionals and the general public.

Also, digital technologies should be in the service of other values, especially solidarity.

Marco Greco (European Patients' Forum) opened his presentation with a challenging question: **Does Data Save Lives?**

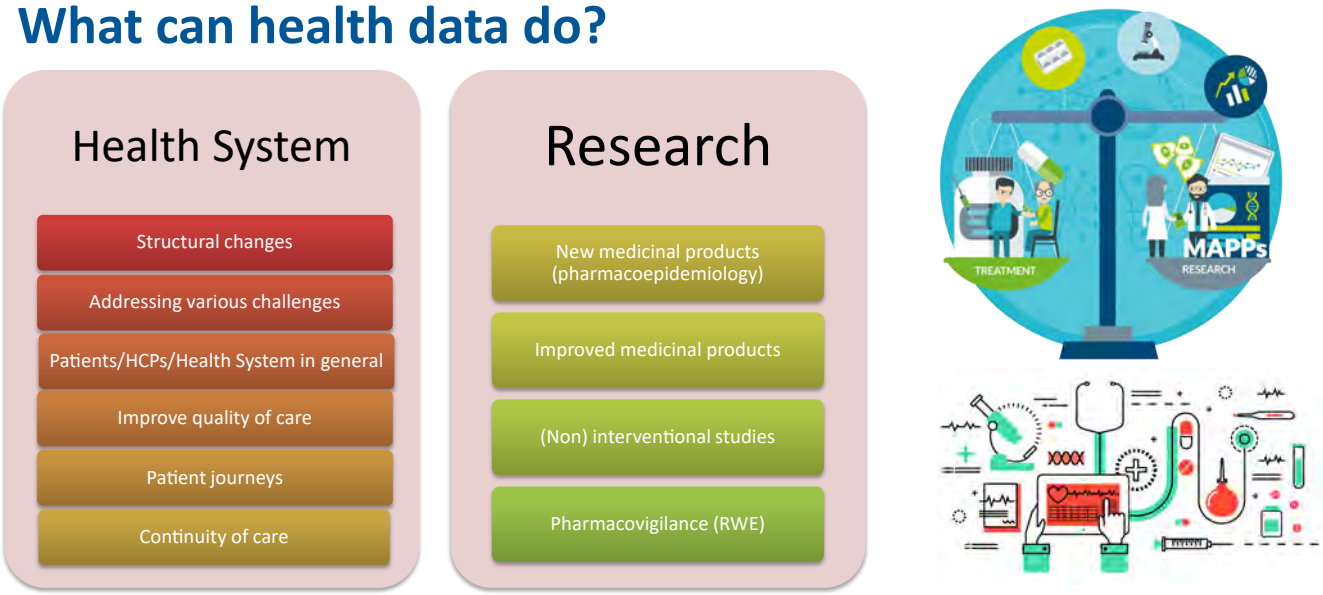


Figure 12 EPF: *What can health data do?*

He explained that big data have the potential to trigger structural changes to the healthcare systems, including the narrative of a patient's journey, the continuity of care and the quality of care, the relation clinician-patients.

Knowing that the GDPR has an impact also on health data, the "carrier" of the most sensible information of an individual, the speaker explained why **regulation** matters to patients: it provides progressive rules that give more rights to citizens and by extension to patients to be informed on the processing of their data, to object to the processing and to be better informed about the use made of their personal data. EPF has developed a **EPF guide to the GDPR** for Patients' Organizations.

He also reminded that **digital health inequalities** are no different than other social inequalities: there is the need of ensuring timely and equitable access to healthcare, avoiding discrimination of the basis of availability of information. Fundamental values of equity and solidarity need to remain at the core of healthcare systems.

He concluded with challenging questions related to the use of big data:

- Can discrimination and stigma be addressed through security and privacy policies?

Digital health inequalities are no different than other social inequalities

- Do medical data "belong" to anyone? They refer to patients but can't be useful unless interpreted according to medical standards
- What is the role of stewardship and governance?

Martin Sedlmayr (TUD Institute for Medical Informatics and Biometry) presented the German Medical Informatics Initiative, aimed at overcoming the geographical limitations to get access to care. The medical informatics initiative will employ IT solutions to enhance patient care and research.

In particular, the goals of the Medical Informatics Initiative are:

- Consolidating patient-oriented clinical data
- Establishing the IT framework for tailored treatments
- Acquiring insights from patient data
- Making new findings immediately available for patient care
- Strengthening medical informatics in Germany

This will facilitate the exchange of data from the healthcare system to clinical and biomedical research, so that data can be used and exchanged across multiple entities and sites – transcending the boundaries of individual institutions and geographical locations. The conclusion was that the **evidence** that promotes better health decisions and better care should be collaboratively generated. He finally mentioned the project **EHDEN**, European Health Data & Evidence Network.

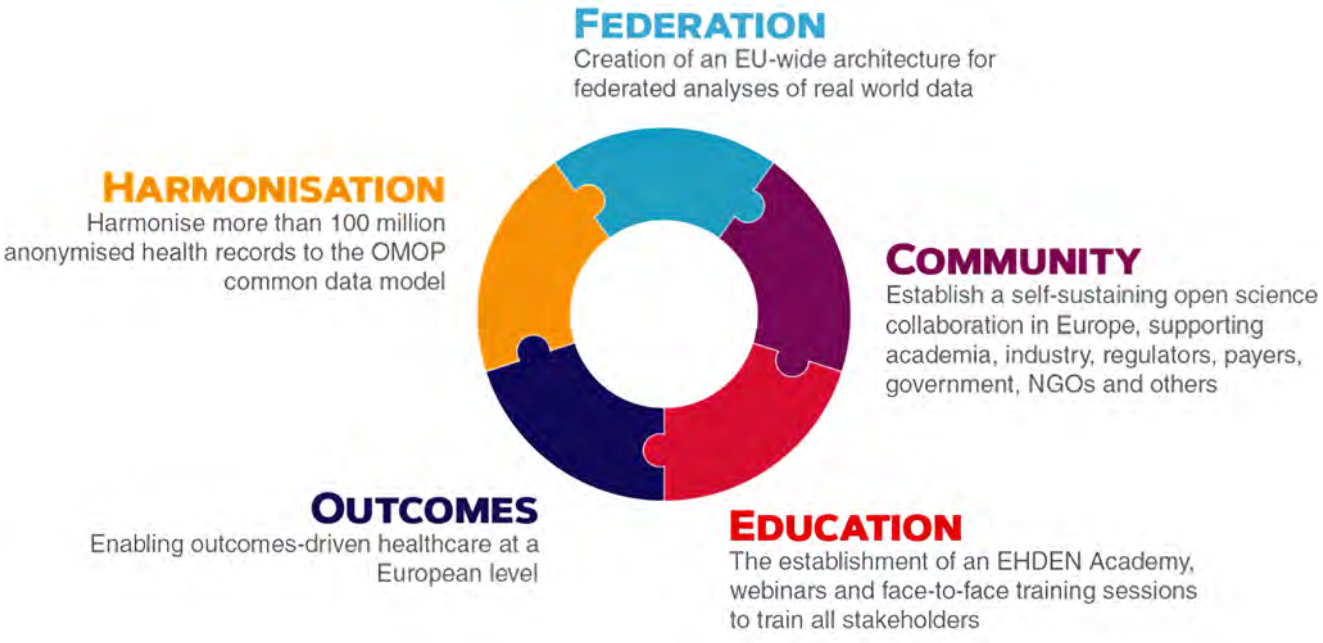


Figure 13: *The Pillars of EHDEN Project*

The final session of the day, SESSION IV: *Health data management: biobanks and healthcare databases* was dedicated to the current **infrastructures** managing big data. The session was chaired by **Denis Horgan**, European Alliance for Personalised Medicine (EAPM).

Eleni Salamaxani (Genomics England) presented the work of her organisation, focusing on the value of genomics data for science and medicine. She presented the "100,000 Genomes Project" that, with the aim of sequencing 100,000 genomes, aims to enable new scientific discoveries and medical insights, to **stimulate industrial and scientific investment**, and to build public support. In terms of long term strategy the 100.000 Genomes will:

- bring benefit to patients
- enable new scientific discovery and medical insights
- stimulate industrial and scientific investment
- build public support

This project has a strong governance system, where the public NHS plays a major role and genomics England acts as main player for its implementation, along with the patients involved. **Ethics** and **transparency** are at the core of the success of the project.

Salamaxani introduced some results achieved so by the programme.

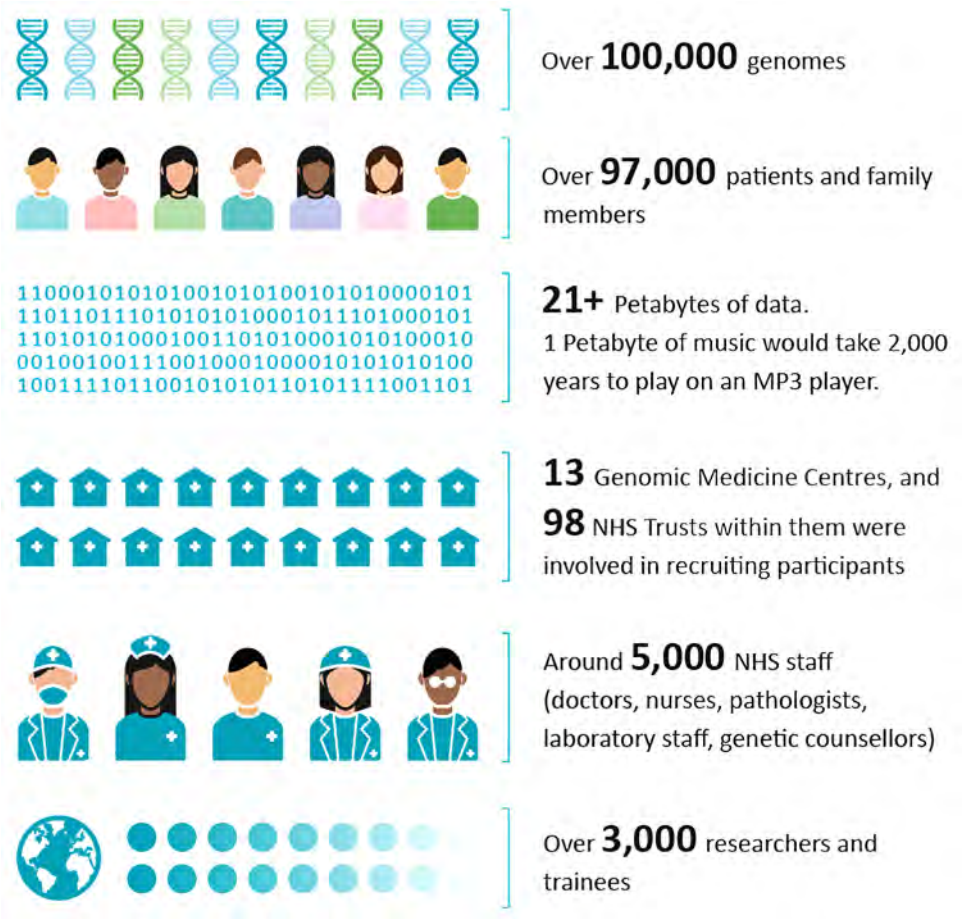


Figure 14: *How the 100.000 genomes project works*

Regarding its operations, there are 13 Genomic Medicine Centres (GMCs) which are located in the major hospitals in England who are identifying, consenting and obtaining samples from suitable patients. These GMCs have local delivery partners which are the smaller local hospitals meaning that there should be access to the program England. Once the samples have been extracted and the data is available for the participants, the samples are sent to a biorepository which plates all the samples for sequencing and stores the remaining sample. The sequencing occurs in a purpose built centre in Hinxton Cambridge which is a high throughput facility which Illumina runs using HiSeq X platforms.

The sequence data is placed into the Genomics England data centre along with the clinical data from the participant.

Genomics England Clinical interpretation Partners – GECIPs, are the clinical and research communities that have access to de-identified data for research and to help with interpretation of challenging cases. There is also a gene consortium made up of pharma companies who can access the de-identified data to drive R&D and clinical trials.

As main outcome of the project, Genomics England as registered a strong positive feedback for the public opinion. Due to data access it is fostering the genomic industry and they are scaling up to 5.000.000 Genomes.

