



eHAction

Joint Action supporting
the eHealth Network

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Information note

WP 5 Innovative Use of Health data

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Acronyms

Acronym	Description
AC	Action Coordinator
AP	Associated Partner
AV	Added Value
CA	Consortium Agreement
CBeHIS	Cross-Border eHealth Information Services
CEF	Connecting Europe Facility
CHAFEA	Consumers, Health, Agriculture and Food Executive Agency
D5.1	Deliverable of Task 5.1 in Work Package 5 of eHealth Action
EC	European Commission
eHAction	eHealth Action – 3 rd Joint Action supporting the eHealth Network
eHDSI	eHealth Digital Service Infrastructure
eHMSEG	eHDSI Member States Expert Group
eHN	eHealth Network
eHOMB	eHealth Operational Management Board
eHPS-EC	eHealth Policy Secretariat - European Commission, DG SANTE Unit B3
EU	European Union
FAIR data	Findable, Accessible, Interoperable and Reusable data
GDPR	General Data Protection Regulation
HP	Health Professional
MS	Member State
MS/C	Member States and/or Countries
MWP	Multi-Annual Work Programme
OECD	Organisation for Economic Co-operation and Development
PA	Priority Area
PLA	Policy Level Action
T	Task
TL	Task Leader
WHO	World Health Organization
WP	Work Package
WPCo-L	Work Package Co-Leader
WPL	Work Package Leader

Purpose

This note provides information about the objectives, scope and planned structure and working methods of Deliverable 5.1, established in WP5 specific to policy level actions.

Objectives

The overall objective of WP5 is to support the application of good practices in Member States (MS) and provide guidance at European Union (EU) level on handling big data in health within the existing EU regulatory framework, on secondary use of personal health data, and consequently to ease the uptake of innovative usage of data across the healthcare sector for the benefits of society, individuals and performance of MS health systems.

Task 5.1 “*Mapping, awareness raising, and policy relevant actions on innovative use of big data in health*” foresees to deliver documents on:

1. Compiled policy-relevant documentation, including the Study on Big Data in Public Health, Telemedicine and Healthcare; this covers topics of big data applications in health and innovations before 2016¹ (hereinafter referred as EU Study) and the effects of GDPR, and review on Member State/country (MS/C) policy-level efforts on governing big data in health, and also assesses the implications of FAIR data principles². This document will also provide information for the eHealth Network (eHN) about expectations on big data, definitions, scope of work, terms, conditions, obstacles, importance to people, as well as the possible re-use of reports on Big Data and Health Analytics;
2. Identified obstacles preventing MS/C policies from being replicable either in other MS/C or on EU level, and proposals on how to overcome these;
3. The outlining of the added value (AV) of big data on the eHN governance level with the EU Study recommendations operationalised; and
4. Information for the eHN on policy-level actions (PLAs), including an initial set of enabling actions based on the recommendations of the EU Study to support awareness raising and communication of the added value of big data to different stakeholder groups, especially at the governance level in MS/C via the eHN (by Month 24 of eHAction).

¹ https://ec.europa.eu/health/sites/health/files/ehealth/docs/bigdata_report_en.pdf

² FAIR data principle: A set of guiding principles in order to make data findable, accessible, interoperable and reusable (Wilkinson et al., 2016). These principles provide guidance for scientific data management and stewardship and are relevant to all stakeholders in the current digital ecosystem. <https://www.nature.com/articles/sdata201618>

Expectations from big data

The recommendations of the EU Study reflect primary expectations from big data, as well as the intention to fill the gap between existing strengths or opportunities and weaknesses or threats.

The success of adapting health systems to new technologies and innovation, however, depends on the way how the enormous potential that health data offers for improving people's health and health systems' performance is designed and used. According to the Ministerial Statement "The Next Generation of Health Reforms" of the OECD Health Ministerial Meeting, 17 January 2017, Paris (hereinafter referred as: OECD Ministerial Statement)³, "due consideration of potential benefits and risks involved is needed to make the most of the vast amount of clinical, administrative, and other types of data being generated in health systems". The OECD Health Ministers welcomed the new Recommendation of the Council on Health Data Governance (see below), which identified core elements to strengthen health data governance and thereby maximise the potential of using health data while protecting individuals' privacy.

