Widespread use of electronic health record systems (EHRs), which provide timely and secure access to comprehensive patient data, delivers significant individual, social and economic benefits in the areas of patient healthcare, public health and clinical research. However, the optimum use of EHRs for clinical research depends upon two key factors: interoperability and the re-use of data for research purposes. This paper focuses particularly on the challenges of the re-use of data, which could have a radical impact on the business of the pharmaceutical industry by opening possibilities for novel approaches in personalised medicine, safety and efficacy of new treatments. Examples of the benefits for clinical research include more efficient management and organisation of clinical trials, and easier validation of disease models and simulators (in silico drug testing), leading to better assessment of efficacy and safety of drugs and faster, more affordable development of therapies targeted at specific patient populations. Specific shorter-term benefits could also be seen in patient recruitment, adverse event reporting, pharmacovigilance and pharmacogenomics. Recently, the European Commission has undertaken efforts to raise awareness among EU Member States and within the healthcare, life sciences and IT industries, of the remarkable potential of EHRs. Results from cross-disciplinary workshops have highlighted the formidable challenges of reconciling privacy regulations, technical compatibility and cooperative processes. None of this will be easy, but the alternative of doing nothing could have a marked, negative impact across the EU.

The positive benefits of timely and secure access to patient data have been recognised by health providers across the EU. The widespread use of EHRs, when combined with the proper organisation, regulatory framework and skills, should lead to improved health care, patient safety and efficiency. However, the potential contribution of EHRs to a wider public health agenda has not, to date, been fully recognised by all stakeholders. Aggregated and anonymised EHR data (at local, regional and national levels) has the potential to bring great benefits to public health, clinical research, evidence-based knowledge translation and pharmacovigilance. This added value of EHR implementation could enable ‘eHealth’ applications that can modernise healthcare and vastly improve clinical research. The interoperability of EHRs will also provide a range of tangible and far-reaching benefits for the patient, the public health sector, and the life sciences and IT industries, and provide EU member states with an important innovation tool.
THE ADDED VALUE OF EHRs

Public healthcare services are an essential part of the European social model, and the right to high quality healthcare is at the essence of European citizenship. More effective use of patient data, medical knowledge and recommendations for treatment are needed to meet the stated European policy goals of improved patient safety, comprehensive chronic disease management, and combating old and new diseases. To realise this, EHRs, based on internationally agreed standards, are an important tool to enable wider collaboration, not only in care provision, but also for research and knowledge creation, management and quality assurance.

One of the greatest potential benefits of the standardised computerisation of health data is the huge opportunity of combining, aggregating and analysing EHRs for clinical research. In this context, health data refers primarily to two cases. Either de-identified data – the identification of data subjects is replaced by codes, such that without a disproportionate amount of resources, it is only possible to trace the data back to data subjects by referencing the key code), or, anonymised data (removing all identifiers that would enable identification of the data subject based on reasonably available means) according to the International Pharmaceutical Privacy Consortium (IPPC) (2).

By ensuring compatibility between the various computer applications, even greater benefits can be expected. The resulting knowledge can provide widespread feedback for clinical practice via new guidelines, alerts, or other decision support. While the benefits of EHRs in direct patient care are widely recognised, the benefits from re-use of EHR data that has been de-identified and aggregated for medical research purposes is grossly underestimated, or even overlooked. The use of patient data for determining individual treatment and re-use of such data in related contexts could be used together to deliver the expected benefits.

Despite the importance of this, only marginal levels of collaboration have developed between healthcare, patients, the life science industry, the research community and others, to explore how the growing adoption of EHRs can contribute to common research initiatives to adapt healthcare systems to 21st century needs. It is time to develop a greater understanding and enhanced political engagement for the wider use of EHR information.

INTEROPERABILITY – A WIN-WIN SITUATION

There are many benefits to the widespread adoption of interoperable EHRs and linking them to clinical research systems. For healthcare delivery, the secure exchange of health information enables safer and more efficient care through avoidance of errors and duplicative examinations, even across linguistic and cultural borders. On a higher level, it will allow for evidence-based decision support tailored to the patient’s needs.

