Think Tank

ROUNDTABLE: **Spain**

The use of existing Big Data to improve healthcare

Proceedings and results from the EIT Health Roundtable Meeting

30 May 2018 at IESE Business School, Barcelona, Spain

Introduction

Using Big Data for healthcare in Spain

This report contains the proceedings and conclusions of a EIT Health Think Tank Roundtable Discussion about the use of Big Data to improve healthcare in Spain. At the 30 May 2018 Roundtable in Barcelona, Spain, leading Spanish experts presented best practices and engaged in discussions that have generated many actionable recommendations.

The Spanish Roundtable was one of several such meetings organised around Europe by the EIT Health Think Tank to obtain regional perspectives that further a discussion on pressing healthcare issues. Conclusions and recommendations stemming from these discussions are used to ensure that EIT Health's strategy and activities focus on what matters most. The Think Tank also guides EIT Health Public Affairs efforts aimed at contributing to health policy and healthcare system improvements across Europe.

The EIT Health Think Tank is a forum of experts and thought leaders cooperating to shape the future of healthcare in Europe. The Think Tank brings together EIT Health Partners with other leading healthcare stakeholders to agree on means for ensuring that innovation reaches the citizens and patients who need it most. Through central and local exchanges, Think Tank members seek to identify healthcare needs and potential solutions to those needs.

By identifying key pressure points and catalysing discussion, the Think Tank drives need-focused innovation within the EIT Health community and beyond, to better meet the needs of European citizens.

The following are proceedings of the EIT Health Think Tank Spanish Roundtable Discussion, held 30 May 2018 at **IESE Business School,** Barcelona, Spain. The document contains summaries of presentations and discussions. These are followed by conclusions that were drawn from these discussions. The recommendations based on these discussions are summarised in a table at the end of this document.

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Participants

Advisors	
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Ramon Roman	Responsible for the area of Big Data and Information Security, Agency for Health Quality and Assessment of Catalonia (AQuAS), Spain
Josep Roca	Professor of Medicine & Senior Consultant, Hospital Clinic de Barcelona, Universitat de Barcelona, IDIBAPS, Spain
Luis Rodriguez	Miguel Servat Type II Researcher, Fundación para la Investigación Biomédica del Hospital Clínico San Carlos, Madrid, Spain
Pablo Serrano	Director of Planning, Hospital Univesitario 12 de Octubre, Madrid, Spain
Maria Torrente	Attending Physician and Lung Cancer Group Researcher, Hospital Puerto de Hierro, Spain
Arnau Valls	Project Manager and R&D Engineer, Hospital Sant Joan de Déu, Barcelona, Spain
Observers	
Jan-Philipp Beck	Chief Executive Officer, EIT Health
Marco Pugliese	Managing Director, EIT Health Spain
Ursula Muehle	Director of Education, EIT Health
Mayra Marin	Executive Officer, EIT Health
Karen Wolstencroft (Rapporteur)	Medical Writer and Communications Consultant to EIT Health

Agenda

Roundtable Meeting Chairman: Toni Dedeu

09:30–10:00	**Introduction**	
	Think Tank in the context of EIT Health	Jan-Philipp Beck
	How we are going to develop our Agenda	Magda Rosenmöller
	Brief presentation of EIT Health European Working Group results	Toni Dedeu
10:15–11:15	**Session 1: Source and quality of data in Spain**	
	Topic 1: Availability of data sets (Big Data) in Spain	Moderator: Ernestina Menasalvas
	Icebreaking presentation: *Public Program of Data Analytic for Research and Health Innovation in Catalonia (PADRIS): where we are after 1 year of work*	Ramon Roman
	Icebreaking presentation: *Sharing data: the experience of collaboration with Massachusetts Institute of Technology (MIT)*	Maria Luaces
	Icebreaking presentation: *Digital transformation and Big Data strategy in SJD Barcelona Children's Hospital: moving towards Data Driven Healthcare Organisation (DDHO)*	Arnau Valls
11:15–11:45	*Coffee break & networking*	All
11:45–14:15	**Session 2: The challenges and opportunities of Big Data in Healthcare – now and in the future**	
11:45–12:30	**Topic 2: Identifying and harnessing the benefits of available data**	Moderator: Raul Mallaina
	Icebreaking presentation: *Use of Data in Clinical Research: experience from InSite European Project*	Pablo Serrano
	Icebreaking presentation: *Use of data in rheumatology: experience with getting evidence-based medicine*	Luis Rodriguez
12:30–13:15	**Topic 3: Working together – Industry and Healthcare provider collaborations**	Moderator: Isaac Cano
	Icebreaking presentation: *Value-based healthcare: the role of Big Data as enabler*	Berta Ortiga
	Icebreaking presentation: *Big Data for Better Outcomes in Hematological Malignancies: The European HARMONY Alliance*	Inmaculada Pérez
13:15–13:45	**Topic 4: Building capacities/capabilities to realise benefits**	Moderator: Blanca Jordán
	Icebreaking presentation: *Use of data in oncology and cancer treatment*	Maria Torrente
13:45–14:15	**Topic 5: Engagement and participation**	Moderator: Giuseppe Fico
	Icebreaking presentation: *Towards person-centric data management framework for active and healthy ageing: Internet of Things and Big Data – two sides of the same coin*	Sergio Guillén
14:15–15:15	*Lunch & networking*	All
15:15–16:15	**Session 3: From ideas to actions**	
	Conclusions of the five topics presented and summarised by each Moderator	Moderators: Toni Dedeu and Magda Rosenmöller
	Targeting the outcomes	
16:15–16:45	*Coffee break & networking*	All
16:45–17:00	Meeting summary and close	Jan-Philipp Beck Toni Dedeu Magda Rosenmöller

Introductory session

Background to the EIT Think Tank on Big Data in Healthcare

PRESENTER:

Jan-Philipp Beck, CEO of EIT Health

Jan-Philipp Beck, CEO of EIT Health, gave the following overview of EIT Health and its goals, as well as the objectives underlying the Think Tank on Big Data in Healthcare and the desired outcomes of the day's Round Table (RT) Meeting:

About EIT Health

EIT Health's slogan is "Together for healthy lives in Europe". The organisation's goal is to identify unmet clinical and economic needs within the complex healthcare systems around Europe. Based on these identified needs, EIT Health then initiates and facilitates innovation by bringing together leaders in education, business, and research.

