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Big data in healthcare: What options are there to put the patients in control of their data?

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Abstract: *Despite of the significant improvement in life expectancy over the past 50 years there are several growing challenges that are putting pressure on the sustainability of EU healthcare systems. This unparalleled situation is offering the right momentum to rethink business models on healthcare systems which require a new strategic approach shifting from a volume to a performance based model- value for money.*

Currently big data does not efficiently contribute for improving healthcare. In an increasingly empowered digital society, big data has now reached every sector in the global economy. Personal data has become a new form of "currency", nevertheless, this "currency" is not flowing in the healthcare sector because **patients are not in control of their medical health data making impossible to build the trust that is needed.**

To reach the full potential of **big data in healthcare** *at the EU level, with a significant economic output in the ecosystem, it is essential to establish a working model of balanced interests, identifying each participant's priorities, challenges and value opportunities focusing around the core of all innovation – the patients' data – overcoming some barriers that are creating inertia, such as privacy protection, legal conformity, standardisation, interconnectivity, benefits and governance.*

The group's recommendation is to create a bottom-up model, focusing on a patient centric approach - the patients' data - from an exclusive to an inclusive ecosystem. Promoting transparency between doctor-patients relations and implementing a new market model – the "banking model" system which will promote patient trust and value perception, key features to successfully implement a new competitive pan-European market. It is necessary to enable individuals to understand and manage, in a secured environment access, the use and value of such individual information in an ecosystem, where the interests of the different stakeholders, the fundamental rights of the patients and the legal constraints are fully taken into account and respected. As patients are the primary source of Patient Health Record data (PHR), it is essential to design a user experience that is well accepted. A chip card model similar to a bank card is proposed to materialise the digital data with the physical object.

The previous recommendations are fully aligned with the core principles and strategic actions of the EC Health Strategy: prosperity, security and solidarity.

An EU Governing Body should drive gradual implementation of these solutions.

1. Introduction- currently big data does not efficiently contribute to improving healthcare

Despite of the significant improvement in life expectancy over the past 50 years[1] there are several growing challenges that are putting pressure on the sustainability of EU healthcare systems which require a new strategic approach. The worst global financial and economic crisis in decades is challenging countries to invent new ways to increase their efficiency, shifting from a volume to a performance based model- value for money. Over the 1995-2010 period, health spending per capita in OECD countries grew three times faster than the income per capita (9.5% GDP). Nearly 7% of GDP comes from government sources. If left unrestrained, health spending could soon exceed realistic limits beyond what governments, social security or family budgets can afford. Long-term trends[2] in society and demography[3,4] are equally challenging, with changes in disease patterns[5], namely, the rapidly changing structure of sicknesses and ageing related diseases. These facts will require investing in the prevention of chronic and re-emerging diseases, illnesses related with lifestyles, as well as promoting primary care and further integrated and innovative approaches.[6,7] Alongside, some market forces are driving healthcare into transformations, namely, increase of complexity for new revolutionary technologies or treatments and for new market entrants with new approaches to healthcare delivery. On the top of that, there is an absence to address the complex needs of frail elderly of a system that is shifting from a local or national to a

1 OECD work on Health 2013-2014; 2012
2 The new agenda for business, WBCSD World Business Council for Sustainable Development; 2010
3 The European Union and the BRIC countries; 2012
4 Demography report 2010 Older, more numerous and diverse Europeans, Eurostat; 2011
5 Health statistics – Atlas on mortality in the European Union; 2009
6 OECD 2012 Preface: High-Performing Health Systems; 2012
7 Europe 2020 Strategy – towards a smarter, greener and more inclusive EU economy?; 2012

trans-national level[8], still, with an inexistent patients' empowerment. In the meantime some opportunities are starting to flourish like personalised medicine, where genomic and proteomics will have a key role on early detection of specific diseases and more effective therapies are expected.

Health is central in people's lives. To support this core value, a new EC Health Strategy[9] was designed (2008-2013 framework) since a cooperative action at Community level is indispensable to support effective policies in healthcare to improve citizens' wellbeing. The political importance of health in all policies reinforces theEU 2020 strategy for growth and jobs and the Citizens' Agenda, emphasising the links between health and economic prosperity, recognising people's right to be empowered in relation to their health and healthcare.

The strategy proposes four core principles: shared health values; "Health is the greatest wealth"; health in all Policies (HIAP) and strengthening the EU's voice in global health,

Underpinning three strategic objectives:

1. **Solidarity:** fostering good health in an ageing Europe;

2. **Security:** protecting citizens from health threats;

3. **Prosperity:** supporting dynamic health systems and new technologies.