From a patient perspective, provided their records are suitably protected against unauthorised access, widespread implementation of EHRs can foster patient empowerment through easier access to personal medical records, leading to a more holistic approach to healthcare through closer co-ordination between care providers and the patient, ultimately resulting in safer and more evidence-based diagnosis and treatment.

From a public health perspective, the re-use of such data would allow more successful management of public health issues dealing with vital aspects of the ‘digital public health vision’, by:

- Enhancing processing of various indicators, benchmarks and trends on public health issues with respect to populations/groups, settings/facilities and regions/geographic units
- Reconciling environmental variables in order to improve understanding of health factors, to identify emerging trends in public health, and to manage public health problems more effectively

From a life sciences perspective, analysing data from interoperable EHRs would contribute to more transparent and safer care through faster and more targeted drug development (3). The re-use of EHR data for clinical research and basic research systems will support and enhance research capabilities (patient recruitment and associated activities) and provide a new, potentially global source of evidence to generate new medical and healthcare knowledge (for example, to develop new tools, speed up the translation of such research findings to the actual point of care and improve pharmacovigilance).

From a technology industry perspective, wide EHR deployment would stimulate a whole high-tech market segment (healthcare technology), helping promote EU market strength and global market share, and attracting R&D investment into the EU. From an innovation perspective, interoperable EHRs could support knowledge discovery and sharing (among EU member states), such as in life science and pharmaceutical development, production of

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new analytical software tools for health data, and the creation of skills and jobs within the EU. By encouraging R&D and technology development, the development of interoperable EHRs could stimulate innovation, contributing to economic growth in Europe.

THE CONTEXT OF EUROPEAN COMMISSION ACTIVITIES
The roots of European policy to foster the widespread implementation of interoperable EHR systems are grounded in the European eHealth Action Plan of 2004 (4). Recently, the EU identified eHealth as one of six particularly promising market segments in a Lead Market Initiative (5). The Initiative aims to accelerate the development of the eHealth market by removing barriers to growth in particular eHealth markets through specific policy actions. The recent European Commission Recommendation on Cross Border Interoperability of Electronic Health Records addresses specific activities needed at both the Member State and EU levels (6). Furthermore, concrete progress in these fields is to be expected from the European Smart Open Services large-scale pilot project, to be undertaken by 12 EU National Health Ministries, their relevant eHealth agencies, and 35 industrial players who are supporting the project through a joint Industry Team (7). In conclusion, the Commission is increasingly engaged in encouraging developments in eHealth.

KEY ACTIONS TO BRING CLOSER CARE AND RESEARCH
Coordinated and collaborative activities are needed to realize the huge benefits for individual citizens, the healthcare systems, and for society at large. However, no stakeholder group on its own can initiate and implement all the actions needed to make this happen. All must work together to address factors that are barriers to progress, and support those elements that can facilitate faster advances. Concentrating on selected recommendations, actions are called for at various levels:

Policy and Legal Level
To avoid further fragmentation of the European eHealth applications market and allow for the re-use of patient data for the outlined purposes, strong support for interoperable EHRs by EU Member States is essential.

The processing of personal data relating to a person’s health is particularly sensitive and requires special protection. Whenever feasible, information from EHR systems should be used only in anonymised or de-identified form. If, however, processing personal data in EHR systems is necessary for a specific medical purpose, then it must fully comply with the rules for protection of personal data. The current EU Data Protection legal framework, as set out in Directive 95/46/EC on Data Protection, prohibits in principle the processing of personal data relating to a person’s health, unless it is done with the consent of the data subject, for health-related purposes, by persons subject to a legal obligation of professional secrecy (8). However, EU Member States may derogate from this general prohibition on processing sensitive categories of data where important reasons of public interest so justify, for example, for wider medical purposes in areas such as public health or scientific research, together with specific and suitable safeguards that protect the fundamental right of personal data protection. However, so far, there is little awareness or co-operation among EU Member States regarding the uniform application of data protection principles in respect to EHR implementation in order to foster the potential use of EHRs for research purposes.