One of the rapidly growing areas of health care innovation lies in the advanced use of data science and artificial intelligence, specially machine learning, computerised vision and natural language processing. The European Council of October 2017 stated that the EU needs a sense of urgency to address emerging trends such as AI "while at the same time ensuring a high level of data protection, digital rights and ethical standards" and invited "the Commission to put forward a European approach to artificial intelligence" that was set out in the Communication from the EC "Artificial Intelligence for Europe" that urged European leaders to put AI at the top of their agendas. The public and private sectors must seize the opportunities that come both from developing innovative AI solutions and applying them to a range of fields, including the healthcare sector where AI has disruptive potential.

In the D5.1 document we will take into consideration the following recommendations which reflect the most important expectations on big data:

- *EU Study recommendation 1 on Awareness Raising:* Develop and implement a communication strategy to increase the awareness of the added value of Big Data in Health and encourage a positive public mind set towards Big Data in Health
- *EU Study recommendation 2 on Education and Training:* Strengthen human capital with respect to the increasing need for a workforce that can utilise the potential of Big Data in Health

3 <http://www.oecd.org/newsroom/oecd-health-ministerial-statement-the-next-generation-of-health-reforms.htm>

- *EU Study recommendation 3 on Data Sources:* Expand existing and explore new sources of Big Data in Health and secure their quality and safety
- *EU Study recommendation 4 on Open Data and Data Sharing:* Promote open use and sharing of Big Data in Health without compromising patients' rights to privacy and confidentiality
- *EU Study recommendation 5 on Applications and Purposes:* Increase target-oriented application of Big Data analysis in health based on the needs and interests of stakeholders including patients
- *EU Study recommendation 6 on Data Analysis:* Identify the potentials of Big Data analysis, improve analytical methods and facilitate the use of new and innovative analytical methods
- *EU Study recommendation 7 on Governance of Data Access and Use:* Implement governance mechanisms to ensure secure and fair access and use of Big Data for research in health
- *EU Study recommendation 8 on Standards:* Develop standards for Big Data in Health to enhance and simplify its application and improve interoperability
- *EU Study recommendation 9 on Funding and Financial Resources:* Ensure purposeful investment steered by the European Commission to warrant cost-effectiveness and sustainability
- *EU Study recommendation 10 on Legal Aspects and Privacy Regulations:* Clarify and align existing legal and privacy regulation of Big Data in Health
- *OECD health ministers' recommendation 1 on Establishing national health data governance frameworks:* Governments establish and implement a national health data governance framework to encourage the availability and use of personal health data to serve health-related public interest purposes while promoting the protection of privacy, personal health data and data security.
- *OECD health ministers' recommendation 2 on Harmonising frameworks between countries:* Governments support transborder co-operation in the processing of personal health data for health system management, research, statistics and other health-related purposes that serve the public interest subject to safeguards consistent with this Recommendation.
 - *European Commission communication on Artificial Intelligence for Europe:* : develop and use AI for good and for all building on EU values and strengths. Capitalise on research and public sector data which can be unlocked to feed AI systems, to make data sharing easier and to open up more data – the raw material for AI – for re-use. This includes data from the public sector in particular

as well as research and health data. (<https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52018DC0237&from=EN>)

- *European Commission High-Level Expert Group on Artificial Intelligence on Ethics Guidelines for Trustworthy AI*: set out a framework for trustworthy AI, A trustworthy approach is key to enabling “responsible competitiveness”, by providing the foundation upon which all those affected by AI systems can trust that their design, development and use are lawful, ethical and robust. These Guidelines are intended to foster responsible and sustainable AI innovation on the assumption that all legal rights and obligations that apply to the processes and activities involved in developing, deploying and using AI systems remain mandatory and must be duly observed which is especially relevant in the healthcare sector and personal health data. (<https://ec.europa.eu/digital-single-market/en/news/ethics-guidelines-trustworthy-ai>)
- *European Commission Communication on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society*: Data is a key enabler for digital transformation. EU should support action of Member States to improve data quality to promote research, disease prevention and personalised health and care to enable better health interventions and more effective health and social care systems. (<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2018%3A233%3AFIN>)

Working definitions

Working definitions were elaborated by WP5 members at the Kick-off meeting in order to lay down statements of the meaning of certain phrases which have been explained in various ways in the literature. The kick-off meeting of Work Package 5 was held on 16th October 2018 in Brussels. The meeting included a workshop to review available definitions and making proposal for the adoption of those ones that are important to empower patients, policy makers and professionals about the innovative use of health data. Experts agreed on defining Health data, Big data in health, Big data analytics in health and Innovative use of health data. These working definitions were introduced to the eHealth Network in November 2018, and are considered as continuously evolving definitions based on the revolutionary and constantly changing nature of the field. Definitions reflect the value-based approach followed in WP5, where value refers to satisfaction of a specific need and replicability at an economical cost.

