BDVA position paper

BDVA's response to the European Commission's public consultation on Health and Care in the Digital Single Market

BDVA Task Force 7 – Healthcare Subgroup

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Scope of the document

In order to promote digital innovation in health and care for the benefits of citizens and health systems in Europe, the European Commission launched public consultation on Health and Care in the Digital Single Market. The main aim of the consultation is to collect information of three main pillars:

I. Citizens' secure access to their health data and the possibility to share it across borders, clarifying citizens' rights and enhancing interoperability of electronic health records in Europe
II. Connecting and sharing data and expertise to advance research, personalise health and care, and better anticipate epidemics
III. Using digital services to promote citizen empowerment and integrated person-centered care.

This document provides a collective answer of the TF7-Healthcare members of the Big Data Value Association (BDVA) on these three pillars.

I. Access to and use of personal data concerning health

To improve efficiency and productivity of the healthcare sector, it is necessary to advance or maintain the quality of care provided, while at the same time, reducing the costs. The fastest, cheapest and most effective way to achieve these goals is to utilize the knowledge that exists in large amount of generated medical data[1]. Current estimates show that medical data is in zettabyte scale and will soon reach the scale of yottabytes[2]. Therefore, exploitation of the knowledge present in medical data has a great potential leading to better clinical outcomes, more tailored therapeutic responses and disease management with improved quality of life. True transformation of the health sector is only achievable if all verticals and stakeholders in the healthcare sector (HealthTech industry, Healthcare providers, Pharma, Insurance etc.) share the data and allow free data flow. Sharing of health data could be beneficial to improve treatment, diagnosis and prevention. At the same time, it will facilitate analysis of data allowing discover of new relationships among different factors that otherwise would not be possible and to generate new and useful insights. Data sharing provides a possibility to offer personalized health services. Sharing the data will facilitate coordination of public health institutions and activities, and creation of global knowledge medical resources to help patients across Europe. Incorporating Big Data analytics and Artificial Intelligence approaches into clinical and non-clinical applications in form of decision support systems will improve health outcomes and patient-specific workflows by identifying gaps, and will reduce system wastes while improving patient's experience. This will require development in (deep) machine learning and clinical decision support algorithms that are accepted by the overall healthcare community.

[1] http://www.healthparliament.eu/documents/10184/0/EHP_papers_BIGDATAINHEALTHCARE.pdf/8c3fa388-b870-47b9-b489-d4d3e8c64bad

[2] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4341817/

Although there are great opportunities regarding the analysis of health data for improving healthcare, there are very important barriers that limit the access and sharing of health data among different institutions and Member States. Besides the political concerns, ethics and emotional concerns have a significant weight in this area since people do not like others profiting from their illnesses. Due to the personal and sensitive nature of health data, special attention needs to be paid to legal and ethical aspects concerning privacy, as well as to privacy-preserving technologies that can overcome some of the current barriers. A shift can be noticed in the techniques used to protect and secure patient data. While for a long time anonymization was considered a useful technique to allow further use of patient data, it is today compromised because of a) the strict legal interpretation of 'anonymization' and b) the wish of patients to be involved and have research results returned to them when useful for their own health. People do not like others profiting from their illness, but are often eager to participate in research to help others if given more control and insight. Giving patients control over and insight in their own health data can help to strengthen patient-centred care after decades of a disease-centred model of care. By changing the perspective to be patient-oriented, this gives patients ownership of their data and gives individuals the opportunity to be active partners in their care within the whole health continuum. Thus, patients should be able to access their own data, decide with whom to share it, and for what purpose. This approach would require that EHRs have the technical capacity to offer several choices and to be personalized based on patient's own decisions. In addition, there is a necessity to have a proper digital infrastructure and solutions that will allow patients to exercise their rights. At the same time, the citizens should not be overwhelmed with all highly granular decisions they need to make.

In a data-driven healthcare environment, interoperability and standardization are key to deploy the full potential of data. However, there are still standardization problems in the healthcare sector, since data is often fragmented or generated in IT systems with incompatible formats and domestic regulations foresee different requirements to record keeping. Having EU health data repositories would allow patients to access their health records even when they are not in their home country. These repositories can also be used as platforms for analysis of the rare diseases, which allows getting insights from data of patients with the same conditions but low geographical occurrence. Furthermore, the systematic collection and analysis of genetic data in combination with diseases, therapies, and outcomes has the potential to dramatically improve the selection of the best treatments (first time right treatments), avoiding harming of patients, and the use of ineffective therapies. Therefore, significant investment in large-scale implementation of shared electronic health records is needed. New and/or updated standards have the potential to make possible to combine and analyse data from different sources, in order to identify insights and facilitate diagnosis. Standards can facilitate interoperability among the components of the data value chain. Standardization across the EU is necessity, since Healthcare policy, delivery, and funding models are all "member country" prerogatives, and not "central EU". National health records are using incompatible ontologies and representations that could be an obstacle for European mobility. While the policy, delivery, and funding can remain national, a standardized data representation, better interoperability, and consistent privacy rules would allow the replication of solutions, thus enabling best practices to be shared across the EU, and smaller countries to fully benefit from developments at scale.