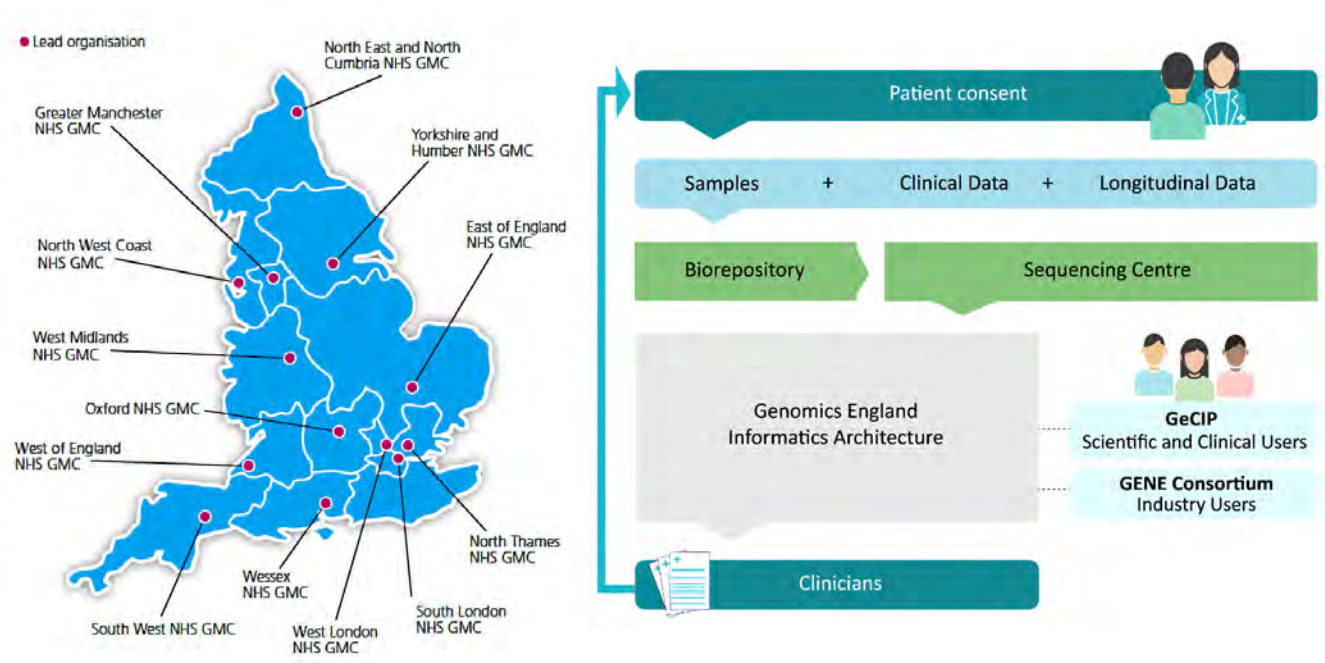


Figure 15: *Operativity of Genomcs England*

Giovanni Corrao (Milan Bicocca) analysed importance of **real world data (RWD)** in healthcare. He started from the current clinical needs for a full utilisation of RWD:

- Better definition difference in patients' features
- Increased understanding of differences in treatment compliance
- Accelerated approval process of new therapies by regulatory agencies

RWD help Tracing 'footprints' of real patients as they access their routine medical care for reconstructing the entire healthcare pathway of patients.

RWD help Tracing 'footprints' of real patients

He then focused on the necessity to produce evidence from RWD (comparison of different pathways, assessment of clinical value and economic value).

The challenges in the use of RWD are:

1. Shared rules for good practice of observational (clinical) research with secondary sources should be adopted and disseminated for generating credible evidence
2. Comparing clinical and economic values of pathways experienced in the recent past by patients for better caring of patients in the future.

Figure 16: *RW D from different sources*

Mary Wang (Fondazione Telethon) closed the talks of the day presenting the functioning of Network of rare genetic biobanks, which has proven to be fundamental for the sharing of data on rare diseases.

Starting from the definition of the Biobank, as an organized collection of human biological material and **associated**

Information stored for **one or more research purposes**, she stressed how a Biobank represents a valuable collection of data, but at the same time it requires a **long-term investment**, the **establishment of governance**, a **shared access policy** and **harmonisation** of datasets.

Biobanks are important research infrastructures for pursuing several goals: for supporting researchers, who might not be able to access the material for their research; for ensuring research reproducibility, guaranteeing the quality of the material stored; for managing ethical and legal issues.

The Telethon network of Genetic Biobank aims to connect biobanks all over Italy with the aim of centralising the management of very rare samples and data, establishing a governance system, harmonising the datasets and the SOP related to research reproducibility.

In addition, there are now formalised collaborations between biobanks and patients organisations.

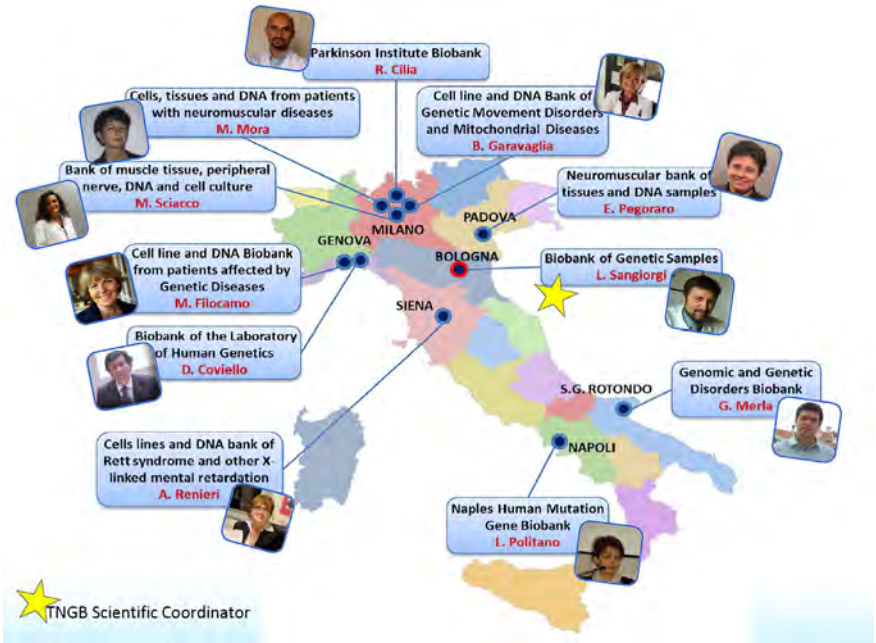


Figure 17: *Network of Biobanks in Italy*

2.1 Main outcomes of the conference

Data that can drive research and enable healthcare transformation, but regulations must be drafted and interpreted to guarantee a secure and safe use of data in the best interest of patients, citizens and communities.

The deluge of data could change how clinical decisions are taken (also within black-box approaches). As most of the health-related data collected can carry errors, to guarantee a safe application of data analysis and machine learning further studies need to be carried out (understanding governance, model validation, explainability).

Data will not replace clinicians, and therefore conditions must be established to not loosen the doctor-patient relation, to maintain human control over machines and to invest in training and education.

To foster the transition towards data driven health and care, a governance system is key. Regions, as the administrative entities closer to the needs of a territory, shall involve all relevant actors to shape new digital health policies, which balance the benefits of new technologies, mitigate the risks (trust, privacy, security to mention a few) and maximise the impact (through accessibility and open science approach).

Regions and intermediate institutions are also critical in addressing potential risk and streamline governance as they are in charge of translating general regulations in operational and day-to-day activities.

New training programs should be created, in order to train new professionals that will soon be needed: a mix of clinicians, doctors, biologists, nurses, managers, sociologists. Investments in education and training should be made now, or there will be a delay in dealing with relevant technological, organizational and ethical issues.

Initiatives like "100.000 Genomes" carried out in UK, which is already leading to new medical discoveries, can be replicated at regional and interregional level. The use of non-genomic health data (clinical, administrative and socio-economic) are at the basis of healthcare reforms and help local authorities to face the economic sustainability of healthcare (as in Lombardy).

KEYWORDS:

#Data save lives

#transformation of health and care

#value of regions

#governance

#health inequalities

#financial pressures of healthcare

#health policies

#infrastructure

#investments

#black box

#patients

#ethics

#Health Technology Assessment

#harmonisation & interoperability

The conference led to the definition of the programme of the workshop: focusing on interoperability, interregional and international infrastructures, management of healthcare system and access to data.

2.2 In situ visits

Along with the conference, Regions4PerMed Partners were invited to take part in two in-situ visits, where they could get acquainted with two sites in Lombardy where big data are central for the regional health system reform. The aim of the in-situ visit is a cross-exchange of knowledge and best practices, to be replicated in other regions.

2.2.1 ARIA: Azienda Regionale per l'Innovazione e gli Acquisti

Regions4PerMed Partners had the chance to meet with representatives of Lombardy informatics, the body responsible for managing and developing the information systems for the various departments of the institutions of the regional system. It builds solutions and services for digital-health, digital-government and e-procurement.

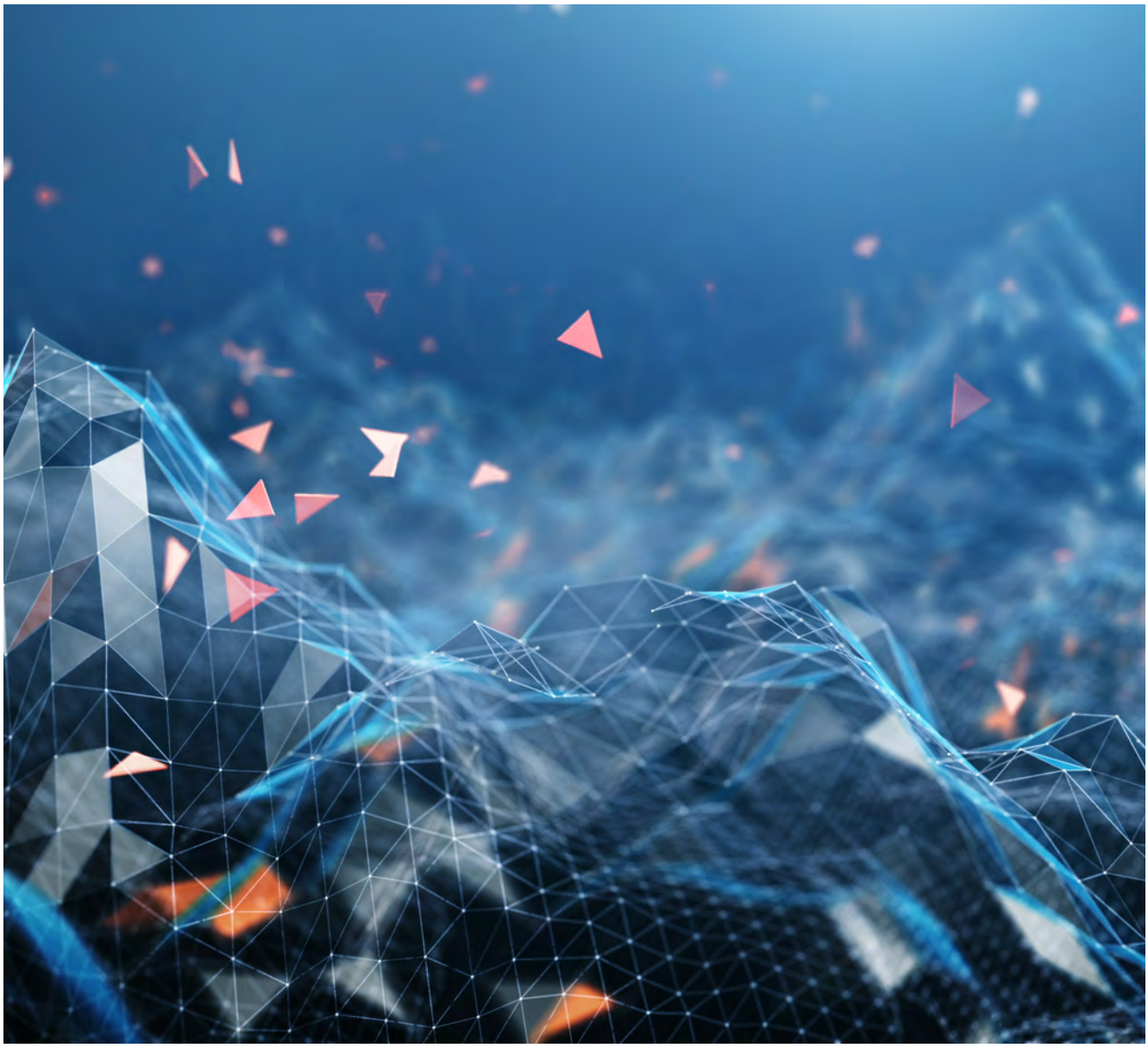
During the visit it was explained how the Lombardy Region is investing in big data applications. Lombardy Region started collecting structured data on healthcare events, resources and costs in the 2000s, mainly to support health care system governance and evaluation, within a regional data warehouse ecosystem that has progressively grown in features and tools offered. Building on this framework, from 2012 on, all chronic conditions have been stratified according to clinical classification, co-morbidities and healthcare economic burden. These Population Health Management insights led to experimental (2012-2017) and then routine care (2018-2019) use of a proactive and personalized care management model that is still driving organizational change by information analysis, data enrichment and algorithms' improvement. The aim is to drive regional healthcare system to be preventive, predictive and sustainable on the long term. Lombardy Informatics is helping Lombardy Region Government in this data driven paradigm shift.

