CEN/TC 251 Health informatics: Business Plan 2019-2022

EXECUTIVE SUMMARY

Business Environment

All countries face a formidable challenge in maintaining acceptable standards of care for their people. This is made more difficult by the need to manage the costs for health and social care, within a changing context of political, economic, social, and technical change. Governments, citizens, patients, professionals and provider organizations have high expectations of good quality healthcare.

In an attempt to meet this challenge, local, regional and national initiatives in Health Informatics (or eHealth) have been implemented, with varied degrees of success. This is inevitable as the sites are affected by different levels of maturity and issues of capacity, both in staffing and in other resources, that mean that the healthcare landscape is an uneven one and the delivery of quality care varies accordingly. There is a bewildering number of initiatives, many overlapping, some diverging and others unaware of the other, leading to a confused, unstable and unproductive market place for health informatics applications. Paradoxically, new digital technologies enable marvellous innovation in healthcare, whereas arguably, the more simple and mundane tasks (as they are wrongly perceived) continue to frustrate, and undermine the gains made.

An important and necessary part of the solution relates to the need for interoperability and interoperable implementations. However, this approach is not sufficient. European efforts have necessarily focused on cross-border applications, providing guidelines and initiatives that promote better collaboration and good practice across member states. New policies around the Digital Single Market, for example, promoting digital transformation of health and care, are insisting that health data and data management are crucial when it comes to empowering citizens and building a healthier society. The new goal for Europe is a data-driven healthcare system.

Benefits

CEN/TC 251 Health Informatics is committed to delivering and maintaining the best quality specifications and standards for the European Member States and for the European Community, thereby boosting European Union action within the Digital Single Market applicable to the healthcare domain. The products CEN/TC 251 delivers reduce the noise in the market place by providing important architectures, frameworks, concepts and terms that enable consistent and coherent implementations.

Whilst CEN/TC 251 does develop standards by itself when required, it prefers to produce specifications in co-operation with other SDOs at a global level and to adapt or adopt international standards for implementation in the European context and jurisdiction. This too helps the European market by making its products accessible to a global consumer base. It also prevents the danger of swamping from other powerful nations by providing a level, open

consensus playing field. CEN/TC 251 recognises and supports stakeholder wishes for fewer, but more universal standards applicable throughout the world without curbing innovation.

CEN/TC 251 is well-placed and enabled to take European Guidelines forward and to formalise them, leading to good practice and powerful frameworks that support semantic interoperability across member states and beyond.   Furthermore, CEN/TC 251 is both sensitive to, and aware of European initiatives, directives and mandates and is committed to providing substantial inputs for the purposes of regulation and platforms for research to build upon.

This Business case highlights the International Patient Summary (IPS) work, which is the current example of CEN/TC251's output; CEN IPS contributes to all of the above benefits, i.e.,
- Reduces the noise of multiple initiatives by providing an open, extensible framework and core dataset that permits multiple implementations to conform in a consistent way.
- It has worked closely with EU projects, participating in as many as possible.   In particular it has partnered with HL7 throughout, effectively providing 4 high quality specifications in just two years. The shared vision and principles between the two SDOs mean that the joint outputs are implementable and global in their application.
- It has taken the eHN guidelines on patient summaries and has formalised them, producing an international standard (prEN17269) and a Technical Specification (prTS17288) that provides guidance as to how it can be implemented within the European context. Furthermore, its development predicted and supports the new policy on data driven architecture (see GDPR and IPS Report) of the Digital Health agenda and provides a starting point for the European EHR Exchange Format.

Priorities

1. CEN/ TC251 will focus on EU requirements as its main priority. Figure 1 illustrates three broad EU strategic areas that the TC will prioritise. The existing programme of work already contributes with work on patient summaries and the EU sponsored series of standards on the Identification of Medicinal Products (IDMP), as well as Systems of concepts for continuity of care, Service architectures and frameworks. Work associated with EU projects such as eStandards, Trillium II and OpenMedicine will also be built on. New work considering guidelines on patient registries and reference networks (ERNs) as well as Apps, devices and sensors will be targeted to empower person-centred care.

Figure 1: **EU Strategy for Digital Transformation in Cross-Border Healthcare: eHealth 2018**

2. The CEN IPS work has shown how productive participation can be to producing useful and usable standards.   Such joined-up engagement will continue to be prioritised. There are still areas of agile standardisation, however, which have to be addressed, particularly how standards can be updated and harmonised in the light of new requirements so as to maintain relevance yet minimise the burden of change. This necessitates finding meaningful ways of providing on-going feedback from implementations.