Organisational Level
The penetration of EHR systems in hospitals, community health centres and private practices is steadily increasing, but in many countries these systems are still isolated and are unconnected to other healthcare information systems. Moreover, each healthcare organisation, and indeed healthcare system, involves a wide range of stakeholders, including clinicians, public health authorities, insurers/payers, academic and industrial researchers, IT vendors, pharmaceutical companies, regulatory authorities, patients and third-party information brokers (organisations involved in anonymising, linking or aggregating data), who often have only a limited understanding of each other’s needs outside their immediate areas of interaction. In order to get the most out of EHR systems, organisational structures and interactions should be optimised. This includes the creation of organisational structures and mechanisms to allow the interacting health sector stakeholders to be involved in EHR system implementations in order to meet multiple healthcare needs: patient care, research and public health.

Technical and Semantic Level
Without agreement on general IT concepts and technical standards, individual, isolated and disparate EHR systems and solutions will prevail. The development of software tools that support interoperability and integration between EHRs, and between EHR entries and electronic data capture (EDC) for clinical trials and basic research data are urgently needed. The use of patient data in EHRs for seamless, collaborative care provision and for the various re-use opportunities mentioned earlier is only feasible if electronic ‘machines’ can exchange and manipulate patient data, and all those involved in health services must then understand and act on this information, even when operating in different languages.

THE WAY FORWARD FOR COORDINATED ACTIONS IN THE EU
A number of activities regarding EHR re-use are currently taking place in both the EU and US. However, from an EU perspective, it is important that member state authorities create a forum to support those involved in EHR system implementation co-operation, so that they may agree on the priority areas that encourage the systematic use of EHR to enhance patient care and facilitate medical research.

Such a forum might take as its starting point three core objectives which would contribute to the development of a system for the re-use of EHR data, while fully respecting patient privacy and the confidentiality of health-related data:

- Develop guidelines for third parties, working as information brokers and based on a trust infrastructure
- Encourage harmonisation of EU Member States’ interpretations of healthcare data privacy legislation, in order to allow the development of suitable legal frameworks for the re-use of patient data for secondary uses
- Define, agree and support the adoption of the technical standards needed to enable system interoperability within the healthcare domain, and between the healthcare and medical
research domains. This might include support for open software tools enabling interoperability and integration between EHRs and between EHR, EDC and basic research systems. This also requires tighter integration between clinical research standards development organisations such as CDISC, with Mandate 403. A first step is to identify priority areas for improving semantic interoperability, such as fields of clinical practice that are of high patient safety relevance and where it is most urgent to bridge the gap between current and good practice (9,10)

WHAT HAPPENS IF WE DO NOTHING?
The recommendations listed above will demand strong political support, appropriate organisational structures, public and private funding and, in particular, a strong professional commitment across the full range of health system stakeholders. We must recognise that the alternative – simply doing nothing – will have large, negative implications across the EU. Firstly, we run the risk of fragmented parallel non-standards-based developments in multiple sectors, entailing a substantial duplication of costs and human effort.

Secondly, a failure to work jointly across the healthcare, drug development and life sciences sectors will forego a crucial opportunity to boost key EU markets (pharmaceuticals, health technology and devices, and eHealth solutions) and counter global competition.

Finally, if we do not address the re-engineering of healthcare in an integrated manner across the range of healthcare stakeholders by implementing at least basic EHR components, we run a significant risk of failing to address more effectively patient safety and quality of care through the sharing of patient data and best practice, of not harvesting the possible benefits for clinical research and faster drug development, and of missing the opportunity for the rapid generation of new medical knowledge. Ultimately, as shown by comprehensive empirical evidence, this will cost lives as well as money. It would also leave the EU, Member States, patients, and the healthcare industries far behind other large nations (such as the US, Japan or Canada). None of this will be easy, but doing nothing could have a detrimental effect that stretches across the EU.

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