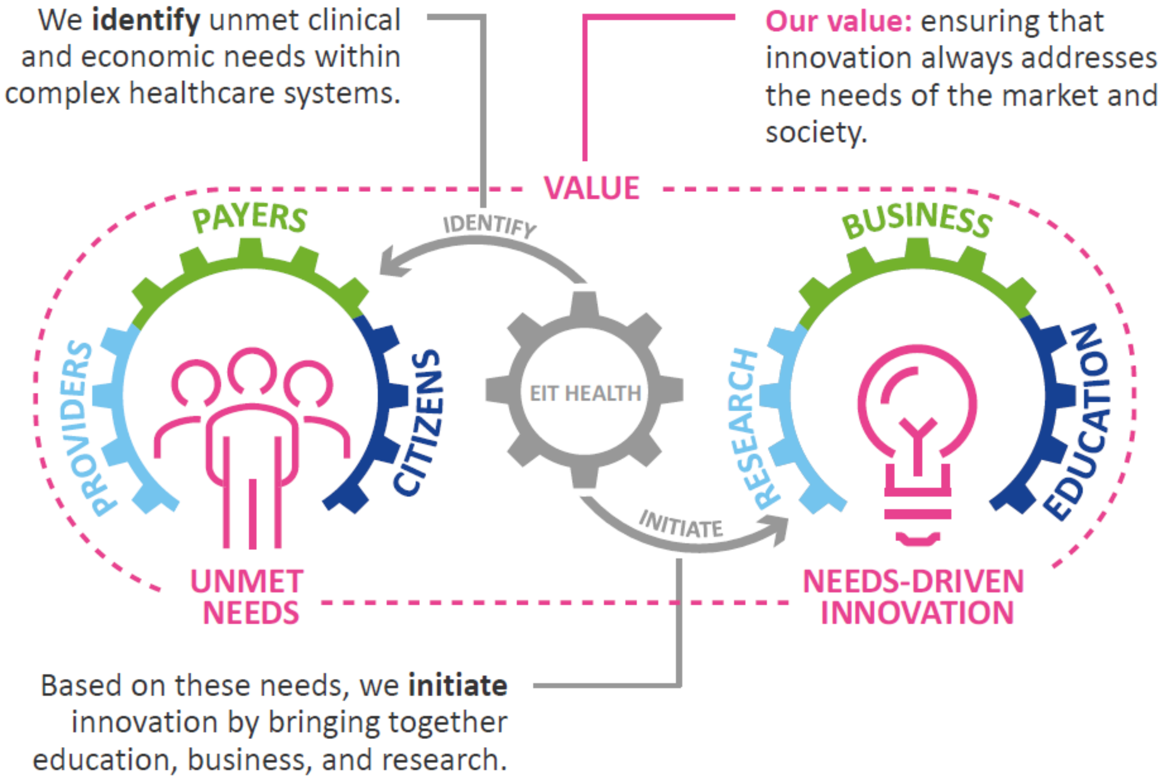
EIT Health is Headquartered in Munich, Germany, and the network comprises six regional offices (Co-Location Centres) in UK–Ireland, Scandinavia, Spain, France, Germany–Switzerland and Belgium–Netherlands – as well as seven further developing innovative regions, the EIT Health InnoStars. The strength of EIT Health lies in the expertise and resources of its unique, diverse and growing network of partners, which currently comprises 140+ leading organisations across all key areas of healthcare (the pharmaceutical industry, medical technology, payers, public and private research institutions, and universities).

EIT Health believes that to bring innovation into the healthcare domain, all these different actors need to be connected, so they bring together world-class thought leaders from partner organisations who can contribute their visions and share their organisations' assets to accelerate innovation.

The value EIT Health brings is in ensuring that this innovation always addresses the needs of the market and of society, to ultimately benefit citizens and patients while supporting economic development in European regions. This focus on "needs-driven innovation" was critical for the day's RT discussions for the Spanish region.

About EIT Health Think Tank

The EIT Health Think Tank is a forum of experts and thought leaders cooperating to shape the future of healthcare in Europe around key topics of relevance and importance in this field. Big Data is one key topic. The Think Tank brings together EIT Health Partners with other leading healthcare stakeholders to agree on means for ensuring that innovation reaches the citizens and patients who need it most. Think Tank members seek to identify healthcare needs and potential solutions to those needs. Think Tank dialogue feeds back into EIT Health activities to ensure resources and innovation are optimised to address healthcare's most pressing issues. It enables a two-way exchange between those who demand health innovation and innovators in the EIT Health partnership who supply it.



We **identify** unmet clinical and economic needs within complex healthcare systems.

Our value: ensuring that innovation always addresses the needs of the market and society.

Based on these needs, we **initiate** innovation by bringing together education, business, and research.

The aim is to bridge the gap between the reality facing healthcare providers with ambitious goals at a European level, recognising that while many innovations are currently being developed and tested around Europe, a large proportion are not implemented and never reach citizens. For each key topic, the objective is to reach a consensus on the challenges faced, to understand the barriers at opportunities, and to agree on needs.

The Think Tank spans both European and regional levels: focusing on topics of European relevance, barriers and opportunities are defined at a regional level (via the RTs), and these findings are then consolidated to derive recommendations for initiatives or policy changes.

Expected outcomes of the Round Table meeting

By the end of the day's RT meeting it was hoped that the following would be achieved:

- Actionable ideas for projects (quick wins) that could be implemented regionally and have measurable impact
- Actionable ideas for projects that can feed into the EIT Health Innovation Platform and inform programming
- Input to the policy-making process at regional and/or European level

Three key messages to help ensure these objectives are achieved are:

1. Let's not only report but also build
2. Do we understand where we have disagreements?
3. Identify actionable outcomes

EIT Health European Working Group on Big Data: Review of results and plans for today's RT meeting

PRESENTERS:

Magda Rosenmöller, Senior Lecturer and Operations Management Academic Director, IESE Business School, Barcelona, Spain

Toni Dedeu, Director, Agency for Health Quality and Assessment of Catalonia, Spain (AQuAS)

Magda Rosenmöller introduced the EIT Health representatives present at the meeting and said that the IESE Business School, part of the University of Navarra, was very pleased to be able to host the Spanish RT meeting.

The work begun in Brussels

Leading up to this meeting in Spain, an EIT Health Working Group (WG) meeting on "*The use of existing Big Data to improve healthcare*:" had taken place at EIT House in Brussels, Belgium, on 24 January 2018. During that meeting the most challenging issues regarding the use of existing Big Data in healthcare were discussed and the WG's recommendations informed the development of three regional Round Table (RT) meeting agendas (in Spain, the UK/Ireland and Scandinavia).

Toni Dedeu gave participants a summary of the discussions that took place at the Think Tank WG meeting in January 2018 in Brussels and explained how that set the basis for this regional RT meeting in Spain. The WG Advisers were representatives of industry, academia, healthcare providers, policy makers. They included experts in digital information and technology, and they met to discuss the topic of: *The use of existing Big Data to improve healthcare in Europe – barriers, opportunities and proposed actions.*

The WG discussions addressed the following questions:

- What are the opportunities relating to existing Big Data in healthcare in Europe?
- What are the barriers?
- Given the assets of EIT Health, what initiatives should the Partners undertake to help address the identified needs?
- How should EIT Health strategy evolve to meet the health challenges in Europe?