1 BUSINESS ENVIRONMENT OF CEN/TC 251

1.1 Background to the topic

Health informatics is information engineering applied to the domain of **health**. The definition of 'Health' is taken from the World Health Organization's declaration of 1948. It is an inclusive one and surprisingly relevant to today's needs, covering more than the alleviation of ill health, but applies also to mental health, social health and to well-being; it implicitly covers genomics, precision medicine and cultural/spiritual matters; it is holistic. The comprehensive scope also recognizes that disease does not respect borders and that solutions, therefore, must overcome any barrier attempting to restrict the delivery of necessary care.

Essentially, Health Informatics is concerned with the quality of healthcare data, and the processes and digital technologies that transform that data, to enhance the quality of healthcare delivery for the benefit of the individual and of society as a whole. 'Health Informatics' has many synonyms/flavours but in Europe, 'eHealth' is probably the most frequently used with 'Digital Health' or variants of the same becoming popular at this time.

Digital Health at least recognizes that digital technologies are rapidly converging with health and healthcare, with everyday living, and society at large to enhance the quality of healthcare delivery. The term is also inclusive and efficient in that 'information', 'communication' and 'computational' technologies are all considered to be an intrinsic part of the interconnected eco-system, along with hardware and software solutions, and services.

Digital Health is a multi-disciplinary domain (covering clinical knowledge, computer science, social sciences, economics, management, public health, policy, to name but a few). Consequently, it involves many stakeholders that can be grouped into four distinct perspectives, as is shown in figure 2. These four perspectives on Digital Health aspire to offset the overly technical connotation of the term, by introducing the individual and societal value that Digital Health is expected to deliver. Trust in the accuracy of health data and its dynamic flow between participants is central to the successful interaction of these four stakeholder groups.
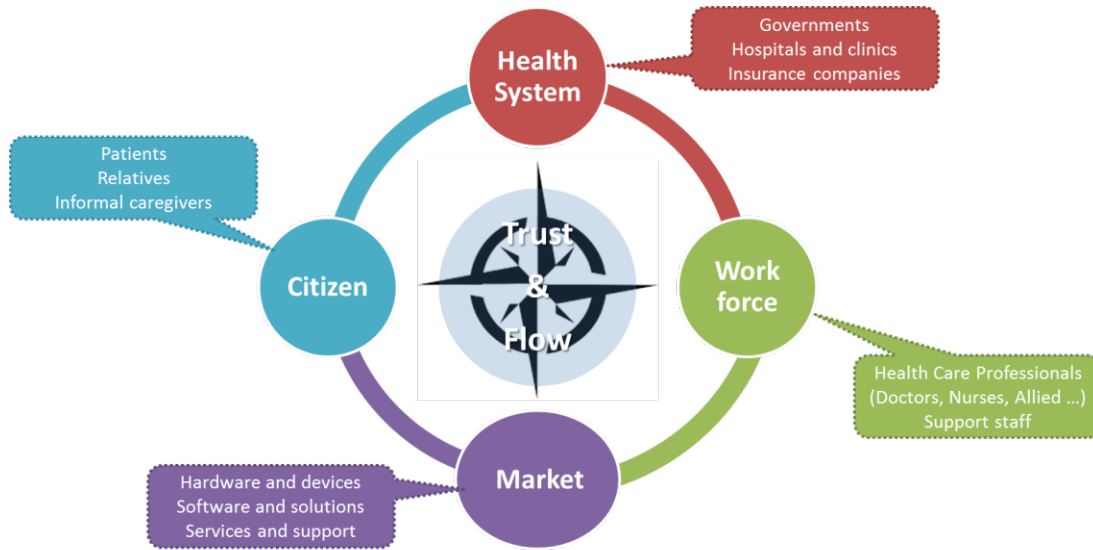
Figure 2: Perspectives on Digital Health – the *e*Standards Compass[1]

The European Union is changing its approach, and terminology, moving towards Digital Health from eHealth. Its new vision is a Europe-wide ecosystem for data-driven healthcare. The core values of trust and flow of health data are fundamental to this vision.

1.2 Description of the Business Environment

The health informatics sector is made up of a number of very large software producers, with a great many small and medium enterprises operating primarily either in domain niches or in geographic areas. This disparate global market is reflected within the CEN member states and presents a challenge. It stifles the free flow of knowledge of and experience in the health informatics industry, thus presenting health care organizations with mounting costs and health informatics vendors with limited potential for growth.

ISO/TC 215 has adopted many CEN/TC 251 standards, making the European input both a valuable contribution and facilitating the uptake of solutions that are relevant for Europe. Where possible the Vienna Agreement[2] process is used to ensure that, for each subject matter area, only one standard is approved by ISO and CEN, and is adopted worldwide. This goal is sought at the request of the end-user organisations and presents a number of challenges where regional or informal 'standards' exist and conflict.