2.2.2 Fondazione IRCCS Istituto Neurologico C. Besta Biobank

The Fondazione IRCCS Istituto Neurologico Carlo Besta is a centre of excellence for the research and treatment of neurological diseases. Besta Institute combines, through a synergic approach, scientific research, diagnosis and treatment that leads to an improvement of therapeutic efficacy in the treatment of neurosurgical and oncological pathologies and of chronic and rare diseases.

The Besta Institute hosts one of the main biobanks in Lombardy and in all of Italy.

The partners could observe biological samples storage (criobank) and how related data are organised in rare disease biobanks, and which processes and software are being used.



3. KA1 First Interregional Workshop

Following the outcomes of the **first conference in May**, it was decided to organise the Workshop in September, to reorganise the inputs and the main discussion points and to trigger new discussions on how Regions can work to tackle the main challenges highlighted.

The hosting partner was again Fondazione Regionale per la Ricerca Biomedica (FRRB), as Work package Leader.

The Workshop took place took place in milan September 2019, on the 23rd and 24th, in Palazzo Lombardia, Auditorium Testori, Piazza Città di Lombardia - Milano, Italy.

The Workshop enabled a close discussion with many European Regional authorities as well as international stakeholders about the implementation of the personalised health principles in terms of policy, investments and governance - the main challenges and opportunities emerged during the R4PM conference and elaborated a list of priority actions to be communicated and disseminated to European regions and policy makers.

With this goal in mind, all speakers have been selected according to their expertise and their ability to trigger a debate.

The final agenda of the workshop, that includes a rationale of each parallel session is added here as annex. The programme has been published on the Regions4PerMed Website as of 1st August 2019.

Each session has been organised with the purpose of leaving extended time to the discussion among participants.

The two days have been planned as follows:

- The morning of DAY 1 was dedicated to keynote speeches introduced and provided insight on the topics that would have been tackled during the parallel sessions.
- The afternoon of DAY 1 was dedicated to the parallel sessions and to the discussions among the stakeholders
- The morning of DAY 2 was dedicated to a wrap-up of the parallel sessions and to the capacity building session
- The afternoon of DAY 2 the interregional committee meeting took place.

The main roles during the parallel sessions are described below:

Chair: His/her role was to open the discussion, introducing the topic, giving the floor to the speakers and managing the Q&A time.

Rapporteur: focusing on the discussion, the Rapporteur took notes during the debate that followed the presentations of the speakers, could raise questions to orientate the debate (in case questions lead the discussion out of topic) and, at the end of the session, summarised the main points discussed, that could be common issues/common solutions, new best practices, suggestions, etc. Those main points were presented by the Rapporteur the day after, during the plenary session.

Speakers: either experts/policy makers/representatives of the public or private sector that will present a "best practice" in the area of the session.

All speakers, Chairs and Rapporteurs have been actively involved in the organisation of the workshop. They were provided with a **briefing document** as a guide to learn about expectations on their roles, biographies and topics of the speakers presentations. In addition, **teleconferences** were organized with Speakers, Chairs and Rapporteurs of each session, to elaborate on session structure and to identify challenging questions, aimed at triggering the debate among participants.

The plan of the workshop was to discuss the topic of Big Data and health governance with Policy Makers, representatives of Universities and Research Hospitals, Organisations active in the field of Healthcare from different Regions.

The Workshop, structured in parallel sessions, focused on four areas: 1) Data integration and interoperability; 2) Investments and Public-Private partnerships; 3) Change management in hospitals (including IT training for doctors, monitoring and management of chronicity); 4) Data Access (to researchers, clinicians and patients).

Approximately 100 people attended the Workshop.

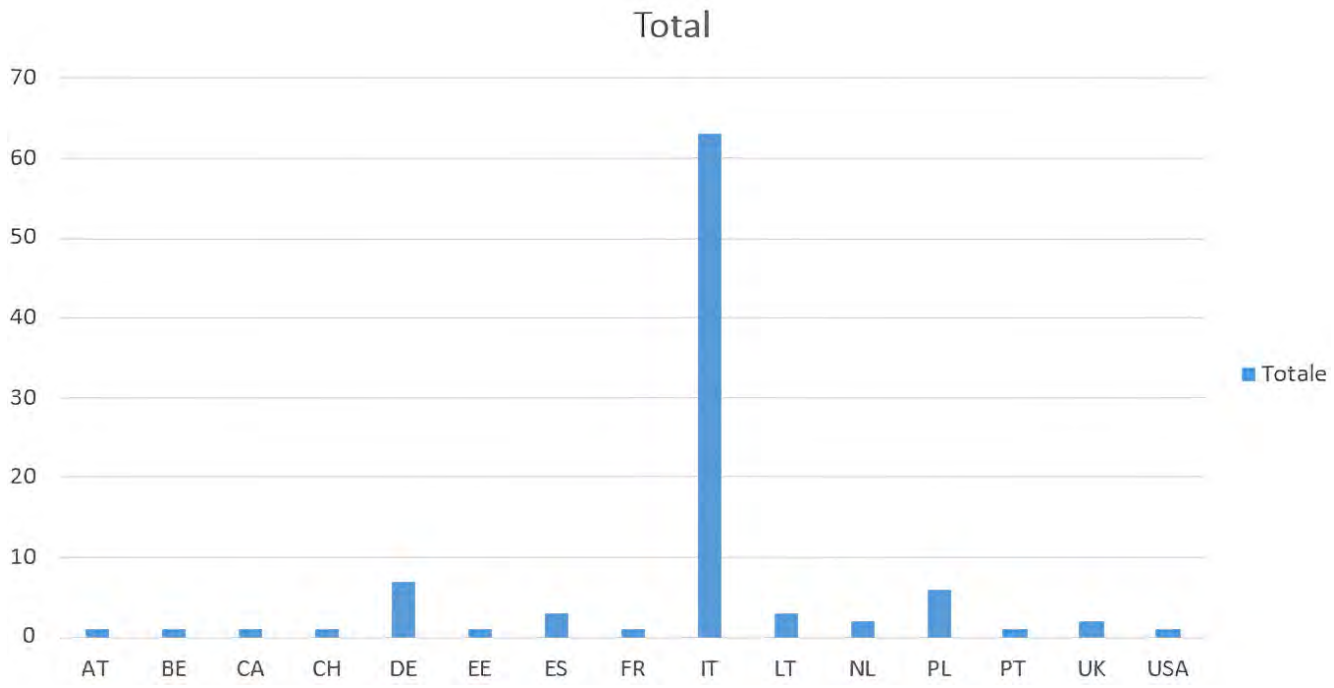


Figure 18: *Workshop Participants per country*

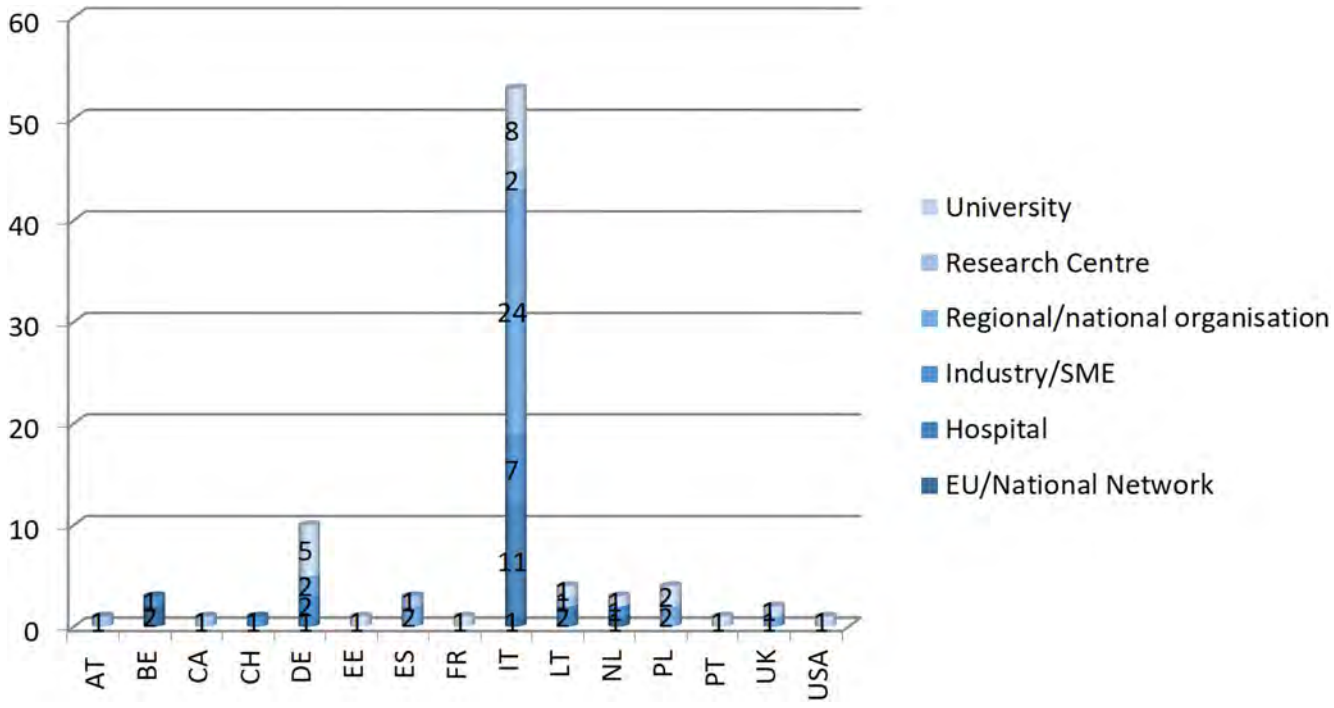


Figure 19: *Workshop Participants: stakeholders*

OPENING SESSION

The day opened greetings and by started with three keynotes lectures, focused on *the role of citizens and patients and the value of data.*

Peter Kapitein (Inspire2Live) gave a poignant presentation, focusing on the role of patients when it comes to decisions that impact their own health. He remarked that, despite the understandable concerns that involve the issues of data privacy and data privacy, **there are risks in saying "NO**" (No to data sharing, no to data accessibility) and in being overcautious with the use of patients data.

This is an enormous "treasure chest" of information that would make possible to see which patients would be successful for which treatment, or those for whom the trial would not be suitable.

Sometimes patients are willing share their data more freely, especially if there is a chance this could improve their health conditions. The decision to be over wary may come with a cost and it may be more expensive than a yes in the long run. Kapitein concluded that often urgency is the trigger for a change.

Enrico Capobianco (University of Miami), focused his presentation on **the value of information (VOI)** - intended as the amount a decision maker would be willing to pay for information before making a decision - that data carry, and how VOI can influence policy and political choices.