Based on the input and feedback on these areas, key topics were suggested for discussion at regional Round Table meetings, with the objective of achieving actionable outcomes with a measurable impact. Initially, the Think Tank participants in Brussels brainstormed and identified key discussion areas relating to Big Data in healthcare. The main topics that emerged were:

- Data sharing – lack of trust, fear of data sharing, impact of General Data Protection Regulations (GDPR)
- Available data – quality, variety of sources, aggregation, how it will be used, governance, accountability & tracking
- Business models, incentives and cultural considerations
- Impact on healthcare professionals
- Impact on clinical trials
- Communication and engagement

Key themes selected

Based on these topics, the WG selected three key themes to form the basis for developing practical, workable ideas and actions:

1. Sources and use of data
2. Building capacities/capabilities to realise benefits
3. Engagement and participation of citizens and patients

The regional RT meetings, like the one in Spain and others to follow, were intended to address these themes, looking at common challenges as well as local challenges specific to each region.

The WG detailed these themes and the challenges they expected the regional RT meetings to address:

Sources and use of data

A huge amount of healthcare data is generated throughout Europe, but only a very small proportion is used to its full potential. The WG therefore recommended that the focus for each RT should be to:

- Define the extent and scope of data in the region.
- Develop a plan for how it can be used and its potential impact on healthcare improvement.
- Identify barriers to use of data, suggest how these can be addressed and what is needed to address these barriers.
- Showcase regional initiatives where Big Data are already being used successfully for healthcare improvement.
- Suggest future opportunities that could be implemented.
- Outline business concepts and how they could be scaled-up.
- Suggest "out-of-the-box" ideas for innovative partnerships and initiatives.

Building capacities/capabilities to realise benefits

The WG considered that exact needs for capacity building would take different forms, depending on the stakeholder, but would encompass education, empowerment and providing an understanding and awareness of the significant benefits Big Data can realise. They recommended RTs focus on:

- Understanding the skill sets needed to bring about innovation and change.
- Improving skill sets for different stakeholders who have different needs and approaches.
- Defining what existing education/capacity-building initiatives are ongoing and what skills will be needed in the future.
- Ensuring patient and citizen participation in new developments.
- Defining business concept and implementation in an effort to encourage entrepreneurship and investment in start-up health technology companies.

Within this topic it was noted that there may be potential synergies with the EIT Health Programmes, Campus (education) and Accelerator (business creation).

Engagement and participation of citizens and patients

For this topic, WG Advisers considered that honest and appropriate communication about Big Data benefits using real-world evidence was key to set the right tone and encourage active engagement and participation from stakeholders – and to build trust. They suggested that the RT discussions that would follow should bear the following in mind:

- Regions would need to develop a communications/participation strategy, personalised to suit different stakeholders.

- Knowledge sharing with open dialogue and transparency were key.
- Communication alone was not sufficient: personal practice and continuous involvement of stakeholders in initiatives was needed to build value and trust.
- Dynamic consent models would enable greater patient/citizen engagement in clinical and research initiatives – a two-way partnership.
- Perhaps something could be learned from other sectors where data is collected and shared, e.g. smart meters, cars.

Setting the agenda for the RT meeting in Spain

Based on the WG's decisions, all discussions and feedback from this RT meeting were to be captured in a meeting report and, along with those of the other regional RT meetings in Scandinavia (Stockholm, Sweden, in July) and UK/Ireland (Oxford, UK, in August), would feed into one single document that would be shared with the EIT Health WG.

Reflecting the WG's recommendations, the Spanis RT agenda and discussions would cover: five main topics:

1. **Access to data:** Where can existing data sets be found in Spain?
2. **What can we do with the available data?:** What are the challenges and opportunities we face that will enable us to get the best out of these data?
3. **Collaboration:** How can the clinical framework and industry partners work better together to achieve this?
4. **Capacities:** What will we need in the future to meet the changing needs of healthcare and the data generated as a result of it?
5. **Communication:** Involving citizens and patients in the health ecosystem.

The final session of the meeting would focus on developing a plan of actionable outcomes, both those that could be implemented regionally and those that could be recommended to EIT Health for action.

Summary of discussions and recommendations

Format of the discussions

Each session stated with three "Icebreaking presentations" looking at different aspects of this topic to illustrate the experiences of ongoing initiatives and the challenges they faced during development.

SESSION 1: **Source and quality of data in Spain**

TOPIC 1: **Availability of data sets (Big Data) in Spain**

MODERATOR: **Ernestina Menasalvas**, Professor,
Universidad Politécnica de Madrid, Spain

ICEBREAKING PRESENTATION:

Public Programme of Data Analysis for Health Research and Innovation in Catalonia (PADRIS): Where we are after one year of work

Ramon Roman, Responsible for the area of Big Data and Information Security,
Agency for Health Quality and Assessment of Catalonia, Spain (AQuAS)

The Catalan Parliament in June 2016 passed a motion to create a Public Programme of Data Analysis for Health Research and Innovation (PADRIS), which allows the use of health data in Catalonia for research. One of the challenges in obtaining the agreement had been that there was no clear regulatory framework to guide how the data could be used. This presentation gave an overview of the first year of work using this data since budget allocation in 2017. The programme is illustrated in Figure 2.

The data set covered by the law includes any information relating to healthcare that is publicly financed by the Catalan Government; it includes all spheres of healthcare (primary, secondary etc) but excludes private sector services. Information had been generated for some time due to the ongoing digitalisation process in Catalonia for most types of data in the healthcare system: electronic health records (EHR), prescriptions, images etc. The aim of PADRIS is to mobilise this health data for research while adhering to all the data protection guarantees demanded by citizens and the current regulations.

