Think Tank

SUMMARY REPORT

The use of existing Big Data to improve healthcare

December 2018

Contents

Background to the EIT Health Think Tank

The EIT Health Think Tank process

The EIT Health Think Tank is a forum of experts and thought leaders who work in collaboration to shape the future of healthcare in Europe. The aim of the Think Tank is to accelerate need-focused innovation in key areas of healthcare within the EIT Health community and beyond, to better meet the needs of European citizens.

The Think Tank is governed by a Steering Committee (SC) who propose topics that are high on the European health agenda to be discussed in annual cycles. Once a topic is identified, the Think Tank brings together a Working Group (WG) of experts, drawing on the strength, knowledge and skills of EIT Health's Partner Network and other stakeholders, to debate that topic and provide their expert information and advice. Outcomes of discussions at this pan-European WG meeting are then used to inform further discussions at regional Roundtable (RT) meetings hosted by EIT Health regions which provide a local context to the topic. This approach allows for discussions that focus on specific local needs while also giving visibility to successful solutions that could be replicated and scaled-up at a European level.

EIT Health is in the unique position of being able to harness the expertise and power of the Partner Network, not only to participate in the Think Tank discussions at European and regional levels, but also to accelerate the development and implementation of ideas generated by the Think Tank to create impact. Through its partnerships, EIT Health has the capability to support promising innovative health projects in reaching their objectives and therefore provides real, innovative healthcare solutions to benefit citizens throughout Europe. In addition, some of these innovative ideas can be progressed alongside the EIT Health portfolio programmes: Accelerator, Campus and Innovation Projects.

The Think Tank format enabled the identification of barriers and the suggestion of creative and collaborative ways to remove them, all of which facilitate the adoption of innovation and improve the sustainability of the healthcare systems of Europe – a key goal of EIT Health as an organisation.

At the conclusion of a cycle of meetings, the Think Tank provides a summary to EIT Health of the discussions arising from both the central WG and regional RT meetings. Conclusions and recommendations stemming from these discussions are used to drive forward initiatives and help guide activities that will have a positive impact on citizen and patient health, and on healthcare systems throughout Europe.

Based on this expert feedback, the Think Tank also guides EIT Health Public Affairs efforts that relate to key policy levers at the European level to drive conducive environments for the uptake and adoption of innovation. The outputs of the Think Tank serve as guidance and recommendations that will be disseminated widely using various communications channels.

The topic for 2018: Big Data to improve healthcare

For its 2018 cycle, the topic of 'The use of existing Big Data to improve healthcare' was chosen as a Think Tank focus topic.

Think Tank 2018: The use of existing Big Data to improve healthcare

The value of healthcare data

The growing use of electronic health information systems and digital patient data in both research and clinical practice has led to the generation of huge volumes of data worldwide. Over the past few decades, the types of healthcare collected has changed significantly in volume, variety and velocity. The term 'Big Data' evolved to reflect the fact that the data generated today is often too large and heterogeneous and changes too quickly to be stored, processed, and transformed into value by traditional technologies. Health data now comprises large and complex digital datasets, including proteomic and genomic data, and more recently, widespread use of mobile devices has enabled the collection of citizen and patient data on a range of health parameters.

However, it is recognised that the combination and analysis of these valuable resources has the potential to give us greater insights into optimum patient management and outcomes, and trends in best practice healthcare delivery, and also costs – so there is an urgent need for innovations to bridge the gap between the potential that technology holds for making use of Big Data and the current ability to widely implement it, importantly, to plan for future changes in the healthcare ecosystem in terms of organisation, capacity and capabilities in the digital age.

The advantages of Big Data analyses go beyond simply improving profit margins and reducing resource wastage but will also be of value in predicting epidemics, improving quality of life, providing better outcomes, and avoiding preventable deaths, particularly from chronic diseases. The large amount of data from the considerable range of different sources provides significant opportunities to stratify patients' diagnosis and treatment on a more individual level and therefore provide a more personalised level of care.

Benefits of using Big Data approaches in healthcare have the potential to be accrued across several levels:

- Research, development and innovation
- Healthcare delivery and healthcare systems
- Pharmacovigilance and public health

The barriers to effective use of Big Data

Despite wide recognition of the significant benefits that use of information from these large datasets (Big Data) could provide, at the present time, the potential of available healthcare data remains largely untapped. This is primarily due to the huge challenges associated with combining and analysing the vast range of different sources of data across regional and national boundaries to provide meaningful information that will ultimately improve the lives of patients and citizens on a population-wide scale.