CEN/TC 251 plays an active role as one of the currently eight members of the Joint Initiative on SDO Global Health Informatics Standardization. The objective of the Joint Initiative is to achieve a harmonized set of health informatics standards across globally recognized topics. Health informatics is at the intersection of information science, computer science, management and care professions and services. It deals with the resources, devices, and methods required to optimise the acquisition, storage, retrieval, and use of information in health care. Health

informatics tools include not only algorithms, computers and technology, but also concept systems, clinical guidelines, metrics, formal medical terminologies, as well as clinical and genomic data representations and analytics related to big data.

1.3 Quantitative Indicators of the Business Environment

According to Statistics MRC, the Global Digital Health Market is accounted for $182.63 billion in 2017 and is expected to reach $665.36 billion by 2026. Growing number of government schemes, the quick improvement of healthcare IT infrastructure, increasing occurrence of cardiovascular disorder and aging population across the world are some of the key factors fuelling the market growth. Increasing adoption of cloud-based systems will be a key trend for market growth. Penetration of smartphones in the health care sector and increase in demand for mobile apps provides ample of opportunities for the market growth.[3]

A recent infographic for Digital Health and Care[4] notes that EU citizens expect:

➢ To access their own health data (90% agree)
➢ To share their health data (80% agree)
➢ To provide feedback on quality of treatments (80% agree)

Meanwhile, healthcare professionals (doctors and nurses alike) bemoan the amount of time they spend doing administrative work "to satisfy the system". Studies show that physicians spend around 35% of their time documenting patient data and the introduction of a structured and standardized Electronic Health Record System is expected to lead to more time documenting and less time for patient care [5]. Several countries are spending considerable amounts of time and money on programs to reduce this administrative burden.

2 BENEFITS EXPECTED FROM THE WORK OF CEN/TC 251

CEN/TC 251 offers a unique channel to produce standards which support the EU policies in the health informatics area. Furthermore, CEN/TC 251 gives Europe a united voice to talk to other SDOs and fora. EN ISO 13606, EHR Communication Architecture and EN ISO 13940, System of Concepts for Continuity of Care have now both been published as formal international standards.

As CEN IPS has shown, CEN/TC 251 can also formalise EU guidelines turning them into international standards whilst retaining faith with European requirements. Other guidelines from research projects in H2020 and Joint Actions, such as the PARENT guidelines on patient registries may be suitable candidates to standardise.

CEN IPS has made a start towards increased standards development productivity and a more agile way of working within CEN/TC 251. CEN/TC 251 seeks to build more partnerships and remain relevant to EU policy and agreements, strengthening the Digital Single Market by building on existing work, and if necessary producing new work to meet emergent and emerging requirements.

3 PARTICIPATION IN CEN/TC 251

All the CEN national member bodies (NMBs) are entitled to nominate delegates to CEN Technical Committees and experts to Working Groups, ensuring a balance of all interested parties. Participation as observers of recognized European or international organizations is also possible under certain conditions. To participate in the activities of this CEN/TC, the experts need to contact the national standards organization in their countries.

CEN/TC 251 is actively engaged with many other standards development organisations (formally as part of the Joint Initiative Council (JIC) in which the main global Health Informatics SDO's participate, e.g. ISO/TC 215, HL7, IHE, SNOMED, DICOM and GS1 to name but 6). Within Europe, close collaboration has been established with HL7's European Office and IHE Europe. It also liaises with consortia and fora to coordinate its work with other organisations that have similar goals.

CEN/TC 251 members are from member states standards organisations and additionally include representatives from a number of related organisations. CEN/TC 251 has established working relationships with:
1. CENELEC through a Joint Technical Committee on Medical Devices (CEN/CLC JTC 3)
2. European Trade Association representing the medical imaging, radiotherapy, health ICT and electromedical industries (COCIR)
3. European Commission and its associated research and deployment projects.

It is evident, however, that only a small number of commercial organizations and not a very large number of user organizations are currently engaged in the work. This, and the small number of NMBs actively participating, has been identified as a weakness of the TC.

4 OBJECTIVES AND STRATEGIES FOR THEIR ACHIEVEMENT

4.1 Defined objectives of CEN/TC 251

CEN/TC 251's first objective is to be recognised and acknowledged as the key coordinating Health Informatics standards organisation within Europe.
- It will focus on the healthcare domain requirements of the European Community and the Digital Single Market and seek to make them globally applicable
- It will formalise EU generated guidelines, create useful and usable frameworks to establish leading practice
- It will deliver relevant standards for regulation and research through participation in EU projects and initiatives

CEN/TC 251's second, related objective is to become a more agile SDO, finding better ways to engage different stakeholder groups, expedite processes and establish relevant feedback mechanisms.

4.2 Identified strategies to achieve CEN/TC 251's defined objectives

CEN/TC 251 has an excellent record for participation in EU projects (its members individually or as CEN/TC 251 were involved in all of the recent EU initiatives rom Antilope to Trillium II). To meet its objectives, this participation must continue and the depth of that participation must be strengthened in order to resource its work.

