From: ▇▇▇▇▇▇▇▇▇▇ (SANTE)
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Subject: Debrief from meeting with Siemens, 04 July 2018
Date: lundi 9 juillet 2018 09:23:18
Attachments: SHS_Vision_Digital-Heatlh_White-Paper_FINAL.PDF

Dear all,

Several representatives of Siemens met with our Director Andrzej Rys on 4th July:

- ▇▇▇▇▇▇▇▇▇▇ EMEA, Siemens Healthineers AG
- ▇▇▇▇▇▇▇▇▇▇▇▇▇▇ France and Head of Zone "France, Belgium and Western Africa", Siemens Healthineers AG
- ▇▇▇▇▇▇▇▇▇▇▇▇▇ Belgium, Siemens Healthineers AG
- ▇▇▇▇▇▇▇ Government Affairs and Policy, ▇▇▇▇ EU Offices, Siemens Healthineers AG
- ▇▇▇▇▇▇▇, Government Affairs and Policy, Director Policy and Reimbursement Strategy, Siemens Healthineers AG

I was asked by Andrzej to attend the meeting. ▇▇▇▇ and ▇▇▇▇▇ from B3, and the B3 ▇▇▇ ▇▇▇▇▇▇, were also present.

Siemems had provided the attached paper ahead of the meeting. In this paper, they call for the establishment of a European Centre for Digital Health.

During the meeting, Siemens indicated their interest in digital health infrastructure for: 1) connecting EHRs, 2) managing an interconnected set of devices such as medical imaging machines, and 3) pooling the data from the previous two points to develop AI algorithms.

▇▇▇▇ posed the question of how industrial partners can contribute to the interoperability work of Pillar 1 of the Communication on the digital transformation of health and care.

Andrzej mentioned that the European Centre for Digital Health is an interesting idea and asked whether this would be in the form of a PPP. He mentioned that it is unclear what the Commission's appetite for new PPPs might be in the new MFF and therefore asked Siemens to explore whether the European Centre for Digital Health can fit within existing PPP instruments.

Siemens responded by indicating that they will check with respect to the IMI PPP and they will also develop the concept for the European Centre for Digital Health further.

At Andrzej's request, I mentioned the work of the study on ESIF investments in health, the 6 thematic areas it covers and the workshops. Siemens is interested to hear about the outcome of the workshops.

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White Paper: Digital Health in Europe

Introduction

This white paper sketches Siemens Healthineers concepts on digitalising health in the European Union and examines strategies and visions for collaboration between the EU, its Members States and third parties in the field of Digital Health. Moreover it suggests creating a nucleus of pan-European expertise to accelerate the pace of digitalisation in healthcare in Europe and position Europe at the forefront of this global trend. It is a first stock-taking of ideas and should be used as a basis for further discussions within the European Commission and the Member States to examine the scope for further collaboration.

The establishment of a Digital Single Market is at the centre of EU policy makers. The European Commission identified healthcare as one area where digitalisation will be especially beneficial for European citizens and their healthcare systems´ sustainability alike. Improved diagnosis, better treatment, cultivating a more favourable working environment for clinicians, soliciting patient feedback, ensuring greater continuity of care and promoting better patient care after discharge, as well as the exploitation the growing potential of connected care are a key interest in this regard.

As in other sectors, medical and health data are raising exponentially, opening up new possibilities in diagnosis, treatment and research. New opportunities are arising from improved data analytics and Artificial Intelligence since such capabilities contribute to precision medicine, clinical decision support systems for health professionals and mobile health tools for individuals to manage their own health and chronic conditions. A long standing debate of utmost importance in Europe and beyond is the lack of compatibility (interoperability) of established health IT solutions and arising new digital solutions. This still hinders the uninterrupted flow of data within a hospital, within networks, within national states, between EU Member States and beyond. This is specifically true in cross-border and international initiatives. Solutions and approaches with a strictly patient centric focus will improve health outcomes.

Digitising Healthcare in Europe

The populations in EU Member States are aging and the number of citizens with chronic diseases and multi-morbidities is growing rapidly. This creates a challenging environment for the sustainability of healthcare systems. At the same time, more and more aspects of professional as well as private life are being digitised and enormous amounts of data are being generated already today – and it will be much more in the future. The availability of this data and the advancing capabilities to process and analyse it create a unique opportunity to improve health and care as we know it today and the efficiency and transparency of its delivery. Furthermore, completely new approaches to managing health, diagnosing and treating diseases and organizing care will occur[1].