Healthcare sector produces unlinked thousands of data. The information is produced as "single-dots" since it is fragmented in four major pools that provide such data: clinical data; payer activity (claims) and cost data; pharmaceutical, medical products and R&D data; patient behavior and sentiment data.[10] Despite the numerous publications that are currently dealing with the Personal Health Record (PHR) they are analyzing its potentials and limitations from various and often opposing perspectives. To reach the full potential of big data in healthcare at the EU level, with a significant economic output in the ecosystem, it is essential to establish a working model of balanced interests, identifying each participant's priorities, challenges and value opportunities focusing around the core of all innovation – the patients' data – overcoming some barriers that are creating inertia, such as privacy protection, legal conformity, standardisation, interconnectivity, benefits and governance.

In an empowered digital society[11] where information and data are increasingly valued, big data has naturally reached every sector in the global economy as a key tool for success. Personal data has become a new form of "currency"[12] , nevertheless, this "currency" is not flowing in the healthcare sector because patients are not in control of their medical health data, making thus impossible to build the trust that is needed.

This unparalleled situation is offering the right momentum to rethink business models on healthcare systems. Under the Young Leaders Programme(YLP) promoted by the Foundation of the European Institute of Innovation and Technology (EIT), the multidisciplinary group of IT, legal, telecommunications and laboratory professionals dedicated on the subject big data in Healthcare, considers that **currently big data does not efficiently contribute for improving healthcare**. Those findings were corroborated after a **wide spectrum dialogue of the team's network across EU countries**, namely, patients with and without chronicle diseases, doctors, pharmaceutical marketing managers, IT professionals, consultants, lawyers, researchers and telecommunication professionals.

8 Redefining Value and Success in Healthcare Charting the path to the future; 2012
9 White Paper- Together for Health: A Strategic Approach for the EU 2008-2013; 2007
10 Big data: The next frontier for innovation, competition, and productivity, McKinsey Global Institute; 2011
11 The Facebook, YouTube, Twitter, Blogs are many examples where the end-users cease personal data despite the fact that they are aware of the risks generated because users fell that they are in control of their data or because the perceived benefit seems much bigger than the incurred risks
12 The value of our digital identity, Boston Consulting Group; 2012

2. Are you talking to me?
Patient data is an asset owned

Similar to any customer information, patient health data has become an asset – used for analytical purposes to gain insight into various aspects of health for better healthcare, better medical treatments and also for commercial exploitation.

The patient however is not in control of their own data and often struggles to even get read access to such information or related use of the individual health record. This generates a currently patient "exclusive" ecosystem around the PHR.

To overcome the barriers many patients feel at present, and to encourage open information sharing in a secured environment, opportunities must be found to put the patients back in control over their own data and enable individuals to understand, manage access and use of such individual information in the ecosystem of interested parties. It is suggested to put the patient in the core of such ecosystem and enable full visibility of the access and use of such data, leveraging legal or commercial models to even monetise health data with the patient as the main beneficiary of such structures. Any serious attempt to provide a European wide capability for better use of health data needs to provide a clear incentive for the sole data asset holder – the patient.