National health systems and databases in Europe are diverse and fragmented, and there is a lack of harmonisation of data formats, processing, and analytics. At an operational level there are also organisational, ethical and legal issues associated with data sharing, including the new General Data Protection Regulation, as well as capability issues.

Importantly, while Big Data holds a huge promise of improvement of health and healthy living, it can also raise big concerns in terms of the privacy and autonomy of European patients and citizens, so these also need to be considered and solutions put in place to address concerns and engage patients in their own health and care.

In addition, although there are a large number of high-quality innovations in the healthcare sector, scale-up and implementation of these products and services is often lacking, thus preventing critical innovation from reaching and impacting citizens' lives.

The European perspective

The European Union is currently working to encourage more effective use of information and communications technology, in particular for delivery of health services, including disease prevention and health promotion, and has various initiatives and strategies in place. The European Commission has allocated €2 billion under the Horizon 2020 programme for research and innovation in Big Data under the call 'Personalising Health and Care' and has since April 2018 a supportive policy for digital transformation of health and care with a strong focus on Big Data.

The role of EIT Health

In recognition of the considerable challenges across Europe but also the immense opportunities in this sector, 'The use of existing Big Data to improve healthcare' was selected as a topic for the EIT Health Think Tank for 2018. The task was to evaluate the current position in Europe, identify barriers, recommend strategies to overcome them, and propose actionable projects and activities to make the best use of Big Data at a regional and European level for the benefit of citizens.

To achieve this, EIT Health believed that dialogue had to take place between healthcare providers and payers on the one hand and innovators, researchers and industry on the other in order to match 'demand and supply' of innovative health solutions relating to the use of existing Big Data resources while preparing for future change. To facilitate this dialogue, EIT Health set up the 2018 Big Data Think Tank with representatives of all these stakeholders to drive the project forward. The programme consisted of a series of activities including pan-European working groups and regional roundtables open to institutions, EIT Health partners, and healthcare stakeholders.

The Big Data Think Tank agenda & programme

To start the Think Tank process for 2018, a WG meeting took place in January 2018 in Brussels that focused on the chosen topic of: 'The use of existing Big Data to improve healthcare'. Their task was to debate the key issues related to this topic with the aim of developing the framework and content of agendas for a series of three individual regional RT meetings in Spain, the UK/Ireland and Scandinavia.

The topics the WG addressed were:

- What are the opportunities regarding existing Big Data in healthcare?
- What are the barriers?
- Where and how can EIT Health and the Partner Network make a difference?

At the Brussels meeting, the Working Group agreed that each Roundtable should be based on the same broad agenda and common themes, but also provide insight from their own 'regional reality' and specific local challenges. They identified three key areas that were considered should form the framework for the RT agendas and discussions:

- **TOPIC 1:** Identifying and harnessing the benefits of available data
- **TOPIC 2:** Building capacities/capabilities to realise benefits
- **TOPIC 3:** Engagement and participation

Regional Roundtable Meetings

Advisors participating in the RT meetings included representatives of industry, academia, healthcare (including payers, and policy makers), and technology from that region.

The three RT meetings[1] took place in:

- IESE Business School, Barcelona, Spain (30th May 2018)
- Keble College, University of Oxford, UK (20th July 2018)
- Karolinska Institute Campus Solna (Stockholm), Sweden (13th August 2018)

Based on the agenda framework specified by the WG, each RT meeting was tasked to achieve the following:

- Suggest actionable ideas for projects (quick wins) that could be implemented regionally and have measurable impact
- Suggest actionable ideas for projects that could feed into the EIT Health Innovation Platform and inform programming
- Provide input into the policy-making process at a regional and/or European level

A separate document is available that gives a more detailed breakdown of the recommendations and proposals made at the individual RT meetings for actionable projects, reflecting their regional variations and differences in the overall agenda focus for each event.

The approach and overall outcomes of the discussion, including a proposed EIT Health Big Data strategy, were presented to and validated by the Think Tank Steering Committee on 9 November 2018.