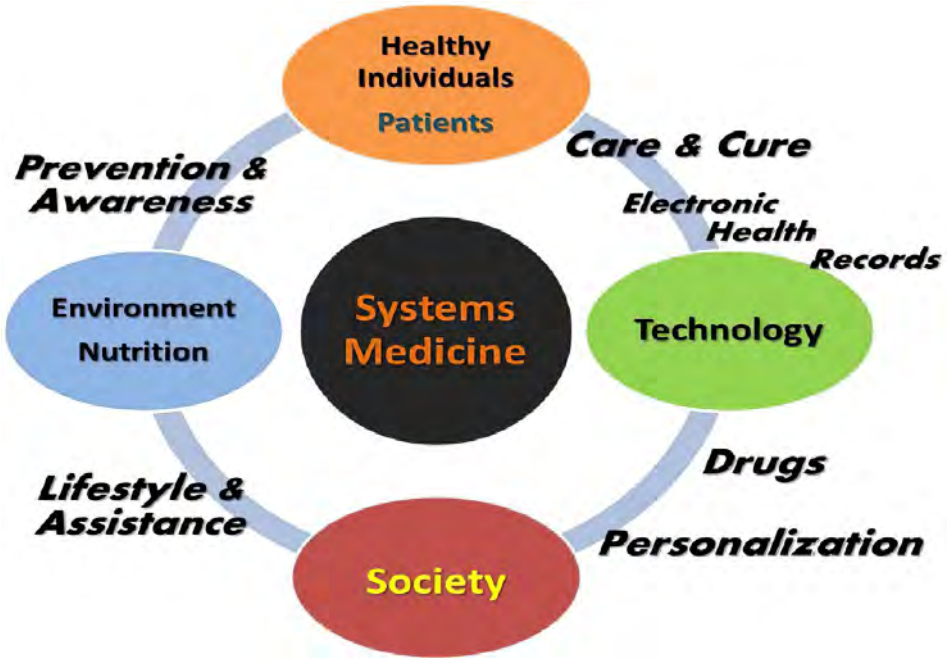


Figure 20: *Health Ecosystem, Capobianco and Trivella , Dec 2014*

VOI is strategic to support decision making processes, elaborate the best strategies and reduce uncertainties. It is also a tool which helps addressing the complexity of research prioritisation.

Data access is the key to advance research and improve health

The value of information and the importance of data sharing were also tackled by **Neeme Tõnisson** (Estonian Genome Centre). He explained how the Estonian Legislation favoured the development of the genome Biobank; the Human Genes Research Act established high qualitative, privacy and ethical standards.

The success of the initiative is well documented by the number of people who have freely provided their data (Fig. 17).

As data access is the key to advance research and improve health, Neeme Tõnisson explained the access model in place.

He explained that the biobank could be used to evaluate new healthcare models and to implement it into the national healthcare system for **personalised risk estimate and personalised management recommendations.** He also explained how an open data-sharing policy can increase citizens and patients' trust (Fig. 18).

Citizens' trust has been put at the core of the project, and presented a Decalogue of rules to follow:

1. Solid legislation, discrimination strictly forbidden on genetic basis
2. No access and decoding for crime investigation
3. Secure and centralised e-Governance and e-Health System in Estonia, accessible by all citizens (electronic ID)
4. Ethics questions always included in any projects involving data and sample use
5. Public information campaigns, regular presence in media
6. MD education, mainly positive views on biobank
7. Individual data return studies and examples, quality of the data, direct benefit for participants
8. No private data leaks to date
9. Dynamic and development-oriented database
10. Data in Estonian Biobank used for improving healthcare on a large scale.

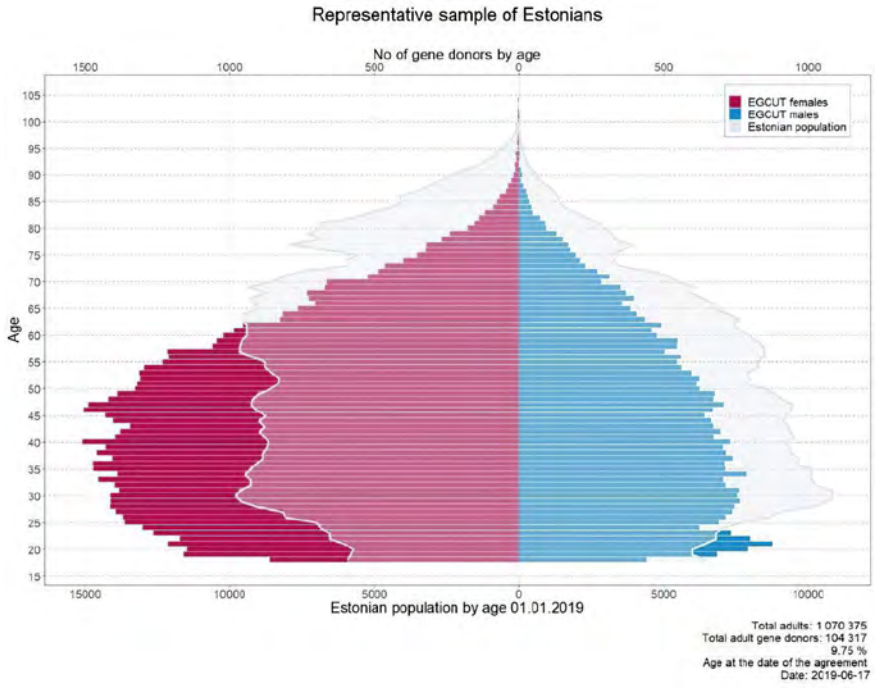


Figure 21: *Representative sample of Estonians*

Following the keynote lectures, the parallel sessions started.

The sessions were organised so that plenty of time could be allocated to discussion and exchange among participants. The talks of the speakers aimed at presenting a best practice/a project/a policy, serving as starting point for the discussion. For each presentation, an abstract is reported.

The purpose was to find common challenges or to agree on polices (projects, practices) that could be successfully replicated in different Regions.

SESSION 1. *Data integration and interoperability*

Health data are often organised in large datasets. These sets are frequently fragmented, and the level of interoperability is currently extremely low. Therefore, part of the challenge is to identify pathways towards a better data integration, in order to address common health concerns in the future. The organisation, interoperability and valorisation of health data represent a keystone for healthcare sustainability in the long run.

Topics discussed:

A) Infrastructural (technology enabling) interventions;

B) Data organisation (eHR and biobanks) and healthcare systems interoperability;

C) Ethical issues related to usability;

D) Privacy and legal interventions to ensure data security and general public acceptance of health data utilization.

CHAIR

Thomas Neumuth, Regions4Permed AB Member, Universität Leipzig, Innovation Center Computer Assisted Surgery (ICCAS), Germany

RAPPORTEUR

Stefania Boccia, **Luca Giraldi**, Università Cattolica del Sacro Cuore

SPEAKER

Luca Augello/John Mason ARIA (Azienda Regionale per l'Innovazione e gli Acquisti)

SUMMARY:

Ideas, barriers & opportunities in healthcare interoperability are to be observed from a regional point of view. The Lombardy Region started quite early in fostering adoption of semantic interoperability and participates in a country-wide EHR exchange that enables key elements to be shared and in EU cross-border exchange of Patient Summary and e-Prescriptions.

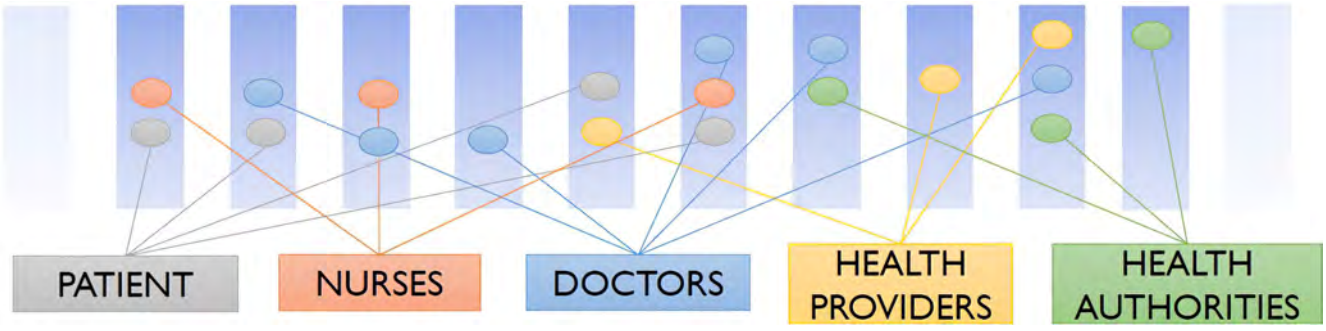


Figure 22: *Interoperability among stakeholders*

SPEAKER

Alonso Sanchez, Navarra Biomed

SUMMARY:

"NAGEN 1,000" is a Spanish regional pilot study incorporating recent advances in cutting edge Whole Genome Sequencing technology into the clinical practice. This project identified the major difficulties and provided original solutions to overcome the barriers for genomic medicine evolvement.

Sanchez explained how pre-existing infrastructures (a non-for profit sequencing platform and a transversal bioinformatics platform) have been leveraged by NAGEN 1.000. He then explained the clinical path of the project.

"NAGEN 1,000" was awarded as the Best Practice in Personalised Medicine by ICPerMed in 2018, and illustrates how translational research and innovation in the field of genomics and personalised medicine is already delivering true benefits to real patients.

With regards to the ethics, legal and social aspects of the project, NAGEN has been developed as part of the Health regulatory local authority. The whole Genome Sequencing is sent back to the patient through the medical record. The clinical Biobank complies with the Patient Protection act.

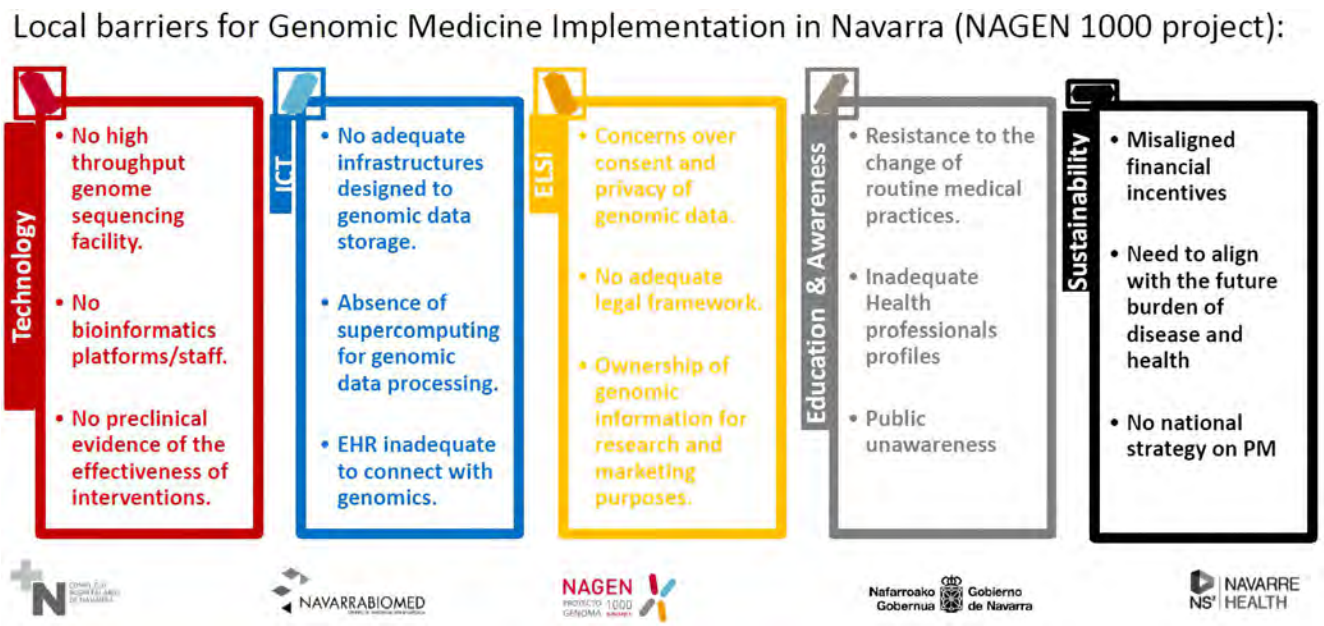


Figure 23: Local Barriers for Genomic Medicine Implementation

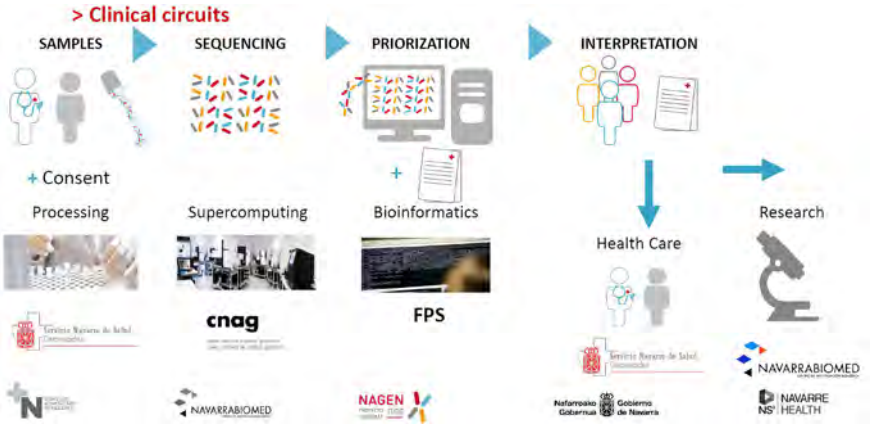


Figure 24: *infrastructures deployed in the NAGEN 1000 programme*

SPEAKER

Claudia Pagliari, University of Edinburgh, UK

SUMMARY:

When we talk about interoperability, the social aspects of interoperability need to be considered, as humans are involved. Interoperability semantic varies across countries, as well as the meaning of "health information". The concepts of "use", "share" and "link" of data are frequently confused. The boundaries of interoperability are blurred, as it is the meaning of "secondary data". The tremendous amount of data need to be regulated not only by political and policy choices but also by a digital ethics framework. Are patients data used only for health purposes? Are patients, and not only them, happy to have data taken by their social media? How far do we want to go with interoperability?