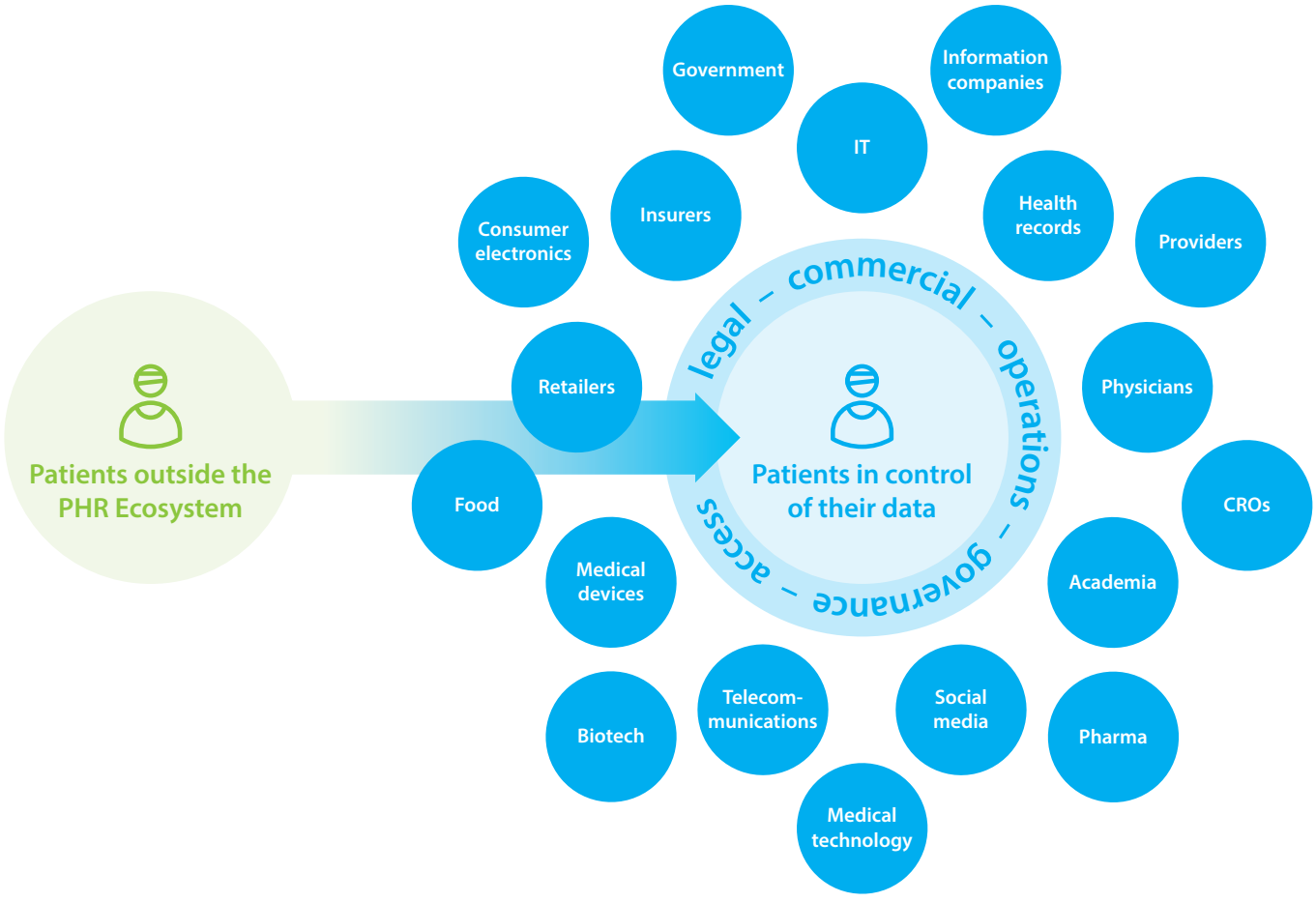

Figure 1: From patient exclusive to Patient Centric PHR Ecosystem

Alongside the overall goal of a patient centric ecosystem, it is important to understand the holistic environment and identify each participant's priorities, challenges, risks and value opportunities. With the patient in control, new barriers will be created, which will challenge the commercial, ethical or legal interests, as well as the ambitions of many other parties.

In order to nurture this idea in such a rough environment, a fair balance has to be reached for everyone participating in this approach, to be clearly incentivised by balancing gain with fair sacrifice, risk with profitable future outlook on the opportunities a European wide PHRs can offer. Figure 2 illustrates a balanced decision framework: the green segments represent the region of benefiting organisations, whereas the red area would contain organisations making a loss. Commercially, a too decentralised compromise environment will most likely not lead to a wide and positive acceptance of the proposed compromise.

Moreover, it is necessary to remember that despite its value, the processing of health data creates ethic and privacy concerns that must be addressed. Health data is considered sensitive data. Therefore, processing of such data is prohibited unless some specific clauses are respected under the influence of antidiscrimination laws in the current European legislative context.[13]

In a cross border perspective, several additional complications may arise: the insufficiently harmonised consent requirements, or ambiguous legal basis, lead to some obstacles in health data exchange within the EU.[14]

In the current legislative context, a solution could be elaborating a governance model for all ethical and privacy related aspects based on a prior study of the highest requirements at the EU level, regarding prior consent of the data subject, purposes of the data processing, recipients of data, data retention period, security and confidentiality requirements. Even though, the efficient implementation of the resulting governance model could always put local and national specificities and patients in a delicate position of the considered ecosystem.

Figure 2: Illustrative balance framework

Putting the patient in full control of their data, as the central piece of the ecosystem, and allow him/her to choose to disclose the data s/he wants to the participants s/he wants is a way to efficiently circumvent most of the legal issues related to privacy and data protection.

The following section will detail the various aspects that need to be taken into consideration for such a European capability with the foremost intention to provide the patients full control over the access and use of their own health data.

13 Directive 95/46 article 8
14 Opinion of the European Data Protection Supervisor on the data protection reform package (www.edps.europa.eu/)

3. Barriers to the system – the market model

Existing publications are usually focused around two different types of barriers to the introduction of an electronic healthcare system:

- **Data management:** focusing on storage and standards
- **Access management:** focusing on use cases

There is however a third fundamental dimension that should be taken into account:

- **Market model:** what market design is needed in order to lift existing barriers and to create a functional ecosphere for all stakeholders?

One could basically consider both, monopoly and competition based market approaches, at either a national or pan-European level. Looking at three major success drivers, a competition based pan-European market design seems the most adequate. A competition based on model would gain best acceptance by the majority of stakeholders.

Since contribution and collaboration of stakeholders is key, their individual influential potential should be equally spread. That is best achieved in an open market that develops optimal outcomes through competing offers. A monopoly on the other hand could lead to the impression that the potential is not equally spread and thereby lead to a blockading attitude in some of the stakeholders.

A competition environment is also expected to develop quicker than a pre-defined monopoly market design, and it leaves room for opportunities to be explored. Speed of development is key for market players in order to gain first mover advantages.