Digitalisation in healthcare will enable healthcare providers to increase value by transforming the delivery of care, empowering patients, improving patient experience and by transforming care into precision medicine focusing further on the individual needs of each and every patient. In diagnostics as well as in therapy, advanced analytics of medical and health data will help to improve diagnostic precision and outcomes. **IT solutions, algorithms, AI and health data** play an ever more important role in processing diagnosis-relevant patient information in a comprehensive and sustainable way and offer new prevention approaches. Especially increased diagnostic quality can ensure saving money by reducing down streaming

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[1] To ensure that this evolution is based on common European values regarding citizens' rights, data privacy and market behaviour, the EU and its Member States need to play a major role in shaping and implementing Digital Health by combining its excellence in medical science and technology with its strength and powerful legacy of putting citizens at the heart of its policies and ensuring safety and security for all.

cost. The European Union is well equipped to support this digital transformation by building on the cross-border health directive and utilizing its role as a facilitator in research and its translation into (clinical) routine.

Digitalisation will impact the entire value chain in healthcare: From research, development and production to planning workflows, equipment and staffing of hospital, from digitising existing products and services to entirely new, purely digital solutions and business models. Moreover, Artificial Intelligence as a multi-faceted instrument in healthcare, its advance algorithms and deep learning abilities hold the potential to transform care delivery and cultivate precision medicine. AI in the future will support each step in the process, from patient examination to detection, characterisation, diagnosis, and therapy decision. A standing debate of utmost importance in Europe and beyond is the lack of compatibility of established health IT solutions and arising new digital solutions. This still hinders the uninterrupted flow of data within a hospital, within networks, within national states, between EU Member States and beyond. This is specifically true in cross-border and international initiatives. Solutions and approaches with a strictly **patient centric focus** will improve health outcomes of EU citizens while overcoming sectoral and national barriers by using binding standards thereby unleashing the full potential of digital health in Europe. Driving the change together by engaging stakeholders and creating multistakeholder platform - from medical societies to patient organisations, from hospitals and payers to industry actors to support the European Union and the Member States' activities will strengthen the digital transformation of healthcare. Siemens Healthineers will co-create the transformation from raw data to diagnostic information to better patient outcome to innovation in sustainable healthcare.

Vision for Digital Health in Europe

On April 25, 2018, the European Commission adopted the "Communication on enabling the digital transformation of health and care in the Digital Single Market; empowering citizens and building a healthier society". It sets the pathway for further action in the upcoming years by stating that "health data and advanced data analytics can help accelerate scientific research, personalised medicine, early diagnosis of diseases and more effective treatments."[2]

Data and information driven solutions will help EU Member States working together on their common challenges such as making their healthcare systems more sustainable, to cooperate more efficiently on cross-border health issues and to improve overall patients' care. To fully explore the potential of driving the digital transformation together, we need to pool our resources and leverage on Europe´s diversity in science, medicine, technology and other adjacent fields of expertise. Only if we leave the perspective of "fragmentation" behind and embrace and build on the potential of multiple European strongholds in academia, clinical and technology, we will be able to play a prominent role in the global race for digital health. One necessity for that is to better streamline existing and newly emerging activities between Member States and between Member States and the European Union – not to do less, but to gain more by facilitating exchange and collaboration.

Thereby Siemens Healthineers suggest establishing a **European Centre for Digital Health** to streamline European expertise and become a globally leading power in Digital Health. This European Centre for Digital Health is meant to globally shape and drive digital health as well as to evaluate the evolution towards digital health. The concrete projects of the Centre are aligned with the ´priorities of the European Commission as defined in the Communication on Digital Health from April 25, 2018 and could embrace existing initiatives like MEGA. The European Centre for Digital Health will play a prominent role in driving its own projects forward as well as integrating and streamlining all EU activities in the fields of digital health.

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[2] https://ec.europa.eu/digital-single-market/en/european-policy-ehealth

Besides the establishment of EU-wide research platforms, the promotion of digital health records for each European citizen is of essential importance for the project.

The availability of all medical and health data is a cornerstone of providing high-quality care and empowering citizens to actively manage their health. Every EU citizen will therefore have access to a personal **digital health record** by 2022. This will be a holistic record accompanying the citizen throughout life, including all medical and health data from birth to death. This health record will be citizen centric and the citizens will have access to it via portal or app. The citizens will be able to actively manage their health and illness by being able to share their data with medical professionals as well as private individuals (spouses, partner, children, parents…). . Citizens will also be able to add health related data from their wearables or other devices into their record. To empower patients and citizens alike, the health record will include, amongst other features, feedback possibilities, provide transparency of treatment costs as well as tools to increase health literacy of the citizens. Prevention strategies as well as post treatment care and analysis will be included via portal or app. To ensure the uninterrupted flow of data and to ensure quality of data interoperability will be ensured by binding international standards (e.g. IHE, DICOM, HL7, HL7 FHYR). Citizens will have transparency as health professionals will be logged when accessing data. Citizens' consent is regulated via the health records and citizens also have the right to donate data.