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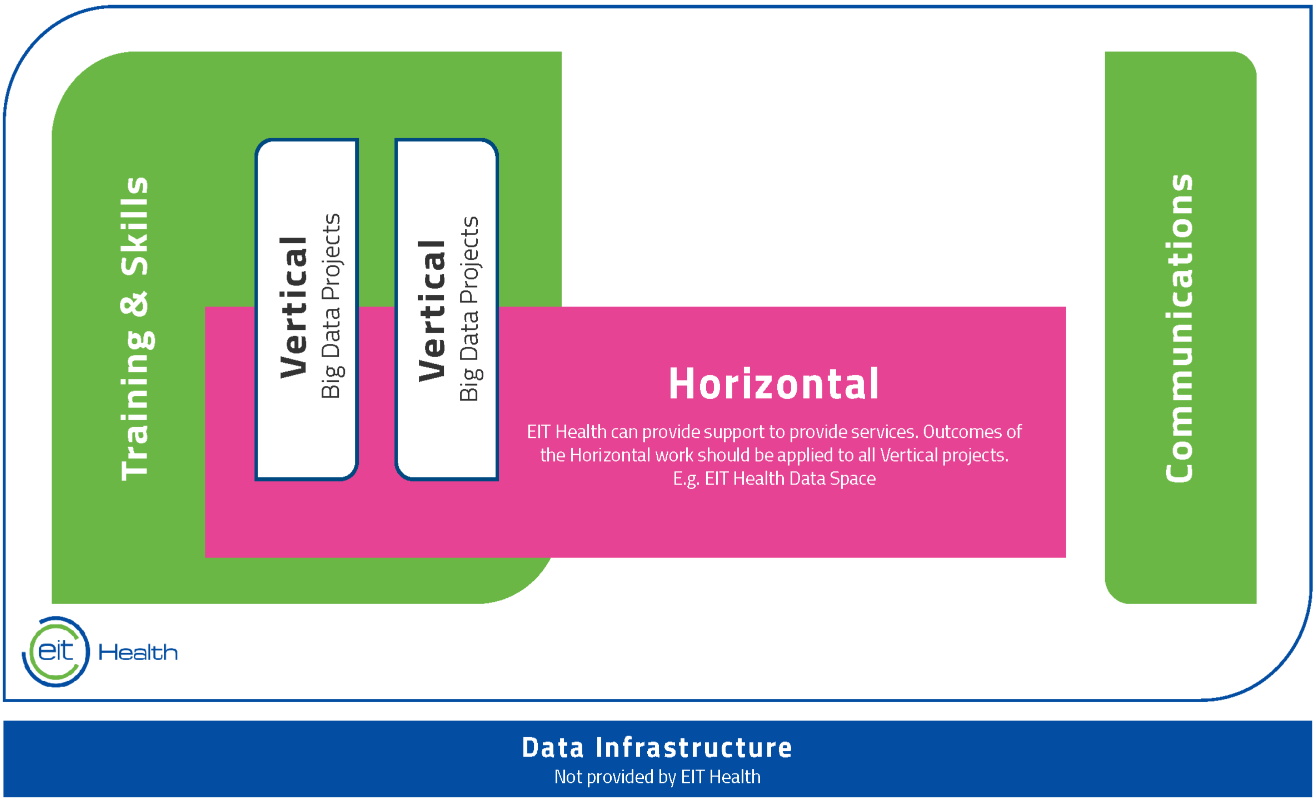
1) Paul Timmers, an Independent Consultant and Visiting Research Fellow in Cybersecurity Policy and Digital Transformation at the University of Oxford, UK, chaired most the meetings in order to provide continuity.

Overview of Recommendation Areas for EIT Health

Overall Outcomes of the Big Data Think Tank



Explanation of terms

INFRASTRUCTURE: Underpinning everything is the infrastructure of data. However, the technical aspects in terms of storage and interconnection of data are not something for EIT Health to undertake.

HORIZONTAL: **'Horizontal' activities provide data space services.** EIT Health can provide support to provide services, i.e. an EIT Health Data Space including, for example, by developing 'One-Stop Shop' access; Electronic Consent Forms and collaboration agreements for partnerships, resolving interoperability issues so that data from various sources can be combined (biobanks, genomic datasets, clinical health records, patient-generated data, etc.), possibly from across various countries in Europe; and by ensuring continuous learning about best practices, ethics, and collaboration models.

- Can learn from existing/regional projects and scale-up to use across EIT Health.
- Outcomes should be applied to all the 'vertical' projects below.

VERTICAL: 'Vertical' projects, often oriented to a particular health condition and outcome based on evidence, e.g. reducing readmissions, improving quality of life, that lead to the development of a better health product or service, and where possible contributing to the horizontal assets.

- Requires collaboration between different stakeholder organisations to deliver this (industry, healthcare, reimbursement etc).
- Needs or develops access to Big Data.
- Needs benefit and performance indicators, e.g. outcomes or value-based healthcare-based indicators and speed of data access/use processes.