Finally, and since the competition market design appears to incentivise the market participants best, market scale could be a decisive criterion in order to open up investment opportunities and attract new entrants. Therefore a pan-European market that allows players to act on an international level is expected to raise a higher amount of sponsoring investment funds than localised solutions within the EU countries.

	Monopoly		Competition	
	Local	Europe	Local	Europe
Stakeholder management	⊖	⊖	⊕	⊕
Speed of development	⊖	⊖⊖	⊕	⊕
Sponsor	⊖	⊖⊖	⊕	⊕⊕

Figure 3: Assessment of market models

After defining our innovation's core - patients' data - we consider now what commercial / market model could bring such ideal to life. When looking at the core requirements previously discussed, a striking similarity to the banking sector becomes obvious.[15]

In order to give data control to the patient s/he needs to obtain fundamental data management rights and opportunities. If compared to a bank account, the patient should be able to put his/her data into a dedicated account from where it is managed. While many existing PHR approaches focus on one centric national or European PHR database, this may not be the only working system.

Very much like in private banking, such accounts could be offered by a variety of institutions, as well as completely independent new bodies which could be found in the market. This may even include government bodies that could be perceived as a commercially neutral entity within the competitive environment (preferred by those who consider their data as highly sensitive or even a basic startup solution for the newborn). The striking aspect of such system would after all be the characteristic of competition.

If data is an asset and has a value that belongs to the patient, he/she should receive compensation for granting access to certain areas of that asset – just like earning interest on savings. Compensation however is not necessarily monetary – it might just be the contribution to something that is perceived as ethically or morally beneficiary. Consequently competition around personal data storage accounts could arise in a number of ways, the most striking being a monetary compensation, i.e. interest. Account providers could furthermore differentiate themselves through beneficiary supplementary services, like better or additional healthcare plans and options.

Competition – under the regulatory constraints of data protection and access regulation as described – would deliver a self-regulating stimulus to the market. Patients would deposit data where they feel safe, fairly compensated, where they can manage their data transparently and with an ease of use. If not satisfied there would always be the option of data withdrawal and transfer into other accounts or potentially even back to offline files. In the context of the processing of health data with potential major risks for the privacy of the patients, the compliance to privacy regulations and the implementation of maybe even highest standards should be considered as a competitive advantage. According to the UK's Data Protection Authority (ICO) and its Commissioner Cavoukian *The 'payoff' to privacy- respecting organisations is (…the…) ultimately, enduring competitive advantage. In a world of increasingly savvy and inter- connected customers, an organisation's approach to privacy may offer precisely the competitive advantage needed to succeed.*

Regarding other forms of compensations and compared to other data driven business models like Facebook, where customers give away personal data and receive a limited personally perceived value out of social networking, the benefit in the PHR market model is transparency over the actual value of different data sets. For example, a patient may receive an offer to disclose certain blood values in participation of an academic study on HIV in return of a monthly monetary refund. While accepting such offer the patient may still choose to refusing participation in another study on brain tumors that offers a monthly refund of less value. Personal data would now become individually compensated by its personal value – whatever the compensation scheme may be (not necessarily monetary as in this example).

It is now essential to consider how such market could be structured. Basically there are three levels in the value chain (Figure 4).

a. Infrastructure

Any PHR solution that offers interconnectability between institutions requires a fundamental infrastructure to build upon. At this level, competition is not an indispensable requirement. As in many other infrastructures like railway, highways or even telecommunication copper networks, one shared network is theoretically enough to serve the population. What is crucial though, is a strong regulation and standardisation in order to achieve a common level of data protection as well as the technical capability of interconnection between all participating players.

b. Platform providers

On top of the infrastructure, various platform providers could provide data storage accounts, as well as the user interfaces that allow data management. This is basically where the idea of a banking-like model would develop its full potential.

c. Analytic insight generators

In order to create benefit on the basis of PHR data it must be shared (to the extent allowed by its owners) with third parties. These are various like insurance companies, universities, research organisations, pharmaceutical companies (…) (Figure 1- Ecosystem). They would interact with the patients through the platform providers who act like a broker. The patient still decides what data to distribute to which institution and whether it is supposed to be anonymous or personalised, always considering the individual added value that is offered in return.

15 http://www.vodafone.com/content/index/about/about_us/privacy/rethinking_personaldata.html