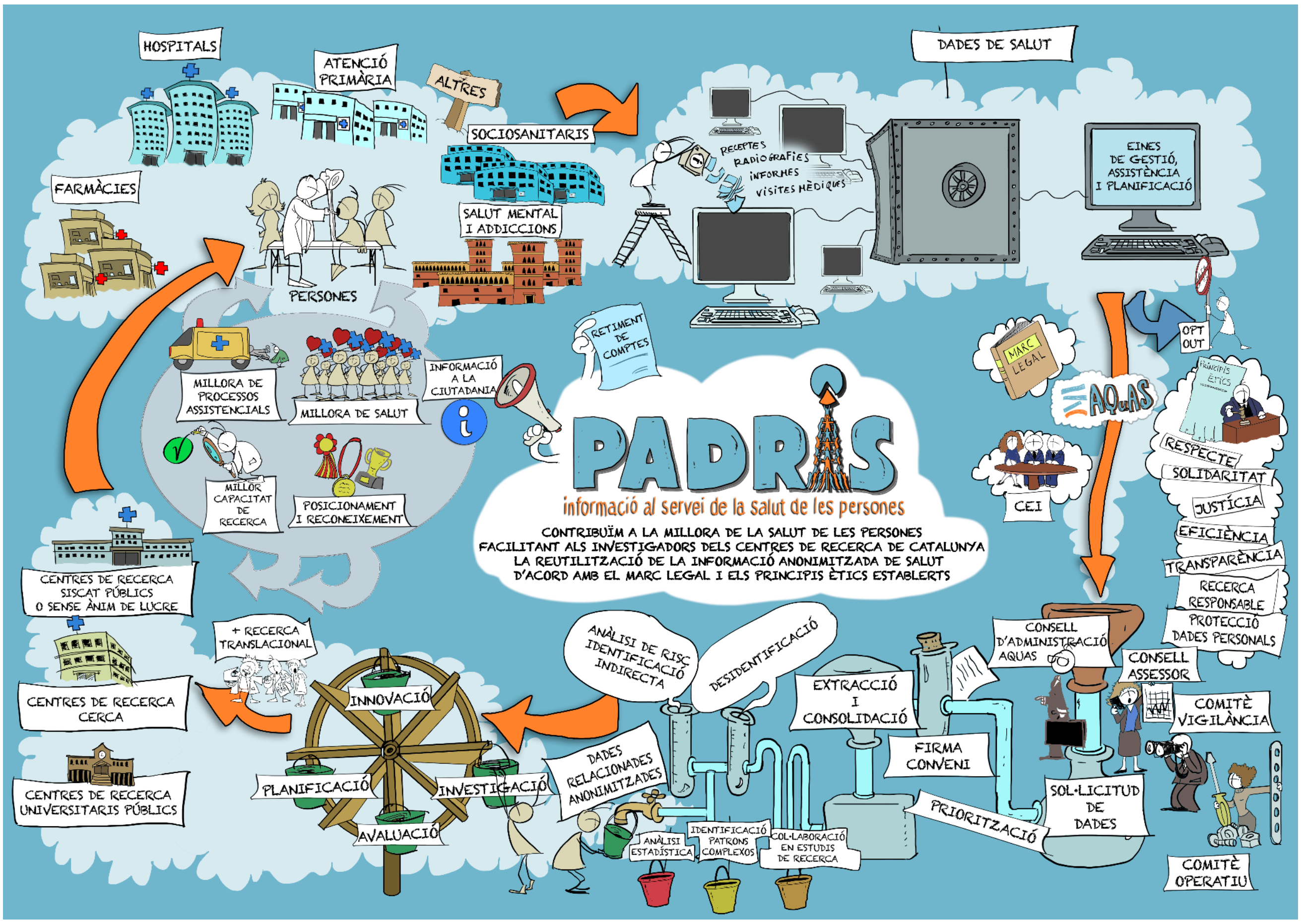


Figure 2: *Public Programme of Data Analytic for Research and Health Innovation in Catalonia (PADRIS).*

In terms of regulatory requirements, although all information is anonymised for research purposes, citizens have the possibility to opt out if they do not want their data used in this way. A set of ethical principles governs the programme, and they include the stipulations that no healthcare resources can be deviated for the programme, research has to be undertaken on rare diseases, data protection regulations have to be adhered to at all times. Furthermore, the research must be transparent and accountable – the resulting research information is available to all.

All projects and initiatives that use this information also have to be fully validated and must have gone through the respective Research Ethics Committee.

In terms of governance, one key aspect of the programme is that it was commissioned by the Agency for Health Quality and Assessment of Catalonia (AQuAS). Governance lies within the administration board of AQuAS. There is a consulting board systematically reviewing the deployment of the programme, and a vigilance committee makes sure all the regulatory requirements are adhered to. The operational section handles data acquisition, anonymisation etc.

All public research centres and public universities have access to the data to undertake research. Each data set is given on the basis of a legal contract and agreement between the Agency and the relevant institution. Most importantly, the Agency is not just giving data to the research team but also working cooperatively with them to publish the results of research.

The goals of data utilisation have always been to provide information back that will improve the health of citizens – there must be social return on investment.

ICEBREAKING PRESENTATION:

Sharing data: The experience of collaboration with Massachusetts Institute of Technology (MIT)

Maria Luaces, cardiologist in SERMAS

Maria Luaces, a cardiologist in SERMAS, gave an overview of the successful collaboration with MIT to share data and knowledge. She noted that data is often seen as sensitive information, which generates suspicion and can lead to limitations on its use.

From a multidisciplinary standpoint, the benefit of data sharing is to use the data given by third parties to identify unmet needs, with a focus on developing solutions – so-called Operations-Related Data Analytics.

This is the basis of the Consortium set up in 2010 between the Madrid Autonomous Regional Government and MIT, which is called "M+Visión" and focuses on innovation, leadership and impact. It is an alliance of leaders in science, medicine, engineering, business and the public sector, dedicated to strengthening the positioning and image of Madrid as the epicentre of biomedical research, accelerating and promoting innovation in biomedical imaging, and also promoting translational research and entrepreneurship. These goals are achieved though the identification of unsolved needs, the solution of which will have global impact.

Key to the functioning of the initiative is the Consortium's own methodology – the IDEA^3 Innovation Method, which is a scalable approach to improving innovation efficiency and can be applied to any task. The aims are to identify and define unmet health technology needs; to shorten development time and develop innovative ecosystems by engaging diverse lifecycle expertise; to improve strategic decisions about actions and resources; and, ultimately, to drive change. This generally happens in three phases: (1) project definition, (2) proof-of-principle (3) acceleration from idea to product. The project team benefits from a range of mentors from diverse fields, including healthcare, academia, research and business, who can share information and data to help them achieve the project goals. The key outcomes are more efficient and strategic thinking, which leads to high impact results being achieved more rapidly.

In only four years, the M+Visión Catalyst teams using the IDEA^3 Innovation Method have achieved significant innovation milestones and have exceeded the MIT benchmark for similar per-dollar research investment. M+Visión has launched 20 biomedical technology innovation projects, driven by 34 international fellows and involving 130 collaborators and 50 faculty from over 30 institutions in Spain and the USA.

Examples of successful M+Visión Catalyst projects include:

- A Catalan engineer who developed a device called Neosonics, which uses high-frequency ultrasound to non-invasively count white blood cells in the cerebrospinal fluid of infants for screening and treatment monitoring in meningitis: http://newborn.solutions/neosonics/
- Development of the neuroQWERTY system, which explores typing interaction with electronic devices as biomarkers for neurodegenerative diseases, such as Parkinson's: https://neuroqwerty.mit.edu/

ICEBREAKING PRESENTATION:

Digital transformation and Big Data strategy in SJD Barcelona Children's Hospital: moving towards Data Driven Healthcare Organisation (DDHO)

Arnau Valls, Project Manager and R&D Engineer, Hospital Sant Joan de Déu, Barcelona, Spain

The reasons for setting up the Data Driven Healthcare Organisation (DDHO) at SJD Barcelona Children's Hospital include recognition of the huge changes in population lifestyle and habits in recent years, changes in the service sector, and the rise in the use of mobile technology across all sectors of society.