COMMUNICATION: Spans both the horizontal and vertical aspects. Communication is needed not just about positive outcomes from projects (V) but also about overall benefits of data sharing (H), to enhance trust and collaboration.

TRAINING & SKILLS: Will need a multidisciplinary range of skills to meet the demands on new Big Data initiatives and work with all the various different forms of health and non-health data.

Key recommendations for actionable projects and activities

Overarching conditions of operation:

Values for stakeholders operating in this area:

- Build on trust, considering hesitation existing when acting in an uncertain environment
- Maintain transparency

Key recommendations:

Development of an EIT Health Data Space:

- Facilitates access to data through a collection of resources and services
    - Resources could include: best practices, for example for data protection
        - Parallel action – dynamic consent models, developing a singular electronic consent form
    - Aim to establish governance framework for collaborative data sharing
    - Software, algorithms, and specifications that enable interoperability and data analytics
- Validation process:
    - A small group of experts to confirm the need and what this would entail
    - Using data at the reach of our network, test data space with select projects
    - Once validated internally, disseminate and scale
- The Data Space will continuously evolve.

Citizen and Patient Engagement:

- Develop a communication strategy/information package for different stakeholders of positive cases examples, to communicate why giving samples to biobanks is important. For healthcare payers, this could include information about how the new services make treatment more cost-effective, highlighting the clinical value of genomics.
- Data donorship: Experience from the UK Biobank shows that 95% of donors would do it again once they understand the benefits. This communication and feedback loop needs to be embedded in all projects.
- Engage with patient organisations and use their communication pathways to reach citizens so they understand the benefits to society of data sharing and use.

Realtime data analytics: Just in time, at the place of intervention.

Interconnecting databases: Biobanks, gene banks, clinical trial records, patient records, patient-generated data, etc.

Funding schemes for new healthcare processes, not just for products and services.

Codes of conduct and guidelines for risk sharing in private–public partnerships that provide transparency on issues such as roles, responsibilities, ethics, contributions and benefits.

Summary list of recommendations:

A full summary list of all recommendations arising from the Big Data Think Tank process under the individual topic headings can be found in the **Appendix at the end of this document:**

1. Identifying and harnessing the benefits of available data
2. Building capacities/capabilities to realise benefits
3. Engagement and participation

Proposal for an overall strategic direction:

On the basis of the EIT Health Think Tank process, we have outlined the following overall strategic direction:

EIT Health will focus its work on Big Data in horizontal data space support and vertical projects, delivering health and care solutions, supported by Big Data training and education of professionals and public communications; in such a way as to ensure fast and responsible access to data for EIT Health participants and deliver quick-win solutions that demonstrate the benefits of Big Data.

EIT Health will pursue this maximally, making use of partnerships with policymakers, authorities and related R&I initiatives.

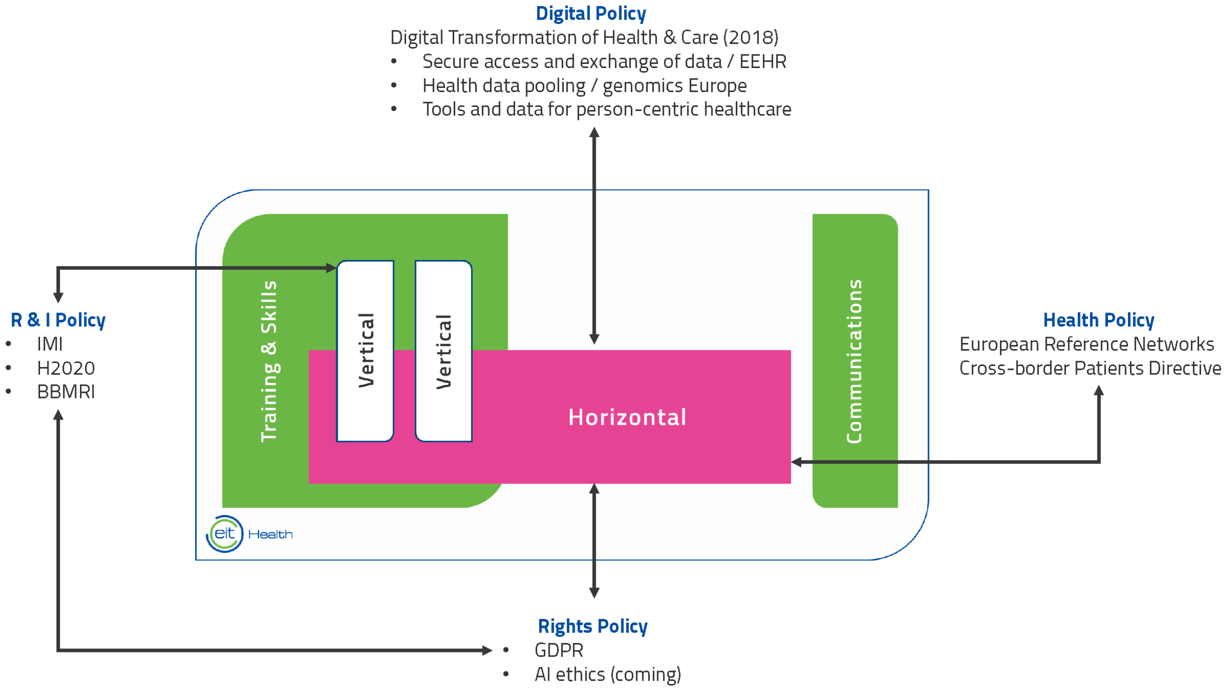
Recommendations within the context of the broader policy environment

