

**THE FUTURE OF HEALTH, BIG DATA, ARTIFICIAL INTELLIGENCE AND POTENTIAL BENEFITS TO PATIENTS
MILAN, NOVEMBER 4TH 2017,
MEETING THE COMMISSIONER DR. VITENYIS ANDRIUKATIS**

REPORT OF THE MEETING

BACKGROUND NOTES

The widespread application of ICT technologies (Internet of Things, Robotics, Big Data, Artificial Intelligence) is expected to bring to healthcare a vast array of benefits such as enabling faster diagnoses and better therapeutic results, improving the quality of life for patients and their families, and making the provision of services more cost-effective.

The production, collection, storage, sharing and analysis of Big Data thanks to artificial intelligence models could lead to an outcomes-based system reducing hospitalization, surgery, and long-term care, and making the healthcare system not only more efficient but also more financially sustainable. Indeed, outcomes-based healthcare allows for investing resources in products that have better results compared to current technologies.

Thanks to digitization, a lot of data from citizens, patients, researchers, healthcare professionals, institutions and industries can be collected in large databases and thus become part of registers and platforms that allow for the exchange of information among many actors, for example between pharmaceutical companies and regulators, among clinicians or between doctors and patients. Consequently, many advantages can be gained at the same time, such as the efficiency and quality of treatment, disease prevention, a better pharmacovigilance and patient safety.

Moreover, genome sequencing, revealing mutations in DNA that influence diseases ranging from cancer to diabetes, allows for a personalized treatment, a concept that has been well known to researchers and practitioners for a long time. This is a powerful tool, along with other techniques such as RNA-seq, which are more responsive to the environment. Collecting large quantities of data and elaborating it, using computing and predictive models, are instrumental in making personalized medicine a reality.

Of course, apart from the initial significant investments in ICT, many other challenges need to be properly addressed, from privacy and cybersecurity to ethical and legislative issues, from the skills gap to the possible replacement of professionals and workers with machines and algorithms. It is, however, evident how Europe may benefit by leading a transformative process of healthcare-based digital technologies.

The European Commission's work on digital health goes back to 2004 when the first eHealth Action Plan was introduced and accepted by the EU Member States. Since then, policy initiatives have been developed to foster the adoption of eHealth throughout the EU.

The adoption in 2011 of the Directive on the Application of Patients' Rights in Cross Border Healthcare (Directive 2011/24/EU) marked a further step towards formal cooperation on eHealth with the aim to maximize social and economic benefits through interoperability and the implementation of eHealth systems¹. The Cross-Border Healthcare Directive aims at giving patients the right to receive medical

¹European Commission, COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS, "eHealth Action Plan 2012-2020 - Innovative healthcare for the 21st century", December

2012. ² European Commission, eHealth: connecting health systems in Europe, June 2016. ³ European Commission, European Reference Networks, Conference Report, 2017.

treatment in another EU Member State and aims to enhance interoperability between electronic health systems and continuity of care and to ensure access to safe, quality healthcare². Not only does the Directive enable patients to be reimbursed for treatment in another EU Member State, it also makes it easier for patients to access information on healthcare and, thus, increase their treatment options.

For patients with rare or complex disorders searching for a diagnosis or struggling to access expert care, the dream of cross-border care is about to become a reality, partly thanks to the European Reference Networks (ERNs) – based on Directive 2011/24/EU. These Networks, launched in March 2017, involved more than 900 highly-specialized healthcare units from over 300 hospitals in 26 EU countries and aim to tackle complex or rare diseases and conditions that require highly specialized treatment and concentrated knowledge and resources. Using a dedicated IT platform and telemedicine tools, a “virtual” advisory board of medical specialists will link up information and expertise that are scattered across the EU, ensuring that information travels to the patient, who has the convenience of staying in their own supportive home environment³.

Participants:

Vytenis Andriukaitis: EU Commissioner for Health & Food Safety

Giuseppe Banfi, Scientific Director & Director, Fondazione San Raffaele Milan,

Diana Bracco: President & CEO Bracco Group

Enrico Cereda, President & CEO IBM

Beatrice Covassi, Head of Representation of the EC in Milan

Stefano Da Empoli President I-Com

Massimo Gaudina, Head of Representation of the EC in Milan

Fabrizio Grillo, Director General Bracco Group

John F. Ryan, Director Public Health, country knowledge, crisis management, DG SANTE EC

Luca Sangiorgi, Coordinator ERN BOND

Maurizio Scarpa, Chair ERN CG and Coordinator MetabERN

Vilija Sysaitė Communication Adviser – Cabinet Commissioner Andriukaitis

Giuseppe Turchetti, Member, ERN Reconnet

¹European Commission, COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE AND THE COMMITTEE OF THE REGIONS, “eHealth Action Plan 2012-2020 - Innovative healthcare for the 21st century”, December 2012. ² European Commission, eHealth: connecting health systems in Europe, June 2016. ³ European Commission, European Reference Networks, Conference Report, 2017.