The European Centre for Digital Health will look into **various models of health records** and how to best implement them. A special focus will be on future technologies such as Blockchain and their added value for citizens and health records.

The Centre will also develop and implement high potential and **moon shot projects such as the** "**digital twin**" project. The vision here is to create a virtual avatar for each European citizen, identical in genetic make-up, medical history etc. so that medical interventions, reaction to certain medication or treatments as well as post treatment behaviour can be tested on the virtual avatar before the intervention or administration on the person. The Centre will bring together all necessary experts ranging from software and virtual reality engineers, clinicians, industry representatives, patient groups to ethics and legal specialities to investigate the potential of this moon shot project for the healthcare system of tomorrow.

Assuming that digital health solutions will become an integral part of health care in the future – from wellness and lifestyle to prevention and early diagnosis to treatment and the monitoring of rehabilitation and after care – it is crucial that citizens and healthcare professionals are able to assess the options and the related opportunities and risks. Today, there is a sharp discrepancy between different EU Member States, different age groups and different professions with regards to the expertise and experience of engaging with digital health solutions.

The Centre will bring together ongoing activities on **Digital Health Literacy** focussing on citizens (like the IC-Health project[3]) and develop further activities to close gaps. It can leverage on all its other activities and provide first hand and world class expertise and experience to educate citizens, but also especially healthcare professionals. The training of these professionals – doctors, nurses and others – will apply a "train-the-trainer" approach which multiplies the effect and ensures that the education reaches the people in the countries and regions. Locally, the educational efforts are meant to link different age groups and professions together in one shared discovery and learning experience, not only passing expertise along, but at the same time building trustful relationships that foster cross-sectoral collaboration in healthcare. This would include a better understanding of **Cyber Security.**

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[3] https://ichealth.eu

The structure of the Centre could look like this:

European Centre for Digital Health

- Become a globally recognised and leading **Centre of Excellence in digital health.**
- Set European and global trends, become a global opinion leader and **anchor European values** into the global digital health debate and projects.
- Given the challenges of European healthcare systems, the Centre shall focus **on research for predictive and prescriptive algorithms** to improve prevention, tackle the most threatening diseases and to ease chronic diseases.
- Create a **supercomputing infrastructure** to ensure the necessary computing capacity and processing power following European privacy and data protection laws.
- Set-up a secure **Sandbox environment** for start-ups and companies to test new innovative digital solutions in a real-life simulation.
- Issue **challenges** to the digital health community to
  1. create new innovate solutions to pressing medical and technological challenges
  2. offer vendors to test the interoperability of their solutions in the sandbox environment (possibly create an interoperability showroom)
  3. improve data and system security by inviting specialists to attack systems in a separate secure Sandbox environment to find and continuously mend possible security risks
- Attract, involve and cross-link the brightest **European talents** and best global potential (data scientists, informatics engineers, clinicians, industry representatives).
- Empower citizens by teaching **health literacy** to ensure that citizens are able to actively manage their own data and are able to take informed decision about their health.
- Involve and empower European regions by setting up several **digital health hubs** in attractive and interested cities or regions (local health ups could have slightly different thematic focus).

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1 *Fundament*

Goal 1: Secure access to and exchange of health data

- Establish and foster EU-wide platforms as basis for the Centre.
- Promote digital health record for all EU citizens.

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Goal 2: Health data pooled for research and precision medicine

- Based on the established EU-wide platform (goal 1)
- Innovative, competitive solutions and best apps for adequate patient use
- Moon shot project to further complement infrastructure and digital solutions: **digital twin** as avatar for each European citizen to predict success of medical interventions and test likely behaviour.
- Challenges issued by the Centre set trend topics and accelerate innovation.

3

Goal 3: Digital tools and data for citizen empowerment and person-centered healthcare

- Based on the established digital health record (goal 1)
- Innovative apps and solutions most valuable and best use for citizens need, medical challenges and necessities of the European health systems
- Promotion of health literacy of the citizens
- Challenges issued by the Centre set trend topics and accelerate innovation

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