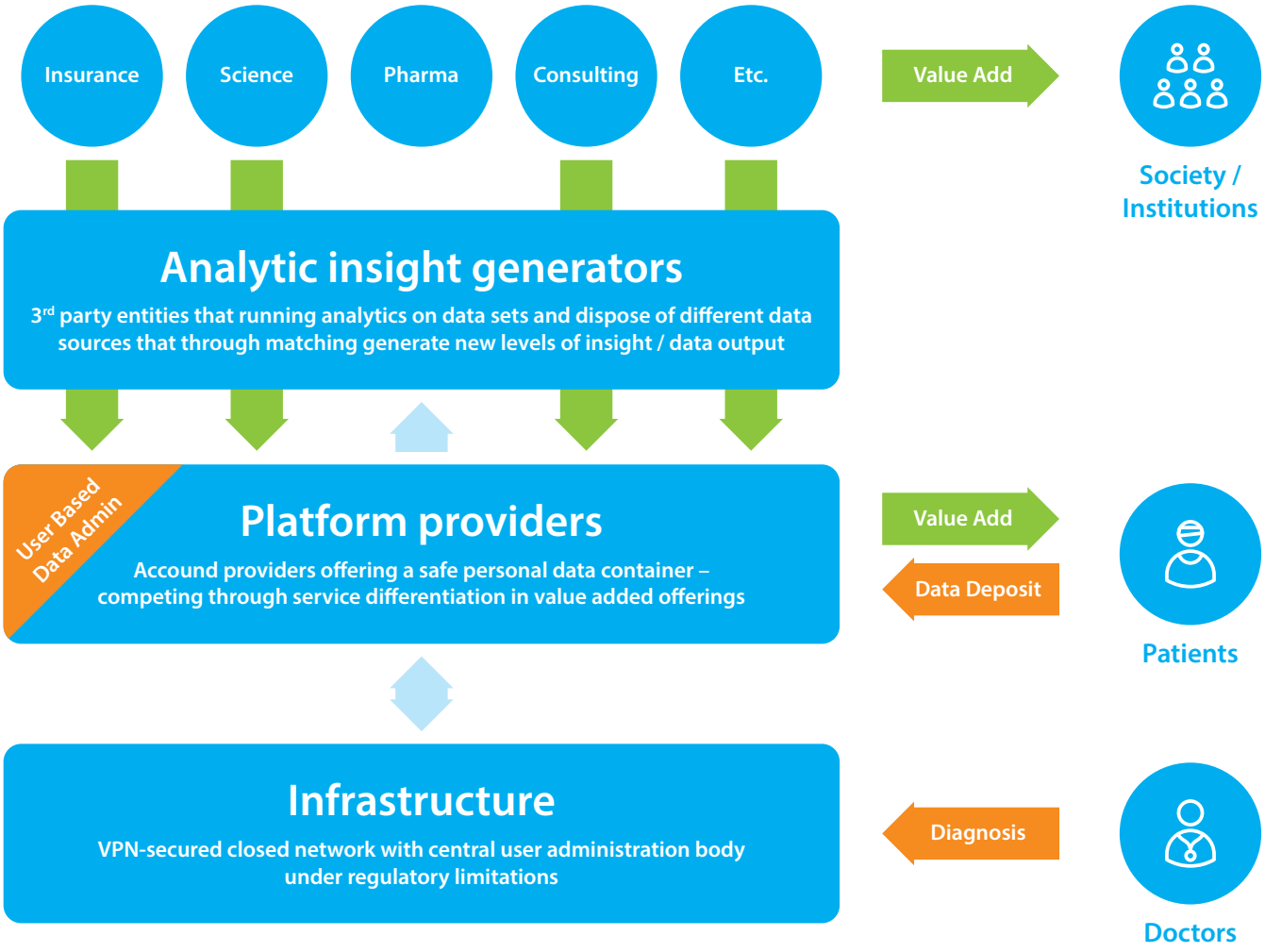

Figure 4: Market scenario based on a "Banking Model"

4. Building trust: how can we put patients at the center

To be able to put the patient at the core of the system it is important to create a platform giving access to patients and doctors with a specific set of key features (Figure5). These features are mandatory and should be considered as an intrinsic part of any platform, in order to guarantee patients have full control over their own data. They include: emergency access rules (a); access rules (b); doctors own their entries (c); hide data (d); data portability (f); withdrawal (g) easy and secure access (f).