Main outcomes from Session 1:

Interoperability can be seen as the result of multiple factors: common language, data harmonization, shared knowledge. This requires a closer collaboration of all the actors involved from multiple levels and from multiple disciplines, as well as an integration of different data (personal, environmental and genomics). Harmonisation and integration cannot stand alone. The acceptance of a common system and the usability of it depends also on those who can get the benefit of interoperable health data: the patients, the caregivers and the citizens, who need to trust the management and the privacy system in which their data is stored.

The regional healthcare system itself can make improvements based on the evidence that emerges from data, especially for that what concerns patients care, governance and research. The availability of data is what makes personalised medicine a reality into the public health system, that not only needs to adopt new technologies and new processes, but also to optimise the use of pre-existing public infrastructures and to provide adequate training both for patients and care-givers.

In the valorisation process of health data, citizen's trust must be at its core. Lessons learnt from long running programmes (Estonia and United Kingdom) should be replicated.

SESSION 2. *Investments on big data infrastructures*

Significant healthcare improvements can be achieved when data-based innovations are applied to the healthcare system. Regions can support this process through international collaborations and partnerships, identifying needs and common values. Clear goals need to be set within public-private networks to create models of best practice. This will trigger a shift in the current state of art, encouraging more local relations, cooperation, and collaborations that will facilitate the uptake of innovative healthcare.

Topics to be discussed:

A) Public investments at regional level;

B) Structural funds, S3 Platforms and interregional investments;

C) Private investments to support multiregional investment pipelines;

D) Public-private-partnerships

CHAIR

Riccardo Colombo, BioRep, Lombardia Cluster Life Sciences

RAPPORTEUR

Maurits-Jan Prinz, European Federation of Pharmaceutical Industries and Associations (EFPIA)

SPEAKER

Margot Jehle, Codex4SMEs

SUMMARY:

The Codex4SMEs network aims to improve healthcare by enhanced adoption of Personalized Medicine. The network will expedite the development of SMEs products in the field of Companion Diagnostics, which are an indispensable tool for optimum application of Personalized Medicine. It will be demonstrated how Codex4SMEs contributes to healthcare improvement.

The project is being implemented under the INTERREG scheme. Among the main issues it tackles:

1. Biobanks are often chained in their own internal rules/ guidelines and this can hamper collaboration.
2. Biobanks and SMEs do not fully collaborate (also because of different ethical standards) therefore slowing innovative developments
3. SMEs request specific samples which are not always available within Biobanks collections

Dr. Jehle provided some key priorities that regional policies can address to improve innovation through Biobanks:

1. Effective framework of regulations that can foster the collaboration of SMEs with biobanks (e.g. potential adaption of internal rules/guidelines for all European biobanks, same access conditions, data-sharing conditions etc.)
2. Supportive Venture Capital role in Europe, focused on supporting sustainable companies, highly skilled workforce.

SPEAKER

Michel Van Speybroeck, Janssen Pharmaceutica NV, Harmony Project

SUMMARY:

Centralize or Federate: harmonizing and integrating clinical data - the Harmony example. Harmony, a collaborative IMI initiative to study 7 different indications in haematological malignancies is bringing different clinical datasets together to allow analysis at scale. Data from different sources is harmonized using the OMOP Common Data Model and integrated into a big data platform.

Technical and socio-ethical challenges with this approach have been discussed and compared with the setup in other IMI initiatives.

The project aims to deliver the following outcomes:

- Enabling health-tech to get to the required maturity level
- Convincing data providers (individual hospitals, universities, registries, regions, countries) of the potential value amidst a plethora of competing initiatives.

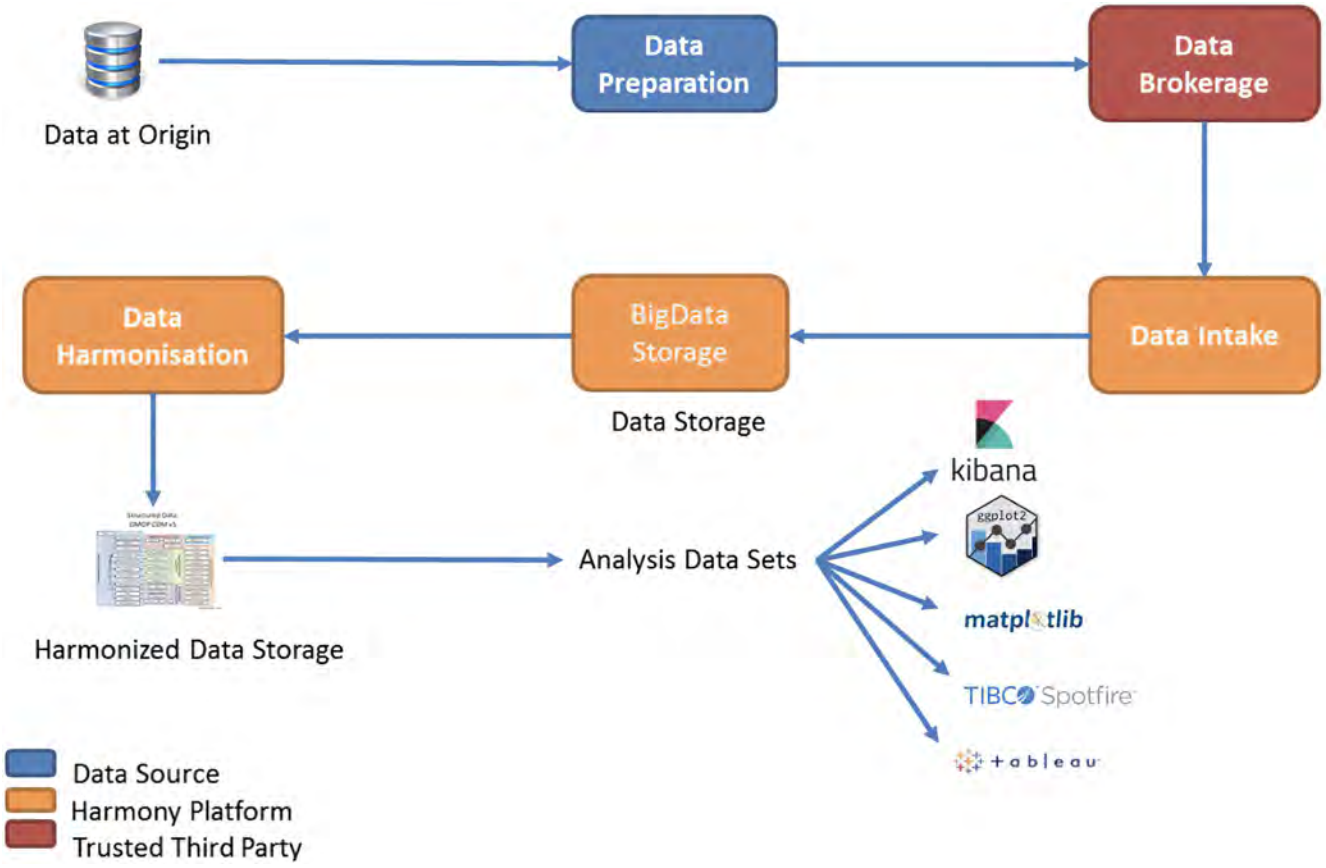


Figure 25: *Harmony roadmap*

SPEAKER

Sabato Mellone, University of Bologna

SUMMARY:

the investments of a Region. As big data can be seen as the future technological pillar of a digital society, a Region can be a key driver of innovation. This is the case of the Emilia Romagna Region, which is not only investing in development and in technology, but it is also building a "data valley", an ecosystem that sees in the same place infrastructures, education and training institutions, research activities and industries.

A Region can be a key driver of innovation

The Region can rely on the "Big Data Association (ABD)" created with the aim of connecting and jointly exploiting the knowledge, research and innovation potential of high performance computers, big data analysis, deep and machine

learning algorithms, high bandwidth networks, as future technological pillars of digital society (more than 90% of supercomputing resources for public research in Italy are managed by ABD members).

Emilia Romagna Region planned the biggest investment in Europe (350 million euros) on Big Data and AI for the creation of the Bologna technology hub in 2020. The aim is to make the hub a worldwide centre of excellence in the field of Big Data and a knowledge and business incubator.

At the end of this process, the Emilia Romagna Region aims to become the European Data Valley.

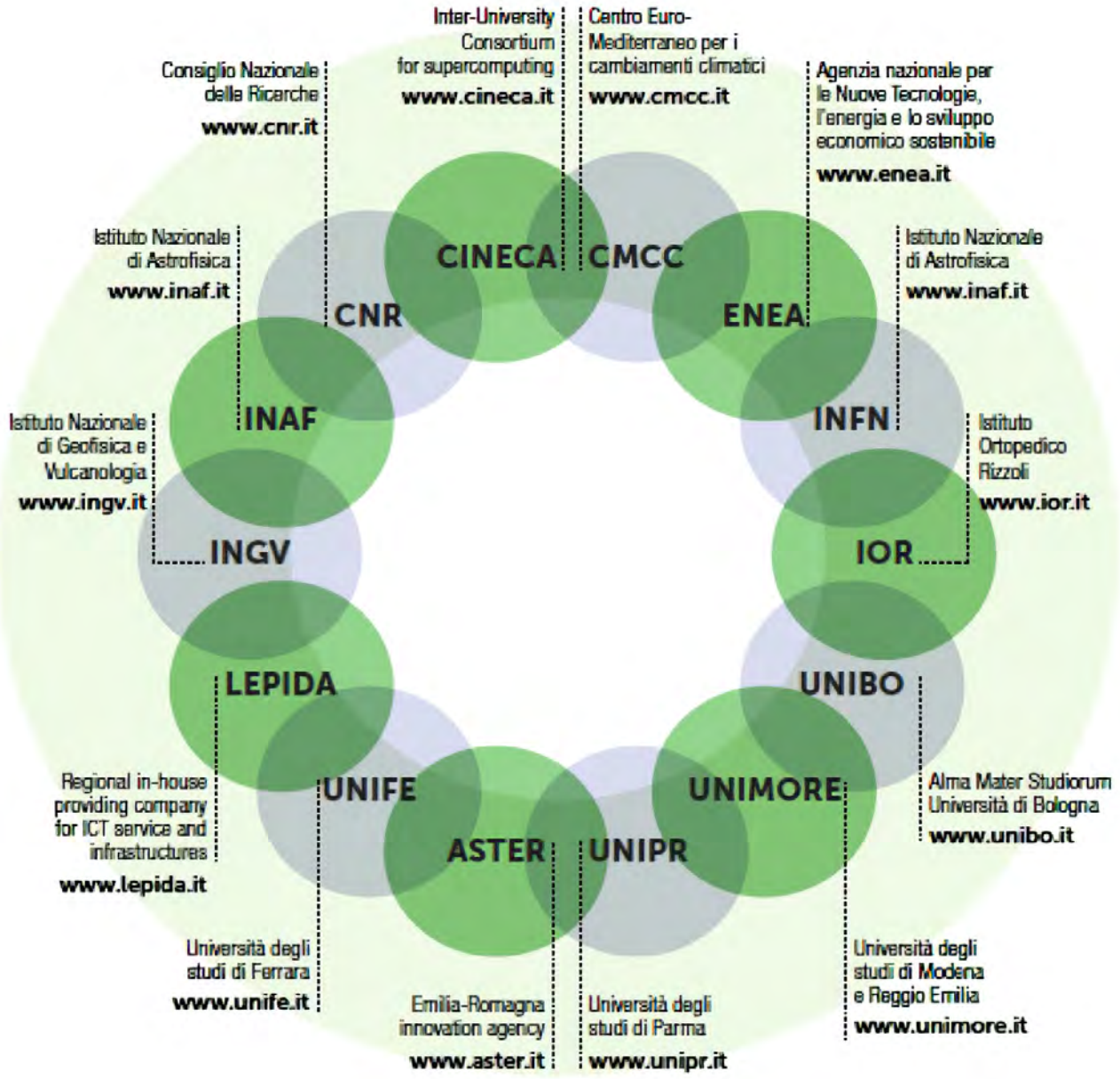


Figure 26: *Big data association*

Main outcomes from Session 2:

Different stakeholders have different areas of interest, but they still can get benefits when data infrastructures rely on a common framework and a common standardisation system. This has an impact on both the public and the private sector, the intersection of which can bring mutual benefits. This can be achieved through a network, a project or a closer collaboration. The aim is to avoid that organisations using data (including biobanks), remain blocked by the red tape. In addition, a common framework can be used not only for the existing projects but could be replicated and generate new and more efficient collaborations.