Dealing with different health data protection regimes across EU Member States creates difficulties in accessing and sharing data at EU level. The implementation of the GDPR is an opportunity to look for alignment, but, inherently, the approach of article 89 GDPR holds the risk of continuing the existing fragmentation in domestic regulations on the use of personal data for research. Only a balanced and coordinated implementation across the EU can foster cross-border exchange of health data for research. Under current legal frameworks, in many circumstances, the health data can be only processed if prior consent has been granted. With having more and more health data generated, the consent-based solutions will represent the barrier for processing the data and optimizing services in real time, since Big Data analytics is constantly generating new insights and correlations among health data. Therefore, complete reliance on consent-based solutions restricts the implementation of new and innovative healthcare services. To certain extend electronic consent solutions could reduce the burden imposed by

paper consents because it would allow to establish a long-term relationship with the patient and ease the process of re-contacting the patient for new research purposes. Reliance on consent could be limited to those situations where only few other privacy-enhancing safeguards can be offered to the patients.

II. Making use of personal data to advance health research, disease prevention, treatment and personalised medicine

Connecting and sharing health data and expertise has a great potential to advance research, to personalise health, and to improve disease management if exploited in a coordinated way and in compliance with EU data protection legislation. Combining health data from different sources has potential to progress innovations and help products development by providing insights that cannot be gathered through individual data sources. Besides, it provides the opportunity to improve efficiency of health and social care organizations, together with the clinical practice, by sharing the best practices among EU Member States. However, health data should be shared in a secure and responsible way, meaning that it can be accessible only to authorized parties and encrypted in a way that it cannot be traced back to the patient. Digital health platforms represent a unified solution for these problems, which enable clinical and other data (from medical system and devices) to be collected, combined and analysed in a secure and privacy-preserving way. Furthermore, through such a platform, a patient would have a possibility to decide on case-by-case basis for which purposes to make available his/her data, which information and with whom to be shared.

The current trend is towards digitization of large amount of medical data, resulting in what is known as Big Data. Big data technologies have the potential to radically improve the quality and accessibility of the healthcare. Nevertheless, there will be use cases, e.g. precision medicine, where the promises brought by Big Data will only be fulfilled through dramatic improvements in computational performance and capacity, along with advances in software, tools, and algorithms. High Performing Computers will be needed to analyse vast amount of clinical and genomic data. Omics data of a patient (genomics, metabolomics, proteomics etc.) in combination with historical data about diseases and outcomes of different treatments allow making decisions whether a certain treatment would be beneficial for a patient, avoiding potential harming and use of inefficient therapies. In life threatening situations, these decisions need to be made in real time. Due to vast amount of data that needs to be analysed, the domain of precision medicine will benefit from using the HPC infrastructure and can help saving lives in an emergency department. Deep learning algorithms have already shown a breakthrough performance in the medical domain. The advantages of the deep learning algorithms is that they can analyse very complex data, such as medical images, videos, text and other unstructured data. Deep learning algorithms will benefit from HPC infrastructure in cases when a large amount of data needs to be used for training of deep neural networks in order to provide relevant inputs to medical specialists as quickly as possible. Reliable, real-time prediction and control of emerging pandemics will be possible by sifting through disparate, complex data sources and models. HPC infrastructure will allow prompt development of the relevant vaccines and prediction and control of threatening pandemics in real-time.