In addition to the recommendations for specific innovation initiatives and projects regarding Big Data detailed above, during the Think Tank process, a number of relevant EU policy levers have also been identified. Deployment of these levers could help generate the most receptive and conducive environment to support the key recommendations.

Although specific, locally-focused discussions relating to a particular local policy context took place at the regional Roundtable meetings, it is important to recognise the broader healthcare landscape that currently exists that will either impede or facilitate the ambitions arising from the Think Tank recommendations. As illustrated in the diagram below, it is necessary not only to recognise the specific and most relevant policy that exists at the pan-European (Union) level, but also to ensure a synergistic and interdependent approach when looking to implement and execute the agreed solutions, such as the Health Data Space.

In the following pages, each relevant policy/legislative area is outlined, with suggestions for how public affairs and effective stakeholder engagement could be deployed to support the most effective implementation of the proposed recommendations. Within this framework, EIT Health intends to embark on an engagement programme, as outlined, to optimise the environment in which solutions and services will be introduced.

Continued assessment will therefore be necessary to determine what is plausible and feasible in light of the current policy environment, and what reform or revision of existing legislation, correlated initiatives and programmes would be required.



Think Tank recommendations (highlighted in blue)

During the EIT Health Think Tank Roundtable sessions recommendations regarding data sharing and integration were provided. While **data sharing and integration** for research is already ongoing, it is currently more difficult between industry and healthcare. EIT Health may have a role to play in coordinating the development of standards for data sharing between public–private partnerships:

- **At a regional level (Spain): as a pilot project, identify a network of five hospitals in five regions, supported as part of an EIT Health program, that could implement a data sharing policy encompassing all the aspects data security etc.**

Harmonisation of data is very expensive, so a first step could be to develop a **metadata catalogue**. It is also a pre-requisite for creating machine learning tools.

- **Develop a metadata catalogue. Not harmonised data, but an information package about what exists and where.**
- **At a regional level (Scandinavia): possible collaboration with BBMRI-ERIC.**

Several pilot projects are already ongoing in Sweden to combine biobank data and health records data, and the Estonian e-Health system is already using this approach.

- **Develop technical solutions for integrating data, for example combining biobank data and health records data together.**

Other than data sharing and integration, an additional challenge mentioned from the WG on their Background Document is **data quality**. The roundtables recommended the following solutions:

- **Find out from the research community what data points they need so these can be built into routinely collected data.**
- **Develop a set of common data standards that can be the template for new datasets, but can be also used for harmonisation of current data.**

In the case of biobanks, having central biomarker validation could enable development of risk models for complex diseases and validation of the new genetic tests based on biobank data. It would also generate evidence of whether the test has predictive power Big cohorts are needed to confirm this. Biobanks should give quality marks to the tests.

- **Create a biomarker validation centre – a network of biobanks that have genomic data available which has been updated with phenotype data from health records.**

Relevant Digital Policy Context

The related legislation/initiatives for Digital Policy focus around the creation of a Digital Single Market, namely:

1. Communication from the Commission to the European parliament, the council, the European economic and social committee and the committee of the regions. A Digital Single Market Strategy for Europe (2015).
2. Communication on the Mid-Term Review on the implementation of the Digital Single Market Strategy. A Connected Digital Single Market for All (2017).
3. Communication from the commission to the European parliament, the council, the European economic and social committee and the committee of the regions on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society (25 April 2018).