Its work should commend itself to the eHealth Network and ensure that policy-makers, as an important stakeholder, consider and recognise its technical expertise in working collaborations. For example, confidence to the market regarding acceptance and adoption of global standards could be strengthened when the eHDSI deployment project for patient summaries would be formally linked to the CEN IPS and HL7 IPS to ensure a harmonised outcome. Meanwhile, healthcare providers and professionals put considerable effort into the internal restructuring of their EHR systems to enable the exchange of meaningful patient summaries, both nationally and cross-border. These efforts are much better spent when harmonised IPS specifications are used throughout Europe and when they are aligned with the US and global EHR market.

The breadth of work under the banner of Digital Health means that CEN TC/251 must encourage active engagement with industry, researchers and academic stakeholders and find ways to give them more opportunity to be involved. Finding new ways to reach out to consumer/clinical/citizen groups will also be a priority.

4.3 Environmental aspects

The standards products of CEN/TC 251 have no direct impact on environmental sustainability matters. However, it would be possible to imply indirect impact by reduction of materials usage where the standards are deployed e.g. in telemedicine, home based care, better public health; improved continuity of care; greater efficiency and effectiveness measures, indicators etc.

The working practice of CEN/TC 251, particularly at the task-group level, has been to reduce in recent years the negative environmental sustainability impact of its standards production activity by increasing the use of telephone and web conferencing technologies to hold meetings. This is a trend we expect to continue for both environmental and economic reasons.

The recognition that our work is part of a wider eco-system means that environmental aspects have implications for societal aspects and vice versa. Digital Health reflects the convergence of technology with the healthcare domain and the re-emphasis upon person-centric and public health has implications as to whether technology empowers or de-humanises. CEN/TC 251 needs to be sensitive about these impacts, striving for beneficial, sustainable outcomes.

5 FACTORS AFFECTING COMPLETION AND IMPLEMENTATION OF THE CEN/TC 251 WORK PROGRAMME

Specific factors that could negatively impact the completion or business community acceptance and use of the CEN committee's standards include (in prioritised order):

1. Policy-makers' uncertainty and their lack of understanding concerning how best to use CEN/TC 251 to support European objectives within the international market. The CEN IPS work has helped to explain our role and products, but educational material that publishes benefits is urgently needed.

2. Acceptance, adoption and recognition of the CEN IPS and HL7 IPS standards set as a key, complementary initiative by eHDSI and the eHealth Network. Multiple projects in related areas require direction to maintain confidence and to foster sustainable solutions, or risk the loss of credibility.

3. Expert resources are not sufficiently available due to lack of stakeholder support – This is a broader version of factor 1 above. However, as this area is multi-disciplinary with many beneficiaries, the range of stakeholders becomes difficult to include. There are a variety of reasons for this: competition from other SDOs; the lack of involvement of competency centres in the more strategic aspects of standardization; unclear support from the EU as to how standardization in eHealth should be resourced; the difficulty of proving value propositions in the absence of suitable feedback mechanisms. Insufficient financial prioritization and resourcing for secretariat and experts' involvement (particularly Small Medium Enterprises, who find involvement punitive). Specific expertise for a project is lacking, which could affect the project's development as well as the credibility of the resulting standard in the business community.

4. Shortage of funding for participation on an international basis and at the regional level will damage both influence and output and reduce EU leads in this fast-moving domain. Given the potential of the $billion market place and its importance for Europe, cited in the 'Quantitative indicators' section of this business plan , the sums invested in standardisation activities are grossly insufficient for the scale of the task.

5. The lack of knowledge about how standards are used, where they are used, and their impact and value across Europe. It would be beneficial to have an accurate overview of what standards (organizations in) the member states are really using. Standards must not be judged just as SDO outputs but positioned in a framework for assessing longer-term outcomes.

Nevertheless, it is important to emphasize, that CEN/TC 251, through its unique position, influence and contribution, is ideally placed to deliver, socialise and maintain a European response to international Health Informatics standards. CEN/TC 251 already does this; it is a focal point for collaboration and leadership in delivering relevant health informatics standards and specifications for Europe and its member states. But it can do better.

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[1] *e*Standards Roadmap for collaborative and sustainable standards development: www.estandards-project.eu

[2] Vienna Agreement process: www.iso.org/va

[3] Digital Health Market Size, Share, Report, Analysis, Trends & Forecast to 2026 – Reuters, Wed Apr 18, 2018

[4] ec.europa.eu/digital-single-market/en/news/infographic-digital-health-and-care-eu

[5] Time Spent on Dedicated Patient Care and Documentation Tasks Before and After the Introduction of a Structured and Standardized Electronic Health Record: www.ncbi.nlm.nih.gov/pubmed/29342479