The aim was to create a "fluid hospital" that removed barriers to patients and reached beyond the hospital walls. A range of tools was employed to give patients better access and allow participation in their healthcare, including patient portals, social media communication and telemedicine.

Many sources of healthcare data existed previously, but they were in silos and not connected, so using them was difficult. The fluid hospital permits a more collaborative approach, with a greater focus on predictive, personalised and preventative medicine. However, in order to store data that came from heterogeneous sources (biological, clinical, devices, social, etc.) and was stored in a range of formats, it was necessary to create a new database. That's why the Health Data Manager Cloud-based Data Lake was developed. It currently holds data for 1.5 million patients.

The database can support clinical decision-making as it gives a 360° view of the patient in a single place. It can be used for research and also for data analysis, for example developing algorithms to predict hypoglycaemic crises.

Development of the DDHO has met with a few barriers and challenges along the way however new technologies exist, for example blockchain, that can help break down those barriers.

DISCUSSION:

Key points raised

FACILITATOR: **Ernestina Menasalvas**, Professor, Universidad Politécnica de Madrid, Spain

RT participants were asked to consider the following:

1. What kind of data is available (structured/unstructured)?
2. What problems involving quality do you encounter, and how do you deal with them?
3. Who decides what data is used for particular projects?
4. How can we best collect and integrate data?

Points made during the discussion:

- RT Meeting participants said they considered the three presentations to be great examples of the use of Big Data in healthcare. They said these kinds of ideas needed to be scaled-up so that data are shared across centres, cities, regions, and ultimately the EU.
- Still, it was deemed necessary to find better ways to build interfaces that enable integration and standardisation of data, regardless of the source, and the barriers to this may not always be technical.
- A cultural change is needed, to offer a more collaborative, open, flexible and transparent approach to data sharing and analysis.
- We need to create a framework where innovation can flourish, so that the potential of the available data can be unlocked, and the different stakeholders who are involved can contribute.
- It was important that data analysis and research focused on *needs* of both healthcare providers and citizens. Therefore it may be necessary to define what data is most valuable to focus on, for example specific data sets for different diseases and the particular questions that need to be answered.
- The issue of private sector exclusion from inputting into the PADRIS and M+Visión projects was discussed. In both cases, industry partners were observers and did not have direct access to any patient data. It was agreed that commercial exploitation of citizen data was an important issue and ethical and regulatory standards were needed to ensure citizen and patient trust and confidence.
- Reciprocity and the need to give back data and information to citizens was considered critical.
- Collaboration in data sharing initiatives is likely to require new types of professions and a multidisciplinary approach that will include data scientists, biomedical engineers etc., working alongside clinicians and healthcare providers. Linked to this was the need to educate and train these different professions to manage biomedical data effectively, to meet the changing needs.
- It was noted that there were two schools of thought regarding data quality, and these two approaches inspire ongoing debate. One school emphasises that data needs to be of good quality and reliable before it is introduced to a database, which means that human expertise might be required for filtering. Another approach would include all data and use new technologies to analyse and extract relevant information.
- Cloud-based technology not only provides a solution in terms of infrastructure, but it also makes it possible to standardise the process of handling data, including maintenance, learning and scalability. One example cited was the current development of the European Open Science Cloud: https://ec.europa.eu/research/openscience/index.cfm?pg=open-science-cloud

SESSION 2: The challenges and opportunities of Big Data in Healthcare – now and in the future

TOPIC 2: Identifying and harnessing the benefits of available data

MODERATOR: **Raúl Mallaína**, International Programmes on Health Research and Innovation, Servicio Madrileño de Salud (SERMAS), Madrid, Spain

ICEBREAKING PRESENTATION:

Use of Data in Clinical Research: Experience from InSite European Project

Pablo Serrano, Director of Planning, Hospital Universitario 12 de Octubre, Madrid, Spain

Pablo Serrano gave an overview of experience at his institution of the InSite Project, the first European real-world data platform (https://www.insiteplatform.com/).

Healthcare has many digital information systems, most notably, EHR. The InSite project undertaken at the Hospital Universitario 12 de Octubre is a joint collaboration between the healthcare and clinical research sectors of the hospital and is utilising EHR data for clinical research. Registry data is a valuable, and often overlooked, source of healthcare information although it is less well standardised than prospective clinical trial data.

The InSite platform was developed as part of the Electronic Health Records for Clinical Research (EHR4CR) project, which is a European project with the objective of making it possible to re-utilise EHR data for research purposes. It is a collaboration between industry, hospitals and academia. Data protection is built into the platform: no patient data is sent, stored on or processed by the central platform; all processes run inside the hospital under hospital control. Only aggregated data leave the hospital.

InSite has a Quality Seal for Research Platforms (QS4RP) obtained from the European Institute for Innovation through Health Data (i~HD). This quality standard aims to provide assurance to healthcare organisations and research centres that the research analyses undertaken using the hospital's EHR information are carried out in secure ways that protect data privacy.

The platform utilises structured data, so the participating centres must provide it in this format, which can be a challenge. The initial stage comprises data characterisation, data modelling and mapping of terminologies, before loading the data and testing and validating the platform and evaluating the results. At an internal level, an important goal is that the information is used to improve the quality of EHR information.

Spain is currently the largest contributor to the InSite project, and within Spain Hospital Universitario 12 de Octubre is the largest contributing centre.

ICEBREAKING PRESENTATION:

Use of data in rheumatology: Experience with getting evidence-based medicine

Luis Rodriguez, Miguel Servat Type II Researcher, Fundación para la Investigación Biomédica del Hospital Clínico San Carlos, Madrid, Spain

Rheumatic diseases are a significant contributor to the global burden of disease and musculoskeletal disorders are known to result in substantial disability. They often occur at a relatively early age and the resulting disability can affect a person's ability to work, either temporarily or permanently.

The Hospital Clínico San Carlos set up a system of early care for such patients by stratifying workers based on their risk of disability due to musculoskeletal disorders, then delivering an early intervention to prevent or treat the disability. Funds have now been granted to establish a platform to classify the risk of a disabling event and to determine the best intervention to prevent it, assess the clinical course, and also evaluate the cost of the intervention.

Since the early 2000s the hospital has been developing digital technologies, including EHRs. A large amount of data has been accumulated from various sources, but the core clinical data is that which the clinician requires to guide treatment and generally includes information on diagnostics, procedures, treatments, adverse effects, overall risk factors and health status, among other things. Secondary sources of data include information on genetics, biomarkers, imaging, and sensors and devices, but this data can only be of value if it can be linked to the core clinical data.

Within the rheumatology department, data from >250,000 visits from 2007–2017 have been evaluated to map levels of disability. The EHR allows a measure of health status and disability to be entered at each visit as an assessment of quality of life. This allows mapping of disability levels associated with certain diseases and conditions.