- **Health data**: patient data in health records (records kept by health professionals and care providers, as well as self-reported health data), data from apps and wearables, any background data that will give insights on the social determinants of health.

- **Big data in health:** Consolidated data from existing fragmented data sources for the purpose of understanding, forecasting and improving health and health system status, needs and performance.⁴
- **Big data analytics in health:** Statistical learning methods and algorithms applied to big data in health, which include descriptive analytics, mining/predictive analytics to support evidence-based decision making, analytical techniques that are ideal for analysing a large proportion of text-based health documents and other unstructured clinical data (e.g., physician's written notes and prescriptions and medical imaging).
- **Innovative use of health data:** The process of translating an idea or invention into a good or service that creates value, or for which customers will pay. To be called an innovation, an idea must be replicable at an economical cost and must satisfy a specific need. Innovation involves deliberate application of information, imagination and initiative in deriving greater or different values from resources, and includes all processes by which new ideas are generated and converted into useful products⁵. The use of health data is considered “innovative” if this use results in better patient outcome and/or higher quality of healthcare delivery and/or higher productivity and performance.
- **Artificial intelligence:** Artificial intelligence (AI) refers to systems that display intelligent behaviour by analysing their environment and taking actions – with some degree of autonomy – to achieve specific goals. AI-based systems can be purely software-based, acting in the virtual world (e.g. voice assistants, image analysis software, search engines, speech and face recognition systems) or AI can be embedded in hardware devices (e.g. advanced robots, autonomous cars, drones or Internet of Things applications). Many AI technologies require data to improve their performance. Once they perform well, they can help improve and automate decision making in the same domain.⁶

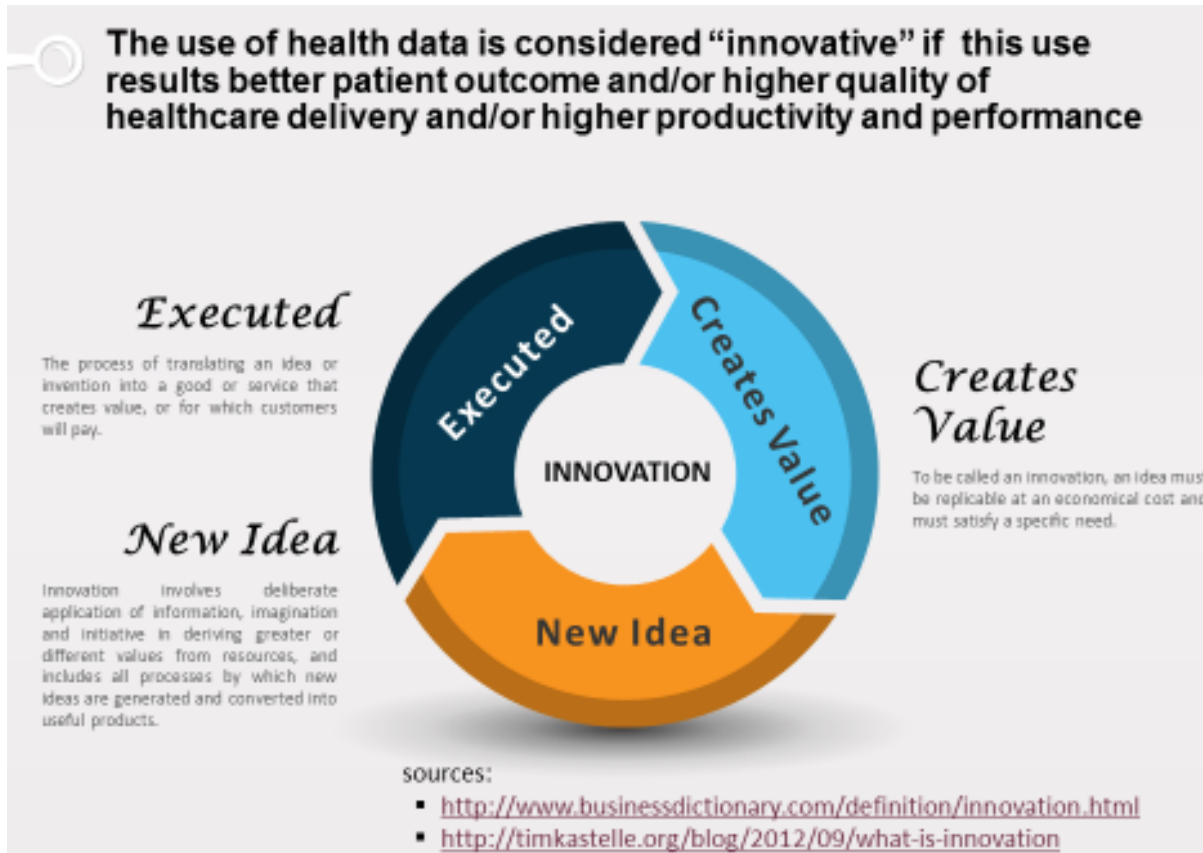
⁴ This definition was derived from the following EU Study definition during the drafting process of this document “Big Data in Health” refers to large routinely or automatically collected datasets, which are electronically captured and stored. It is reusable in the sense of multipurpose data and comprises the fusion and connection of existing databases for the purpose of improving health and health system performance. It does not refer to data collected for a specific study. (Source: EC Study on Big Data in Public Health, Telemedicine and Healthcare available at https://ec.europa.eu/health/sites/health/files/ehealth/docs/bigdata_report_en.pdf)

