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European data-driven economy: A lighthouse initiative on Personalised Medicine ☆

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Big data for personalised medicine

> *"By 2020, the EU should endeavour to achieve widespread benefits for patients and citizens from personalised healthcare by defining in 2015, and subsequently executing a* ***Data Strategy for Personalised Medicine****" (EAPM, 2014)*

In respect of Personalised Medicine, *Big Data* represents the vast and continuously growing amount of health information (including biomedical and environmental) and its usage to drive innovation in translational research and health outcomes tailored to the individual. Using these data to first understand the cause of disease, the medical profession can then develop new drugs and therapies to find the cure, as well as other health interventions targeting the individual. The personalised, individual approach requires advanced technologies and processes to collect, manage and analyse the information and, even more importantly, to contextualise it, integrate it, interpret it and provide rapid and precise decision support in a clinical and public health context.

Not only does Big Data offer the potential to revolutionise the effectiveness of health interventions, it may also help ensure the more effective management of resources in what are increasingly cash-strapped public healthcare systems. Over the coming decades, the financial sustainability of health systems will become more and more challenging as the population ages. The number of over 65s in Europe will increase by 75%[1] by 2060. Alongside this ageing population there is likely to be an associated rise in chronic illness which will lead to spending on health and social care reaching unsustainable levels unless we are able both to increase the quality of health outcomes and the efficiency of healthcare resources. Big Data, in theory, offers the potential to do both. It is widely acknowledged that 'value-based' approaches to the management of care are an ideal way forward. Big Data will be a key enabler of this. And in future, physicians and health managers should have real-time, real-world evidence on what works and what does not for each patient. Moreover, other trends, such as mHealth, will bring the benefits of Big Data much closer to the citizen. That should lead to more informed individuals, and more rational and less wasteful decision-making.

Getting a *Data Strategy for Personalised Medicine* right in Europe would yield multiple benefits. Not only would it accelerate the development of more effective treatments and potentially help with the management of healthcare resources as described above, it would also act as a foundation for private sector investment and jobs in R&D in Europe. Global developments in approaches to Big Data in healthcare are of major importance to the future of several industries

☆**About EAPM**: The European Alliance for Personalised Medicine brings together Europe's leading healthcare experts and patient advocates to improve patient care by accelerating the development, delivery and uptake of personalised medicine and diagnostics. It is calling for the European Commission, the European Parliament and EU member states to help improve the regulatory environment so that patients can have early access to personalised medicine, and so that research is boosted.

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[1]European Commission (2012) "The 2012 Ageing Report".

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including startups and SMEs on ICTs, pharmaceuticals, medical devices and others. A coherent strategy for Big Data would, for example, have a direct effect on the attractiveness of a given health system for the placement of clinical trials. The European Union should see Big Data as a strategic investment that could drive industrial competitiveness.

On the path to personalised care

Nobody likes getting sick. But when we do, it is vital that our doctors have access to the best information and diagnosis techniques available. Thankfully, emerging technologies such as analytics tools for big data can help healthcare professionals improve diagnoses and reshape the way medicine is practiced.

People are also becoming more aware of and receptive to the powerful impact that big data could have on their lives. A recent global study[2] found that most people are optimistic about technology innovations advancing healthcare and are willing to participate in virtual healthcare visits with their doctor. The survey also found they would be open to using health sensors in their bodies and throughout their daily lives. From mHealth technologies to remote monitoring and sensor systems, new technological innovations are key to the future of a more personalised approach to healthcare.

mHealth and wearables

The European Commission has recently issued a Green Paper on mHealth[3] that points to its potential for improving prevention, efficiency, patient empowerment and economic development in healthcare.

Fitness and wellness enthusiasts today are pioneering technology and devices that are worn on or embedded into the body, such as wearable bracelets that combine technological innovation with fitness in new ways. With these types of devices people can better track their heart rate, perspiration and skin temperature to provide data and insights into how their daily routines are affecting their health and wellness.

In the near future, information may be obtained through different wearable or ingestible devices that may help predict changes in the body to prevent emergencies. The information may automatically be shared with healthcare teams for simpler management, as well as anonymously pooled with other people's data to help scientists and researchers find cures and to more rapidly develop effective medications.

Electronic health records

Organisations around the world are starting to realise the importance of the role of data on their efforts to improve the healthcare system. By investing in highly scalable data compute, storage, networking and software capabilities, businesses are equipping themselves with the tools to improve care, discover new insights, reduce costs and meet emerging care models.

The European Union Directive 2011/24/EU on patients' rights in cross-border healthcare,[4] inter alia, invites Member States to draw up guidelines on effective methods for enabling the use of medical information for public health and research.

The digitisation of health data provides the raw materials as there is no way to meaningfully use paper records. It would not all happen at once, but having electronic data in the long run will help improve patient safety, aid the discovery of new cures and treatments, and give healthcare providers access to a more-complete patient medical history to help with diagnosis and determine the right treatment (Shabo, 2013)[5].

Computers are now fundamentally changing scientists' ability to track and use the process of trial and error. Today, instead of testing new drugs on thousands of patients to determine whether they are going to work, the pharmaceutical industry can use computer-simulated experiments based on huge amounts of both old and current data to more quickly deliver results. More theoretical tests can be done in less time, with lower cost and lower risk. This means that by the time drugs are tested, they are closer to being broadly usable, and the time required to distribute them to doctors and patients is reduced.

Individualisation and omics

Increasingly, people are embracing a future healthcare system that will allow them to get care beyond hospital walls, anonymously share their information for a healthier community, and enable better patient outcomes or improved personalised care that takes into account an individual's specific genetic makeup.

It is fair to say that the advances leading to the availability of biomedical data, very much driven by digitisation and the decreasing costs of human full genome sequencing (in 2014 a US company announced the $1000 barrier had been conquered[6]) have outpaced Moore's Law,[7] heralding a new era for healthcare comparable to that which computers did to transform society over the past decades. Equally important is the development and dissemination of tools and processes able to analyse and interpret the data, thus really creating new knowledge that can benefit patients accurately and directly, rather than at the endpoint of a lengthy process riddled by trial and error treatments and policy bottlenecks.

[2] http://newsroom.intel.com/community/intel_newsroom/blog/2013/12/09/the-world-agrees-technology-inspires-optimism-for-healthcare.

[3] COM(2014) 219 final, GREEN PAPER on mobile Health ("mHealth") http://ec.europa.eu/digital-agenda/en/news/green-paper-mobile-health-mhealth.

[4] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:EN:PDF.

[5] Shabo A. The patient-centric translational health record. *Pharmacogenomics*. 2013;14(4):349–52.

[6] http://www.businessweek.com/articles/2014-01-14/illuminas-dna-supercomputer-ushers-in-the-1-000-human-genome.

[7] *Moore's Law* is the observation that the transistor count of integrated circuits, with respect to minimum cost, doubles every 24 months. In other words, it foresees the doubling of 'compute power', for the same cost, every two years. Today this period has actually been reduced to roughly 18 months.