Using a machine-learning approach, a predictive model for rheumatoid arthritis mortality has been developed and validated using two cohorts from different hospitals in Madrid (Lezcano-Valverde et al, 2017: https://www.ncbi.nlm.nih.gov/pubmed/28860558).

DISCUSSION:

Key points raised

FACILITATOR: **Raúl Mallaína**, International Programmes on Health Research and Innovation, Servicio Madrileño de Salud (SERMAS), Madrid, Spain

There was discussion of the challenges of data availability for rare diseases and the potential benefits of data aggregation to increase volume of available data:

- Three million people in Spain and 30 million around Europe suffer from rare diseases. Diagnosis is often prolonged and difficult, and delays in receiving the right treatment can have long-term effects on patient welfare, as well as social and economic impacts. It was suggested that data sharing and the use of artificial intelligence might lead to better diagnosis in cases of rare disease. In addition, telecommunications technology may also be helpful in aiding diagnosis.
- Pharmaceutical companies often have difficulty when developing drugs for rare diseases. For example, recruiting sufficient patients to clinical trials can be challenging due to low overall numbers. It was noted that the European Directive on Clinical Trials requires that it is mandatory to devote a significant part of the European budget to rare diseases. Due to the low numbers entering clinical trials, sources such as retrospective examination of EHR might provide additional useful data.
- A participant commented that one of the challenges of obtaining information on rare diseases in children is legislation, as currently, parents, rather than the children themselves, need to give consent.
- It was noted that the InSite platform also had a similar problem with low patient numbers in rare diseases. One solution could be greater collaboration between institutions to combine data.
- As illustrated by the example in the field of rheumatology presented by Luis Rodriguez, Big Data offers the opportunity for significant cost savings in healthcare coupled with improvements in productivity, by enabling identification of people at risk and then implementing early preventative strategies or treatments.
- It was agreed that it is important to learn from, and build on, positive examples of data sharing, such as the InSite experience. They are a good examples of public/private collaboration. At the end of the original 2-year financing, pharmaceutical industry funding took over, to support continuation of individual research projects.

TOPIC 3:

Working together: Industry and healthcare provider collaborations

MODERATOR: **Isaac Cano**, Hospital Clínic de Barcelona, Systems Medicine, Barcelona, Spain

ICEBREAKING PRESENTATION:

Value-based healthcare: the role of Big Data as enabler

Berta Ortiga, Manager Integrated Health Solutions MITG Iberia, Benelux & France, Medtronic

Rather than talking about a specific case example, Berta Ortiga chose to review the overall strategy of Medtronic, a global med-tech company, to address the new digital health environment. The company's vision is to meet universal healthcare needs by improving clinical outcomes, expanding access to care, and optimising costs and efficiency. Their three strategic priorities are:

- therapy innovation – introducing and delivering meaningful therapies and procedures;
- globalisation – addressing the inequities in healthcare access globally;
- and economic value – helping lead the creation of value-based healthcare solutions.

To help achieve this, a start-up venture – "Integrated Health Solutions" – was created within the company. The objective of the venture is not to sell more products but to lead the change towards selling solutions. It was created for three main reasons: to meet the changing needs of the health system, to evolve from a transactional relationship model to a collaborative one, and to focus on value generation. Value is results divided by resources. We need to move away from thinking about commercialisation and selling a product and move towards an offer that centres on the process and a culture of co-responsibility – payment linked to results. We need to meet needs and solve challenges, and the outcome has to be measured to determine its impact. Medtronic intends to be part of this transformation and move towards value-based healthcare – value versus volume.

There is a vast amount of structured and unstructured healthcare data, both within and outside of hospitals, but this information requires knowledge before it can have any impact on change. In the meditech sector, there is a lot of focus on the process and the device, but it is important to ensure that this all works well with other parts of the healthcare system in a more agile way. We usually associate the transformation of a sector with new technologies, but while new technologies have a significant influence, they have never transformed a sector by themselves. For effective transformation it is necessary to define a business model that links a solution to a market need.

ICEBREAKING PRESENTATION:

Big Data for Better Outcomes in Haematological Malignancies: The European HARMONY Alliance

Inmaculada Pérez, Director of Digital Health, GMV, Madrid, Spain

GMV is a global technology company working in many different sectors, including digital health. The HARMONY (Healthcare Alliance for Resourceful Medicine Offensive against Neoplasms in Haematology) (www.harmony-alliance.eu) is a public–private partnership comprising 53 partners in 11 countries. These partners share the goal of using Big Data technologies to deliver information that will help to improve the care of patients with haematological malignancies.

The HARMONY Alliance was established in January 2017 and will last for a period of five years. It brings together academic institutions, clinical disease networks, patient advocacy groups, clinicians and pharmaceutical companies, as well as regulatory agencies, health technology assessment bodies, experts in economics and ethics, and information and communication technology specialists. HARMONY aims to gather together, integrate and analyse anonymous patient data from a number of high-quality sources. This will help to define clinical endpoints and outcomes for these diseases, and the insights generated will facilitate and improve decision-making, to ultimately give the right treatment to the right patient at the right time.

The project has centralised content and is the first and largest public-private partnership project in haematological malignancies. It is a comprehensive project involving access for all relevant stakeholders, including patients, advocates, policy makers, regulators, HTAs, pharmaceutical companies and academia. A data lake has been created that will combine high-quality clinical data with omics data, to improve the outcomes in patients with haematological malignancies. By making use of Big Data technologies, HARMONY aims to accelerate more efficient drug development, regulatory evaluation, access appraisal, and treatment strategies, so the system is designed to be very agile and inexpensive. The project is currently ongoing, has scalability, and should allow integration with other, similar projects.

There are three key phases of development:

- preparation – privacy risk analysis, the quality management process, intake of data;
- harmonisation – standardisation, common data model, enrichment;
- outcomes – smart data, analysis – both descriptive and predictive.

Data privacy and security are paramount, not only regarding the data but also the infrastructure. Controls and security are applied to four layers – the physical, network, host and application/services layers. The system works with the concept of "de facto" anonymisation, so there is a balance between obtaining evidence and maintaining privacy.