All stakeholders involved share responsibilities in this process.

- *The main stakeholders involved, and their relevant tasks are:*
- *Governments (regional and national): making data from health system accessible*
- *Biobanks: making working with companies/SMEs a priority*
- *Industry: co-investing in infrastructure and public-private partnerships; creating value for patients*
- *Hospitals and research centres: using data not only for research purposes but also outcomes analyses.*

Policy makers shall work on a common framework for harmonising data and easing the secured sharing. Industry shall co-invest in infrastructures and public-private partnerships, aware of the impact it can have on citizens and patients. Finally, research, private and healthcare sectors shall try to work and collaborate more closely, to allow each actor to learn about the needs of the other, the already existing solutions and how to invest more efficiently.

SESSION 3. *Healthcare organisations in a changing environment*

The implementation and use of integrated data science offers healthcare organizations the opportunity to: i) combine traditional (clinical) datasets, including data from the electronic health records, with emerging big data sources, ii) enable better patients management, as well as implementation of continuous patient monitoring and real-time laboratory results. Platforms can enable cost-effective and scalable analytics for information as key to comprehensive access to health care.

Topics discussed:

- **A)** New models for earlier "taking care approach" (enabling prevention and prediction approaches)
- **B)** Continuity of care and management of chronicity
- **C)** Healthcare budgeting, reimbursement models;
- **D)** Healthcare staff, challenges of data integration in hospitals and general medical care

CHAIR:
Elio Borgonovi, Regions4Permed AB Member.

RAPPORTEUR:
Pritesh Mistry, Royal College of General Practitioners, UK.

SPEAKER:
Luís Velez Lapão, Instituto de Higiene e Medicina Tropical, Universidade Nova de Lisboa, Lisboa, Portugal.

SUMMARY:
The path towards the Digital Transformation of health:
The role of organisations, regulations and new business models.

The advantages from digitalisation can be substantial. However, the challenges associated with digital transformation of healthcare organizations are poorly understood. A path towards digital transformation is discussed based on new research, examples from other industries and from healthcare.

The advantages from digitalisation can be substantial. However, the challenges associated with digital transformation of healthcare organizations are poorly understood

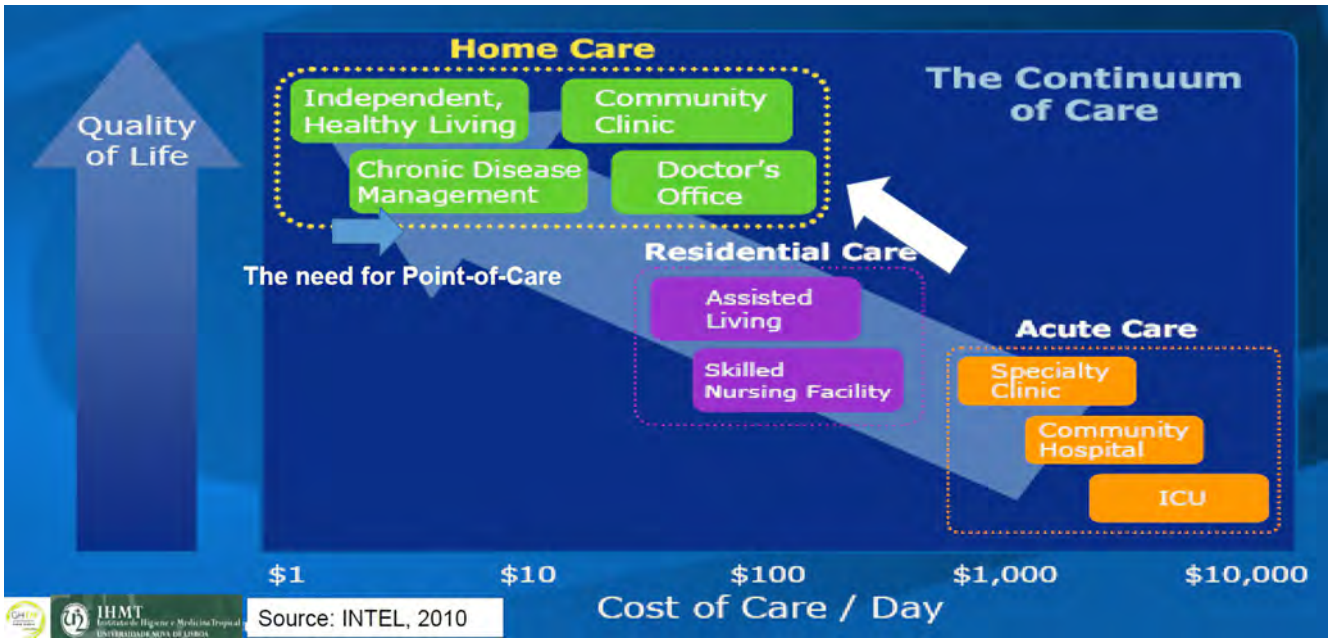


Figure 27: Delivering more efficient and higher quality of care

More than a technological change, we are facing an organizational challenge towards new ways of delivering more efficient and higher quality healthcare. Proper education, new business models and regulations are also key to enable a straightforward process.

The speaker he concluded his presentation with recommendations for new digital healthcare models:

- Improving the information management governance: data governance rules and big data research in healthcare should be strengthened, especially in the present and upcoming generations of health professionals (qualified human resources multidisciplinary teams)
- Adopting a European approach aiming to reduce inequalities (European regulations promoting digital health)
- Creating innovation teams to help tackle the translation and adoption of new digital health technologies into the real world with real patients (transforming health organization with new models of health delivery).

SPEAKER:
Guido Grignaffini and **Giovanni Delgrossi**, ASST Vimercate, Milan, Italy.

SUMMARY:
The presentation focused on the experience of the Vimercate Hospital, which implemented a new organisational model based on significant changes in the management of assistance and care services to citizens, in outpatient procedures and in some professional roles, while ensuring efficiency in all processes. The new model includes new professional roles, such as "Clinical Manager" and "Case Manager" and a new IT architecture, based on big data and machine learning algorithms.

The use of data coming from Electronic Medical Records (diagnosis, diary, therapy, parameters, blood exams, clinical rankings, assistance needs) will be developed to achieve the following objectives:

1. Design and implement predictive algorithms, built on the basis of available clinical data to predict the development of the chronic disease, in terms of evolution of clinical parameters, prevention of clinical complications, patient re-hospitalization reduction
2. Design and implement a predictive model to outline the evolutionary scenario of chronic diseases, based on the different treatment and innovative healthcare organization models (planning forecast).