We acknowledge that the definition will be further refined and continuously monitored during the life of the project, together with the Authors of the Study taking into consideration of the real file evolution of the field.

⁵ Source: <http://www.businessdictionary.com/definition/innovation.html>

⁶ Source: <https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:52018DC0237&from=EN>

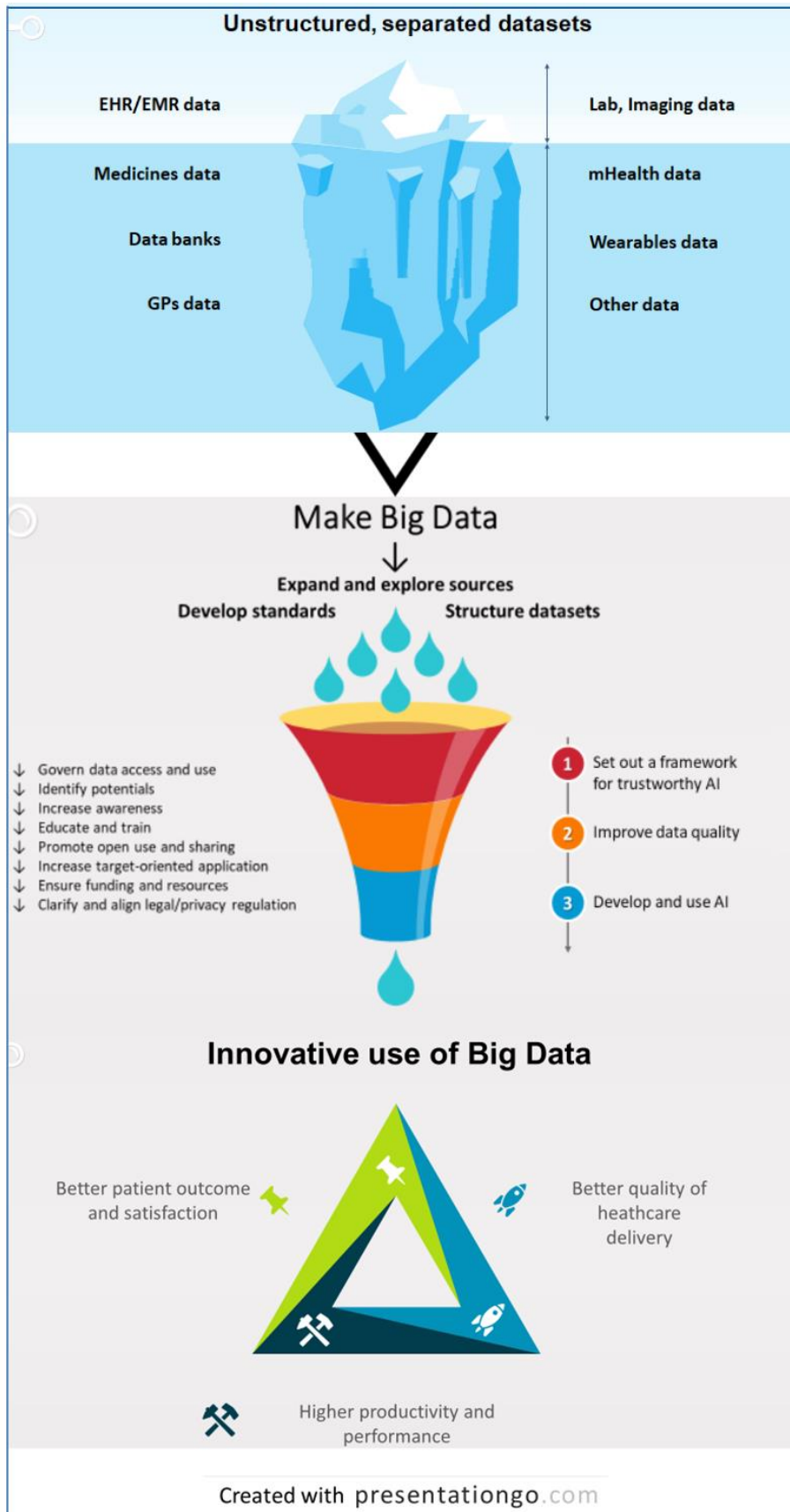
Figure 1 below illustrates the definitions of innovation⁷ and innovative use of health data:



Created with presentationgo.com

⁷ source: <http://timkastelle.org/blog/2012/09/what-is-innovation>

Figure 2 below illustrates how unstructured, separated health data can be transformed into Big Data and used in innovative ways:



Scope

D5.1 “*Report for the information of the eHN on policy level actions*” will compile policy-relevant documentation, including the EU Study and the effects of GDPR, and review on MS/C policy level efforts on governing big data in health.

The work on task level within WP5 follow the logic of “expectations - obstacles - relevant actions”. Based on this logical order the main scope of 5.1 is to:

- build on expectations identified in 5.2 from literature review and analysis
- identify the main obstacles, barriers that prevent the satisfaction of those expectations
- examine the expectation-obstacle-action relation with respect to a) policy-relevant documentation; b) EU study and OECD Ministerial Statement; c) effects of GDPR; and d) review of MS/C policy level efforts on governing big data in health
- prepare the background information for relevant policy level recommendations in 5.3.

Identifying obstacles that prevent MS/C policies from being replicable either in other MS/C or on EU level, as well as proposing how to overcome them, will be in the scope of the task in order to enable the communication of the value of big data to different stakeholder groups and to provide a way for public health promotion, preventive measures and care from the analysis of big data across the healthcare sector and MyData following FAIR data principles (i.e. Findable, Accessible, Interoperable, Reusable). The added value of big data on eHN and governance level with the EU Study recommendations will be outlined and operationalised by the methods introduced below. We also intend to acknowledge the growing importance of Artificial intelligence in the healthcare sector and its implications in secondary data use governance and implementation processes, in accordance with EC policy recommendations.

In the report for the information of the eHN on policy-level actions, an initial set of enabling actions will be introduced to support awareness raising and communication of the added value of big data to different stakeholder groups, especially on the governance level in MS/C via the eHN.

The “effective implementation of digital technologies in health is widely recognised as being crucial in establishing efficient, well-functioning health systems, and empowering patients as part of a transition to integrated person-centred care and ensuring that the vital health information which underpins the future of clinical care and decisions is made available when and where it is most needed.”⁸ Therefore, D5.1 recommendations will be also focused on transferring the lessons learnt in order to help MS/C to overcome obstacles, as well as avoid the usual case that the use of digital technologies in the current healthcare system and services will surely result only in more expensive solutions and treatments.

⁸ WHO Regional Office for Europe Symposium on the Future of Digital Health Systems in the European Region, Copenhagen, Denmark, 6–8 February 2019

Practical barriers and obstacles

Identification of obstacles preventing MS/C policies from being replicable either in other MS/C or on EU level, as well as the proposal on how to overcome these, require collection of clear and complex information on the state of:

- creation of EU level data networks
- data ownership
- data as capital – who should benefit from utilisation
- sharing results and best or worst practices how data saves lives
- selecting what can/will be replicated and what can't/won't
- setting priorities among practices and experiences which were selected to replicate
- informed consent (or if no negative consent is provided, then data can be used for innovative purposes)
- Big Data quality requirements for secondary data use
- data security, safety and privacy.