KEY ISSUES FOR THE DEBATE

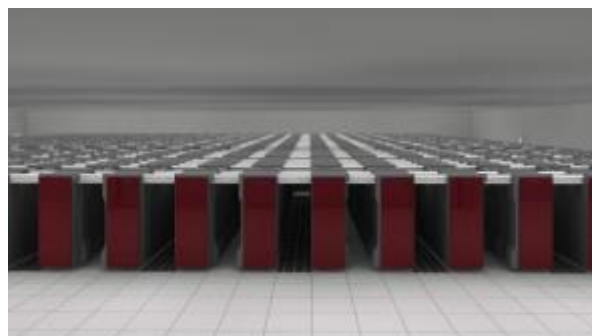
1. *What are, today, the barriers to be removed in order to reap, on a massive scale, the benefits of a fully mature and interoperable eHealth system in Europe?*
2. *How can be promoted cross-border cooperation in order to achieve wider interoperability between eHealth systems?*
3. *What policies and standards are underway to support European Reference Networks (ERNs)? How do we remove possible barriers between countries? What is the role EU institutions should play?*
4. *Which policies can help improve investment conditions in some Member States in order to accelerate transition to digital health services?*
5. *How can public and private organizations collaborate in speeding up the digital transformation in healthcare?*
6. *What is the role of EU based start-ups and scale-ups in helping this process and, in the meantime, contribute to economic growth?*
7. *How do we safeguard the privacy and the security of health data? On the other hand, how can we take advantage of the opportunities provided by Big Data in order to develop personalized medicine and allow for a transition to an outcomes-based system?*
8. *How is drug discovery concretely affected by Big Data and AI techniques?*
9. *What are the main obstacles to the application of AI tools in healthcare?*

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Briefing on the discussion

BIG DATA MANAGEMENT AND ERNs: Big data management represent one of the biggest challenges for modern medicine, in particular the volume, the variety, the velocity of access, the veridicity and the value of the data require new tools and new expertise to help doctors in the diagnosis, management and decision pathway for therapy. National health systems are diversified in Europe rendering the interoperability difficult and exchange of data almost impossible.

Nevertheless, the access to big data is a must and all countries are facing this issue with sometime innovative solution as, for example, in the case of Japan, a new K computer is been created, with a cost of 173M Euros, to connect and allow the exchange of data among all the Japanese HCPs. (see figure) <http://www.aics.riken.jp/fs2020p/en/>



The major issue of the discussion was on the fact that ERNs require the management of big data for the diagnosis, the development of registries, clinical trials and generation of new therapies and analysis of data banks infrastructures which require to be interconnect and put in line in an interoperable way. It was point out that one of the important breakthrough offered by the ERNs is the generation of tools to allow the connection of all the about 300 HCPs present in the 24 ERNs as an example of collaborative interoperability. The ERNs are a unique example for the creation of a new structures to facilitate the private-public interaction. Examples can be offered by the need of sharing complex images and the creation of new tools to empower the patients in supplying physicians with daily real life data, beside the ones collected during controls. So fundamental is the prospect of telemedicine to be experimented by ERNs, and a e-prescription to increase the QoL of the patients. The Commissioner stressed the need of developing common strategies throughout the 26 countries involved in the ERNs and to do everything needed to null the fragmentation of care, the interaction among hospitals and to engage all the possible DGs at the EC to work on this. He is willing to work closely with the ERNs to succeed in this and foster the collaboration to generate the resources needed and to facilitate the communication with the EU Ministries of Health on this.

ACTION: The Commissioner is requiring an action plan to be discussed with him and realized inside the next 18 months.

INTEGRATION WITH THE HEALTH SYSTEM: Another major issue of discussion has been regarding the need of integrating the ERNs activities. This is not to be intended only as integration of reimbursement and recognition of the activities of the ERNs inside the HCPs, it must be oriented also toward an integration and transparency of data among HCPs and the possibility to access to data in a cross-regional-cross-border way. This is an issue where the fragmentation is having a major role and need to be overcome. Registries, and generation of data for the patient health care require vocable infrastructures and new strategies to facilitate the communication among HCPs.

MS political support is needed and interaction with different stakeholders will be the determinant point for success.

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2012. ² European Commission, eHealth: connecting health systems in Europe, June 2016. ³ European Commission, European Reference Networks, Conference Report, 2017.

Maurizio Scarpa,
Chair ERNCG

ACTION: The Commissioner is requiring an action plan to be discussed and realized inside the next 18 months regarding integration with Health Systems and Legal Entity of ERNs.

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