Potential policy engagement related to the Think Tank recommendations

The most concrete and relevant engagement will be with the April 2018 Digital Transformation Communication, in each of its three pillars (see diagram and recommendations above):

1. In the first pillar the EEHR will be a Commission proposal in 2019, but as regards access to data the EIT horizontal work (e.g. guidelines) should be made available to the EC as soon as it becomes available.
2. In the second pillar the 19 signatory countries[2] of the 1 million genomes declaration could be contacted via the EIT Health to facilitate rapid access to these data by EIT Health projects.
3. In the third pillar any concrete examples of health and care EIT projects should be provided to the European Commission (EC) as they become available.

It is recommended that the EIT Health prepares a dedicated document to the EC to explain above plans, and regularly (at least 3 times p.a.) updates this with actual deliverables.

Think Tank recommendations (highlighted in blue)

Data quality is closely linked to **data collection and analysis**, in this regard the roundtables gave the following recommendations:

- **Develop tools for automatic collection, analysis and reporting of health data.**
- **Investigate how we can use artificial intelligence and decision support to help complex patients with multiple conditions set smart health goals.**

Apart from technical challenges, the lack of trust from the citizens (but not only limited to them) with whom they will share their data, needs to be taken into consideration also as a very important point. The proposals the RT gave regarding **consent use of data** (part of TOPIC 3: Engagement and participation) are:

- **Develop new dynamic consent models that put the citizen/patient at centre of process – needs work/research to understand what is acceptable to them regarding how their data are used.**
- **Research possible ways of developing a pan-European electronic, harmonized process of citizen consent for use of data with secure identification by bank ID, and safe and secure access (blockchain) to data.**

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2) Austria, Bulgaria, Croatia, Cyprus, Czech Republic, Estonia, Finland, Greece, Italy, Latvia, Lithuania, Luxembourg, Malta, Portugal, Slovenia, Spain, Sweden, The Netherlands, UK (as per 12 November 2018).

Relevant Rights Policy Context

The related legislation/initiative regarding Rights Policy is regulation (EU) 2016/679 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation) 2016, which came into force on 25 May 2018

Potential policy engagement related to the Think Tank recommendations

For concrete engagement with the GDPR it will be necessary to work together with other health initiatives that interact with GDPR processes. An example is indicated in the diagram above, namely BBMRI, but this is certainly not the only one.

EIT Health's guidance should be joined up with similar guidance from e.g. BBMRI, if needed be made specific to the EIT Health, and provided to the EDPS and the EC. EIT Health should therefore actively engage with GDPR implementation EIT Health should have a data protection monitoring facility to translate data protection experiences (including DPA cases) into information and guidance for its participants. CLC's can ensure national monitoring of developments.

Think Tank recommendations (highlighted in blue)

A single electronic consent form would negate the need to collect several individual consent forms before each intervention.

- **Research possible ways of developing a pan-European electronic, harmonized process of citizen consent for use of data with secure identification by bank ID, and safe and secure access (blockchain) to data.** (Note: This recommendation is also included on the consent use of data – Rights Policy.)

Relevant Health Policy Context

The related legislation/initiatives regarding Health Policy are

1. Directive 2011/24/EU on the application of patients' rights in cross-border healthcare (2011)
2. European Reference Networks

Potential policy engagement related to the Think Tank recommendations

The relevant Health Policy is followed by the eHealth Network (of state secretaries) and the eHealth Stakeholder Group. EIT Health can engage via national representatives for the former and via its partners in case these are also in the Stakeholders Group for the latter. In any event, a dedicated document will be needed. A presentation by EIT Health into either group can be requested.

Think Tank recommendations (highlighted in blue)

Funding is also a significant issue to take care of, as mentioned on the Roundtable session in Stockholm, Sweden. The proposal was:

- **EIT Health should consider developing funding schemes for new healthcare processes not just for products and services.**

Research and Innovation Policy (Funding) Context

The related legislation/initiatives regarding Research and Innovation Policy are EC funding programs such as:

1. Horizon 2020 Work Programme 2018–2020: Demographic Change and Wellbeing which includes topics such as personalised topics, digital transformation in health and care and cybersecurity in health and care.
2. New opportunities for digital health start-ups and SMEs (From 2017)
3. EU-funded Research and Innovation in the field of ICT for Health, Wellbeing and Ageing. (From 2016)
4. The Innovative Medicine Initiative (IMI) (From 2017)
5. The Connecting Europe Facility (CEF) (2014–2020)

Potential policy engagement related to the Think Tank recommendations

Given prioritization of digital and health, but also focusing of future funding it is essential to establish links to all structured related R&I initiatives, IMI, BBMRI, AAL, and minimally have an exchange of experiences, and better, establish collaboration agreements such as transfer of project results and joint work on horizontal issues. It is also essential to avoid duplication with recent past H2020 work, for which an analysis is necessary.