DISCUSSION:

Key points raised

FACILITATOR:**Isaac Cano**, Hospital Clínic de Barcelona, Systems Medicine, Barcelona, Spain

- In order to achieve effective public–private partnership, a good business model is needed that reflects a strategic mission of shared risk.
- This shared risk needs to be accompanied by sharing of data and knowledge between the parties involved. New technologies, such as cloud-based computing, might facilitate data sharing and collaboration.
- Companies need to be open to new ways of working that do not consider the product and the service separately but are value-based and meet specific needs. This demands a change in the traditional commercial relationship.
- Codes of conduct and ethical standards are recommended for any public–private partnership, to ensure safety and security of data on both sides. This might make it easier to share information.
- While generating data lakes is of considerable value, to some degree the new GDPR requirements may make it more difficult to share data in this way. There needs to be a change of mindset, including at the individual citizen level, to understand the benefits of sharing and analysing data, and the additional value data has when combined.
- Generating trust at each stage of the data sharing and analysis process with all stakeholders involved was considered to be a challenge.
- While aggregate data is useful in some cases (for example feasibility studies), confidential handling of anonymised individual patient data may be necessary to add meaning to particular research studies.
- It was noted that one of the goals of the EU's Horizon 2020 project was to create a large health data network. This would necessitate healthcare providers building interoperable data systems.
- It was suggested that there was an ambiguity/division between using data for "research" and for "innovation" – public–private partnerships are generally trying to improve on a process or service and this would fall under innovation rather than research. The difference between the two can create a barrier regarding ethical approval for use of data.

TOPIC 4: **Building capacities/capabilities to realise benefits**

MODERATOR: **Blanca Jordán**, Head of Health Market at Atos Research and Innovation, Atos, Spain

ICEBREAKING PRESENTATION:
Use of data in oncology and cancer treatment

Maria Torrente, Attending Physician and Lung Cancer Group Researcher, Hospital Puerto de Hierro, Spain

Maria Torrente gave an overview of the work of that the Medical Oncology Department at the Hospital Puerta de Hierro-Majadahonda is doing in partnership with the software company Atos.

Her presentation focused on a pilot project in lung cancer, a complex disease with high incidence and mortality. A tool has been developed to enable the use of Big Data to improve treatment safety and outcomes, and to deliver precision medicine, in treating lung cancer. Typically, once a node is detected in the lung, an assessment is made as to whether it is malignant or benign. If it is malignant, then this leads to a series of invasive diagnostic tests (often repeated many times), different treatment options, possible adverse effects, and potential comorbidities. In many cases, these interventions do not necessarily improve survival. Different treatments work well in some patients and not others even when they have the same genetic mutation, and often we do not know the reason why. The resulting disease burden and progression creates a significant family and social burden.

In addition, there is a high degree in interpatient heterogeneity in terms of genetics, as well as intertumour heterogeneity, so there are significant difficulties in predicting tumour dynamics and associated outcomes.

Big Data integration might enable us to detect new patterns in patient characteristics and risk factors, an improvement that would give new insights into improved treatment strategies.

Current approaches to cancer management need to be improved in terms of:

- Identification of factors related to cancer, whether occupational, social, dietary or family related.
- Detection of subjects at risk of developing cancer by risk stratification.
- Early detection (which is critical in lung cancer): non-invasive screening that is without side effects, efficient and with high sensitivity/specificity capable of identifying patients suspected of developing the disease.
- Detection of especially sensitive populations not yet identified.
- Development of new and more effective therapies with less toxic effects.

At the Hospital Puerta de Hierro-Majadahonda, they initially set up a successful telephone service that helped prevent 47.4% of patients going to the ER and 46.8% of unscheduled visits to the Medical Oncology department. This was developed further into the OncoApp, an information and self-management tool for patients. This mobile app allows home monitoring and has a decision support platform. The data generated will also be of use for future Big Data analysis and learning.

The hospital is also involved in two Horizon 2020 projects, one in personalised medicine and another in information and communication technologies.

Analysis of all these data will ultimately help to improve overall survival of patients and allow optimised care and faster access to care by means of teleconsultation and telephone call service through OncoApp. It will also allow investigation and implementation of algorithms that predict to drug interactions and help identify risk patterns and prognosis.

DISCUSSION:

Key points raised

FACILITATOR:**Blanca Jordán**, Head of Health Market at Atos Research and Innovation, Atos, Spain

- With the rise in digital healthcare and technology, it is important that the different representatives of the multidisciplinary team involved in using Big Data use (clinicians, engineers, data analysts etc) can "talk" to each other – training will be needed so they are able to speak the same technical languages.
- Unless we have properly trained people who span both clinical sciences and technology, it will not be possible to manage and make best use if the Big Data available to us. A good regional example, Bioinformatics Barcelona Association (http://www.bioinformaticsbarcelona.eu/), was established to meet the need for generating synergies between biology and computer science. The Association builds a stronger union between biology and IT and establishes high-quality education and training programmes to develop talent in this area.
- The concept of lifelong learning is also valuable: once people are qualified in their primary field, they should continue to develop to meet the needs of their role, which may mean incorporating skills from other disciplines – cross-functional learning.

Some training resources in these new roles have already been established, for example the University of Valencia offers a degree in biotechnology. It was also suggested that "co-creation" is a valuable part of the process of training in these new roles – learning from experience and everyday practice. This has to be linked to the creation of companies.

TOPIC 5: **Engagement and participation**

MODERATOR: **Giuseppe Fico**, Senior Researcher, Project Manager - Health Area Coordinator, Life Supporting Technologies, Universidad Politécnica de Madrid, Spain

ICEBREAKING PRESENTATION:

Towards person-centric data management framework for active and healthy ageing: Internet of Things and Big Data – two sides of the same coin

Sergio Guillén, Chief Innovation Officer, MySphera S.L., Valencia, Spain

Sergio Guillén gave an overview of the only large-scale pilot project on smart living environments for healthy ageing. It is a huge pioneering project involving 50 partners, and 40% of it is taking place in Spain. Three regions in Spain are reference sites for the project. The aim is to support and extend independent life outside of institutions by developing a person-centred, active and healthy ageing (AHA) internet-of-things (IoT) ecosystem. In this setting, the individual is the main source of the data, which is obtained via smart sensors in their living environments. The information is stored securely and used for analysis. Users of the data include individuals, and also other organisations and service providers, who can create services from the data for the individuals (the data generators) to consume.

Currently, this type of data management ecosystem is being developed and deployed at nine sites in Europe. It offers opportunities for analytics and Big Data. The system generates an environment that is co-creative and, importantly, allows citizen engagement.

Big Data on health does not currently exist in this kind of social setting, outside of the healthcare sector. The project is therefore creating the environment to enable Big Data to be generated and used to create new knowledge – essentially, Big Data by design.

DISCUSSION:

Key points raised

FACILITATOR: **Giuseppe Fico**, Senior Researcher, Project Manager - Health Area Coordinator, Life Supporting Technologies, Universidad Politécnica de Madrid, Spain

- Research impact assessment has a role to play in evaluating the impact on citizens and patients of research investments and activities. This needs to be communicated in a transparent and understandable way to different stakeholders – the data we generate needs to be accounted for within society.
- Big Data generated in the social context can provide business intelligence models, for example for city councils to determine the benefits of services to citizens. Furthermore, "real-time" data from individuals can trigger services that are needed in a short time frame (e.g. in the case of falls).
- It was proposed that patients and citizen engagement might be improved if they could see the benefits of research that uses their data – by somehow linking their personal EHR to specific research projects and outcomes.