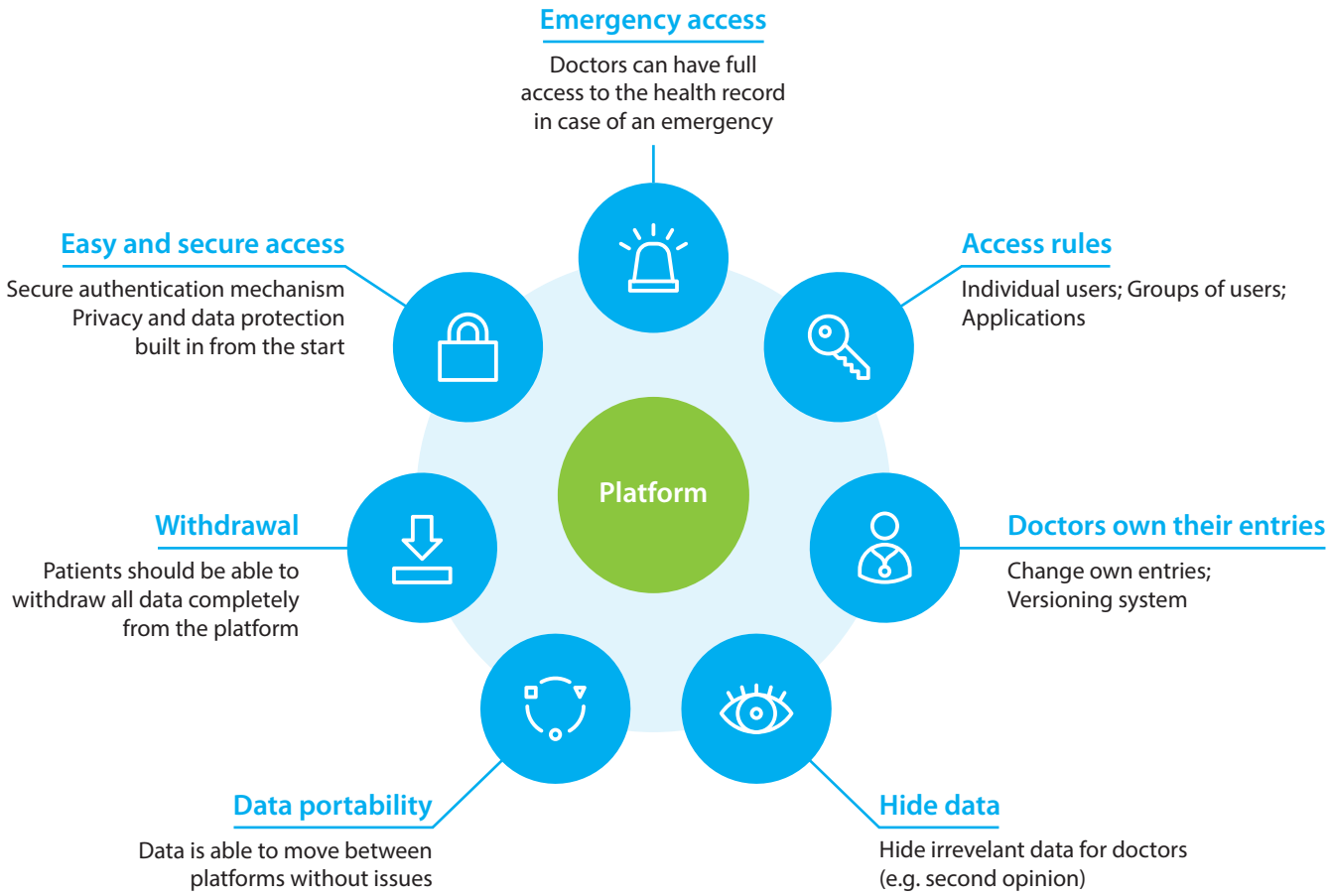

Figure 5: Intrinsic platform's features

a. Emergency access rules

In this case, there should be a possibility for the patient to verify which kind of information was checked.

However, in the current legal framework such access could only be possible under very strict conditions. As mentioned, Article 29 of Data Protection Working Party (a group gathering all European data protection authorities) does not consider that a general consent can be sufficient to allow the processing of health data or any data considered sensitive data under the Directive 95/46.

The proposal for the adoption of a new regulation on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) drafted by the European Commission could offer an opportunity to find a solution.

Concerning health data, this draft regulation aims to provide further possibilities on the processing of personal data if justified by a number of legitimate reasons for the benefit of individuals and society as a whole (…)[16], in particular in the context of ensuring continuity of cross-border healthcare. Therefore, even if some commentators regret that this Regulation does not go far enough on the way to harmonisation[17], it seems like the right tool for the regulators to allow such emergency access (and more globally to think about the potential and barriers of big data in health care in general). Therefore the ongoing debate on this new regulation should be attentively followed in order to anticipate any change of the regulatory framework in the near future.

b. Access rules

In order for any third party to use or read the patients data (or part of), it will be necessary that the user gives his explicit consent to such access. This access will always have to be restricted in time depending on the purpose for which it is granted by the patient to the concerned third party. By doing this, the patient's data is never longer exposed more than necessary.

Granting a general practitioner reading rights would be an example of granting an individual user reading rights. When going into a hospital and seeing different departments and specialists it should be considered to grant reading rights information to the whole hospital during the time of a visit.

Applications that rely on data they collected from users to provide a useful user experience should also be allowed to read data from the patient's medical record.

In all hypotheses, clear information shall be given to the patient in order to put him in a capacity to assess the situations in which somebody will be able to access to his data. As recommended by the Article 29 Data Protection Working Party[18], no general agreement of the patient could be considered as valid and the individual concerned shall be given, in a clear and understandable manner, accurate and full information of all the relevant issues, in particular, the nature of the disclosed data, the purpose of the access to the data, all categories of persons able to access the data and possible transfers.

c. Doctors own their entries

When a doctor adds information to patient's file s/he will control the entries. The Doctor can change them whenever s/he wants. According to the health standards, there would also be a versioning system that holds all versions of data entered. If necessary, the different versions of a diagnosis can be tracked.

d. Hide data

Patients may choose if they want to hide sections of their PHR. For instance, when going for a second opinion to a new doctor it might be advisable to hide some parts of the patient record.

e. Data portability

When users have the ability to withdraw their data it is logical that this data should be easily portable. This will add the benefit that a user can move their data without much effort from one service provider to another.

f. Withdrawal

In order for the patient to have a genuine free choice and be able to withdraw his/her consent without detriment, the patient shall be clearly informed and regularly reminded of his/her rights and notably of the 'right to be forgotten' and 'right to delete'.