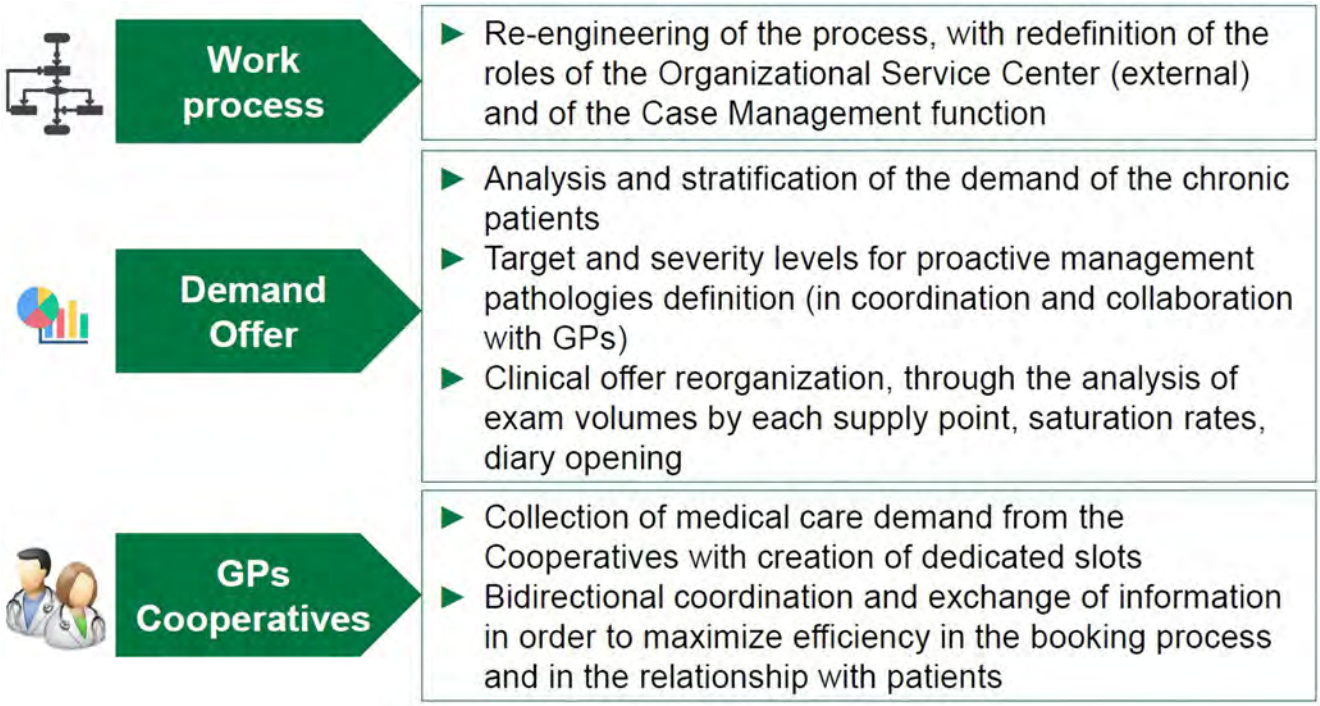


Figure 28: *New organizational model of Vimercate Hospital*

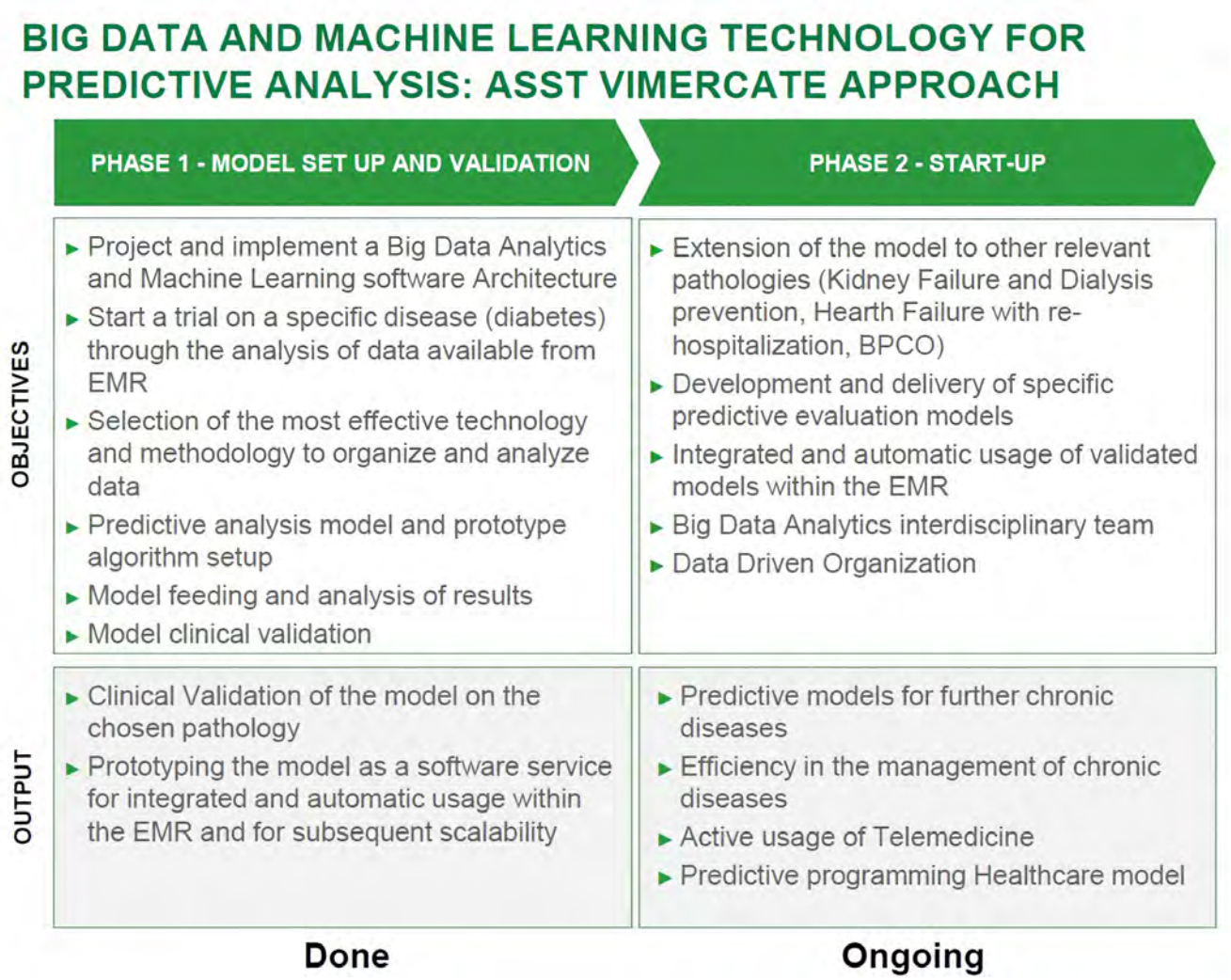


Figure 29: *Big Data and Machine learning Approach*

SPEAKER:
Robin Weidemann, University Hospital Carl Gustav Carus, Technische Universität Dresden, Germany.

SUMMARY:
Digital technologies offer substantial scientific potential for better patient care and a smarter medical workplace. In contrast to established and well-funded molecular research structures (including the Dresden campus), the interface between technology and medicine is scientifically and structurally under-developed. With the new Else Kröner-Fresenius Center for Digital Health they aim to bridge the last meter, centimeter or micrometer from the digital world to disease pathophysiology and therapy. The centre provides a distributed hands-on "living lab" on the Medical Campus including operating rooms, regular and ICU beds.

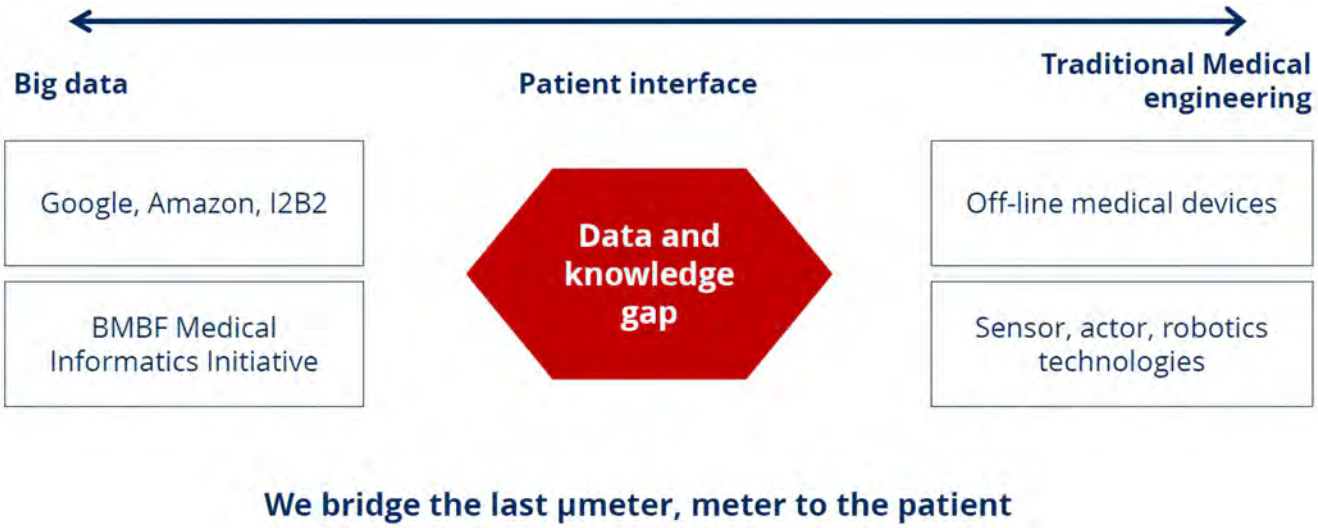


Figure 30: *Big Data and Machine learning Approach*

To face some of the biggest issues that hamper the deployment of digital technologies (lack of data access, regulatory jungle, lack of trained staff, lack of funds), a number of solutions have been sought and a process for the uptake of these solution in the clinical settings has been designed.

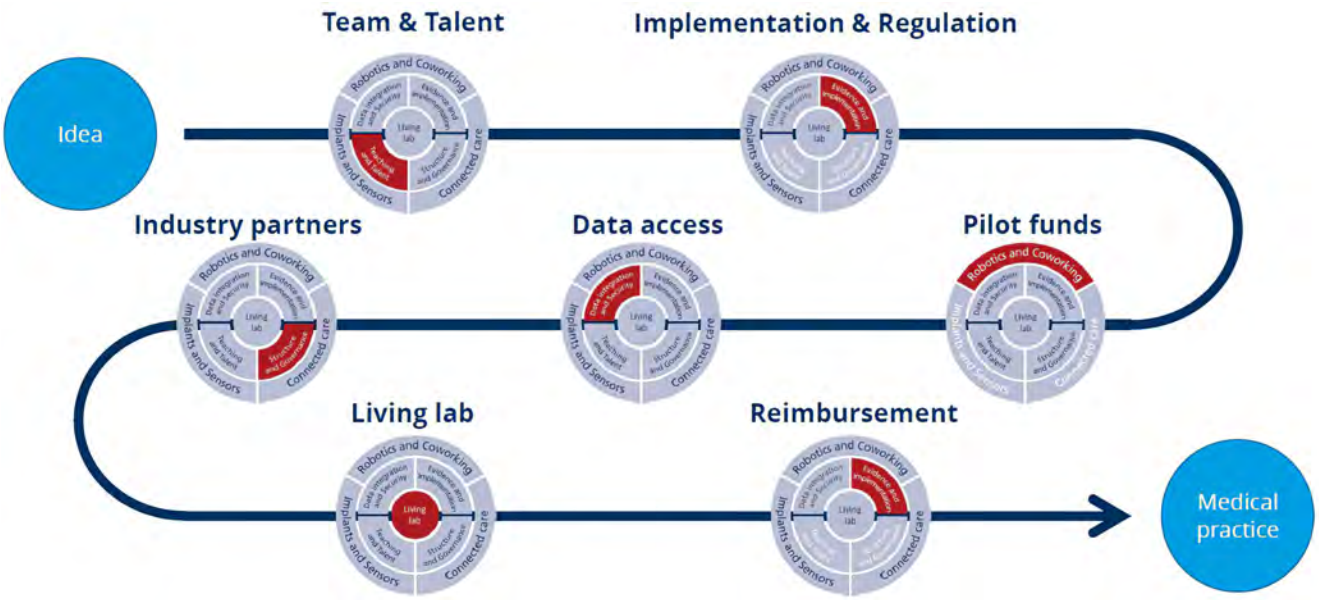


Figure 31: *Approach to uptake digital solutions in clinical settings.*

Main outcomes from Session 3

With the rapid advancement of technologies and scientific discoveries, healthcare systems are put under stress, coupled with the need of more data-trained staff and not sufficient financial resources.

To make technology a real useful support, organizational changes need to take place, not only in the IT field. Investments in resources, training but also changes in more efficient processes seem to be the key for a sustainable and efficient healthcare system.

A move from a reactive to a proactive system is needed to embrace the opportunities offered by the technology, understand the processes and prepare the workforce, tackling the issue of a gap between clinical and technical competences.

Interdisciplinarity is a key aspect to take full advantage of real world data.

Regions can support these changes, elaborating policies to:

- *support change across levels (organisation, regional and national)*
- *encourage the adoption of an adaptive management that can support existing care delivery demands while being able to innovate*
- *train cross-disciplinary team with new skills*
- *simplify the regulatory environment*
- *Invest in infrastructure and implementation*

SESSION 4. *Promoting access to data*

Access to health-related data either regionally, nationally and cross-border in a secure way and in full compliance with the ethical and legal principles improves life for citizens and helps innovators find the next generation of digital solutions and medical treatments. Whilst the EU is setting strategies to support eHealth digital services, Regions can accelerate its implementation.

Topics discussed:

- **A)** Access to data for researchers to advance clinical research;
- **B)** Access to data for innovators for new and improved solutions;
- **C)** Access to data for citizens to improve self-management, as a new form of patients engagement

CHAIR and RAPPORTEUR
Birute Tumiene, Vilnius University Hospital Santaros Clinics, Lithuania

SPEAKER
Antonio Barone, ARIA (Azienda Regionale per l'Innovazione e gli Acquisti)

SUMMARY:
Lombardy Region started collecting structured data on healthcare events, resources and costs in 2000. A privacy by-design environment has been built to allow universities and research institutions to perform studies on behalf of the regional system change towards preventive, predictive and sustainable healthcare. ARIA is helping Lombardy Region in this data driven paradigm shift, that will soon be extended to offer more benefits to the research ecosystem.

He spoke about the Lombardy Information Hub, which aims to improve the significance of research activities, provide deeper analyses and increase the impact of results for the Lombardy ecosystem.

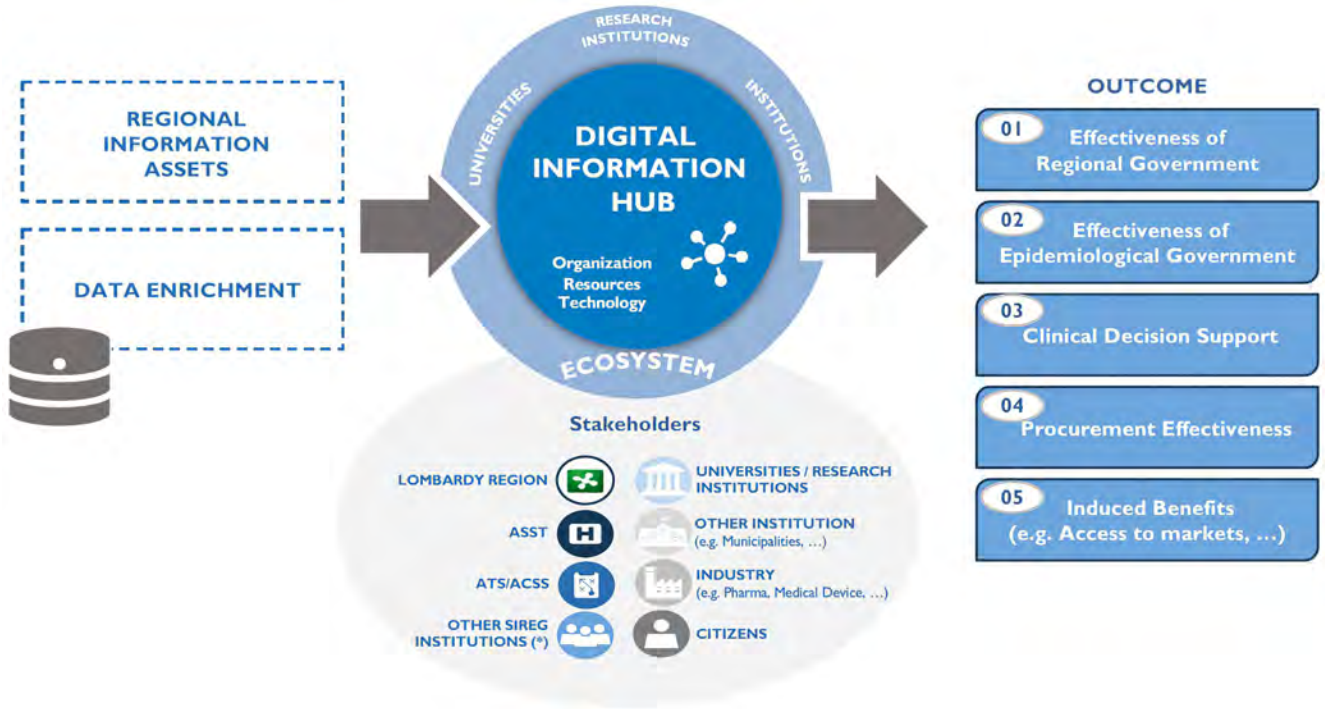


Figure 32: *Lombardy digital information hub overview*

SPEAKER
Torsten Leddig, Greifswald University

SUMMARY:
His talk, "secondary use of research data - experiences from over 10 years of data sharing" was about the importance for medical research to generate and elaborate data, collected through research or care, and to make them available for secondary use.