SESSION 3: **From ideas to actions**

Conclusions from the five topics

KEY POINTS AND RECOMMENDED ACTIONS:

Key points and recommended actions that may be of potential interest to EIT Health for future initiatives are highlighted. These points inform our Summary of Recommendations.

MODERATORS:

Magda Rosenmöller, Senior Lecturer and Operations Management Academic Director, IESE Business School, Barcelona, Spain

Toni Dedeu, Director, Agency for Health Quality and Assessment of Catalonia, Spain (AQuAS)

CONCLUSIONS FROM TOPIC 1: **Availability of data sets (Big Data) in Spain**

- The challenge of data access is often more of a cultural/mindset challenge rather than a technical one – multidisciplinary teams need to be ready for the change in order to realise the benefits.
- We need to develop a common framework/platform for innovation in order to collaborate and standardise processes etc, that will enable the potential of Big Data to be unlocked.
- We need to develop guidelines, protocols and methodologies so organisations can understand how to use and integrate data.
- We need to do away with the idea of competitiveness – we are all in this together and aiming for the same goal of health improvement for citizens.
- We must engage citizens in understanding the reasons for data sharing, the outcomes of the analysis and research, and the way they can help in this process – empower patients and give them greater access to improve the quality of data and ensure it is correct.
- It is important to define the *needs* that any data analysis is trying to address.
- Could there be an international consensus on open data access for research?

CONCLUSIONS FROM TOPIC 2:

Identifying and harnessing the benefits of available data

AND TOPIC 3:

Working together: Industry and healthcare providers collaborations

SUMMARISED BY: **Raul Mallaina and Isaac Cano**

- One of the strengths of Big Data and data integration is overcoming situations where there is a low number of subjects, limiting the data available from clinical trials or individual registries. Examples include rare diseases and data on pregnancy – as pregnant women are usually excluded from trials.
- Using Big Data to identify people most at risk of a disease, and then implementing early preventative strategies or treatments, can help to realise significant savings in the cost of healthcare, and improvements in productivity due to less disability.
- We need to ensure strategic alignment of public–private partnerships so both sides understand the goals and create a win–win situation.
- **Codes of conduct and ethical standards are necessary for public–private partnerships to ensure security of data and stakeholder trust. Development of standards may be something that EIT Health could help to drive and centralise.**
    - Some standards already exist, for example in the regional projects presented at the meeting today, some of which involve EIT Health collaboration.
    - It was noted that the EU had developed a code of conduct for data technicians, although it was not yet fully validated.
- **Currently no guidelines exist regarding shared risk in partnerships between industry and healthcare for innovation projects, so these need to be developed. This is a possible action for EIT Health to coordinate.**
    - Need to develop cooperative relationship models with a shared risk agreement – traditionally industry has always been looked to for investment and therefore assumes the burden of risk, but they cannot do this indefinitely.
    - While there will be overlap, generally industry partners will have a role in data preparation, standardisation, and setting up the data warehouse, while healthcare providers will then use the framework to analyse data and generate results.
- **One idea for regional action is to identify a network of five hospitals in five regions in Spain and support them as part of an EIT Health programme that could implement a data sharing policy encompassing all the aspects of data security etc., as a pilot programme.**
    - This would guarantee data sharing and create a data ecosystem.
    - This network could then develop best practices for training, engagement etc which could ultimately be scalable to a whole country level and beyond.
    - Spain already has a shared clinical history project – this may be an opportunity to learn from their experiences and improve upon them.
- In addition to "thinking big", smaller projects that will deliver "quick wins" also need to be considered; this will also limit the risk.

CONCLUSIONS FROM TOPIC 4: **Building capacities/capabilities to realize benefits**

SUMMARISED BY: **Blanca Jordán**

- Need a cultural change so that research, innovation and clinical practice are brought together.
- Lifelong learning and cross-functional training (and re-training) in all aspects of Big Data will become increasingly important to meet the changing, complex demands of healthcare technology roles – synergy with EIT Health Campus.
- Training of citizens in the value of Big Data and what it means for them in terms of the results that are generated: needs leadership to drive forward.
    - It is a difficult and ambitious concept to think of training the population as a whole and it may be better to start by engaging with patients who will directly benefit from the data initially, giving them the tools to self-manage, before expanding more widely.
    - Both bottom up and top down approaches are essential – healthcare managers also need to understand the value of Big Data and the benefit of having empowered citizens.
- Need healthcare professionals to embrace and engage in technical training so they have the skills to participate in Big Data initiatives and collaborate with data analysts. This may require changes to medical/nursing school curricula.

CONCLUSIONS FROM TOPIC 5: **Engagement and participation**

SUMMARISED BY: **Giuseppe Fico**

- A priority should be the engagement of regulators and key decision makers in healthcare – engage with EU DG Sante?
- **Co-Creating Innovative Solutions for Health (CRISH) is an EIT Health Campus training programme and an example of patient engagement. The objective of CRISH is to bring together key stakeholders of the health sector, including patients, who will learn to co-create innovative processes, products or services that will improve the health of populations through the identification of unmet needs.**
- Need to measure outcomes of Big Data initiatives to enable feedback and learning from successes – identify what works, scale-up to an EU level and set new standards.

Summary of Recommendations

1. Training and skills development	Training in Big Data and new technologies will be critical for healthcare professionals, regulators and policy makers – there are synergies and future opportunities with EIT Health Campus.
2. New collaborative business models	New models that share the burden of risk will become increasingly important and allow innovation to progress in the context of "co-creation". These new ways of working, which are different from the traditional commercial relationship, will require their own set of ethical standards and codes of conduct to be developed. • **Codes of conduct and ethical standards are necessary for public–private partnerships to ensure security of data and stakeholder trust. Development of standards may be something that EIT Health could help to drive and centralize.** • **Currently no guidelines exist regarding shared risk in partnerships between industry and healthcare for innovation projects so these need to be developed. Possible action for EIT Health to coordinate.**
3. Data sharing and integration	While data sharing and integration for research is already ongoing, it is currently more difficult between hospitals. EIT Health may have a role to play in coordinating the development of standards for data sharing between public–private partnerships. • **An idea for regional action is to identify a network of five hospitals in five regions in Spain and support them as part of an EIT Health programme that could implement a data sharing policy encompassing all the aspects of data security etc., as a pilot programme.**
4. Citizen and patient engagement	It will be important to be bold in the approach to citizen empowerment and data access, and clearly define what is meant by this. Health literacy education and enabling citizens to manage their own health is a key factor. This is in line with recent EU communications and proposals for sharing of healthcare data (http://europa.eu/rapid/press-release_IP-18-3364_en.htm) and reflects the fact that the vast majority of citizens want access to healthcare data and are willing to share it if they can see the benefits. • **A good example of successful patient engagement is the EIT Health Campus project, CRISH.**

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