Conclusions and proposed strategy moving forwards

The Roundtable Meetings brought together many experts and advisors who contributed to insightful and thoughtful discussion on the important topic of the use of Big Data in healthcare. Of particular application was the local context each meeting offered – providing a greater understanding of what aspects were most relevant, meaningful and needed in each region: What actions were necessary and, more critically, were they feasible, implementable, and ultimately beneficial?

Perhaps not surprisingly, many of the topics discussed touched upon many well-known and routine, but unresolved challenges in accessing and harnessing Big Data. Issues around interoperability, speed, governance and compliance, ethics and legal, data storage and harmonisation, to name but a few. They suggest an insurmountable task. However, it is recognised that the reasons that the status quo has been maintained for so long is not due to lack of need, prohibitive processes or existing frameworks, but due to lack of an effective catalyst that can kick start and co-ordinate activity across numerous stakeholders, led by a common purpose. Striving for such far reaching but unanimously desired ambitions requires time, commitment, continued momentum and leadership.

In light of the proposed project to create a Health Data Space, (the concept of which is currently being validated with a number of key consultants), EIT Health will focus its work on Big Data in the horizontal Data Space support, on vertical projects delivering health and care solutions, supported by Big Data training and education of professionals and public communications.

This will be undertaken in such a way as to ensure fast and responsible access to data for the EIT participants and deliver quick win solutions that demonstrate the benefits of Big Data.

EIT Health recognises the vast potential of utilising healthcare-related data to improve patient outcomes and the well-being of the citizens of Europe. Specifically, in relation to the organisation's portfolio of projects, many solutions and services rely on the optimised ability to access, generate, interpret and apply data to help inform their innovation journeys. One such project, RABBIT, launching in Scandinavia, aims to accelerate access to biobanks and population registries. This project will be an important correlate and beneficiary of the Health Data Space.

Big Data was defined as key healthcare priority within EIT Health's newly created six Focus Areas which provide the framework for the request of proposals for the annual call cycle for 2020. It was as a result of describing Focus Area 2, **'Harnessing the power of Real-World Data'** that the inaugural subject matter for the Think Tanks was conceived.

To this end, EIT Health requests that patients and citizens, partners and innovators, students and entrepreneurs think about the challenges presented by this topic: how can we collaborate to develop solutions to the issues raised? We request that you offer us your time, your resources, your ideas and your concepts, and in return, EIT Health will create and strengthen the critical alliances to collectively become the catalyst for change. EIT Health will pursue this by maximally making use of partnerships with policy-makers, authorities, and related research and innovation initiatives.

However, it is not possible for EIT Health to tackle this vital subject alone. By coming together, the outcome of these discussions will be more than this report joining the others.

APPENDIX:

Summary of Recommendations for EIT Health

Please reference the section called 'Overview of recommendation areas for EIT Health' for a detailed description of recommendation area terms **vertical, horizontal, training & skills**, and **communications**.

TOPIC 1: Identifying and harnessing the benefits of available data

CATEGORY	**RATIONALE AND PROPOSALS**
Data access Vertical	There is a wide variety of healthcare data, but the challenge is to access and use raw data in a meaningful way. • **There is a potential for projects/research into areas where clinicians would benefit from access to more basic data, analysed and presented in a meaningful way that enables them to make informed clinical decisions and drug choices. Suggested pilot project – data from patients with multimorbidities.** • **Improve access to preclinical data: biological assays can provide predictive information – this is a potential area for funding support as it is cost effective compared to clinical trials.**
Data sharing and integration Horizontal	While data sharing and integration for research is already ongoing, it is currently more difficult between industry and healthcare. EIT Health may have a role to play in coordinating the development of standards for data sharing between public–private partnerships. • **At a regional level (Spain): as a pilot project, identify a network of five hospitals in five regions, supported as part of an EIT Health program, that could implement a data sharing policy encompassing all the aspects data security etc.** Harmonisation of data is very expensive, so a first step could be to develop a metadata catalogue. It is also a pre-requisite for creating machine learning tools. • **Develop a metadata catalogue. Not harmonised data, but an information package about what exists and where.** • **At a regional level (Scandinavia): possible collaboration with BBMRI-ERIC.** Several pilot projects are ongoing in Sweden to combine biobank data and health records data, and the Estonian e-Health system is already using this approach. • **Develop technical solutions for integrating data, for example combining biobank data and health records data together.**