Several barriers prevent using Big Data analytics. Even though there is a huge amount of data, the data has been stored in individual silos. Data collected by different healthcare providers e.g. GP clinic and hospital, is never shared outside these institutions. Even on a level of the hospital, data generated in different systems (MRI, CT scanner, EHRs, laboratory etc.) is not integrated through one system. Besides, medical data generation and storage is not limited only to healthcare providers, but also, pharma and insurance companies also hold the information about drugs and insurance claims that can provide even deeper insights into a patient's condition or specific disease. Nowadays, IoT and wearable technology allows patient to generate data in free-living conditions. Data is often fragmented and comes in many different formats (images, text, vital/physiological data, laboratory data etc.) that can be structured or unstructured. Lack of interoperability and standardization makes combing data from multiple

sources impossible. Legal framework that is different among EU Member States makes data sharing and utilization complex. To be able to utilize full potential of Big Data technologies in healthcare domain, data silos have to be broken, to allow sharing and free flow of data among different stakeholders. Due to a sensitive nature of health data, special attention needs to be paid to legal and ethical aspects concerning privacy. Advance of privacy-preserving technologies can overcome these barriers. Furthermore, developing policies and technologies will contribute towards enabling Digital Single Market strategy. The whitepaper from BDVA TF7 Health subgroup – "Big Data Technologies in Healthcare" provides detailed overview of needs, opportunities and challenges of using Big Data technologies in the healthcare sector[3].

European Commission can stimulate the use of data and digital tools to advance research, disease prevention and personalised medicine by:

- Increasing awareness of benefits of controlled access and sharing of medical data by dissemination of successful cases and broadcasting know-how solutions
- Ensuring development in digital health domain by providing economic incentives for value-based reimbursement models
- Developing coherent funding framework for health transformation projects that proves the advantages and benefits of using health data for research, personalized medicine, disease prevention and treatment
- Making personalized services affordable by providing funding for public and private healthcare providers for implementation of their data plans
- Assuring development and funding in digital infrastructure for facilitation of sharing medical data
- Improving regulations for the use of Big Data technologies
- Facilitating deployment of interoperable solutions

III. Promoting uptake of digital innovation to support interaction between citizens and health care providers

With the development of IoT technologies, there are many possibilities to perform remote monitoring of patients through different means (health trackers, smart homes, wearables, patient portals etc.). Patient-generated data[4] helps to close the gaps in information, by providing opportunity for long-term monitoring and management of chronic and cardiac diseases such as diabetes, congestive heart failure and many others. Essential factors for improvement of health and care services are results obtained in different research areas, based on statistics or evidence collected by public authorities and sharing of the best practices (e.g. by execution of large scale pilots that demonstrate how health sector can be transformed). Through patient portals, citizens/patients can provide their feedback and report outcomes of the treatment, which are foundation for 'Value-Based Healthcare (VBHC)[5]'. In healthcare, pay-for-performance is a model that offers financial incentives to the healthcare provider for improvement made in quality and effectiveness of healthcare. Healthcare provider is not paid for treating a patient, but for the outcome. In this case, care processes and paths can be traced and decision about specific therapies can be made based on empirical evidence supported by a huge database of patient-reported outcomes. The EU health systems need to progress towards VBHC that reduces systems' waste and increases the quality of care. This requires definition of outcome-based reimbursement mechanisms and improvement of health systems performance measurement.

To support goals of disease prevention and better treatment, EU should provide support for knowledge transfer between Member States for clinical practice improvement, and for further research

[3] http://bdva.eu/sites/default/files/Big%20Data%20Technologies%20in%20Healthcare.pdf
[4] Deering, Mary Jo. (2013). Issue Brief: Patient-Generated Health Data and Health IT. The Office of the National Coordinator for Health Information Technology
[5] http://bdva.eu/sites/default/files/Big%20Data%20Technologies%20in%20Healthcare.pdf

that will be utilized for development of new health and care services. To make a sustainable healthcare (VBHC), EU should promote common approaches for feedback mechanisms about quality of treatment.

About BDVA

The Big Data Value Association AISBL (BDVA) is an Industry-driven and fully self-financed international non–for-profit organisation under Belgian law. BDVA has over 180 members all over Europe with a well-balanced composition of large, small, and medium-sized industries as well as research and user organizations.

The objectives of the Association are to boost European Big Data Value research, development and innovation and to foster a positive perception of Big Data Value. In particular, BDVA aims at:

- strengthening competitiveness and ensuring industrial leadership of providers and end users of Big Data Value technology-based systems and services;
- promoting the widest and best uptake of Big Data Value technologies and services for professional and private use;
- establishing the excellence of the science base of creation of value from BIG DATA.

The Big Data Value Association (BDVA) is the private counterpart to the EU Commission to implement the BDV PPP programme (Big Data Value PPP). The BDV PPP was launched at the end of 2014, but its operationalization has been especially pushed forward with the launch of the LEIT work programme 2016/2017.

About the Authors

This position paper is delivered as part of the work of BDVA Task Force 7- Health Subgroup and it provides collective answer of the TF7 Healthcare members of Big Data Value Association.

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