The presentation focused on the experiences with Use & Access processes gained by the Transfer Unit in Greifswald. He also provided and gave a short overview of the current developments for sharing clinical data for research in Germany.

He stressed the importance of sharing data for the following reasons:

1. Steady expansion of data sets;
2. Fostering national and international collaboration
3. Increasing the visibility of Greifswald

SPEAKER
Francesca Sofia, Epilepsy Alliance Europe

SUMMARY:
Changing what is possible in medicine through patient engagement and access to data. The possibility to aggregate information about clinical features, genetics, electrophysiological data, pharmacological responses,

lifestyle, and patient-reported outcomes of persons with epilepsy, holds the promise to change the way we presently treat and cure epilepsy.

Francesca Sofia focused on the importance of explaining the value of data to citizens and patients, most of whom have already some knowledge about. Explaining big data and showing what benefits they can bring is fundamental to create trust.

Patient-driven initiatives in this direction may lead to a paradigm shift in the biomedical and healthcare sectors. The patient generated data are increasing and they are important to shape a value-based care that requires multiple medical approaches and shared information and data.

Regions may play a great role in connecting, working as the interface between patients and healthcare providers.

The value of small data also needs to be fully understood; big data goes hand in hand with small data: big data will always end up in a patient perspective, in a face to face relationship with a patient.

Explaining big data and showing what benefits they can bring is fundamental to create trust

Main outcomes from Session 4

Generation and access to data are strictly connected. To make good use of them, data need to be of high quality. Hence, increasing the amount of quality data available is a priority, although how to organise them and how to make them accessible is a multilevel decision. First, patients are the owners and the generators of data. Although most of them are aware of what data are, not everyone knows their value and what benefits they can bring. More patients' expertise is needed. Secondly, the administrators, especially the regional policy makers who have a deeper understanding of the need of the territory, shall have a say on the structure of the databases, who can access them and to what level.

What we reported here as main learnings from each session was successfully presented by the rapporteurs and discussed with all participants the day after the parallel session. Rapporteurs were moderated by **Denis Horgan**, EAPM, one of Regions4PerMed Advisory Board Members.

3.1 Capacity building session

During the capacity building session examples of regional collaborations and best practices were described to Regional stakeholders.

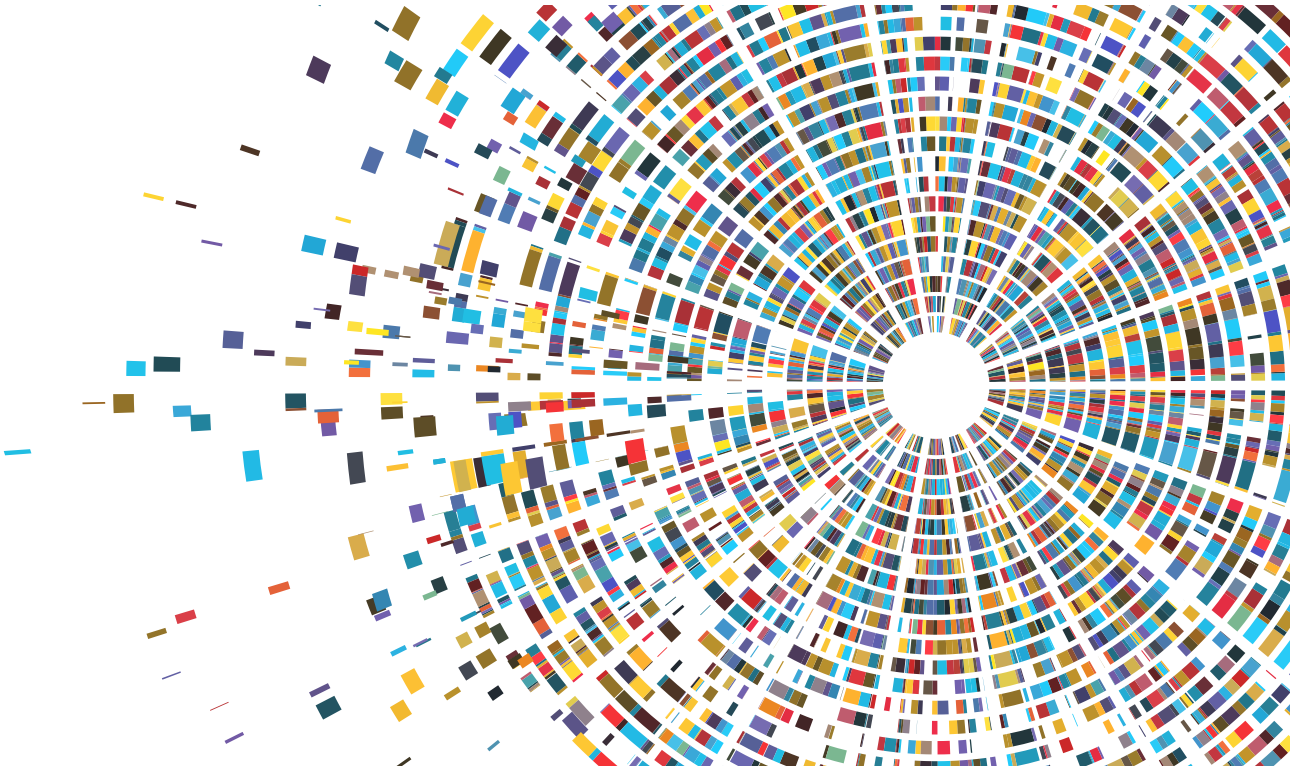
Although European Countries and Regions are different on many levels, offering different perspectives about the complex theme of big data in health, EHR and health governance can be of the utmost importance.

Specifically, invited speakers were asked to give a "policy-oriented talk" , since it was expected to listen to projects and policies that show how Regions – clearly in coordination with the national strategy- can have an impact on the implementation of personalised medicine.

This is why three "examples" were selected: one from a regional perspective (Emilia Romagna Region), one from an Interregional Collaboration (4 Motors of Europe) and one from a European organisation of regional and local health authorities (EUREGHA).

The leading questions of the sessions were the following:

- What is the current situation in our Regions?
- What is the level of implementation of Big Data in health, in EHR and in the whole governance system?
- Why is in the interest of Regions to invest in big data in Health?



From the perspective of Emilia Romagna Region, presented by **Sabato Mellone** investing in new data-driven technology is key not only for scientific advancements, but also to create an eco-systems where interdisciplinary of fields of research can results in new discoveries, new research and more jobs opportunities. He presented the "Emilia Romagna data valley project", where a variety of Actors (the Region, the university, industries and research centres) work together in the same spaces. What keeps the system together is a **common vision**, a purpose. The path to become a data valley can be very long, especially in the health data field: from the regional healthcare services online, to the EHR, to the integration of regional with national data, to the big data approach- a clear policy goal shall lead all activities and investments.

The **Four Motors for Europe** has been one of the first European networks of regions. Following the signature of a cooperation agreement on September 9th, 1988, the Regions of Auvergne-Rhône-Alpes (France), Baden- Württemberg (Germany), Catalonia (Spain) and Lombardy (Italy) established a collaboration which, starting from economic related issues, has been growing including other areas of cooperation.

The Four Motors of Europe network is characterised by a close collaboration without institutions of their own. The presidency changes every year according to a fixed turn.

The network has established a working group on e-health and care

Recently, the network has established a working group on e-health and care. The goal of the group is to explore the areas of the digital innovation in the healthcare sector, opening the way for new partnerships for data driven health policies. So far, the Four Motors for Europe Working Group on Smart Health and Smart Care held four Workshops, one international conference and a Joint Position Paper "Equity in a digital health and care system – Bridging social and digital divide in times of demographic change". There it is stated that *"The four highly industrialized and research-oriented Four Motors regions will join forces, exchange knowledge and work closely together on the implementation of solutions for a sustainable future of our health and care systems –and for the benefit of the European citizens".*

While Auvergne Rhones-Alpes representatives could not attend the workshop, both Baden-Württemberg and Catalunya delegates - hosted by the Lombardy Region - could provide an insight on their practices, their experiences and their objectives in the field of big data in health, and how they intend to collaborate together in the framework of the Four motors.

Daniel Buhr from the Social and Technological Innovation in Baden - Württemberg (Germany) explained how the Region is planning its investments towards a more data-driven approach starting from the state of art, which is a very functional but still fragmented healthcare system with no national strategy on digital health and care. However, in Baden-Württemberg there is an ongoing transformation towards a person-centred and integrated health and care system. A number of regional policy strategies are being elaborated, especially with regards to the implementation of personalised medicine.

Josue Sallent Ribes of the Fundació TIC Salut Social (Catalunya) gave an overview of the public Catalan health system, of the HC3 (the Catalan EMR) and presented a best practice in radiological archive and image management. This best practice involves data sharing between health and social systems. The Catalan system is very advanced in the informatisation of the health system, and the EMR contain a wide variety of data. The process of information exchange strategy between the Health Department and the Social Department in Catalonia requires a lot of attention, as it represents an import form of interoperability of data: information is shared between social services and health providers.

This has required a number of factors: common legal framework, semantic interoperability and an important ICT infrastructure.

EUREGHA is a network of 15 European Regional and Local Health Authorities focused on public health and four Observer Members. Created in 2006, the aim of the network is to work as reference for regional and local authorities on health-related issues. Creating synergies, participating in EU projects and initiatives, EUREGHA is committed to give voice to the local and regional authorities in EU health policy towards the EU institutions. EUREGHA, with its role of European network of Regions, represents a platform of exchange and dialogue between the Regional Authorities and the European policy makers, contributing to shape the cohesion policy instruments.

3.2 Co-creation meeting

At the end of the workshop, the co-creation meeting was organised with project partners, Interregional Committee members and regional and national representatives interested in joining, with the aim of pursuing the debate opened in the workshop.

The meeting, structured as a flexible and informal dialogue among participants, was focused on the lessons learnt during the Workshop, its outcomes and the steps forwards, in particular on the possible joint actions among Regional stakeholders.

The interregional workshop was also an important occasion to open the debate and collect more inputs on the next Key strategic Areas.

As main result, the necessity to select or develop a definition of Personalised Medicine that best fits the aims and objectives of the Regions4PerMed Project emerged.

4. Key messages to European Regions

The conference and the interregional Workshop have defined the role that Local and Regional Authorities can play in implementing personalised health, which is key for the creation of a new data-driven system in the healthcare sector. Although in Europe there are different political systems and a national coordination in the health domain may be prevailing, what emerges is that Local and Regional Authorities have a deeper knowledge of their territory and can leverage different sources to drive investment in infrastructures and enable technologies.

Regions, as administrative entities closer to the needs of a territory, shall involve all relevant actors to shape new digital health policies, bearing in mind the purpose of the technology - its impact, benefits and the risks it can bring and all related issues such as trust, privacy, security and, at the same time, accessibility and open science.

Political and administrative policies adopted at regional level usually require a shorter time before they can be implemented, with a more effective impact. This is particularly true when it comes to the health sector and to the innovation related to big data (including the adoption of EHR), where targeted policies support the standardisation of processes.

Also, a local governance is likely to be perceived as more effective, and hence more trustworthy, by its citizens[1].

The complex issue of big data in health requires a constant dialogue among the different actors involved, and a regional coordination can facilitate the meeting and exchanges of all stakeholders. Regions can create new interregional and cross border links, aimed at creating collaboration among areas that demonstrate many similarities.

Regions also have a strong interest in developing new data-driven technology. Big data, in health as it is in different sectors, are a strategic investment that can lead to scientific, social and economic advancements, boosting industrial competitiveness. Specifically, given the multiple use of big data as well as their application, Regions can enable the creation of a "data ecosystem".

1. *This has been observed also in small Countries, like Estonia.*


Regions4PerMed