If a patient decides to withdraw his/her data from any platform it should be possible for each category of access rights s/he has been granted.

g. Easy and secure access

From a legal/data protection perspective, when dealing with data processing with such risk potential, the compliance of the system is extremely dependent on a high level of data security. The European data protection authorities require demonstrating that any access by unauthorised persons is virtually impossible and prevented.

The way of accessing this data should happen in the most secure way, while at the same time the system should be unlimitedly available for authorised professionals within the limits of the rights they are granted. A possibility to reach high security standards could be to give chip cards to patients with a type of security level currently used by online banking. It should be at least a two or three factor authentication.

Every action that is performed on the patient's record would have to be recorded in an access log giving the possibility to check if needed who had access to the patient's data at a certain time. Erasing this log should be possible.

Privacy and data protection concerns should be embedded from the early stage of conception to their implementation, use and disposal. Such concept usually referred to as *privacy by design* should be applied throughout the entire life cycle of the system. The aim is that security and privacy would become the default setting of the system, preventing privacy risks instead of remedying to it once they already happened.

5. Sharing the benefits-perceiving the value

One of the root causes of the non-adoption of global PHRs by patients is the lack of perceived benefit. Privacy issues in other domains have shown how the cost of losing privacy can be balanced by the value of perceived benefit. For instance, while strongly rejected at first, video cameras in the street have been widely accepted by the general opinion because of the increase of perceived safety. Therefore when creating a system to enable PHRs at a global level, the focus should not only be put on reducing perceived cost but also on increasing perceived benefit.

16 Whereas 122 and 123 of the Proposal for a Regulation of the European Parliament and of the council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) [2012/0011 (COD)]
17 Opinion of the European Data Protection Supervisor on the data protection reform package (www.edps.europa.eu/)
18 00323/07/EN WP 131 Working document on the processing of personal data relating to health in electronic health records

While evident when stated as such, this statement does not seem to have been guiding previous attempt in building efficient PHRs. In these systems, a lot of effort has been introduced in reducing the financial costs, the time required by the patient to import data and to use the system, etc. The usual assumption is that the perceived benefit does not need to be increased because having data centralised is a benefit as such and indeed, most stakeholders know how a centralised database would improve their practice if they had access to it: physicians would be able to make better diagnostics and prescribe more efficient medications; pharmaceutical companies would be able to improve their drugs; health insurance companies would be able to improve cost-effectiveness of treatments, etc. But while these benefits will ultimately have positive consequences on the patient, they are not sufficiently perceptible. One might argue that improving diagnostic and medication is a very direct benefit to the patient, but patients (at least in European countries) currently perceive treatment as being the responsibility of the healthcare community. Once a disease is diagnosed, the patient relies on his/her physicians and the clinical community to treat him. Therefore an improvement in diagnostic and medication while directly benefiting to the patient, actually internalises a problem which otherwise is external (responsibility of the physician).

In order for the patients to completely endorse a global PHR, they must receive a share of the benefits. All stakeholders who see a benefit in centralised data should find a way to share benefits with the patients in a direct, individualised, measurable and possibly short term way in order for them to be well perceived. In this case, the "banking model" described previously could meet the needs of this benefit sharing. Indeed, as it opens the way for third parties to directly interact with the patients, deals concerning data could be proposed to the patient. As this would be done in individualised way, the value could be tailored to the needs of the individuals and not enforced to the whole population.

Several categories of benefit for the patients could be envisaged.

Short term, very individual and direct benefits such as:

- **Increase in the ease of access to the medical community:** this includes the possibility to do online or over the phone advices and prescriptions, the possibility to get advices anonymously, etc.
- **Increase in provider choice:** this includes the possibility to get advice from multiple physicians and to change more easily from one to another or from one treatment option to another.
- **Money incentives:** this is the most obvious benefit when thinking about the banking model. Data could be sold for research studies, they could be sold to insurance companies for premium rebates,…

Mid-term, potential benefits for individuals such as:

- **Health monitoring:** while treatment is seen as the responsibility of the health care community, good health is usually seen as the responsibility of individuals. Centralising health related data could allow personalised analytics, prevention and behavioral change propositions.
- **Increase in safety:** this includes the possibility to give easy access to health providers in emergency situations, to have all data available when abroad, etc.

And long term global benefits such as:

- **Greater good:** the possibility of choosng which to which research studies the data will be given to, much like fundraisers exist today.