Data quality, standardisation and validation Horizontal	Standardising capture and curation of data. Different data formats are big problem for integration. There is a need for common understanding of the minimum requirements for data quality in for use in medicine. • **Find out from the research community what data points they need so these can be built into routinely collected data.** • **Develop a set of common data standards that can be the template for new datasets, but can be also used for harmonisation of current data.** In the case of biobanks, having central biomarker validation could enable development of risk models for complex diseases and validation of the new genetic tests based on biobank data. It would also generate evidence of whether the test has predictive power Big cohorts are needed to confirm this. Biobanks should give quality marks to the tests. • **Create a biomarker validation centre – a network of biobanks that have genomic data available which has been updated with phenotype data from health records.**
Data collection and analysis Vertical	Potentially a big area for research. • **Develop tools for automatic collection, analysis and reporting of health data.** • **Investigate how we can use artificial intelligence and decision support to help complex patients with multiple conditions set smart health goals.**

TOPIC 2: Building capacities/capabilities to realise benefits

CATEGORY	**RATIONALE AND PROPOSALS**
Training and skills Training and Skills	Training in Big Data and new technologies will be critical for healthcare professionals, regulators and policy makers to meet the demands of Big Data initiatives in healthcare. • **There are potential synergies and future opportunities with EIT Health Campus activities.** • **Develop training programs (preferably massive open online courses) for MDs, but also for other stakeholders to educate about these new technologies and ways of working, for example.** o **Genomics and bioinformatics** o **New clinical guidelines** o **New IT systems** o **Cost–benefit cases, ELSI and awareness** o **How to implement new ways of working**

New collaborative business skills Horizontal	New business models for public–private partnerships that share the burden of risk will becomes increasingly important and allow innovation to progress in the context of 'co-creation'. These new ways of working, which are different to the traditional commercial relationship, will require their own set of ethical standards and codes of conduct to be developed to ensure security of data and stakeholder trust. Currently no guidelines exist regarding shared risk in partnerships between industry and healthcare for innovation projects. New ways to achieve stakeholder alignment and agreements are needed. What are the common value propositions that will bring the resources they each have together for a common purpose – smarter healthcare and more efficient research? Can more be done to promote European cohesion regarding governance and codes of practice for data sharing and use? Harmonisation of guidelines and standards would speed up the contractual process of data access and sharing, as well as facilitating the process of scaling up to a European level in the future. • **EIT Health could help to drive and centralize the development of such standards and guidelines for business models include rules for data access, clear funding/payment agreements (where necessary, e.g. biobanks) and a legal and regulatory framework.** • **It will be helpful to research the current models of collaborative ways of working between healthcare and industry, and where they are successful.** • **Potential project for EIT Health to form an international multi-stakeholder group (academia, industry, healthcare etc) to discuss and accelerate this with clear milestones and timelines.** • **In the case of SMEs, develop a framework and ecosystem for collaborations – sandboxing was suggested.** • **At a regional level (Scandinavia): provide support to harmonize collaborations with industry on Big Data initiatives, leveraging the existing mutual trust between countries in this region.** • **Develop data access business models, rules for access, with clear funding/payment agreements to justify the access cost and ensure the biobank's sustainability.**
Funding Vertical	• **EIT should consider developing funding schemes for new healthcare processes not just for products and services.**

TOPIC 3: Engagement and participation

CATEGORY	RATIONALE AND PROPOSALS
Citizen and patient engagement Communication	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. • **Develop a communication strategy/information package for different stakeholders of positive cases examples, to communicate why giving samples to biobank is important. For healthcare payers, this could include information about how the new services make treatment more cost-effective, highlighting the clinical value of genomics.** • **Engage with patient organizations and use their communication pathways to reach citizens so they understand the benefits to society of data sharing and use.**
Understanding citizen and patient views Vertical	Need research into models and methods for listening and responding to citizens and patients to understand from them the negative attitudes to data sharing and what would change this. • **Facilitate public consultations on perceptions, preferences, priorities for the security and privacy of personal health data?** • **Potential research project: societal views of ethics and transparency around Europe.**
Consent for use of data **Horizontal**	A single electronic consent form would negate the need to collect several individual consent forms before each intervention. • **Develop new dynamic consent models that put the citizen/ patient at centre of process – needs work/research to understand what is acceptable to them regarding how their data are used.** • **Research possible ways of developing a pan-European electronic, harmonized process of citizen consent for use of data with secure identification by bank ID, and safe and secure access (blockchain) to data.**

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