Importance to people

Acknowledging the need to reorient health systems to be more knowledge-based and patient centred, D5.1 will reflect the results of the further work of OECD and other organisations in order to :

- Reorient health systems to be more knowledge-based (new health statistics to measure and compare patient-reported experiences and outcomes in health care; highlighting best practice: key indicators of health and health system performance which identify relative strengths for all countries to share, and learn from);
- Enhance the people-centred focus of health systems and policies and promote high-value care;
- Provide new approaches to public health surveillance of diseases, risk factors and preventive care;
- Modernise delivery models (artificial intelligence; new technologies; the future of the health workforce);
- Better self-control of patients through data utilisation;
- Decrease the information asymmetry of patients;
- Provide better health outcomes and more personalised therapy for patients;
- Secure better-quality health delivery based on data analysis;
- Provide free flow of data and better access to care provision;
- Improve data security and data protection level for patients;
- Explain why innovative use of health data is important to our citizens;
- Show how people would really benefit from innovation and innovative use of health data.

Methods

One of the key elements of the working methods selected to produce D5.1 builds on the re-use of reports on Big Data and Health Analytics.

The recommendations developed by the EU Study contain suggestions on how to utilise the strengths and exploit the opportunities of Big Data for Public Health without threatening the privacy or safety of citizens and patients in terms of strengthening and supporting their health and improving the performance of Member States' health systems. Combining the fields targeted by the recommendations of the EU Study with the approach of the WHO⁹, policy actions for innovative use of big data in health are clustered around the following functional areas:

1. Awareness raising and communication
2. Education and training (as well as human capital)
3. Data sources
4. Data analysis
5. Open data and data sharing
6. Applications and purposes
7. Governance of data quality, access and use (as well as stakeholders)
8. Standards (and protocols) (as well as technological development)
9. Funding and financial resources
10. Legal aspects and privacy regulation (as well as data protection).

In order to prepare mapping, awareness raising and policy-relevant actions, WP5 will assess whether there are underperforming functions in the value chain of converting data into innovation in health. Where underperformance appears, relevant policy action will be mapped. Recommended ways and intensity of awareness raising will be determined according to the level of underperformance.

Inspired by an OECD publication in 2013¹⁰ and other relevant articles^{11, 12} this assessment will analyse whether the value chain consists of: 1) generating, capturing, collecting and cleaning data (in order to scout the value); 2) storing, securing, protecting and processing data (in order to create and valorise the value); 3) the motivation of stakeholders (influenced or defined by non-negotiables, differentiators and dissatisfiers), comparing satisfaction of specific needs to

⁹ [From Innovation to Implementation: eHealth in the WHO European Region. Copenhagen: WHO Regional Office for Europe, 2016.](#)

¹⁰ [Exploring data-driven innovation as a new source of growth: Mapping the policy issues raised by "big data". OECD Publishing, 2013.](#)

¹¹ [Top 10 Challenges of Big Data Analytics in Healthcare. Jennifer Bresnick, healthitanalytics.com, June 12, 2017](#)

¹² 'How to Get Ecosystem Buy-In' by Martin Ihrig and Ian MacMillan, HBR March–April 2017

the replicability at economical cost (in order to engineer the value); and 4) the stewardship, querying, analysis, reporting, visualisation, updating, sharing or distribution of the relevant data (in order to foster the uptake of the value). According to the findings of the assessment, necessary policy relevant actions will be identified.

To set the priority order for when the deliverables of the current task will be finalised, results of Task 5.2 will be considered in order to make use of the methods, use cases and practical solutions delivered by the task.

Additional relevant recommendations of key documents issued by international organisations will be assessed as well, e.g. OECD recommendation on health data governance (2017)¹³, to take into consideration findings and proposals on:

- How using health data can advance health policy objectives;
- The obstacles to using health data effectively in most countries (including obstacles to utilise drivers of data use)
- Better policy frameworks to get more out of health data.

Deliverable structure

D5.1 will be delivered as a report and will be mainly built on the combined structure of the EU Big Data Report, and follow the MS/C policy performance along the lines of the WHO function areas. Where underperformance is identified, relevant recommendations will follow on the policy level. Consideration will be established around the level of innovation, based on the OECD value chain structure, and appropriate level of awareness raising actions will be based on the position and maturity level of the problematic or enabling elements within the value chain. Further consideration will be made around the potential of the identified blocks and enablers to be validated, to raise awareness not only on the MS/C level but also the EU level.

The report will also examine the need for an open consultation process with engagement of relevant external stakeholders in the review and expert opinion of current guidelines and action plans, including public and private/industry relevant partners. If such consultation is deemed necessary, the actual partners will be engaged based on the stakeholder mapping of the project.

¹³ <http://www.oecd.org/els/health-systems/health-data-governance.htm>