Some of the above benefits could be possible even without adopting the "banking model" system; nevertheless, it will enable new means of proposing value to the patient. The working group's recommendation is that by giving full access control to the patients in a competitive market, they will perceive these benefits more than in other systems. The proposed benefit categories are not meant to be exhaustive. The banking model will allow creativity and innovations to emerge from all stakeholders enabling new ways of interaction with the patients.

6. Implementation steps

The implementation of the suggested solution largely depends on the establishment of an appropriate regulatory framework. As suggested, the adequate market design with its stimulating incentive mechanisms is crucial in order to unlock the potential of a variety of use cases within the ecosystem (each requiring an individual implementation).

Since the suggested market design requires a regulatory framework it is now recommended for the EU regulatory bodies to evaluate the institutionalisation of such scheme. Political parties, member state representatives, market / business and stakeholders need to be heard in order to initiate the decision making process that could lead to such regulation. The political dimension of this implementation process is not within the scope of this document and should be tackled in-depth in a separate evaluation.

7. Conclusions

Currently big data does not efficiently contribute for improving healthcare because **patients are not in control of their medical health data**. The "personal data currency" is not flowing **making impossible to build the trust that is needed**.

Health is central in people's lives. This increasingly perception may be seen in the number of app downloads directly or indirectly related with healthcare.[19]

The group's recommendation is to create a **bottom-up model**, focusing on the core of all the innovation, the **patient's data - from an exclusive to an inclusive ecosystem**.

The "zamboni effect"[20] is a paradigmatic example of the actual exclusive healthcare

19 In Google play store there are more than 100 apps related with Healthcare. Just five apps have more than 20 Million downloads (twice the population of Portugal).
20 New York Times: A Controversial 'Cure' for M.S; Paul Tullis; October 26, 2012

system patients' perception. Promoting **transparency between doctor-patients** relations and implementing the **presented "banking model system"** will promote **patient trust and value perception**, which are key features to successfully implement a new **competitive model**. It is necessary to enable individuals to understand and manage, in a secured environment access to allow the use and valuation of such individual information in an inclusive ecosystem, where the **interests of the different stakeholders, the fundamental rights of the patients and the legal constraints are fully taken into account and respected**. As patients are the primary source of PHR data, it is essential to design a user experience that is well accepted. A **chip card model** similar to a bank card is proposed **to materialise the digital data with the physical object**.

The PHRs may include a range of data, including demographics, personal and family medical history, medication and allergies, chronicle diseases, immunization status, laboratory test results, radiology images, vital signs, personal stats like age and weight, smoker status (…). In order to have a fully EU wide system, the **standardisation**[21] codification and the **centralisation**[22] level to be achieved are vital to have a reliable and on-time data.

The recent evolutions of the debates on the new EU regulation on the protection of personal data and notably the draft report issued on January 16, 2013 by the Committee on Civil Liberties, Justice and Home Affairs[23], should be reinforced and seems to follow the same idea when insisting on the fact that *"health data, which is extremely sensitive, may only be used without the consent of the data subject if it serves an exceptionally high public interest and in this case must be anonymised or at least pseudynomised using the highest technical standards"*.

The previous recommendations are fully aligned with the core principles and strategic actions of the EC Health Strategy:

Solidarity – Understanding patients in 360º will improve transparency between the doctor-patient relations, promoting health throughout the lifespan. A segmented monitoring and advanced statistical approach to patient profiles would help to identify those that are in risk of developing a specific disease linked to social, economic or environmental factors. It will open new windows to customise actions- "tailored solutions"-identifying the best treatments for specific patients and what the most effective preventive actions are, tackling inequities in health.

Security – Pandemics or major physical and biological incidents and bioterrorism pose major threats to health. Interconnected and standardise codification of symptoms, prescriptions, exams (…) will promote an on-time and reliable access to data, enhancing EU Community's coordination to respond rapidly to health threats globally.

Prosperity – Capturing the PHR data will accelerate the development of new drugs. Imagine that a statistical population having a chronicle disease (e.x diabetes, depression, hypertension), take the same active pharmaceutical ingredients (API) for years but none of them have a specific type of diseases. This type of information will be very important to understand expanded or adverse effects that some molecules or analogues may have helping the R&D development. The proposed healthcare competitive model will promote health with the development of new technologies, namely, information and communication technologies (ICT), genomics, biotechnology and nanotechnology fostering a competitive and sustainable future for Europe.

A EU Governing Body should drive the gradual implementation of these solutions.

21 This topic is discussed throughout several projects Eurorec, Ramit and OpenEHR foundation SemanticHealthNet and EHR4CR
21 Towards a sustainable data warehouse approach for evidence based healthcare, N. Stolba, PhD thesis, 2007. An example of such system is the American healthcare insurance companies and Health Care Cost Institute that were merged and provide data to research institutions to reduce treatment costs.
23 Draft report on the proposal for a regulation of the European Parliament and of the Council on the protection of individual with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) (COM(2012)0011 – C7-0025/2012 – 2012/0011(COD))